Federal Register

Tuesday,
January 4, 2005

Part III

Department of Agriculture

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 96

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Final Rule and Notice

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 96

[Docket No. 03–080–3]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the importation of animals and animal products to establish 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 byproducts, and we are adding Canada to this category. We are also establishing conditions for the importation of certain live ruminants and ruminant products and byproducts from such regions. These actions will continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on the importation of certain commodities from minimal-risk regions for BSE, currently only Canada.

EFFECTIVE DATE: March 7, 2005.

FOR FURTHER INFORMATION CONTACT: For information concerning ruminant products, 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.

For information concerning live ruminants, contact Lee Ann Thomas, Director, Technical Trade Services, Animals, Organisms and Vectors, and Select Agents, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

For other information concerning this rule, contact Dr. Gary Colgrove, Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

I. Purpose

This document makes final, with changes, a proposed rule that the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA or the Department) published in the **Federal Register** on November 4, 2003 (68 FR 62386–62405, Docket No. 03–080–1). In that document, we proposed to establish 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 byproducts, and to add Canada to this category. The proposal also set forth conditions for the importation of certain live ruminants and ruminant products and byproducts from BSE minimal-risk regions. We solicited public comment on the proposed rule and its underlying risk analysis and other supporting analyses for 60 days ending on January 5, 2004. At the time the proposed rule was published, BSE had never been detected in a native animal in the United States and only a single case in a native animal had been reported in Canada (in Alberta in May 2003). In December 2003, BSE was detected in an imported dairy cow in Washington State. This document describes the course of this rulemaking before and after the detection in Washington State, including how the rulemaking was affected by additional BSE-related safeguards imposed by USDA's Food Safety and Inspection Service (FSIS) in January 2004. It also responds to public comments received on the proposed rule and its underlying risk analysis and other supporting analyses, both before the original closing date on January 5, 2004, and during an extended comment period that closed on April 7, 2004, and explains the changes we are making in this final rule.

II. Summary of Changes Made in This Final Rule

Based on our continued analysis of the issues and on information provided by commenters, we have made certain changes in this final rule from the provisions we proposed in November 2003, as supplemented by our March 2003 notice of the extension of the comment period. Those changes, summarized in the list below, are discussed in detail in our responses to comments.

1. For bovines imported from a BSE minimal-risk region for feeding and then slaughter (referred to as feeder cattle), we are making the following changes:

- We are requiring that feeder cattle be permanently marked before entry as to country of origin with a brand or other means of identification approved by the Administrator, rather than by an ear tattoo as proposed. Feeder cattle imported from Canada must be marked with ''C∧N.''
- We are requiring that feeder cattle be individually identified before entry by an eartag that allows the animal to be traced back to the premises of origin and are specifying that the eartag may not be removed until the animal is slaughtered.
- We are requiring that the animal health certification currently required under existing § 93.405 for certain live animals imported into the United States include, for feeder cattle imported from a BSE minimal-risk region, additional information relating to animal identification, origin, destination, and responsible parties.
- We are requiring that feeder cattle be moved from the port of entry to a feedlot in a sealed means of conveyance and then from the feedlot to a recognized slaughtering establishment in a sealed means of conveyance. The cattle may not be moved to more than one feedlot.
- When referring to the destination of feeder cattle imported into the United States, we are using the terminology ''the feedlot identified on the APHIS Form VS 17–130'' rather than ''designated feedlot.''
- We are specifying that the physical location of the feedlot of destination and the person responsible for movement of the cattle be identified on the documentation required for movement from the port of entry to the feedlot.

2. For sheep and goats imported from a BSE minimal-risk region for feeding and then slaughter (referred to as ''feeder sheep and goats'') we are making the following changes:

- As with cattle, we are requiring that feeder sheep and goats be permanently marked before entry as to country of origin (with the requirements for marking modified as appropriate for sheep and goats). Feeder sheep and goats imported from Canada must be marked with ''C.''
- As with cattle, we are requiring that feeder sheep and goats be individually identified before entry by an eartag that allows the animal to be traced back to the premises of origin and are specifying that the eartag may not be removed until the animal is slaughtered.
- We are continuing to refer to the feedlot of destination for feeder sheep and goats as a ''designated feedlot'' and are adding criteria for such feedlots. The sheep and goats may not be moved to more than one designated feedlot.
- We are requiring the same additional information on the health certification required under § 93.405 as described above for feeder cattle.
- We are requiring that feeder sheep and goats be moved from the port of entry to a designated feedlot as a group in a sealed means of conveyance, not be

commingled with any sheep or goats that are not being moved directly to slaughter from the designated feedlot at less than 12 months of age, and be moved from the designated feedlot to a recognized slaughtering establishment in a sealed means of conveyance.

3. For sheep and goats imported from a BSE minimal-risk region for immediate slaughter, we are prohibiting the importation of sheep and goats that are positive, suspect, or susceptible for TSEs.

4. We are moving the provisions for the importation of feeder sheep and goats from Canada from proposed § 93.436 to § 93.405 and § 93.419.

5. We are moving the provisions for the importation of sheep and goats from Canada for immediate slaughter from proposed § 93.436 to § 93.419 and § 93.420.

6. We are clarifying in § 93.420 that all ruminants imported from Canada for immediate slaughter must be moved to a recognized slaughtering establishment in a sealed means of conveyance.

7. We are not specifying in our regulations that the intestines from bovines imported from Canada be removed at slaughter in the United States and be disposed of in a manner approved by the Administrator.

8. We are not including any import restrictions because of BSE for live cervids (e.g., deer, elk) and cervid products from a BSE minimal-risk region.

9. We are specifying that there are no import restrictions because of BSE for camelids (i.e., llamas, alpacas, guanacos, and vicunas) from a BSE minimal-risk region.

10. We are also providing in § 94.18 for the overland transiting of products derived from bovines, sheep, and goats from a BSE minimal-risk region that are eligible for entry into the United States. Additionally, we are clarifying that the existing provisions in § 94.18 for the transiting of ruminant products from regions in which BSE exists or that pose an undue risk of BSE apply only to transiting at air or sea ports.

11. We are requiring that bovines, sheep, and goats imported from a BSE minimal-risk region be subject to a ruminant feed ban equivalent to requirements established by Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services at 21 CFR 589.2000. This is a change from our proposal that the ruminants ''are not known to have been fed ruminant protein, other than milk protein.''

12. In the definition of *bovine spongiform encephalopathy (BSE) minimal-risk region,* we are rewording the factor that said a BSE minimal-risk region is one that has ''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'' to say instead that the region is one in which ''a ruminant-to-ruminant feed ban is in place and is effectively enforced.''

13. We are providing that meat, meat byproducts, and meat food products derived from bovines from a BSE minimal-risk region may not be imported into the United States unless an air-injected stunning process was not used at slaughter and unless the specified risk materials (SRMs) and the small intestine were removed in the exporting region, consistent with the FSIS regulations at 9 CFR 313.15 and 310.22 for stunning and processing in the United States. We are defining SRMs as those materials designated as such by FSIS in 9 CFR 310.22, to include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle.

14. We are removing the proposed requirement that imported meat derived from bovines from BSE minimal-risk regions be derived only from animals less than 30 months of age when slaughtered.

15. We are removing the proposed requirement that meat derived from bovines in a BSE minimal-risk region that are slaughtered in that region come from animals slaughtered at a facility that either slaughters only bovines less than 30 months of age or complies with an approved segregation process.

16. We are clarifying that the final rule applies to ''meat,'' ''meat byproducts,'' and ''meat food products'' as defined by FSIS.

17. We are removing the requirement that hunter-harvested meat be accompanied by a certificate of the national government of Canada.

18. We are clarifying the type of ruminant offal from a BSE minimal-risk region that is allowed importation into the United States.

19. We are providing that tallow may be imported from a BSE minimal-risk region provided the tallow is composed of less than 0.15 percent insoluble impurities and is not commingled with any other material of animal origin.

20. We are providing that, except for gelatin allowed importation under § 94.18(c), gelatin imported from a BSE minimal-risk region must be derived from the bones of bovines that were subject to a ruminant feed ban equivalent to the requirements established by FDA at 21 CFR 589.2000 and from which SRMs were removed.

21. We are providing that sheep casings may be imported from a BSE minimal-risk region provided the sheep from which the casings were derived were less than 12 months of age when slaughtered and were subject to a ruminant feed ban equivalent to that of FDA at 21 CFR 589.2000.

22. We are adding and revising definitions in this final rule to clarify the meaning of certain terms used in the rule.

III. Background

A. Bovine Spongiform Encephalopathy

APHIS regulates the importation of animals and animal products into the United States to guard against the introduction of various animal diseases, including BSE. The regulations are contained in 9 CFR parts 92, 93, 94, 95, and 96.

BSE is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). In addition to BSE, TSEs include, among other diseases, scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and variant Creutzfeldt-Jakob disease in humans. The agent that causes BSE and other TSEs has yet to be fully characterized. The theory that is most accepted in the scientific community is that the agent is a prion, which is an abnormal form of a normal protein known as cellular prion protein. The BSE agent does not evoke any demonstrated immune response or inflammatory reaction in host animals. BSE is confirmed by postmortem microscopic examination of an animal's brain tissue or by detection of the abnormal form of the prion protein in an animal's brain tissues. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is extremely resistant to heat and to normal sterilization processes. BSE is spread to cattle primarily through the consumption of animal feed containing protein from ruminants infected with BSE.

BSE was first diagnosed in 1986 in the United Kingdom. Since then, there have been more than 187,000 confirmed cases of BSE in cattle worldwide. The disease

has been confirmed in native-born cattle in 20 European countries in addition to the United Kingdom, and in some non-European countries, including Japan, Israel, and Canada. Over 95 percent of all BSE cases have occurred in the United Kingdom, where the epidemic peaked in 1992/1993. Agricultural officials in the United Kingdom have taken a series of actions to mitigate BSE, including making it a reportable disease, banning mammalian meat-and-bone meal in feed for all food-producing animals, prohibiting the inclusion of animals more than 30 months of age in the animal and human food chains, and destroying all animals showing signs of BSE and other potentially exposed animals at high risk of developing the disease. As a result of these actions, most notably the feed bans, the annual incidence of BSE in the United Kingdom has fallen dramatically. The figure below illustrates the downward trend in BSE cases among cattle born after implementation of the feed ban.

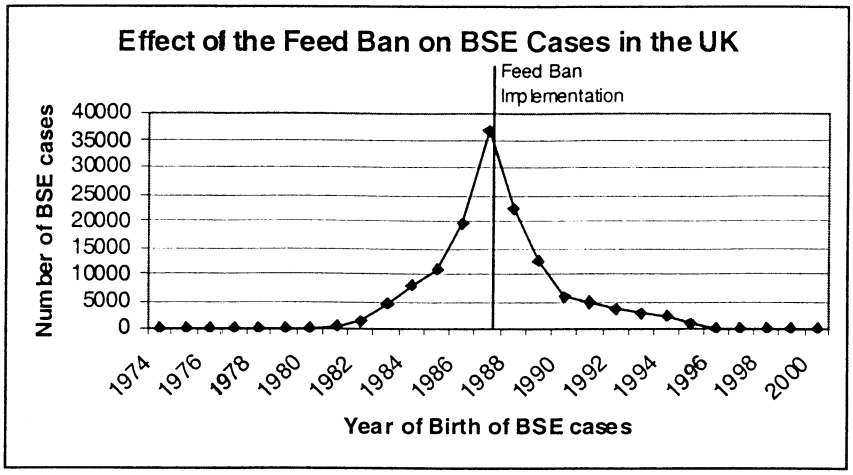

Figure 1.–Confirmed cases in UK cattle born after feed ban implementation. [Note: The first feed ban was implemented in the summer of 1988 (before fall calving).]

Variant Creutzfeld-Jakob disease (vCJD), a chronic and fatal neurodegenerative disease of humans, has been linked via scientific and epidemiological studies to exposure to the BSE agent, most likely through consumption of cattle products contaminated with the BSE agent. To date, since vCJD was first identified in 1996, approximately 150 probable and confirmed cases of vCJD have been identified. The majority of these cases have either been identified in the United Kingdom or were linked to exposure that occurred in the United Kingdom, and all cases have been linked to exposure in countries with native cases of BSE. Some studies estimate that more than 1 million cattle may have been infected with BSE throughout the epidemic in the United Kingdom. This number of infected cattle could have introduced a significant amount of infectivity into the human food supply. Yet, the number of cases of vCJD identified to date suggest a substantial species barrier that may protect humans from widespread illness due to BSE.

B. APHIS' Regulatory Approach to BSE: Past and Present

Since 1989 APHIS has prohibited the importation of live cattle and other ruminants and certain ruminant products, including most rendered protein products, into the United States from countries where BSE is known to exist. In 1997, due to concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, APHIS added an additional classification of countries as regions of undue risk for BSE and extended importation restrictions on ruminants and ruminant products to all of the countries in Europe. In December 2000, APHIS expanded its prohibitions on imports of rendered ruminant protein products from BSE-restricted regions to include rendered protein products of any animal species, due to concern that cattle feed supposedly free of ruminant protein may have been cross-contaminated with the BSE agent. The same importation restrictions apply to regions where BSE has been confirmed in a native animal and regions that present an undue risk of BSE because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance (9 CFR 94.18).

In effect then, until implementation of this final rule, countries have fallen into one of three categories with regard to BSE:

- Regions in which BSE is known to exist;
- Regions that present an undue risk of BSE because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance; and
- Regions that do not fall into either of the above two categories.

This regulatory framework recognized only two risk situations—those regions considered free of BSE and those regions considered to present a BSE risk—and prohibited the importation of live ruminants and most ruminant products from those regions considered to present a BSE risk.

In our November 2003 proposed rule, we explained that we believed it was appropriate to establish an additional category of regions with regard to BSE—the BSE minimal-risk region. We stated that regions that could be eligible for a minimal-risk classification would be (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 that 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. We proposed to add Canada to the new BSE minimal-risk category and also proposed conditions for the importation of certain live ruminants and ruminant products and byproducts from BSE minimal-risk regions.

Our proposed definition of BSE minimal-risk regions included the standards we would use to evaluate the BSE risk from a region and to classify a region as one of minimal risk for BSE. To qualify as a BSE minimal-risk region, we proposed that a region be one that meets the following standards:

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. Such measures include the following:

- 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;
- Surveillance for BSE at levels that meet or exceed recommendations of the Office International des Epizooties (OIE, also now referred to as the World Organisation for Animal Health) for surveillance for BSE; and
- A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE agent, with no evidence of significant noncompliance with the ban.

2. In regions where BSE was detected, the region 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, 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.

We stated in our proposal that we would use these standards as a combined and integrated evaluation tool, basing a BSE minimal-risk classification on the overall effectiveness of control mechanisms in place (e.g., surveillance, import controls, and a ban on the feeding of ruminant protein to ruminants). We noted that this approach would differ from some of the numerical guidelines specified by OIE in its recommendations for a BSE minimal-risk country or zone (discussed below).

Basis for Focused Regulatory Restrictions

Our proposed rule was based on a number of considerations. A significant amount of research has been conducted on BSE since the disease was initially identified and since we first established our regulatory framework to protect against the introduction of BSE. (Please note: In this final rule, we use the term ''importation'' to mean the movement of animals or products into the United States or another country and the term ''introduction'' to mean the movement of a disease agent into the United States or another country.)

While there are many unanswered questions, both research studies and field epidemiological experience have demonstrated effective control measures to prevent spread of this disease. Ongoing studies have identified specific tissues where the majority of infectivity appears to reside, so that these tissues can be removed from the food chain. Early epidemiological work identified contaminated feed as the primary method of spread of the disease between animals. Continued monitoring and surveillance in Europe—where the exposure is assumed to be the highest—have demonstrated the effectiveness of control measures that have been enacted, such as feed bans that prevent the recycling of the agent. This increased body of knowledge provides a sound and compelling scientific basis for more focused regulatory restrictions with regard to BSE than those we have been operating under.

A more focused approach is also supported by the international community, as evidenced by the evolution of BSE guidelines adopted by the OIE (Ref 1). The OIE is recognized by the World Trade Organization (WTO) as the international organization responsible for development and periodic review of standards, guidelines, and recommendations with respect to animal health and zoonoses (diseases that are transmissible from animals to humans). The OIE guidelines for trade in terrestrial animals (mammals, birds, and bees) are detailed in the Terrestrial Animal Health Code (Ref 2). The OIE guidelines on BSE, contained in Chapter 2.3.13 of the Terrestrial Animal Health Code, and supplemented by Appendix 3.8.4 of the Code, currently provide for five possible BSE classifications for regions. For each classification, the guidelines recommend different export conditions for live animals and products, based on the risk presented by the region. This framework not only recognizes different levels of risk among regions, but provides for trade in live animals and products under certain conditions even from regions considered high-risk under the OIE guidelines.

As a member of the OIE, the United States, represented by APHIS, has been actively involved in the development of OIE guidelines and fully supports the OIE position that gradations in BSE risk among regions should be recognized and that trade should be commensurate with risk. Although APHIS did not incorporate the text of OIE's BSE guidelines into its proposed rule, the agency based its standards on these guidelines. The standards contain the same basic factors for assessing a region's BSE status as the OIE guidelines (e.g., import requirements, incidence, surveillance, feed restrictions, etc.). APHIS also considered the OIE guidelines, in conjunction with other relevant factors and available information, when evaluating Canada as a BSE minimal-risk region, and will do so in the future in evaluating other countries that may apply for minimal-risk status under our regulations. It is in this context that APHIS' standards and the OIE guidelines should be viewed.

We believe it is important to explain the relationship of our standards to the OIE guidelines because a number of commenters questioned why we did not adopt the OIE guidelines outright and/or assumed that differences in text meant that APHIS had rejected the OIE guidelines. While there are differences between the APHIS standards and the OIE guidelines, these differences reflect the different purposes and uses of the OIE guidelines and our standards.

The OIE guidelines are designed to provide a science-based reference document for international trade in animals and animal products. To this end, the OIE Terrestrial Animal Health Standards Commission draws upon the expertise of internationally renowned specialists to draft new and revised articles of the Terrestrial Code in light of advances in veterinary science. Draft texts are circulated to member countries for review and comment and, as a general rule, are adopted based on consensus of the OIE membership. Articles adopted by the membership provide guidance for use by veterinary authorities, import/export services, epidemiologists and all those involved in international trade. OIE guidelines are not intended to be prescriptive; each member nation may determine its own appropriate level of protection and, therefore, establish its own import requirements. (In accordance with Article 5 of the WTO ''Agreement on the Application of Sanitary and

Phytosanitary Measures'' (WTO–SPS Agreement), WTO members are obligated to base their import requirements on an assessment of risk, taking into account the standards, guidelines, and recommendations, and the risk assessment techniques developed by the relevant international organizations.)

Regulations, which may be based on the OIE guidelines, are prescriptive, as they are intended to be enforced as written and are not designed to be a point of reference. Furthermore, because rulemaking may take considerable time, the most successful regulations must also be flexible enough to allow a country to consider individual circumstances among its trading partners, as well as changes in science, without undergoing constant revisions. One reason that APHIS has decided not to simply adopt the OIE guidelines as regulations is that they are constantly evolving and subject to change. Some chapters, in fact, such as the one on BSE, are continually being updated as new information becomes available. For example, the OIE is currently considering proposing a three-tier country classification system for BSE as an alternative to the existing five-tier system. In 2004, the OIE changed the recommended reported incidence rate for minimal-risk regions from less than 1 case per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age to less than 2 cases per million during that time period within that cattle population. This example of a numeric threshold points to another reason that APHIS chose not to adopt the OIE guidelines as regulations. In some cases, holding a country to a rigid criterion without consideration of compensatory risk reduction measures may not be scientifically justified and unfairly discriminate against regions where the overall conditions indicate equivalence with minimal BSE risk. In other cases, rigidly applying a numeric criterion without a thorough consideration and evaluation of relevant factors (e.g., the quality of a country's surveillance program and the supporting veterinary infrastructure) could result in trade with a region that may meet OIE guidelines but, nonetheless, present, in our view, an undue risk of BSE introduction. Therefore, rather than incorporate the text of the OIE guidelines into our regulations, APHIS chose to base its evaluation on OIE guidelines in a way that allows us to consider an individual country's specific situation and to analyze risk based on the overall effectiveness of actions taken by the country to prevent the introduction and spread of BSE.

As stated above, APHIS considered the OIE guidelines in evaluating whether Canada met our proposed standards, and we plan to consider them in assessing whether other countries that may apply for minimal-risk classification meet our standards. To illustrate how we would use the OIE guidelines for minimal-risk regions in applying our own standards, we can look to our evaluation of the incidence of BSE with respect to Canada. Although APHIS' standards do not include a numerical threshold for incidence, our standards provide that a region must have in place risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. In concluding that measures taken in Canada had prevented widespread exposure and/or establishment, we compared Canada's incidence rate of two infected cattle in 2003 out of a population of 5.5 million cattle over 24 months of age with OIE's recommendation of less than two infected cattle per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age. Canada's incidence rate (0.4 per million head of adult cattle) is well below the current OIE recommendation regarding incidence in minimal-risk regions. We also considered that the reported rate of disease cannot be considered independently from either the level and quality of disease surveillance or from the position on the epidemic curve. In this regard, we note that Canada exceeds the OIE recommended level of testing. We also consider Canada's surveillance program for BSE in cattle to be of high quality because it includes active surveillance for BSE in cattle that is appropriately targeted based on known risk factors. Also, because Canada implemented import restrictions and a feed ban before detection of BSE in any indigenous animals, it is more likely that the incidence of BSE in Canada is decreasing (on the down slope of the epidemic curve), rather than increasing (on the up slope).

The November 2003 Proposed Rule

As explained above, our proposed standards for minimal-risk regions were based on the OIE guidelines for BSE minimal-risk regions, using those guidelines as a reference. We based our proposed classification of Canada as a minimal-risk region, as well as our proposed mitigation measures for live ruminants and ruminant products and byproducts from Canada, on an analysis of risk APHIS prepared entitled, ''Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States.'' The analysis drew on a number of sources of information, including scientific literature, results of epidemiological investigations, data provided by the Canadian Government, a quantitative analysis (i.e., uses numerical values) of the risk of BSE in Canada prepared by the Canadian Food Inspection Agency (CFIA), and quantitative analyses of the consequences of BSE being introduced into the United States prepared by the Harvard Center for Risk Analysis at Harvard University (HCRA) and the Center for Computational Epidemiology at Tuskegee University (Ref 3) (discussed in more detail below under the heading ''Harvard-Tuskegee Investigation of BSE Risk in the United States''). This analysis was made available to the public when the proposed rule was published in November 2003.

We solicited public comment on the proposed rule and its underlying risk analysis and other supporting analyses for 60 days ending on January 5, 2004. As noted, at the time the proposed rule was published, BSE had never been detected in a native animal in the United States, and only a single case in a native animal had been reported in Canada (in Alberta in May 2003).

The Reopening of the Comment Period and Explanatory Note

On December 23, 2003, less than 2 weeks before the close of the comment period for our proposed rule, USDA announced a presumptive positive case of BSE in a dairy cow in Washington State. Samples had been taken from the cow on December 9 as part of USDA's BSE surveillance program. The BSE diagnosis was made on December 22 and 23 by histopathology and immunohistochemical testing at the National Veterinary Services Laboratories in Ames, IA, and was verified on December 25 by the international reference laboratory, the Veterinary Laboratories Agency in Weybridge, England.

Upon detection of the BSE-positive cow in Washington State, USDA, FDA, and other Federal and State agencies, along with CFIA, immediately began working together to perform an epidemiological investigation (Ref 4), trace any potentially infected cattle, trace potentially contaminated rendered product, increase BSE surveillance, and take additional measures to address human and animal health.

The epidemiological investigation and DNA test results confirmed that the infected cow was not indigenous to the United States, but rather was born and most likely became infected in Alberta, Canada, before Canada's 1997 implementation of a ban on feeding mammalian protein to ruminants.

Following detection of the imported BSE-infected cow in Washington State in December 2003, further safeguards on human and animal health were implemented in the United States by FDA and FSIS. These actions are described in more detail below under the headings ''Measures Implemented by FSIS'' and ''Measures Implemented by FDA.''

In response to comments from the public requesting an extension of the comment period and in order to give the public an additional opportunity to comment on the proposed rule in light of these developments, on March 8, 2004, we published a notice in the **Federal Register** (69 FR 10633–10636, Docket No. 03–080–2) reopening and extending the comment period until April 7, 2004. The notice also announced the availability of a document titled ''Explanatory Note'' that discussed each component of the original risk analysis and related information in light of the new BSE case. (You may view the Explanatory Note document on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.* Click on the document titled ''Analysis of Risk—Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004.'')

The Explanatory Note stated that APHIS did not consider the detection of a second BSE case to have an effect on the conclusions of the original risk analysis and explained why. The original risk analysis addressed the likelihood that animals might have been infected before Canada implemented its feed ban in 1997 and also concluded that compliance with the feed ban in Canada would have minimized the likelihood of infectivity from these animals spreading to other ruminants in Canada.

As noted above, the epidemiological investigation and DNA test results indicated that the infected cow most likely became infected before Canada's 1997 implementation of a ban on feeding mammalian protein to ruminants. Both animals diagnosed with BSE were older than 30 months of age. The cow found to have BSE in December 2003 also was imported into the United States when it was older than 30 months; the proposed rule would not have allowed the importation of cattle 30 months of age or older.

The Explanatory Note observed further that, although an additional animal of Canadian origin had been diagnosed with BSE since the time APHIS published its November 2003 proposed rule and risk analysis, the fact remained that only two cases of BSE had been detected in animals born in Canada. The Explanatory Note also discussed the additional BSE control measures taken by Canada after BSE had been detected in that country.

The March 2004 notice that reopened and extended the comment period on our proposed rule also proposed allowing the importation of beef from Canada, regardless of the age of the cattle from which it was derived, provided other specified mitigating conditions were met, and invited comment on this change from our November 2003 proposal. The original proposal would have required the beef to come from cattle that were less than 30 months of age at the time of slaughter.

We explained in the notice that the change in our thinking was based on the changes FSIS made in its regulations in January 2004, and the fact that Canada had also implemented the changes made by FSIS. Among other things, FSIS required that cattle tissues considered at particular risk of containing the BSE agent in infected animals (referred to as ''specified risk materials'' or SRMs) be removed from cattle at slaughter and prohibited their use in human food. FSIS designated as SRMs the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle. To ensure effective removal of the distal ileum, FSIS also required that the entire small intestine be removed and be disposed of as inedible. FSIS did not restrict the age of cattle eligible for slaughter, because the removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that pass both ante-mortem and post-mortem inspections (i.e., apparently healthy cattle); FSIS and FDA regulations prohibit the use of other cattle in human food. The Canadian Government had already established equivalent safeguards in Canada in July 2003. In addition, because regions wishing to export meat and meat products to the United States must follow processing practices equivalent to those of FSIS, the FSIS requirements effectively require removal of SRMs from all cattle slaughtered outside the United States when meat derived from those cattle is intended for export to the United States, which would prevent such materials from entering the food chain in the United States. Additionally, FDA's feed ban prohibits ruminant protein from entering the ruminant feed chain. Therefore, we stated in our notice that we did not believe it was necessary to require that beef imported from BSE minimal-risk regions be derived from cattle under 30 months of age, provided measures equivalent to those of FSIS regarding SRM removal are in place in the exporting region and provided such other measures as are necessary (e.g., a prohibition on the use of air injection stunning devices, controls to prevent cross-contamination) are in place.

We received a total of 3,379 comments on the proposed rule from the public by the close of the comment period on April 7, 2004.

C. Background Information for APHIS' Response to Comments

Before discussing the comments received, we consider it useful to discuss a number of documents and actions that contributed to the basis for our establishment of a BSE minimal-risk region category and our inclusion of Canada in that category. These include: Measures implemented by FSIS and FDA to further reduce BSE risk in the United States; the Harvard-Tuskegee investigations of BSE risk in the United States; a memorandum from Joshua Cohen and George Gray of the HCRA; measures taken in Canada in response to BSE risk prior to May 2003; a 2002 Canadian assessment of BSE risk in that country; the epidemiological investigation and a report by an international review team following the diagnosis of BSE in a cow in Canada in May 2003; additional measures taken in Canada; and an update to the APHIS analysis of the risk of allowing the importation of ruminants and ruminant products and byproducts from Canada.

Roles of Different Agencies

Protecting human and animal health from the risks of BSE is carried out on the Federal level primarily by APHIS regarding animal health and FSIS regarding food safety, in coordination with the following FDA Centers: The Center for Veterinary Medicine regarding animal feed; the Center for Food Safety and Applied Nutrition regarding foods other than meat, poultry, and egg products; and other Centers regarding drugs, biologics, and

devices containing bovine material. These agencies collaborate, issuing regulations under their respective authorities, to implement a coordinated U.S. response to BSE.

APHIS is promulgating this final rule under the authority of the Animal Health Protection Act, which gives the Secretary broad discretion to regulate the importation of animals and animal products when he or she determines it to be necessary. As discussed below, FSIS and FDA have recently published regulations regarding BSE to protect human health. Because of the specific focus of each of these three agencies, provisions for similar products may sometimes differ slightly in the agencies' respective regulations as appropriate based on the intended consumer.

Measures Implemented by FSIS

FSIS, in a series of three interim final rules that were published and made effective on January 12, 2004, took additional measures to prevent the BSE agent from entering the human food supply. In its interim final rule titled, ''Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle'' (FSIS Docket No. 03–025IF; 69 FR 1861), and referred to below as the SRM rule, FSIS designated certain cattle tissues as SRMs and prohibited their use in human food. As noted earlier, FSIS designated as SRMs the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle as SRMs. FSIS also required removal of the entire small intestine and disposal of it as inedible to ensure effective removal of the distal ileum.

To facilitate enforcement of the SRM rule, FSIS has developed procedures to verify the approximate age of cattle that are slaughtered in official establishments. Such procedures, based on records or examination of teeth, are intended to ensure that SRMs from cattle 30 months of age and older are effectively segregated from edible materials (Ref 5).

As provided by the SRM rule, materials designated as SRMs if they are from cattle 30 months of age and older will be deemed to be SRMs unless the establishment can demonstrate that they are from an animal that was younger than 30 months of age at the time of slaughter.

Further, FSIS developed procedures to verify that cross-contamination of edible tissue with SRMs is reduced to the maximum extent practical in facilities that slaughter cattle or process carcasses or parts of carcasses of cattle, for cattle both younger than 30 months of age and 30 months of age and older (Ref 5).

The SRM rule also declared mechanically separated beef (MS(beef)) to be inedible and prohibited its use for human food. Additionally, the SRM rule prohibited all non-ambulatory disabled cattle for use as human food.

The second interim final rule, titled ''Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems'' (FSIS Docket No. 03–038IF; 69 FR 1874–1885), prohibited products produced by advanced meat recovery (AMR) systems from being labeled as ''meat'' if, among other things, they contain central nervous system (CNS) tissue. AMR is a technology that enables processors to remove the attached skeletal muscle tissue from livestock bones without incorporating significant amounts of bone and bone products into the final meat product. FSIS had previously established and enforced regulations that prohibited spinal cord from being included in products labeled ''meat.'' The interim final rule expanded that prohibition to include dorsal root ganglia (DRG)—clusters of CNS tissue connected to the spinal cord along the vertebral column. In addition, because the vertebral column and skull of cattle 30 months of age and older have been designated as SRMs, they cannot be used for AMR. Because they are not SRMs, the skull and vertebral column from cattle younger than 30 months of age are allowed to be used in AMR systems. However, establishments that use skulls and vertebral columns in the production of beef AMR product must be able to demonstrate that such materials are from cattle younger than 30 months of age.

The third interim final rule, titled ''Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter'' (FSIS Docket No. 01–0331IF; 69 FR 1885–1891), prohibited the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle, because the use of such devices may force large fragments of CNS tissue into the circulatory system of stunned cattle where the fragments may become lodged in edible tissues.

Also on January 12, 2004, FSIS published a notice, ''Bovine Spongiform Encephalopathy Surveillance Program,'' announcing it would no longer pass and apply the mark of inspection to carcasses and parts of cattle selected for BSE testing by APHIS until the sample testing has been completed, and the result is negative (FSIS Docket No. 03–048N; 69 FR 1892).

Measures Implemented by FDA

FDA, like FSIS, has taken additional measures to prevent the BSE agent from entering the human food supply. In an interim final rule published in the **Federal Register** on July 14, 2004, ''Use of Materials Derived from Cattle in Human Food and Cosmetics,'' FDA prohibited SRMs (the same as defined by FSIS), the small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and MS(beef) from use in FDA-regulated human food, including dietary supplements, and cosmetics (69 FR 42255; FDA Docket No. 2004N–0081).

In an advance notice of proposed rulemaking issued jointly by FDA, FSIS, and APHIS on July 14, 2004, ''Federal Measures to Mitigate BSE Risks: Considerations for Further Action'' (69 FR 42288–42300, FDA Docket No. 2004N–0264, FSIS Docket No. 04–021ANPR, APHIS Docket No. 04–047–1), FDA requested additional information to help it determine the best course of action to reduce the already small risk of BSE spread through animal feed. (We refer to the advance notice of proposed rulemaking below as the ''USDA/FDA joint notice.'')

FDA continues to conduct inspections to monitor compliance of domestic feed mills, renderers, and protein blenders with regulations it put in place in 1997 to prevent recycling of potentially infectious cattle tissue through ruminant feed. (FDA regulations at 21 CFR 589.2000 prohibit the feeding of most mammalian protein to ruminants in the United States.) FDA also has expanded the scope of its inspections to include other segments of animal feed production and use, such as transportation firms, farms that raise cattle, and animal feed salvage operations. Compliance with the feed ban by U.S. feed mills, renderers, and protein blenders is currently very high. As of July 2004, conditions or practices warranting regulatory sanctions had been found in less than 1 percent of inspected facilities (Ref 6).

Harvard-Tuskegee Investigation of BSE Risk in the United States

In April 1998, USDA commissioned the HCRA at Harvard University and the Center for Computational Epidemiology at Tuskegee University to conduct a comprehensive investigation of BSE risk

in the United States. The report was completed in 2001 and released by the USDA. Following a peer review of the Harvard-Tuskegee Study in 2002 (Ref 7), the authors responded to the peer review comments (Ref 8) and released a revised risk assessment in 2003 (Ref 3). The report, widely referred to as the Harvard Risk Assessment or the Harvard Study, is referred to in this document as the Harvard-Tuskegee Study.

The Harvard-Tuskegee Study reviewed available scientific information related to BSE and other TSEs, assessed pathways by which BSE could potentially occur in the United States, and identified measures that could be taken to protect human and animal health in the United States. The assessment concluded that the United States is highly resistant to any amplification of BSE or similar disease and that measures taken by the U.S. Government and industry make the United States robust against the spread of BSE to animals or humans should it be introduced into this country.

The Harvard-Tuskegee Study concluded that the most effective measures for preventing the potential spread of BSE are: (1) The ban placed by APHIS on the importation of live ruminants and ruminant meat-and-bone meal from the United Kingdom since 1989 and all of Europe since 1997; and (2) the feed ban instituted in 1997 by FDA. The Harvard-Tuskegee Study further indicated that, if introduction of BSE had occurred via importation of live animals from the United Kingdom before 1989, mitigation measures in place in the United States at the time the Study was conducted would have minimized exposure and worked to eliminate the disease from the U.S. cattle population.

The Harvard-Tuskegee Study also identified three practices that could create a pathway for human exposure to the BSE agent or the spread of BSE should it be introduced into the United States: (1) Non-compliance with FDA's regulations prohibiting the use of certain proteins in feed for cattle and other ruminants; (2) rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed; and (3) the inclusion of high-risk tissues from cattle, such as brain and spinal cord, in products for human consumption.

The Harvard-Tuskegee Study's independent evaluation of the potential risk mitigation measures predicts that a prohibition against rendering of animals that die on the farm would reduce the number of potential cases of BSE in cattle following hypothetical exposure by 82 percent as compared to the base case scenario, and that a ban on SRMs (which included, according to the evaluation, the brain, spinal cord and vertebral column, ''gut,'' and eyes) from inclusion in human and animal food would reduce potential BSE cases in cattle by 88 percent and potential human exposure to BSE by 95 percent as compared to the base case scenario (Ref 9).

In 2003, following the identification of BSE in a native-born cow in Canada, USDA, working with HCRA, evaluated the implications of a then-hypothetical introduction of BSE into the United States from Canada, using the same simulation model developed for the initial Harvard-Tuskegee Study. This assessment, titled ''Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada'' (Ref 10), confirmed the conclusions of the earlier Harvard-Tuskegee Study—namely, that a very low risk exists of BSE becoming established or spreading should it be introduced into the United States.

Cohen and Gray Memorandum

Following receipt of comments from the public on its November 2003 proposed rule, APHIS requested the HCRA to respond to comments that pertained to the Harvard-Tuskegee Study. The HCRA's response to the comments, authored by Joshua Cohen and George Gray, was reported to APHIS in a June 18, 2004, memorandum, referred to below as ''the Cohen and Gray memorandum.'' The memorandum also updates the model used in the Harvard-Tuskegee Study with new data from the FDA addressing two critical model parameters—mislabeling of products containing prohibited ruminant protein and contamination of nonprohibited protein with prohibited protein. You may view the memorandum on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.* Click on the document titled ''Analysis of Risk—Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004.''

Measures Taken in Canada in Response to BSE Risk Prior to May 2003

Import restrictions. Canada imposed import restrictions to guard against the introduction of BSE, starting in 1990. In that year, Canada prohibited the importation of live cattle from the United Kingdom and the Republic of Ireland. In 1994, an import ban was imposed on all countries where BSE had been detected in native cattle. 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 following a comprehensive risk assessment. 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.

Canada has also restricted the importation of ruminant products, including meat-and-bone meal, 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 have been 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.

Feed ban. A crucial element in preventing the spread and establishment of BSE in a country is the implementation of a ruminant-to-ruminant feed ban. Canada implemented a feed ban in 1997 that prohibits the feeding of most mammalian protein 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 equivalent to the feed ban in place in the United States, with the addition that Canada prohibits the feeding of plate waste and poultry litter to ruminants.

Canada has provided information, including statistics on compliance, demonstrating that an effective feed ban is in place in the rendering, feed manufacturing, and livestock raising industries. Few cattle born before implementation of the Canadian feed ban are alive today, given that most male cattle are slaughtered before 24 months of age and given the normal cull rates for beef and dairy cows. It is estimated that 39.4 percent of the beef cattle born in 1996 are alive today. It is estimated that 5.8 percent of the dairy cattle born in 1996 are alive today.

Infected animals typically exhibit clinical signs of BSE 4 to 6 years after infection, and 95 percent of infected cattle exhibit clinical signs in less than 7 years. Since cattle born before the feed ban would now be 7 years of age or older, any remaining infected cattle, if present, would likely be showing clinical signs of BSE that would allow their detection through Canada's BSE surveillance system.

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. CFIA indicates that, with respect to the inedible rendering sector, full compliance with the feed ban requirements has been consistently achieved, and that, with respect to the Canadian commercial feed industry, CFIA has identified noncompliance of ''immediate concern'' in fewer than 2 percent of feed mills inspected during 2003–2004. Those instances of noncompliance of ''immediate concern'' are dealt with when identified. According to CFIA, noncompliance of immediate concern includes situations where direct contamination of ruminant feed with prohibited materials has occurred, as identified through inspections of production documents or visual observation, and where a lack of appropriate written procedures, records, or product labeling by feed manufacturers may expose ruminants to prohibited animal proteins (Ref 11).

Surveillance. Canada has an adult cattle population of approximately 5.5 million cattle older than 24 months of age. The current OIE Code, Appendix 3.8.4, references adult cattle populations as those greater than 30 months and recommends examining at least 300 samples per year from high-risk animals in a country with an adult cattle population of 5 million, or 336 samples per year in a country with an adult cattle population of 7 million. Even though the adult cattle population in Canada is defined as greater than 24 months of age and OIE defines it as greater than 30 months of age, Canada has met or exceeded this level of surveillance for the past 7 years, thus exceeding the OIE guidelines. Active targeted surveillance was begun in Canada in 1992, with numbers of annual samples ranging from 225 in 1992 to current levels of over 15,800 per year. This surveillance has continued to be targeted surveillance, with samples obtained from adult animals exhibiting some type of clinical signs or considered high risk for other reasons that could be considered consistent with BSE. During the time Canada has been conducting surveillance for BSE, BSE has been detected in only two cattle indigenous to Canada—the cows diagnosed with BSE in May and December 2003.

Canadian 2002 BSE Risk Assessment

In December 2002, CFIA issued an assessment of the risk of BSE in Canada. The assessment evaluated BSE risk factors and correlating risk mitigation measures being taken in Canada, as well as surveillance being conducted in that country to detect any BSE-infected animals. The risk assessment analyzed the possibility that BSE infectivity was introduced into Canada through 665 cattle imported into Canada from Europe between 1979 and 1997, when Canada implemented its feed ban. The analysis indicated a low potential for cumulative introduction of infectivity into Canada via these cattle and further suggested that the likelihood of the spread and establishment of BSE in Canada, both before and after the 1997 feed ban, was negligible (Ref 12).

Epidemiological Investigation and a Report by an International Review Team

On May 20, 2003, CFIA reported a case of BSE in a beef cow in northern Alberta. Following the detection of the BSE-infected cow, Canada conducted an epidemiological investigation of the BSE occurrence, working with, among others, APHIS representatives. The epidemiological investigation showed that the animal was born before implementation of the feed ban in 1997, and that exposure likely occurred prior to or near the time of the imposition of the feed regulations. Although a specific source of infection was not identified, the most likely source of exposure was feed that contained protein from an infected animal imported from the United Kingdom between 1982 to 1989.

Additionally, the epidemiological investigation focused on rendered material or feed that could have been derived from the carcass of the infected cow. As part of that investigation, a survey was conducted of approximately 1,800 sites that were at some risk of having received such rendered material or feed. The survey suggested that 99 percent of the sites surveyed experienced either no exposure of cattle to the feed (96 percent of the sites) 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. Depopulation of Canadian herds possibly exposed to the feed in question was carried out by the Canadian Government. Canadian officials conducted a wide-ranging investigation of possible exposure to the feed in question and carried out depopulation of Canadian herds possibly exposed to the feed. On each of those farms where the investigation could not rule out the possibility of exposure to feed that may have contained rendered protein from the infected animal, the herds were slaughtered and tested. All of those animals tested negative for BSE and their carcasses were disposed of in ways, such as disposal in landfills, to ensure that they did not go into the animal food chain (Ref 13).

In June 2003, an international review team (IRT) of animal disease experts assessed the CFIA's investigation of the May 2003 case of BSE and Canada's overall protective measures. The IRT noted the quality of the Canadian investigation and the effectiveness of protective measures in place in Canada. The IRT recommended a number of actions to further enhance the safety of human and animal health, including putting in place a national requirement that SRMs be removed from products destined for consumption; a review of animal feed restrictions; strengthened tracking and tracing systems; improved disease testing and surveillance; and additional efforts to improve disease awareness among producers, veterinarians, and the public (Ref 14).

Additional Measures Taken in Canada

Response to the IRT Report. Subsequent to the IRT report, in July 2003 Canada implemented the requirement that SRMs be removed from cattle at slaughter (Ref 15). Additionally, Canada implemented enhanced measures for identification and for tracking and tracing, as well as for increased BSE surveillance and testing. We discuss the increased surveillance and testing in greater detail below. (Ref 16).

Epidemiological Investigation of the Case in Washington State. As noted above, in December 2003, BSE was detected in a Canadian-origin cow in Washington State. Canada, along with the United States, conducted a rigorous epidemiological investigation. As with the May 2003 case, the epidemiological investigation showed that the animal was born in Canada before implementation of the feed ban in 1997 and, in all likelihood, was exposed to

BSE before or near the time the Canadian feed ban was imposed. As with the May 2003 case, although a specific source of infection was not identified, the investigation indicated that the most likely source of exposure was feed that contained protein from an infected animal imported from the United Kingdom between 1982 to 1989. Again, the investigation resulted in the destruction and testing of a large number of potentially exposed cattle, and testing resulted in no further evidence of infection.

Increased Surveillance. In January 2004, the Canadian Government announced that it would increase its level of BSE testing. As of December 1, 2004, Canada had tested more than 15,800 animals for BSE in 2004, all with negative results, and has announced its goal of testing at least 30,000 animals in 2005. The surveillance program focuses on testing high-risk cattle: dead, dying, diseased, and down cattle over 30 months of age and cattle showing neurological symptoms consistent with BSE. This level of testing represents a significant increase over previous testing levels; surveillance levels in Canada have increased to current levels from under 500 animals per year in 1996.

Update to APHIS' Risk Analysis and Summary of Mitigation Measures and Their Applicability to Canada as a BSE Minimal-Risk Region

In order to add transparency to APHIS' basis for establishing a BSE minimal-risk category and including Canada in that category, we are making available a separate update of factors and measures that mitigate the risk of BSE and their applicability to imports from Canada. This update, titled ''Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004,'' can be viewed on the Internet at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.* Click on the document titled ''Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004.''

The update extends the discussions APHIS provided previously in its risk analysis, explanatory note, proposed rule, and notice extending the comment period. In the update, we summarize the APHIS standards for a BSE minimal-risk region and the factors considered in our evaluation of such a region. We expand on our considerations of Canada as a minimal-risk region in the context of those standards. In accordance with OIE guidelines (Chapter 1.3.2), the original analysis had four major components: (1) Release assessment; (2) exposure assessment; (3) consequence assessment; and (4) risk estimation. In the update, we discuss in detail two of these four components—the release assessment and exposure assessment—and provide, in more depth, data relevant to our consideration of BSE risk. Finally, the update addresses information that has become available subsequent to our original analysis.

IV. Comments From the Public

As noted above, we received a total of 3,379 comments from the public by the close of the comment period on April 7, 2004. They were from members of Congress, representatives of State and local governments, livestock producers, importers and exporters, organizations representing livestock producers, organizations representing processors and distributors of animal products and byproducts, individual companies, representative of foreign governments, a national animal health association, human health associations, the academic community, and other members of the public.

Subjects of Comments Received

A number of commenters supported the rule and recommended no changes to the proposed provisions. Other commenters supported the rule in general but recommended certain changes to the proposed provisions. Others comments consisted only of recommended changes, objections to the rule in general or to specific provisions, or requests for clarification. In general, the comments we received on the proposed rule can be categorized as follows:

- Comments on the proposed standards for BSE minimal-risk regions;
- omments on whether Canada should be recognized as a minimal-risk region;
- Comments on the proposed risk mitigation measures for the importation of live ruminants from Canada;
- Comments on the proposed risk mitigation measures for the importation of ruminant meat and meat products derived from animals in Canada;
- Comments on the risk analysis;
- Comments on the economic analysis;
- Comments on the environmental analysis;
- Comments advocating that we delay implementation of this rule or withdraw the proposal;
- Comments on miscellaneous issues related to the proposed rule.

We discuss these comments by topic below.

Clarification

We note that, in order to clarify our intent in this final rule, we are making a change to the proposed minimal-risk standards that was not addressed by commenters. One of the standards we proposed to evaluate for a BSE minimal-risk region was whether 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. In this final rule, we are clarifying that the BSE detection referred to in that factor is detection in an animal indigenous to the region, consistent with the OIE guidelines for BSE. We are making this change to distinguish between the risk of BSE from detection in indigenous animals and imported animals. In this regard, detection of the disease in an indigenous animal suggests that transmission of the agent has occurred in the region, whereas an imported case does not.

In this final rule, we are making several other clarifications of our regulations. These additional clarifications are discussed below, following the discussion of comments, under the heading ''V. Additional Clarifications.''

A. Proposed Standards for BSE Minimal-Risk Regions

Some of the comments we received on our proposed rule agreed with the standards proposed for a BSE minimal-risk region and supported our proposed classification of Canada as such a region. However, a number of other commenters questioned the clarity of and basis for the BSE minimal-risk standards. Others disagreed that Canada should be considered such a region.

Proposed Minimal-Risk Standards in General

Issue: One commenter requested that APHIS reconsider the approach of establishing a category of BSE minimal-risk region. The commenter stated that, because OIE already lists a category very similar to APHIS' BSE minimal-risk category, referring to ''minimal risk'' in the proposal is an unnecessary duplication of definitions and could lead to confusion. The commenter also suggested that APHIS link definitions and the consequent treatment of animals and meat products to the OIE Code. Several commenters said that APHIS should not adopt criteria for BSE minimal-risk regions that differ from

OIE guidelines for BSE minimal-risk regions or questioned APHIS' basis for doing so. One of these commenters stated that OIE guidelines have highly detailed and specific criteria that allow the identification of minimal-risk regions and said that APHIS did not provide sufficient analysis in the proposed rule to support the creation of a new minimal-risk category. Some others said that APHIS did not adequately describe the scientific basis for deviating from the OIE guidelines, particularly with respect to time during which ruminant feed restrictions have been in place.

Response: We are making no changes based on these comments. We consider the definition of *BSE minimal-risk region* in this rule to be clear. We have explained our reasoning in detail for adopting performance standards for the critical factors, and discussed at some length our conclusion that some regulatory flexibility is essential. We noted the that the OIE guidelines are fluid, and discussed above in section III. B., under the heading ''APHIS' Regulatory Approach to BSE: Past and Present,'' that OIE may revise its BSE classifications in the near future.

As discussed above in section III. B. under the heading ''More Focused Regulatory Restrictions,'' although APHIS did not incorporate the text of OIE's BSE guidelines into its proposed rule, the agency based its standards on those guidelines, and the APHIS standards contain the same essential factors for assessing a region's BSE status as the OIE guidelines (*e.g.*, import requirements, incidence, surveillance, feed restrictions, etc.). The proposed rule and associated risk analysis explain where APHIS' proposed standards for minimal-risk regions departed from OIE guidelines. The preamble to the proposed rule discussed how we would use those standards to evaluate the BSE risk of a region. We said we would use the standards as a combined and integrated evaluation tool in evaluating a region, focusing on the overall effectiveness of all control mechanisms in place (*e.g.*, surveillance, import controls, and a ban on the feeding of ruminant protein to ruminants). We further explained that, in regions where BSE had been diagnosed, we would base our evaluation on the overall effectiveness of all control mechanisms in place at the time BSE was diagnosed in the region, and on actions taken after the diagnosis (*e.g.*, the epidemiological investigation of the occurrence). We agree that this approach differs from the OIE's in that it does not adhere to specific numerical recommendations specified in some of the OIE guidelines, but, as discussed earlier, the OIE guidelines are in flux and are meant to be a reference document. Further, disqualification of a region for failure to precisely meet one OIE recommendation would not account for a region's potential to present an overall minimal risk for BSE by exceeding other OIE recommendations or other relevant factors bearing on a risk to animal health.

We discussed in the proposed rule's preamble how we applied our standards for minimal risk to an evaluation of Canada's BSE risk. For example, we stated that, although Canada has had a feed ban in place for only 7 years (1 year less than provided for by OIE), this time period may be conservative because of the variability in the incubation period for BSE. Based on an analysis of data collected in the United Kingdom, the Harvard-Tuskegee Study (Ref 17) estimates that the variability distribution for the BSE incubation period in cattle has a median (50th percentile) of approximately 4 years and a 95th percentile of approximately 7 years. Based on the best-fit parameter values provided in the Harvard-Tuskegee Study (Ref 18), the mean (expected value) of the incubation period distribution is estimated at 4.2 years, and 7.5 years (August 1997 through January 2005) represents the estimated 97.5th percentile of the incubation period. We determined that the duration of the feed ban in Canada adequately addresses the expected BSE incubation period, taking into consideration all of the actions Canada has taken to prevent the introduction and control the spread of BSE (*e.g.*, import controls, level and quality of surveillance, effectiveness of feed ban, epidemiological investigation of detected cases, and depopulation of herds possibly exposed to suspected feed sources). We, therefore, concluded that a feed ban of less than 8 years' duration was appropriate for Canada. Canada, in fact, meets all OIE guidelines for a minimal-risk region, except for the duration of its feed ban.

We also note that OIE's guidelines for BSE include not just guidelines for classifying regions according to risk, but corresponding guidelines for trade in cattle, meat, and meat products from regions, according to the region's BSE risk classification. Our rule is consistent with this two-part OIE approach of considering a region's overall BSE risk status in combination with appropriate import restrictions for specific commodities.

Issue: A few commenters said that adopting criteria less stringent than OIE guidelines could result in other countries' perceiving the United States as having a greater BSE risk status and, therefore, prohibiting or restricting imports of cattle and beef from the United States. One commenter observed that OIE has five risk classifications for regions and said that, while some countries may choose to trade with high-risk regions, the United States should trade only with countries determined to be free of BSE.

Response: We are working diligently on an international level to ensure that BSE-related trade restrictions are based on sound science and a realistic understanding of the risks presented by the commodities we are proposing for trade. We do not believe it is appropriate to limit trade in cattle, meat, and meat products only to regions determined to be free of BSE if there are measures that can be applied to mitigate the risk of those commodities introducing BSE into the United States. There are such mitigation measures, consistent with those we have proposed. In fact, OIE guidelines provide for trade in cattle of any age, as well as beef and many other cattle products, even from countries that are considered high risk for BSE.

Issue: One commenter said that he was not opposed to APHIS' adopting criteria for minimal-risk regions that differ from OIE guidelines, but that APHIS' criteria put too much emphasis on import controls and epidemiological investigations and not enough on risk management measures in a country under consideration. The commenter mentioned a variety of risk mitigation measures in place in the European Union, including removal of SRMs; a ban on the feeding of mammalian meat-and-bone meal (MBM) to cattle, sheep, and goats; a suspension on the use of processed animal protein in feeds for any animals farmed for the production of food since January 2001, with the exception of fish meal for pigs and poultry; high processing standards for the treatment of ruminant animal waste; surveillance measures in accordance with the OIE Code; an ongoing awareness program for veterinarians; compulsory notification of all cattle showing clinical signs of BSE; testing of risk animals (fallen stock, emergency slaughtered animals, and animals with clinical signs at post-mortem inspection) over 24 months of age and healthy slaughtered animals over 30 months of age; culling policy for animals with a high probability of receiving the same potentially infected feed as a BSE case and offspring of female BSE cases; approval of rapid tests with the same sensitivity as the confirmatory methods.

Response: We agree with the commenter regarding the effectiveness of an integrated BSE risk management approach, and APHIS' standards for minimal-risk regions consider risk management measures such as those mentioned by the commenter. As discussed above, the standards we proposed for a BSE minimal-risk region included the need for risk mitigation measures to have been in place even before detection of BSE. These would be considered under the broad criteria that form our definition of minimal-risk region. Specifically, those standards include: (1) Having in place risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease, including import restrictions, surveillance for BSE at levels that meet or exceed OIE recommendations, and a ban on the feeding of ruminant protein to ruminants; (2) conducting, in regions where BSE has been detected, an epidemiological investigation sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE; and (3) taking additional risk mitigation measures, as necessary, in regions where BSE has been detected.

We emphasize, in this final rule, import controls as actions to avoid the introduction of the BSE infectious agent, and epidemiological investigations as action to promptly determine the extent of introduction. However, we also place value on risk management actions that were already in place in cases where BSE is detected.

Issue: Several commenters stated that APHIS' proposed standards for a minimal-risk region were relatively ambiguous compared to the corresponding provisions of the OIE Code. One such commenter stated this is partly because the proposal did not have an objective acceptable threshold regarding the extent of BSE infection in the country and a minimum enforcement period of effective measures, including a feed ban. Consequently, recommended the commenter, the United States should either: (1) Prepare objective guidelines that would allow exporting countries to determine their status with a certain level of predictability; or (2) investigate and approve more than one country. The commenter stated that the latter option would give other countries a much clearer idea of what is acceptable.

Response: As explained previously, while there are differences between the APHIS standards and the OIE guidelines, these differences reflect the different purposes and uses of the OIE guidelines and our standards. The OIE guidelines are designed to provide a science-based reference document for international trade in animals and animal products. Articles adopted by the OIE membership provide guidance for use by veterinary authorities, import/export services, epidemiologists and all those involved in international trade. OIE guidelines are not, however, intended to be prescriptive; each member nation may determine its own appropriate level of protection and, therefore, establish its own import requirements.

In contrast, regulations, which may be based on the OIE guidelines, are prescriptive, as they are intended to be enforced through an appropriate enforcement and compliance program. Furthermore, as rulemaking may take considerable time, the most successful regulations must also be flexible enough to allow a country to consider individual circumstances among its existing and potential trading partners, as well as advances in science, without undergoing constant revisions.

As explained previously, specific numeric recommendations in the OIE guidelines have changed over time and can be expected to change further in the future. Rigid adherence to each specific standard would disqualify some regions that present an overall minimal risk for BSE, despite not quite meeting one standard, as a result of exceeding certain other guidelines. We do not consider the suggested approach to provide a sufficient level of flexibility to allow consideration of the nature of BSE and the need to acknowledge and address varying permutations of risk among different regions on a case-by-case basis. Under the Animal Health Protection Act (AHPA) (7 U.S.C. 8301–8317), ''the Secretary may prohibit or restrict the importation or entry of any animal, article, or means of conveyance * * * if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock'' (7 U.S.C. 8303(a)). However, neither the AHPA nor the Secretary (or officials delegated by the Secretary) has delineated through regulations all the specific conditions that might be considered necessary to protect against the introduction of animal diseases or pests. This flexibility is necessary for APHIS to evaluate situations involving specific animal diseases or pests of concern and impose specific importation conditions necessary to mitigate the risk of the introduction of such diseases and pests.

The use of rigid criteria may limit the scope of acceptable alternatives for mitigating risk. This is particularly critical for trade-related issues. The situations in individual regions differ significantly, and each region defines its own particular spectrum of control measures. An equivalent level of risk might be reached using various combinations of different control measures. In this context, it is quite possible that a region that does not meet a particular numeric standard could compensate for any risk with other control measures. A case in point is Canada. Although Canada does not precisely meet the OIE guideline for duration of a feed ban, its control measures in other areas (such as surveillance and import restrictions) more than compensate for this. In some cases, holding a country to a rigid criterion without consideration of compensatory risk reduction measures may inappropriately discriminate against regions where the overall conditions indicate minimal BSE risk. In other cases, uniformly applying a numeric criterion without a thorough consideration of qualitative factors (*e.g.*, the quality of a country's surveillance program and the supporting veterinary infrastructure) could result in trade with a region that presents an undue risk of BSE introduction. In order to make rational decisions, APHIS needs the flexibility to make case-by-case determinations regarding the animal health status of particular regions. In fact, the OIE guidelines state that risk assessment should be flexible, in order to deal with the complexity of real-life situations. Specifically, the OIE Code states that risk assessment must be able to accommodate the variety of animal commodities, the multiple hazards that may be identified with an importation, the specificity of each disease, detection and surveillance systems, exposure scenarios, and types and amounts of data and information (Ref 19).

With regard to investigating and recognizing additional countries as BSE minimal-risk regions, that process begins with a request by the country interested in being considered, along with submission by that country of the necessary information. Several countries, in fact, submitted data in conjunction with their comments on our proposed rule. In those cases where the information exchange between the requesting country and the United States is at a very preliminary stage, it will likely be some time before we have all of the information needed and can complete our evaluation. Once an evaluation is completed, we will provide an opportunity for public comment through a proposed rule to

add the region to our list of minimal-risk regions for BSE.

Issue: Two commenters questioned why we did not include the preparation of a risk analysis as a criterion for minimal-risk status, pointing out that a risk analysis is a basic requirement for OIE country classification for BSE under the OIE guidelines. One of these commenters said that the OIE guidelines regarding BSE minimal-risk require that a risk analysis be conducted and appropriate measures be taken to manage any risk identified. In contrast, said the commenter, instead of focusing on a region's total risk analysis process (as the OIE guideline does), APHIS focuses only on whether the region's risk mitigation strategies are adequate to prevent ''widespread exposure and/or establishment of the disease.'' The commenter questioned whether this approach would allow a region's potential BSE risk to be adequately assessed and addressed before the region was considered minimal-risk.

Response: We consider an analysis of risk to be an inherent and integral component of the evaluation of a particular region with regard to BSE. Further, such an analysis is required under the WTO–SPS Agreement and the North American Free Trade Agreement. We encourage any region proposing trade to conduct such a risk analysis and include it with the documentation and data that APHIS requires. However, we did not include the preparation of a risk analysis by a region in our standards for minimal-risk status because APHIS itself intends to assess the BSE risk of a region using the criteria that were listed. APHIS routinely performs a risk analysis when proposing to allow imports, not just regarding BSE, but also with regard to other diseases of concern. A case in point is the risk analysis we prepared for this rulemaking. The standard mentioned by the commenter-whether a region's risk mitigation strategies are adequate to prevent widespread exposure and/or establishment of the disease—is only one factor that will be considered in the risk analysis. That factor itself has subsets concerning import restrictions, surveillance for BSE at levels that meet or exceed OIE guidelines, and a ban on the feeding of ruminant protein to ruminants. In addition, our risk analysis would assess whether, in regions where BSE has been detected, the region: (1) Had conducted an epidemiological investigation sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE and (2) had taken, and was continuing to take, additional risk mitigation measures, as necessary, such as, for example, increased surveillance. With regard to Canada, our risk analysis assessed both the risk mitigation measures in place before the diagnosis of BSE in that country and the actions Canada took after the detection.

Issue: Two commenters recommended that we provide more specificity about how APHIS would evaluate whether a region meets the criteria for minimal-risk status. One of the commenters called the proposed standards for minimal-risk regions ''a series of ill-defined factors'' and complained that no mechanisms for enumerating or weighing these factors were set forth in the proposal. The other commenter agreed with the approach of evaluating a region for minimal-risk status using a combined and integrated evaluation tool, rather than basing the evaluation on single-factor values such as OIE recommendations on feeding. However, the commenter suggested that how a region meets APHIS' standards should be quantitatively as well as qualitatively evaluated and that the results should be measured in terms of the relative importance to the combined and integrated overall evaluation (*e.g.*, surveillance might need to be different from the OIE recommendation and weighted more heavily than some other standards). The commenter suggested further that, in evaluating regions beyond Canada, APHIS should publish for public comment detailed risk assessments, as well as the results of the combined and integrated evaluation of the factors used to determine risk for establishing any BSE minimal-risk region.

Response: We consider it necessary and appropriate not to specify in the regulations mechanisms for enumerating or weighing the standards for a minimal-risk region. As discussed above under the heading ''More Focused Regulatory Restrictions,'' holding a country to a rigid criterion without consideration of compensatory risk reduction measures may, in some cases, unfairly discriminate against regions where the overall conditions indicate equivalence with minimal BSE risk. In other cases, uniformly applying a numeric criterion without a thorough consideration of qualitative factors (*e.g.*, the quality of a country's surveillance program and the supporting veterinary infrastructure) could result in trade with a region that presents an undue risk of BSE introduction.

Application of Standards to Other Countries

Issue: A number of commenters raised questions regarding how the proposed standards for BSE minimal-risk regions would be applied to countries other than Canada. Some commenters stated it appeared the standards were tailored to meet the situation in Canada. Several commenters proposed additional countries for classification as BSE minimal risk and suggested that those countries be included in this rulemaking. One commenter requested that APHIS publish for public comment evaluations done for regions beyond Canada. One commenter recommended that applications for BSE minimal-risk recognition from regions with similar status as Canada be rejected. Conversely, another commenter recommended that any countries that currently have standards that equal or exceed those of Canada should be included as BSE minimal-risk regions in this final rule.

Response: We stated in our proposed rule that we would consider requests from other countries for recognition as minimal-risk regions once the regulatory framework defining a BSE minimal-risk region had been established through this rulemaking. We will evaluate other countries using the same standards we used for evaluating Canada. Countries wishing to be recognized as minimal-risk regions by APHIS need to apply for such recognition by following the procedures set forth in 9 CFR part 92, ''Importation of Animals and Animal Products: Procedures for Requesting Recognition of Regions.'' Although the 11 factors listed in part 92 are not the same as the standards listed in this rule for BSE minimal-risk regions, they are broadly applicable to any change in disease status and are compatible with the BSE minimal-risk standards in this rule. As noted above, several countries submitted data in conjunction with their comments on our proposed rule. Once all of the necessary information is received, we will conduct an evaluation of the request and, if a proposal appears warranted, provide an opportunity for public comment through a proposed rule to add the region to our list of minimal-risk regions for BSE. A final rule based on the proposed rule would need to be issued before imports could begin.

Issue: One of the standards for minimal-risk status was that a region in which BSE has been detected must have had in place, prior to the detection of BSE in the region, risk mitigation measures adequate to prevent widespread exposure to and/or establishment of the disease. Several commenters asked how, according to that criterion, countries that reported cases of BSE before scientific studies had determined appropriate risk

mitigation requirements would be able to be considered BSE minimal-risk regions.

Response: We agree that countries that were among the first to diagnose BSE will, under the standards in this rule, not qualify as BSE minimal-risk regions. Because of the lengthy incubation period of the disease, by the time BSE was diagnosed in such countries and control measures were implemented, the chances that the disease had significantly spread were great. However, individual regions may apply to APHIS to be able to export to the United States specific products under conditions that could differ from those in our current regulations. Such applications should be submitted in accordance with 9 CFR part 92 and will be considered when received by APHIS.

Measures to Prevent Widespread Exposure or Establishment

Issue: In our proposed definition of *BSE minimal-risk region* in § 94.0, we provided that such a region must maintain, and, in the case of regions where BSE was detected, must have had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. One commenter asked the following questions: (1) What exactly are the risks to be addressed and mitigated by the country seeking minimal-risk status; (2) what risk mitigation measures are deemed adequate; and (3) what are the standards to be used to judge whether the measures are adequate?

Response: As discussed in the preamble to our proposed rule, in evaluating whether a country had in a place risk mitigation measures adequate to prevent widespread exposure or establishment of BSE, we would consider whether the country had in place:

- 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;
- Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE; and
- A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

We provided, further, that, in regions where BSE was detected, a minimal-risk region must have 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 must continue to take such measures. Additionally, the region must have taken additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continue to take such measures.

We did not specify numeric thresholds for each of the above criteria. As discussed above, because rulemaking may take considerable time, the most successful regulations must also be flexible enough to allow a country to consider individual circumstances among its trading partners, as well as changes in science, without undergoing constant revisions. Further, in some cases, holding a country to a rigid criterion without consideration of compensatory risk reduction measures may not be scientifically justified and may unfairly discriminate against regions where the overall conditions indicate minimal BSE risk. In other cases, rigidly applying a numeric criterion without a thorough consideration and evaluation of relevant factors (e.g., the quality of a country's surveillance program and the supporting veterinary infrastructure) could result in trade with a region that may meet numeric criteria but, nonetheless, present, in our view, an undue risk of BSE introduction. Therefore, APHIS chose to base its evaluation on OIE guidelines in a way that allows us to consider an individual country's specific situation and to analyze risk based on the overall effectiveness of actions taken by the country to prevent the introduction and spread of BSE.

Issue: As noted above, one of the proposed standards for a BSE minimal-risk region was that, in regions where BSE was detected, the region ''had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease.'' One commenter asked for clarification of the meaning of ''widespread exposure or establishment,'' of whether moderate exposure or establishment is acceptable, and of how many cases are acceptable in both humans and animals. Another commenter stated that the wording in the definition could create disagreements with regions applying for BSE minimal-risk status as to whether the disease is widespread in a particular region.

Response: APHIS has set no specific thresholds for an acceptable number of cases in humans or animals. Rather, the Agency will conduct an evaluation of the BSE situation in a region according to the factors in that region and define mitigations appropriate for the conditions. APHIS would consider in its evaluations OIE recommendations regarding the recommended maximum number of BSE cases per million at different BSE risk levels.

As an example, APHIS considers the situation that existed in the United Kingdom and certain other European countries in the 1990s to be clearly an example of widespread exposure or establishment, and also one that would clearly contribute to a high-risk categorization under OIE guidelines (Ref 1). Widespread BSE exposure in the United Kingdom was at its peak in the early 1990's, as reflected by the finding of more than 30,000 cases per year in 1992–1993. The situation has improved dramatically with the stringent control measures that have been imposed in the United Kingdom. This has also been the case in other European countries that have had what we consider ''widespread exposure.'' It is important to note that, in each of these situations, BSE was detected and control measures were then instituted, resulting in some delay until the effects of the control measures could become apparent. These situations were very different, for example, from the situation in Canada, where: (1) Control measures were in place before the detection of the disease; (2) only two animals of Canadian origin have been confirmed with BSE; (3) both were born before implementation of Canada's feed ban; and (4) Canada has maintained other protective measures (including import restrictions) that would help preclude a significant level of infectivity from being transmitted to the cattle population.

Surveillance

Issue: One commenter stated that the premise in the proposed rule that prevalence of BSE will be lower in regions with adequate prevention and control measures does not take into account that the level of determined prevalence is dependent on the quality and level of surveillance in each region. The commenter expressed concern that, although a country may say it has low prevalence, its surveillance may be inadequate to accurately measure the prevalence.

Response: We agree with the commenter concerning the importance of a valid and effective surveillance program. One of the first evaluations we make regarding a country or other region seeking a particular animal health status is the effectiveness and

reliability of its veterinary infrastructure, including its surveillance programs.

Issue: One commenter recommended that the specific content of adequate surveillance systems be detailed in the regulations.

Response: In this rulemaking, we require that a region seeking BSE minimal-risk status conduct surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for the disease. As noted above, in establishing its guidelines, the OIE Terrestrial Animal Health Standards Commission draws upon the expertise of internationally renowned specialists to draft new and revised articles of the Terrestrial Code in light of advances in veterinary science. Therefore, the OIE guidelines are constantly evolving and subject to change. In order to make our regulations flexible enough to allow us to accommodate internationally recognized changes in science without making constant revisions to the regulations, we are basing our requirements for surveillance on OIE recommendations, but are not specifying numeric thresholds in this rule.

Feed Restrictions

Issue: One of the standards we proposed for a BSE minimal-risk was that the region have ''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.'' Several commenters took issue with this factor. The commenters stated that the absence of evidence of noncompliance is not evidence of compliance and that this standard could be met by countries with no or minimal compliance monitoring. The commenters stated that the feed ban should be enforced by an inspection program, including sampling and testing of feed, as recommended by the IRT. Another commenter took issue with the words ''appears to be,'' recommending instead that the factor should address whether a feed ban is or is not an effective barrier in a particular region. One commenter stated that specific guidelines for compliance, including on-farm compliance, should be provided.

Response: We concur that the lack of evidence of noncompliance may not be evidence of compliance. We did not intend for the proposed rule to produce or allow for the result described by the commenter. For this reason, we are changing the wording of the factor referred to by the commenter to provide instead that ''a ruminant-to-ruminant feed ban is in place and effectively enforced.'' It was, and continues to be, our intent to evaluate all relevant factors thoroughly. Determining whether a feed ban has been effectively enforced will involve a review by APHIS of a number of interrelated factors, including: The existence of a program to gather compliance information and statistics; whether appropriate regulations are in place in the region; the adequacy of enforcement activities (e.g., whether sufficient resources and commitment is dedicated to enforcing compliance); a high level of facility inspections and compliance; accountability of both inspectors and inspected facilities; and adequate recordkeeping. Our individual evaluation of the BSE status of a region will assess these factors and evaluate any contribution to risk.

Issue: Several commenters expressed concern regarding a U.S. recommendation to the OIE that the OIE feed ban duration standard be reduced from 8 to 5 years. One commenter recommended that USDA champion a continuation of the current OIE standard. Commenters stated that shortening the standard from an 8-year feed ban was inadvisable because it is possible some residual ruminant protein feed in some countries would be fed for several years after a feed ban went into effect.

Response: The APHIS recommendation that the OIE standard for the minimum duration of a feed ban be reduced from 8 years to 5 years was based on the estimated average incubation period of the BSE agent in cattle. As discussed above, the Harvard-Tuskegee Study (Ref 17) estimates that the variability distribution for the BSE incubation period in cattle has a median (50th percentile) of approximately 4 years. Based on the best-fit parameter values provided in the Harvard-Tuskegee Study (Ref 18), the mean (expected value) of the incubation period distribution is estimated at 4.2 years. However, the OIE decided not to change the standard.

Epidemiological Investigation

Issue: A commenter expressed concern with the proposed factor for a BSE minimal-risk region related to an epidemiological investigation. This factor stated that, in regions where BSE has been detected, a minimal-risk region must have ''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.'' The commenter stated that the standard focuses on the conduct of an investigation and not whether there were definitive findings resulting from such an investigation. The commenter also took issue with our explanation in the preamble that ''an investigation following a detected case would include, among other things, an investigation to determine the most likely source of the animal's exposure to BSE,'' saying that the ''most likely source'' is not a definitive finding.

Response: Certainly, the quality of the investigation and its results and findings must be carefully evaluated. However, definitive findings are not always possible or necessary in an epidemiological or scientific investigation. If a region is able to explain the approach it has taken in its investigation and produce adequate information regarding the most likely source of infection, the lack of a definitive finding can be within normal scientific parameters. Uncertainty may, in many instances, be compensated for in other areas, such as through appropriate mitigations. Depending on the quality of the epidemiological investigation, the absence of definitive findings may be less important than whether there are adequate measures in place to address disease risk.

Additional Measures

Issue: One commenter expressed concern with the proposed factor for a BSE minimal-risk region that requires that, in regions where BSE was detected, the minimal-risk region ''took additional measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.'' The commenter objected to our explanation in the preamble that additional risk mitigation measures could include ''a broad eradication program, increased surveillance, or additional import restrictions,'' expressing concern that the statement indicates that additional measures either could or could not include those listed by APHIS.

Response: We intended the additional mitigation measures that were listed by the commenter (a broad eradication program, increased surveillance, and additional import restrictions) to be examples of possible additional measures that might be necessary. In pointing to those measures, we did not intend to provide a definitive list of additional mitigation measures we might consider; rather, the examples were intended to provide a sense of the types of measures we might consider. Indeed, in the discussion of OIE standards in the updated risk analysis,

we provide several more examples of additional mitigation measures we are considering, e.g., an ongoing awareness program for veterinarians, farmers, and workers involved in transportation, marketing, and slaughter of cattle; compulsory notification and investigation of all suspected cases of BSE; and examination in an approved laboratory of brain and other tissues collected within the framework of the surveillance and monitoring system. As we stated in the preamble of our proposal, measures will be required that are appropriate depending on the conclusions of the risk analysis that is required following a BSE diagnosis.

Human Health Risks

Issue: Several commenters recommended that the definition of *BSE minimal-risk region* specifically list actions taken to minimize human health risks, which the commenter said should be equal to or more stringent than those in the United States. The commenters stated that the definition should require, for example, that minimal-risk regions do the following: (1) Ban use of non-ambulatory cattle; (2) hold product/carcass until negative results are obtained; (3) prohibit air-injected stunning; (4) remove high-risk tissues; and (5) prevent the inclusion of central nervous system tissue in ''meat'' products.

Response: The issues raised by the commenters relate to the equivalency of standards for the production of meat in countries that export to the United States. The FSIS regulations in 9 CFR 327.2 provide that, to be eligible to export meat and meat products to the United States, a foreign country must be able to certify that it applies to its own meat processing establishments requirements equivalent to those in the United States. Under those regulations, exporting countries are required to provide documentation supporting how their meat inspection system is equivalent to that of the United States. FSIS determines whether the systems are equivalent. The FSIS procedures for evaluating such equivalency are discussed below in more detail, under the heading ''Verification of Compliance in the Exporting Region.'' Each of the requirements recommended by the commenter are currently required of meat processing establishments in the United States and, therefore, are applicable to establishments in foreign countries that wish to export meat and meat products to the United States.

Tracking and Labeling

Issue: One commenter recommended that requirements for a minimal-risk region include existence of a national animal identification and tracking program, adequate and active testing and monitoring programs for all OIE List A animal diseases, and product labeling to enable tracking of the product.

Response: Although the standards for a BSE minimal-risk region in this rule do not specifically require a national animal identification and tracking program, they do include a requirement for an effective epidemiological investigation and the ability of authorities in the region to conduct traceback and trace-forward of animal feed or rendered material. An evaluation of these capabilities will include consideration of animal identification. Although we acknowledge the importance of adequate testing and monitoring for OIE List A diseases with regard to whether and under what conditions animals and animal products should be allowed importation from a particular region, those diseases are already addressed individually in the regulations in 9 CFR 92, 93, 94, 95, 96, and 98. Further, we do not consider List A diseases to fall under the scope of this rulemaking. List A diseases are defined by OIE as transmissible diseases that: (1) Have the potential for very serious and rapid spread, irrespective of national borders; (2) are of serious socioeconomic and/or public health consequences; and (3) are of major importance in the international trade of animals and animal products. BSE is not included as an OIE List A disease but, instead, is categorized as a List B disease. List B diseases are considered to be (1) of socioeconomic and/or public health importance within countries and (2) significant in the international trade of animals and animal products.

With regard to product labeling in the exporting region, it is not clear to us from the comment what type of labeling the commenter is referring to.

Testing of Ruminants

Issue: One commenter stated that, if BSE is diagnosed in a country, the United States should not accept ruminants and ruminant products from that country until the country tests all cattle over 20 months of age at slaughter. Other comments recommended that we require that all cattle slaughtered in such a country be tested for BSE. Some commenters recommended that such testing be carried out by USDA representatives in Canada.

Response: We understand the interest expressed by some commenters in testing certain cattle for slaughter. However, no live animal tests exist for BSE and the currently available postmortem tests, although useful for disease surveillance (i.e., in determining the rate of disease in the cattle population), are not appropriate as food safety indicators. We know that the earliest point at which current testing methods can detect a positive case of BSE is 2 to 3 months before the animal begins to demonstrate clinical signs. We also know that the incubation period for this disease—the time between initial infection and the manifestation of clinical signs—is generally very long, on the average of about 5 years. Accordingly, we know there is a long period during which, using the current methodology, testing an infected animal that has not demonstrated clinical signs of the disease would, incorrectly, produce negative results. If, however, the infected animal is already exhibiting some type of clinical signs that could be consistent with BSE, then the test is not likely to produce false negative results.

Development of reliable food safety indicators will require improved understanding of the pathogenesis of the disease and improved laboratory methods. However, if BSE is present in a country's cattle population, various mitigation measures, such as feed bans and removal of SRMs, are available to prevent the spread of BSE in cattle and to prevent human exposure to the BSE agent. The United States and Canada have already implemented such measures. The results of an enhanced animal surveillance program for BSE, announced by the Secretary on March 15, 2004 (Ref 20), and currently underway, which will help determine the prevalence of BSE in the United States, should the disease exist, and will provide information that will indicate whether these measures should be adjusted. But measures such as SRM removal and the prohibition of the use of non-ambulatory cattle in human food will ensure a safe meat supply. Testing of individual animals, especially if it is performed on clinically normal animals at slaughter, is not in itself an effective risk mitigation measure for protecting public health. The purpose of a surveillance program is to gauge the level of BSE prevalence. This can be achieved through targeted sampling, as is being carried out in the United States and Canada.

For these reasons, we do not consider the testing at slaughter of every bovine over 20 months of age, or the testing of every bovine at slaughter, to be scientifically justified or meaningful in the context of either human or animal health. Making this a criterion for minimal-risk regions would not contribute to human or animal health protection beyond the protection

achieved by a statistically and epidemiologically valid surveillance plan, coupled with the risk mitigations specified in this rule.

B. Recognition of Canada as a Minimal Risk Region

Issue: A number of commenters questioned whether Canada has made improvements to its systems (*e.g.*, surveillance infrastructure, surveillance levels, removal of SRMs, feed ban compliance) sufficient to warrant the resumption of exports of ruminants and ruminant products to the United States. Other commenters contended that Canada has not effectively enforced its feed ban and that further investigation and enforcement is necessary.

Response: Enhancements Canada has made to its surveillance levels are discussed above in section III. B. under the heading ''Additional Measures Taken in Canada'' (Ref 16). Additionally, Canada has added a rapid test as a routine screening tool and has expanded the number of laboratories approved to run BSE tests. These steps should shorten the interval between collection of samples and diagnosis. In July 2003, the Canadian Government issued requirements for the removal, identification, control, and disposition of SRMs (Ref 15). The Canadian SRM requirements for products eligible for importation into the United States are equivalent to requirements in the United States.

Based on the information available to us, including communication with and visits to Canada, we have concluded that Canada has effectively enforced its feed ban. Canada implemented a feed ban in 1997 that prohibits the feeding of most mammalian protein to ruminants. The Canadian feed ban is essentially the same as the feed ban in place in the United States. Canadian Government authorities inspect rendering facilities, feed manufacturers, and feed retailers to ensure compliance with the feed ban. Procedures to reduce the likelihood of cross-contamination are in place at all feed mills that handle both prohibited and nonprohibited feeds. As discussed below under the heading ''Prevalence of BSE in Canada,'' CFIA indicates that compliance with the feed ban is very high.

Issue: Several commenters expressed concern about the 4 months that passed between the death of the BSE-infected Canadian cow in January 2003 and the diagnosis of BSE in May 2003. The commenters stated that this delay in diagnosis indicates that disease surveillance and laboratory disease diagnostic capabilities in Canada are not equal to those in the United States.

Response: It is true that the May 2003 case of BSE in Canada was not confirmed until 4 months after the death of the animal. This delay was due to a combination of factors, primarily the fact that the sample was not identified as ''suspect'' for BSE. Samples were taken from the cow at slaughter because it was non-ambulatory. The animal passed ante-mortem inspection but was condemned on post-mortem inspection for pneumonia. Because the cow did not display classic clinical signs of BSE, samples were tested as they would be for any routine surveillance sample. Also, because the sample was identified as part of routine surveillance, the laboratory did not place a high priority on it for testing. In order to address the delay, Canada has changed its surveillance approach, primarily by using rapid screening tests for BSE. We consider BSE surveillance and diagnostic capabilities in Canada to be equivalent to and as effective as those in the United States.

Issue: One of the standards we proposed for qualification as a BSE minimal-risk region was that a region conduct surveillance for BSE at levels that meet or exceed OIE guidelines. One commenter objected to that standard with regard to Canada, stating OIE surveillance recommendations are intended for countries that have not diagnosed a case of BSE in native cattle. A number of commenters stated that Canada should not be considered a BSE minimal-risk region until that country increases its surveillance levels for BSE, so that the disease situation in Canada is better understood. Some commenters raised concerns that Canada's proposed level of testing was much lower than what the United States has proposed for U.S. testing. One commenter recommended that a surveillance program test all high-risk cattle in Canada during a period of at least 12 to 18 months.

Response: The commenter's suggestion that OIE surveillance recommendations are intended for countries that have not diagnosed a case of BSE in native cattle is incorrect. The OIE testing guidelines apply to any country or zone, whether or not BSE has been diagnosed in a native animal. As discussed above, Canada has an adult cattle population of approximately 5.5 million cattle older than 24 months of age. The current OIE Code, Appendix 3.8.4, references adult cattle populations as those greater than 30 months and recommends examining at least 300 samples per year from high-risk animals in a country with an adult cattle population of 5 million, or 336 samples per year in a country with an adult cattle population of 7 million. Even though the adult cattle population in Canada is defined as greater than 24 months of age and OIE defines it as greater than 30 months of age, Canada has met or exceeded this level of surveillance for the past 7 years, thus exceeding the OIE guidelines. Additionally, OIE recommends sampling of target cattle that display clinical signs compatible with BSE and cattle that have died or been killed for reasons other than routine slaughter. Canada again exceeds OIE guidelines by conducting active targeted surveillance that, in addition to sampling animals that display clinical signs that could be considered consistent with BSE, includes sampling animals with risk factors for BSE.

Also, in May 2004, the Canadian Government initiated enhancements of its BSE surveillance program. This enhanced surveillance program focuses on determining a maximum prevalence of BSE in Canada and will allow the Canadian Government to improve further, if necessary, the effectiveness of Canada's BSE risk management measures. Under the plan, Canada is progressively increasing the number of animals tested annually to be able to detect BSE at a level as low as 1 in 1 million animals. During 2004, through December 1, a total of more than 15,800 samples had been obtained. Testing may reach 30,000 animals in 2005. This level of testing represents a significant increase over previous testing levels; surveillance levels in Canada have increased to current levels from under 500 animals per year in 1996. Canada's testing program, like that in the United States, focuses on those animals most at risk of BSE. Because the cattle population in Canada is much smaller than the cattle population in the United States, Canada does not need to test the same number of animals as the United States (where testing of over 200,000 animals has been announced) to reach high levels. Surveillance testing of 30,000 animals in Canada is equivalent to the U.S. target of sampling 240,000 to 300,000 animals. With the import requirements APHIS is establishing for live animals and products from Canada, there is simply no scientific basis to wait until Canada has completed 12 to 18 months of enhanced surveillance before allowing imports from that country.

Issue: In the preamble to our proposed rule, we discussed the epidemiological investigation that Canada conducted after the diagnosis of a BSE-infected cow in Canada in May 2003. Among other things, the investigation focused on rendered material or feed that could

have been derived from the carcass of the infected cow. CFIA traced the potential movement of material from the infected cow to rendering facilities and then to feed mills and determined that the risk of the material having been mislabeled as ruminant feed was extremely low. As noted below under the heading ''Other Comments Related to the Risk Basis for the Rule,'' as part of that investigation, a survey was conducted of approximately 1,800 sites that were at some risk of having received such rendered material or feed. The survey suggested that 99 percent of the sites surveyed experienced either no exposure of cattle to the feed (96 percent of the sites) or only incidental exposure (3 percent of the sites). We stated in our proposal that 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. One commenter recommended that all cattle that were part of the 1 percent limited exposures be slaughtered before Canada is classified as a BSE minimal-risk region.

Response: As discussed above, depopulation of Canadian herds possibly exposed to the feed or in question was carried out by the Canadian Government, which conducted a wide-ranging investigation of possible exposure to the feed in question and carried out depopulation of Canadian herds possibly exposed to the feed. On each of those farms where the investigation could not rule out the possibility of exposure to feed that may have contained rendered protein from the infected animal, the herds were slaughtered and tested, in each case with negative results.

Issue: One commenter asked whether APHIS consulted with or sought the opinion of leading international scientific experts with regard to the proposed mitigation measures and, if so, whether those experts considered those risk mitigation measures adequate.

Response: The risk mitigation measures in this rulemaking are equivalent to those measures considered appropriate by the OIE, which are guidelines developed by teams of international veterinary and other scientific experts. Additionally, following the diagnosis of BSE in Canada in May 2003, a review team of international experts evaluated the situation and reported favorably on the measures being taken in that country with regard to BSE. Those measures are equivalent to those set forth in this rulemaking.

Issue: One commenter asked whether the epidemiological investigation conducted by Canada following the diagnosis of BSE in May 2003 was the only information from Canada used in developing the proposed rule.

Response: As we note above, APHIS was able to effectively evaluate the animal disease situation in Canada and risk mitigation measures taken by that country based on information such as the 2002 Canadian assessment of BSE risk in that country, the epidemiological investigation that Canada conducted following the diagnose of BSE in Canada in May 2003, and on continuing exchanges on multiple animal health issues, as well as on a long history of trade with Canada and close and continued interaction and communication with Canadian authorities. As discussed above in section II. C., under the heading ''*Update to APHIS'' Risk Analysis and Summary of Mitigation Measures and Their Applicability to Canada as a BSE Minimal-Risk Region,*'' APHIS has developed an update to the risk analysis that APHIS conducted for the November 2003 proposed rule. The update elaborates on the available scientific information and on the analysis supporting the rule. It is also designed to make the process APHIS followed in evaluating the risk of imports from Canada more transparent (Ref 21).

C. Risk Mitigation Measures for Importation of Ruminants

How the Rule Applies to Camelids, Cervids, Bison, and Water Buffalo Alpacas and Other Camelids

Issue: In § 93.436 of our proposed rule, we provided that the importation of any ruminant from a BSE minimal-risk region would be prohibited unless the animal met the conditions we proposed for various types of live ruminants from the region. The types of ruminants for which we provided import conditions in § 93.436 were bovines, ovines (sheep and goats), and cervids (*e.g.*, deer, elk). The proposed provisions did not include conditions for the importation of camelids (llamas, alpacas, guanacos, and vicunas).

A number of commenters stated that prohibiting the importation of camelids because of BSE was not justifiable. The commenters cited a number of reasons why camelids should be allowed importation from BSE minimal-risk regions, including, said the commenters, the following:

- Camelids are physiologically distinct from ruminants and are not true ruminants. For instance, camelids have a three-compartment stomach, whereas other animals considered ruminants have a four-compartment stomach;
- Camelids are traditionally used for fiber, recreation, and show, rather than for food;
- Purebred registries for camelids ensure the animals' health and identification;
- Camelids are not fed high-protein feeds;
- Camelids are resistant to the BSE agent and do not transmit the disease to other camelids or any other species; and, in fact, no camelid has been diagnosed with a TSE;
- Prohibiting camelids from a BSE minimal-risk region would not be consistent with OIE guidelines, both because the OIE guidelines on BSE relate only to bovines, and because OIE recommends that an importing country not be more trade-restrictive than necessary to achieve the desired level of protection.

Other commenters recommended ways of tracking the location of camelids in the United States if they were allowed importation from BSE minimal-risk regions. One commenter requested that camelids that had been exported from the United States to Canada for breeding purposes before the May 2003 diagnosis of BSE in Canada be allowed to be returned to their original U.S. premises.

Response: Although we agree that taxonomic differences exist between camelids and ruminants such as cattle, sheep, and goats, we do not consider those differences to be sufficient to exclude camelids from being regulated as ruminants with regard to most diseases of concern. Regardless of their taxonomic classification, camelids meet the definition of ruminants and are susceptible to ruminant diseases, including foot-and-mouth disease and tuberculosis. However, with regard to BSE, we agree it is not necessary to prohibit the importation of camelids from minimal-risk regions. Although we recognize there are unknowns with regard to susceptibility to BSE, given the mitigation measures that must be in place for a region to be recognized as minimal risk for BSE, and the facts that there have been no diagnosed cases of BSE in camelids and that camelids are not typically fed ruminant byproducts, we agree it would be highly unlikely BSE would be introduced into the United States through the importation of camelids from BSE minimal-risk regions.

Therefore, in this final rule, we are providing in § 93.436(f) that camelids from a BSE minimal-risk region may be imported into the United States without any restrictions related to BSE. However, such animals will continue to be subject to all other applicable import

requirements in part 93, subpart D, for ruminants imported into the United States. We are also amending § 93.400 of the regulations to add a definition of *camelid* to mean all species in the family *Camelidae*, including camels, llamas, alpacas, guanacos, and vicunas.

Issue: One commenter questioned why we proposed restricting the importation of alpacas because of BSE but not the importation of mink, felines, and mice, which are also susceptible to certain TSEs. Another commenter questioned why the restrictions regarding BSE in the regulations apply only to four-stomached animals, despite the fact that certain single-stomached animals have been be shown to be susceptible to BSE and that certain other animals, such as horses, also eat animal byproducts. One commenter asked whether the occurrence of the disease in single-stomached animals suggests that the root cause of BSE may be the environment and that the disease has not been adequately defined.

Response: Although BSE belongs to the family of diseases known as TSEs, and certain species other than those classified as ruminants have been known to be infected with some form of TSE, natural infections of BSE have been confirmed only in cattle, other bovines, some zoo animals including exotic felines, and domestic cats. Experimental infections of BSE can be induced in certain other species, such as mice and sheep. Animals that have been experimentally inoculated with BSE are prohibited entry into the United States except for entry under permit for research. Zoological animals are restricted to entry under permit to recognized zoological parks. Research indicates that BSE spreads primarily through the ingestion of ruminant feed containing protein and other products from ruminants infected with BSE. Because domestic felines (1) are rarely infected with BSE, even in BSE high-risk regions, (2) are generally not rendered for animal feed, and, (3) if rendered, are precluded from ruminant feed by the FDA feed ban, the importation of domestic felines from BSE-affected regions is not considered a significant risk. We do not have any evidence to suggest that it is necessary to establish prohibitions or restrictions on the importation of non-ruminant animals because of BSE.

Cervids

Issue: In our proposed rule, we included provisions for the importation of live cervids from a BSE minimal-risk region, but only if such cervids were to be moved directly to slaughter in the United States and met other conditions, including that the cervids not be known to have been fed ruminant protein, other than milk protein, during their lifetime. One commenter stated that it would be impossible to verify the feeding practices for cervids. Conversely, a number of commenters stated that our proposed provisions regarding cervids were too stringent. A number of commenters stated that live cervids should be allowed importation for any reason from BSE minimal-risk regions. Several pointed out that BSE has not been identified in cervids. Several commenters recommended specific conditions for the importation of live cervids for any reason from a BSE minimal-risk region. One recommended that the cervids be farmed animals originating from herds that have participated for at least 3 years in a CWD surveillance program. Another commenter recommended that it be required that the cervids were born after implementation of the required feed ban, were not known to have been fed ruminant proteins prohibited under the feed ban, are identified by permanent identification enabling tracing of the animal back to the herd and dam of origin, and were members of a herd that participates in a TSE surveillance program and that is not known to have been affected with a TSE.

Response: In this final rule, we are not including restrictions on the importation of cervids from a BSE minimal-risk region for reasons relating to BSE. The import restrictions we proposed took a conservative approach in that they were based on evidence of cervid susceptibility to CWD, rather than susceptibility to BSE. We extrapolated from CWD susceptibility of cervids to predict a theoretical risk that cervids might also be susceptible to BSE. However, APHIS, like many of the commenters, is aware of no epidemiological data indicating cervids are naturally susceptible to the BSE agent. Published observations indicate that, during the height of the BSE outbreak in 1992 and 1993 in the United Kingdom, exotic ruminants of the *Bovidae* family in zoos were affected with BSE, while cervids, which are members of the *Cervidae* family, were not (Ref 22). Therefore, even in regions that have high levels of circulating infectivity and that should be considered high risk for BSE, BSE susceptibility in cervids was not observed.

Although specific challenge studies have not been conducted to evaluate the experimental infectivity of BSE in cervids, natural infection has not been observed. At least some of the certification requirements for cervids in the proposed rule were focused on TSEs in general rather than BSE specifically. For example, the proposed requirements included certification that the cervids had been members of a herd that was subject to TSE surveillance and that was not known to be infected with or exposed to a TSE. Upon reconsideration, APHIS concluded that restrictions relating to general TSE-related factors in the absence of demonstrated BSE in cervids would be outside the scope of this regulation, which was intended to focus on BSE.

In addition, it should be noted that Canada, as a BSE minimal-risk region, is not likely to have high circulating levels of the infectious agent. Since no infected cervids were observed in captive zoo cervids (unlike in other bovine species) in the United Kingdom at a time when there were high levels of circulating infectivity, it is unlikely that infected cervids will be detected in a BSE minimal-risk region. Therefore, the available information suggests that importation of cervids from Canada does not pose a risk of importing BSE into the United States.

APHIS considers these observations to be evidence suggesting that cervids from BSE minimal-risk regions should not be restricted for BSE, even in view of the fact that no controlled studies have been conducted on cervid susceptibility to BSE. Although APHIS is not restricting cervids for BSE, it will maintain requirements related to cervids for other diseases, including CWD. General surveillance for CWD will detect any TSE exposure, thus providing additional assurances.

We are adding a definition of *cervid* to § 93.400 to mean all members of the family *Cervidae* and hybrids, including deer, elk, moose, caribou, reindeer, and related species. This definition is the same as the definition of *cervid* used in 9 CFR part 55 with regard to CWD. Additionally, we are amending the definition of *cervid* in § 94.0 to also be consistent with the definition in § 55.1.

Issue: One commenter recommended that the regulations require that all cervids imported into the United States from Canada be tested for TSEs such as CWD.

Response: We are making no changes based on the comment. There is no evidence that cervids affected with CWD pose a risk for BSE and we do not consider such testing warranted.

Bison and Water Buffalo

Issue: Many of the provisions in our proposed rule had to do with the importation of bovines and bovine products from a BSE minimal-risk region. Several commenters asked that

the regulations include a definition of *bovine* and that such a definition make it clear whether ''bovine'' includes bison and water buffalo.

Response: We are adding a definition of *bovine* to the definitions in §§ 93.400, 94.0, and 95.1 to mean *Bos taurus* (domestic cattle), *Bos indicus* (zebu cattle), and Bison bison (American bison). These types of bovines were those for which our risk assessment determined whether the proposed risk mitigation measures would be appropriate. Water buffalo may not be imported into the United States under this rule.

Issue: Several commenters recommended that the restrictions and prohibitions for bovines in this rule not apply to bison because of husbandry and feeding practices within the bison industry. At the least, said the commenters, bison should be allowed entry into the United States from Canada if they were born after the required feed ban and were fed no ruminant protein. The commenters stated that, among other factors, there has never been a reported case of BSE in bison in North America, farmed bison are not fed high-levels of protein and are not fed animal byproducts under industry association codes, and bison in Canada have been under a disease surveillance program since 1992.

Response: We are making no changes based on these comments. The reference to bovines in the proposed rule included bison. As such, live bison may be imported from BSE minimal-risk regions subject to the same conditions as other bovines. Published information from the United Kingdom (Ref 22) indicates that, along with other bovines, bison are susceptible to BSE. Because such susceptibility has been demonstrated, we do not consider it prudent to assume that voluntary industry practices will be sufficient safeguards against the disease.

Issue: Another commenter wanted to eliminate obstacles to importing wood bison from Canada for conservation and restoration projects in Alaska.

Response: We will consider this comment in developing our planned rulemaking regarding the importation from BSE minimal-risk regions of live bovines other than those addressed in our November 2003 proposed rule.

Identification of Bovines, Sheep, and Goats From BSE Minimal-Risk Regions

Issue: In § 93.436(b)(3) and (d)(3) of our proposed rule, we included the requirement that for bovines, sheep, and goats imported from a BSE minimal-risk region for feeding and then slaughter, the inside of one ear on each animal be permanently and legibly tattooed with letters identifying the exporting country, and that animals exported from Canada be tattooed with the letters ''CAN.'' Several commenters said tattoos were not sufficient to permanently identify animals because such markings can become illegible over time and cannot be effectively monitored without restraining the animal. Other commenters stated that ear tattoos can be obscured by dirt and hair, are not readily visible—particularly on animals with dark-skinned ears—and are difficult to apply under winter conditions. A number of commenters recommended that identification of country of origin by hot iron branding be required for cattle imported for feeding from BSE minimal-risk regions.

Response: We agree that tattoos might not provide effective, readily visible, permanent identification of the country of origin of bovines. Therefore, we are requiring in § 93.436(b)(3) that bovines imported for feeding and then slaughter from a BSE minimal-risk region be permanently and humanely identified before arrival at the port of entry with a distinct and legible mark identifying the exporting country, properly applied with a freeze brand, hot iron, or other method, and easily visible on the live animal and on the carcass prior to skinning, unless the bovine is imported for immediate slaughter in accordance with § 93.429. The mark must not be less than 2 inches or more than 3 inches high, and must be applied to each animal's right hip, high on the tail-head (over the junction of the sacral and first cocygeal vertebrae). Animals exported from Canada must be so marked with ''CAN''.

We are also requiring in this final rule that a brand or other specified form of permanent identification be used to mark sheep and goats that are imported for feeding and then slaughter. We are providing in § 93.419(d)(1) that sheep and goats imported for feeding and then slaughter from a BSE minimal-risk region be permanently identified before arrival at the port of entry. We will require humane identification with a distinct, permanent, and legible mark identifying the exporting country, properly applied with a freeze brand, hot iron, or other method before arrival at the port of entry, and easily visible on the live animal and on the carcass prior to skinning. The mark must be not less than 1 inch or more than 1¼ inches high. In all cases, the permanent identification must identify the country of export. Animals exported from Canada must be so marked with ''C''.

Additionally, we are providing that other means of permanent identification may be used upon request if deemed by the APHIS Administrator as adequate to humanely identify the animal in a distinct and legible way as having been imported from the BSE minimal-risk region.

Issue: One commenter recommended that the regulations provide that cattle requiring the identifying mark be branded on the left cheek.

Response: Although we agree that branding should be required for cattle imported for feeding from a BSE minimal-risk region, we disagree it is necessary to require that the brand be applied to the cheek of the animal. Facial branding is more stressful for cattle than branding the hind quarters. We consider a brand on the right hip to be adequate for quick identification of the animal as an export from a BSE minimal-risk region.

Issue: Several commenters recommended that all live cattle that have been imported into the United States from Canada be permanently identified with a hot iron brand.

Response: We do not consider the action requested by the commenters necessary. Canada, like the United States, was proactive in implementing a BSE prevention program. Canada has had a ruminant feed regulation in place since 1997. 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 additional countries as those 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. Canada has also conducted surveillance in high-risk cattle to monitor the effectiveness of these measures. The combination of these factors makes Canadian-origin cattle currently located in the United States a very low risk for infection with BSE and, in combination with the safeguards in place in the United States, makes them very unlikely to cause the amplification of BSE in U.S. cattle or pose a health risk to U.S. consumers.

The identification recommended by the commenters would require the use of significant resources of time, personnel, and funding, and would provide in return information that is of minimal value. The question that must be answered is whether BSE is present in the U.S. cattle population. This can be done only through the extensive targeted surveillance program underway in the United States. Canadian-origin animals will be included in targeted

surveillance efforts being carried out in this country. Attempting to track Canadian imports—animals that are not contributing significantly to increased risk at this time—will serve only to draw resources away from the targeted surveillance efforts.

Issue: One commenter recommended that the regulations require that cattle imported from a BSE minimal-risk region for immediate slaughter be electronically identified as part of a recognized national system.

Response: We are making no changes based on this comment. We consider the sealing requirements for the means of conveyance transporting the animals adequate to ensure immediate slaughter of the animals.

Issue: One commenter stated that the requirement for permanently identifying sheep and goats probably violates international agreements that forbid a country from applying health or food safety standards to foreign products that are not met by domestically produced products. The commenter stated that, because the BSE statuses of Canada and United States are now similar, similar standards should be adopted.

Response: We are making no changes based on the comment. BSE has been detected in two cows indigenous to Canada, whereas a BSE-infected animal indigenous to the United States has not be detected to date. The domestic animal health regulations that govern interstate movement in the United States are based on differences in disease status among States. Because the United States makes no distinctions among States with regard to BSE, a tattoo requirement would be meaningless for interstate movements.

Issue: One commenter recommended that permanent marking with a brand or tattoo be required for all livestock imported into the United States, unless the animals are moved in a sealed conveyance to immediate slaughter.

Response: We do not consider it necessary to apply the permanent marking requirements of this rule to all livestock imported into the United States. The purpose of the branding requirement in this rule for cattle, sheep, and goats is to allow for quick and easy identification of the animals as having been imported from a BSE minimal-risk region, not to track the animals.

Issue: A number of commenters recommended that, to be able to more effectively maintain identity of animals imported from a BSE minimal-risk region for feeding and then slaughter, and to be able to trace the animals back to the premises of origin, some form of individual identification should be required, such as an eartag. Some commenters stated that the identification should allow for tracing back to the animal's dam.

Response: We agree that it is important to be able to trace cattle, sheep, and goats that are imported from a BSE minimal-risk region for feeding and then slaughter back to the animals' premises of origin, and concur that an eartag can be an effective method of individual animal identification. Therefore, we are requiring in § 93.436(b)(4) for bovines and in § 93.419(d)(2) for sheep and goats that an eartag of the country of origin that is determined by the Administrator to meet the standards for official eartags in the United States and to be traceable to the premises of origin (which we are defining in § 93.400 as the premises where the animal was born) be applied to bovines, sheep, and goats imported for feeding and then slaughter, before the animals' entry into the United States. We do not, however, consider it necessary to require that the eartag make it possible to trace the animal back to its dam. If an infected animal is diagnosed, epidemiological investigation and, if necessary, depopulation will involve all animals of potential concern in the herd of origin.

Issue: Several commenters recommended that we require maintenance of individual identification of imported animals throughout the lifetime of each animal.

Response: We agree that removal of the animal's individual identification would prevent USDA from reconciling the required APHIS movement forms to confirm that all animals are slaughtered as required. Therefore we are requiring in § 93.436(b)(4) for feeder bovines, and § 93.419(d)(2) for feeder sheep and goats, that no person may alter, deface, remove, or otherwise tamper with the individual identification placed on each animal that is in the United States or moving into or through the United States and that such identification may be removed only at slaughter.

Issue: One commenter recommended that APHIS require electronic identification for cattle, sheep, and goats, in addition to the permanent identification.

Response: As discussed above, we are requiring individual identification of bovines, sheep, and goats imported from BSE minimal-risk regions for feeding and then slaughter. However, the national animal identification plan announced by the Secretary of Agriculture on March 15, 2004, does not mandate the use of any particular technology, including electronic identification, and we are not requiring that the individual identification under this rule be electronic. Further, there is little infrastructure for reading electronic identification devices in the United States. Therefore, individual identifications would still require visual reading.

Issue: One commenter recommended that, for bovines less than 30 months of age, we require eartags that allow traceback to the producer of origin with verification for ownership history, movement history, and compliance with the ruminant feed ban. This commenter and other commenters recommended that we require that the eartags be a form of electronic identification.

Response: As we discussed above for cattle imported into the United States from a BSE minimal-risk region for feeding and then slaughter, we are requiring that an official eartag of the country of origin that is determined by the Administrator to meet the standards for official eartags in the United States and to be traceable to the premises of origin be applied to the animal before its entry into the United States. With regard to cattle from Canada, since January 1, 2001, Canada has required all cattle to be identified with machine-readable eartags (radio frequency identification or bar coded) that would allow them to be traced to their herd of origin within Canada. With regard to verification of feed ban compliance, this rule requires that such verification accompany cattle exported to the United States in the form of a certificate issued either by a full-time salaried veterinary officer of the national government of the region of origin, or 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. We do not consider it necessary or practical for the individual animal identification to also be a means of verifying individual on-farm compliance with the feed ban regulations. As discussed above, we also do not consider it practical at this time to require that the identification be electronic, due to the fact that such identification would require availability and general use of readers, which is currently not the case.

Issue: Several commenters requested that the proposed requirement for an ear tattoo be replaced in the case of bison with a requirement for an electronic eartag.

Response: As discussed above, we agree with the need for an eartag as a means of tracing animals to their premises of origin. However, we consider it necessary that the animal also be marked in some permanent and

easily visible way as having been imported from a BSE minimal-risk region. In the case of bison from Canada, this would be a brand or other permanent ''CAN'' mark on the right hip. The hip brand is necessary so that bovines from a BSE minimal-risk region that are not imported for immediate slaughter can be easily identified as such in feedlots and at slaughter or if they are illegally diverted from the feeder/slaughter chain. The purpose of the mark is to provide permanent identification and eartags cannot be relied upon to be permanent identification.

Issue: Several commenters recommended that APHIS allow the use of forms of individual identification other than those specified in the regulations, provided such means of identification are deemed acceptable by the APHIS Administrator. One commenter stated that APHIS should not limit the use of acceptable technologies to identify animals from BSE minimal-risk regions. Instead, APHIS should establish standards for animal identification and traceability systems.

Response: We agree that there may be acceptable means of identifying animals in addition to those we are specifying and, as stated above, have provided for approval by the Administrator of other adequate means of identification. At this time, U.S. standards for animal identification and traceability are under development and will be made available for public comment in future rulemaking.

Issue: One commenter stated that we should allow retinal vascular imaging as a form of animal identification.

Response: At this time, we do not consider retinal scanning alone to provide adequate identification of animals because the scans cannot be performed more than a few hours after death. Due to tissue deterioration, it is extremely difficult to obtain a valid scan.

Movement to Feedlots and Then to Slaughter

Issue: We proposed to require that bovines, sheep, and goats imported from a BSE minimal-risk region for feeding and then slaughter be moved directly from the port of entry to a designated feedlot. We proposed to define *designated feedlot* in § 93.400 as ''a feedlot indicated on the declaration required under § 93.407 as the destination of the ruminants imported into the United States.'' Paragraph (b) of § 93.407 requires presentation by the importer of a declaration for imported ruminants that includes, among other information, the name of the person to whom the ruminants will be delivered and the location of the place to which such delivery will be made. Several commenters asked how APHIS will verify that imported cattle moved to a feedlot were not moved from the feedlot other than to slaughter. Many commenters requested that the regulations include criteria for approval of a feedlot as a designated feedlot. A number of commenters recommended specific criteria for such approval.

Response: Based on these comments, we consider it necessary to clarify our intent as to what we meant by a designated feedlot in the proposal and where and how we are using that term in this final rule.

In this final rule, we are still requiring, as proposed, that cattle from a BSE minimal-risk region imported into the United States for feeding and then slaughter (which we refer to as feeder cattle) must be moved from the port of entry to an identified feedlot, but we are not calling that feedlot a ''designated feedlot.'' In our proposal, it was our intent that a feedlot for cattle be ''designated'' only in the sense that it was identified as the location to which the cattle would be moved for feeding and then movement to slaughter. We did not specify criteria for designated feedlots for either cattle or sheep and goats and did not require that cattle from BSE minimal-risk regions be segregated from other cattle at feedlots. Because there has been no demonstrated lateral transmission of BSE from bovine to bovine (the most likely cause or transmission in bovines appears to be through ingestion of infected ruminant protein), we considered it sufficient to ensure that the imported cattle be clearly marked as to country of origin.

FSIS's January 2004 SRM rule, discussed above under the heading ''Measures Implemented by FSIS,'' which requires that SRMs be removed from all cattle at slaughter—both from cattle born and raised in the United States and from imported cattle—further supports the conclusion that it is not necessary to require segregation of imported feeder cattle from U.S. feeder cattle while at a feedlot before slaughter. Individual identification, permanent marking indicating the country of origin, and movement only under an APHIS-issued movement permit (the physical destination of the cattle must be identified on all documents described in § 93.407 and on APHIS Form VS 17–130) will allow monitoring and tracking of the imported cattle as they move from the port of entry to the identified feedlot and then to a recognized slaughtering establishment. This process is as follows.

Movement of cattle to feedlots and then to slaughter. Means of conveyance containing cattle for feeding and then slaughter will be presented to an APHIS port veterinarian at a border port listed in § 93.403(b) or as provided in § 93.403(f). These cattle must be accompanied by the health certificate from the region of origin (in this case Canada) that is required under § 93.405. The health certificate must list the eartag number of each of the animals in the shipment. Additionally, the animals must be accompanied by the certification required from the country of origin under § 93.436(b)(5) regarding the age, feeding history, and identification of the cattle. The means of conveyance must have been sealed in the region of origin with seals of the national government of the region of origin. (The requirement for sealing of the vehicle is discussed below under the heading ''Sealed Means of Conveyance.'')

The APHIS port veterinarian will review the paperwork and inspect the shipment to ensure that it is being imported in compliance with the regulations. The APHIS port veterinarian will then complete and sign APHIS Form VS 17–30, ''Report of Animals, Poultry, or Eggs Offered for Importation.'' (This is a standard form completed by APHIS port veterinarians as certification of the inspection and release of animals offered for importation from any region.) The APHIS port veterinarian will also complete and sign APHIS VS Form 17–130, ''Permit for Movement of Restricted Animals,'' which will authorize the movement of the animals to a feedlot. The APHIS VS Form 17–130, which must identify the physical location of the feedlot and the individual responsible for the movement of the animal, must also be signed by the owner or the shipper of the animals, to certify that the livestock will be delivered to the consignee without diversion.

The cattle must be moved as a group to the feedlot indicated on the APHIS VS Form 17–130. When the cattle arrive at the feedlot, the seal must be broken only by an accredited veterinarian or by a State or USDA representative or his or her designee. The person breaking the seal will indicate on the APHIS VS Form 17–130 where and when the animals were received and the number of animals received, as well as the date and time the seal was broken. The form will be signed by the person breaking the seal and a copy sent to the APHIS Area Office or Regional Office. APHIS or

State officials may spot-check this process at the feedlot. (In this final rule, we are adding a definition of *State representative* to the definitions in § 93.400 to mean a veterinarian or other person employed in livestock sanitary work of a State or a political subdivision of a State who is authorized by such State or political subdivision of a State to perform the function involved under a memorandum of understanding with APHIS. This definition is consistent with the definition of *State representative* as used elsewhere in the APHIS regulations. Section 93.400 already includes a definition of *accredited veterinarian*.)

Once at the feedlot designated on the import documents and the movement permit, the cattle must remain there until transported to a recognized slaughtering establishment and must not be moved to different feedlots, onto range, or to cattle sales. As provided in § 93.436(b)(4) regarding individual identification by eartag of each animal, the eartag required under this rule must not be removed from any of the animals. The feedlot operator must be able to account for all incoming cattle from BSE minimal-risk regions—those sent to slaughter and those that die at the feedlot.

When the cattle are to be sent to slaughter, an accredited veterinarian or a State or USDA employee must complete APHIS VS Form 1–27 at the feedlot and seal the means of conveyance. The APHIS VS Form 1–27, which must identify the physical location of the recognized slaughtering establishment and the individual responsible for the movement of the animal, must also be signed by the owner or the shipper of the animals, certifying that the livestock will be delivered to the consignee without diversion. This APHIS Form VS 1–27 must accompany the cattle to the slaughtering establishment, along with a copy of the APHIS VS Form 17–130 and the health certificate that accompanied the animals from the port of entry to the feedlot. Upon arrival of the means of conveyance at the slaughtering establishment, a USDA representative will break the seal, complete the APHIS VS Form 1–27, and return all the paperwork that accompanied the animals to either the APHIS Area Office or Regional Office. Although we acknowledge that this process will involve time and costs for the importer and the feedlot owner, it will provide APHIS with a means of monitoring the movement of these shipments. However, following implementation of the National Animal Identification System currently under development, we will evaluate the effectiveness of tracking these shipments by the national identification system compared to tracking by means of the documents required by this rule. In recognition of the possibility that alternative effective means of monitoring movement may be developed, we are providing in this final rule that the animals shipped must be accompanied by the movement documentation described above or other movement documentation deemed acceptable by the Administrator.

Movement of sheep and goats to feedlots and then to slaughter. The requirements in this final rule for the movement of feeder sheep and goats from a BSE minimal-risk region from the port of entry to a feedlot and then to slaughter are the same as those described above for the movement of cattle. However, provisions regarding the feedlots themselves for sheep and goats are more detailed than those for cattle, due to the fact that transmission of BSE among sheep and goats could potentially differ from transmission among bovines. In this final rule, we are using the term ''designated feedlot'' for the feedlot of destination of the sheep and goats. We discuss the criteria and rationale for designated feedlots for sheep and goats below under the heading ''Designated Feedlots for Sheep and Goats.''

Issue: With regard to ruminants moved to a U.S. feedlot and then to slaughter, one commenter asked whether APHIS or FSIS would verify that the animals are properly permanently identified.

Response: The accredited veterinarian who issues the APHIS VS Form 1–27 for movement to slaughter will verify that the required identification is on the animal and record it on the form.

Issue: Several commenters recommended that the regulations require that means of conveyance carrying livestock from BSE minimal-risk regions to feedlots (*i.e.*, feeder cattle) in the United States be sealed at the border. Several commenters questioned why cattle for immediate slaughter must be moved as a group, but those going to a designated feedlot will be allowed to be moved to slaughter at varying times and to different slaughter facilities. The commenters said this defeats the purpose of control over and traceback of imported animals. Another recommended that the rule clarify how bovines from BSE minimal-risk regions sent to designated feedlots will be kept separate from U.S. bovines. Several commenters expressed concern that the potential diversion of feeder cattle would result in their being over 30 months of age when slaughtered. A number of commenters recommended that the possibility of the diversion of feeder cattle for breeding use could be eliminated by requiring that feeder cattle from BSE minimal-risk regions be neutered before importation. Other commenters recommended that feeder cattle from Canada be required to be moved to quarantined feedlots.

Response: All of the above comments were in response to our proposal to allow feeder cattle to be imported from BSE minimal-risk regions provided they were moved to a designated feedlot as a group, then were moved directly to slaughter. These comments were made based on the premise that, to be in accord with the proposed requirements, Canadian feeder cattle needed to be segregated from U.S. feeder cattle. However, because of the identification and movement requirements discussed above and the recent FSIS requirements for the removal of SRMs from all cattle at slaughter in the United States, we do not consider it necessary to segregate Canadian and U.S. feeder cattle.

However, as an added safeguard that the animals are moved directly from the port of entry to a feedlot and from the feedlot to a recognized slaughtering establishment, we are requiring in this final rule that means of conveyance carrying feeder cattle from the U.S. port of entry to a feedlot have been sealed in the region of origin with seals of the national government of the region of origin. We are providing that such seals must be broken only at port of entry by the APHIS port veterinarian or at the feedlot by an accredited veterinarian or a State or USDA representative or his or her designee. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the feedlot. We are also requiring that means of conveyance carrying cattle from the feedlot to a slaughtering establishment be sealed with seals of the U.S. Government before leaving the feedlot.

Issue: One commenter stated that neutered male animals should be allowed to utilize range resources without having to go directly to confined feedlots.

Response: This rule requires that the physical location of the cattle be identified. Because of the inherent difficulties involved in identifying and gathering those cattle on range that were imported from a BSE minimal-risk region and must be slaughtered before they are 30 months of age, we are not providing that feeder cattle imported from a BSE minimal-risk region may be placed on range. They must be put into

the feedlot identified on the APHIS movement permit and other accompanying documentation to help ensure they are slaughtered in a timely manner.

Maximum Age of Cattle, Sheep, and Goats Imported From a BSE Minimal-Risk Region

Issue: APHIS proposed to limit live cattle imported from a BSE minimal-risk region to those that would be less than 30 months of age at slaughter. A number of commenters expressed concerns regarding that maximum age. The commenters stated that, because there have been multiple detections of BSE in cattle less than 30 months of age in Europe and Japan, APHIS should decrease the maximum age for imports. Recommended maximums ranged from 18 to 28 months of age. Several commenters requested that APHIS more comprehensively state and validate the scientific basis for determining that cattle in the 20 to 30 month age range do not present a risk of BSE. Another commenter cited evidence from Britain that the commenter said indicates some cattle may be fast incubators of the disease and, therefore, have the potential to introduce detectable levels of BSE into the food chain. One commenter expressed concern that, because bulls are routinely slaughtered at 19 to 22 months old, they may be too young to test positive for the disease, even though those animals may be infected with BSE. One commenter stated that with prion diseases, the incubation time tends to become shorter the longer a specific prion has been circulating within a species.

Response: As discussed in our proposal, pathogenesis studies—where tissues obtained from orally infected calves were assayed for infectivity—have illustrated that levels of infectious BSE agent in certain tissues vary with the age of an animal. Infectivity was not detected in most tissues in cattle until at least 32 months post-exposure. The exception to this is the distal ileum (a part of the intestines), where infectivity was confirmed in the experimentally infected cattle as early as 6 months post-exposure, and the tonsils, where infectivity was confirmed at 10 months post-exposure.

Research demonstrates that the incubation period for BSE in cattle is linked to the infectious dose received—*i.e.,* the larger the infectious dose received, the shorter the incubation period. While some cases of BSE have been found in cattle less than 30 months of age, these are relatively few and have occurred 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).

In our proposal, we set out a list of standards we will use to evaluate the BSE risk from a region and determine whether it is appropriate to classify that region as a region of minimal-risk for BSE. We stated that we would use these standards as a combined and integrated evaluation tool, basing a BSE minimal-risk classification on the overall effectiveness of control mechanisms in place (*e.g.,* surveillance, import controls, and a ban on the feeding of ruminant protein to ruminants). Given the low level of circulating infectivity in minimal-risk regions, we proposed a 30-month age limit for cattle and proposed that the intestines be removed from those imported cattle. As discussed already, following the detection of a BSE-positive cow in Washington State in December 2003, FSIS implemented additional measures to protect the human food supply in the United States—including a requirement that SRMs be removed from all cattle—and prohibited the use of SRMs in human food.

Under these circumstances, we continue to consider 30 months of age to be the appropriate age threshold for removal of most SRMs. We are evaluating whether cattle over 30 months of age could be safely imported into the United States from a BSE minimal-risk region under the same conditions as younger cattle, since SRM removal is now standard operating procedure for all cattle 30 months of age and older that go to slaughter in the United States. However, we are not making a change with regard to live cattle over 30 months of age in this final rule, because, as stated in our March 8, 2004, notice, we are currently evaluating the appropriate approach regarding live cattle other than those specified in our proposal and intend to address that issue in a supplemental rulemaking proposal in the **Federal Register.**

Issue: Several commenters asked why we proposed that live sheep and goats 12 months of age and older would not be allowed importation into the United States. One commenter noted that we said in our proposal that we would allow cattle less than 30 months of age to be imported from BSE minimal-risk regions because BSE infectivity was not detected in most tissues in cattle until at least 32-months post-exposure to the agent. In contrast, said the commenter, although we stated BSE infectivity has not been demonstrated in most tissues in sheep and goats until 16 months post-exposure, we proposed to prohibit the importation of live sheep and goats 12 months of age or older from a BSE minimal-risk region. The commenter noted that APHIS was establishing a safety margin of 2 months for cattle (6.25 percent) (32 months/30 months), but 4 months (25 percent) for sheep and goats. The commenter requested that APHIS provide the scientific basis for determining whether this distinction is significant.

Response: As noted above, research has indicated that the levels of infectious agent in certain tissues vary with the age of an animal. Infectivity in cattle was not detected in most tissues until the animal was at least 32 months post-exposure. In sheep and goats, infectivity has not been demonstrated in most tissues until 16 months of age post-exposure. The 30-month age limit for cattle imported from minimal-risk regions is accepted internationally in BSE standards set by various countries and is consistent with OIE guidelines and target surveillance (Ref 23). We proposed a 12-month age limit for sheep and goats based on the research regarding infectivity in such animals and, practically speaking, because 12 months is consistent with the age at which lambs are generally sent to slaughter.

Issue: Several commenters recommended that, rather than using the age of an animal as a risk mitigation measure, APHIS should follow OIE guidelines that allow the movement of cattle born after an effective feed ban was implemented, provided appropriate risk mitigation measures are applied during slaughter and processing.

Response: The import conditions proposed by APHIS for importation of bovines for immediate slaughter from BSE minimal-risk regions included several restrictions, including both age of the animal and the requirement that the animal not be known to have been fed ruminant protein. Those conditions were analyzed together in our risk analysis, which did not differentiate among the efficacy of the alternative risk mitigation options. Based on that analysis of risk, we are including both conditions in this final rule.

Issue: One commenter asked if, since the May 2003 diagnosis of a BSE infected cow, CFIA has tested a statistically ''responsible'' number of brains of cattle less than 30 months of age in order to state with confidence that the region does not have younger animals that would test positive, as has happened in the United Kingdom and Japan.

Response: APHIS published a risk assessment in November 2003 that discussed the risks and identified

mitigation measures necessary for the import of certain live cattle and products from minimal-risk countries, and does not consider such testing on the part of Canada to be necessary before importation of these commodities. Experience in the United Kingdom and other parts of Europe in dealing with widespread BSE outbreaks, unlike the limited number of infections in Canada, has shown that testing cattle that are non-ambulatory, dead on the farm, or showing clinical signs consistent with BSE is the method most likely to disclose BSE if it is present in the cattle population. If BSE is not detected through testing of such ''high-risk'' animals, there is little or no benefit to testing other cattle populations. It should be noted that CFIA, like APHIS, has conducted active surveillance since 1992 and implemented an expanded surveillance program on June 1, 2004. As of December 1, 2004, a total of more than 15,800 samples had been obtained in Canada, all with negative results for BSE.

Verification and Enforcement of Age Limits

Issue: For ruminants entering the United States from a BSE minimal-risk region for immediate slaughter, one commenter recommended that U.S. border officials and the receiving slaughtering establishment accept the age verification prepared by accredited Canadian veterinarians in order to expedite movement of the animals from the source feedlot to the slaughtering establishment. The commenter stated that such expeditious movement is important both from an animal welfare perspective and a product quality perspective. Conversely, another commenter indicated that USDA veterinarians should have the option of refusing entry to any cattle that appear to be 30 months of age or older.

Response: As with the importation of all livestock into the United States, APHIS port veterinarians will be responsible for assuring that shipments of animals presented for import fulfill all necessary import requirements before their release from the border port. However we agree with the commenter who stated that verification of the animals' age can be made based on review of the certificate that is required by this rule to accompany the shipment of live bovines, sheep, and goats from BSE minimal-risk regions. Further, we agree that verification by means of the certificate will expedite movement of the animals to their destination.

Therefore, instead of requiring, as we proposed in § 93.436(a)(4) and (c)(4) for bovines and sheep and goats, respectively, that means of conveyance that are used to move the animals to immediate slaughter be sealed with seals of the U.S. Government at the port of entry, we are requiring in § 93.436(a)(4) for bovines and § 93.420(a) for other ruminants that the means of conveyance be sealed in the region of origin with seals of the national government of the region of origin. Such animals will undergo visual inspection by U.S. inspectors at the port of entry while they are in the means of conveyance. However, we are also providing in those sections that if U.S. inspectors at the port of entry consider it necessary to unseal the means of conveyance, the means of conveyance must be resealed with seals of the U.S. Government.

Also, as discussed below under the heading ''Sealed Means of Conveyance,'' we are requiring that bovines, sheep, and goats imported from a BSE minimal-risk region for movement to a feedlot be moved in a means of conveyance that is sealed with seals of the national government of the region of origin. As with animals imported for immediate slaughter, such animals will undergo visual inspection by U.S. inspectors at the port of entry while they are in the means of conveyance and, as with animals imported for immediate slaughter, if U.S. inspectors at the port of entry consider it necessary to unseal the means of conveyance, the means of conveyance must be resealed with seals of the U.S. Government.

Issue: Several commenters stated that determining the age of animals is not an exact science and that USDA should more clearly set out how it expects to enforce the 30-month age limit for slaughter.

Response: Under this rule, cattle imported from a BSE minimal-risk region must be accompanied by certification by an authorized veterinary representative of the region of origin that the animals entering the United States are less than 30 months of age. In its January 2004 SRM rule, FSIS explained that the Agency's inspection program personnel will confirm the age of cattle, both of U.S. and foreign origin, that are slaughtered in official establishments, by means of documentation that identifies the age of the animal and, where necessary, by examination of the dentition of the animal to determine whether at least one of the second set of permanent incisors has erupted (the permanent incisors of cattle erupt from 24 to 30 months of age).

Issue: A number of commenters asked what will be done with imported feeder cattle if they are determined to be over 30 months of age when received for slaughter.

Response: If FSIS concludes the animals are 30 months of age or older, or if it cannot be determined that the animals are less than 30 months of age, all SRMs will be removed, which would include brain and central nervous system tissue, along with the animal's tonsils and the distal ileum of the small intestine. FSIS will notify APHIS when such situations arise and APHIS will initiate enforcement action as appropriate. As we noted in APHIS'' March 2004 notice reopening the comment period on the proposed rule, APHIS is currently evaluating the appropriate approach regarding live cattle 30 months of age and older and intends to address that issue in a supplemental rulemaking in the **Federal Register.** (Please note: Although the wording we used in our notice did not specifically state the live animals we would evaluate for potential future rulemaking would be cattle and other animals other than those already included in the proposal, we consider our intent to have been clear in the context of the issues discussed in that notice.)

Importation of Cattle Other Than Those Going to Slaughter

Issue: Our proposed rule provided that all ruminants would be prohibited importation from a BSE minimal-risk region, except for those imported in accordance with the provisions of the proposed rule. The only bovines for which conditions for importation were included in the proposed rule were those being moved either directly to slaughter or to a designated feedlot for further feeding before slaughter. In both cases, the proposed provisions limited importation to bovines that would be less than 30 months of age at slaughter. Similar provisions were proposed for sheep and goats that would be less than 12 months of age at slaughter. In effect, this provided for the continued prohibition on the importation of breeding cattle, sheep, and goats from Canada that APHIS imposed following the diagnosis of a BSE-infected cow in that country in May 2003.

Several commenters supported a continued prohibition on the importation of breeding cattle from Canada. One commenter stated that such animals should not be allowed into the United States from Canada until the year 2012, 15 years after the implementation of the feed ban in that country.

Many commenters, however, stated that the regulations should allow the importation from a BSE minimal-risk

region of cattle intended for other than immediate slaughter or slaughter after further feeding. One commenter recommended that APHIS open the border to breeding stock under 36 months of age. Another commenter recommended that cattle born after 2000 be allowed importation. A number of commenters stated that live cattle born after implementation of the feed ban in the BSE minimal-risk region should be allowed importation. Others said that cattle that were born before implementation of the feed ban, but other than in a high-risk area of the BSE minimal-risk region, should be allowed importation. Several commenters stated that no importation measures over and above the exporting country's being a BSE minimal-risk region would be necessary if the United States requires the removal of all SRMs upon slaughter in this country.

A number of commenters recommended more specific conditions under which breeding cattle should be allowed importation from BSE minimal-risk regions generally or from Canada specifically. One commenter requested that the importation be allowed for cattle that are temporarily brought to the United States for livestock expositions. Some of the other conditions recommended by commenters are the same ones we proposed to apply to the importation of ''feeder'' or ''fed'' cattle, such as that the animal was born after implementation of the feed ban and was not known to have been fed prohibited ruminant protein. In addition, several commenters recommended that the animal have permanent identification traceable back to the dam and herd of origin and not be progeny of a BSE suspect or confirmed animal. One commenter recommended that identification be in the form of an electronic eartag. Another commenter expressed confidence that breeding cattle imported from a BSE minimal-risk region could be adequately monitored using a permit process along with health certification before importation and by requiring recordkeeping by importers of animal transfers or disposal, including use in the food chain.

Another commenter requested that the regulations allow the importation of registered cattle that were born in the United States and were taken to Canada at least 1 year following implementation of the ruminant feed ban in Canada, and also their offspring. The commenter provided suggested means of verifying the origin of the animal, including a tattoo of the breed registration number and accompaniment by the animal's registration certificate. Another commenter requested that U.S. origin cattle that are stranded in Canada be allowed to return to the United States if accompanied by a certification by the Government of Canada that, in accordance with Canada's feed ban, the animals have been not been fed ruminant protein while in that country.

One commenter recommended that cattle over 30 months of age be allowed importation if the animals have tested negative for BSE. One commenter recommended allowing the importation of breeding stock that are found to be negative to a new BSE test.

One commenter stated that pregnant heifers should be allowed importation if, after calving in the United States, the heifers are slaughtered before reaching 30 months of age. One commenter recommended allowing the importation of breeding cattle under 30 months of age or, alternatively, donor dams born in the United States and owned by U.S. producers. At the minimum, stated the commenter, such donor dams should be eligible to be returned to the herd of the owner, along with offspring resulting from embryo transfer.

One commenter stated that, because BSE is not transmitted horizontally, the regulations should allow for the temporary importation of cattle into the United States for purposes such as livestock shows and rodeos, breeding, and semen collection, as long as the animal has permanent identification and tracking is carried out that the Administrator deems appropriate to ensure that the animal is returned to its country of origin.

Response: We have carefully reviewed and considered the commenters' requests to allow the importation of cattle other than cattle less than 30 months of age for immediate slaughter and cattle imported for feeding and then slaughter at less than 30 months of age. As we stated in our March 8, 2004, notice, we are currently evaluating the appropriate approach regarding other live cattle and intend to address that issue in a separate proposed rule in the **Federal Register.** We are taking the information provided by commenters into consideration in conducting the evaluation. However, at this time, we are making no changes in this final rule to allow the importation of cattle from BSE minimal-risk regions other than those for immediate slaughter, or for feeding then and slaughter, at less than 30 months of age.

There is no BSE test for live animals at this time. The risk assessment made available by APHIS in conjunction with the November 2003 proposed rule assessed the risk of resuming trade in designated ruminants and ruminant products from Canada. The analysis was conducted primarily in the context of feeder animals imported for slaughter. Special circumstances that might relate to breeding animals were not addressed. The analysis considered various risk factors associated with feeder animals for slaughter and mitigations of those risks. The age of the animal and the effect of a feed ban were two of the most significant factors. APHIS determined that cattle that are less than 30 months of age are unlikely to have infectious levels of the BSE agent and that animals born after the feed ban was implemented are unlikely to have been exposed to the infectious agent. The combination of these factors caused us to conclude that we could safely import cattle for feeding and slaughter or for immediate slaughter that (1) were less than 30 months of age; (2) were subject to a ruminant feed ban; (3) were imported through designated ports of entry and, if moved directly to slaughter, were moved in a sealed means of conveyance; (4) were accompanied from the port of entry to a recognized slaughtering establishment by VS Form 17–33, or were accompanied by an APHIS Form VS 17–130 for movement to the feedlot designated on the import documents and by APHIS Form VS 1–27 for movement from the feedlot; (5) were moved as a group to either a designated feed lot or recognized slaughtering establishment and (6) had their intestines removed at slaughter.

The assessment did not consider the effects of these risk mitigation measures individually. Because we did evaluate the individual effects of these mitigation measures and the fact that we did not address the special circumstances related to breeding animals in our risk analysis, at this time we are not providing for the importation of such animals from BSE minimal-risk regions.

Request for Bans on Imports of Live Animals

Issue: Several commenters expressed concern regarding the importation of any live cattle from Canada and requested that the importation of such animals continue to be prohibited. One commenter questioned how we can be certain that live animals from Canada are not affected by BSE, given there is currently no method available for testing live animals for the disease.

Response: We acknowledge there are currently no approved live animal tests for BSE. However, our comprehensive analysis and evaluation leads firmly to the conclusion that the conditions specified in this rule for the importation of ruminants and ruminant products from BSE minimal-risk regions will be

effective and will protect against the introduction of BSE into the United States. In our proposal, we set out a list of standards we would use to evaluate the BSE risk from a region and determine whether it is appropriate to classify that region as a region of minimal-risk for BSE. We stated that we would use these standards as a combined and integrated evaluation tool, basing a BSE minimal-risk classification on the overall effectiveness of control mechanisms in place (*e.g.,* surveillance, import controls, and a ban on the feeding of ruminant protein to ruminants).

In addition, we proposed individual risk mitigation measures for specific commodities, including live animals intended for importation from BSE minimal-risk regions, to further protect against the introduction and transmission of BSE in the United States. For live animals, such measures include: Maximum age requirements, movement restrictions and use within the United States, identification requirements, and removal of SRMs. As noted, our proposed rule specified removal of the intestines. However, FSIS has since issued regulations regarding SRM removal in all cattle slaughtered in the United States, including the removal of the tonsils and distal ileum in cattle of any age.

Canada has implemented strong measures to guard against the introduction, establishment, and spread of BSE among cattle in that country, to detect infected animals through surveillance, and to protect the Canadian animal and human food supplies. Among other things, Canada has taken the following actions: Maintenance of stringent import restrictions since 1990; prohibition of the importation of live ruminants and most ruminant products from countries that have not been recognized as free of BSE; surveillance for BSE since 1992; implementation of a feed ban in 1997 that prohibits the feeding of most mammalian protein to ruminants; and extensive epidemiological investigations after the case of BSE in May 2003 and the Canadian origin case in Washington State in December 2003. Given these and other measures taken by Canada (*e.g.,* requirements for removal of SRMs), and the conditions in this rule for the importation of ruminants and ruminant products from BSE minimal-risk regions, it is highly unlikely BSE would be introduced through the importation of live cattle for immediate slaughter or for feeding and slaughter under this rule.

Issue: One commenter stated that, because every infected cow in North America has been a Holstein cow from Canada, APHIS should specifically prohibit the importation of dairy (in general, Holstein) cows. Another commenter stated that the differences between the risk profiles of dairy and beef cattle should be taken into account; that the feeding practices of dairies are more risky than those used by beef producers. The commenter requested that APHIS increase BSE testing for dairy cattle.

Response: We are making no changes based on these comments. (It should be noted that, contrary to the commenter's statement, the cow that was diagnosed as BSE-infected in Alberta Canada in May 2003 was a beef cow and not a Holstein cow.) BSE is spread primarily through the use of ruminant feed containing protein and other products from ruminants infected with BSE. In cattle, oral ingestion of feed contaminated with the BSE is the only documented route of field transmission of the disease (Ref 24). Although there is no evidence to indicate that the breed of cattle is a risk factor for BSE, there is some evidence that the use of BSE-contaminated ruminant protein results in an increased risk of BSE in dairy cattle compared to beef cattle. However, this is most likely due to the differences in feeding practices between dairy and beef producers, because dairy cattle routinely receive high-protein feeds during milk production. In regions with an effective feed ban on ruminant protein, the differences in feeding practices should not significantly increase the level of risk, given that no ruminant protein is fed to either beef or dairy cattle.

Issue: One commenter stated that APHIS should prohibit the importation for slaughter of any foreign animal born before the feed ban that is intended for human consumption or rendering. Another commenter stated the cattle born in Canada in a high-risk area before implementation of that country's feed ban should be prohibited importation.

Response: From the context of the first comment, it appears the commenter is referring only to the importation of bovines. Practically speaking, the guidelines of both commenters will be met by the combination of the required feed ban and the provision limiting the importation of bovines to those less than 30 months of age.

Importation of Cattle for Subsequent Export of Meat

Issue: One commenter stated that we should allow the importation of live cattle for slaughter through eastern U.S./Canadian border ports and allow the meat to be exported to Canada for use at fast food outlets.

Response: We are making no changes based on the comment. We consider it necessary to apply the same risk mitigation measures regarding the importation of cattle from Canada for slaughter regardless of the intended destination of the meat derived from the animals. With regard to exportation of beef to Canada, this rule does not place any restrictions on the export to Canada of meat from cattle slaughtered in the United States. Those meat commodities that can be exported to Canada from the United States can be found at *http://www.inspection.gc.ca.*

Cattle Importations From Any Region

Issue: One commenter stated that all beef cows imported into the United States from any country should be processed as a group.

Response: Our proposal concerned the importation of live ruminants and ruminant products from regions that present a minimal risk of introducing BSE into the United States. Requirements regarding the importation of beef cows from elsewhere in the world are beyond the scope of this rulemaking.

Importation of Veal Calves

Issue: Several commenters recommended that veal calves not be subject to the ban on the importation of live ruminants from Canada that the United States established in May 2003, because veal calves are a low-risk commodity due to their diet and their age at slaughter.

Response: Veal calves are eligible for importation into the United States under this rule.

Basis for Restrictions on Sheep and Goats

Issue: In § 93.436(b) and (c) of our proposed rule, we proposed to allow the importation of sheep and goats from a BSE minimal-risk region for either immediate slaughter or for feeding and then slaughter, provided specified conditions were met. These conditions included, among others, the requirements that the sheep or goats be less then 12 months of age when slaughtered and not have been known to have been fed ruminant protein, other than milk protein, during their lifetime. Additionally, we proposed to require that sheep and goats imported for feeding and then slaughter be moved directly from the port of entry to a designated feedlot and then to slaughter.

A number of commenters recommended that, because the OIE guidelines do not specifically address

sheep or goats with regard to BSE, the importation of sheep and goats from BSE minimal-risk regions not be restricted.

Response: We are making no changes based on this comment. Of the family of TSE diseases, one that has been known to occur naturally in sheep and goats is scrapie. With regard to sheep and goats and scrapie, the OIE guidelines recommend that all animal TSEs be considered when doing a risk assessment for the scrapie status of a country. There is currently less than complete understanding of the exact nature of TSEs and, in particular, their capability to cross species lines or adapt to new species; however, one theory is that BSE originated from scrapie (Ref 25). The OIE *Terrestrial Animal Health Code* (the OIE Code) discourages the importation of breeding animals from countries with scrapie or risk factors for TSEs in small ruminants, unless the animal originated from a scrapie-free flock. Because Canada is not free of TSEs, it is appropriate under the OIE Code to restrict the importation of breeding sheep and goats from Canada or any region that is not free of TSEs in sheep and goats or that has not conducted adequate surveillance to establish freedom. It is also appropriate to establish measures to prevent the diversion of imported feeder sheep or goats into breeding flocks in the United States. Since natural scrapie and the TSE in sheep caused experimentally by the BSE agent can't be differentiated by current routine diagnostic tests, APHIS intends to develop proposed rulemaking that would regulate for all TSEs in sheep and goats in this manner. In order to reestablish trade in low-risk sheep and goat commodities from BSE minimal-risk regions in a timely manner, we are addressing sheep and goats imported for immediate slaughter and for feeding and then slaughter in this rulemaking.

Issue: A number of commenters recommended that breeding, feeder, and slaughter sheep and/or goats of any age, or feeder sheep and/or goats of any age be allowed unrestricted entry from a BSE minimum-risk region. Other commenters recommended that such animals be allowed entry if they were born after the implementation of a ruminant feed ban in the region, were not known to have been fed protein prohibited by the required feed ban, and are permanently identified in such a way that would allow tracing back to the dam and flock of origin. Several commenters recommended that breeding sheep and goats under 12 months of age be allowed importation. One commenter recommended that any sheep from a scrapie-monitored premises or sheep of any age that have been genotyped for scrapie resistance be allowed entry into the United States from a BSE minimal-risk region.

Response: Sheep and goats over 12 months of age, such as breeding sheep and goats, were addressed in our risk assessment as animals with the potential to have infectious levels of the BSE agent. We consider it necessary to require risk mitigation measures to ensure that such animals do not introduce BSE into the United States. We are currently evaluating the type of mitigation measures needed to control risks associated with these animals and may conduct rulemaking in the future regarding the requirements necessary for the safe importation from BSE minimal-risk regions of such animals.

Issue: One commenter questioned the advisability of allowing the importation from BSE minimal-risk regions of live sheep and goats younger than 12 months of age, stating that BSE infectivity has been shown to be more widely distributed in sheep tissue than in that of cattle.

Response: Although the commenter is correct that results from experimental infections of sheep have shown that the BSE prion is more widely distributed in sheep tissues than in cattle, infectivity could not be demonstrated in most tissues until at least 16 months post-exposure to the agent.

Sheep and Goats and Other TSEs

Issue: Several commenters questioned how the proposed requirements for the importation of sheep and goats from BSE minimal-risk regions relate to other sections of APHIS animal import regulations, particularly those with regard to scrapie, a TSE for which there are import restrictions in part 93 and for which an eradication program exists in the United States. One commenter recommended that Canada be required to implement a country-wide scrapie eradication program identical to the U.S. system, along with an active surveillance system that meets or exceeds U.S. criteria and numbers. The commenter stated that such an eradication and surveillance system would reduce risk and eventually eradicate scrapie in the Canada, as well as any other variant TSE expressed in a manner clinically similar to scrapie, thereby reducing the risk of BSE entering the United States through the importation of sheep from Canada.

Response: We agree with the commenter that a strong scrapie program in Canada will mitigate scrapie and possibly BSE risks for the United States. Historically, the United States has not significantly restricted the movement of sheep and goats into the United States from Canada with regard to TSEs because our ongoing bilateral trade relationship made it likely that our countries shared the same scrapie types and because both countries have maintained similar control and eradication programs for scrapie and prevention programs for BSE. Since the occurrence of BSE in two native Canadian cows, there is a now a very small risk that Canadian sheep and goats might have been exposed to BSE in feed and that BSE or a variant scrapie type may have been transmitted to sheep or goats, and an even more remote risk that BSE or a variant of BSE has become established through lateral transmission to other sheep and goats. We note that strong, although not mandatory, programs exist in Canada for surveillance and certification of sheep and goats with regard to scrapie. Although the proposed rule did not address the possible relationship of these programs in Canada to requirements for importing sheep and goats from minimal-risk regions for BSE, we consider it appropriate to restrict the importation of sheep and goats from BSE minimal-risk regions if certain conditions exist for those animals with regard to BSE or scrapie.

Because of the differing nature of the BSE risk in sheep and goats as compared to that in bovines, we have reconsidered placing the import conditions for live sheep and goats from BSE minimal-risk regions in § 93.436 as proposed (''Ruminants from regions of minimal risk for BSE''). The parallel construction of that section—two paragraphs addressing requirements for bovines, followed by two paragraphs addressing requirements for sheep and goats—may give the impression that sheep, goats, and bovines all present the same risk profile and require exactly parallel restrictions. In fact, the risks associated with importing sheep and goats include a very small risk that some sheep and goats may have naturally contracted, and might theoretically laterally spread, BSE or a variant of BSE, and a somewhat larger risk that sheep and goats affected by scrapie variants may spread these diseases. The primary risks presented by sheep and goats are related to scrapie and laterally transmissible variants that may or may not be related to BSE, not classic BSE.

To correct this erroneous impression, we are moving the requirements for sheep and goats out of § 93.436 and into other sections of the CFR that more generally address importation of sheep and goats (§§ 93.419 and 93.420). While these changes will implement the

requirements necessary for the current situation, because Canada is the only listed BSE minimal-risk region in § 94.18(a)(3), we will need to reexamine these changes in the future if other countries are added to the list.

One of the other changes we are making in this final rule is to amend § 93.405, which has exempted sheep and goats from Canada that are not imported for immediate slaughter from restrictions that apply to sheep and goats from most regions of the world due to scrapie. Under this final rule, those restrictions will also apply to feeder sheep and goats from Canada.

We are amending §§ 93.419 and 93.420. Under the existing regulations, § 93.419 has included provisions specifically for the importation of sheep and goats from Canada, other than those for immediate slaughter. In this final rule, we are including in § 93.419 most of the conditions for the importation of sheep and goats from Canada that we set forth in § 93.436 of our proposal. However, those conditions that apply exclusively to sheep and goats from Canada for immediate slaughter, as opposed to feeding and then slaughter, we are including in § 93.420, which currently includes conditions for the importation of ruminants from Canada for immediate slaughter.

The existing provisions in § 93.420 for the importation of ruminants from Canada for immediate slaughter require that the ruminants be consigned from the port of entry directly to a recognized slaughtering establishment and there be slaughtered within 2 weeks from the date of entry. Additionally, § 93.420 provides that such ruminants will be inspected at the port of entry. In this final rule, we are retaining those provisions in § 93.420 and are adding in that section the requirements we proposed for sheep and goats from BSE minimal-risk regions for immediate slaughter that the ruminants be moved as a group to the slaughtering establishment in sealed means of conveyance. However, as discussed above under the heading ''Verification and Enforcement of Age Limit of Ruminants,'' we are requiring that the means of conveyance be sealed in the region of origin. As we proposed for sheep and goats for immediate slaughter, we are also specifying that the seals may be broken at the recognized slaughtering establishment only by a USDA representative. The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33, which shall include the location of the recognized slaughtering establishment. By including these provisions in § 93.420, they will be applied to sheep, goats, and other ruminants from Canada. This change to § 93.420 represents a codification of conditions that APHIS has already been requiring by policy. (Please note: These same provisions with regard to bovines for immediate slaughter from BSE minimal-risk regions, including Canada, are included in § 93.436 as proposed.)

Additionally, we are providing in § 93.420 that sheep and goats may not be imported from Canada for immediate slaughter if any one of the following conditions exists:

- The animals have tested positive for or are suspect for a TSE;
- The animals have resided in a flock or herd that has been diagnosed with BSE; or
- The animals' movement is restricted within Canada as a result of exposure to a TSE.

These prohibitions preclude the entry of sheep and goats most likely to pose a risk for TSE transmission. For the reasons described above, we are also requiring in § 94.19(c) and (d) of this final rule that meat, meat byproducts, meat food products, and carcasses of ovines and caprines from BSE minimal-risk regions not be derived from animals that were positive, suspect, or susceptible for TSEs. We are adding definitions of positive for a *transmissible spongiform encephalopathy* and *suspect for a transmissible spongiform encephalopathy* to §§ 93.400 and 94.0.

Designated Feedlots for Sheep and Goats

Issue: One commenter recommended that we include in the regulations specific criteria for designated feedlots for sheep and goats and methods and criteria according to which inventory control and traceability can be achieved once feeder lambs are imported.

Response: Because of the uncertainty regarding BSE infectivity and transmissibility in sheep and goats, we concur that it is appropriate to establish criteria for designated feedlots for sheep and goats from BSE minimal-risk regions to ensure that such animals from are not commingled with U.S. sheep and goats not going to slaughter or U.S. sheep and goats older than those eligible for entry from a BSE minimal-risk region. Scrapie, the best-studied TSE in sheep and goats, is laterally transmitted from sheep/goats to sheep/goats (most frequently either through exposure to an infected placenta or placental fluids or to environments contaminated with these tissues and fluids). Because experimental BSE in sheep has a tissue distribution that closely mimics that of scrapie in sheep, it is reasonable to conclude that BSE, if transmitted to sheep in feed, might be laterally transmitted. Until the risk of lateral transmission is better defined, we consider it prudent to ensure that sheep and goats of unknown TSE status are not commingled with U.S. sheep and goats not being moved to slaughter.

Therefore, in § 93.400, we are adding a definition of *designated feedlot* to mean a feedlot that has been designated by the Administrator as one that is eligible to receive sheep and goats imported from a BSE minimal-risk region and whose owner or legally responsible representative has signed an agreement to adhere to, and is in compliance with, the requirements for a designated feedlot. We are also adding specific requirements for a designated feedlot to § 93.419, ''Sheep and goats from Canada.'' Under these requirements:

- The owner of the designated feedlot or the owner's representative must monitor sheep and goats entering the feedlot to insure that all sheep and goats imported from a BSE minimal-risk region have the required ''C'' brand.
- Records must be kept at the feedlot of the acquisition and disposition of all sheep and goats imported from a BSE minimal-risk region that enter the feedlot. Such records must include the official eartag and all other identifying information; the date the animal was acquired by the feedlot and the animal's age at the time; the date the animal was shipped to slaughter and the animal's age at the time; and the plant where the animal was slaughtered. For sheep and goats imported from a BSE minimal-risk region that die in the feedlot, the eartag must be removed and be kept on file at the feedlot, along with a record of the disposition of the carcass.
- Copies must be maintained at the feedlot of the VS 17–130 forms that indicate the official identification number of the animal and that accompany the animal to the feedlot and then to slaughter.
- Inventory and other records must be kept at the feedlot for at least 5 years.
- The feedlot must allow inspection by and provide inventory records to State and Federal animal health officials upon their request.
- Eartags on animals entering the feedlot must not be removed unless such removal is necessary for medical reasons. In such cases, and in cases where eartags are otherwise detached from the animal, an official scrapie program eartag assigned to the feedlot for this purpose or another form of official identification must be applied to the animals from which the eartags were

removed and must be cross-referenced in the designated feedlot's records to enable matching with the original eartag.

• Either the entire feedlot or designated pens within the lot must be terminal for sheep and goats to be moved directly to slaughter at less than 12 months of age.

• If the inventory cannot be reconciled or if animals are not moved to slaughter as required, the feedlot's status as a designated feedlot will be withdrawn by the Administrator.

Distribution of BSE Agent in Goats

Issue: In our proposed rule, we stated that, in the absence of data regarding distribution of the BSE agent in goats, it is assumed that such distribution would be similar to distribution of the agent in sheep tissues. One commenter stated that in the absence of scientific data such an assumption should not be made.

Response: We disagree. Because distribution of the TSE scrapie is similar in sheep and goats, we consider it more logical to assume similarity of potential BSE distribution in sheep and goats than dissimilarity.

Ovine Embryos and Semen

Issue: One commenter stated that because ovine embryos and semen have not demonstrated BSE infectivity, they should be allowed importation from a BSE minimal-risk region.

Response: We are making no changes based on this comment. Under the existing regulations, semen from sheep and goats is currently not prohibited importation from regions listed in § 94.18(a) as being affected with or at undue risk of BSE and will not be prohibited importation from BSE minimal-risk regions. However, we consider it necessary to prohibit the importation of ovine and caprine embryos from BSE minimal-risk regions. No studies have been conducted to date with regard to the BSE risk of ovine and caprine embryos. In the absence of an assessment of risk from such materials, we consider it prudent to continue to prohibit the importation of ovine and caprine embryos from regions listed in § 94.18(a), which will include, under this rule, BSE minimal-risk regions.

Determining Age by Break Joint Technique

Issue: One commenter recommended that instead of using less than 12 months as the age of eligibility for sheep imported from a BSE minimal-risk region, the maximum age for sheep should be determined by the ''break joint'' technique that is used by FSIS to classify lamb.

Response: We are making no changes based on this comment. The break joint in young lambs and goats is a cartilaginous area of the cannon bone that is not ossified. This joint ossifies with age to become what is called a spool joint. The break joint (or spool joint) method for establishing the maturity of a lamb or goat is not a FSIS regulation, but is instead contained in a guideline pamphlet published by the Agricultural Marketing Service (AMS) entitled ''Official United States Standards for Grades of Slaughter Lambs, Yearlings and Sheep'' (Ref 26). This method was never presented as a truly reliable method for identifying animals of less than 12 months age, but instead was intended to provide general marketing methods and practices for agricultural commodities so that consumers could obtain the quality of product they desire.

The break joint method is not sufficiently accurate to determine the age of sheep or goats for the risk mitigation purposes of this rule. Also, the break joint can not be readily determined in live animals and is therefore not useful in determining the age of slaughter sheep. Therefore, we are making no changes based on this comment.

Sealed Conveyances and Movement to Immediate Slaughter

Issue: In § 93.436 of our proposed rule, we included requirements that bovines, sheep and goats, and cervids imported from a BSE minimal-risk region for immediate slaughter be moved from the port of entry to a recognized slaughtering establishment in conveyances sealed at the port of entry with seals of the U.S. Government. We proposed, further, that the seals could be broken only at the recognized slaughtering establishment by a USDA representative. (As discussed above, we are requiring in this final rule that the means of conveyance be sealed in the region of origin.) One commenter asked what procedures will be followed with regard to the animals if broken seals or missing cattle are discovered at the slaughter plant and what procedures APHIS will follow if a truck cannot be adequately sealed at the port. The commenter also stated that USDA representatives should not include employees of the slaughtering establishment. Another commenter asked what the verification process would be concerning APHIS documents and sealed conveyances.

Response: APHIS has provisions whereby the Agency enters into compliance agreements with the management of approved slaughtering establishments. These have proven to be exceptionally effective across a range of programs. We will work in accordance with these agreements and in close cooperation with FSIS to ensure that animals are accounted for and will take appropriate remedial measures as necessary.

We do not expect, as a practical matter, to encounter situations where a means of conveyance cannot be adequately sealed at the port. As noted, we are requiring in this final rule that the means of conveyance be sealed in the region of origin before reaching the U.S. port of entry. If for some reason the APHIS inspector at the port needs to break the seal, resealing a means of conveyance that had previously been sealed is not expected to be a problem and there are several types of seals that can be used.

Immediate Slaughter

Issue: In our proposal, we noted that, under the definition of *immediate slaughter* in § 93.400, ruminants imported into the United States for immediate slaughter must be slaughtered within 2 weeks of the date of entry into the United States. Several commenters recommended that, in order to better control the movement of the cattle in the United States, the regulations not allow 2 weeks for slaughter,. Another commenter asked which government official will oversee and verify that all animals are sent to slaughter within the 2 weeks following entry into the United States. Other commenters wanted to know what steps will be taken if the cattle are not slaughtered within the required time period.

Response: We continue to consider it appropriate to define immediate slaughter as slaughter within 2 weeks after entry into the United States. Animals imported for immediate slaughter must be moved directly from the port of arrival to the slaughter facility. However, cattle moved into the United States for slaughter are not always slaughtered as soon as they arrive at the slaughtering establishment. Because of the effects of stress and shrinkage during shipment, they are often held at the slaughtering establishment to improve body condition. Also, the date the animals are slaughtered is dependent on the workload at the slaughtering establishment. The 2-week period was established to allow time for arrival, processing, conditioning and slaughter of the animals in a reasonable amount of time. Because recognized

slaughtering establishments must have full-time Federal or State veterinary inspectors on the premises, official government oversight of the arrival and penning of the animals is available. APHIS Form VS 17–33 accompanies every shipment of animals imported for immediate slaughter and must be returned to the APHIS veterinarian at the port of entry after the animals are slaughtered. Any establishment that fails to comply with its agreement with APHIS will have its approval to receive further shipments of restricted animals for slaughter suspended.

Methods of Disposal

Issue: Paragraphs (a)(6) and (b)(10) of § 93.436 of our proposed rule included the requirement that the intestines of bovines imported from a BSE minimal-risk region be removed at slaughter in the United States. Paragraphs (a)(7) and (b)(11) of § 93.436 of the proposed rule required that the intestines be disposed of in a manner approved by the Administrator. Several commenters asked for clarification regarding who we were referring to as the ''Administrator.''

Response: In APHIS'' regulations, including the definitions in § 93.400 regarding the importation of ruminants into the United States, ''Administrator,'' unless otherwise identified, is defined as ''The Administrator of the Animal and Plant Health Inspection Service or any other employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, to whom authority has been or may be delegated to act in the Administrator's stead.''

However, in this final rule, we are not specifying that SRMs and other tissues removed at slaughter in the United States from bovines imported from a BSE minimal-risk region be disposed of in a manner approved by the Administrator. FSIS regulations governing disposal already exist in that Agency's regulations at 9 CFR 310.22, 314.1 and 314.3, and we consider it appropriate that the FSIS provisions be followed with regard to disposal.

Issue: A number of commenters stated that we should specify the potential means of disposal of removed intestines and verification of such disposal. Several commenters stated that materials requiring disposal under the regulations should be rendered by a licensed rendering company, with materials resulting from rendering being subject to FDA feed rules. In all cases, stated commenters, rendering should be the main option, and any other method must have to conform to the transportation, traceability, and pathogenic reduction requirements currently imposed on the rendering industry. Several commenters stated that disposal options should include only rendering, incineration, or alkaline digestion at an approved and licensed facility. Other commenters stated that burial, landfilling, composting, or burning should not be disposal options. Several commenters asked what FSIS will require of slaughtering establishments to ensure that the intestines are removed and disposed of properly.

Response: In its SRM rule, FSIS established provisions regarding disposal of SRMs. In the explanatory information to that rule, FSIS stated: ''In this interim final rule, FSIS is requiring that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs....'' FSIS provided further that the establishments must address their control procedures in their Hazard Analysis and Critical Control Point (HACCP) plans, sanitation standard operating procedures, or other prerequisite programs, and that FSIS will ensure the adequacy and effectiveness of the establishment's procedures. The FSIS SRM rule also requires that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle maintain daily records that document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs. The rule provided in 9 CFR 310.22(c) that SRMs must be disposed of in accordance with the FSIS requirements for disposal in 9 CFR 314.1 and 314.3. Those regulations provide that allowable means of disposing of the materials include tanking (inedible rendering), or-in those establishments that do not have facilities for tanking-incineration or denaturing.

The comment period for the SRM rule closed on May 7, 2004. FSIS is assessing the comments it received on the rule, including those regarding the issue of disposal, and will determine whether to maintain or modify the requirements of the rule. In determining whether to approve a manner of disposal, FSIS will consult with FDA and the U.S. Environmental Protection Agency.

Issue: Some commenters stated that, in addition to being prohibited from the food chain, SRMs should also be prohibited from being rendered.

Response: FSIS considers SRMs to be unfit for human food. Therefore, such materials may be rendered only as inedible (not for human consumption). As discussed above, the allowable means of disposing of the materials include tanking (inedible rendering) or-in those establishments that do not have facilities for tanking-incineration or denaturing.

Issue: Several commenters asked whether proper disposal of intestines includes utilizing intestines in a meat-and-bone meal product that is used as a feed ingredient for nonruminant animals. The commenters stated that the distal ileum should be allowed to be processed into meat-and-bone meal for feeding to nonruminant animals because there is a high level of compliance with mandatory feed restrictions in United States.

Response: We are making no changes based on these comments. FDA regulates the ingredients used in animal feed, including SRMs.

Testing at Slaughter

Issue: A number of commenters recommended testing increased numbers of cattle for BSE at slaughter in the United States. Some commenters stated that determining which cattle are to be tested should depend on the animals' ages. Guidelines ranged from testing all cattle over 24 months of age to all cattle over 30 months of age. One commenter recommended testing all cattle imported from a BSE minimal-risk region that were born before 2000. Some commenters recommended testing all cattle from Canada. Others recommended testing of all cattle sent to slaughter in the United States or all cattle that die in any location. One commenter recommended that the importer be required to have each imported animal that dies other than by slaughter tested at an accredited veterinary diagnostic laboratory.

Response: APHIS, in cooperation with FSIS and FDA, has developed an intensive national BSE surveillance plan. The goal of this plan is to test as many cattle in the targeted high-risk population as possible in a 12-to 18-month period. Experience in the United Kingdom and other parts of Europe has shown that testing cattle that are non-ambulatory, dead on the farm, or showing clinical signs consistent with BSE is the method most likely to disclose BSE if it is present in the cattle population. This enhanced surveillance was begun on June 1, 2004. As of December 7, 2004, 136,153 cattle had been tested, all with negative results.

Over a period of 12–18 months, APHIS will test as many cattle as possible in the targeted high-risk population. Data obtained in this effort will demonstrate whether BSE is actually present in the U.S. adult cattle

population and, if so, help provide estimates of the level of the disease. This data will also help determine whether risk management policies need to be adjusted. The key to surveillance is to look at the population of animals where the disease is likely to occur. Thus, if BSE is present in the U.S. cattle population, there is a significantly better chance of finding the BSE within this targeted high-risk cattle population than within the general cattle population.

Non-Ambulatory Disabled (Downer) Animals

Issue: Many commenters stated that no beef derived from non-ambulatory (''downer'') animals should be allowed either to enter the United States or enter the U.S. food supply. Other commenters stated that meat from any downer animal should be held until the animal is tested for BSE, and should be allowed into the food supply only if the animal tests negative. Some commenters stated that downer animals should be allowed to go to custom slaughtering for the owner's personal use.

Response: The issues raised by the commenters concern the safety for human consumption of beef slaughtered in the United States, which USDA addresses through its food safety agency, FSIS. As discussed above under the heading ''Measures Implemented by FSIS,'' that agency has determined that the carcasses of non-ambulatory disabled cattle are unfit for human food under section 1(m)(3) of the Federal Meat Inspection Act (FMIA), and that all non-ambulatory disabled cattle that are presented for slaughter will be condemned (*i.e.*, not passed for human consumption). With regard to Canada specifically, that country is not allowing non-ambulatory animals to be slaughtered for export.

Issue: One commenter expressed concern that Canada has not adopted the same BSE risk mitigation measures adopted by the United States, such as not prohibiting downer animals from entering the human food chain.

Response: As noted above, Canada is not allowing non-ambulatory animals to be slaughtered for export. All of the FSIS requirements imposed on the U.S. domestic beef supply as a consequence of that agency's January 12, 2004, rulemakings also apply to foreign countries that are eligible to export beef to the United States. The foreign country's inspection program must be deemed by FSIS to be equivalent to the U.S. inspection program before the country can ship beef to the United States. This means that SRMs must have been properly removed in the exporting country consistent with the U.S. requirements, and that non-ambulatory disabled cattle be prohibited for human food purposes. FSIS has an on-going verification system to assess the effectiveness of the equivalency determination made for each foreign country deemed eligible to export meat to the United States, as discussed below under the heading ''Verification of Compliance in the Exporting Region.''

Issue: Several commenters expressed concern that if non-ambulatory animals are excluded from slaughter in the United States, the current targeted surveillance systems will miss the chance to test these animals.

Response: We disagree with the commenter that non-ambulatory animals will not be tested under the U.S. targeted surveillance system. Even before the FSIS determination that all non-ambulatory disabled cattle that are presented for slaughter will be condemned, these types of animals have often moved through channels other than for human consumption. A comparison of testing records before and after the FSIS determination indicates that this category of animals was being tested before that determination and continues to be tested.

Use of Blood in Ruminant Feed

Issue: Several commenters stated that we should continue to prohibit the importation of live cattle from Canada because, according to the commenters, that country allows the feeding of blood and certain other ruminant products to cattle that are banned in the United States. Another commenter expressed concern that the proposal did not contain adequate verification that cattle imported from Canada are not fed animal blood.

Response: The CFIA feed ban was implemented in 1997 to prevent BSE from entering the food chain. The CFIA's feed ban, equivalent to the FDA prohibition on the feeding of most mammalian protein to ruminants, prohibits materials that are comprised of protein, including meat-and-bone meal, derived from mammals such as cattle, sheep and other ruminants, as well as salvaged pet food, plate waste and poultry litter. Products exempt from CFIA's feed ban include pure porcine and equine proteins, poultry and fish proteins, milk, blood, and gelatin, and non-protein animal products such as rendered animal fats (*e.g.*, beef tallow, lard, poultry fat). These are products that are also exempt from the FDA prohibition. (Please note, however, that as discussed above in section III. C. under the heading ''Measures Implemented by FDA,'' in an advance notice of proposed rulemaking issued jointly by FDA, FSIS, and APHIS on July 14, 2004, FDA requested additional information to help it determine the best course of action regarding the feed ban.)

In 2001, the EU Scientific Steering Committee (SSC), a scientific advisory committee for the EU, considered the amount and distribution of BSE infectivity in a typical case of BSE and estimated that, in an animal with clinical disease, the brain contains 64.1 percent of the total infectivity in the animal and the spinal cord contains 25.6 percent. Thus, the brain and spinal cord of cattle with clinical BSE are estimated to contain nearly 90 percent of the total infectivity in the animal. According to the EU SSC, the remaining proportion of infectivity in a typical animal with clinical BSE is found in the distal ileum (3.3 percent), the dorsal root ganglia (2.6 percent), the spleen (0.3 percent), and the eyes (0.04 percent). Similar conclusions on the relative infectivity of specific tissues from an infected cow have been reached by Comer and Huntley in their evaluation of the available literature (Ref 27).

We have noted that recent scientific studies have indicated that blood may carry some infectivity for BSE; however, those studies have concerned blood transfusions in animals. Additional research is necessary to determine which animals may become infected with BSE via blood, as well as the amount of infectivity contained in blood. We continue to consider it appropriate to recognize Canada as a minimal-risk region because that country has taken a number of measures that would make it unlikely that BSE would be introduced from that country into the United States. The measures include a feed ban equivalent to that in effect in the United States.

In addition to CFIA's feed ban on ruminant protein, Canada has taken additional measures to protect against the importation and possible spread of BSE. Such measures include: Import restrictions on live ruminants and ruminant products from countries that have not been recognized as free of BSE, surveillance and monitoring for BSE, and epidemiological investigation following the detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction and spread of the disease. Because of the mitigation measures taken by Canada to guard against the introduction and spread of BSE, we consider there to be minimal risk of infected blood entering the food chain from that region. However, to ensure the adequacy of feed restrictions for ruminants imported from Canada and other regions that may be

recognized as minimal-risk regions for BSE in the future, we require in this rule that ruminants must have been subject to a ruminant feed ban that is equivalent to the requirements established by the U.S. Food and Drug Administration. That provision replaces the condition in our proposal that required that ruminants not be fed ruminant protein, other than milk protein, during their lifetime.

Animal Inventories

Issue: One commenter recommended that the regulations require that cattle and other ruminants imported from a BSE minimal-risk region be accompanied by certification of the exact number of animals being shipped and the individual identification of the animals.

Response: Section 93.407 of the existing regulations requires a declaration of, among other information, the number of ruminants presented for import. Additionally, on a working basis, we have interpreted the requirement in § 93.405 that ruminants imported into the United States from Canada for other than immediate slaughter be accompanied by certification to include official identification of the ruminants. However, in order to make clear our intent, we are amending § 93.405 by adding a new paragraph (a)(4) to specify that the information on the certificate required by that section must include the following: (1) The name and address of the importer; (2) the species, breed, number or quantity of ruminants or ruminant test specimens to be imported; (3) the purpose of the importation; (4) individual ruminant identification, which includes the eartag required by this final rule and any other identification present on the animal, including registration number, if any; (5) a description of the ruminant, including name, age, color, and markings, if any; (6) region of origin; (7) the address of or other means of identifying the premises of the herd of origin and any other premises where the ruminants resided immediately prior to export, including the State or its equivalent, the municipality or nearest city, or an equivalent method, approved by the Administrator, of identifying the location of the premises, and the specific physical location/destination of the feedlot where the ruminants are to be moved after importation; (8) the name and address of the exporter; (9) the port of embarkation in the foreign region; and (10) the mode of transportation, route of travel, and port of entry in the United States.

We are also specifying in § 93.436 that an official identification and any other identification on bovines imported for feeding and then slaughter from a BSE minimal-risk region must be listed on the APHIS Form VS 17–130 that must accompany the animals from the port of entry and on the APHIS Form VS 1–27 that must accompany the animals to slaughter. For sheep and goats, that requirement is in § 93.419. With regard to ruminants imported from a BSE minimal-risk region for immediate slaughter, the requirement that the animals be accompanied to slaughter by APHIS Form VS 17–33 for movement to slaughter will enable tracking of the animals following importation. Additionally, ruminants moved directly to slaughter must be moved in means of conveyance that was sealed in the region of origin and that is opened only by a USDA representative. We consider these requirements adequate to ensure immediate slaughter of such ruminants.

Transiting of Live Ruminants Through the United States

Issue: One commenter stated that there would be little risk in allowing the transiting through the United States of products and live animals that have been recognized as low-risk by another country and in accordance with OIE standards. Several commenters expressed concern that the current prohibition on the importation of sheep and goats from Canada has unnecessarily eliminated the transiting of sheep and goats from Canada through the United States to Mexico and other Latin American countries. The commenters noted that the regulations as proposed would allow live sheep and goats imported from a BSE minimal-risk region to be moved to designated feedlots in other than a sealed means of conveyance, and that, therefore, the regulations should also allow the transiting of lambs to Mexico.

Response: We agree that the issue of the transiting of live sheep, goats, and bovines through the United States from a BSE minimal-risk region should be considered. As we noted in our March 2004 notice reopening the comment period on the proposed rule, we are currently evaluating, and intend to address in a supplemental rulemaking in the **Federal Register,** the importation of live animals under conditions other than those specified in our proposed rule.

Issue: One commenter asked how APHIS will ensure that cattle are not exported from Canada to Mexico, then re-exported from Mexico into the United States.

Response: As noted above, in this final rule we are codifying our interpretation that, under the requirements of § 93.405, live cattle imported into the United States, including cattle from Mexico, must be accompanied by a certificate that includes, among other information, the region of origin of the animals.

Movement Forms

Issue: One commenter stated that FSIS policies need to be established to ensure that agency's inspectors return the VS Form 17–33 (which must accompany imported livestock to immediate slaughter) to the APHIS Port Veterinarian in a timely manner.

Response: We agree that close collaboration and timely coordination between APHIS and FSIS is necessary, and both agencies are committed to establishing the most appropriate mechanism to achieve that result. APHIS is in the process of developing written instructions for FSIS personnel at approved slaughtering establishments and will submit those instructions to FSIS before this rule is implemented.

Issue: One commenter recommended that the rule not be implemented until certain Veterinary Services forms and a memorandum are updated.

Response: The documents referred to by the commenter are periodically reviewed and updated. As currently written, the forms provide sufficient information regarding the number and species of animal, as well as the seal numbers that are applied to the means of conveyances.

Issue: Several commenters recommended that importers be required to account for all cattle, whether dead or sold.

Response: The necessary accountability regarding the location, movement and disposition of animals will be provided by the requirement that movement permit APHIS Form VS 17–130, which identifies the physical destination of the animals and the person responsible for the movement of the animals, accompany all movements in the United States of feeder cattle imported from BSE minimal-risk regions.

Age and Feed Verifications

Issue: Several commenters asked whether FSIS will verify the following information: (1) That animals are less than 30 months of age at slaughter; (2) that CFIA is using the same procedure for determining animal age as FSIS; and (3) that ruminants imported from BSE minimal-risk regions for slaughter were not fed ruminant protein.

Response: Countries eligible to export meat to the United States must have a meat inspection system equivalent to the U.S. meat inspection system (as discussed below in section IV. D. under the heading ''Verification of Compliance in the Exporting Region''), including a system for verifying that SRMs are properly identified and removed from the human food supply. FSIS has an ongoing verification system to assess the effectiveness of the equivalency determination made for each foreign country deemed eligible to export meat to the United States. For live cattle, the FSIS-inspected slaughtering establishment is required by FSIS to implement procedures to determine the age of cattle in order to properly deal with SRMs. FSIS verifies that the establishment is meeting the regulatory requirements. Any cattle deemed to be 30 months of age and older must have those tissues that are considered SRMs in such animals, as well as the small intestine, removed and disposed of as inedible material.

Regarding verification procedures for ensuring that an animal has not been fed ruminant protein during its lifetime, APHIS will not recognize a region as a BSE minimal-risk region unless APHIS has first determined that the region has in place and is effectively enforcing a ruminant-to-ruminant feed ban and that the region has a reliable veterinary infrastructure that can certify that the requirements of this rule with regard to individual shipments have been met. For FSIS, part of that agency's equivalency determination is based on the total system for ensuring that the BSE-infective agent is appropriately controlled. FSIS would rely upon certifications made by the government of the exporting country in order to assess compliance with these requirements.

Certification of Feed Ban Compliance

Issue: Several commenters requested that the regulations require that the owner of ruminants imported from BSE minimal-risk regions be responsible for certifying that their animals have not been fed ruminant protein. One commenter further recommended that all imported cattle, regardless of their region of origin, be accompanied by an affidavit stating the animals have not been fed ruminant-derived protein.

Response: One of the requirements in this rule regarding the importation of feeder and slaughter cattle from a BSE minimal-risk region is that they have been fed in compliance with the ruminant feed ban of the region of origin and, further, that the ruminant feed ban is equivalent to the requirements established by the FDA. That provision will replace the requirement in our proposal that such animals not have been fed ruminant protein, other than milk protein, during their lifetime. Certification for import must be provided by the government of the exporting country—in this case, CFIA. For the purposes of international trade, the country of export is required to issue the official health certification required by the importing country.

We do not consider it necessary to require that all imported cattle, regardless of their region of origin, be accompanied by an affidavit stating the animals have not been fed ruminant-derived protein. Cattle are not permitted importation from those regions listed in § 94.18(a)(1) as regions in which BSE exists, nor are they permitted importation from regions listed in § 94.18(a)(2) as those that pose an undue risk of BSE. For regions that are included in neither of these categories, except for those regions listed in § 94.18(a)(3) as BSE minimal-risk regions, we do not consider it warranted based on risk to require certification that ruminants imported into the United States were subject to a feed ban.

Issue: One commenter recommended that, because the United States already considered the scope and application of a feed ban in Canada before proposing to designate that country as a BSE minimal-risk region, the required certification for live ruminants and ruminant products from Canada not include a statement concerning compliance with the feed ban for individual commodities. The commenter requested that the certification be required to address only any additional measures taken to prevent against the introduction of BSE into the United States, such as verification of age for live animals and removal of SRMs for beef. Another commenter stated that a broad certification addressing the feed ban established in the region of origin would be more appropriate than certification based solely on the knowledge of the certifying officer.

Response: We are making no changes based on these comments. We consider it necessary for possible traceback efforts that the verification statement regarding compliance with the feed ban requirements be included on the documentation that is provided when animals or commodities are presented for entry at U.S. border stations. Such certification for individual commodities will require that the certifying individual have knowledge of the origin of the commodities.

Border Stations

Issue: Several commenters expressed concern that cattle are being imported into the United States illegally after dark on back roads. One commenter stated that border ports should be open 24 hours a day, 7 days per week. Another commenter asked whether APHIS or FSIS will verify CFIA procedures to ensure that cattle were imported into the United States through an APHIS-designated port of entry.

Response: U.S. Customs and Border Protection (CBP), Department of Homeland Security, monitors every port of entry with officers, 24 hours per day, 7 days per week, to ensure security at America's borders and ports of entry and, among other things, protect our agricultural and economic interests from harmful pests and diseases. Because CBP monitors every port of entry around the clock, we are confident that all shipments of live animals entered through those ports, including cattle imported from Canada, will be referred to APHIS and meet all applicable laws and regulations before importation into the United States. The issue of attempts at illegal smuggling is one that must be dealt with at any country's borders. APHIS' regulations in § 93.408 explicitly require that all live cattle imported into the United States be inspected by APHIS' Veterinary Services at designated ports of entry. Any individual who violates the regulations is subject to civil and criminal penalties in accordance with the AHPA.

Issue: Several commenters expressed concern that our proposal did not designate a sufficient number of U.S./Canadian land border ports for the importation of live ruminants and ruminant products from Canada and requested that we establish additional land border ports in Minnesota, Montana, and North Dakota. Commenters specifically requested that we designate Dunseith, ND, as a port of entry. One commenter said that if our proposal were made final, a significant portion of renewed trade from Canada would be in the form of live animals. The commenter expressed concern that, because the proposal listed only three designated ports of entry convenient to the Canadian prairie Provinces, any delays at the ports of entry could become a serious animal welfare issue.

Response: Section 93.403(b) of the regulations lists 20 designated ports of entry for the importation of live ruminants from Canada. Seven of those ports are in either Minnesota, Montana, or North Dakota. Dunseith, ND, is listed as a designated port of entry for live

ruminants. The remainder of the designated ports are in Idaho, Maine, New York, Vermont, and Washington.

With regard to meat and edible products derived from ruminants in Canada, we proposed that such commodities from Canada could be imported into the United States from Canada only through the border ports we listed in § 94.19(k) of our proposal. Proposed § 94.19(k) listed fewer ports of entry for meat and edible products from Canada than are listed in § 93.403(b) for the importation of live animals. This is because the number of ports designated for meat and edible products is limited by the availability of facilities for FSIS personnel trained in the inspection of such commodities to conduct their required inspections.

We do not have any evidence to suggest that the land border ports listed in §§ 93.403(b) and 94.19(g) (redesignated from § 94.19(k) of the proposal) will be inadequate to provide inspection and import-related services for ruminant products and live ruminants entering the United States from Canada. Therefore, we are not making any changes in response to the comments. However, if, in the future, we add other countries to the list of BSE minimal-risk regions, or if the volume of imported commodities warrants it, we will adjust the list of designated ports accordingly.

Timing of Health Inspections

Issue: One commenter recommended that the regulations require that animals intended for importation into the United States be inspected by an accredited veterinarian within 24 hours before shipment and be accompanied with a certificate of veterinary inspection.

Response: We are making no changes based on this comment. The regulations in § 93.408 explicitly require that all live cattle imported into the United States from Canada be inspected at the port of entry. Animals imported into the United States under this rule will be visually inspected by a U.S. inspector while on the means of conveyance at the port of entry. (Also, as noted above under the heading ''Verification and Enforcement of Age Limit of Ruminants,'' U.S. inspectors at the port of entry will, if they consider it necessary, unseal the means of conveyance at the port of entry.) Section 93.418 requires certificates of veterinary inspection for cattle other than for immediate slaughter. Requiring that such inspection be conducted within 24 hours of export would not be consistent with our current requirements for health certificates that require issuance of such certificates by the exporting region within 30 days of export, and would be unnecessary because the animals would be reinspected at the border 24 hours or less after inspection in the exporting region. From the standpoint of ensuring animal health and detecting disease, it is preferable to have two inspections up to 30 days apart.

D. Risk Mitigation Measures for Importation of Ruminant Products and Byproducts

Age of Animals From Which Meat Is Derived

Issue: In § 94.19 of our proposed rule, we provided that meat derived from bovines slaughtered in a BSE minimal-risk region could be imported into the United States under certain conditions. One of the conditions was that the meat be derived from bovines that were less than 30 months of age when slaughtered. One commenter stated that the OIE and Canada prohibit the importation of meat products and carcasses from bovines less than 30 months of age; therefore, the United States should do the same. Conversely, a number of commenters stated that, provided all SRMS were removed from the animals, it was unnecessary to require that the animals from which the meat was derived were less than 30 months of age at slaughter. With the removal of the SRMs, said the commenters, the risk of BSE would be sufficiently mitigated.

Response: We consider the commenters' recommendation to allow the importation of meat from bovines of any age under certain conditions to have merit. As we discussed in our March 8, 2004, extension of the comment period on our November 2003 proposed rule, and as we discuss above in section III. C. under the heading ''Measures Implemented by FSIS,'' the FSIS SRM rule designated the following tissues in cattle as SRMs and prohibited their use in human food: The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle. To ensure effective removal of the distal ileum, FSIS requires removal of the entire small intestine and prohibits its use in human food.

These prohibitions do not restrict the slaughter of cattle in the United States based on age. The only role the age of the cattle plays in FSIS actions is in determining whether certain tissues (*e.g.,* central nervous system tissues) in the animal should be considered SRMs due to the animal's age.

Under FSIS regulations, meat inspection systems and processing requirements in Canada and in any country authorized to export meat and meat products to the United States must be equivalent to those in the United States in order for meat and meat products to be eligible for importation. Under these circumstances, we no longer consider it necessary to require that meat from bovines that is imported from a BSE minimal-risk region be derived only from animals less than 30 months of age, or that the animals were slaughtered in a facility that either slaughters only bovines less than 30 months of age or has in place a process adequate to segregate the meat from other meat slaughtered at the facility.

With regard to meat from sheep, goats, and other ovines and caprines, neither the proposed rule nor this final rule identifies SRMs in ovines and caprines that could be removed to eliminate any potential infectivity from products derived from the animals. Therefore, this final rule will require, as proposed, that meat from sheep or goats or other ovines or caprines from a BSE minimal-risk region be derived from animals that were less than 12 months of age when slaughtered, and we are adding the same condition for the importation of meat byproducts and meat food products derived from ovines or caprines. We discuss the issue of meat byproducts and meat food products below.

We disagree with the commenter who stated that international guidelines preclude the importation of meat products and carcasses from bovines less than 30 months of age from countries that OIE would consider to be minimal risk for BSE. The OIE guidelines recommend allowing the importation of meat from cattle of any age from such minimal-risk regions, provided the necessary risk mitigation measures are taken (*e.g.,* the meat contains no part of the brain, eyes, spinal cord, skull or vertebral column, or protein products derived from such materials).

What Constitutes Meat

Issue: In our proposed rule, we stated that, to be considered meat that is eligible for importation into the United States from a BSE minimal-risk region, a product would have to meet the FSIS definition of *meat* in 9 CFR 301.2. The FSIS regulations provided that, 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 or 30 mg. We noted in the preamble of our proposal that, except where the FSIS definition of *meat* was specifically referenced in our proposal, when we used ''meat'' we meant the standard dictionary definition of the term. One commenter stated that ''meat,'' as defined according to its common usage, could mean several different things. The commenter recommended that how we intend to use the term in the regulations should be specific to its purpose.

Response: In order to avoid confusion, in this final rule we are using the term ''meat'' in all cases to mean *meat* as defined by FSIS. In its AMR rule, FSIS revised the definition of *meat* in 9 CFR 301.2 to mean, ''The part of the muscle of any cattle, sheep, swine, or goats that is skeletal or that is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels that normally accompany the muscle tissue and that are not separated from it in the process of dressing. * * *'' FSIS provided further that meat does not include the muscle found in the lips, snout, or ears, and that meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia.

Additionally, in this final rule, we are clarifying that meat, meat byproducts, and meat food products from bison qualify as meat, meat food products, and meat byproducts under this rule, even though such commodities derived from bison are not included under the FSIS definitions.

Meat Byproducts and Meat Food Products

Proposed § 94.19 prohibited 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 a BSE minimal-risk region, unless conditions allowing for the importation of a specified commodity were included in that section or in § 94.18. In § 94.19, we proposed conditions for the importation of the following commodities: Fresh (chilled or frozen) bovine whole or half carcasses or other meat; fresh (chilled or frozen) bovine liver; fresh (chilled or frozen) bovine tongues; fresh (chilled or frozen) carcasses or other meat of ovines and caprines; fresh (chilled or frozen) meat or dressed carcasses of hunter-harvested wild sheep, goats, cervids, or other ruminants; fresh (chilled or frozen) meat of cervids either farm-raised or harvested on a game farm or similar facility; fresh (chilled or frozen) meat from specified wild-harvested musk ox, caribou or other cervids; and gelatin.

Issue: A number of commenters expressed concern that the proposed rule did not specifically include conditions for the importation of processed meat products. The commenters stated that products processed for edible use from boneless cuts of beef and other parts of the carcass from cattle of any age should be allowed importation, provided SRMs were removed from the cattle from which the products were derived. One commenter stated that, by incorporating FSIS's regulatory description of meat from 9 CFR 301.2, APHIS excluded from importation from a BSE minimal-risk region meat food products that are separately defined by FSIS as ''any article capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle.'' The commenter stated that this prohibits the importation of a wide range of products for which there is no discernible risk factor.

Response: We agree it is not necessary to prohibit the importation of processed meat products and byproducts from ruminants that meet the conditions in this rule for the importation of meat. Therefore, we are providing in § 94.19 of this final rule that, along with meat as defined by FSIS, the importation conditions in this rule also apply to those products that are included in the FSIS definitions of *meat food product* and *meat byproduct* in 9 CFR 301.2.

In those definitions, *meat byproduct* is defined as ''any part capable of use as human food, other than meat, which has been derived from one or more cattle, sheep, swine, or goats. * * *'' *Meat food product* is defined as ''any article capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, except those exempted from definition as a meat food product by the [FSIS] Administrator in specific cases or by the regulations in * * * [9 CFR part 317], upon a determination that they contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and provided that they comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions as to assure that the meat or other portions of such carcasses contained in such articles are not adulterated and that such articles are not represented as meat food products. * * *''

Additionally, we are not specifying in this final rule that the meat and meat commodities imported into the United States under this rule must be chilled or frozen. Chilling or freezing meat and meat products does not affect the BSE risk from those commodities.

Cervid Products

Issue: A number of commenters addressed the issue of the importation of products derived from cervids, including meat, antlers, trophies, and urine. One commenter objected in general to the importation of any hunter-harvested wild ruminant products. Most of the other commenters who addressed the issue of cervid products recommended that they be eligible for importation from a BSE minimal-risk region. Some commenters said such products should be eligible for importation without restriction. Others suggested specific conditions for importing such products. Several commenters recommended that we prohibit the importation of offal derived from cervids from BSE minimal-risk regions, because of the susceptibility of cervids to CWD.

Response: As we discuss above under the heading ''Cervids,'' in this final rule we are not prohibiting or restricting the importation of cervids from BSE minimal-risk regions because of BSE. APHIS is aware of no epidemiological data indicating that cervids are naturally susceptible to the BSE agent. Published observations indicate that, during the height of the BSE outbreak in 1992 and 1993 in the United Kingdom, exotic ruminants of the *Bovidae* family in zoos were affected with BSE, while cervids, which are members of the *Cervidae* family, were not (Ref 22). Therefore, even in regions that have high levels of circulating infectivity and that should be considered high risk for BSE, BSE susceptibility in cervids was not observed. Therefore, in this final rule, we are not imposing any restrictions on cervid products from BSE minimal-risk regions because of BSE.

Issue: Several comments recommended that products from wild cervids, especially from the United Kingdom, be allowed importation into the United States regardless of the exporting region's BSE status. The commenters stated that wild deer by

their nature are not fed ruminant protein, that no TSE has ever been recorded in the deer population in the United Kingdom, and that surveillance of wild deer is ongoing in the United Kingdom, with no evidence of prion.

Response: We are making no changes based on the comments, other than those we are making in this final rule with regard to cervid products from BSE minimal-risk regions. The provisions we proposed, and the risk analysis we conducted in conjunction with this rulemaking, concerned ruminant imports from BSE minimal-risk regions. We consider the issue of the importation of ruminant products from BSE-affected regions to be outside the scope of this rulemaking.

What SRMs Should Be Removed

Issue: One commenter stated that we said in our proposal that a region we might classify as minimal risk for BSE could, strictly speaking, be classified as a moderate-risk country or zone under OIE guidelines. The commenter stated that OIE recommends, for moderate-risk countries or zones, that meat and meat products for export not contain brain, eyes, spinal cord, distal ileum or mechanically separated meat from skull and vertebral column from cattle over 6 months of age. The commenter expressed concern that, for cattle under 30 months of age from BSE minimal-risk regions, we proposed to require only the removal of the intestines at slaughter.

Response: In our proposal, we did not make a general statement that BSE minimal-risk regions by our guidelines might be classified as BSE moderate-risk countries by OIE guidelines. Our discussion was particular to the situation in Canada. Our evaluations concluded that, according to our proposed standards, Canada qualified as a BSE minimal-risk region. We indicated that, although a strict reading of the OIE standards relative to the duration of a feed ban would classify Canada as a moderate-risk country until 2005, our integrated approach to evaluating the BSE status of a country considers the length of a feed ban within the context of all control measures in place. Further, 7 years represents the 95th percentile of the incubation period distribution; therefore, there is a rational basis for departing from the OIE guideline of 8 years. We considered the sum total of the control mechanisms in place at the time of diagnosis (e.g., effectiveness of surveillance, import controls, and feed ban) and the actions taken after it (e.g., epidemiological investigations, depopulation), thereby allowing the actions CFIA took in other elements to compensate for a shorter feed ban duration than recommended by OIE. Consistent with OIE guidelines, we consider the 30-month age standard for SRMs-except for tonsils and the distal ileum, as discussed below-to be adequate for regions such as Canada that we consider to be minimal-risk for BSE. If countries (or other regions) other than Canada apply for a BSE minimal-risk designation under this rule, we will evaluate such requests on a case-by-case basis, and consider, as we did for Canada, the combination of factors affecting the risk of BSE being introduced into the United States from such countries or other regions.

According to OIE guidelines, in a minimal-risk region, all of the tissues listed by the commenter except the distal ileum need be removed only from cattle over 30 months of age. The distal ileum need not be removed from cattle of any age. FSIS regulations define tonsils and the distal ileum as SRMs regardless of the age of cattle and require their removal. These definitions are applicable to meat from cattle slaughtered in the United States, as well as to meat imported from eligible foreign sources. To be consistent with the FSIS requirements, we are requiring in § 94.19(a)(2) and (b)(2) that meat and other bovine products imported into the United States from a BSE minimal-risk region be derived from cattle that have had SRMs and the small intestine removed in accordance with the FSIS regulations.

Issue: Several commenters recommended that not just intestines, but also brains, eyes and spinal tissue be prohibited from the food chain or rendering.

Response: As discussed above in section III. C. under the heading ''Measures Implemented by FSIS,'' that agency's SRM rule applies to meat from cattle slaughtered in the United States, as well as to meat from eligible foreign sources. As noted, we are requiring that meat and other bovine products from a BSE minimal-risk region be derived from animals that have had SRMs removed in accordance with the FSIS regulations.

Removal of SRMs

Issue: One commenter stated that an exporting region would generally be unable to accurately certify that ''SRMs have been removed,'' and that APHIS should require instead certification that ''a majority of the known SRMs have been removed.'' For example, said the commenter, when a carcass-splitting band saw is used to split a carcass through the spinal cord, bone dust mixed with spinal cord tissue is left on the exposed cut surfaces of the vertebral column before removal of the spinal cord. Also, said the commenter, captive bolt pistols, when penetrating the skull during the stunning procedure, provide a source of hematogenous spread of central nervous system tissue to the carcass, although not as much as when air stunning devices are used. The commenter also stated that if BSE is anything like scrapie, perhaps steam is not an adequate means of sterilizing equipment after being used on BSE-contaminated tissues, given the heat-resistant nature of the scrapie agent. Another commenter raised similar issues, stating that the U.S. Government should discontinue contamination of beef with prions from the central nervous system and change allowable methods of slaughter and processing. The commenter recommended that captive bolt stunning be replaced by electrical stunning, that immobilization of the animal by a pithing rod be prohibited, and that no sawing through the spinal cord be permitted.

Response: On January 12, 2004, FSIS published an interim final rule prohibiting the use of penetrative captive bolt devices that deliberately inject air into the cranial cavity of cattle, because that method of stunning has been found to force visible pieces of central nervous system tissue (known as macro-emboli) into the circulatory system of stunned cattle. The comment period on that interim final rule closed on May 7, 2004, and FSIS is assessing the comments on this issue. At this time, FSIS considers the current stunning methods allowable for use in the United States to be practical and effective, based on a review of published studies on stunning methods.

Regarding the cross-contamination issues identified by the commenter, FSIS has developed procedures to verify that cross-contamination of edible tissue with SRMs is reduced to the maximum extent practical in facilities that slaughter cattle or process carcasses or parts of carcasses of cattle, both animals younger than 30 months of age and 30 months of age and older. If an establishment uses dedicated equipment to cut through SRMs, or if it segregates cattle 30 months of age and older from cattle younger than 30 months of age, then the establishment may use routine operational sanitation procedures (*i.e.*, no special sanitation procedures are required). If the establishment does not segregate cattle 30 months of age and older from younger cattle, equipment used to cut through SRMs must be cleaned and sanitized before it is used on carcasses or parts from cattle less than 30 months of age. FSIS believes

that, due to the multiple risk mitigation measures implemented in the United States to prevent the spread of BSE, these procedures will reduce to the extent possible cross-contamination of carcasses with high-risk tissues. However, to assist in determining whether it should strengthen the measures required of establishments, on March 31, 2004, FSIS issued a press release during the comment period for its SRM rule that specifically requested public comment on methods to prevent cross-contamination of carcasses with SRMs. The type of measures described above have also been implemented in Canada.

Advanced Meat Recovery Systems

Issue: Several commenters stated that AMR systems (a technology that enables processors to remove the attached skeletal muscle tissue from livestock bones without incorporating significant amounts of bone and bone products into the final meat product) are notorious for containing tissue derived from the dorsal root ganglia (an SRM) in the final product, and recommended that the use of AMR be prohibited in the United States when slaughtering animals of Canadian origin. Additionally, the commenters recommended that products that contain AMR meat should not be allowed into the United States from BSE minimal-risk regions.

Response: In its AMR rule, FSIS amended its description of meat to make it clear that, to be considered meat, AMR product may not include significant portions of bone or related components, such as bone marrow, or any amount of central nervous system-type tissues. Additionally, FSIS'' AMR rule provided that AMR systems may not use bones classified as SRM (vertebral column and skull of cattle 30 months of age and older). The AMR rule states that, if skulls or vertebral column bones from cattle 30 months of age and older are used in AMR systems, the product exiting the AMR system is adulterated, and the product and the spent bone materials are inedible and must not be used for human food. FSIS stated that the potential for human exposure to the BSE-infective agent is prevented in products prepared from cattle 30 months of age and older using AMR systems because the AMR product cannot include source materials from the skull or vertebral column or contain any amount of brain, trigeminal ganglia, spinal cord or dorsal root ganglia. AMR systems can be used to prepare meat from the skull and vertebral column of cattle under 30 months of age. However, these source materials from cattle under 30 months of age are not designated as SRMs. The FSIS requirements are applicable to domestic beef as well as to beef from a foreign country deemed eligible for export to the United States.

Request for Clarification of Intent

Issue: One commenter stated that the proposed rule seemed to allow the importation of some products containing bone or even SRMs. The commenter requested that APHIS clarify whether this was the intent, and, if so, provide the scientific justification for that decision.

Response: It is not clear to us what provisions in the proposed rule the commenter is referring to. It is not APHIS' intent to allow the importation of any SRMs from BSE minimal-risk regions. SRMs must be removed from imported cattle at slaughter in the United States and must have been removed from cattle in the exporting country from which meat and meat products are derived. The skull and vertebral bones are included in the definition of SRMs (both according to the Canadian regulations and those of the United States because of the possibility that those bones might contain dorsal root ganglia) so ''bones of concern'' as far as BSE are concerned are not allowed importation. Other bones have not been shown to pose a risk of BSE infectivity.

Tonsils and Third Eyelid

Under our proposed rule, intestines would have been the only tissues required to be removed at slaughter from cattle less than 30 months of age from a BSE minimal-risk region. We also proposed that beef imported from a BSE minimal-risk region be derived only from bovines less than 30 months of age from which the intestines had been removed.

Issue: One commenter stated that the EU SSC recommends also that tonsils of bovines of any age be regarded as a BSE risk. Several other commenters stated that, although our proposed rule required removal of only the intestines, Canada requires removal of all SRMs from animals at slaughter, and that U.S. citizens should be afforded the same level of protection as Canadian citizens. The commenters stated that because tonsils and third eyelid lymphoid tissue have been demonstrated to have possible BSE infectivity in animals as early as 10 months post-inoculation, USDA should not only require removal of all SRMs from animals and products imported from minimal-risk regions, but also from all cattle slaughtered in the United States.

Response: We are assuming that the commenters who referred to ''animals'' in these comments were referring to bovines and bovine products from BSE minimal-risk regions. As discussed above in this document under the heading ''Age of Animals from Which Meat is Derived,'' requirements for removal of SRMs in Canada for meat and meat products eligible to be imported and U.S. requirements are currently equivalent. All of the requirements that were imposed by FSIS'' SRM rule on cattle slaughtered in the United States also apply to meat imported into the United States from foreign countries eligible to export the beef to the United States. FSIS'' SRM rule identified tonsils as SRMs. Tonsils of all cattle, regardless of age, must be removed. Based on FSIS's requirements, all regions intending to import meat and meat products into the United States will also have to remove the tonsils from cattle of all ages from which the meat and meat products are derived. As noted, we are providing in this rule that we consider SRMs to be those identified as such by FSIS.

With regard to the third eyelid, there is no evidence that the third eyelid lymphoid tissue is a tissue at risk of infectivity for BSE in bovines. The only TSE agents that have been found in the third eyelid are scrapie in sheep and CWD in deer and elk. PrP^{res} (the pathological form of the prion protein) has not been found in the third eyelid of cattle. There have been no reports of its presence in goats. Therefore, neither FSIS nor APHIS considers the third eyelid to be an SRM.

Distal Ileum

Issue: A number of commenters took issue with the requirement in our proposal that the intestines be removed from cattle less than 30 months of age from BSE minimal-risk regions, even though we stated in the explanatory information of our proposal that the distal ileum (a part of the small intestine) is the only part of the intestine that is likely to have infectious levels of the BSE agent. Several comments stated that we were incorrect in stating in our March 8, 2004, notice reopening the proposed rule comment period that FSIS classifies the small intestine of cattle of all ages as an SRM. The commenters stated that the FSIS rule classifies only the distal ileum as SRM, but requires removal of the entire small intestine as a means of ensuring the removal of the distal ileum. The commenters stated that APHIS should recommend removal only of the distal ileum. Other commenters stated that, at most, APHIS should require removal of the small intestine. One commenter recommended removal of the last 70

inches of the small intestine, rather than the entire small intestine. Another commenter provided an anatomical description of the bovine small intestine that the commenter said could be used to develop a model of certification for the removal and disposal of the distal ileum.

Response: The commenters are correct that FSIS classified the distal ileum from cattle of all ages as an SRM and not the entire small intestine. FSIS requires removal of the entire small intestine to ensure effective removal of the distal ileum. Canada has the same requirements. This final rule on BSE minimal-risk regions adopts FSIS'' requirements regarding removal of SRMs and the small intestine. In its SRM rule, however, FSIS acknowledged that methods might exist for processors to effectively remove the distal ileum without removing the entire small intestine and requested comments on that issue. The comment period for the FSIS interim final rule closed on May 7, 2004.

Issue: One commenter stated that, although beef casings are currently allowed into the United States from countries not listed as BSE-affected or posing an undue risk of BSE, the FSIS rule requires the removal of the entire small intestine from all cattle of all regions regardless of BSE status. In addition, stated the commenter, the FSIS rule has prevented the importation of the entire intestines of cattle from regions where no BSE exists if the exporting country cannot certify removal of the small intestine. The commenter recommended that exporting countries that do not fall into any of the U.S. BSE risk categories should not be required to remove any SRM, much less certify the removal of the entire small intestine.

Response: In addressing FSIS' application of its regulations to countries other than BSE minimal-risk regions, the commenter is raising an issue that goes beyond the scope of the APHIS rulemaking. In both its SRM rule and the USDA/FDA joint notice, FSIS specifically requested comment on the issue of removal of the distal ileum.

Tongue and Liver

Issue: In § 94.19(d) of our proposed rule, we provided that bovine tongues could be imported from BSE minimal-risk regions if the tongues were 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 were removed at slaughter. Several commenters stated that the regulations should prohibit either the importation of all tongues from bovines from BSE minimal-risk regions, or the importation of tongues from bovines 30 months or older. Some of the commenters stated that the risk from tongues is unacceptable because the tongue is attached to the tonsils, which are likely to contain the BSE infectious agent in an infected animal.

Response: We do not consider it necessary to prohibit the importation of bovine tongues from a BSE minimal-risk region, provided the conditions set forth in this rule are met. As we stated above under the heading ''What Constitutes Meat?,'' the tongue (but not the peripheral glandular material) is a muscle included in the FSIS definition of *meat,* and, to date, BSE infectivity has not been detected in muscle meat of cattle. In this final rule, we are not including a separate paragraph that includes the conditions for importing tongues from BSE minimal-risk regions. Tongues will be subject to the same requirements as other meat.

We do acknowledge, however, as we did in our proposed rule, that it is necessary to ensure that the tongues come from bovines from which the tonsils have been removed. As we discuss above under the heading ''Age of Animals from Which Meat is Derived'' and elsewhere, we believe, from an animal health perspective, to consider as SRMs those tissues listed by FSIS as SRMs. Under that listing, tonsils of all cattle, regardless of age, must be removed. Several procedures exist for removal of tongues so that they are effectively separated from the tonsils, including cutting of the tongue at its base and cutting the hyoid bones and associated structures to liberate the tongue from the tonsils.

Issue: Several commenters stated that the proposed rule did not make clear why APHIS would require that bovine tongues or tallow from a BSE minimal-risk region be derived from animals that were born after the implementation of an effective feed ban, while the same requirement was not proposed for liver. Similarly, another commenter questioned why the age of an animal should be a factor regarding some products from a BSE minimal-risk region, such as meat, and not others, such as tongue and liver. Several commenters recommended that the regulations require that bovine liver from BSE minimal-risk regions be from cattle under 30 months of age and that certification be required that this and any other requirements for liver have been met.

Response: Under this rule, tongues, which, as we noted, are included in the FSIS definition of *meat* in 9 CFR 301.2, will be subject to the same requirements as other meat, including the requirement that the tongues be derived from bovines that were subject to a ruminant feed ban during their lifetime equivalent to the requirements established by FDA. Thus it is unnecessary for us to retain the separate conditions for tongues that appeared in § 94.19 of the proposed rule, including the condition that the tongues be derived from bovines that were born after the region implemented an effective ban on the feeding of ruminant protein to ruminants. Also, as discussed in this document under the heading ''Age of Animals from which Meat is Derived,'' we are not including the requirement we proposed that meat from bovines from BSE minimal-risk regions be derived from animals that were less than 30 months of age when slaughtered. Liver, which falls under the FSIS definition in 9 CFR 301.2 of meat *byproducts,* will be subject to the same importation requirements in our rule as meat.

With regard to certification, § 94.19 as proposed and as set forth in this final rule already requires certification that the requirements for liver and other commodities regulated under that section have been met.

Issue: One commenter asked how APHIS could conclude that the intestines of cattle are not safe, but the tongue and liver are.

Response: Our proposed requirement that the intestines of cattle from BSE minimal-risk regions be removed was based on evidence that BSE infectivity could exist in the distal ileum of bovines as young as 6 months of age. Similar infectivity has not been demonstrated in the tongue or liver of bovines of that age.

Milk and BSE Risk

Issue: One commenter stated that milk was a dangerous prion carrier and that milk protein is an unacceptable risk.

Response: At this time, there is no scientific evidence that milk and milk products are sources of BSE infectivity that would pose any BSE risk to public or animal health. Milk and milk products are regulated by the FDA and the safety of milk is discussed in ''BSE Questions and Answers'' that can be accessed on that agency's Web site at *http://www.cfsan.fda.gov/comm/bsefaq.html.*

Verification of Compliance in the Exporting Region

Issue: A number of commenters stated that USDA should conduct monitoring to ensure that imported products meet the FSIS definition of *meat.* One commenter recommended that APHIS specify the methods that will be used to conduct such verification. Several commenters asked whether APHIS or FSIS will verify the CFIA procedures necessary to ensure compliance with this rule. Other commenters questioned whether USDA can verify the practices of Canadian producers and the meat industry in that country. One commenter stated that verification should include the presence of USDA personnel in Canadian beef processing plants.

Response: As required under the FMIA, FSIS ensures that imported meat in the U.S. marketplace is safe, wholesome, unadulterated, and properly labeled by (1) determining if foreign countries and their establishments have implemented food safety system and inspection requirements equivalent to those in the United States and (2) reinspecting imported meat and poultry products from those countries through random sampling of shipments. Countries eligible to export meat to the United States must have a meat inspection system determined by FSIS to be equivalent to the U.S. meat inspection system, including a system for verifying that SRMs are properly identified, segregated, and removed from meat that is exported to the United States. FSIS has a system to verify the ongoing equivalence of each foreign country deemed eligible to export beef to the United States. The FSIS equivalency determination is based on the country's inspection system for appropriately controlling the BSE-infective agent.

FSIS conducts annual system equivalence audits, as required by the FMIA, to verify that the foreign country's inspection system remains equivalent to that required in the United States. This audit includes a sampling of export-certified foreign establishments. FSIS's audit system focuses on two essential components of safe food production that must be present in a foreign food regulatory system: (1) Industry process control, which is executed by establishments through sanitary procedures such as sanitation, HACCP and quality assurance systems, and microbial/chemical testing programs; and (2) government inspection, verification, and enforcement activities exercised in a form and at an intensity appropriate to ensure the effectiveness of industry process controls and detect noncompliance. Foreign food regulatory system audits are conducted in four phases: Planning, execution, evaluation, and feedback. Each of these phases is discussed below:

1. *Planning.* FSIS prepares a consolidated annual plan to audit each country that exports meat, poultry, or egg products to the United States. Individual country audit plans are based, in large part, upon prior experience with the exporting country. For example, all previous FSIS audit reports are reviewed to identify issues for inclusion in the current audit. Port-of-entry reinspection data are also reviewed at this time to determine trends and identify areas of special interest for audit. These documents and data are used by FSIS to develop an audit plan that is customized for each country. The plan includes a list of foreign establishments selected for centralized records review. A subset of these establishments is further selected for on-site audit. FSIS uses a statistical method for establishment selection. Additional establishments may be added for cause.

2. *Execution.* An auditor (or in some cases an audit team) is dispatched to the exporting country's inspection headquarters and/or to sub-offices as agreed in the audit protocol. Opening discussions are held with exporting country officials to determine if the national system of inspection, verification, and enforcement is being implemented as documented, and to identify significant trends or changes in operations. The FSIS auditor examines a sample of program records that provide evidence of the exporting country's regulatory activities and accompanies officials of the exporting country on field visits to a representative sample of establishments eligible to export to the United States. Exporting country officials conduct a review to verify that each selected establishment continues to achieve the U.S. level of sanitary protection. Particular attention is paid to how eligible establishments address food safety hazards, some of which may be different from those encountered in the United States. FSIS auditors observe establishment activities and correlate review findings made by exporting country officials. Selected microbiological and chemical laboratories are also reviewed, and a farm or feedlot is visited to verify animal drug controls. In a closing meeting, the FSIS auditor provides exporting country officials with an overview of conditions observed and ensures that audit observations are clearly understood.

3. *Evaluation.* FSIS conducts a post-audit evaluation of all data collected on-site. When evaluating audit data, FSIS considers how sanitary measures of the foreign food regulatory system compare to those used in the United States and determines whether the foreign system cumulatively provides the same level of protection.

4. *Feedback.* FSIS then sends the exporting country a draft audit report and provides the country an opportunity to respond to the audit's findings. After consideration of comments from the country, a final report is prepared. An action plan is mutually developed to address any issues raised by the audit. These issues are tracked by FSIS until resolution and are automatically included as items of special interest in the next audit.

All reports of initial equivalence audits and equivalence verification audits are posted on the FSIS Web site *(http://www.fsis.usda.gov/regulations/foreign_audit_reports_past/index.asp)* when they are final, which is immediately after the final version is delivered to the audited country.

Meat From Beef vs. Dairy Cattle

Issue: One commenter suggested distinguishing meat obtained from beef cattle from meat obtained from dairy cattle.

Response: We are making no changes based on this comment. We are not aware of any benefits in addressing BSE mitigations or risk that would be derived from identifying meat as having come from beef or dairy cattle.

Request for Import Bans

Issue: A number of commenters requested bans on certain commodities from Canada or other countries. Commenters stated that APHIS should not allow the importation of Canadian beef. Other commenters requested that APHIS not allow the importation of beef (some commenters specified ground beef) or animal feedstuffs from any country. None of these commenters provided data or other information to support their requests.

Response: We are making no changes based on these comments. Under the Animal Health Protection Act, the Secretary of Agriculture (or official delegated in accordance with 7 CFR 2.22 and 2.80) may prohibit or restrict articles if the Secretary determines such prohibition or restriction is necessary to prevent the introduction or dissemination within the United States of any pest or disease of livestock. The Secretary has determined that the

measures in place in Canada relative to BSE, together with the import risk mitigations required by this rule, would be effective in preventing the introduction of BSE into the United States via meat and meat products imported from Canada. Further, the United States, as part of the World Trade Organization, cannot set up arbitrary barriers to trade that would prohibit the importation of animal products if the risk of such products introducing livestock diseases or pests into the United States can be mitigated.

Animal feed containing animal products may currently be imported into the United States under an import permit that sets out the conditions for such importation. Feed containing ruminant protein other than milk protein is prohibited importation into the United States from any region listed in § 94.18(a), which lists regions in which BSE exists, those that pose an undue risk of BSE, and, under this final rule, those that are considered BSE minimal-risk regions.

Offal

Issue: The regulations prior to this rule prohibited the importation of offal from any region listed in § 94.18(a). Prior to this rule, the only regions listed in § 94.18(a) were those in which BSE exists and those that present an undue risk of introducing BSE into the United States. As noted, however, in this final rule, we are including in § 94.18(a)(3) a list of BSE minimal-risk regions.

Paragraphs (a) and (a)(1) of the regulations in § 95.4—which deal with restrictions due to BSE on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum—prohibit the importation of specified materials from regions listed in § 94.18(a), unless the materials meet conditions set forth in § 95.4.

In § 95.4(g) of our proposal, we set forth risk mitigation measures under which offal derived from cervids from BSE minimal-risk regions could be imported into the United States. However, we did not include provisions in our proposed rule for the importation of offal from ruminants other than cervids. The proposal was limited to cervid offal because cervid offal was among the most commonly imported low-risk commodities from BSE minimal-risk regions. We proposed to define *offal* in § 95.1 to mean the parts of a butchered animal that are removed in dressing, consisting largely of the viscera and trimmings, which may include, but are not limited to, brains, thymus, pancreas, liver, heart, and kidney.

A number of commenters addressed the importation of offal other than cervid offal for edible and inedible purposes. One commenter recommended that the only requirement for the importation of offal from Canada should be certification from the Canadian Government that the fresh offal and other edible by-products are derived from bovines that were slaughtered and processed in a facility approved and inspected by the Government of Canada, and from which SRMs had been removed. Other commenters expressed concern that the proposed definition of *offal* in § 95.1 would preclude the importation of hearts and kidneys from cattle from BSE minimal-risk regions and recommended that such organs be allowed importation provided they do not come in contact with SRMs. Several commenters noted that, although the proposed regulations and definition of *offal* in part 95 would prohibit the importation of liver from cattle from BSE minimal-risk regions, the provisions in proposed § 94.19(c) provided for the importation of bovine liver from BSE minimal-risk regions if no air-injected stunning was used at slaughter. One commenter stated that it was not clear whether our proposed definition of *offal* applied to cervids. The commenter also recommended that the word ''trimmings'' be removed from the proposed definition of *offal* because its inclusion could be construed to prohibit the importation of meat trimmings. One commenter stated that the import prohibitions in part 95 should apply only to tissues that have been proven to potentially harbor the BSE infective agent.

Response: We agree with the commenters that there is no scientific reason to limit the importation of offal from BSE minimal-risk regions to offal derived from cervids and that the criterion for whether products, including offal, derived from ruminants are allowed importation into the United States should be whether those products pose a risk of introducing BSE into the United States. Consequently, in this final rule, we are defining offal to mean ''the parts of an animal that are removed in dressing, including meat, meat byproducts, and organs,'' and, for clarity's sake, are specifying in § 95.4(g) the conditions for the importation of offal from BSE minimal-risk regions. The conditions for importation of offal from ruminants from BSE minimal-risk regions are the same as those set forth in § 94.19 of this final rule for the importation of meat, meat byproducts, and meat food products. We are providing in § 95.4(g) that offal derived from ruminants from BSE minimal-risk regions is allowed importation into the United States if the offal is derived from cervids or if the offal is derived from bovines, ovines, or caprines and the following conditions are met:

1. *If the offal is derived from bovines, the offal:*

- Contains no SRMs and is derived from bovines from which the SRMs were removed;
- Is derived from bovines for which an air-injected stunning process was not used at slaughter; and
- Is derived from bovines that were subject to a ruminant feed ban equivalent to the requirements established by FDA.

2. *If the offal is derived from ovines or caprines, the offal is derived from animals that:*

- Have not tested positive for and are not suspect for a TSE (we are adding definitions of *positive for a transmissible spongiform encephalopathy* and *suspect for a transmissible spongiform encephalopathy* to § 95.1 of the regulations);
- Were less than 12 months of age when slaughtered and that are from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by FDA;
- Have resided in a flock or herd that has not been diagnosed with BSE; and
- Have not had their movement restricted in the BSE minimal-risk region as a result of exposure to a TSE.

As required for meat, meat byproducts, and meat food products in § 94.19, we are requiring certification from the country of origin that the offal meets the above requirements and are requiring that the offal, if arriving at a U.S. land border port, arrives at a port listed in § 94.19(g).

Tallow

Issue: One commenter stated that it does not make sense to prohibit the importation of tallow from Canada but allow the importation of Canadian beef and veal.

Response: The proposed rule did not prohibit the importation of tallow from BSE minimal-risk regions. We provided in proposed § 95.4(f) that tallow could be imported from a BSE minimal-risk region if the tallow is composed of less than 0.15 percent protein and meets certain other conditions specified in the proposal.

Issue: One commenter said there is no scientific basis for requiring that tallow eligible for importation contain no more than 0.15 percent impurities. The commenter stated that research

conducted by Dr. D.M. Taylor, *et al.,* of the Animal Health Institute, Edinburgh Scotland, failed to find an association between the occurrence of BSE and the consumption of tallow by cattle, and that in studies using BSE-spiked tallow, no infectivity was found in crude, unfiltered tallow extracted from rendered meat-and-bone meal. The commenter stated that the study was validated by injecting spiked BSE tallow intracerebrally into experimental mice without resulting demonstrated changes associated with TSEs. The commenter stated further that, in 1991, the World Health Organization (WHO) assembled consultants who determined tallow not to be a risk to animal or human health. Additionally, stated the commenter, the Harvard-Tuskegee Study refers to the safety of tallow.

Response: The research referenced by the commenter documents the results of mouse assays. We are unaware of any studies that have been performed using cattle experimentally fed tallow infected with BSE with resulting absence of infectivity. Based on the scientific evidence currently available, it is not possible to dismiss the possibility that ingestion of tallow infected with BSE creates a risk of the transmission of BSE. This conclusion is consistent with the OIE Code, Article 2.3.13.1., which recommends that one of the conditions for the importation of tallow from any country, regardless of its BSE status, be that the tallow is protein-free (*i.e.*, have a maximum level of insoluble impurities of 0.15 percent in weight).

While WHO concluded that because of the proteinaceous nature of TSE agents, they will tend to remain with the cellular residues of meat-and-bone meal during the extraction process rather than being extracted with the lipids of tallow, the EU SSC considers that possible TSE risks associated with tallow will result from protein impurities that may be present in the end product, because it is expected that TSE agents, if present in the product, would be associated with those impurities (Ref 28).

Issue: One commenter specifically supported the proposed provisions regarding edible tallow. Another commenter supported the proposed conditions except for the requirement that the intestines of the bovine had been removed at slaughter and the requirement that the bovine not have been fed ruminant protein other than milk protein. Instead, said the commenter, the requirement regarding feeding should refer instead to adherence to the CFIA and FDA feed bans. Another commenter stated that importation of all tallow should be prohibited. Several commenters stated that tallow should be accepted from BSE minimal-risk regions only if all SRMs were removed from the bovines from which the tallow was derived, segregation of the tallow from potentially risky materials is carried out in the region of origin, and the tallow is accompanied by certification by the owner of the animal from which the animal was derived that the animal was not fed ruminant protein. Other commenters recommended that there be no restrictions on the importation of tallow from BSE minimal-risk regions. One commenter stated that it was not scientifically defensible to require that tallow not be derived from an animal that died otherwise than by slaughter. Several commenters stated that, under the OIE Code, tallow is considered protein-free if it contains no more than 0.15 percent impurities, and that protein-free tallow should be allowed importation without further restriction. Several commenters said such tallow should be allowed importation no matter what the BSE status of the region of origin. The commenters stated further that, even if tallow intended for food, feed, fertilizers, cosmetics, pharmaceuticals including biologicals, or medical devices is not protein-free, it should be allowed importation if (1) it came from bovines that were subject to ante-mortem inspection with favorable results, and (2) had not been prepared using SRMs. One commenter also recommended that derivatives of non-protein-free tallow intended for the uses listed above be allowed importation without restriction.

Response: In this rule, we are making some changes to the requirements we proposed regarding the importation of tallow from BSE minimal-risk regions. We agree that protein-free tallow will not pose a risk of introducing BSE into the United States. As noted above, this conclusion is consistent with the recommendation in the OIE Code that protein-free tallow (maximum level of insoluble impurities of 0.15 percent in weight) be considered a commodity that may be imported without restriction, regardless of the BSE status of the exporting country. Therefore, we are removing the restrictions we proposed for the importation of protein-free tallow from BSE minimal-risk regions that could be used in animal feed, except for the requirements that the tallow be accompanied by certification that it is protein-free and, if arriving at a land border port, that it arrive at a port listed § 94.19(g). Additionally, with the commenter who recommended segregation of the tallow from any other risky products for BSE. We are also adding language to § 95.4(f) to indicate that the listed importation requirements for tallow are for tallow imported into the United States from BSE minimal-risk regions as listed in § 94.18(a)(3).

Therefore, in this final rule, § 95.4(f) authorizes the importation of tallow from BSE minimal-risk regions that could be used in animal feed, provided the tallow is accompanied by official documentation certifying that: (1) The tallow is protein-free tallow (maximum level of insoluble impurities of 0.15 percent in weight); and (2) after processing, the tallow was not exposed to or commingled with any other animal origin material. The requirements of our proposal pertaining to the port of arrival of the shipment and the requirement that each shipment be accompanied by an original certificate will remain. We intend to address the importation of tallow from regions other than BSE minimal-risk regions in future rulemaking.

Under the existing regulations in § 95.4, tallow derivatives are allowed importation from regions listed in § 94.18(a) as regions affected with BSE or that pose an undue risk of BSE. Likewise, under this rule, tallow derivatives from BSE minimal-risk regions will be eligible for importation into the United States.

Tallow and Offal Testing and Inspection

Issue: One commenter requested that our rule include the methods that will be used to test or inspect at the border any tallow or offal intended for importation into the United States from a BSE minimal-risk region to ensure that BSE-contaminated tallow or offal does not enter this country.

Response: For tallow or offal subject to the FMIA to enter the United States, it must originate from a country where the inspection system has been determined by FSIS to be equivalent to the U.S. meat inspection system. As part of its equivalence determination, FSIS requires that certified establishments in foreign countries eligible to export meat product to the United States develop, implement, and maintain written procedures for the removal, segregation, and disposition of materials identified by FSIS as SRMs, to ensure that such materials are not used for human food. Thus, the use of SRMs in the production of edible tallow and offal imported into the United States is prohibited. When shipments reach the U.S. border, they are subject to reinspection by FSIS. Such reinspection can include review of documentation, product examination, and laboratory testing. If the product is not covered under the FMIA, FDA

enforces its import restrictions applicable to those products.

Issue: One commenter recommended that the importation of any organ meat into the United States from a BSE minimal-risk region be prohibited.

Response: We are making no changes based on this comment. Some bovine tissues have demonstrated infectivity, whereas others have not. Tissues that have demonstrated infectivity are designated as SRMs and must be removed and disposed of as inedible. The small intestine of all cattle must also be removed and disposed of as inedible to ensure effective removal of the distal ileum. There is no BSE basis for prohibiting the importation of other tissue, including other tissue that is organ meat.

Sheep Casings

Issue: As discussed above, in this rule we are adding the category of BSE minimal-risk regions to the existing categories in § 94.18(a) of regions where BSE exists or that present an undue risk of BSE. Several commenters stated that, although our proposed rule would allow the importation of live sheep from BSE minimal-risk regions under certain conditions, there was no mention of amending part 96, which, among other things, prohibits the importation of casings (bovine or other ruminant casings) from any region listed in § 94.18(a). Because BSE minimal-risk regions will be listed in § 94.18(a), said the commenters, this will preclude the importation of sheep casings from BSE minimal-risk regions. The commenters stated that APHIS should address this inconsistency by amending § 96.2(b) to allow the importation of casings from BSE minimal-risk regions such as Canada.

Response: The commenters are correct that we did not address the importation of sheep casings from BSE minimal-risk regions in the proposed rule. We agree that sheep casings imported from a BSE minimal-risk region that are derived from sheep that were less than 12 months of age when slaughtered and that were from a flock subject to a ruminant feed ban equivalent to the requirements of FDA pose no more of a BSE risk than live sheep that meet the same conditions imported from such a region. Therefore, we are providing in § 96.2(b) that sheep casings from a BSE minimal-risk region that are derived from animals less than 12 months of age when slaughtered and that were from a flock subject to a feed ban equivalent to FDA's may be imported into the United States from a BSE minimal-risk region, provided the casings are accompanied by an original certificate stating those conditions have been met. The certificate must be written in English. The certificate must be issued by an individual authorized to issue such a certificate under the provisions of current § 96.3, which contains provisions for the issuance of certificates of animal casings from any foreign region. Upon arrival of the sheep casings in the United States, the certificate must be presented to an authorized inspector at the port of arrival. We are also adding a new paragraph (d) to § 96.3 to provide that the required certification for sheep casing imported from BSE minimal-risk regions must be included on the certification required by that section.

Bile

Issue: One commenter expressed concern that our proposed rule did not include provisions for the importation of bile from BSE minimal-risk regions. The commenter stated that bile is synthesized in the liver and recycled from the intestines back to the liver before being stored in the gall bladder. In addition, said the commenter, bile has very low protein content, has never been found to contain any BSE agent, and has been classified by the EU in the same low-risk category as milk and liver. The commenter stated that if APHIS will allow the importation of bovine liver without regard to the age of the animal from which it was derived, then the importation of bile should also be allowed, because the process of collecting bile includes removing the gall bladder from the liver before emptying it.

Response: The opinion of the European Union Scientific Steering Committee (Ref 29) includes bile in category IV—no detectible infectivity in a BSE-infected animal. However, because we did not address the importation of bile from a BSE minimal-risk region in our risk analysis for the proposed rule, we are not including bile in this final rule as a product eligible for importation from a BSE minimal-risk region. However, we intend to address the importation of ruminant bile from such regions in separate rulemaking.

Blood Products

Issue: One commenter recommended that APHIS allow the importation of blood products, including serum and products derived from serum, from a BSE minimal-risk region, provided the product is accompanied by certification by the exporting country that the blood was collected at the time of slaughter in a hygienic manner from either (1) a fetus or an animal that is less than 30 months of age; or (2) an animal older than 30 months of age that was either a live animal or stunned with a non-penetrating stunning device. The commenter noted that APHIS stated in its proposed rule that infectivity has not been detected in bovine tissues apart from the distal ileum until at least 32 months post-exposure. As a result, said the commenter, the probability that blood collected from animals less than 30 months of age at slaughter might be contaminated with BSE is negligible. The commenter stated that, for animals older than 30 months, the potential that blood might be contaminated with BSE infectivity following stunning can be effectively mitigated by ensuring that blood is collected either from animals slaughtered with a non-penetrating stunning device or from live animals.

Response: We did not address the importation of blood and blood products from BSE minimal-risk regions in the risk analysis we conducted for this rulemaking. Currently, conclusive science is lacking regarding the risk of BSE transmission by blood and blood products. Scientific studies researching TSE infectivity and blood have to date been limited to mouse bioassay. In those studies, infectivity in mice was not demonstrated (Ref 30). However, in studies with sheep, TSE infectivity in blood was demonstrated. To date, there are no known cattle studies researching TSE/BSE infectivity and blood.

Fetal Bovine Serum

Issue: A number of commenters recommended that APHIS allow the importation of fetal bovine serum (FBS) from BSE minimal-risk regions. Commenters stated that FBS is collected from fetuses, which, if allowed to develop into calves, would meet the under-30-months-of-age criterion of our proposal. Further, it is collected under a controlled system that ensures that it is not exposed to SRMs. One commenter stated that there have been no documented cases of transmission of BSE from cow to fetus during pregnancy.

Response: We are making no changes based on the comments. There is no conclusive data to indicate whether BSE is transmitted by blood or blood products such as FBS. The commenters did not identify the uses to which FBS would be applied. Were serum to contain infectious levels of the BSE agent, it might pose a risk for livestock if used in certain applications such as bovine vaccine production or bovine embryo transfer, or for other products brought into direct exposure with ruminants. Unless and until there is conclusive data to demonstrate that BSE is not transmitted by blood and would

not be a contaminant of FBS, we consider it necessary to prohibit the importation of FBS from BSE minimal-risk regions. However, we realize that more information is necessary on this subject, and we are working with FDA to assess the risk from FBS and related materials and their various uses.

Issue: One commenter recommended that, because of the need for FBS and the potential serious consequences of BSE in FBS, APHIS should pursue rulemaking to allow the importation of FBS under certain conditions from countries affected with foot-and-mouth-disease.

Response: We have taken the commenter's guideline under consideration, but consider it outside the scope of this rulemaking, and are making no changes based on the comment in this final rule.

Gelatin and Collagen

Issue: In § 94.19(j) of our proposal, we proposed to allow the importation of gelatin from BSE minimal-risk regions, provided the gelatin was derived from the bones of bovines that were less than 30 months of age when slaughtered and that were not known to have been fed ruminant protein other than milk protein during their lifetime. One commenter stated that those restrictions on the importation of gelatin were unnecessary and that the only requirement for the importation of gelatin from a BSE minimal-risk region should be that the bones used in the production of gelatin did not include the skull or vertebral columns from animals older than 30 months of age.

Response: Consistent with the changes we discuss above under the heading ''Age of Animals from which Meat is Derived'' regarding the effectiveness of the removal of SRMs in mitigating BSE risk, we are removing the proposed requirement that the gelatin be derived from the bones of bovines less than 30 months of age when slaughtered and are requiring instead that the gelatin be derived from the bones of bovines from which the SRMs were removed. Also, consistent with the changes we discuss above under the heading ''Certification of Feed Ban Compliance,'' we are revising our provisions regarding gelatin from BSE minimal-risk regions to require that the bovines from which the gelatin was derived were subject to a ruminant feed ban equivalent to that established by FDA.

We are also adding language to the regulations to clarify how the provisions regarding gelatin in § 94.19(f) of this final rule differ from the existing provisions regarding gelatin in § 94.18. The existing provisions in § 94.18 have allowed the importation of gelatin under import permit from regions in which BSE exists or that pose an undue risk of BSE. APHIS issues such a permit only after determining that the gelatin will be imported only for use in human food, human pharmaceutical products, photography, or some other use that will not result in the gelatin coming in contact with ruminants in the United States. We are making no changes to those provisions. The provisions in § 94.19(f) of this final rule regarding gelatin from BSE minimal-risk regions allow for the importation of certain gelatin over and above that eligible for importation under § 94.18(c)—*i.e.*, if the gelatin from a BSE minimal-risk region meets the conditions of § 94.19(f), it will not be limited to uses that will not result in the gelatin coming in contact with ruminants in the United States. To clarify this, we are identifying the gelatin addressed in this final rule in § 94.19(f) as gelatin not allowed importation under § 94.18(c). Additionally, we are making a nonsubstantive wording change to § 94.18(b) to clarify that the only gelatin derived from ruminants from regions listed in § 94.18(a)(1) or (a)(2) as regions in which BSE exists or that pose an undue risk of BSE that is eligible for importation is gelatin that meets the requirements of § 94.18(c).

Issue: One commenter recommended that collagen also be addressed in the regulations and be allowed importation from a BSE minimal-risk region under the same conditions as gelatin.

Response: Collagen derived from hides is not considered a risk (hides are exempt from most restrictions). However, collagen can be derived from bones. In addition, collagen is not subjected to the same extreme conditions of processing as is gelatin. We believe there is a need for more research regarding the risk from bone-derived products that have the potential for direct exposure to ruminants and are making no changes based on the comment.

Issue: One commenter requested that this final rule confirm there will be no restrictions on the importation of gelatin and collagen from hides or skins.

Response: According to the OIE guidelines, hide-derived products should be allowed unrestricted entry because they do not pose a BSE risk. At this time, we allow the importation of hide-derived gelatin and collagen under permit.

Issue: One commenter stated that all gelatin derived from the bones of bovines should be prohibited importation into the United States because there have been instances of people contracting vCJD from gardening with bone meal.

Response: We are making no changes based on this comment. We assume the commenter linked gelatin and bone meal because both products are derived from bones.

In this rule, we are allowing the importation of gelatin from a BSE minimal-risk region only if the gelatin is derived from bovines from which SRMs have been removed in the exporting region, and, further, that the bovines from which the gelatin was derived were subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration.

To date, there is no known link between bone-derived gelatin and vCJD and we are unaware of any evidence that shows that handling bone meal can cause vCJD. Additionally, on January 9, 2004, the Centers for Disease Control issued a *Morbidity and Mortality Weekly Report* (Ref 31) that confirms that since 1996, surveillance efforts have not detected any cases of indigenous vCJD in the United States.

Importation of Animal Feed From Canada

Issue: Several commenters stated that the importation of feed that contains animal byproducts from Canada should be prohibited. Another commenter addressed the requirements in part 95 of the regulations regarding certification for the importation of products used in animal feed into the United States. The commenter stated that, because obtaining original certifications for each load of feed can be time-consuming and expensive for feed mills not located close to government veterinary certification services, the Canadian regulations allow faxed copies of veterinary certificates to accompany loads of feed, with the understanding that the feed mill will keep a copy of the original on file once it arrives at the mill. The commenter requested that APHIS honor this form of certification for feed containing animal protein, or, at a minimum, for feeds containing only vitamins and minerals as the only animal source of ingredients in the feed.

Response: We are making no changes based on these comments. We did not propose any changes to the provisions in 9 CFR part 95 regarding the importation of meat meal and bone meal for animal feed and consider the comments to be outside the scope of the proposal.

Issue: One commenter recommended a prohibition on the importation of feed and feed byproducts from either of the

two Canadian feed mills that have been associated with BSE-infection in that country, unless such feed is submitted to routine FDA inspection.

Response: We do not consider it practical or necessary to place restrictions on individual feed mills that may have handled high-risk material more than 5 years ago. We consider current USDA and FDA import restrictions on processed animal proteins from BSE countries, including minimal-risk countries, adequate to provide the necessary protection to public and animal health.

Plate Waste and Poultry Litter

Issue: One commenter stated that plate waste and poultry litter have the potential of exposing ruminants to BSE infection and should be among the materials prohibited in feed for ruminants.

Response: This final rule requires that the ruminant feed ban in BSE minimal-risk regions be equivalent to that of FDA in the United States. As discussed above in section III. C. under the heading ''Measures Implemented by FDA,'' in an advance notice of proposed rulemaking issued jointly by FDA, FSIS, and APHIS on July 14, 2004, FDA requested information to help it determine the best course of action with regard to the ruminant feed ban.

Cooperative Service Agreements

Issue: 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, § 95.4(c) exempts certain materials from the restrictions under certain conditions. One of the conditions for such an exemption is that the facility where the materials are processed and stored 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. In our proposed rule, we proposed that, for facilities in a BSE minimal-risk region, 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 necessary. One commenter stated that cooperative service agreements should be required for all countries in order to maintain uniformity.

Response: We are making no changes based on the comment. In order for APHIS to consider a region eligible for BSE minimal-risk status, APHIS would have evaluated the region's veterinary infrastructure as well as the risk of BSE in the region. This rule requires that equivalent inspections be performed by the veterinary authorities of such minimal-risk regions, thereby relieving the need for cooperative service agreement cost recovery mechanisms for APHIS to conduct the site inspections. As noted, however, APHIS reserves the right to conduct site inspections as needed.

Issue: Several commenters addressed the fact that the FDA ban on feeding ruminant products to ruminants in this country has included an exemption allowing mammalian blood and blood products to be used in ruminant feed. One commenter, referring to the APHIS proposed requirement that ruminants imported into the United States not have been feed ruminant protein other than milk protein, asked how APHIS will handle cattle that were fed blood meal before FDA announced in January 2004 that it will eliminate the blood and blood product exemption. Another commenter stated that the proposed rule contained inadequate verification that a similar tightening of restrictions will be taken by Canada.

Response: At this time, both the United States and Canada allow the use of bovine blood and blood products in ruminant feed. Therefore, the feeding requirements for ruminants in Canada are currently equivalent to those here in the United States. We are requiring in this final rule that bovines imported from a BSE minimal-risk region have been fed in accordance with the feed requirements that were in effect in the United States at that time. Therefore, herd owners in minimal-risk regions will have to meet any new U.S. feed requirements in order for their animals to be eligible for export to the United States. As discussed above in section III. C. under the heading ''Measures Implemented by FDA,'' FDA has requested additional information to help it determine the best course of action regarding the feed ban.

Importation Based on Origin of Meat

Issue: One commenter recommended that APHIS should allow the importation of (1) meat that originated in the United States and was processed in a BSE minimal-risk region, and (2) meat that originated in a region not listed in § 94.18 (a)(1) or (2) as a BSE-affected or undue-risk region.

Response: Even before this final rule, the regulations in § 94.18 allowed for the situations described by the commenter by allowing the importation into the United States of meat, meat byproducts, and meat food products derived from ruminants that had never been in a region listed in § 94.18(a). That provision would allow the importation of U.S. origin meat that was processed in a BSE minimal-risk region. However, the commodities must meet all other applicable importation conditions in part 94 of the regulations.

E. Risk Basis for the Classification of Canada

Of the 3,379 comments that APHIS received on the proposed rule, approximately 15 questioned the risk basis for the proposed classification of Canada as a minimal-risk region for BSE. These comments focused largely on the nature of our risk analysis; APHIS' use of the Harvard-Tuskegee Study; whether the risk analysis provided sufficient data and adequately considered uncertainties; the prevalence of BSE in Canada; and whether existing regulations should be maintained. The issues raised by these commenters are discussed below by topic.

Nature of the Risk Analysis

Issue: One commenter stated that USDA has not presented an appropriate risk analysis that supports the proposed action to allow the importation of ruminants and ruminant products from Canada. The commenter said that the risk analysis presents opinions, judgments, and conjectures rather than relevant data and the results of transparent and sound quantitative analysis.

Response: We disagree with the comments. We believe that our risk analysis provides a solid basis for action by the Secretary under the Animal Health Protection Act (7 U.S.C. 8301–8317), USDA's statutory authority for animal health regulations, and that it meets Federal guidelines and requirements related to rulemaking, including the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and Executive Order 12866, Regulatory Planning and Review.

Experts in the field of risk analysis generally agree that different methods of risk assessment are appropriate in different circumstances. OIE Guidelines for Import Risk Analysis involving trade in animals and animal products (Ref 19), for example, recognize both qualitative and quantitative risk assessment methods as valid. Likewise, Codex Alimentarius (Ref 32), the international standard-setting organization for food safety, encourages the use of quantitative information in risk analysis to the extent possible, but provides that food safety risk analysis may be either qualitative or quantitative.

APHIS' risk analysis, which relied on both qualitative and quantitative

information, including the Harvard-Tuskegee Study's quantitative analysis of the risk of BSE spreading if introduced into the United States (Ref 3), provided the information necessary to make informed, scientifically sound, well-reasoned decisions for our action with respect to Canada.

Issue: The same commenter maintained that APHIS' risk analysis fails to answer questions about the impacts of the proposed rule on human health, including: What is the probable change to human health risk (*i.e.,* frequency and severity) that would be caused by each alternative risk management option considered (*e.g.,* reopening the border to less restricted imports, importing under different types of restrictions, keeping the status quo), and how certain is the change in health risk caused by each proposed action? Specifically, the commenter stated that the risk analysis does not provide ''any quantitative or substantive qualitative estimation of the frequency and severity of adverse health effects from the different decision alternatives, beyond undefined adjectives such as 'low,' offered without any clear explicit interpretation or any explicit verifiable derivation from data.''

The commenter stated that these questions, and analogous questions for animal health, are usually considered essential components of a health risk assessment. For example, said the commenter, a Joint United Nations Food and Agricultural Organization/World Health Organization Expert Consultation ''defines risk characterization (corresponding approximately to what USDA terms 'risk estimation') as the 'integration of hazard identification, hazard characterization [*i.e.,* dose-response or exposure-response relation] and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties.' '' The commenter also pointed to a similar definition used by the Codex Alimentarius Commission: ''The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment.'' The commenter asserted that ''qualitative reassurances do not constitute an adequate risk analysis.''

The commenter also stated that the Harvard-Tuskegee Study found ''available information inadequate'' to assess the risk of U.S. consumers developing vCJD from cows or meat. The commenter said that when maintaining the status quo will have no adverse impact on public health, and a proposed change could have a negative impact on public health, sound public policy dictates that the change not be made until all information needed to adequately assess the public health risk is available.

Response: The commenter suggested that the risk analysis for the rulemaking answer very specific questions about the precise impacts of the rule on human health. As the Harvard-Tuskegee Study noted, the information necessary to quantitatively assess the risk of humans contracting vCJD as a result of consuming BSE-contaminated food products is not available (Ref 33). Thus, the Harvard-Tuskegee Study quantified potential human exposure, but did not estimate how many people might contract vCJD from such exposure. That does not mean, however, that there is insufficient information about the potential impacts of the rule on human health. The Harvard-Tuskegee Study concluded that only a small amount of potentially infective tissues would likely reach the human food supply and be available for human consumption. As explained above, that amount was based on conditions as they existed in 2001, before safeguards implemented recently by FSIS and FDA, including prohibitions on the use of air injection stunning devices at slaughter and prohibitions on the use of nonambulatory cattle and SRMs in human food. These newly implemented safeguards, as well as additional information that indicates that compliance with feed restrictions in the United States is better than had been estimated, makes it far less likely that even small amounts of infective tissue would reach the human food supply and be available for human consumption. Further, we know that, despite estimates that more than 1 million cattle may have been infected with BSE during the course of the epidemic in the United Kingdom, which could have introduced a significant amount of infectivity into the human food supply, only 150 probable and confirmed cases of vCJD have been identified worldwide. This data suggests a substantial species barrier that may protect humans from widespread illness due to ingesting BSE-contaminated meat. This barrier suggests that it is unlikely that there would be any measurable effects on human health from small amounts of infectivity entering the food chain. We believe that this information allows an appropriate assessment of the effects of this rulemaking on human health.

Regarding the commenter's assertion that our risk analysis lacked essential components and provides only qualitative assurances, we disagree. As explained earlier, APHIS analyzed the risk of BSE being introduced into the United States through the importation of live ruminants and ruminant products and byproducts from Canada under the proposed rule. In doing so, we drew on a number of sources of information, including the Harvard-Tuskegee Study, which, as noted, specifically and quantitatively assessed the consequences of an introduction of BSE.

APHIS' risk analysis began with identifying the hazard as ''the BSE risk that might be posed by importation of designated commodities and animals into the United States from Canada.'' Carefully scrutinizing both qualitative and quantitative information, we characterized the hazards to animal health, public health, the environment, and trade and evaluated the likelihood that U.S. livestock would be exposed to infectious levels of BSE from any of the commodities that would be allowed into the United States under the proposed rule.

Based on the hazard identification, hazard characterization (referred to in our risk analysis using the OIE terminology, ''release assessment''), and exposure assessment, APHIS' risk analysis then estimated the adverse effects likely to occur—that is, we characterized the risk. The hazard identification, release assessment, and exposure assessment clearly indicated that it is unlikely that infectious levels of BSE would be introduced into the United States from Canada with any of the commodities included in the assessment, and that, even if the BSE agent were introduced into the United States, it would be extremely unlikely to enter commercial animal feed and thereby infect U.S. cattle or to result in human exposure to the BSE agent.

This conclusion was based on multiple factors, each of which reduces risk. These factors include the low number of infected animals or products that might conceivably be imported into the United States from Canada even without the mitigations applied by this rule, given the import and feed restrictions in place in Canada; the low reported incidence rate in that country coupled with Canada's active surveillance program—both of which satisfy and exceed the OIE guideline for a minimal BSE risk country or zone; the further reduction in risk associated with imports as a result of the mitigation measures imposed by this rule; the very

low likelihood of tissue from an infected animal entering the U.S. animal feed chain or the human food chain as a result of past and recent safeguards imposed by USDA and FDA on slaughter practices, the prohibitions of nonambulatory cattle and SRMs in human food, and animal feed restrictions, both in Canada and the United States; and the very low likelihood that any such tissue would contain infectious levels of the BSE agent, and be present in sufficient quantities in feed consumed by susceptible animals to cause infection.

Issue: The same commenter stated that the Secretary's own advisory committee cautioned against making BSE-related regulatory decisions until a more thorough scientific risk analysis is completed. The commenter cited the Report of the Secretary's Advisory Committee on Foreign Animal Diseases, Measures Related to Bovine Spongiform Encephalopathy in the United States, February 13, 2004.

Response: The February 13 report to the Secretary cited by the commenter (Ref 34) discusses a report prepared by an international review team (IRT) that, at the Secretary's request, reviewed the U.S. response to the case of BSE in Washington State and recommended measures that could be taken to provide additional public or animal health benefits. The IRT, which was established as a subcommittee of the Secretary's Advisory Committee, delivered its report to the Secretary's Advisory Committee on February 4, 2004. The IRT report was titled ''Measures Relating to BSE in the United States'' (Ref 35). The February 13 report said that the IRT's conclusions about the level of BSE likely to be circulating in the United States and North American cattle populations were different from those of the Harvard-Tuskegee Study. The February 13 report stated, ''The Committee must have this issue of risk resolved prior to completing its recommendations to the Secretary. It is imperative that the Secretary has the best available science and more precise risk assessments in order to make appropriate regulatory decisions.'' The regulatory decisions referred to in the report involve decisions by the Secretary about whether and how to respond to recommendations of the IRT, particularly those related to exclusion of SRMs and non-ambulatory cattle from human and animal food supplies in the United States. The IRT also made recommendations related to surveillance of U.S. cattle for BSE, laboratory diagnosis of samples taken for surveillance purposes, animal identification, and other domestic measures, such as educational programs, that could provide additional public or animal health benefits. None of the IRT's recommendations pertained to import restrictions. Accordingly, the specific statement cited by the commenter is not relevant to this rulemaking. We have responded to and are in the process of evaluating the balance of the committee's recommendations. We, of course, agree that sound regulatory decisions must be based on a scientifically sound risk assessment and the best available science, and we believe we have adhered to that standard in this rule.

APHIS' Use of the Harvard-Tuskegee Study

Issue: The same commenter maintained that the Harvard-Tuskegee Study was prepared for purposes other than to serve as support for a decision to allow the importation of live ruminants and ruminant products from Canada. Moreover, said the commenter, it was prepared before the BSE cases in 2003 and, even though the authors have updated their analysis, none of the simulation runs or analyses were specifically appropriate for the action that USDA propose, and none claimed to model the current situation in Canada. The commenter said that USDA does not explain how the Harvard-Tuskegee Study, which did not use Canadian data, can even be used as an analytic tool to support reclassifying Canada's risk status. At best, said the commenter, the Harvard-Tuskegee Study should be viewed as a first-cut ''screening'' risk analysis, whose conclusions suggest the need for additional refined risk analyses.

Response: We agree that the Harvard-Tuskegee model is not appropriate for modeling the situation in Canada. We did not employ the model to that end. Rather, we used the model to evaluate the likelihood that BSE would spread if introduced into the United States from Canada. As explained previously, the Harvard-Tuskegee Study analyzed the risk that BSE would spread if introduced into the United States. The Harvard-Tuskegee model doesn't specify the external source of the infectivity, only its size and timing. Therefore, it is relevant to evaluating the consequences of introducing BSE into the United States from any country. In fact, because of the similarities between the measures in place in Canada and the United States, when CFIA conducted its assessment of the risk of BSE in Canada, it used the Harvard-Tuskegee model as a base.

APHIS conducted a separate analysis to determine the risk of BSE being introduced into the United States through live ruminants or ruminant products or byproducts imported from Canada, and concluded that it is unlikely that infectious levels of BSE would be introduced into the United States from Canada as under the proposed rule. Drawing on the Harvard-Tuskegee Study, then, APHIS also concluded that, even if the BSE agent were introduced into the United States, it would be extremely unlikely to enter commercial animal feed and thereby infect U.S. cattle, or to result in human exposure to the BSE agent. This is where the Harvard-Tuskegee Study is useful and directly applicable to this rulemaking.

As discussed above, USDA commissioned the HCRA and the Center for Computational Epidemiology at Tuskegee University to conduct what we now refer to as the Harvard-Tuskegee Study in 1998. The objective of the Harvard-Tuskegee Study was to analyze and evaluate the measures implemented by the U.S. Government to prevent the spread of BSE in the United States and to reduce the potential exposure of Americans to the BSE agent. The Harvard-Tuskegee Study reviewed available scientific information related to BSE and other TSEs, assessed pathways by which BSE could potentially spread in the United States, and identified measures that could be taken to protect human and animal health in the United States.

The Harvard-Tuskegee Study evaluated the potential for the establishment and spread of BSE in this country if 10 infected cows were introduced into the United States. The Harvard-Tuskegee Study concluded that, if introduced, BSE is extremely unlikely to become established in the United States (Ref 36). This conclusion was based on the estimation that ''the disease is virtually certain to be eliminated from the country within 20 years after its introduction'' under the model's base case assumptions (*i.e.*, the most likely scenario) assuming 10 infected cattle were introduced into the United States. The study's conclusions also were based on the preventive measures already in place in the United States at the time the study was conducted. The Harvard-Tuskegee Study also concluded that, should BSE enter the United States, only a small amount of potentially infective tissues would likely reach the human food supply and be available for human consumption. For the purpose of quantifying both animal and human exposure to the BSE agent, the Harvard-Tuskegee Study expressed the amount of infectivity in terms of cattle oral

ID_{50}s. A cattle oral ID_{50} is the amount of infectious tissue that would be expected to cause 50 percent of exposed cattle to develop BSE. By tracking cattle oral ID_{50}s in the tissues of cattle through slaughter, processing, rendering, animal feeding, and human consumption, the model can evaluate the human exposures and animal health consequences of introducing BSE in imported animals or meat.

The Harvard-Tuskegee Study concluded that, based on conditions as they existed in 2001, the three practices that could contribute most to either human exposure or the spread of BSE, should it be introduced into the United States, were noncompliance with FDA's feed restrictions, rendering of animals that die on the farm and illegal diversion or cross-contamination of the rendered product in ruminant food, and inclusion of high-risk tissue, such as brain and spinal cord, in human food. As noted earlier in section III. C. in the discussion of Federal actions since December 2003, FSIS and FDA have implemented comprehensive safeguards that both agencies have concluded provide exceptionally effective protection to both human and animal health, and a higher level of protection than contemplated in 2001.

Even without these additional safeguards, however, the Harvard-Tuskegee Study concluded that, based on conditions as they existed in 2001, if 10 infected cows were introduced into the United States, only five new cases of BSE in cattle would be expected. In fact, the Harvard-Tuskegee Study predicted that there was at least a 50 percent chance that there would be no new cases at all. The extreme case (95th percentile of distribution) predicted 16 new cases of BSE in cattle and 180 cattle oral ID_{50}s available for potential human exposure over 20 years. Even the highest of these predictions indicate a small number of cases of BSE and extremely small potential for human exposure. With the additional safeguards implemented in the United States in 2004 (*i.e.*, the FSIS requirement that SRMs be removed from all cattle at slaughter and the condemnation of non-ambulatory disabled cattle presented for slaughter), this already small potential is reduced even further. This outcome is dramatically different from the experience in the United Kingdom, where it is estimated that there were nearly 1 million infected animals and millions of cattle oral ID_{50}s were available for potential human exposure (Ref 36).

In all cases, even the most extreme, the Harvard-Tuskegee Study concluded that the United States is highly resistant to the spread of BSE or a similar disease and that BSE is extremely unlikely to become established in the United States (where establishment is defined as continued occurrence after 20 years). Thus, APHIS' statement that the Harvard-Tuskegee Study found that, even if BSE were to enter the United States, it would be unlikely to spread, is an accurate representation of the Study's findings. Again, it must be emphasized that the Harvard-Tuskegee Study did not factor in the additional safeguards in place in the United States today.

As mentioned earlier in connection with our revised risk analysis, the HCRA recently updated its model using updated estimates for some of the model parameters, based on new data about compliance with feed restrictions. The results are even lower estimates of risk than previously predicted. This recent revision is discussed in more detail in the response to the next comment.

Issue: The same commenter maintained that APHIS' risk analysis represented the Harvard-Tuskegee Study as being more definitive and reassuring than it really is by stating that the Study found, even if BSE were to enter the United States, that it would be unlikely to spread. The commenter said that APHIS gave inadequate consideration to worst case scenarios, which the commenter referred to as ''low-frequency, potentially high health consequence events,'' and to the sensitivity analysis in the Harvard-Tuskegee Study.

The commenter stated that the Harvard-Tuskegee Study reports that its sensitivity analysis indicates that the predicted number of additional cattle infected is particularly sensitive to the assumed proportion of ruminant meat-and-bone meal (MBM) that is mislabeled and the assumed proportion of properly labeled MBM that is incorrectly fed to cattle. The commenter stated that the predicted human exposure is likewise sensitive to these parameters. The commenter stated that assigning worst case values to even two of the three sets of parameters (demographic assumptions and MBM production; feed production; and feed practice) is sufficient to shift the conclusion based on the base case scenario that ''imported BSE cases will probably die out'' to ''imported cases will probably start an epidemic.'' The commenter further stated that, even if a subset of the key drivers were assigned values within its allowed uncertainty range, spread of BSE is highly likely, which suggests the need for a much more thorough risk analysis. The commenter stated that the findings of the Harvard-Tuskegee Study should have driven USDA to commission additional refined data gathering, development of more refined models, and consequent refined risk analysis.

Response: APHIS is confident that it appropriately represented the Harvard-Tuskegee Study as demonstrating that BSE would be unlikely to spread even if it were to be introduced into the United States.

Sensitivity analysis evaluates the degree to which changes in the data used in a model affect the model's results. The Harvard-Tuskegee Study used a sensitivity analysis to mathematically evaluate the extent to which variations in input data affected the modeled results, including the likelihood that BSE would spread if introduced, rather than die out. The Harvard-Tuskegee Study evaluated the effects of changes when one model parameter was assigned a worst case value but other model parameters were held at values assigned in the base case, as well as the effects of assigning worst case values to multiple model parameters at the same time. (The base case values represent the Harvard-Tuskegee Study's, and USDA's, best estimates of what is likely to be representative of conditions in the United States. Extreme case scenarios are those in which some or all model parameters are given worst case values; in the worst of the extreme case scenarios, all model parameters are simultaneously assigned worst case values.)

We evaluated the Harvard-Tuskegee Study's sensitivity analysis and extreme case scenarios and used the results as a key factor in reaching our conclusion that the risk from importing Canadian animals and products is very low.

According to the Harvard-Tuskegee Study, changing the value assigned to most model parameters had only a limited influence on results. That is, even when they were assigned their worst case values, the results were not substantially different from what was predicted when all model parameters were assigned their base case values.

The model parameters that had the most significant effects on the Harvard-Tuskegee model results were: (1) The misfeeding rate (proportion of correctly labeled prohibited feed that is incorrectly administered to cattle); (2) the feed mislabeling rate (proportion of prohibited feed incorrectly labeled as nonprohibited); and (3) the render reduction factor (amount by which the rendering treatment reduces the amount of BSE infectivity).

When Harvard-Tuskegee conducted its original analysis in 2001,

establishing realistic bounds for the values of some of these model parameters was complicated by the limited amount of available information. For example, data on feed ban compliance indicated the fraction of facilities out of compliance with the feed ban regulations, but not the fraction of all prohibited material passing through noncompliant facilities. Second, the data did not differentiate between technical violations (*e.g.*, incorrect paperwork) and substantive violations. Harvard-Tuskegee therefore estimated the frequency of violations indirectly (Ref 36).

Simultaneously assigning estimated worst case values to the model's demographic model parameters (*i.e.*, proportion of animals that die on farm that are rendered, relative susceptibility vs. age for BSE in cattle, and the incubation period for BSE in cattle) and all MBM production, feed production, and feed administration model parameters at the same time resulted in a 75 percent chance that BSE would not become established in the United States. The ''upper tail of the distribution'' (*i.e.*, the 25 percent chance that BSE would spread in the worst of the worst case scenarios) is what concerned the commenter.

To reduce uncertainty about the importance of extreme case scenarios, we requested, as the commenter suggested, additional data gathering and refinement of the analysis. Specifically, we asked Joshua Cohen and George Gray at the HCRA in 2004 to refine its risk analysis to incorporate additional, more recent data on the mislabeling of products containing prohibited ruminant protein and the contamination of nonprohibited feeds with ruminant protein. Cohen and Gray ran the model using updated worst case values for model parameters related to ruminant MBM production and feed production. No new information on the rate of misfeeding was available, so Cohen and Gray continued to use the same value for misfeeding as had been used previously. However, because the misfeeding rate has the greatest influence on the predicted number of infected cattle following the introduction of BSE into the United States, Cohen and Gray ran multiple sets of simulations to determine how its value influenced the predicted results. Values tested included the original worst case value of 15 percent, as well as a range of values below that, from 0 percent to 12.5 percent.

Cohen and Gray used the most recent FDA data to estimate probabilities for mislabeling and contamination in MBM production (rendering) facilities and feed production facilities. Mislabeling occurs when a producer fails to label a product with prohibited material (*e.g.*, ruminant material) as ''Do not feed to cattle or other ruminants.'' Contamination may occur when a prohibited product is incorporated into a nonprohibited product, or when prohibited and nonprohibited products are handled by the same facility without proper segregation or cleaning and disinfection.

Since the publication of the 2001 Harvard-Tuskegee Study, FDA has collected and distributed additional information on compliance with its feed restrictions that quantifies the number of facilities out of compliance and provides information on the nature of violations discovered. With respect to the number of noncompliant facilities, FDA's databases do not report the size of the facilities (*i.e.*, amount of material produced), so Cohen and Gray conservatively estimated that noncompliant facilities were the same size on average as compliant facilities. With respect to data on the nature of violations discovered, Cohen and Gray relied on data collected by FDA before September 2003, because it provides better detail on the nature of violations than data collected afterward. Data collected before September 2003 is reported as the total number of firms with at least one violation and designates each violation as a case in which (1) products were not labeled as required; (2) the facility did not have adequate systems to prevent commingling, or (3) the facility did not adequately follow recordkeeping regulations. More recent data do not provide this level of detail.

Cohen and Gray reported their results in a June 18, 2004, memorandum to the Agency (Ref 37). The following table (Table 2 in the analysis) shows the original and revised assumptions for rates of contamination and mislabeling at MBM production (rendering) facilities and feed production facilities.

ASSUMPTIONS FOR MISLABELING AND CONTAMINATION

Parameter	MBM production			Feed production		
	Base case 2003 [a] (percent)	Worst case 2003 [a] (percent)	Revised worst case [b] (percent)	Base case 2003 [a] (percent)	Worst case 2003 [a] (percent)	Revised worst case [b] (percent)
Probability of contamination	14	25	1.8	16	16	1.9
Proportion of prohibited material transferred to nonprohibited material per contamination event	0.1	1	1	0.1	1	1
Mislabeling probability	5	10	2.3	5	33	4

[a] Values from Cohen *et al.* (2003)
[b] Values developed for the 2004 assessment.

This table shows that, not only are the revised worst case estimates for certain of the model parameters much lower than the original worst case estimates, they are also lower than the base case estimates.

The predicted results based on the revised estimates show, with 95 percent confidence, that BSE will not spread if the misfeeding rate is 7.5 percent or less. Even when higher misfeeding rates are assumed, however, the results indicate that BSE spread would be very slow.

Using the terminology of the model, the value of R_0 determines whether the number of BSE infected cattle will increase or decrease over time and how rapidly. R_0 is calculated based on information put into the model, including information on the number of infected animals slaughtered, the amount of infectivity remaining after rendering, and the quantity of ruminant MBM that is consumed by cattle. Values of R_0 greater than 1 indicate an outcome where the number of infected animals will increase; values less than 1 indicate an outcome where the disease will decrease and eventually disappear. The degree to which R_0 is greater than or less than 1 is a measure of the rapidity with

which the disease will increase or decrease.

Using even the highest estimated misfeeding rate of 15 percent, Cohen and Gray found that the value of R_0 is 1.23, only slightly higher than 1, which indicates a very slow rate of spread in the worst case. HCRA noted in its 2004 analysis that data to characterize the misfeed rate would be very useful and might make it possible to judge whether a misfeed rate of more than 7.5 percent is even plausible. Regardless, the risk of BSE spreading at even a very slow rate when the highest estimated misfeeding rate is used assumes that no further mitigation measures are taken that could prevent the disease from spreading in the cattle population. As mentioned previously, FDA continues to conduct inspections to monitor compliance of feed mills, renderers, and protein blenders with the 1997 feed ban rule and has expanded the scope of its inspections to monitor compliance with the 1997 feed ban rule.

Issue: The same commenter stated further that the Harvard-Tuskegee Study noted that a ''true validation of the simulation model * * * is not possible'' due to lack of direct, real world experience with importing BSE-infected cattle.

Response: Although the Harvard-Tuskegee model is not amenable to formal validation through controlled experiments that monitor and measure the consequences of introducing BSE into a country, Harvard-Tuskegee did test its model using a real world situation. As a test of the model's plausibility, Harvard-Tuskegee modeled the small BSE outbreak identified in Switzerland following the introduction of BSE infectivity from the United Kingdom. Working with experts in Switzerland, the authors identified appropriate values for model parameters necessary to appropriately characterize that country's practices and procedures and then simulated the introduction of BSE infectivity. The simulation took into account risk management actions, such as feed bans instituted by the Swiss. HCRA found that the model's predictions were ''reasonably close to empirical observations (Ref 38),'' providing confidence in the model's structure and approach.

Issue: The same commenter stated that the need for more refined quantitative risk analysis is further increased by the fact that the Harvard-Tuskegee Study did not thoroughly model spatial (or other) heterogeneity of BSE risks. In other words, the Study did not, in the commenter's words, consider the extent to which some herds are particularly susceptible, or if other rare conjunctions of unfavorable conditions occur in a small fraction (e.g., less than 1 percent of cases) of a large number of replicates (e.g., farms, processing runs, etc.) each year in the United States, then, by chance, combinations of worst case conditions may occur several times per year at random locations, leading to sporadic adverse animal and human health events. The commenter further stated that the Harvard-Tuskegee Study authors noted something similar, stating, ''Many of the simulation results are 'right skewed, meaning that the average value often exceeds the median (50th percentile) and can sometimes exceed even the 95th percentile.' '' The commenter stated that while the average case is reassuring, the extreme cases are not, and said that extreme cases need to be better quantified. Such analysis of low frequency, potentially high health consequence events from removing current restrictions on Canadian beef imports appears to have been omitted entirely from any of USDA's risk analyses, and is not fully addressed by the Harvard-Tuskegee Study, which indicates the possibility of such events but does not address them specifically for the Canadian situation, which was not the focus of that study.

In summary, the commenter stated, it is not concern about the average case or base case alone that should inform the risk analysis component of decision making in this case, but concern about the less likely but high consequence events and the upper tail of the risk distribution that should be the focus of substantive analysis. Unless some credible information is provided about how frequently adverse events are expected to occur with and without the proposed changes, it is impossible to make an informed judgment about whether the economic benefits outweigh the human and animal health risks.

Response: We disagree that the Harvard-Tuskegee Study did not model the heterogeneity of BSE risks sufficiently to allow it to provide meaningful information for decisions about this rulemaking. We believe that our risk analysis does provide sufficient information about the potential for adverse events.

Specifically, the Harvard-Tuskegee Study considered differential susceptibility of cattle with respect to age, as well as differential infectivity by duration of infection and differential exposure by usage type and age. In their June 18, 2004, memorandum Cohen and Gray conclude ''There is no evidence that susceptibility differs substantially among animals of the same age * * * [E]ven if susceptibility does vary * * *, there is no reason to believe the Harvard-Tuskegee model would substantially * * * underestimate the degree to which the disease would spread * * *'' (Ref 37).

The Harvard-Tuskegee Study did not consider heterogeneity in virulence of BSE strains, clustering of rare events within geographic areas or affected populations, or varying susceptibility between breeds of cattle. The commenter did not provide any evidence or data to show that such heterogeneities exist, and we are unaware of any such data or evidence that would allow the modeling suggested by the commenter. To our knowledge, there is nothing in the scientific literature that concludes that one herd or breed is more susceptible to BSE than another. Cohen and Gray concur (Ref 37). We also note that, while samples from a few cattle in Japan and Italy have recently demonstrated some unusual patterns on Western blot tests, which suggests a possibility that different strains of BSE may exist, the evidence is far from conclusive and could be explained by other factors (Ref 39). Thus, there is no information at this point about the existence of different strains, much less about differences in virulence among strains, that could be modeled. In the absence of such data or evidence, any consideration of the potential impacts of these heterogeneities would be purely hypothetical and speculative, and would not provide an appropriate basis for making regulatory decisions. However, we continue to monitor the latest scientific research, and will certainly consider any significant information that becomes available.

APHIS' risk analysis evaluated known BSE risks and provided a rational, scientific basis for our classification of Canada as a BSE minimal-risk region and for determination that the application of specified mitigation measures would allow for the safe importation of certain animals and products from Canada. Further, our assessment of actions taken by the Canadian Government lead us to place Canada on the list of BSE minimal-risk regions.

Data and Uncertainties

Issue: The same commenter asserted that USDA's recent re-analysis (the Explanatory Note) was not adequately sensitive to data and did not attempt to address uncertainties and that its conclusions are, therefore, unsupportable.

Specifically, the commenter said that APHIS' conclusion and supporting reasoning that the second case does not alter the risk estimate ''violates

principles of sound statistical inference and risk assessment, which teach that observing a second adverse event in a monitored population in a comparatively short period of time after the first observation is informative and should significantly inform (i.e., update) data-driven risk estimates, especially when there is a high prior uncertainty about model parameters.''

Codex Alimentarius and other sources, said the commenter, specify that a risk analysis should include uncertainty analysis. The commenter said that major technical questions and uncertainties that should be addressed and modeled include: the roles of horizontal and vertical transmission (if any); susceptibility distribution within cattle of the same age; variability of virulence of different new BSE cases; proportion of infected animals in Canada (''low'' we are told, but how long, on what basis, and with what confidence); detection probability per case (and hence the number of true cases per observed case); the age distribution at first infection; the latency period (and its distribution) until expression; the potential for clustering of rate events within geographic areas, processing plants, affected populations, etc.; the status and extent of current and future compliance and attendant consequences of noncompliance (such as mislabeling, etc.) in Canada and the United States; and differences in the likelihood of spread of BSE in different geographic areas or for different strains of BSE, different types of cattle, etc. The commenter maintained that these and other sources of uncertainty make initial perceptions about risk sufficiently uncertain that the number of cases of BSE actually detected should shape updated beliefs. When the observed rate increases from one to two detected cases in the past year, said the commenter, estimated risks should increase correspondingly. (In Bayesian terms, noted the commenter, the prior should be sufficiently diffuse or noninformative, given the above uncertainties, so that the posterior is heavily driven by the data, rather than by the prior * * *).

Response: We disagree with the suggestion that a second infected cow of Canadian origin should have altered the conclusions of our risk analysis—namely, that the BSE risk associated with importing ruminants and ruminant products and byproducts from Canada as proposed would be very low. Our Explanatory Note explained that a comprehensive investigation conducted by APHIS in coordination with Canadian authorities indicated that the second BSE-positive animal, found in Washington State, most likely became infected in Canada before Canada's feed ban was put in place in 1997. The apparent or reported rate of disease is meaningful when considered in conjunction with the level and quality of disease surveillance and from the position on the epidemic curve. Canada is well below the reported incidence rate that the OIE recommends for minimal-risk status (i.e., 2 detected cases per million animals during the last 4 consecutive 12-month periods) and, with over 15,800 animals tested as of December 1, 2004, Canada far exceeds the OIE surveillance guidelines for BSE. Further, Canada implemented import restrictions and a feed ban prior to detection of BSE in any indigenous animals. The downward pressure exerted by a feed ban—which the early experience in the United Kingdom demonstrated to be substantial even if only partially implemented—and the time of controls before detection of the disease indicate that it is more likely that the incidence of BSE is decreasing in Canada rather than increasing. Although the reported or apparent incidence of BSE in Canada has increased since May 2003, we are also aware that infected animals born before the feed ban in 1997 have entered the age when they are more likely to be detected, given the incubation period, and that surveillance for BSE in North America has increased. APHIS' designation of Canada or any country as a BSE minimal-risk region is based on the sum total of a country's prevention and control mechanisms for the disease. These include import restrictions, surveillance, feed restrictions, epidemiological investigations, and other measures. It is our view that these factors, evaluated together, provide a better indication of a country's BSE risk than any single numeric threshold criterion for BSE incidence. Therefore, while the discovery of a second infected cow alters Canada's reported incidence rate, the change does not affect the conclusions of our risk analysis. Similarly, it would not have affected Canada's categorization or classification as a BSE minimal-risk region according to OIE guidelines. We note in particular that this rule will not allow the importation of cattle born before Canada implemented its feed ban.

In its decisionmaking, APHIS considered both qualitative and quantitative information. With regard to uncertainty analysis, although APHIS' risk analysis for the proposed rule did not include a separate section entitled ''Uncertainty Analysis,'' the analysis did, in fact, address uncertainty throughout.

For example, in its analysis of BSE risk from imports from Canada, APHIS' risk analysis documented and described the current state of knowledge of BSE epidemiology based on the outbreaks in the United Kingdom and other parts of Europe. While the analysis indicates that BSE transmission occurs primarily through contaminated feed, it also states that uncertainty exists as to whether this is the only mechanism by which the disease may be spread. Having considered this lack of certainty, APHIS errs on the side of caution by requiring further risk mitigation measures, as discussed in the risk analysis, such as age limitations on live animals imported into the United States. The risk analysis states, ''* * * [A]lthough risk factors can be identified with some certainty, individual risk mitigation measures may be difficult to apply precisely. For example * * * it has not been established with certainty that contaminated feed is the only pathway. Furthermore, it cannot be assumed that there is complete compliance with a feed ban, which is the most effective mitigation for contaminated feed. Therefore, [APHIS] considered it necessary to mitigate risk arising from alternate pathways or lack of compliance with a feed ban.''

The Harvard-Tuskegee Study (Ref 3), referred to in the context of APHIS' risk analysis, uses probability distributions. That Study includes probability distributions for many of the model's parameters, including the age at which animals first become infected, the incubation period of BSE, and the level of compliance with a feed ban. Use of these probabilistic input parameters allows the results of the Harvard-Tuskegee Study to be expressed probabilistically, thereby being explicit about the implications of several key sources of uncertainty inherent in the model.

We did not attempt to estimate the number of BSE-infected animals that might be imported into the United States under this rule. We have confidence in Canada's BSE control measures and the rule's required mitigation measures and note, further, that BSE incidence and surveillance in Canada are well within the OIE guidelines for BSE minimal risk. We note further that the Harvard-Tuskegee Study concluded that, even if a small quantity of infectivity were introduced into the United States, it is not likely to cause the establishment of BSE.

With respect to the commenter's assertion that there is so much uncertainty about the situation in

Canada that detection of the second infected cow should be given significant weight in shaping our beliefs, we disagree that we failed to adequately consider the data or to give appropriate weight to the detection of BSE in a second cow of Canadian origin.

Although the commenter suggests that APHIS should have used a Bayesian technique in estimating the prevalence of BSE in Canada, such a technique would have started with the same information base-it would have been informed by the available historical surveillance data, including that acquired since implementation of the Canadian feed ban and import restrictions, which would be relevant to the current prevalence estimate. The projected trajectory of the disease is down, because of the downward pressures the measures have been shown to exert on the incidence of disease in such a region. We know that Canada had two indigenous cases of BSE in an adult cattle population of 5.5 million (a reported incidence rate that is well within the OIE guidelines for a minimal-risk country). Even before the discovery of two Canadian-origin animals with BSE, we had information from both active and passive surveillance about the prevalence of BSE in Canada and we would have used that information to construct a prior distribution. Finally, we note Canada has tested thousands of animals for BSE, and Canadian surveillance since the most recent detected case has increased significantly. As of December 1, 2004, Canada had tested over 15,800 animals in 2004 with no additional BSE cases found.

Issue: The same commenter stated that USDA should conduct a risk analysis that, in addition to addressing the uncertainties already listed in the comment concerning the second case, addresses the following:

Exposure

- What is the probable prevalence of BSE in Canada now and in the future under the proposed conditions. The modeling should explicitly document the data and assumptions used to answer it, specifically including compliance rates with any existing or future management strategies such as feed bans.
- What is (and has been) the likely age distribution of BSE infections among Canadian ruminants over time? A variety of models from the United Kingdom and Japan address the issue of ''hidden'' (unobserved) prevalence and the age distribution of unobserved cases.

Exposure-Response

- What is the probability distribution for R_0 (R_0 being the likelihood that the disease will amplify or diminish over time)?
- What is the frequency distribution of R_0 in different herds/locations/populations in the United States where Canadian ruminants might be imported?

Risk Characterization

- How much would the probability of a U.S. epidemic in the next 10 years increase if Canadian ruminants are imported under the proposed conditions? (This is driven by the probability that $R_0 > 1$ and the expected time until the first BSE import starts an epidemic.)
- If $R_0 < 1$, then how would the equilibrium level of sporadic outbreaks or cases in the United States increase if Canadian ruminants are imported? What is the total harm per outbreak? Putting these two together, what is the increment (mean and variance) in flow of harm per unit time from allowing the imports?

Response: A thorough discussion of why it is not necessary to determine a precise numeric measurement of prevalence of BSE in the Canadian cattle population follows, under the heading ''Prevalence of BSE in Canada.''

The commenter's other points seek to determine the likelihood of different scenarios occurring, given changes in variables. As explained previously, APHIS largely based its conclusions about the likelihood of BSE spreading if introduced into the United States on the Harvard-Tuskegee Study. The Harvard-Tuskegee Study evaluated the effects of changes when one model parameter was assigned a worst case value but other model parameters were assigned base case values, as well as the effects of assigning worst case values to multiple model parameters at the same time. We are confident that the extreme scenarios presented by Harvard-Tuskegee are extremely unlikely to occur and that the base case represents the most likely scenario given the available information. Cohen and Gray's memorandum (Ref 37), discussed in response to a previous comment, substantiates this. Second, we are confident that, even if the most extreme case occurred, few cases of BSE would result and even fewer cases of vCJD. Again, this is substantiated by Cohen and Gray's memorandum, which indicates that even in the most extreme case, the disease will still spread very slowly, leaving time to intervene. Neither the Harvard-Tuskegee Study nor the Cohen and Gray memorandum considered recently strengthened safeguards on slaughter practices, including a ban on the use of air injection stunning devices, requirements for removal of SRMs, and a ban on the use of nonambulatory cattle in human food, that would provide further increases in protection for human and animal health.

Issue: The same commenter stated that APHIS' assertion that it is unlikely that BSE would be introduced from Canada under the proposed rule is not the result of any rational analysis based on independently verifiable, explicit calculations from data. In fact, said the commenter, applying the methods of the Harvard-Tuskegee Study, some BSE imports would be expected under the proposed rule if the age distribution of BSE in beef and the probability of erroneous labeling or routing put at least some positive probability, even if only 0.0001 percent per animal, on such an import.

Response: We disagree with the comment and with the assumption inherent in it. Our decision and the critical evaluation and analyses on which it is based are scientifically sound and entirely consistent with our statutory authority. APHIS, and indeed all regulatory agencies, are called upon each day to make informed and reasonable decisions without numerical calculations. APHIS has made such decisions for years. Although rigorous experimental research, which forms the scientific basis for determining which tissues harbor the BSE agent in infected cattle, can be fed into computer modeling, it is not necessary in all cases to base decisions on numerical calculations. There is a wide body of independently verifiable scientific evidence regarding BSE, including how to control and eliminate the disease. Based on qualitative and quantitative evidence, we have concluded that the risk associated with imports under this rulemaking is very low. Regarding the commenter's second point, we did not assert that there is zero probability that BSE would be introduced from Canada under the conditions we proposed. Rather, we concluded that such imports are unlikely. Furthermore, the Harvard-Tuskegee Study demonstrated that, even if a small amount of infectivity were introduced into the United States, it would be unlikely to spread and result in the establishment of BSE. In accordance with the Animal Health Protection Act, the Secretary has concluded quite reasonably that restrictions on the importation of ruminant meat and meat products from Canada, but not prohibition of those

commodities, is necessary to prevent the introduction of BSE from Canada.

APHIS carries out an array of animal and plant health regulatory programs, governing both domestic and imported commodities. In none of these programs, many of which have been in place for years, is it possible to assure that there is zero risk. Indeed, were we to make trade dependent on zero risk, foreign, as well as interstate, trade in animals and animal products would cease to exist.

Issue: The same commenter quoted APHIS as stating that, ''[a]lthough the BSE-infected cow in Washington State was more than 30 months of age when diagnosed, it was obviously not imported under the conditions of the yet-to-be-implemented proposed rule and would not have been allowed to be imported under the proposed rule.'' The commenter said that USDA has not shown it is impossible for BSE to occur in some cattle less than 30 months of age or that some cattle older than 30 months of age might be inadvertently imported.

Response: As discussed above, the epidemiological investigation conducted by APHIS and others following the detection of BSE in a cow in Washington State in December 2003 indicated that the cow was born in Canada early in 1997 before Canada initiated a feed ban. This animal and all others born before Canada's feed ban would now be at least 7 years old. Because the rule requires that all cattle imported into the United States from Canada be less than 30 months old, no animals born before Canada's feed ban will be allowed to enter the United States under this rule. Furthermore, the rule also requires that cattle imported from Canada be slaughtered before they are 30 months of age. In actual practice, because cattle imported into the United States from Canada will be coming in for slaughter or for feeding and slaughter, the large majority will be less than 24 months of age (most male cattle are slaughtered before 24 months of age). FSIS has established procedures for checking an animal's age at slaughter through records and/or dentition. These procedures apply to both domestic and imported cattle and we are confident they are effective in determining age. The appropriate SRMs based on age will be removed from any cattle that are determined to be 30 months of age or older based on those procedures, and APHIS will take enforcement action as necessary.

With regard to the possibility that BSE could occur in cattle younger than 30 months of age, research demonstrates that the shorter incubation period (*i.e.*, infection developing in less than 30 months) is apparently linked to younger animals receiving a relatively large infectious dose (Ref 40). The younger cases have occurred primarily in countries with significant levels of circulating infectivity. Specifically, BSE was found in animals less than 30 months of age in the United Kingdom in the late 1980's to early 1990's, when the incidence of BSE was extremely high. This research also suggests that a calf must receive an oral dose of 100 grams of infected brain material containing high levels of the infectious agent to produce disease within a minimum of approximately 30 months (Ref 40). All available evidence leads to the conclusion that the level of infectivity in the Canadian cattle population is low and that compliance with the feed ban is high. Further, infectivity in animals younger than 30 months has in most cases been confined to tonsils and distal ileum, both of which would be removed at slaughter in the United States.

Prevalence of BSE in Canada

Issue: The same commenter specifically argued that APHIS should present quantitative evidence of the true prevalence of BSE in Canada and that the risk analysis for the rule should take this into account. The commenter said that the risk analysis only discusses the prevalence of BSE in Canada in vague, subjective terms such as ''very low'' and ''unlikely'' to generate cases in the United States, but that recent history now suggests that figure is 100 percent. The commenter asserted that more quantitative information is needed on the likely prevalence of BSE infections in Canadian ruminants and ruminant products that would be imported under the proposed rule (true prevalence, not just detected or qualitatively perceived). How likely is it, asked the commenter, that BSE prevalence in Canada could be 0.01 percent or 0.1 percent, or 1 percent, given current and prior testing? The commenter stated the belief that available data could help provide useful upper bounds.

Response: We disagree with the comment. Precise measurement of true prevalence of BSE is difficult to achieve, given the constraints of current testing methods available. It should be noted that no country in the world is attempting to officially define the true prevalence of BSE in its entire cattle population. Reports of incidence rates are indications of detectable levels of disease. Current testing methodology can only detect BSE, at the earliest, a few months before an animal exhibits clinical signs and, therefore, limits the ability to measure true prevalence in the entire cattle population. Data obtained through targeted surveillance can be extrapolated to make inferences about prevalence in broader populations as necessary. However, a specific calculation of true prevalence of BSE is not necessary to determine whether risk management policies or control policies are appropriate or need to be changed, and the importance of determining an exact prevalence rate should not be overstated.

We also disagree with the commenter's assertion that APHIS needs to establish a more precise estimate of the true prevalence of BSE in Canada for this rulemaking. Our risk analysis presented compelling evidence that the prevalence of BSE in Canada is low. The absence of a precise numeric measurement of prevalence of BSE in the Canadian cattle population is not an absence of information to inform estimates. As we have stated, we will use a combined and integrated approach that examines the overall effectiveness of control mechanisms in place when evaluating a country for BSE minimal risk. We believe that such an evaluation will provide a better indication of a country's BSE risk than simply a numeric threshold for BSE incidence or prevalence.

The threshold for incidence set by OIE for BSE minimal-risk regions is less than 2 cases per million cattle over 24 months of age during each of the last four consecutive 12-month periods. There have been two cases of BSE in Canadian-origin cattle since May 2003 out of an adult (over 24 months of age) cattle population of 5.5 million (0.4 per million) and no cases before May 2003. While we recognize that the number of detected cases does not, by itself, allow for a determination of prevalence, the number may be taken as a strong indication in countries with active surveillance that the mitigation measures in place to prevent the introduction and spread of BSE are working, thus prevalence is likely to be low. As we have discussed elsewhere, this is the case in Canada, which has had strict import controls in place since 1978 and instituted its feed ban, equivalent to that of the United States, on the same date as the United States in August 1997. Canada has also conducted surveillance for BSE since 1992 and has met or exceeded OIE guidelines for surveillance since 1995. It should be noted that OIE guidelines refer to the reported incidence of BSE infection or levels of detectable disease.

The commenter is incorrect in asserting that recent history suggests that Canadian imports are 100 percent likely to generate cases of BSE in the United States. While our risk analysis

evaluated whether an infected ruminant or ruminant product from Canada might be imported, and concluded that the risk was considered ''low,'' that risk was considered in the context of the proposed mitigation measures. In addition, the risk analysis considered the likelihood that such an animal or product would spread the disease to other animals within the United States; in other words, whether the imported source of infectivity would generate new cases within the United States.

Issue: The same commenter asserted that the HCRA's ''Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada'' (Ref 10) (referred to below as the Canada Study) contradicts the statement in APHIS' risk analysis that the prevalence of BSE in Canada is ''low.'' According to the commenter, the Canada Study states that the prevalence of BSE in Canada cannot be determined because of the absence of strong evidence about the prevalence of BSE in the Canadian herd. The commenter also took issue with a statement we made that, although a second case of BSE was detected in an animal of Canadian origin, the total number of diagnosed cases attributed to that country remains low. According to the commenter, this statement is irrelevant and misleading. The commenter said that what matters for risk assessment purposes is the occurrence rate per unit time, not the total (cumulative) number ever diagnosed, and that two diagnosed cases in less than 1 year is not self-evidently a ''low'' rate.

Response: APHIS' assessment of the prevalence of BSE in Canada was related to the small number of cases detected through an active surveillance program, and was not contingent upon there being only one case. The statement from the Canada Study that the prevalence of BSE in Canada cannot be determined is taken out of context and used by the commenter to imply that no judgment about the prevalence of BSE in Canada may be made. The Canada Study actually stated that, in the absence of strong evidence about the prevalence of BSE in the Canadian herd, the authors chose to posit a hypothetical introduction of five BSE-positive bulls into the United States instead of calculating a probability of such an introduction. The model used by the HCRA was not set up to gauge the probability of the introduction of BSE into the United States, but rather to calculate the outcome if the BSE agent were introduced. Moreover, the unavailability of precise data for a quantitative estimate of the prevalence of BSE in Canada does not preclude an evaluation and judgment about the prevalence of BSE in Canada. APHIS proposed to classify Canada as a minimal-risk region after considering substantial evidence about the BSE situation in that country, including information on the incidence of cases of BSE and level of surveillance, as well as other relevant factors such as the quality of Canada's BSE surveillance program and its veterinary infrastructure.

Issue: The same commenter stated that, until the source of contaminated feed for the two cows is determined, it is not possible to determine whether infectivity occurred before or after the feed ban was implemented in Canada because of the animals' ages and the 2–8 year incubation period for BSE. The commenter asserted that, if the infectivity occurred after the feed ban was implemented, this suggests a continuing risk of BSE in younger Canadian cattle. The commenter therefore maintained that APHIS must determine the source of the contaminated feed or test more representative samples of Canadian cattle to conclude that the prevalence of BSE in Canada is low. Specifically, said the commenter, Canada plans to test 8,000 head in the next 12 months under limited surveillance; it should be required to test all cattle over 24 months of age for 2 years. The United States should not relax restrictions for countries of unknown prevalence.

Response: As discussed previously, we disagree that Canada is a country of unknown prevalence for BSE or that a precise measurement of prevalence must be made before cattle from Canada are allowed to be imported into the United States. As determined by the epidemiological investigations conducted after their detections, both the May and December 2003 cases of BSE involved cows born before Canada implemented its feed restrictions. Both cows were most likely to have become infected by consuming contaminated feed at very early ages, most likely before the feed ban was implemented.

Animals born before Canada's feed ban would now be at least 7 years old. At this stage of the incubation period, most remaining cattle infected before the feed ban was implemented would be symptomatic. In light of the active surveillance program in Canada, as well as restrictions on the slaughter of animals with symptoms compatible with BSE, any such infected cattle are likely to be detected and to be eliminated from the food chain. Because this rule requires that all cattle imported into the United States from Canada be less than 30 months old at the time of importation and slaughter, no animals born before Canada's feed ban will be allowed to enter the United States under this rule. The age of cattle can also be verified at the time of slaughter through records and/or dentition. As noted above, the appropriate SRMs based on age will be removed from any cattle that are determined to be or suspected of being 30 months of age or older and enforcement action will be taken as necessary by APHIS. Further, as noted in response to a previous comment concerning the possibility that BSE could occur in cattle younger than 30 months of age, infectivity in such young animals has been associated with a high incidence of infectivity in the cattle population where the animal originates. This is not the case with Canada. Further, infectivity in animals younger than 30 months has in most cases been confined to tonsils and distal ileum, both of which would be removed at slaughter in the United States and Canada.

Issue: One commenter stated that the APHIS risk analysis builds upon the Harvard-Tuskegee Study's conclusion that the introduction of BSE into the United States would be an unlikely event. However, the fact that the remains of the December 2003 cow are known to have entered the food chain renders APHIS' risk analysis relative to human health issues nonapplicable and outdated.

Response: We disagree. The Harvard-Tuskegee Study did not address the likelihood of the introduction of BSE infectivity into the United States. However, the Harvard-Tuskegee study did conclude that, even if a small amount of BSE infectivity were introduced into the United States, the disease is unlikely to spread and become established. We are confident that the incidence of BSE in U.S. cattle, if any, is and will remain extremely low.

The epidemiological investigation that was conducted following detection of an imported cow in Washington State (Ref 4) determined that the animals was born before implementation of a ban in Canada on feeding mammalian protein to ruminants and was most likely to have become infected before that feed ban was implemented. Additionally, the investigation determined that the animal was imported into the United States in 2001 at approximately 4 years of age, was more than 30 months of age when diagnosed, and clearly would not have qualified for importation under the provisions of this final rule.

To date, BSE has never been confirmed in indigenous U.S. cattle. We cannot state with certainty that BSE will

never occur in indigenous animals or that material from BSE-infected animals will never enter the human or bovine food supply. We note, however, that an interim rule published by FSIS on January 12, 2004, excludes all non-ambulatory disabled cattle and all SRMs, regardless of the health status of the animal from which they are taken, from the human food supply. In addition, FDA has banned any material from non-ambulatory cattle and SRMs from all cattle from FDA-regulated human food, including dietary supplements, and cosmetics. These rules and other Federal measures described previously ensure stringent protection of the U.S. food supply.

Issue: One commenter said that the term ''isolated cases'' used in the March 4 request for comment is very subjective and asked how we could use the word ''isolated'' when we do not know the prevalence of the disease in the Canadian national herd. The commenter stated that we should clarify what we meant so that appropriate comment could be provided on whether to allow high-risk, over 30-month-old, animals into the United States. The commenter stated further that USDA should not relieve restrictions on imports from Canada until Canada tests a significant percentage of its cull animals, with a major emphasis on the highest risk animals, over the next 2–5 years, without any significant positive findings.

Response: The terms ''isolated cases'' and ''isolated'' were not used in the March 2004 notice or the Explanatory Note., nor did APHIS propose to allow the importation of any live cattle over 30 months of age from Canada.

Finally, as discussed in response to several comments, we do not believe it is necessary to wait to relieve restrictions on imports from Canada until such testing as the commenter suggests has been conducted. Although active surveillance must be conducted to ensure that prevention and control measures implemented by a country are providing adequate protection, there is sufficient evidence already, based on nearly a decade of active surveillance in Canada at levels that have met or exceeded OIE guidelines, for us to conclude that Canada's prevention and control measures have been effective.

Issue: One commenter said that the discovery of a Canadian cow with BSE in Washington State, coupled with the previous finding of a BSE cow in Alberta, indicates that the Canadian feed supply was contaminated as late as 1997. The commenter stated that the infected cattle were from two different herds and utilized different feed sources and concluded that other infected cattle undoubtedly exist. The commenter also concluded that since both the United States and Canada have been doing surveillance for several years without a diagnosed case, these cases must be considered as the first cases to appear on the epidemiological curve. The commenter stated further that the epidemiological curve for BSE is an extended one and must be considered at this time likely to continue for several more years, perhaps 5 to 10, and that no Canadian cattle should be allowed to enter the United States until sufficient time has elapsed for any remaining infected cattle to be identified and removed from the Canadian cattle population.

Response: We disagree with the comment. While it is possible that additional BSE-infected cattle may exist in Canada, we have confidence that if such cattle do exist the number is small. First, Canada has not imported ruminant MBM from any country with BSE since 1978 (Ref 12). Second, Canada has prohibited the feeding of ruminant MBM to ruminants since August 1997, and CFIA has verified high levels of compliance with the feed ban by routine inspections of both renderers and feed mills (Ref 12). Third, Canada has traced and destroyed all remaining cattle imported from the United Kingdom (Ref 12). Fourth, Canada has traced and destroyed the majority of the cattle that comprised the birth cohorts of the two Canadian BSE cases (Ref 11 and 13). Fifth, Canada has conducted surveillance for BSE since 1992 and has conducted targeted surveillance at levels that have met or exceeded OIE guidelines since 1995 (Ref 12 and 13).

Even if BSE-infected cattle do remain in Canada, they are likely to be older animals that were exposed before Canada's feed ban in 1997. Because this rule requires that imported animals be less than 30 months old, such animals could not legally enter the United States under this rule. Even if an infected cow did enter the United States, the Harvard-Tuskegee Study indicates it would be unlikely to lead to the spread of BSE in cattle or to human exposure to the BSE agent.

Regarding the suggestion that the two BSE-infected Canadian cows must be considered as the first cases to appear on the epidemiological curve, we disagree. The evidence strongly indicates that the two Canadian cases do not represent the beginning of a multi-year, exponentially expanding outbreak such as occurred in the United Kingdom. In the United Kingdom, where BSE was first detected, measures to prevent and control the spread of the disease were implemented only after the disease had reached epidemic proportions. In countries such as Canada, where effective measures were implemented before detection of any case of BSE, and well before detection in any indigenous animal, the situation is quite different. The best scientific evidence from the United Kingdom and other countries is that BSE is spread primarily by contaminated feed and that prohibiting the feeding of ruminant-origin protein to ruminants prevents disease spread. Canada has had such a feed ban for over 7 years. While a few older animals born before Canada initiated its feed ban may have been exposed to BSE and may yet develop clinical signs, Canada has taken every necessary step to prevent an epidemic. While additional cases may occur in cattle born before implementation of Canada's feed ban, the epidemiological evidence indicates the number of new cases, if any, will be limited by the downward pressure of the comprehensive mitigations in place.

Issue: One commenter stated that, because the source of infection has not been identified for either BSE-positive cow of Canadian origin, the possibility exists that more asymptomatic cases may be present in Canadian herds, and that additional BSE-positive cattle have already gone to slaughter. The commenter stated that APHIS should not relieve restrictions on importations from Canada in the midst of an outbreak of uncertain size. Another commenter expressed concern that Canada admitted to identifying two feed mills not in compliance with the mandate to cease mixing mammalian tissue into cattle feed. The commenter stated that these mills were the source of the feed that led to the two identified cases of BSE in Canadian cattle.

Response: As we stated in the March 2004 Explanatory Note to our risk assessment, epidemiological evidence indicates that both of the BSE-infected animals of Canadian origin were born before implementation in that country of a ban on the feeding of ruminant protein to ruminants, that they were most likely exposed to the BSE agent through consumption of contaminated feed, and that epidemiological follow-up has identified the feed mills where the contaminated feed most likely originated.

From an epidemiological standpoint, it would be virtually impossible to definitively pinpoint a ''source of infection'' that occurred over 7 years ago. Canada has, however, evaluated the various potential sources of infection and has concluded that the source of

infection was most likely a bovine imported from the United Kingdom in the 1980's.

We agree it is possible there may be other asymptomatic BSE-infected animals in Canada. However, because the two BSE-infected animals were born before the feed ban, there is no evidence to suggest that the feed ban is ineffective. The feed mills identified as having provided possibly infected feed most likely distributed that feed before the ban was implemented. The feed mills complied with CFIA feed ban regulations after they were implemented and have a good compliance record based on CFIA inspections. CFIA indicates that with respect to the inedible rendering sector, full compliance with the feed ban requirements has been consistently achieved, and that with respect to the Canadian commercial feed industry, non-compliance of ''immediate concern'' has been identified in fewer than two percent of feed mills inspected during the period April 1, 2003, to March 31, 2004. Those instances of noncompliance of ''immediate concern'' are dealt with when identified (Ref 11). According to CFIA, non-compliance of immediate concern includes situations where direct contamination of ruminant feed with prohibited materials has occurred, as identified through inspections of production documents or visual observation, and where a lack of appropriate written procedures, records, or product labeling by feed manufacturers may expose ruminants to prohibited animal proteins.

An effective feed ban is an important part of the mitigation measures proposed for the importation of ruminants and ruminant products from a BSE minimal-risk region. However, the feed ban is not the sole mitigation in this rule. In addition to the risk-mitigating effect of the feed ban, importations of cattle and cattle products will also be subject to the import restrictions described in this rule. Those restrictions are based on the scientifically demonstrated likelihood of the BSE agent residing selectively in various tissues of animals of specified species and ages. Based on our analysis of the risk of such importations, it is highly unlikely that the BSE agent will be transmitted to the cattle population of the United States or into the U.S. human food supply through ruminants or ruminant products or byproducts imported into the United States under this rule.

Additionally, the rule prohibits the importation of any cattle 30 months of age or older, which includes cattle born before Canada implemented its feed ban. This age restriction was not in place when the cow that was detected as positive for BSE in December 2003 was imported into the United States.

Issue: One commenter expressed concern that some cattle under 30 months of age and, therefore, eligible for importation from Canada under the proposed rule, might be offspring of cattle born before the feed ban (and thus offspring of potentially infected cattle). The commenter noted that Canadian officials indicated that 68 British cattle that died or were slaughtered in Canada more than 10 years ago are the probable source of the original BSE infection in Canada. The commenter stated that current OIE guidelines do not recommend the immediate culling of offspring in the case of index or cohort animals, provided they are excluded from food and feed chains at the end of their lives. The commenter stated that until all animals born in Canada before the feed ban have been properly identified, as well as their offspring, the risk of importing one of these animals into the United States remains a risk that USDA has not adequately recognized. Other commenters also stated that there are likely additional undetected cases of BSE in Canada resulting from exposure to contaminated feed and that we should not relieve import restrictions at this time. One commenter stated that there are still breeding cattle alive in Canada that may have been exposed to the similar infectious material as the two BSE-positive cows identified in Alberta, Canada, and Washington State.

Response: We disagree that the possible presence of additional animals in Canada, infected before implementation of the Canadian feed ban, present risks that have not been addressed for this rulemaking. As stated in responses to several other comments, it is possible that cattle born before Canada initiated its feed ban in August of 1997 may still exist in Canada. Because these cattle are now 7 years old or older, this rule will not allow them to be imported into the United States. Offspring of such cattle, which may be eligible for importation, are not likely to be infected with BSE. Although some evidence suggesting maternal transmission exists, such transmission has not been proven and, if it occurs at all, it occurs at very low levels not sufficient to sustain an epidemic (Ref 41). Canada has conducted extensive investigations of both of the two known BSE-infected animals in Canada and culled all of those animals' herdmates and offspring, all of which tested negative for BSE. Based on the low prevalence of BSE in Canadian cattle combined with the unlikely occurrence of maternal transmission, we concluded that cattle eligible for importation from Canada under this rule are highly unlikely to have BSE. Breeding cattle of any age may not be imported into the United States from Canada under this rule.

Issue: One commenter stated that Canada has offered no scientific proof that it has either contained or eradicated BSE from its cattle herd, and that the two BSE-infected cattle detected were discovered despite a very limited testing program in effect in both the United States and Canada at the time.

Response: We disagree. We believe Canada has established through import restrictions, a rigorous feed ban and ongoing surveillance that BSE is contained and that the necessary mitigation measures are in place to detect and prevent the dissemination of BSE infected material and eradicate the disease. Our rule is not predicated on eradication of BSE from a region. Canada meets our requirements for a minimal-risk region in part because the country has had an active, targeted surveillance program since 1992, and has exceeded OIE guidelines for BSE surveillance for more than the past 7 years. Additionally, as discussed above, Canada has significantly broadened that surveillance program.

Issue: One commenter stated that, because BSE has a long latency period, it is not possible to know at present the exact disease status of Canada.

Response: We concur that at present it is not possible to know with certainty whether any additional cows in Canada are infected with BSE. However, as documented in our risk analysis, we have concluded that the surveillance, prevention, and control measures implemented by Canada, in combination with the import restrictions imposed by this rule, will comprehensively mitigate the risk of introducing BSE into the United States through imported Canadian-origin animals and animal products.

Whether Existing Regulations Should be Maintained

Issue: One commenter stated that APHIS has not demonstrated that the current regulations applicable to regions where BSE exists are not necessary in all cases. According to the commenter, the Harvard-Tuskegee Study said import restrictions and the feed ban in the United States were the two most important reasons the United States was unlikely to have BSE. The commenter maintained that these regulations are essential now that BSE has ''crossed the Atlantic'' and pointed out that most

countries that have reported a single case of BSE in a native animal have had additional cases either the following year or within the next several years. The commenter further stated that, according to the Harvard-Tuskegee Study, if BSE were introduced into the United States, it would be eliminated within 20 years, but only if the conditions affecting the spread of BSE remained unchanged for the 20 years following its introduction. The commenter maintained that time frame is not acceptable. The commenter stated that the regulations should not be relaxed without a comprehensive scientific evaluation of the implications of such relaxation. The commenter further recommended that APHIS immediately upgrade its present safeguards and restrictions for all imported beef and cattle and mobilize all its available resources to vigorously enforce these restrictions. One other commenter also noted the Harvard-Tuskegee Study's statement that the ban on the importation of live ruminants and ruminant MBM is the most effective measure for reducing the spread of BSE and maintained that USDA should ''follow this recommendation from its own funded study.''

Response: As discussed above, we have determined that it is appropriate, based on science, to use our standards for minimal-risk regions as a combined and integrated evaluation tool, focusing on the overall effectiveness of control mechanisms in place (*e.g.*, surveillance, import controls, and a ban on the feeding of ruminant protein to ruminants).

The commenters' paraphrasing of the Harvard-Tuskegee study is misleading. What the study actually said was, ''Measures in the U.S. that are most effective at reducing the spread of BSE include the ban on the import of live ruminants and ruminant MBM from the [United Kingdom] (since 1989) and all of Europe (since 1997) by USDA/APHIS, and the feed ban instituted by the Food and Drug Administration in 1997 to prevent recycling of potentially infectious cattle tissues.'' APHIS' restrictions on imports from regions listed in § 94.18(a)(1) and (a)(2) are very restrictive and APHIS is not reducing those restrictions.

As noted, since our proposed rule was published, FSIS and FDA have both strengthened their requirements concerning slaughter practices and food restrictions. The Harvard-Tuskegee Study's predictions that, if BSE entered the United States in as many as 10 cattle, few new cases of BSE would result and the disease would be eliminated within 20 years, at most, were based on the control measures existing in 2001. The Harvard-Tuskegee Study did not take into account recent regulatory changes concerning the use of rendered ruminant origin materials or active measures, such as culling and testing, that would be taken in response to an outbreak and for the purpose of eradication. If BSE were detected in a cow native to the United States, APHIS would work with other Federal agencies and State governments to eradicate preventable disease as quickly as possible. In combination with the recent changes in Federal regulations, we are confident that BSE would be eradicated in substantially less than 20 years.

Regarding the possibility of additional cases being discovered in Canada, for reasons given in response to other comments on this issue, we would expect that number, if any, to be very low. This is based on the fact that Canada has had comprehensive BSE prevention and control measures in place for many years, and that the two animals found in 2003 with BSE were older animals likely to have been exposed to contaminated feed before implementation of the feed ban.

Remove Import Restrictions

Issue: Several commenters stated that, because BSE is considered a North American problem, the APHIS risk analysis and the proposed mitigation measures should be revisited, and restrictions on movement from Canada should be removed.

Response: APHIS does not agree that the restrictions included in this rule should be removed. Based on our risk analysis, we consider these restrictions appropriate at this time to protect the United States from the introduction of BSE from minimal-risk regions such as Canada. BSE has been detected in two cows indigenous to Canada and, at this time, BSE has not been detected in any ruminant indigenous to the United States.

Other Comments Related to the Risk Basis for the Rule

Issue: One commenter stated that APHIS has not properly analyzed the risk associated with Canada's inability to identify the source of the BSE case discovered on May 20, 2003. The commenter stated that, because the cow diagnosed with BSE in May 2003 could have consumed contaminated feed after the feed ban was in place and up to the age of 3, and because Canada cannot definitively say that the cow's remains did not enter the ruminant feed chain, other Canadian cattle are likely to be infected. APHIS did not present the full range of risk possibilities associated with this scenario and, instead, presented only a best case scenario. Therefore, we should not relieve restrictions on imports.

Response: The CFIA in May 2003 confirmed BSE in a cow from northern Alberta that was slaughtered in January 2003. In response, CFIA immediately started an exhaustive epidemiological investigation. U.S. representatives worked in conjunction with Canada during the investigation, the results of which are available on the CFIA Web site (Ref 13). The investigation considered a wide range of possible sources of infection, including two possible routes of MBM exposure, maternal transmission, exposure to chronic wasting disease via domestic or sylvatic cervids, exposure to scrapie, and the possibility that the infected animal may have originated in the United States. CFIA concluded, consistent with scientific knowledge from the United Kingdom and Europe, that the most likely source of BSE for the infected cow would have been the consumption of feed containing MBM of ruminant origin contaminated with the BSE prion before the United States and Canada implemented a feed ban in August 1997. CFIA also concluded that the original source of the BSE prion in MBM is likely to have been from a limited number of cattle imported directly into either Canada or the United States from the United Kingdom in the 1980s, before BSE was detected in that country.

Proving the source of an infection is rarely easy, particularly when the infection occurred, as in this case, 6 or 7 years earlier. CFIA's epidemiological investigation was thorough and complete and its conclusions consistent with scientific knowledge about BSE and the facts associated with this case. CFIA did identify the source of the infection with as much certainty as is reasonable to expect. APHIS is confident that CFIA's conclusions are accurate.

As discussed above, the epidemiological investigation additionally focused on rendered material or feed that could have been derived from the carcass of the infected cow. As part of that investigation, a survey was conducted of approximately 1,800 sites that were at some risk of having received such rendered material or feed. The survey suggested that 99 percent of the sites surveyed experienced either no exposure of cattle to the feed (96 percent of the sites) 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. Depopulation of Canadian herds possibly exposed to the feed in question was carried out by the Canadian Government. Canadian officials conducted a wide-ranging investigation of possible exposure to the feed in question and carried out depopulation of Canadian herds possibly exposed to the feed. On each of those farms where the investigation could not rule out the possibility of exposure to feed that may have contained rendered protein from the infected animal, the herds were slaughtered and tested. All of those animals tested negative for BSE and their carcasses were disposed of in ways, such as disposal in landfills, to ensure that they did not go into the animal food chain.

Issue: One commenter, in light of the detection of two BSE-positive cows of Canadian origin, criticized the Canadian risk assessment for having concluded that ''993 times out of a thousand, there would be no BSE infection in Canada as the result of importation of cattle from the UK and Europe from 1979 to 1997.''

Response: Canada's risk assessment concluded that there is a very small probability that BSE was introduced into Canada as a result of the importation of cattle from the United Kingdom or elsewhere in Europe from 1979 to 1997. The estimated probability of at least one infection of BSE occurring before 1997 was 7.3×10^{-3} or, as the commenter noted, that 993 times out of a thousand, there would be no BSE infection in Canada as the result of importation of cattle from the UK and Europe from 1979 to 1997'' (Ref 12). However, the Canadian risk assessment did not conclude that no infected animal would ever be found. Both Canada and the United States have conducted aggressive surveillance for BSE designed to detect the disease should it exist in our cattle populations. Other controls are in place to ensure that the disease does not spread and amplify in the cattle populations or result in human exposure.

Issue: One commenter stated that the United States has a zero tolerance policy for fecal, ingesta, or milk contamination on livestock carcasses or meat products. The commenter said that these contaminants can result in diseases that are treatable, even though they may cause severe illness and death, but stated that BSE causes a disease in humans that invariably causes death and asked why we could find an acceptable risk for BSE, which is always terminal, when we have zero tolerance for contaminants, which may cause diseases which are treatable.

Response: The comment suggests an inconsistency that is not present. The policy of zero tolerance is consistent for adulterants whether the adulterant is *E. coli* O157:H7 or the BSE agent. Under FMIA, a meat food product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601 (m)(3)). FMIA requires that FSIS inspect the carcasses, parts of carcasses, and meat food products of amenable species to ensure that such articles are not adulterated (21 U.S.C. 604, 606). FMIA gives FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the provision of the Act (21 U.S.C. 621).

FSIS recognizes the agent that causes BSE as an adulterant under FMIA (Ref 42). The infective agent that causes BSE, however, is not fully characterized or easily identified. USDA's Agricultural Research Service is currently conducting research to further characterize the agent that causes BSE. Pathogenesis studies have confirmed that certain tissues of cattle (*i.e.*, the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column—excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum, and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle) are predisposed to harboring the infective agent that leads to BSE. FSIS, as part of its January 12, 2004, rulemaking, designated these tissues as SRMs, declaring that they are inedible, and prohibited their use for human food. For these BSE rules, FSIS also used the adulteration provision, which relies upon the determination that certain cattle and parts are unfit for human food because of the uncertainty associated with onset of the disease and the value of the testing results.

E. coli O157:H7 is well characterized and recognized by industry as associated with fecal contamination that is transferred from hide or digestive tract onto carcass during dehiding. As a result, industry recognizes that sanitary dressing is a critical step in the production of safe beef, particularly regarding *E. coli* O157:H7. In contrast, the infective agent for BSE cannot be easily identified and removed in the same way as fecal content. As a result, FSIS has a zero tolerance for SRMs (*i.e.*, any evidence that SRMs were not properly controlled as inedible will result in the product being considered as adulterated) that scientific studies confirmed as associated with the BSE agent. Furthermore, FSIS excludes non-ambulatory cattle from the human food supply because European surveillance data have shown a higher incidence of BSE in non-ambulatory disabled cattle than in healthy slaughter cattle. Therefore, the inconsistency in tolerance suggested by the commenter does not exist.

The FMIA requires that FSIS inspect the carcasses, parts of carcasses, and meat food product of all cattle, sheep, swine, goats, horses, mules, or other equines that are capable for use as human food to ensure that such articles are not adulterated (21 U.S.C. 604, 606). If the carcasses, parts of carcasses, and meat food products are found, upon inspection, to be not adulterated, FSIS marks them as ''Inspected and passed'' (21 U.S.C. 604, 606, 607).

F. Economic Analysis for the Rulemaking

In accordance with Executive Order 12866 and the Regulatory Flexibility Act, we assessed the potential economic costs and benefits of our November 2003 proposed rule and its potential effects on small entities. We included a summary of our economic analysis in the proposed rule and indicated how the public could obtain a copy of the full economic analysis.

A number of commenters addressed the potential economic effects of the proposed rule. Some of the comments focused on the rule in general or specific provisions of the rule, while others addressed our analysis of the potential economic effects of the rule. We discuss below each of the issues raised by commenters. Because some of the comments were technical in nature, we have tried to use the commenters' wording where practicable. Therefore, the manner in which we characterize each of the issues reflects the commenters' viewpoint.

The issues are grouped into eight sections:

- Economic modeling;
- Prices and quantities;
- Social welfare changes;
- Consumer demand;
- Feeder animal movement and feedlot requirements;
- U.S. beef exports;
- Effects on small entities; and
- Other.

1. Economic Modeling

Issue: The APHIS economic analysis of the potential impact of the proposed rule falls short of estimating the larger economic impacts this rule could have on the U.S. economy. It provides only a limited analysis of the effect of imports of Canadian cattle and beef on prices in the United States and ignores

the impacts this rule will have on associated industries and their productive output, as well as on employment.

Response: The commenter provides his own analysis of impacts, using multipliers to demonstrate economy-wide effects. (Multipliers measure total change throughout the economy resulting from one unit change for a given sector.) Effects can be described as direct, indirect, or induced. Direct effects represent the initial change in the industry in question. Indirect effects are changes in inter-industry transactions as supplying industries respond to increased demands from the directly affected industries. Induced effects reflect changes in local spending that result from income changes in the directly and indirectly affected industry sectors (Ref 43).

We acknowledge that the rule will have effects that reach beyond the cattle producing and processing sectors. However, the analysis presented by the commenter estimates only the negative impacts to the wider economy while ignoring the positive impacts. The commenter calculates that a reduction in U.S.-supplied feeder cattle of 283,182 head reduces sales by $181.2 million and causes a $701.2 million loss to the economy, assuming a multiplier of 3.87. However, the analysis for the proposed rule also showed an increase in the total number of feeder cattle fed in the United States of 221,318 head. When valued at $938 per head, the resulting additional fed cattle generate $207.6 million in additional sales for U.S. feedlot operators. Applying the commenter's choice of a 3.87 multiplier yields an economic gain of $803.4 million from feeding these additional feeder cattle. The result is a net gain to the U.S. economy of $102.2 million for importing the 504,500 feeder cattle from Canada. The same type of analysis would also apply to slaughter cattle and carcass beef.

However, the multipliers the commenter chose for his analysis are Type II, which include direct, indirect, and induced effects. We consider the use of Type I multipliers (only the direct and indirect effects) more appropriate for the calculation of impacts of changes in cattle supplies as well as changes in exports. Income loss and reduced consumer spending that might occur in one part of the cattle industry due to this rule need to be balanced against the growth in income and spending that can be expected to occur in other parts of the industry. In recognition of the commenter's observation that the rule will have impacts on associated industries, we include in the analysis for this final rule a multi-sector model of feed inputs, animal production, and animal product processing for a number of agricultural sub-sectors besides cattle and beef. Using this model, we estimate effects of reestablished imports from Canada in terms of changes in gross revenue. For the cattle sector, gross revenues are simulated to decline in 2005 by between 3.85 percent and 4.81 percent and for the beef processing sector, by between 1.26 percent and 1.59 percent. This model does not provide measures of change in welfare for the United States because of the rule; however, welfare changes would be smaller than the change in gross revenue identified by the model.

Issue: The decrease in the quantity of cattle supplied by the United States is a longer-term effect than the analysis suggests. Because the calf-crop that will produce beef in 2005 has already been conceived, this reduction will not occur until at least 2006. If the decrease in quantities supplied by U.S. entities is a short-term consequence (such as cattle held on feed for longer periods), then the longer-term price impact of holding supplies should be calculated.

Response: The model used to estimate effects of the proposed rule did not specify the period of time over which U.S. cattle producers would reduce herd size in response to price declines following resumption of imports from Canada. We expect that the resumption of cattle imports from Canada will have effects both in the near term (adjustment of the length of time animals are fed) and longer term (adjustment of calf retention and breeding decisions). We acknowledge that the comparative statics model abstracts from the problem of what becomes of the cattle that are already in the system, ready to be marketed in the near term; however, we believe the net benefits identified by the model are robust to this abstraction.

Holding cattle longer on feed depends mainly on feed prices relative to expected slaughter prices. Favorable forage conditions are expected to result in more cattle being placed on winter pasture and then moved to feedlots after the grazing season ends. Record-high feeder cattle prices in the United States will continue to pull more heifers into the feedlots than are retained for breeding. Effects described by the analysis should be viewed as including both near-term and longer-term effects.

Issue: Calculating results on a weekly rather than an annual basis allows the ''surge effect'' to be more clearly reflected. Annual averages smooth the price impacts. Weekly surges have been shown to exhibit a powerful effect, both fundamentally and psychologically on cattle and beef markets.

Response: The commenter's reference to surge effects concerns weekly price swings that can affect cattle and beef markets. While we understand that market disruptions can occur within a short time period, we are unable to model expected impacts of the rule on a weekly basis, as we are unaware of any data with sufficient depth and precision to model weekly effects. Annual data used in the analysis of welfare impacts generally capture the very short-term market events that may occur, even if they are not described in detail. In the analysis for this final rule, price effects are estimated over the one or two quarters that the backlog of Canadian fed and feeder cattle are expected to be imported.

Issue: The entire model is heavily dependent on elasticities calculated in 1996. The current situation in U.S. beef supply and demand is very different from that year's; there have been shifts in demand since 1996.

Response: The elasticities used in the analysis for this final rule have been revised from those used for the proposed rule. The revised elasticities are provided by USDA Economic Research Service, based on historical price and quantity data. The price elasticities of supply and demand, respectively, are 0.61 and −0.76 for fed cattle, 0.40 and −0.89 for feeder cattle, and 0.84 and −0.80 for wholesale beef. For comparison in our consideration of near-term price effects during importation of the cattle backlog in the analysis for the final rule, we calculate the results using supply and demand elasticities reduced by one-half. Buyers and suppliers of cattle can reasonably be expected to be less responsive to price changes in one or two quarters than over a year.

2. Prices and Quantities

Issue: In its economic analysis, APHIS estimated that reestablished slaughter cattle imports from Canada of 840,000 head would result in a price decline for such animals of $1.30 per cwt. With regard to feeder cattle, APHIS estimated that reestablished feeder cattle imports from Canada totaling 504,500 head would result in a price decline of 72 cents per cwt. However, if you affect the price of a 1,200-pound finished steer by $1.70 per cwt, then you have to change the price of an 800-pound feeder steer by more than 80 cents per cwt.

Response: The commenter apparently confused the $1.30 per cwt drop in price with the percentage decline it represents, i.e., 1.7 percent. In the economic analysis for this final rule, we

find the decline in prices for fed cattle in 2005 to range from $1.95 to $2.72 per cwt. For feeder cattle, the decline in prices ranges from $0.61 to $1.22 per cwt.

Issue: With constant demand, if you increase supply by 1 percent, you affect the price by 3 to 5 percent. Before the May 2003 ban on ruminant imports into the United States, Canada shipped about 3 percent of its cattle to the United States, both feeder and finished. Accordingly, with finished cattle bringing about $100 per cwt, the estimated effect on the U.S. market should be at least $9 per cwt.

Response: The commenter describes a change that graphically can be portrayed as movement to a lower price on a vertical (constant) demand curve, due to an outward supply shift. In reference to the percentage of cattle shipped from Canada, we believe the commenter did not mean to write ''3 percent of their cattle,'' but rather 3 percent of cattle marketed in the United States. With this change and a fixed demand, the percentages set forth by the commenter would lead as stated to at least a $9 per cwt drop in price.

However, this projected price decline is too large for several reasons. While demand for feeder and finished cattle is inelastic, it is not perfectly inelastic. Demand will increase as price falls, moderating the price decline. The own price elasticities of demand (percentage change in demand for a given percentage change in price) used in the analysis for this final rule are −0.89 for feeder cattle and −0.76 for fed cattle. These are considered short-run elasticities. In addition, the increase in overall supply will be less than the number of cattle imported from Canada. The imports will partly result in an increase in the total supply of cattle sold in the United States, but also partly displace U.S.-produced cattle. Lastly, while the percentages and prices used by the commenter are not specific, inaccuracies do spuriously contribute to the commenter's conclusion. Cattle under 30 months of age imported from Canada in 2002 comprised about 2 percent of the U.S. market for such animals, not 3 percent. Annual 2005 prices forecasted in November 2004 for choice steers (Nebraska, Direct, 1100–1300 lbs), according to USDA World Agricultural Supply and Demand Estimates, range from $82 to $88 per cwt, not $100 per cwt.

Issue: With the loss of other foreign markets for Canadian beef, Canada will probably send more cattle to the United States.

Response: We agree that because of the closure of foreign markets for Canadian beef, there are additional cattle in Canada that are likely to be shipped to the United States with the resumption of imports. This backlog of Canadian cattle is included in the analysis for this final rule.

Issue: A thorough analysis detailing the entire scale of impacts on exports due to the proposed rule is warranted. For example, the economic analysis shows the proposed price effect of importing 840,800 slaughter cattle from Canada. It indicates an increase in the number slaughtered in the United States of only 66,350 and a decrease in the number supplied by the United States of 474,450, yielding a price decrease of $1.30 per cwt. What calculations were used to arrive at these numbers?

Response: Impacts on U.S. exports were addressed in the economic analysis for the proposed rule by considering a range for possible foreign market losses if importing countries do not agree with the U.S. categorization of Canada as a BSE minimal-risk region. Reestablished imports from Canada of 840,800 head of slaughter cattle were estimated to result in an increase of 366,350 head in the total number of cattle slaughtered and displacement of 474,450 head that would have been supplied by U.S. entities. These calculations are based on the partial equilibrium model referenced in footnote 4 of the economic analysis, and a price-quantity baseline as shown in table 2 of the analysis. The same model, but with more current baseline data and estimates on expected cattle imports from Canada, is used in the analysis for this final rule.

Issue: The calculation used to determine the annual number of feeder cattle fed at U.S. feedlots assumes inventory turnover of three times per year, an average of 120 days on feed. This assumes that all feedlots are 100 percent full each day of the year. Due to seasonal supply shortages (e.g., there were 11 percent less cattle on feed during the third quarter of 2003 than the first quarter of that year) and an average of 150 days on feed, industry turnover averages are much closer to 2.5 times per year. Using 2.5 inventory turns per year, the number of feeder cattle fed in U.S. feedlots becomes 27,273,750 head per year. This is 5,454,750 head (17 percent) less than the 32,728,500 calculated using three inventory turns per year. An overstated inventory number understates the price impact related to resumption of cattle imports.

Response: We concur that we may have used too large a number of inventory turns per year in calculating the number of feeder cattle fed at U.S. feedlots. The baseline number of feeder cattle marketed in 2005, for feedlots with capacities greater than 1,000 head, is assumed to be 22,125,000 head, as provided by the USDA Office of the Chief Economist.

Issue: The baseline slaughter cattle information table uses a slaughter cattle price of $78.16 per cwt, the average price of choice steers for the first two quarters of 2003. The market has been over $100 per cwt this fall [the fall of 2003] and Cattle-Fax [a member-owned information organization serving producers in all segments of the cattle industry] forecasts a price of $87 per cwt for the second quarter of 2004. Due to the non-typical price structure that is forecast well into 2004, the price of $78.16 per cwt clearly translates into understated market damages.

Response: In the analysis for this final rule, we use a price range for fed cattle of $82 to $88 per cwt, based on the annual forecast for 2005, as of November 2004 (USDA World Agricultural Supply and Demand Estimates). This price range takes into consideration continued high U.S. demand for beef and present restrictions on U.S. beef exports.

Issue: If the scenarios described in the proposed rule regarding the potential loss of export markets assume an eventual recovery of these lost markets, costs need to be estimated representing recovery efforts. If the assumption is a terminal loss of markets, then a long-term accumulated loss value should be estimated and reported.

Response: We do not assume a permanent loss of export markets. Since publication of the proposed rule, many countries have established restrictions on U.S. cattle and beef due to the Washington State BSE discovery. It is not clear to us what is meant by ''recovery efforts,'' but we believe it is likely the commenter is referring to negotiations between the United States and its trading partners for the resumption of cattle and beef imports from the United States. In the analysis for this final rule, we consider how the rule may influence these countries' future decisions with respect to the lifting of the import restrictions.

Issue: The cost/benefit analysis of the proposed rule shows little if any benefit and underestimated cost to U.S. producers, feeders and packers. It should also be noted that the benefits are limited, as the December prices of Alberta feeder cattle were 10 to 18 percent higher than those of December 2002 and the prices of Alberta slaughter cattle were 7 to 9 percent higher than those of December 2002.

Response: The analysis for the proposed rule estimated price declines

for feeder and fed cattle, given a resumption of imports from Canada. As a group, U.S. entities in competition with firms exporting the Canadian cattle can be expected to experience reduced earnings. They will sell fewer cattle at lower average prices. Entities buying feeder and fed cattle at lower average prices due to the increased supply from Canada can be expected to experience increased earnings. Quantities of cattle assumed to be imported from Canada are based on the backlog that has built up because of current restrictions and on historic import levels. Once the backlog has cleared in 2005, prices for feeder and fed cattle in Canada relative to prices in the United States will influence the number of Canadian cattle sold in the United States and, therefore, the ultimate price effects as well.

Issue: With the December 2003 BSE discovery in Washington State, we have a very clear example of negative price impact from losing our export markets. The only export market currently closed that we estimate would remain open under the least favorable reaction to the APHIS proposal is Mexico. The January Live Cattle contract fell from $90.80 per cwt to $73.50 per cwt, or approximately 19 percent. This negative price impact has not only deflated fed-cattle prices, but is also discounting feeder cattle and calf prices. Every animal slaughtered will take discounts each time it is sold, resulting in heavy cumulative discounts. The APHIS proposal shows potential losses from a 32 percent reduction in beef exports (approximately Japan's portion) to range from $1.65 to $1.93 per cwt on a live weight basis. Another very clear example of the significance of Japan as an export market is demonstrated by the loss of 44 percent of the volume of beef and beef variety meat exports to Japan in 2001–2002 due to the discovery of BSE in Japan. Industry economists estimated the sharp decline in exports to Japan negatively impacts fed cattle prices in the United States by $2.50 per cwt to as much as $4.00 per cwt. Nor was the impact confined to the beef industry—shockwaves rippled through the grain and oilseed sectors, as well as the shipping industry. It is important to realize that this impact was felt from only a 44 percent loss of the Japan market * * *[I]t took nine months to make significant progress and full recovery had not occurred in the trade sector after one year. Determining the actual price impact of lost export markets appears much more amplified than the APHIS proposal suggests.

Response: Although prices for cattle did decline sharply immediately following the Washington State BSE discovery in December 2003, they quickly rebounded. Forecasted annual 2005 prices for feeder cattle, as of October 2004, are $94 to $100 per cwt. This is one of the baseline price ranges used in the analysis for this final rule. Beef prices are also forecasted to remain high despite export restrictions. A wholesale light Choice boxed beef price for 2005 of $141 to $147 per cwt is used in the analysis. In the discussion of possible effects of this rule on U.S. exports, we acknowledge the premium earnings foregone due to closed foreign markets.

Issue: The economic analysis assumes a scenario where U.S. markets are unaffected with BSE—a scenario that is no longer true. In addition, it accepts as justification, in part, for the economic risks, the high prices received by cattle producers and feeders in recent months. However, if you adjust dollars for inflation, producers received less for cattle than they did 40 years earlier.

Response: The analysis for this final rule takes into consideration existing conditions for the U.S. cattle and beef markets. Today's cattle prices, adjusted for inflation, may well be lower than 40 years ago, but this fact is not pertinent in considering expected benefits and costs of the rule.

Issue: Annual imports of beef into the United States rose from 3.6 billion pounds in 1995 to 5.5 billion pounds in 2000. In addition, other factors, such as the declining share of the retail dollar passed on to U.S. producers, have already injured the U.S. cattle industry. To open the border will accentuate this problem. Opening the border to live cattle imports combined with Canadian beef imports will result in supplies being increased by 9 percent and will result in an 18 to 20 percent decline in prices. When the Canadian border was opened to beef imports into the United States, our cattle prices declined 20 percent.

Response: The economic analysis performed for the proposed rule did not indicate the cattle and beef increases suggested by the commenter. The analysis showed that with resumption of imports from Canada, the number of fed cattle may increase by about 3 percent, the number of feeder cattle by less than 2 percent, and beef supplies by less than 1 percent (given ongoing boneless beef imports). We expect a decline in prices due to these increased supplies, but not an 18 percent to 20 percent decline. With the resumption of beef imports from Canada in 2003, there was an increase in cattle prices (choice steers, Nebraska, 1100–1300 lbs) from $78.49 per cwt in the second quarter, to $83.07 per cwt in the third quarter, to $99.38 per cwt in the fourth quarter (USDA World Agricultural Supply and Demand Estimates). The analysis for this final rule indicates a decline in cattle prices for 2005 of roughly between 0.63 percent and 3.2 percent due to reestablishment of imports from Canada, depending on the category of cattle frame and underlying import assumptions.

Issue: The beef analysis for the proposed rule used two different baseline prices for beef, $3.00 and $3.50 per pound. It should be noted that these values for beef may be low. USDA's Economic Research Service (ERS) quotes beef prices at $4.32 per pound in November 2003, a record high.

Response: In the economic analysis for the proposed rule, we noted that $3.00 and $3.50 per pound were used as baseline prices to take into consideration affected beef products lower in value than choice cuts. In the analysis for this final rule, we use a wholesale beef price range of $141 to $147 per cwt (light Choice boxed beef), a forecasted annual 2005 price provided by USDA Economic Research Service.

3. Social Welfare Changes

Issue: Despite APHIS' assertions that price decreases associated with the renewal of trade of feeder and slaughter cattle with Canada would not significantly affect buyers or sellers of slaughter cattle, APHIS must recognize that these costs would be borne entirely by relatively few small businesses, whereas the consumer surplus (in the form of reduced beef prices) would be spread out among millions of consumers.

Response: We acknowledge that consumers who benefit from the expected price decreases will outnumber U.S. livestock producers and other entities harmed by the same price decreases. The economic analysis indicates that the net change in welfare due to these impacts within the United States will be positive.

Issue: Three scenarios in the analysis for the proposed rule are used to evaluate reestablished cattle and beef imports from Canada, assuming (1) no loss, (2) 32 percent loss, and (3) 64 percent of U.S. beef export markets. Based on the APHIS analysis, producers and feeders lose under all three scenarios. Packers gain only if export markets are maintained while live cattle imports resume. Benefits to retailers/consumers are positive under each assumption. The only net benefit scenario for all sectors occurs if live cattle imports resume and export markets are maintained.

Response: The commenter is correct in concluding that the economic analysis for the proposed rule indicated that loss of export markets due to the rule could result in an overall negative impact for the United States. The analysis was clear in stating that we do not know how other countries would react to reestablished imports from Canada. Since publication of the proposed rule, many countries have established import restrictions on U.S. cattle and beef because of the Washington State BSE discovery. In the analysis for this final rule, we consider how the rule may influence these countries' future decisions with respect to lifting of the import restrictions. Possible trade effects of the rule cannot be discussed with the same confidence as expected domestic impacts.

Issue: APHIS' use of ''consumer surplus'' is theoretically questionable. By making a direct offset between the ''consumer surplus'' of public and the ''producer surplus'' of the industry, APHIS assumes that these surpluses are both measurable and comparable between producers and consumers. The concentration of the negative impacts on a relatively small number of industry participants and the wide diffusion of benefits across millions of consumers suggests that the true impact is much more negative than the analysis suggests.

Response: Benefit-cost analysis, the approach used for analyzing Federal regulations, determines whether benefits to society as a whole outweigh costs to society as a whole. Costs and benefits are not borne equally by all groups in a society. When measured in monetary units, comparing changes in consumer and producer surplus is well within standard economic theory, regardless of whether the number of entities differs across producers and consumers. This standard application of economic theory, moreover, is recommended in OMB guidance (Ref 44).

Issue: An impact that is particularly germane is that of other countries shutting their borders to U.S. exports based on the proposed rule. Although this has been addressed in the analysis, it depends upon increased ''consumer surplus'' to offer generous offsets to the crippling losses on the beef industry.

Response: APHIS' economic analysis for the proposed rule found that the net effect of the resumption of cattle imports from Canada would be positive for both feeder cattle and slaughter cattle—that is, the action would benefit U.S. buyers more than it would harm U.S. sellers. The analysis for this final rule also shows net positive effects. This is not surprising, as it is a standard result of microeconomic theory that opening a formerly restricted market benefits consumers in that market more than it hurts producers participating in the market when it was closed. Prior to the Washington State BSE discovery, exports of U.S. beef and ruminant products were earning 7.5 billion annually. Immediately afer the discovery, these export earnings fell by 64 percent. As of November 2004, the export decline had been reduced to 41 percent of pre-BSE levels. (Source: USDA Transcript, Release No. 0497.04, November 9, 2003.)

Issue: Serious concerns exist about the analytical framework that finds offsets for every producer loss as a gain in consumer surplus.

Response: We disagree. It is a standard result of microeconomic theory that expanding the supply in a formerly restricted market causes both an increase in consumer surplus and a decrease in producer surplus among producers participating in the market before it was opened. The analysis would cause more concern if this were not the case.

Issue: In its economic analysis for the proposed rule, APHIS' states that estimated price declines for producers/suppliers and consumers/buyers of slaughter cattle, feeder cattle, and beef due to allowing imports of live cattle from Canada would largely reflect a return to the more normal market conditions that prevailed before Canada's BSE discovery. APHIS' economic analysis states that these ''more normal'' market conditions would come at an annual decrease of $448.7 million for sellers of cattle. APHIS' analysis also claims a ''net benefit'' from reopening the border that presumably is based on consumers' savings through lower beef prices. APHIS needs to reevaluate its economic analysis in light of the current situation and in light of other trends in the beef industry, taking into account the economic situation of cattle farmers and ranchers.

Response: APHIS used the phrase ''more normal market conditions'' in reference to our nation's long history of trade with Canada in cattle and beef and has omitted this wording in the analysis for the final rule to avoid any misunderstanding. The net benefits estimated in the analysis result from the gains for consumers and other purchasing entities (due to the price declines) exceeding the losses for producers and other parties whose products will compete with the imports from Canada.

Issue: Do normal conditions suggest livestock values that reflect negative margins for U.S. producers? If so, that is science that must be considered in the rule, because producers operating at a loss are less able to invest in disease prevention, surveillance, and response.

Response: The rule is expected to result in price declines, but such declines do not equate to negative margins for U.S. producers. Clearly, those producers with smallest net revenues will be the most affected. Given current prices, it is not expected that the rule will cause producers to reduce their investments in disease prevention, surveillance, and response.

Issue: The APHIS analysis shows no benefit to the U.S. live cattle industry or consumers for assuming greater risk. How will reopening the border benefit consumers? How will reopening the border benefit producers?

Response: The economic analysis for the proposed rule showed that beef consumers could be expected to benefit due to lower prices. Producers, if in competition with fed and feeder cattle that would be imported from Canada, are not expected to benefit because of the reestablished imports. However, owners of slaughter facilities, for example, are expected to benefit because of the additional supply of fed cattle. The analysis showed that gains to consumers would exceed losses to producers, for a net gain overall. These same conclusions are reached in the analysis for this final rule.

Issue: Since the United States closed its border to the importation of Canadian cattle under 30 months of age, the beef processing industry in Weld County, Colorado, which is the largest contributor to the local economy there, has been experiencing significant financial losses and is at risk of losing the entire beef industry in that area. The risk from the importation of beef, with its limited inspections, far exceeds the potential problems associated with importation of live cattle from Canada.

Response: As shown in the economic analysis for the proposed rule, buyers of feeder cattle can be expected to benefit from resumption of imports from Canada. Communities such as that identified by the commenter that are dependent on processing industries will gain from the reestablished trade. Removal of SRMs at slaughter and other required risk-mitigating measures of this rule will ensure that beef entering the United States from Canada satisfies animal health criteria the same as or equivalent to those required in the United States.

Issue: In the analysis for the proposed rule, expected effects of the rule on the

fed and feeder cattle markets were examined in separate scenarios. The results of these two scenarios indicate that when fed cattle imports are resumed, producers' surplus declines by $448 million. When feeder cattle imports are resumed, producers' surplus declines by $182 million. APHIS concludes that these impacts would be independent and that increased imports of feeder cattle would benefit feedlot owners. Lower prices for feeder cattle are more likely, however, to pass through the market channel to consumers, and feedlot producers are not likely to realize significant benefits from the lower prices for feeder cattle. This suggests that the impacts of these events [reestablished fed cattle and feeder cattle imports from Canada] would be additive, implying that opening the border to trade with Canada on fed cattle and feeder cattle would likely have an effect of more than $630 million.

Response: Benefits from lower prices for feeder cattle and fed cattle may be at least partially realized by entities further down the marketing chain, including consumers. Revenue margins for feedlot operators may be characterized by greater rigidity than is implied in the analysis for the proposed rule. This possibility is acknowledged in the analysis for this final rule. Impacts described from reestablishing fed and feeder cattle imports from Canada would be additive. Their addition does not negate the fact that expected benefits outweigh expected costs of resumption of imports.

4. Consumer Demand

Issue: A significant negative reaction by importing countries regarding the safety of Canadian beef may very well translate into a U.S. consumer backlash should U.S. beef and beef products be perceived as unsafe. What are the long-term costs and implications of domestic market share loss to other protein sources?

Response: According to Cattle-Fax, U.S. domestic beef sales and demand remained strong after the discovery of a single cow diagnosed with BSE in the state of Washington. Three months after Canada announced a case of BSE, limited trade resumed with the United States, and imports of Canadian boneless meat from animals less than 30 months of age at slaughter began entering the United States. There has been no evidence that domestic consumers substituted other protein sources due to either the BSE discovery in Washington State, or in response to resumed imports of Canadian boneless meat. There is no indication that domestic consumers had a negative reaction to resumed imports of Canadian boneless meat. Rather, all market reports indicate that consumer demand for beef remains strong, even in light of over 70 countries imposing import bans on U.S. cattle and beef products in response to the BSE case in Washington. In fact, the National Cattleman's Beef Association, along with the Cattlemen's Beef Board, administered checkoff surveys of U.S. consumers in January 2004 that indicated that 97 percent of consumers were aware of BSE and a record 89 percent were confident in the safety of domestic beef on the market. That confidence level increased to 91 percent in February surveys. Because there were no discernible losses in consumer confidence or demand for domestic beef, and likewise no domestic market share loss to other protein sources in response to a single case of BSE in Washington State or in response to resumed imports of Canadian boneless meat, we would not expect this climate to change in light of increased imports of associated Canadian commodities.

Issue: Even if U.S. practices are adequate to avoid amplification of BSE after it is imported in Canadian animals, it is clearly wrong to assume, as APHIS does, that a limited number of U.S. cases associated with Canadian-born animals will not materially injure the U.S. industry and consuming public. The fallout over the Washington State BSE case has shown that quite clearly. Cattle prices are dropping on the basis of a single Canadian-born cow slaughtered in the United States. The loss of economic confidence in the beef supply has clear negative impacts on producer revenue. In APHIS' analytical approach, it should also have clear negative impacts on ''consumer surplus,'' since the downward shifting of the demand curve reflects the reduced potential for enjoyment of beef by a shaken public. Assurances—such as we had in December of 2003—of overall safety of the U.S. beef supply will help mitigate this impact. However, the economic impacts are large even if ''it is highly unlikely that such an introduction would pose a major animal health or public health threat.''

Response: U.S. beef consumers have not reduced beef consumption since the discovery of BSE in an imported cow in the United States, nor are there indications of a long-term impact of the discovery on the domestic demand for beef. Following the BSE discovery in Washington State in December 2003, a sudden price decline was short-lived. Prices today have largely recovered, with the projected 2004 price range for choice steers (Nebraska, 1100–1300 lbs) ranging from $84 to $88 per cwt, compared to prices of $67.04 and $84.69 for 2002 and 2003, respectively (USDA World Agricultural Supply and Demand Estimates). U.S. cattle and beef markets since the single BSE occurrence in Washington State have, if anything, reflected the strength and resilience of these industries and the high level of confidence consumers hold with respect to the health and safety of U.S. cattle and beef. We do not expect the rule to result in an increase in risk of BSE in the United States. Removal of SRMs at slaughter and other risk-mitigating measures of the rule will ensure that beef entering from Canada satisfies animal health criteria that are the same as or equivalent to those required in the United States.

Issue: The most serious problem with the economic analysis for the proposed rule is the failure to take seriously the costs to both the producer and the consumer as a result of loss in confidence associated with even a very limited incidence of BSE in the United States.

Response: Consumer confidence is an issue of concern for APHIS; however U.S. consumers do not appear to have reacted to the case of BSE reported in Washington State in a way that demonstrates profound loss of confidence. There were short-term price effects in U.S. markets for cattle and beef, but there do not appear to have been longer-term decreases in the demand for beef or increases in the demand for substitute protein sources such as chicken and pork. In this respect, U.S. consumers' reaction appears to differ from the reaction of consumers in countries like Germany, Japan, and the United Kingdom following BSE discoveries in those countries.

Issue: The economic analysis for the proposed rule is no longer applicable to current cattle market conditions, due to the Washington State BSE discovery.

Response: The economic analysis for this final rule takes into consideration market changes that have occurred since the initial analysis was done. The Washington State BSE discovery has had a significant effect on U.S. beef exports, but it has had little effect on domestic demand, as reflected in continuing high price levels for beef and cattle.

Issue: Once animals are allowed in, if boneless cuts are the only exports allowed, what will happen to the remaining cuts? Are they going to be dumped into our markets?

Response: Beef imported from Canada, like beef from cattle of U.S.

origin, will be consumed domestically or exported to another country depending on prices, trade arrangements, and the numerous other factors influencing the beef market. APHIS cannot predict the eventual use, other than to note current restrictions on U.S. beef exports.

Issue: The most important impact of APHIS' proposed rulemaking is the potential for BSE cases in the United States caused by the importation of Canadian cattle. This is dismissed almost offhandedly in the published analysis. This conclusion has already been proven wrong and is the most glaring deficiency in the economic analysis of the proposed rule. Additionally, the proposed rule ignores the potential economic impact should Canada discover additional cases of BSE while the United States is known to be importing Canadian beef and cattle.

Response: The risk mitigation measures included in the proposed rule were developed to ensure that ruminants and ruminant products imported from Canada pose a minimal BSE risk to the United States. Under the conditions of this final rule, the cow of Canadian origin that was diagnosed with BSE in Washington State would not have been eligible for importation into the United States. We do not expect the rule to result in an increased risk of BSE in the United States, given the risk-mitigating measures put in place in Canada and the monitoring of the movement of imported cattle that will be required. Removal of SRMs at slaughter and other risk-mitigating measures of the rule will ensure that beef entering from Canada satisfies animal health criteria the same as or equivalent to those required in the United States.

Issue: The APHIS analysis ignores the cost the rule would have if a second BSE event occurred on U.S. soil due to the transmission, or market and consumer perception of transmission, resulting from this rule, or even the increased risk that producers and consumers would incur from trade with Canada when there is risk of introduction of BSE. A BSE outbreak would cause demand for beef to decline and an increase in human health concerns. Estimates of the cost of the 1986 outbreak on the British economy, with a herd size of 12.04 million head, are $5.8 billion. Given that the U.S. herd size is 8 times larger, a worst-case scenario suggests the impacts on the United States could be as large as $46.4 billion.

Response: U.S. consumers have not appeared to reduce beef consumption in response to the BSE case found in Washington State. The commenter refers to the economic impact of BSE in the United Kingdom, applying it to the North American situation. It is important to note, as reported by Mathews and Buzby, that the total number of confirmed cases of BSE in the United Kingdom has exceeded 175,000 on over 35,000 farms, compared to the 2 confirmed cases in native North American cattle (Ref 45). We do not expect the rule to result in an increased risk of BSE in the United States.

5. Feeder Animal Movement and Feedlot Requirements

Issue: APHIS did not consider in its economic analysis the costs of ensuring compliance with risk mitigation measures. Such verification (*e.g.*, determination of animal age through dentition and the auditing of health certificates) will be burdensome and costly. Simply obtaining, tracking, and recording the necessary information will be time-consuming and take an undeterminable amount of man-hours.

Response: We acknowledge there will be additional costs to U.S. cattle feeding and packing operations that decide to import Canadian cattle. The additional costs will include, but not be limited to, those associated with increased recordkeeping requirements. These costs will vary by operation. In the analysis for the final rule, we approximate the cost of inspection and certification for movement of Canadian feeder cattle from the port of entry to a feedlot and ultimately to a slaughter facility. As with other business expenditures, affected U.S. firms will include additional recordkeeping costs associated with importing Canadian cattle in their cost calculations, and will purchase Canadian cattle only if the expected returns of doing so outweigh the costs.

Issue: Designated feedlots and slaughter facilities will need to develop a sound segregation plan for Canadian cattle. This adds another level of regulation, cost, and complexity. Without a national animal identification system, which is at least 2 years away, the only way for U.S. feedlots to keep segregation integrity with regard to U.S. and Canadian cattle would be to keep cattle in country-specific pens. This in itself would make it extremely difficult for feedlots to effectively manage cattle health care and feed costs, costing the industry millions of dollars annually. The only way to comply would be for feedlots to establish ''Canadian regions'' within each facility and construct separate hospital treatment facilities. This would also include the tracking of individual animal movements within designated feeding facilities, segregated transportation schedules and staged slaughter times—which requires a more efficient and effective communication link than current industry standards.

Response: In this final rule, there are no requirements for designated feedlots with regard to feeder cattle imported from Canada. Further, the rule does not require feedlots or slaughter facilities to develop segregation plans for live cattle from Canada. Canadian feeder cattle, and feeder sheep and goats, moved from the port of entry to a feedlot and from the feedlot to slaughter must be accompanied by an APHIS Form VS 17–130 to the feedlot and from the feedlot to slaughter by an APHIS Form VS 1–27. These forms will list all animals moved. This final rule will also require that feeder cattle be individually identified before entry by an eartag that allows the animal to be traced back to the premises of origin. The eartag may not be removed until the animal is slaughtered.

Issue: The costs of segregating Canadian cattle from U.S. cattle include additional downtime and changeover time (between processing imported Canadian cattle versus others), increased quality control and regulatory inspection, and a doubling of sku [stock keeping unit] inventory requirements (for ''export only'' sales under the Bovine Export Verification (BEV) program). Furthermore, these costs will definitely place smaller Northern tier single-plants at a disadvantage compared to those in other regions.

Response: Segregation/tracking of Canadian-origin product at the processing stage and beyond will not be necessary to ensure that the products are safe. We address issues concerning the BEV program in our responses to other comments.

Issue: The proposed rule requires that sheep and goats imported from a BSE minimal-risk region be less than 12 months of age if imported for immediate slaughter or for feeding and then slaughter. Was the cost of managing and maintaining imported Canadian sheep and goats as a separate group included in the economic analysis?

Response: The cost of managing and maintaining imported Canadian sheep and goats as a separate group was not included in the economic analysis for the proposed rule. Whether individual feedlot operations consider it worthwhile to handle imports from Canada—*i.e.*, whether the expected additional revenue exceeds the costs associated with feedlot designation—will be an individual choice and will be voluntary on the part of feedlots.

In this final rule, we specify that sheep and goats not for immediate slaughter will be required to be moved to designated feedlots. Criteria for designated feedlots include a written agreement between the feedlot's representative and APHIS that the feedlot will not remove eartags from animals unless medically necessary and cross-reference with the original eartag any eartag that must be replaced on an animal, will create and maintain acquisition and disposition records for at least 5 years, will maintain copies of APHIS movement permits, will allow Federal and State health officials to inspect the premises and animals upon request, and will designate either the entire feedlot or designated pens within the feedlot as terminal for sheep and goats to be moved only directly to slaughter at less than 12 months of age.

Issue: The record high prices for cattle that farmers and ranchers received during the summer and fall of 2003 have given way to limit[ed] down drops in live and future cattle prices. In addition, the market analysis done for the proposed rule ignores recent changes in Americans' diets and cattle herd culling due to extended drought conditions throughout the United States. The economic analysis also ignores that Canadian cattle were captive supplies for cattle that may have been used to manipulate United States cattle markets. These factors were not considered by APHIS in weighing the costs and benefits of the proposed rule.

Response: Record high prices for cattle during the summer and fall of 2003 primarily resulted from tight cattle supplies due to weather conditions and the ban on imports from Canada. With resumption of imports from Canada and improved forage conditions, there will be an increase in the cattle supply, causing downward pressure on prices received by domestic producers. APHIS, of course, does not have authority under statutory mandate to regulate marketing practices such as packer ownership of captive cattle, and any issues presented by packer ownership of cattle supplies is outside the scope of this rule. The economic analysis does not consider captive cattle supplies in examining the costs and benefits of this regulation.

6. U.S. Beef Exports

Issue: The economic analysis does not estimate the impact on the U.S. beef cattle industry as a result of trading partner discomfort with the lessening of restrictions on the importation of ruminants and their products from Canada. APHIS must rework the economic analysis to take this significant impact into consideration.

Response: In the economic analysis for the proposed rule, we addressed possible impacts of the rule on U.S. cattle and beef exports. Consideration was given to the possibility that importing countries may not agree with the United States' categorization of Canada as a region of minimal risk. That part of the analysis, regarding possible restrictions on cattle and beef imports from the United States by other countries because of the rule, addressed possible impacts due to ''trading partner discomfort.'' The analysis for this final rule takes into consideration current restrictions on U.S. beef exports and addresses the question of how the rule may affect these restrictions.

Issue: The negative trade scenarios outlined in the cost-benefit analysis of the proposed rule are based upon there continuing to be very few countries in the world that fully adopt or embrace the recommendations of the OIE regarding imports from BSE-affected countries. Such an underlying assumption is rapidly changing. The possibility that the United States would face lasting negative trade effects as a result of implementation of the proposed rule seems increasingly remote.

Response: In the economic analysis for the proposed rule, we did not assume there would be lasting negative trade effects. However, neither could we assume that negative trade reactions might not result if importing countries did not accept the U.S. categorization of Canada as a BSE minimal-risk region. We now have a different situation, with beef imports from the United States prohibited by a number of countries. It is possible that, because of the rule, these countries may either delay lifting current restrictions on cattle and beef imports from the United States or become more open to reestablishment of the imports. The analysis for this final rule addresses these possible impacts for U.S. beef exports.

Issue: In its cost-benefit analysis, APHIS does not appear to have considered the recent U.S. experience with the cost of segregating U.S. origin meat from Canadian meat to meet Japan's demand that we ship to that country only U.S. born and slaughtered meat. To the extent there are data or estimates available regarding the cost to the U.S. industry to meet Japanese demands, this should be considered in APHIS' analysis.

Response: We believe that the commenter is referring to the voluntary BEV program. Under the BEV program, USDA's Agricultural Marketing Service certifies through compliance audits that beef and other products exported by an eligible supplier are derived from cattle slaughtered in the United States. The BEV program, while ongoing for Canada and Mexico, has been terminated for Japan pending resumption of U.S. beef exports to that country. The BEV program will not be affected by this rule.

Issue: Even if BEV-compliant slaughter facilities do not import Canadian live cattle, they will have to comply and certify they are not receiving Canadian-origin cattle from feedlots and adopt new BEV regulations.

Response: As noted above, the BEV is a program, not a regulation, and is not covered by this rule. Slaughter facilities, if necessary, will be able to identify Canadian-origin cattle by the animal identification requirements included in the rule.

Issue: The proposed analysis calculated the price effect from lost export markets by using elasticities and price information. A large factor that was not analyzed was the loss in premiums that the U.S. beef industry gains by ''upgrading'' cuts with a low value in the United States by sending them to markets that pay a much higher price for them. Japan is the main premium market for U.S. beef and beef variety meats. Based on 2000 research conducted by the United States Meat Export Federation, the extra value achieved by U.S. beef exports is $1.2 billion per year (Ref 46). The loss of export markets will directly pass those markets' portions of this loss of value back to the U.S. beef industry. These losses are in addition to the losses caused by an increased supply of beef on the U.S. market. The extent to which export premiums support prices of domestic beef should be further analyzed.

Response: In the economic analysis accompanying the proposed rule, we stated that we were unsure how other countries would react to a resumption of ruminants and ruminant products from Canada. Because of the Washington State BSE discovery, most U.S. beef exports are now restricted. The question has become how the rule might affect current restrictions. In addressing this issue, we acknowledge the premium earnings foregone due to closed foreign markets.

Issue: The proposed rule fails to take into account the value of the entire animal to the industry. The rule appears to look at muscle cuts, but ignores the ''drop value'' of products such as variety meats, rendered products and goods that utilize such items as a base ingredient (*i.e.*, pet foods). No analysis was done for the potential loss of variety meat exports, both in terms of increased

supply in the United States and lost premiums. Beef variety meat (BVM) exports to Japan averaged 149,388 metric tons from 2000–2002 and averaged $309 million in value. Japan is the number two market for BVM, while Korea is number four with an average of 22,949 metric tons valued at an average $36.5 million from 2000–2002. The Livestock Marketing Information Center states ''The byproduct value can have a considerable impact on current slaughter cattle prices.'' In mid-November, the byproduct (drop credit) value surpassed $10 per cwt on a live weight basis. This is a significant proportion (ten percent) of the entire animal value. What are the costs of losing these variety meat markets?

Response: In response to the single case of BSE in Washington State, many export markets placed bans on imports from the United States. As the commenter states, Japan was the second largest market for U.S. BVM. Exports of BVM to Japan, January to March for 2003 and 2004, illustrate the significance of lost sales. During these three months in 2003, 18,988 metric tons of BVM valued at over $41 million were exported to Japan. During the same months in 2004, only 154 metric tons of BVM with a value of $1.4 million were exported. A question addressed in the analysis for the final rule is whether the rule, in itself, can be expected to affect the restrictions on U.S. beef exports and therefore the continued loss of premium earnings on beef variety meat.

Issue: It is assumed, although not stated in the proposed rule, that beef and variety meats would be segregated through processing beyond slaughter. If this is not done, all economic advantages of prior animal segregation are lost, while the associated costs of segregation are incurred by the industry with no benefit accruing to the domestic or international consumer.

Response: This final rule does not impose any requirements vis-a-vis labeling, segregation, or preservation of identity of the product of Canadian feeder or slaughter cattle. Once imported Canadian cattle are moved to slaughter, the application of FSIS rules for the removal and disposal of SRMs will prevent adverse consequences related to BSE.

Issue: Costs of plant segregation lines were not included in the analysis. Assuming that the proposed rule allows the reestablishment of Canadian beef and cattle imports, and our export markets, mainly Japan and Korea, require that no Canadian beef be exported to them, the costs of animal and beef segregation would become a direct cost to the U.S. beef industry.

Response: APHIS agrees that there could be operational and recordkeeping costs associated with exporting U.S. beef to Asian markets once they reopen, if the importing countries require that the products be derived from cattle of U.S. origin. However, if such requirements were placed on U.S. exports, the effects would be attributable to the policies of the importing countries, not to this rule.

Issue: The APHIS analysis fails to address the likelihood that U.S. beef export customers would reject the proposed actions.

Response: In the economic analysis for the proposed rule, APHIS addressed possible effects of the rule on U.S. cattle and beef exports. Consideration was given to the possibility that importing countries might not agree with the U.S. categorization of Canada as a region of minimal risk. In the analysis for this final rule, we consider whether the rule may influence other countries' decisions with regard to lifting of current restrictions on U.S. beef.

7. Effects on Small Entities

Issue: With regard to potential effects of the rule on small entities, economies of scale dictate that larger entities will be better able to absorb increased fixed costs on a per-unit basis. Segregation costs in packing and processing sectors will have a larger impact on smaller entities. It is believed that larger entities are better situated to absorb market volatility than smaller firms. The history of production agriculture has shown that smaller producers have higher costs of production and face higher risks associated with lower market prices. The economic analysis as proposed by USDA would have harsher consequences on smaller enterprises.

Response: APHIS agrees that larger entities will be better able to absorb costs associated with the rule than smaller entities, such as costs of segregating sheep and goats less than 12 months of age at designated feedlots. We expect entities that envisage a profit by doing so to make the capital investments and plan for the operating outlays that may be required to import such ruminants from Canada.

Issue: The claim that the impacts on small business cannot be estimated due to lack of data is not correct. There is considerable data available from USDA's National Agricultural Statistics Service (NASS) on livestock inventories by operation size. There is clearly adequate data to define small business impact. APHIS should complete a more thorough economic analysis of these impacts, particularly in light of the events of December 2003. Such an analysis should be made available for public comment before consideration of adoption of the proposed rule.

Response: APHIS showed in table 19 of the economic analysis for the proposed rule that the great majority of entities in industries expected to be directly affected by the rule are small, based on NASS data and Economic Census data. It is understood that effects of the rule will differ among entities, depending on specific business circumstances. APHIS does not have data that would allow a comprehensive analysis of potential economic effects for small entities beyond the price declines and welfare gains and losses that are described generally. We are unaware of NASS data or additional data available from the producer segment of the livestock industry that can be used to more finely examine these variations in impact. However, we do provide as an example possible effects of the rule on earnings by small beef cow operations.

Issue: Any resumption of Canadian live cattle imports should be carefully studied to ensure there is no negative impact on the U.S. cattle market. Such analysis should focus on specific geographic areas, especially Idaho and the Pacific Northwest.

Response: The various price and welfare effects described in the analysis are for the nation as a whole, because reestablished imports from Canada will not be restricted by region. However, it is recognized that regions of the United States that historically have been more closely associated with cattle imports from Canada can be expected to be more heavily affected by the rule. An example of possible effects on northern U.S. packing plants is referred to in the analysis of impacts of small entities.

8. Other

Issue: Costs of removing intestines are not included in the analysis. This would be a requirement of cattle imported from Canada and associated costs should be outlined. Associated costs include the costs of removal as well as the loss of the intestine as a product as opposed to removal of only the distal ileum. The intestines are a significant product for international markets.

Response: The FSIS SRM rule requires removal of the small intestine from all cattle slaughtered in the United States. For illustrative purposes, the FSIS Regulatory Impact Analysis estimates small intestine disposal costs to be $0.22 per animal, the value of the small intestine (casings and trepas) to be $12.21 per animal, and the value of alternative industrial uses of small intestine to be $0.33 per animal.

G. Environmental Assessment for the Rulemaking

Consistent with the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), and regulations of the Council on Environmental Quality (CEQ) for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), we prepared an environmental assessment (EA) 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 our proposed rule. In December 2004, we revised the EA to address the detection of a BSE-infected cow in Washington State in December 2003 and actions subsequently taken by Federal agencies to further protect the U.S. food supply from potential BSE infection. Other revisions to the EA include the addition of more detail about the available disposal methods of BSE-infected carcasses and information regarding disposal requirements for SRMs of cattle that are now required to be removed in the United States when establishments slaughter cattle or process cattle carcasses or cattle parts. The EA may be viewed on the Internet at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.*

Issue: One commenter asked whether APHIS considered the appropriate disposal of intestines in its EA.

Response: The revised EA gave an overview of the four methods that would be approved for disposal of diseased carcasses and discussed the FSIS SRM rule, which required slaughter establishments and establishments that process the carcasses or parts of cattle to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. In its SRM rule, FSIS discussed the need for establishments to have the flexibility to choose the disposal method or methods most appropriate for them; however, general disposal procedures are found in 9 CFR 314.1 and 314.3.

Issue: One commenter stated that APHIS should work with FSIS to develop an environmental impact statement (EIS) for this rulemaking. The commenter suggested that the proposed rulemaking would have potentially significant environmental effects and establishes a precedent for future actions with potentially significant environmental effects.

Response: The commenter is distinguishing between an EA such as the one we have prepared for this rulemaking and an EIS. An EA is a concise public document by which a Federal agency briefly provides its analysis for determining whether to prepare an EIS or a finding of no significant impact (CEQ NEPA Implementing Regulations, 40 CFR 1508.9). An EA identifies and assesses the significance of potential impacts on the environment of the proposed action. Its purpose is to provide any agency with the appropriate environmental information to make an informed decision about the proposed action and assist the agency in deciding whether an EIS is needed. An EIS is a more extensive environmental analysis that seeks to compare potential positive and negative environmental effects and weigh negative environmental effects against an action's other objectives. As discussed above, APHIS has prepared an EA that analyzes the potential environmental effects of the proposed rule. (Instructions for obtaining or viewing the revised EA are included below under the heading ''National Environmental Policy Act.) The revised EA provides additional information on the anticipated nature and extent of environmental consequences and the relevance of preventive actions to protect public health and safety. Based on the known cause of BSE; on the risk information cited to and referenced in the EA; on the preventive actions set forth in this rulemaking and on other mitigation requirements imposed by FSIS, FDA, and the U.S. Environmental Protection Agency; and on the history of BSE in this country, this rulemaking should not significantly affect the quality of the human environment. The CEQ NEPA Implementing Regulations define significance in terms of intensity, including the degree to which the action may establish a precedent for future actions with significant effects or that it represents a decision in principle about a future consideration (40 CFR 1508.27(b)(6)). This section of the CEQ regulations does not apply to this rulemaking because: (1) The EA concludes that the effects are not significant, (2) there is no evidence that any effects in the rulemaking would be cumulative or cumulatively significant, and (3) any future importations from other countries that might eventually be designated BSE minimal-risk regions under this rulemaking will be considered in separate NEPA analyses.

H. Withdraw or Delay Implementation of Rule

Withdraw or Delay Rule for Economic Reasons

Issue: A number of commenters recommended that APHIS withdraw, delay, or restrict implementation of the rule because of its potential negative economic effects on the U.S. livestock and livestock product industry, due to the potential significant influx of cattle from Canada over a short period of time. Additionally, said the commenters, the rule could harm the U.S. export market and its BSE status in the eyes of other countries if trade is allowed with Canada or if requirements less stringent than OIE recommendations are adopted. Further, commenters recommended that APHIS delay implementation of the rule until Canada removes its unfair restrictions on exports from the United States, and delay the rule until all U.S. export markets that were closed due to the December 2003 detection in an imported cow in Washington State are reopened. According to the commenters, if the rule is implemented, APHIS should do one or more of the following to minimize market disruptions:

- Offer an extended window for implementation that closely corresponds with the cattle industry's standard feeding period of 135 to 150 days;
- Resume imports of live cattle in small increments and build up over a 3 to 5 year period;
- Do not allow cattle for immediate slaughter to be imported before feeder cattle;
- Establish a monthly quota for imported cattle until the backlog of cattle from Canada is reduced;
- Stagger resumption of imports of live cattle according to the feeding and weight of the animals;
- Restrict tonnage of imports to the amount that was being imported before restrictions on Canadian imports were established.

Response: APHIS does not have authority to restrict trade based on its potential economic impact, market access effects, or quantity of products. Under its statutory authority, APHIS may prohibit or restrict the importation or entry of any animal or article when the agency determines it is necessary to prevent the introduction or dissemination of a pest or disease of livestock. However, APHIS is actively negotiating with trading partners to reestablish our export markets.

Issue: One commenter stated that the importation of live cattle from Canada should not be resumed until Canada is able to verify that actions equivalent to those imposed by FDA have been in place for at least 30 months before such importation begins.

Response: As stated above, we consider the feed ban in Canada to be equivalent to the one established and enforced by FDA in the United States,

and we consider the feed ban to have been equivalent for more than the 30 months recommended by the commenter.

Issue: One commenter referred to an announcement by CFIA of its intention to conduct further inquiry into the importation of cattle into Canada between 1982 and 1989, their herds of origin in the United Kingdom, and the resulting use of rendered materials and feed distribution from 1986 until 1993. The commenter stated that the information from this phase of CFIA's investigation is vital to determining the risks of allowing further imports from Canada.

Response: We acknowledge the potential value of further inquiry by CFIA in understanding the origin and nature of BSE in North America. However, the epidemiological investigations into both BSE cases (the BSE cow detected in Canada in May 2003 and the BSE cow imported into the United States from Canada and later slaughtered in Washington State) have indicated that it is likely the infected cows were born in Canada before implementation of the feed ban and thus were likely to have been infected under risk conditions that no longer exist. Under this rule, in combination with safeguards in place in Canada and in the United States, we consider the risk that BSE-infected or contaminated animals or animal products will enter the United States from Canada and expose U.S. livestock through feeding of infected materials to susceptible animals to be extremely low. Consequently, we do not consider it necessary to delay implementation of this rule until CFIA completes its inquiry.

Request for Public Meetings

Issue: Several commenters requested that public meetings be held before this rule is made final. One of the commenters requested that USDA convene a meeting of beef producers and consumers to develop a strategy to protect our beef industry and consumers.

Response: We do not believe that public meetings at this time would identify any issues that have not already been raised in the comments received on our proposed rule. As discussed above, we initially provided a 60-day comment period on our November 4, 2003, proposed rule, which closed on January 5, 2004. On March 8, 2004, we reopened the comment period for an additional 30 days until April 7, 2004. Additionally, we gave notice we would consider any comments on the proposed rule we had received between January 6, 2004 (the day after the close of the original comment period) and March 8, 2004. We received a total of 3,379 comments during the 5-month period between November 4, 2003 and April 7, 2004, and do not consider it necessary to hold public meetings before proceeding with this final rule.

Issue: A number of commenters requested the delay of this rulemaking until the investigation of the December 2003 detection of BSE in a cow in Washington State was completed. Several commenters requested that APHIS wait until all appropriate domestic measures to reduce BSE risk are in place before allowing the importation of ruminant products from regions that have had a BSE case. Another commenter requested that APHIS not implement the proposed rule until the advance notice of proposed rulemaking published by APHIS in the **Federal Register** on January 21, 2003 (''Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species'' (68 FR 2703–2711, Docket No. 01–068–1)), and the advance notice of proposed rulemaking published by FDA in the **Federal Register** on November 6, 2002 (Ref 47) are followed by proposed and final actions. Several commenters requested that the final rule not be implemented until USDA has expanded BSE surveillance, testing, and prevention efforts and has increased funding for BSE research, education, and development of rapid tests to detect the disease in live animals.

Response: We do not consider it necessary to delay implementation of this final rule. As discussed above in section III. B. under the heading ''Reopening of the Comment Period and Explanatory Note,'' an extensive investigation of the detection of the BSE-infected cow in Washington State has been completed. Since publication of the proposed rule and following the detection of the imported BSE case in Washington State, the United States has redirected resources towards planning, implementation, and enforcement of national policy measures to enhance BSE surveillance and protect human and animal health. In that regard, both USDA and FDA have initiated additional food and feed safety measures, discussed previously in this document. In addition, USDA has initiated an enhanced BSE surveillance program that targets cattle from populations considered at highest risk for BSE, Also, FSIS public health veterinarians have begun assisting in APHIS' BSE animal surveillance efforts by collecting brain samples from all cattle condemned during ante-mortem inspection at Federally inspected establishments. This will allow APHIS to focus on sample collection at locations other than Federally inspected establishments, such as rendering operations and farms. Details of the BSE surveillance plan are available at: *http://www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03-15-04.pdf.*

Strengthening of the passive surveillance system for BSE through outreach and education is an integral part of the USDA surveillance plan. In this regard, APHIS has developed plans to enhance existing educational materials and processes in conjunction with other Federal and State agencies. These outreach efforts will inform veterinarians, producers, and affiliated industries of the USDA surveillance goals and the sometimes subtle clinical signs of BSE, and will encourage reporting of suspect or targeted cattle on-farm and elsewhere. One of the tools for reporting high-risk cattle, announced on June 8, 2004, is a toll-free number (1–866–536–7593).

To help cover additional costs incurred by industries participating in the surveillance plan, and to help encourage reporting and collection of targeted samples, USDA may provide payments for certain transportation, disposal, cold storage, and other costs.

In addition, increased funding has been requested for USDA's Agricultural Research Service (ARS) to further study BSE. Examples of research projects ARS is actively engaged in include: Development of information and methods to characterize and differentiate among the known prion diseases of ruminant livestock and cervids, including BSE; development and validation of diagnostic and surveillance tests for BSE and CWD and development of intervention strategies for these diseases; development of biological and biochemical methods for detection of the transmissible agent in animal tissues and in the environment; identification and development of new methods and collaborative arrangements with other institutions for detecting animal proteins, especially prion proteins (PrP), in fields, barns, abattoirs, animal feed, feed additives or other animal products; and development of novel techniques for destruction of prion molecules.

It is important to note that all of the above measures are specifically designed to further minimize risks of BSE to animal and human health in the United States that were already low, as characterized by the Harvard-Tuskegee Study, even before the measures taken since December 2003. Because APHIS' risk analysis was based on the controls in place before these improvements, we

consider it unnecessary to delay the implementation of this rule until additional measures are in place.

General information and links to relevant APHIS documents are available at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.* General information and links to relevant FSIS documents are available at *http://www.fsis.usda.gov/oa/news/2004/bseregs.htm.* General information and links to relevant FDA documents are available at *http://www.fda.gov/cvm/index/bse/bsetoc.html.* In addition, the joint APHIS-FSIS-FDA advance notice of proposed rulemaking published on July 14, 2004, provides an overview of all Federal actions taken related to BSE and requests comment on additional measures under consideration.

Issue: A number of commenters recommended not only that APHIS follow OIE guidelines for BSE minimal-risk status, but that the Agency also delay any rulemaking action until new guidelines regarding BSE risk have been set by OIE. Commenters noted that APHIS was involved in discussions with the international community regarding such guidelines. One commenter stated that OIE is only in the process of developing guidelines that would be consistent with the standards for minimal-risk regions in the proposal.

Response: OIE guidelines have continually evolved and are likely to continue evolving, which is one reason that APHIS has decided not to simply adopt the OIE guidelines as regulations. The United States and other countries routinely propose revisions of the OIE BSE chapter (and other animal disease chapters) and make comments on draft OIE guidelines through official channels. These comments reflect technical and scientific issues relevant to the United States. The recommendations are reviewed by an *ad hoc* committee. As appropriate, the *ad hoc* committee issues a report suggesting revisions to existing OIE chapters. These are presented for adoption at the next General Session of the International Committee.

For instance, in April 2004, the OIE *ad hoc* committee issued a report proposing an example of a simplified BSE classification scheme. This report followed a meeting held in Paris on April 15 and 16, 2004, which resulted from OIE discussions in 2003 regarding the OIE's desire to simplify the BSE risk categorization system while retaining its scientific base. The report included an example of a simplified BSE categorization scheme. It is planned that a simplified scheme will be proposed for possible adoption in 2005.

OIE experts proposed a revision of the risk categories and a reduction in their number from five (''free,'' ''provisionally free,'' ''minimal risk,'' ''moderate risk,'' and ''high risk'') to three (''negligible risk,'' ''controlled risk,'' or ''undetermined risk''). The report stated that the three-category system offered the best science-based practicable approach to the epidemiology of BSE in combination with an emphasis on the safety of commodities for trade rather than on a classification of country status. This overall approach, currently under consideration by OIE, is a scientifically sound approach consistent with APHIS' approach in this final rule, which evaluated in an integrated way the risk conditions existent in the exporting region in combination with risk mitigation measures for commodities. These proposed OIE changes, as well as current OIE guidelines, reinforce the validity of the approach APHIS adopted, which also includes an evaluation of risk in regions seeking to be categorized as minimal risk, coupled with an intense focus on commodity mitigations.

Issue: Several commenters made various statements to the effect that we should not proceed with the rulemaking at this time because of a lack of certainty about the prevalence of BSE in Canada. Several commenters stated that the December 2003 find means that Canada no longer has a single case, and that Canada cannot now be considered a minimal-risk for BSE. One other commenter specifically disagreed with APHIS' conclusion that the additional case of BSE of Canadian origin does not significantly alter the original risk estimate. Another commenter stated that, based on the respective cattle populations, the detection of BSE in 2 cows of Canadian origin is the equivalent of 15 positive cases in the United States in less than a year and that, therefore, the risk of BSE from Canada is too high to resume imports. Several commenters asked whether the finding of a second BSE cow of Canadian origin will preclude Canada from consideration as a BSE minimal-risk region.

Response: The diagnosis of BSE in a cow of Canadian origin in Washington State in December 2003 does not preclude Canada from being considered a BSE minimal-risk region. Under this rule, a determination of minimal-risk status is based on an evaluation of all of a country's BSE prevention and control measures and not on any single criterion, such as the number of reported cases of BSE or any numerical threshold for prevalence. While we did not quantitatively estimate the true prevalence of BSE in Canada, we did evaluate the evidence involving the reported incidence of BSE and the nature and level of BSE surveillance for minimal risk regions in general and for Canada in particular. There is ample evidence to support the conclusion that the prevalence in Canada is very low and that Canada has implemented BSE prevention and control measures adequate to prevent widespread exposure and/or establishment of the disease.

Further, and, we believe, very importantly, the epidemiological evidence obtained shows that both animals referred to by the commenters were likely to have been infected before implementation of the Canadian feed ban. As noted, cattle born before the 1997 feed ban are not eligible for importation under this rule. Therefore, the detection of BSE in the two animals does not reflect the current risk conditions in Canada and the U.S. import conditions addressed in the analysis and proposed rule. In addition to the measures currently in place in Canada that make it unlikely that new cases are developing, the import restrictions in this rule and safeguards in place in the United States make it highly unlikely that the BSE agent will be introduced into the United States from Canada, spread to the U.S. cattle population, or enter the U.S. human food supply through ruminants or ruminant products or byproducts imported into the United States from Canada.

Issue: A number of commenters recommended that APHIS not allow the importation of cattle, beef, or beef products from Canada until more time has passed. The periods of time suggested by commenters ranged from 2 years to 12 years. Commenters provided various reasons for their recommendations. While some commenters recommended a delay only in allowing the importation of cattle, others requested a moratorium on all imports of live cattle, fresh beef, pre-cooked beef, and beef products until a specified period of time has elapsed or until exporters can prove the commodities are BSE-free. Some stated generally either that it requires a substantial amount of time until a region can be considered to present no risk or that more information is necessary on Canada's BSE prevention efforts. One commenter recommended that the importation of live cattle from Canada not be resumed until USDA can assure the U.S. beef industry and the public that it has done a complete analysis of the Canadian livestock production system to ensure that

potential exporters are in full compliance with U.S. regulations that seek to prevent the introduction and spread of BSE in the United States. Others said that APHIS should follow WHO guidelines, which various commenters said recommend waiting periods of from 4 to 12 years from the date of detection of BSE. Several commenters recommended that the importation of beef and live cattle from Canada be prohibited until 30 months from May 20, 2003, the date a BSE-infected cow in Alberta, Canada was diagnosed.

Response: We do not consider it necessary to delay implementation of this final rule. We have evaluated the BSE risk mitigation measures for ruminants and ruminant products in place in Canada and consider them equivalent to the measures that are in place in the United States. These measures are discussed in more detail in this document under the headings ''Reopening of the Comment Period and Explanatory Note'' (section III. B), ''Measures Implemented by FSIS'' (section III. C.), ''Verification of Compliance in the Exporting Region'' (section IV. D.), ''Measures Taken in Canada in Response to BSE Risk Prior to May 2003'' (section III. C.), and ''Epidemiological Investigation and a Report by an International Review Team'' (section III. C.). As noted above, APHIS conducted a risk analysis for this rulemaking. The risk analysis took into account the Canadian measures already in place, as well as our proposed mitigation measures for importation. Based on our analysis of risk, we concluded that any BSE-risk was thoroughly mitigated under the proposed import restrictions. Additional measures implemented since that time, both in the United States and Canada, further reduce risks.

With regard to the reference to WHO guidelines for waiting periods, we are unaware of WHO standards regarding the time periods the commenters' recommended for delay of this rule. The most recent WHO guidelines (Ref 48) reference OIE guidelines for trade, which include provisions for trade of live cattle and meat and meat products under certain conditions even from countries that would be considered high risk for BSE under OIE guidelines.

In addition, it is very important to note again the point made in the technical discussion in the risk analysis that certain commodities, such as muscle meat, are a BSE low-risk commodity in and of themselves. In that discussion, we pointed out that even cattle carrying the BSE infectious agent are unlikely to carry that agent in tissues that have not had demonstrated infectivity (*e.g.*, muscle, liver, skin, hide, milk, embryos) or products derived from these tissues.

Require Certification From All Countries

Issue: One commenter requested that APHIS not implement this rule with regard to Canada until the Agency requires certification regarding livestock feed production from all U.S. trading partners, similar to that required by this rule for minimal-risk regions, and requires them to allow the United States to perform random investigations and testing of their production facilities as a condition of market access.

Response: We do not consider it necessary to postpone implementation of this rule for the reason recommended by the commenter. APHIS evaluates regions on an individual basis to assess the risk of importing animals and animal products into the United States. When supported by such an evaluation, restrictions are imposed as necessary on imports from exporting regions. As part of the evaluation related to BSE, we evaluate the livestock feed practices. We impose import restrictions necessary to ensure that the practices are appropriate. In addition, we have the authority to and will, of course, re-evaluate regions when necessary (§ 92.2(g)). We consider the requirements spelled out in this rule to be comprehensive and sufficient to mitigate the risk of BSE introduction into the United States.

Tracking of Animals

Issue: Several commenters stated that a national tracking system compatible with the Canadian system should be established in the United States before importations occur. One commenter recommended methods for efficiently administering such an identification system.

Response: We do not consider it necessary to delay implementation of this rule until a national animal identification system is implemented in the United States. The animals that will be allowed importation under this rule will either be moved directly to slaughter or be officially and permanently identified and moved within a short period of time under APHIS movement permit to slaughter once in the United States.

Issue: A number of commenters requested that importation of ruminants and ruminant products from Canada not be resumed until more research on BSE is done. Another commenter mentioned that the science of prions is in its infancy and disputed the notion that prions appear only in older animals and not in milk or muscle.

Response: We do not consider it necessary to wait until more research is conducted or more information from Canada is available before implementing this rule. We consider the BSE research upon which we based the proposed rule and this final rule to be very substantial, and consider the mitigation measures in this rule to be very well supported by the research. We discussed the research upon which we based this rulemaking in the risk documents we made available with our November 2003 proposed rule and March 2004 notice of extension of the comment period. Additionally, in the update to our risk analysis described above in section II. C. under the heading ''Update to APHIS' Risk Analysis and Summary of Mitigation Measures and Their Applicability to Canada as a BSE Minimal-Risk Region,'' we describe the sequential risk barriers that Canadian imports will be subjected to. The commenter who disputed whether prions appear only in older animals and not in milk or muscle did not provide any data to support that contention and we are unaware of any reports that demonstrate BSE infectivity in ruminant milk and skeletal muscles.

I. Miscellaneous

Consider Regionalizing Parts of Canada

Issue: Some commenters suggested that APHIS regionalize Canada to differentiate Canadian provinces where BSE-infected cattle have been detected from provinces that have not had a BSE case.

Response: We are making no changes based on the comments. The information currently available to us does not suggest a difference in risk factors between provinces in Canada to the extent that would be necessary to justify such regionalization. Consequently, APHIS is categorizing all of Canada as a BSE minimal-risk region.

Effectiveness of Existing Regulations

Issue: One commenter stated that the detection of BSE in a cow slaughtered in Washington State indicates that even the existing regulations are not sufficiently robust to protect the U.S. cattle industry and the consumer from the introduction of BSE.

Response: From the time of the diagnosis of a BSE-infected cow in Canada in May 2003 until implementation of this final rule, the importation of live ruminants from Canada has been prohibited. As we discussed in the Explanatory Note to our risk analysis and in section III. B.

above under the heading ''Reopening of the Comment Period and Explanatory Note,'' the epidemiological investigation of the imported BSE-positive cow slaughtered in Washington State shows that the infected cow was not indigenous to the United States and most likely became infected in Canada before that country's implementation of a feed ban, and, therefore does not reflect current risk conditions. Furthermore, all cattle identified in the United States as possibly having been from the Canadian source herd of the infected cow were euthanized and tested for BSE, and all of the animals tested negative. Because there is a small probability that BSE can be transmitted maternally, the two live offspring of the infected cow were also euthanized. A third had died at birth in October 2001. All carcasses were properly disposed of in accordance with Federal, State, and local regulations. Also, in conjunction with USDA's investigation, FDA conducted an extensive feed investigation. By December 27, 2003, FDA had located all potentially infectious product rendered from the BSE-positive cow in Washington State. The product was disposed of in a landfill in accordance with Federal, State, and local regulations. This rule by its terms requires that any cattle imported into the United States from Canada were born after the implementation of that country's feed ban.

Enforcement of Current Regulations

Issue: One commenter suggested that USDA focus its limited resources on effectively enforcing current BSE regulations, rather than subjecting the U.S. industry and consumers to what the commenter viewed as an increased BSE risk. The commenter stated that import data obtained through reports from the Economic Research Service (ERS) in 2001 and the Foreign Agricultural Service (FAS) show that several BSE-affected countries have exported beef to the United States. Also, the commenter said Japan should have been listed as an ''undue risk'' country because it did not implement internationally recommended feed import restrictions and because its import requirements were less restrictive than those acceptable for import by the United States.

Response: APHIS has examined U.S. import statistics reported by ERS and FAS that the commenter stated indicated the importation of products from countries with cases of BSE in violation of current APHIS import rules. In many cases, these reports have turned out to be erroneous. In the import databases, several commodities—including those that are restricted from importation and those that are not—may be included in a given category of imports, so the data are subject to misinterpretation. In addition, we have identified certain errors in the reports, such as the miscoding of imports that actually came from Australia as having originated in Austria. Further, import codes are based on tariff needs rather than on animal health needs, which makes it difficult to use the reports to determine compliance with animal health based trade restrictions. We are satisfied that our current import requirements are being properly enforced.

With regard to imports from Japan, following the finding of the first case of BSE in Japan in 2001, APHIS immediately banned the importation of live ruminants and ruminant products and byproducts from that country, and codified that ban by publishing an interim rule in the **Federal Register** on October 16, 2001 (66 FR 52483–52484, Docket No. 01–094–1), that added Japan to the list in § 94.18(a) of regions in which BSE exists. Before detection of BSE in Japan, that country was not listed as a region that posed an undue risk of BSE. At the time the ''undue risk'' category was developed, the focus was on trading practices among Member States of the European Union, because the European Union was where BSE was first detected and its Member States largely follow uniform trade practices. It is not clear to us from the comment what import practices in Japan are being referred to. The lack of a feed ban was not specifically part of the rationale for establishing the ''undue risk'' category.

Follow-Up to Washington State Detection

Issue: Following detection of BSE in an imported cow in Washington State in December 2003, one commenter recommended that a group of USDA stakeholders be assembled to work with the Secretary of Agriculture's BSE advisory group to address all issues arising out of the epidemiological investigation, emergency response, and mitigating measures announced by the Secretary on December 30, 2003.

Response: Following detection of BSE in December 2003 in an imported dairy cow in Washington State, USDA and other Federal and State agencies worked together closely to perform an epidemiological investigation, trace any potentially infected cattle, trace potentially contaminated rendered product, increase BSE surveillance, and take additional measures to protect human and animal health. USDA worked in collaboration with the CFIA in conducting the investigations. Additionally, an international team of scientific experts (the IRT) convened by the Secretary of Agriculture as a subcommittee of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases (SACFADP) reviewed the U.S. response and recommended actions that could provide additional meaningful human or animal health benefits in light of the North American experience. Both the IRT and the full SACFADP include governmental and nongovernmental representatives who made recommendations for enhancements of the national BSE response program in the United States (Ref 34 and 35).

Imports From Canada Before May 2003

Issue: Several commenters recommended that BSE surveillance in the United States be targeted at cattle imported from Canada into the United States before May 2003.

Response: This recommendation does not directly apply to this rulemaking but, rather, to our animal surveillance program for BSE. Nevertheless, to address the potential risk posed by these earlier imports, USDA and the U.S. Department of Health and Human Services have opted to focus resources on activities that offer the most direct protection of animal and public health. These included applying SRM removal requirements, enforcing the feed ban, and very aggressively increasing overall surveillance in the United States. The Departments have determined that focusing on these measures will be very effective and will do far more to lessen the possibility of BSE-infected material affecting animal health or reaching the public than devoting resources to the exceptionally difficult task of tracing Canadian-origin animals and conducting a surveillance program focused on such Canadian-origin animals.

Possible Causes of BSE Infection

Issue: One commenter asked whether it is known conclusively that cattle can become infected with BSE through eating contaminated materials.

Response: Oral ingestion of feed contaminated with the abnormal BSE prion protein is the only documented route of field transmission of BSE (Ref 49) although other routes have been considered. Thus, the primary source of BSE infection appears to be commercial feed contaminated with the infectious agent. The scientific evidence 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 and can result in the infection of other animals that consume the material.

Canadian Prohibition of Imports

Issue: One commenter noted that in 1996 Canada prohibited imports of live ruminants from any country not recognized as free of BSE, and asked why, now that BSE has been detected in cattle indigenous to Canada, the United States would take a different approach than Canada did and allow imports from that country.

Response: The BSE situation addressed by Canada in 1996 was significantly different from the BSE situation in that country today. Actions taken now can be based on scientific research and information that was not available in 1996. In 1996, BSE concerns were focused on the United Kingdom and other countries with a high incidence of the disease. In addition, significant concern existed regarding the risks of possible human exposure to the BSE agent if the importation of live cattle from those regions were allowed. At that time, the apparent link between BSE and vCJD had just been announced, and predictions were being made of huge numbers of cases of vCJD. Since 1996, understanding of the disease has increased significantly, as has our knowledge of and experience with measures that can be taken to mitigate the risk. In addition, the predictions related to numbers of human cases have been scaled down dramatically, reflecting a better understanding of the true exposure that might have occurred. Today, effective import conditions can be designed to address specific risk issues.

U.S. Approach to BSE as Compared to Other Diseases

Issue: Several commenters expressed concern that APHIS' import policy with regard to BSE seems to differ from its general policy with regard to other foreign animal diseases. One commenter stated that, with most diseases, APHIS does not allow importation until adequate surveillance has been done to prove freedom from the disease. However, with regard to BSE, stated the commenter, APHIS allows imports from a region until a case of BSE is identified in that region. The commenter stated that APHIS should define standards for all levels of trade with various countries concerning BSE. Another commenter said that a country should be classified into one of the BSE established categories before trade in ruminant and ruminant products can be established.

Response: With regard to trade from BSE-affected countries, in § 94.18(a)(1) APHIS currently maintains a list of regions where BSE is known to exist. Additionally, § 94.18(a)(2) lists regions that present an undue risk of BSE 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 for BSE. APHIS prohibits the importation of live ruminants and certain ruminant products and byproducts both from regions where BSE is known to exist (and that are not considered BSE minimal-risk regions) and from regions of undue risk, even though BSE has not been diagnosed in a native animal in the latter regions.

As a newly discovered disease, BSE was limited in its geographic distribution to the United Kingdom and certain other countries in Europe. There was no evidence to suggest the disease existed elsewhere in the world. This situation lent itself to the policy of adding regions to lists of BSE-affected regions or regions that present an undue risk of BSE based on evidence of the disease's existence in those regions or on evidence that there was an undue risk of the disease existing in those regions, rather than assuming that BSE exists in every country of the world unless proven otherwise. This is consistent with our approach to other diseases, such as African horse sickness, which has never been shown to exist in countries other than in Africa and some countries on the Arabian Peninsula. Also, in contrast to infectious diseases that can be diagnosed relatively quickly, BSE has an extremely long incubation period.

If the commenter who discussed the need to conduct adequate surveillance to prove freedom from a disease before allowing importations was referring to the proposed provisions that would allow the importation of ruminants and ruminant products from Canada, it should be noted that we did not propose to consider Canada as a region free of BSE. Rather, in this rule we are creating a new category of regions that present a minimal risk of introducing BSE into the United States via imported ruminants and ruminant products and byproducts. This category is in addition to the categories of regions where BSE exists and regions that present an undue risk for BSE. We are adding conditions to allow the importation of certain live ruminants and ruminant products and byproducts from BSE minimal-risk regions (at this time, only Canada). As discussed in our proposed rule and in this **SUPPLEMENTARY INFORMATION** section, we will evaluate other regions as potential BSE minimal-risk regions upon their request and submission of the necessary information.

We described in the proposed rule and the risk analysis conducted for this rulemaking that Canada has conducted BSE surveillance since 1992. For the past 7 years, Canada has tested more than the minimum number of samples recommended by OIE. Additionally, we consider Canada to have exceeded the OIE guideline for surveillance by conducting active targeted surveillance, as has been done in the United States. We concluded that Canada's level of surveillance is adequate for that country to be recognized as a BSE minimal-risk region.

Change in BSE Status

Issue: One commenter stated that this rule should include criteria for determining when the BSE minimal-risk status of a region will be changed to a status of higher or lower risk, and should include how criteria for such a change in classification will be reviewed and evaluated.

Response: We acknowledge that there may be situations where the BSE minimal-risk status of a region should be changed to a status of higher or lower risk. As proposed, however, this rulemaking was intended to establish and address standards for recognizing a region as a BSE minimal-risk region, along with mitigation measures for the importation of susceptible animals and animal products from such regions. We have taken the commenter's recommendation under review, and, if we determine that standards for movement to a higher or lower risk status should be promulgated, we will propose those standards in a separate rulemaking. The provisions in § 92.2(g) recognize the need to conduct ongoing monitoring of a region's animal health status and provide that a region that has been granted animal health status under the APHIS regulations may be required to submit additional information pertaining to animal health status or allow APHIS to conduct additional information collection activities in order for that region to maintain its status.

WHO Guidelines

Issue: One commenter stated that the WHO does not recognize ''minimal-risk BSE countries'' and that WHO policy is not to allow imports of beef or cattle from BSE countries. Therefore, said the commenter, the import of beef and cattle from Canada should not be allowed.

Response: As discussed above under the heading ''Withdraw or Delay Implementation of Rule,'' we are not aware of any WHO guidelines that reference specific trade policies. It is the OIE guidelines (Ref 2) that are relevant in this regard, and OIE guidelines include provisions for trade in live cattle and meat and meat products from countries in all categories—including those at high risk for BSE.

Indemnity for U.S. Producers

Issue: One commenter asked whether USDA will indemnify U.S. producers if our trading partners question movement and identification controls for cattle imported from Canada and Canadian feeder cattle become unmarketable.

Response: APHIS will not indemnify U.S. producers for the actions of trading partners.

Recognize Isolated Donor Herds

Issue: Several commenters requested that the regulations allow ruminant products to be collected from isolated herds that have been controlled to be free from exposure to contaminated feed and animal diseases, and that APHIS work with companies that currently have such herds to established harmonized standards for BSE freedom.

Response: We are making no changes based on these comments. There are currently no procedures in place for classifying herds as BSE free, and it would not be appropriate to add such criteria in this final rule. However, APHIS welcomes information from interested parties on recommended criteria for BSE-free herds.

Feed Ban and Processing Compliance in the United States

Issue: One commenter recommended that we check more rigorously for violations of the ban on ruminant products in ruminant feed in the United States. Another commenter stated that FDA data from 2000 and 2002 indicate low compliance with the ban on feeding ruminant protein to ruminants in the United States.

Response: The United States, through the FDA, implemented a feed ban prohibiting the use of most mammalian protein in feeds for ruminant animals, effective August 4, 1997. This prohibition appears in 21 CFR part 589.2000. Compliance with the 1997 FDA feed ban is currently very high. Current compliance numbers are not readily comparable with numbers that were published in 2000 and 2002. The two sets of compliance numbers were drawn from different databases and used different presentation formats. Current numbers differentiate between serious and minor violations of the feed rule, the latter of which generally consist of minor recordkeeping deviations. Previous compliance numbers included those minor recordkeeping as part of the total number of violations. A level of high compliance by feed mills, renderers, and protein blenders has been noted for a number of years. BSE inspection results are accessible on the Internet at *http://www.fda.gov/cvm/index/bse/RuminantFeedInspections.htm.*

Animal Feed Restrictions

Issue: Several commenters requested that no animal protein and fat be allowed in feed for farm animals, so as to prevent the possibility of cross-contamination of concentrate feed in mills and accidental misfeeding on farms that contain different species of animals. Several commenters requested that SRMs be banned from use in all animal feed.

Response: As noted, the FDA enforces a feed ban prohibiting the use of most mammalian protein in feeds for ruminant animals and compliance with this feed ban is currently very high. In the joint FDA-FSIS-APHIS advance notice of proposed rulemaking published July 14, 2004, FDA requested additional information to help it determine the best course of action with regard to the feed ban. As discussed above under the heading ''Measures Implemented by FSIS,'' FSIS bans the use of SRMs in human food.

Products for Human Consumption

Issue: One commenter stated that USDA should act to ensure that no central nervous system tissue (CNS) is found in meat destined for human consumption. The commenter said that a survey conducted by FSIS in 2002 regarding the use of advanced meat recovery (AMR) systems in the United States indicated that 74 percent of establishments surveyed tested positive for CNS tissue contamination. (AMR is a technology that enables processors to remove the attached skeletal muscle tissue from livestock bones without incorporating significant amounts of bone and bone products into the final meat product.)

Response: With regard to beef product derived from an AMR system, FSIS reported that their 2002 survey indicates that approximately 76 percent (25 of 34) of the establishments whose AMR product was tested had positive laboratory results for spinal cord, dorsal root ganglia (clusters of nerve cells connected to the spinal cord along the vertebral column), or both in their final beef AMR products. However, as discussed in this **SUPPLEMENTARY INFORMATION** section under the heading ''Measures Implemented by FSIS,'' in an interim final rule published and made effective on January 12, 2004, FSIS expanded the previous prohibition against spinal cord tissue being present in meat derived from AMR systems to include all CNS tissue. In addition, in its January rulemaking, FSIS prohibited the manufacture of mechanically separated beef, as well as the production of AMR using SRMs.

Issue: A number of commenters stated that APHIS should make final its proposed rule only if the United States bans all rendered products from the human food supply.

Response: FSIS has identified those tissues that are unfit for human consumption regardless of whether cattle exhibit signs of BSE. As a result, all SRMs, as well as the small intestine, are prohibited from entering the human food supply, and if rendered, may be used only in inedible rendering.

Issue: As discussed above under the heading ''Measures Implemented by FDA,'' FDA has prohibited SRMs, the small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and MS(beef) from use in FDA-regulated human food, including dietary supplements, and cosmetics. One commenter stated that the APHIS was silent on whether Canada plans to adopt those new FDA restrictions.

Response: FDA applies any restrictions it establishes on the use of products in the United States to products imported into the United States and will enforce those restrictions with regard to imports from Canada accordingly.

Restrictions on Product Use Due to Clinical Signs of BSE

Issue: One commenter stated that, to avoid consumer problems, Federal agencies should provide that any animals exhibiting symptoms of BSE may be used only for pet food.

Response: All cattle slaughtered in Federally inspected establishments in the United States are subject to inspection. FSIS inspectors examine cattle to identify any symptoms of disease, including signs of central nervous system impairment. Cattle that are suspect for any reason are examined by an FSIS veterinarian to determine whether the animals are eligible for slaughter. Cattle that show signs of systemic illness and disease are condemned and are not allowed into the human food supply. As noted, FDA currently prohibits the feeding of most

mammalian protein (other than that from horses and pigs) to ruminants, and is developing a proposed rule to further strengthen the feed ban.

Uniform Standards

Issue: Several commenters requested that this rule not be implemented until a uniform set of BSE standards has been agreed upon among the United States, Canada, and Mexico. The commenters stated that particular relevance should be placed on a ban on the inclusion of blood meal in ruminant feed and on the segregation of lines in feed mills, as FDA announced it was planning to propose.

Response: The United States has been discussing a North American approach to the BSE issue for a number of years. Officials from the United States hold annual meetings with Canadian and Mexican technical experts from counterpart agencies that cover animal health, public health, diagnostics, and research. These meetings have contributed to greater understanding and harmonization of BSE control and prevention policies among the three countries. In fact, the United States, Canada, and Mexico have an agreement to recognize BSE region evaluations conducted by any of the three countries, using the same standards.

Currently, the United States is working with Canada and Mexico to develop a joint North American BSE strategy that promotes international guidelines protecting public and animal health, while encouraging the use of science- and risk-based trade measures in order to maintain sound disease surveillance and transparent reporting. Some of the preliminary results from those discussions are reflected in this final rule, such as the changes from our proposed provisions regarding the importation of live cervids into the United States (discussed above under the heading ''*Cervids*'').

Issue: One commenter recommended that implementation of this rule be delayed until there is a clear consensus among trading partners as to what constitutes SRMs.

Response: As noted above, the United States is working with Canada and Mexico to develop a joint North American BSE strategy and those three countries agree on what constitutes SRMs. APHIS is also interested in maintaining consistency with OIE guidelines regarding SRMs, although in certain cases the USDA considers it prudent to exceed the guidelines currently recommended by OIE.

Country-of-Origin Labeling

Issue: A number of commenters recommended that country-of-origin labeling be required in the United States so that beef imported from Canada would be so labeled. Some commenters suggested APHIS postpone implementation of this rule until such labeling is in place in this country. Several commenters raised concerns about how the United States would be able to certify U.S.-produced material as free of Canadian-sourced material.

Response: Under the Farm and Security and Rural Investment Act of 2002 and the 2002 Supplemental Appropriations Act, USDA is required to implement a mandatory country of origin labeling program (COOL) (Ref 50). USDA's Agricultural Marketing Service (AMS) published a proposed rule on the COOL program on October 30, 2003 (68 FR 61944–61985, Docket No. LS–03–04). Under the proposal, retailers would be required to notify their customers of the country of origin of all beef (including veal), lamb, pork, fish, and selected other perishable commodities being marketed in their stores. In addition, the AMS proposal identified criteria that these commodities must meet to be considered of U.S. origin. In January 2004, President Bush signed Public Law 108–199, which includes a provision to delay until September 2006 the implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish. The COOL program, when implemented, will address the labeling concerns raised by commenters with regard to APHIS'' proposed rule. APHIS does not consider it necessary to delay implementation of this rule until those labeling provisions are implemented. In its October 30, 2004 proposal, AMS noted, in discussing Section 10816 of Public Law 107–171 (7 U.S.C. 1638–1638d) regarding COOL that the ''intent of the law is to provide consumers with additional information on which to base their purchasing decisions. It is not a food safety or animal health measure. COOL is a retail labeling program and as such does not address food safety or animal health concerns.''

Jurisdiction

Issue: One commenter expressed the need for elimination of what the commenter termed conflicts of jurisdiction between the agencies of the Federal Government that oversee public health and safety. As an example, stated the commenter, the November 2003 APHIS proposed rule gives APHIS precedence over FSIS in determining whether an animal or its food products are safe to import, even though APHIS does not have authority to regulate food derived from the animal. One commenter stated that this rulemaking should be under the control of a human health agency because USDA has no expertise in the subject area. Another commenter suggested as a possible solution to what the commenter viewed as overlapping agency authorities the development of a single food agency in the United States to oversee all aspects of the food product safety system.

Response: We disagree with the commenters' assessments. The issues of protecting human and animal health from the risks of BSE are sufficiently diverse to require involvement of multiple agencies acting under their respective authorities. This work is carried out primarily through the USDA agencies of APHIS for animal health and FSIS for food safety, along with FDA. USDA has the statutory authority to protect both animal agriculture (AHPA) and public health (the Federal Meat Inspection Act, the Poultry Products Inspection Act of 1968, and the Egg Products Inspection Act).

APHIS regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases, including BSE. FSIS is responsible for ensuring the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged, whether produced domestically or imported. To ensure the safety of imported products, FSIS maintains a comprehensive system of import inspection and controls, which includes audits of a region's foreign inspection system, port-of-entry reinspection, and annual review of inspection systems of foreign countries eligible to export meat and poultry to the United States. These two USDA agencies, under their respective authorities, act together in the prevention, monitoring, and control of BSE in the U.S. livestock and meat and meat products food supply.

USDA agencies coordinate their responsibilities with FDA's Center for Veterinary Medicine regarding safety of animal feed. Likewise, such coordination is carried out with the FDA's Center for Food Safety and Applied Nutrition regarding the safety of all foods other than meat, poultry, and egg products, and with other FDA Centers having responsibility for drugs, biologics, and devices containing bovine material. These agencies collaborate, issuing regulations under their respective, to implement a coordinated U.S. response to BSE.

Private Testing for BSE

Issue: Several commenters recommended that private companies be provided the opportunity to do their own testing for BSE.

Response: APHIS has considered carefully the possibility of allowing private companies to conduct their own BSE testing, and remains convinced that allowing such testing for private marketing programs is inconsistent with USDA's mandate to ensure effective, scientifically sound testing for significant animal diseases and to maintain domestic and international confidence in U.S. cattle and beef products. As we continue to deal with the complexities of BSE, we consider it important to maintain clarity with regard to the purpose of USDA's BSE testing and the results such testing yields. As explained previously, currently available post-mortem tests, although useful for disease surveillance, are not appropriate as food safety indicators.

User Fees

Issue: One commenter stated that the $94.00 fee for a permit to import animals and products into the United States is unfair to private individuals and that there should be a minimal or no fee for permits.

Response: The issue raised by the commenter pertains to general import procedures and is not within the scope of this rulemaking. However, with regard to the general issue of user fees, under APHIS' regulations, user fees are charged for the services APHIS provides related to the importation, entry, or exportation of animals and animal products. As provided in 9 CFR part 130, APHIS charges all individuals a $94.00 fee for processing an application for a permit to import live animals, animal products or byproducts, organisms, vectors, or germplasm (embryos or semen) or to transport organisms or vectors. These charges are necessary for APHIS to recover the costs of providing these services. APHIS does not receive funds appropriated by Congress for these activities, and Congress has directed APHIS to charge user fees to recover its costs. The $94.00 cost for APHIS'' processing of applications for permits to import products was set in August 2001 (66 FR 39628–39632, Docket No. 99–060–2) based on the average of the actual volumes of each type of application processed in fiscal years 1998 and 1999. The user fee amount includes cost components for the salaries of employees involved in the processing applications, along with costs of billings and collections, rent, equipment (such as computer technologies), Agency overhead, and departmental charges.

Flexibility and BSE Research Advances

Issue: One commenter recommended that this rule explicitly provide administrative flexibility to the Administrator, with the understanding that the flexibility granted to the Administrator would be applied on the basis of risk assessment and sound science. The commenter stated that such an approach would provide for transparent and predictable application of the rule, while accommodating the evolution of scientific knowledge and risk mitigation processes, new product development, market demand, and revisions to OIE standards or WHO guidance. Another commenter requested that USDA review the provisions in this final rule 2 years after publication to see if technology and research advances warrant changes in the regulations. Another commenter requested that APHIS reassess the rule in 5 or 10 years.

Response: We are making no changes based on these comments. In developing this rule, we considered the best current BSE research available to us and designed the standards for minimal-risk regions to provide for some flexibility. We continually evaluate our regulations to consider advancement in knowledge and science.

Zero Risk

Issue: Several commenters disagreed that importations of ruminants and ruminant products should be allowed under certain conditions from regions that APHIS considers minimal risk for BSE. Some commenters said that countries exporting such commodities to the United States should present a ''zero risk'' of BSE, not a minimal risk. Even with a zero risk standard, said one of these commenters, it would be incorrect to say any region is BSE free and that the most that can be said is testing has not been conducted for BSE in that region.

Response: Zero risk is virtually, if not completely, impossible to achieve. As noted above, if we were to make trade dependent on zero risk, foreign, as well as interstate, trade in animals and animal products would cease to exist. APHIS agrees with the conclusion expressed in international trade agreements, such as the WTO-SPS Agreement and NAFTA, that trade should be commensurate with risk. Under these agreements, participating nations, including the United States and U.S. trading partners, have agreed to base conditions for importations on risk assessment and international standards. Regarding the risk associated with regions that have no or inadequate surveillance for BSE, we do not currently accept live ruminants or ruminant products from these regions, either because they are listed in § 94.18 as a BSE-restricted region or because they have not applied for status necessary to trade in ruminants or ruminant products with the United States, which would involve an evaluation by APHIS of the region for other diseases, such as foot-and-mouth disease and rinderpest, as well as for BSE.

The Harvard-Tuskegee Study

Issue: One commenter asked why USDA requested Harvard to conduct a risk analysis to evaluate the effectiveness of the U.S. system with the presence of Canadian products in U.S. channels, instead of requesting that Canada conduct a similar risk assessment of its system.

Response: As discussed above under the heading ''Harvard-Tuskegee Investigation of BSE Risk in the United States,'' in April 1998, USDA commissioned Harvard and Tuskegee Universities to conduct a comprehensive investigation of BSE risk in the United States. The purpose of the Harvard-Tuskegee Study was to assess the effectiveness of the U.S. domestic system with regard to BSE. The initial study did not specifically address the risk of BSE being introduced into the United States from Canada. The study was completed in 2001 and released by the USDA. Following a peer review of the Harvard-Tuskegee Study in 2002, the authors responded to the peer review comments and released a revised risk assessment in 2003 (Ref 2).

In 2003, using the same simulation model developed for the initial study, the HCRA evaluated the implications of a then-hypothetical introduction of BSE into the United States from Canada (Ref 10). Again, this was an assessment of the internal system in the United States, rather than an assessment of the risk of BSE in Canada. This assessment confirmed the conclusions of the earlier study-namely, that a very low risk exists of BSE becoming established or spreading should it be introduced into the United States. In December 2002, the CFIA, Science Branch, issued a risk assessment that evaluated the risk for BSE in Canada. (Ref 12).

J-List

Issue: One commenter stated that, when the border is opened, we should remove Canadian cattle from the ''J-list.''

Response: The ''J-list'' referred to by the commenter is a list of commodities that the Secretary of the Treasury has exempted from the general requirement in 19 U.S.C. 1304(a) that all products that are imported into the United States be marked as to country of origin. Among the commodities excepted by the Secretary of Treasury from this requirement are live livestock. The commenter's request is beyond the scope of this rulemaking, which does not address U.S. Department of Treasury requirements. However, we note that, under this rule, all cattle, sheep, and goats imported from Canada for other than immediate slaughter must be permanently identified before exportation to the United States as being of Canadian origin.

Comments on Issues Outside the Scope of This Rulemaking

A number of comments raised issues addressed topics outside the scope of the provisions of the proposed rule. These comments included the following issues: Concern regarding the effect of regulations in general on the cost of raising cattle; concern regarding the inhumane treatment and shipment of animals; recommendations regarding the terminology to use when referring to the euthanization of animals; requests for meetings with APHIS officials to discuss product development; concern that APHIS appears to be giving the issue of BSE minimal-risk regions a higher priority than domestic cattle disease programs; prohibiting the lambing of U.S. sheep on pastures where scrapie might be a problem; a recommendation that we require cattle exported from the United States to Canada to have a USDA identification tag and be marked with a brand; a recommendation that all livestock be allowed to live out their lives; a recommendation that cattle not be slaughtered before 30 months of age and that sheep and goats not be slaughtered before 12 months of age; and requests that the Canadian government pay U.S. cattle producers for economic and administrative losses due to the detection of a BSE-infected cow in Washington State.

V. Additional Clarifications

Transiting of Ruminant Products Through the United States

We are providing in § 94.18(d) that meat, and edible products other than meat, that are eligible for entry into the United States from a BSE minimal-risk region may, under certain conditions, be transited overland through the United States for export to another country.

The existing regulations in § 94.18(d) have allowed the transiting through the United States for immediate export, under certain conditions, of meat, and edible products other than meat, that are otherwise prohibited importation into the United States because they are derived from ruminants that have been in a region listed in § 94.18(a) as a region either in which BSE exists or that poses an undue risk of BSE. Before our listing Canada in this rule in § 94.18(a)(3) as a BSE minimal-risk region, the only regions listed in § 94.18(a) were countries from which transport of ruminant products to and through the United States would necessarily involve shipment by air or sea. Therefore, we have interpreted the existing provisions for transiting the United States in § 94.18(d) to apply only to such transiting at air or sea ports in the United States for export to another country. The increased risk from overland shipment would have required mitigation measures in addition to those listed in existing § 94.18(d).

Now that BSE has been detected in a country (Canada) from which overland shipment of ruminant products is feasible, we consider it necessary to clarify our intent with regard to the existing transiting provisions in § 94.18(d) to make it clear that transiting of shipments otherwise prohibited importation into the United States because of a region's BSE status may be done only at air or sea ports in the United States. We are revising the wording in § 94.18(d) to make this clear.

However, because we consider Canada to be a region of minimal risk for BSE, we are adding provisions to this final rule that will allow the overland transiting through the United States of products from BSE minimal-risk regions that are derived from bovines, sheep, or goats. These conditions appear in § 94.18(d) of this final rule and require that, in addition to meeting the existing transiting conditions in § 94.18(d), such shipments must meet additional conditions that are set forth in § 94.18(d)(5), which provide that the shipment must be exported from the United States within 7 days of its entry, the commodities must not be transloaded while in the United States, and a copy of the import permit required under the transiting conditions must be presented to the Federal inspector at the port of arrival and the port of export in the United States.

A reasonable question would be: ''If products are eligible for entry into the United States from a BSE minimal-risk region, why is it necessary to establish conditions for their transiting through the United States?'' The reason for restricting overland transiting to low-risk products from BSE minimal-risk regions is that shipments for controlled transit are not intended for ultimate entry into the United States and generally do not need the same manner of border inspection as shipments intended for U.S. entry. In recognition of this, we are combining the existing transiting requirements and those of this final rule with limitations on the type of products eligible for transiting to further ensure that such products do not present a risk of introducing BSE into the United States.

Part 95, which deals with the importation of inedible products, has provisions in § 95.4(f) that are similar to those in § 94.18(d) regarding transiting of products. In this final rule, we are making the same changes to § 95.4 as those discussed above with regard to § 94.18(d).

Definition of Inspector

Sections 93.400 and 95.2 each contain a definition of *inspector.* Section 94.0 contains a definition of *authorized inspector.* These definitions refer to an individual responsible for certain functions at a port of arrival or export in the United States. Each of the definitions refers to an individual either employed by APHIS or authorized by the Administrator to enforce the regulations. However, these definitions do not reflect the reassignment of certain responsibilities from APHIS to the Department of Homeland Security's Bureau of Customs and Border Protection by the Homeland Security Act of 2002. Therefore, we are replacing the definitions of *inspector* and *authorized inspector* in those sections with new definitions that read as follows: ''Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.'' Similarly, we are updating §§ 94.18(d)(3) and 95.4(f)(3) (which is redesignated as § 95.4(h)(3) in this final rule), which have required notification of the APHIS Plant Protection and Quarantine Officer at ports of arrival and export, to refer instead to notification of the inspector. We are also adding the definition of *authorized inspector* to § 96.1 to clarify the use of that term in part 96 of the regulations.

Definition of Flock

Before this final rule, the term *flock* was defined in § 93.400 to mean ''a herd.'' However, 9 CFR part 93, subpart D, includes provisions that refer to a ''flock or herd.'' To eliminate this redundancy and to clarify our intent, we

are a making a nonsubstantive change to § 93.400 to define *flock* as ''a group of one or more sheep maintained on common ground; or two or more groups of sheep under common ownership or supervision on two or more premises that are geographically separated, but among with there is an interchange or movement of animals.'' This definition is the same as the existing definition of *herd* in § 93.400, except that the revised definition of *flock* refers specifically to sheep.

Wording Clarification

We are also amending § 94.18(a)(1) to make it clear that imports of ruminants and ruminant products from Canada are not subject to the restrictions of that paragraph.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be economically 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.

The regulations in 9 CFR parts 93 to 96 include provisions that prohibit the importation of ruminants and most ruminant products (meat and certain other products and byproducts) from (1) regions where BSE exists and (2) regions that present an undue risk of introducing BSE into the United States because of import requirements less restrictive than those that would be acceptable for import into the United States or because of inadequate surveillance.

In this rule, APHIS is establishing an additional category of regions that present a minimal risk of introducing BSE into the United States. This category will include (1) those regions in which a BSE-infected animal has been diagnosed but in which measures have been taken that reduce the risk of BSE being introduced into the United States, and (2) those regions in which BSE has not been detected, but that cannot be considered BSE-free. In this rule, APHIS (1) sets forth the standards the Agency will consider before listing a region as one of minimal risk for BSE, (2) lists Canada as the only BSE minimal-risk region at this time, and (3) establishes measures to mitigate any risk that BSE would be introduced into the United States through the importation of ruminants and ruminant products from a BSE minimal-risk region. Future requests received from other regions to be considered BSE minimal-risk regions will be evaluated.

On May 20, 2003, CFIA 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 that listed Canada as a region where BSE exists, thereby prohibiting the importation of ruminants and most ruminant products from Canada, effective May 20, 2003.

Following the discovery 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 be possibly at risk for BSE. Subsequently, Canada asked APHIS to consider resumption of ruminant and ruminant product imports into the United States, based on information regarding the following: 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.

The prohibition was modified on August 8, 2003, to allow the importation of certain ruminant-derived products from Canada under APHIS Veterinary Services permit. The most important commodity that can enter by permit is boneless bovine meat from cattle less than 30 months of age.

This study analyzes ruminant and ruminant product imports from Canada that will be allowed to resume because of this rule. Expected benefits and costs are examined in accordance with requirements of the Office of Management and Budget for benefit-cost analysis as described in Circular A–4, ''Regulatory Analysis,'' which provides guidance for agencies on the analysis of economically significant rulemakings as defined by Executive Order 12866. Effects on small entities are also considered, as required by the Regulatory Flexibility Act.

Although not addressed in the analysis, Canadian producers and suppliers of ruminants and ruminant products will clearly benefit from the resumption of exports to the United States. In 2002, about 90 percent of Canadian beef exports and virtually all (99.6 percent) of Canada's cattle exports were shipped to the United States. Canada's cattle producers reportedly had one million more head of cattle on their farms on July 1, 2004, than they did one year earlier. This increase is largely due to the collapse of Canadian cattle exports.

Below is a summary of our economic analysis. A copy of the full economic analysis is available by contacting the individual listed under **FOR FURTHER INFORMATION CONTACT**. You may also view the economic analysis on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html*. Click on the listing for ''Economic Analysis, Final Rule, Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities (APHIS Docket No. 03–080–3.)''

The commodities that will be allowed to be imported from Canada under specified conditions under this final rule can be summarized as:

- Bovines, as long as they are slaughtered at less than 30 months of age, and as long as those bovines not imported for immediate slaughter are moved to a single feedlot before slaughter;
- Sheep and goats (ovines and caprines), as long as they are slaughtered at less than 12 months of age, and provided sheep and goats not imported for immediate slaughter are moved to a single designated feedlot before slaughter;
- Cervids of any age;
- Camelids (*i.e.*, llamas, alpacas, guanacos, and vicunas);
- Meat from bovines, ovines, and caprines; and
- Certain other products and byproducts, including bovine livers and tongues, gelatin, and tallow.

Model and Assumptions

Cattle and beef imports comprise 99 percent of the value of commodities that will be allowed entry from Canada because of this rulemaking, and they are therefore the focus of the analysis. The model used is a net trade partial equilibrium welfare model. Net trade is defined as the absolute value of the difference between exports and imports. Individual country trade with the United States is not modeled. Non-spatial means that price and quantity effects resulting from geographic differences in market locations are not included. Therefore, price and quantity effects obtained from the model are assumed to be the average of effects across geographically separated markets. Partial equilibrium means that the model results are based on maintaining a commodity-price equilibrium in a limited portion of the overall economy.

Economic sectors not explicitly included in the model are assumed to have a negligible effect on the model

results. Welfare refers to benefits or losses to society, as measured by changes in consumers' willingness to pay for commodities beyond their actual price (a measure of utility known as consumer surplus) and changes in producers' revenue beyond their variable costs (a measure of returns to fixed investment known as producer surplus).

This quantitative economic modeling approach is appropriate because the rule changes are specific to the U.S. cattle and beef sectors, are focused in extent, and have only limited extensions into non-agricultural sectors of the economy. A disadvantage of the model is the lack of linkages between the cattle production and beef processing sectors. This disadvantage is addressed through the presentation of results from an agricultural multi-sector model that recognizes such linkages.

We estimate effects of additional supplies to the United States of fed cattle and feeder cattle, due to resumption of imports from Canada. The additional quantities of cattle, all things equal, will cause prices to fall. The model indicates the expected price decline and the increase in quantity demanded and decrease in domestic production/supply that will occur in response to the fall in price. Summing welfare gains for consumers/buyers and losses for producers/ suppliers (changes in consumer and producer surplus) yields estimated net benefits for the United States. For beef, we expect a small decline in imports from Canada with the rule due to the replacement of beef produced from fed cattle by beef produced from cows, as explained below. Estimated effects for beef are in the opposite direction from those for cattle, with losses for U.S. consumers/ buyers outweighing gains for U.S. producers/suppliers. The effects for beef are much smaller than the effects for cattle.

Cattle imports from Canada. There are three components to the number of cattle under 30 months of age that are expected to be imported from Canada: A quantity that would be imported normally, a quantity that would have entered if cattle imports from Canada were not prohibited (termed the backlog); and a quantity of fed cattle that would be expected to be displaced from slaughter in Canada by increased cow slaughter for the export of processing beef to the United States.

For the first component, the quantities of fed and feeder cattle that would enter normally are based on average imports for 2001 and 2002: About 652,400 fed cattle and about 311,400 feeder cattle in 2005, with somewhat lesser quantities in years 2006–2009 because of assumed expanded slaughter capacity in Canada.

The backlog is the additional Canadian cattle that may have accumulated due to the closing of the border to live ruminant imports in May 2003. Importation of the backlog or some fraction of it would begin as soon as the rule is in effect, with most of these fed and feeder cattle expected to enter in 3 to 6 months.

Calculation of the size of the backlog is based on the change in Canada's cattle inventory from July 2003 to July 2004. The backlog may include about 394,500 fed cattle under 30 months of age and about 204,000 feeder cattle. The backlog of cattle over 30 months of age (not eligible for importation under the rule) numbers about 462,500 head.

The third component of expected cattle imports, an additional supply of fed cattle derives from another change included in the rule-namely, removal of the requirement that beef imported from Canada come from cattle slaughtered at less than 30 months of age. We expect this change to result in a large increase in cow slaughter in Canada for the export of processing beef to the United States. We discuss these expected effects here in greater detail.

Our assumptions regarding (1) the shift in Canada from slaughter of fed cattle under 30 months of age to slaughter of cattle (principally cows) over 30 months of age, for the export of processing beef to the United States, and (2) the shipment to the United States of the fed cattle under 30 months of age not slaughtering in Canada, are based on relative prices and margins in the two countries for fed cattle, cows, fed beef, and processing beef. As of mid-November 2004, a Canadian packer could buy a cow for about US$17 per cwt and sell the processing-grade beef for about US$123 per cwt. The packer also could buy a fed steer or heifer at about US$67 per cwt and sell the beef for about US$132 per cwt. In the United States, the cow would cost a packer about $55 per cwt and the beef would sell for about $125 per cwt; a fed steer or heifer would cost about $85 per cwt and the beef would sell for about $135 per cwt.

Although differences in weights and dressing percentages do not permit the direct comparison of live animals to dressed meat, the difference between the relative purchase prices to sales prices indicate that the margin buying cows and selling processing beef is much larger for a Canadian packer than it is for a U.S. packer. Canadian packers are prevented from taking greater advantage of this large margin by Canada's relatively small market for cow beef. Canadian production of processing beef has already displaced much of Canada's imported product. Without a larger demand, increased production would cause the Canadian price of processing beef to decline sharply.

The United States is already providing Canada with additional demand for beef from fed cattle, through the importation of boneless beef under permit from cattle slaughtered at less than 30 months of age. The United States, in a sense, is currently importing Canada's surplus production of fed beef. Allowing the United States to import Canadian beef from cattle slaughtered at more than 30 months of age would enable Canada to produce and sell much larger quantities of processing beef without fearing the significant price collapse that would likely occur if the entire additional product were only for the Canadian market.

This is not to say that the price of processing beef or cow prices in the United States would not decline from their current levels due to the supply from Canada, but we would not expect a sharp decline. Two facts concerning the U.S. supply of processing beef underlie this reasoning. First, U.S. cow slaughter is forecast to decline in 2005, as producers begin to rebuild herds that have been characterized by diminishing cow inventories for several years. Second, cow retention for herd rebuilding is also expected to take place in Australia and New Zealand, major sources of processing beef for the United States. Their beef exports are forecast to remain largely unchanged in 2005. As long as principal Asian markets continue to prohibit entry of U.S. beef, any increase in imports of beef from Australia and New Zealand by these markets may limit the supply of beef from Australia and New Zealand into the United States.

With the rule, entry of Canadian steers and heifers is expected to result in steer and heifer prices in the two countries becoming more similar. For example, in 2002, fed steer prices in Alberta averaged about US$63 per cwt, while in the United States, the Nebraska Direct Choice steer price averaged about $67 per cwt. Given the difference in mid-November 2004 prices for fed cattle, $67 per cwt in Canada and $85 per cwt in the United States, shipment of fed cattle to the United States will be an attractive alternative for Canadian producers, at least until Canadian prices rise to the level of U.S. prices (adjusted for grade differentials and minus transportation and transaction costs).

Prices for slaughter cows in the two countries are expected to continue to differ because Canadian cattle more

than 30 months of age will not be allowed entry by the rule, despite a ready market for them at slaughter facilities located in the Northern United States. Thus, in the absence of trade in those cattle, the backlog of cattle over 30 months of age will remain until increased cow slaughter in Canada reduces their inventory. We would expect the price of cows in Canada to increase as slaughter increases in response to opportunities to export beef from cattle more than 30 months of age to the United States. However, the margin earned from slaughtering cows in Canada and exporting the processing beef to the United States is likely to remain favorable (though decreasingly so as Canada's backlog of cattle more than 30 months of age is reduced).

It is assumed that the Canadian slaughter sector is operating at full capacity. Key to assumptions underlying this analysis is the willingness of Canadian slaughter facilities to add cow slaughter shifts or days to their operations at the expense of steer and heifer slaughter. We believe they would want to do so, given the price differentials in Canada and the United States and the opportunity for Canadian beef exports to the United States from cattle slaughtered at more than 30 months of age. With the rule, beef imported from Canada would no longer be required to come from a slaughter facility that either slaughters only cattle less than 30 months of age or complies with an approved segregation process, which may permit increased flexibility in scheduling cow slaughter.

In 2005, APHIS expects this shift by Canada to exports of processing beef and additional fed cattle to the United States to take place throughout the year, not during one or two quarters as assumed for the backlog of steers and heifers under 30 months of age. Beyond 2005, additions to Canadian slaughter capacity are expected to allow increased slaughter of cattle of all ages. Canada has been able to increase its slaughter numbers during the past year, but the opening of new plants and major expansion of current processing facilities to accommodate increased cow slaughter will likely take some years. The lack of excess slaughter capacity in Canada and the described price differentials are the basis for the assumed shift to increased cow slaughter in Canada for the production of processing beef for export to the United States, and the assumed additional imports of Canadian fed cattle.

In 2005, the maximum number of imported fed cattle displaced from Canadian slaughter may equal the backlog of cattle over 30 months of age (assumed to be slaughtered for the export of processing beef to the United States), about 460,000 head. For years 2006–2009, we assume the number of fed cattle displaced from slaughter in Canada and exported to the United States to decline, as Canada's slaughter capacity increases and Canada's cow prices trend upward. However, all things equal, as long as live cattle imports from Canada are limited to animals less than 30 months of age and the U.S. demand for processing beef is high, beef imports from Canadian cow slaughter may be favored.

Uncertainty surrounds both the assumed backlog quantities and the quantity of fed cattle expected to be displaced by cows slaughtered in Canada and exported to the United States. We acknowledge these uncertainties by also conducting the analysis using one-half of the assumed backlog and one-half of the assumed number of displaced fed cattle.

After the backlog of cattle has been imported, imports of cattle under 30 months of age from Canada are expected to continue at historic levels elevated by the importation of the fed cattle displaced from Canadian slaughter by the slaughter of cows. We therefore expect the largest impact of the rule to occur during the first 3 to 6 months that the rule is in effect. In order to assess these very near-term price impacts, we estimate effects of the rule for the first and second quarters of 2005, in addition to the five-year analysis of welfare effects. As in the analysis of welfare impacts, we acknowledge uncertainty about the quantity of cattle what will enter from Canada by conducting a sensitivity analysis of near-term price effects using one-half of the assumed backlog and one-half of the assumed number of displaced fed cattle.

Beef imports from Canada. Boneless beef entering from Canada under permit represents a large share of historic beef imports from Canada. Before the Alberta BSE discovery, Canada's share of U.S. beef imports was about 41 percent (90 percent of fresh/chilled beef imports and 4 percent of frozen beef imports). Currently, Canada's share of U.S. beef imports is about 32 percent (fresh/chilled beef, 85 percent; frozen, 3 percent). For this reason alone, the effect of the rule for beef imports will be much smaller than the effect for cattle imports. Canadian beef entering the United States by permit is included in the baseline for the analysis.

As described, we expect Canadian cows to be slaughtered in place of fed cattle for the export of processing beef to the United States, given Canada's limited capability to increase its slaughter capacity in the short term. A cow that is slaughtered produces less meat than a fed steer or heifer due to a lighter weight and lower dressing percentage. Recent statistics from Canada indicate an average difference in beef produced from one steer/heifer and one cow of 150 pounds. In 2005, assuming Canada is fully utilizing all available slaughter capacity, the decrease in beef production would total about 69 million pounds if the backlog of about 460,000 cattle over 30 months of age is slaughtered in place of steers and heifers. To take into consideration possible declines in Canada's domestic consumption of beef as beef prices rise slightly relative to other meats, and therefore movement of beef from the domestic to export markets, we reduce the decline of 69 million pounds by one-third, to 46 million pounds.

The forecast for Canada's beef exports worldwide in 2005 is 570,000 metric tons. U.S. imports of beef from Canada are forecast to equal about 86 percent of Canada's total beef exports, or about 490,200 metric tons. The 490,200 metric tons is equivalent to 1,081 million pounds. In other words, Canada's beef exports to the United States, compared to what would have been exported without this rule, can be expected to decline in 2005 by 4.3 percent (46 million pounds divided by 1,080 million pounds) because of the displacement of steer/heifer slaughter by cow slaughter in Canada. The decrease in Canadian beef exports to the United States because of this displacement is assumed to diminish in years 2006–2009, as Canada's slaughter capacity expands.

Processing-grade beef is not perfectly substitutable for fed beef. The two commodities compete in different but closely related markets. This distinction is not included in the analysis because the model is based on aggregate beef price ranges and elasticities. Increased supplies of processing beef are expected to compete with fed beef in the same fashion as other close substitutes. Thus, allowing imports of beef from cattle slaughtered at over 30 months of age, together with fed cattle imports augmented by the cattle displaced from Canadian slaughter, is expected to result in lower prices for U.S. steers and heifers.

As with the assumed backlog and displaced fed cattle imports, there is uncertainty as to the amount of beef from Canadian cow slaughter that will be imported by the United States. Accordingly, we include in the sensitivity analysis a reduction by one-

half of the assumed change in beef imports from Canada. In 2005, for example, this reduced amount would represent a decrease in beef imports from Canada of 2.1 percent from what would have been imported without the rule.

Welfare and Near-term Price Effects of the Rule for Cattle and Beef

Welfare effects. Welfare effects of the rule for cattle and beef are summarized in Table 1. Present values and annualized values of welfare gains and losses over the five-year period 2005–2009, are determined using 3 percent and 7 percent discount rates, in both 2005 and 2001 dollars.

TABLE 1.—PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS, 2005–2009

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Present, 2005 dollars	3	$2,982,088	−$2,907,462	$74,626
	7	2,592,201	−2,525,852	66,349
Present, 2001 dollars	3	2,810,618	−2,740,283	70,335
	7	2,443,150	−2,380,616	62,534
Annualized, 2005 dollars	3	651,153	−634,858	16,295
	7	632,214	−616,032	16,182
Annualized, 2001 dollars	3	613,711	−598,353	15,358
	7	595,861	−580,610	15,251

Note: The present and annualized values are taken from Appendix H, based on assumed import of the backlog, import of fed cattle displaced from slaughter in Canada by increased cow slaughter for the export of processing beef to the United States, and beef imports from cows slaughtered in place of fed cattle.

The present value of the net benefit of the rule for cattle and beef is estimated to range in 2005 dollars between $66.3 million and $74.6 million, depending on the discount rate used. Over the five-year period, the annualized value of the net benefit in 2005 dollars, depending on the discount rate, ranges between $16.2 million and $16.3 million.

The largest effects for cattle are expected to occur in 2005, when the backlog would be imported and the displacement of fed cattle slaughter by cow slaughter would be largest. The impact for fed cattle would be greater than for feeder cattle because of the larger number of fed cattle expected to be imported. For fed cattle, the annual price declines may range from an average of 3.2 percent in 2005 to 1.3 percent in 2009. For feeder cattle, the price declines range from an average of 1.3 percent in 2005 to 0.6 percent in 2009.

Estimated net benefits in 2005 for fed cattle are estimated to range from $25.0 million to $26.9 million, and for feeder cattle, from $10.4 million to $11.0 million. In each successive year, the net benefits are expected to become smaller, such that by 2009 they may range for fed cattle from $3.8 million to $4.3 million, and for feeder cattle, from $4.3 million to $4.8 million.

Effects of the rule for beef attributable to the change in beef imports from Canada are expected to be much smaller than those for cattle. For example, the expected 2005 net welfare loss (because of the decline in imports due to cow slaughter replacing fed cattle slaughter) in 2005 dollars is estimated to range between $94,000 and $98,000. Average percentage increases in price may range from 0.09 percent in 2005 to 0.01 percent in 2009, suggesting nearly negligible impacts. If the beef-equivalent of the fed and feeder cattle imported from Canada is considered, the supply of beef in the United States increases and the price of beef decreases by 1 to 2 percent from 2005 baseline levels. Smaller decreases from baseline projections would occur after 2005 because the volume of imported animals declines.

Effects may be even smaller for U.S. producers than these percentages indicate, given that nearly all U.S. beef imports from countries other than Canada consist of processing beef. Demand for imported processing beef has increased drastically as ground beef sales continue at a robust pace. At the same time, U.S. production of processing beef has fallen to record lows because of the cyclical decline in cow slaughter.

Table 2 shows the results of the sensitivity analysis, assuming importation of one-half of the backlog, one-half of the fed cattle expected to be displaced from slaughter in Canada, and one-half of the expected replacement of fed cattle beef imports derived from fed cattle by beef imports derived from cows. The present value of the net benefit for cattle and beef in this case is estimated to range in 2005 dollars between $48.9 million and $56.1 million, depending on the discount rate used. Over the five-year period, the annualized value of the net benefit in 2005 dollars, depending on the discount rate, may range between $11.9 million and $12.3 million—that is, about three-fourths of the expected annualized net benefit with the rule.

TABLE 2.—SENSITIVITY ANALYSIS BASED ON REDUCED IMPORT QUANTITIES: PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS, 2005–2009

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Present, 2005 dollars	3	$2,571,323	−$2,515,180	$56,144
	7	2,211,115	−2,162,168	48,947
Present, 2001 dollars	3	2,423,472	−2,370,557	52,915
	7	2,083,976	−2,037,844	46,132

TABLE 2.—SENSITIVITY ANALYSIS BASED ON REDUCED IMPORT QUANTITIES: PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS, 2005–2009—Continued

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Annualized, 2005 dollars	3	561,460	−549,201	12,259
	7	539,270	−527,333	11,938
Annualized, 2001 dollars	3	529,176	−517,622	11,554
	7	508,262	−497,011	11,251

Note: The present and annualized values are midpoints taken from Appendix I, based on assumed imports of one-half of the backlog, one-half of the fed cattle numbers, and one half of the replacement of fed cattle beef imports by cow beef imports.

In this scenario, the impact in 2005, in particular, would be smaller because of the fewer cattle imported. For fed cattle, the annual price declines may range from 2.3 percent in 2005 to 1.2 percent in 2009. For feeder cattle, the price declines over the five-year period may average 0.7 percent. Estimated net benefits in 2005 for fed cattle may range from $12.9 million to $13.9 million, and for feeder cattle, from $8.0 million to $8.5 million. In each successive year, the net benefits are expected to become smaller, such that by 2009 they may range for fed cattle from $3.5 million to $3.9 million, and for feeder cattle from $4.3 million to $4.8 million.

The estimated percentage decrease in the price of fed cattle, if one-half of the backlog and one-half of the fed cattle expected to be displaced from slaughter in Canada were imported, would be about 1 percent less than when we assume importation of the full backlog and full quantity of displaced fed cattle (2.3 percent decrease compared to a 3.2 percent decrease). For feeder cattle, the difference in the effect is smaller in absolute terms, but larger in relative terms (0.6 percent decrease compared to a 1.3 percent decrease). In both cases the effects are expected to diminish over the five-year period.

Near-term price effects. As expected, price effects are larger when the backlog is assumed to enter in one quarter rather than two quarters, and are larger for fed cattle than for feeder cattle, given the larger number of fed cattle expected to be imported. For example, for fed cattle, the decrease in price when the backlog is assumed to enter entirely within one quarter is estimated to be 5.4 percent, assuming a price elasticity of supply of 0.61 and a price elasticity of demand of −0.76. When the backlog of fed cattle is assumed to enter over two quarters using the same price elasticities, the decline in price is estimated to be 3.8 percent. Entry of the backlog of feeder cattle over the two quarters could result in price declines of 1.9 percent, for the same elasticities, compared to a possible price drop of 3.3 percent when the enter entirely within one quarter.

The less elastic the price elasticities (the less responsive sellers and buyers are to price changes), the larger the expected percentage changes in price. When the supply and demand elasticities are halved (supply elasticity of 0.30 and demand elasticity of −0.38), for example, and fed cattle are assumed to enter within two quarters, the decrease in price could be 4.8 percent, compared to a price decrease of 3.8 percent when a supply elasticity of 0.61 and demand elasticity of −0.76 are used.

When the assumed backlog and assumed number of imported fed cattle displaced from Canadian slaughter are halved as a sensitivity analysis, the near-term price effects are found to be smaller overall, with the smaller elasticities again yielding larger price decreases. For example, the percentage decrease in price for fed cattle entering over two quarters is estimated to be 2.5 percent for a supply elasticity of 0.61 and a demand elasticity of −0.76 (compared to a 3.8 percent price decline when the full backlog and number of displaced fed cattle are imported). If the supply elasticity were 0.30 and the demand elasticity were −0.38, the price decline is estimated to be 3.2 percent (compared to 4.8 percent for the full cattle import numbers). Similarly, smaller percentage price declines are observed for feeder cattle when in the sensitivity analysis the backlog and the number of imported fed cattle displaced from Canadian slaughter are halved.

Other Impacts of the Rule

We consider other effects of the rule besides those estimated for cattle and beef, including: The results of an agricultural multi-sector analysis; costs that may be incurred in monitoring the movement of imported Canadian feeder ruminants; effects for ruminant products other than cattle and beef; and possible effects of the rule on U.S. exports.

Multi-sector analysis. Some commenters on the analysis for the proposed rule emphasized the integrated structure of the cattle and beef processing industries, and noted potential effects of the rule on other sectors of the economy. APHIS agrees that a multi-sector analysis can capture industry interactions that are missing from single-sector analyses. We therefore report the results of an analysis based on a model that includes the animal feed, animal production, and animal product processing sectors.

While the major vertically linked marketing channels are included in this model, effects of the rule farther downstream in the economy are not modeled. For example, economic benefits to surrounding communities of increased employment in slaughter plants receiving greater supplies of cattle due to reopening of the Canadian border are not captured by the model, nor are similar economic losses resulting from reduced spending in communities by cattle producers due to reductions in their returns. These effects are believed to be very small on a national basis, but may show some geographic concentration.

The multi-sector analysis simulates percentage changes in prices and gross revenues (price multiplied by the quantity sold) using the assumed 2005 range of imported Canadian cattle (roughly 1.5 million to 2 million head, fed and feeder cattle combined). The results of the analysis show for the combined livestock, feed, and grain sectors, a possible decline in gross revenues of 1.4 percent to 1.7 percent. For the beef and cattle sectors, the gross revenue declines may range from 1.3 percent to 1.6 percent, and from 3.9 percent to 4.8 percent, respectively.

With respect to the change in the price of cattle in 2005, the multi-sector analysis indicates a possible decline of between 3.3 percent and 4.1 percent, compared to 2005 price declines estimated in the single-sector analyses of between 0.6 percent and 1.3 percent

for feeder cattle, and between 2.3 percent and 3.2 percent for fed cattle. To the extent that sector interactions result in expanded effects as indicated by these relative price declines, welfare gains and losses will be larger than are indicated in Table 1. The multi-sector model simulates price and revenue changes, but does not yield measures of welfare change. However, this model does indicate a decline in consumer expenditures by about 1 percent, a finding that supports the estimated consumer welfare gains attributable to the rule.

The multi-sector analysis also examines possible effects if beef consumption in the United States were to decline by 2 percent because of consumers' perception of increased risk of BSE with the rule. Compared to the assumption of no consumer response, this scenario shows that there would be a decline in beef and cattle prices by an additional 0.2 percent to 0.4 percent, causing gross revenues for the beef and cattle sectors to fall by an additional 0.2 percent to 0.5 percent.

A third scenario considered in the multi-sector analysis is partial restoration of beef exports to Japan, such that U.S. beef exports in 2005 would double, from an expected 0.3 million metric tons to 0.6 million metric tons. In this instance, gross revenue for the cattle sector (assuming 1.5 million head of Canadian cattle are imported) could decline by 1.7 percent, compared to a possible decrease of 3.9 percent assuming no change in U.S. beef exports. For the beef sector, gross revenue losses of 1.3 percent may become gains of 2.2 percent because of the exports to Japan. For both sectors, increased U.S. exports could moderate by at least one-half the price declines due to resumption of cattle imports from Canada.

Monitoring the movement of feeder cattle. Movement within the United States of feeder cattle (and feeder lambs and goats) imported from a BSE minimal-risk region such as Canada—from the U.S. port of entry to a feedlot and from the feedlot to slaughter—will require that certain inspection and record keeping safeguards be satisfied. The increased cost of these requirements is considered a cost to this rulemaking. These include certification of each animal's identification (by eartag and branding), age, and feeding history. Feeder cattle will be listed on the APHIS Form VS 17–130 that accompanies the animals from the port of entry and on the APHIS Form VS 1–27 that accompanies the animals to slaughter.

Costs of the process can be approximated by considering the time Federal or State officials or their designees would spend monitoring the movement of these cattle. We approximate the cost of performing the inspections and related tasks to be $10 per animal, based on direct salary, personnel benefits, administrative support costs, agency overhead, and departmental charges, and using a simplified example developed by APHIS Veterinary Services. Given the number of feeder cattle that may enter because of the rule, the overall cost in 2005 would be between $4.1 million and $5.2 million

Commodities other than cattle and beef. Other, less major commodities that will be allowed entry under the rule and for which we have data are sheep, goats, and farmed cervids; meat from these ruminants; and bovine tongues and livers. In all cases, reestablished imports from Canada will have small effects on the U.S. supply of these commodities and the welfare of U.S. entities. Feeder lambs and goats will be required to be moved to designated feedlots. As with feeder cattle from Canada, movement of feeder lambs and goats from the port of entry to feedlot and from feedlot to slaughter will be monitored, which will lead to a small cost.

U.S. exports. The rule, of course, will have no immediate effect for U.S. exports to countries that currently prohibit beef imports from the United States. It could influence these countries' future decisions regarding resumption of beef imports from the United States. A country may consider the rule to lend justification to a decision to continue to prohibit entry of U.S. beef because of concern about BSE risks posed by Canadian cattle, even though there would be no scientific basis. In such a case, there would be continued premium losses over and above the domestic value of the products, especially for beef variety meats. On the other hand, resumption of U.S. imports from Canada may help convince other countries of the sanitary safety of both U.S. and Canadian beef. Any effects the rule may have for future U.S. beef exports may vary from one trading partner to another.

Alternatives to the Rule

Alternatives to the rule would be to 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 modify the commodities and/or import requirements specified in the rule. By maintaining current import restrictions, the net benefits of reestablishing imports from Canada of fed and feeder cattle, and beef not by permit, and other affected commodities would not be realized. Two possible modifications would be to (i) require that imported beef come from cattle slaughtered at less than 30 months of age, or (ii) continue to prohibit the entry of live ruminants.

Beef only from cattle less than 30 months of age. The proposed rule would have required beef imports from Canada to come from cattle slaughtered at less than 30 months of age. In a notice that reopened the comment period for the proposed rule, APHIS stated that it no longer believed that it would be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided measures are in place to ensure that SRMs are removed when the animals are slaughtered, and that such other measures as are necessary are in place. Canada is removing SRMs at slaughter and fulfilling other required measures.

Requiring that beef come only from cattle slaughtered at less than 30 months of age would continue the prohibition on Canadian cows and bulls as source animals, and eliminate effects of the rule for beef. Continuing to limit imports from Canada to veal from calves and beef from steers and heifers would cause Canada's cow and bull inventories to continue to grow and exert downward pressure on Canada's cow prices, which are already well below U.S. price levels. Canadian suppliers would be prevented from participating in the current high-demand market in the United States for processing beef, and U.S. processors would not benefit from the additional source of supply during a time when U.S. cow slaughter is cyclically low.

This alternative would maintain the status quo in terms of beef imports, other than removing permit requirements and broadening the commodities allowed to be imported beyond boneless beef. In terms of the quantity of beef imported, we expect that these changes would have a very small effect, given the large share of Canada's historic exports that enter currently.

This alternative would affect cattle imports from Canada by removing the incentive for Canadian cows to be slaughtered in place of fed cattle, since the processing beef would not be allowed to be imported by the United States; there would not be the displaced fed cattle assumed to be available for import under the rule. The number of fed cattle imports would be fewer than

with the rule, especially in 2005, and price and welfare impacts, including net benefits, would be smaller.

Welfare effects of this alternative for cattle and beef are summarized in Table 3. Present values and annualized values of welfare gains and losses over the five-year period 2005–2009 are determined using 3 percent and 7 percent discount rates in both 2005 and 2001 dollars.

TABLE 3.—ALTERNATIVE OF CANADIAN BEEF IMPORTS ONLY FROM CATTLE LESS THAN 30 MONTHS OF AGE: PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF THE EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS 2005–2009

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Present, 2005 dollars	3	$2,399,299	−$2,345,160	$54,139
	7	2,064,181	−2,016,794	47,387
Present, 2001 dollars	3	2,261,339	−2,210,314	51,026
	7	1,945,490	−1,900,828	44,662
Annualized, 2005 dollars	3	523,898	−512,076	11,821
	7	503,434	−491,877	11,557
Annualized, 2001 dollars	3	493,774	−482,632	11,142
	7	474,487	−463,594	10,893

Note: The present and annualized values are midpoints taken from Appendix U, based on the assumed backlog imports.

The present value of the net benefit of the alternative for cattle and beef is estimated to range in 2005 dollars between $47.4 million and $54.1 million, depending on the discount rate used (with the rule: Between $66.3 million and $74.6 million). Over the five-year period, the annualized value of the net benefit in 2005 dollars, depending on the discount rate, may range between $11.6 million and $11.8 million (with the rule: Between $16.2 million and $16.3 million).

The largest effects for cattle are expected to occur in 2005, when the backlog is imported. Since allowing Canadian beef imports only from cattle slaughtered at less than 30 months of age would not affect the number of feeder cattle expected to be imported, effects for feeder cattle would be the same as with the rule.

Possible effects of this alternative for future U.S. exports would differ from possible effects with the rule only if other countries perceived BSE-risks associated with Canadian beef produced from cattle slaughtered at less than 30 months of age as different from those associated with Canadian beef produced from cattle slaughtered at more than 30 months of age.

There would be no known reduction in risk of BSE introduction under this alternative. Removal of SRMs at slaughter and other required risk-mitigating measures of the rule will ensure that beef entering from Canada satisfies animal health criteria the same as or equivalent to those required in the United States.

Near-term price effects of this alternative would be similar to those of this rule. For example, for fed cattle the decrease in price when the backlog is assumed to enter entirely within one quarter is estimated to be 4.4 percent (with the rule: 5.4 percent), assuming a price elasticity of supply of 0.61 and a price elasticity of demand of −0.76. When the backlog of fed cattle is assumed to enter over two quarters using the same price elasticities, the decline in price is estimated to be 2.8 percent (with the rule: 3.8 percent). Entry of the backlog of feeder cattle over the two quarters could result in a price decline of 1.9 percent under this alternative and using the same elasticities, compared to a possible price drop of 3.3 percent when the backlog is assumed to enter entirely within one quarter. The expected effects are the same for feeder cattle under this alternative and with the rule because their number is assumed to be unaffected by whether Canadian beef imports are restricted to being derived from cattle less than 30 months of age. When the supply and demand elasticities are halved (supply elasticity of 0.30, and demand elasticity of −0.38, for example, and fed cattle are assumed to enter within two quarters, the decrease in price is estimated to be 3.6 percent (with the rule, 4.8 percent), compared to a decrease of 2.8 percent (with the rule, 3.8 percent) when a supply elasticity of 0.61 and demand elasticity of −0.76 are used.

No live ruminants. Direct effects of this alternative would be equivalent to expected effects of the rule only for ruminant products. We would expect the same effect for beef as with the rule; imports of beef from cows would replace imports of beef from fed cattle, yielding, for the five-year period 2005–2009, present value losses for consumers of between $73.9 million and $78.8 million, gains for producers of between $73.7 million and $78.5 million, and net welfare losses of between $264,000 and $283,000, compared to the baseline (3 percent discount rate, 2005 dollars). There would also be net benefits forgone by the continued prohibition on the importation of sheep and goats. Possible effects of this alternative on future U.S. exports would likely be small, since it would maintain the current prohibition on imports of live ruminants from Canada.

In sum, the rule is preferable in terms of expected net benefits to the status quo (continuing to prohibit the entry of Canadian ruminants, and the entry of Canadian ruminant products other than those allowed by permit), and to the two alternatives discussed: Limiting beef imports to cattle slaughtered at less than 30 months of age or allowing entry of ruminant products but not live ruminants. Risks of BSE introduction would not be reduced to any known degree by selecting one of the alternatives in place of the rule. We believe that listing Canada as a minimal-risk region subject to the required risk-mitigating measures is a balanced response, based on scientific evidence, to Canada's request that certain ruminant and ruminant product imports by the United States be allowed to resume.

Final Regulatory Flexibility Analysis

As a part of the rulemaking process, APHIS evaluates whether regulations are likely to have a significant economic impact on a substantial number of small entities. The resumption of ruminant and ruminant product imports from Canada will most importantly affect the cattle industry, reducing prices and increasing supplies. Entry of fed cattle

(and fed sheep and goats) will benefit U.S. slaughtering establishments, and entry of feeder cattle (and feeder sheep and goats) will benefit feedlots. Also, entry of beef from cattle slaughtered at over 30 months of age will benefit some U.S. meat and meat product wholesalers and packers by providing an additional source of processing beef. At the same time, these imports will increase the competition for U.S. and foreign suppliers of these commodities.

The main industries expected to be affected by the rule are composed predominantly of small entities, as indicated by the 1997 Economic Census, the 2002 Census of Agriculture, and USDA's ''Cattle on Feed'' (February 20, 2004). The small entities number in the hundreds of thousands, with cattle producers comprising the largest number. For beef cattle ranching and farming, the 2002 Census of Agriculture indicates a total of about 657,000 operations, of which nearly 656,000 are considered small entities. For cattle feedlots, more than 91,000 of the approximately 93,200 total operations are small entities. For sheep and goat farming, 44,000 out of about 44,200 operations are considered small entities. Small entities similarly dominate, in terms of percentage operations, other affected industries, including animal slaughtering, meat and meat byproduct processing, and meat and meat product wholesaling.

Notwithstanding the prevalence of small entities, the concentrated structure of affected industries is well-documented. In the U.S. meatpacking industry, for example, four firms handle nearly 80 percent of all steer and heifer slaughter. The cattle feedlot industry is also highly concentrated. Data from 2003 show that only 2 percent of feedlots have capacities greater than 1,000 head, and yet these larger feedlots market 85 percent of fed cattle.

Imports from Canada that will be allowed to resume are expected to have a larger effect on the fed cattle market than on the feeder cattle market. Prices and welfare of producers and suppliers will decline because of the additional supply and the welfare of consumers and buyers will increase. Net benefits of the rule will be positive.

The analysis provides an estimation of possible price effects for small-entity and other producers and processors during the first 3 to 6 months that the rule is in effect, when impacts may be greatest due to the expected importation of the backlog. Depending on the assumed elasticities of supply and demand and the period over which the backlog enters, the estimated price declines could range from 1.9 percent to 4.4 percent for feeder cattle and from 3.8 percent to 6.9 percent for fed cattle. For the year 2005, the model indicates a possible decline in feeder cattle prices of 1.3 percent and a possible decline in fed cattle prices of 3.2 percent.

To give these average percentage price decline some perspective, we consider as an example their effect on earnings by small U.S. beef cow herds. Based on data from the 2002 Census of Agriculture, the average value of sales of cattle and calves by small-entity beef cow operations was about $26,700. Given the forecast feeder cattle baseline price for 2005 of between $94 and $100 per cwt, the 2005 estimated price decline of 1.3 percent would be equivalent to a decrease of between $1.22 to $1.30 per cwt, or a decrease in annual revenue of between $326 and $347, assuming no reduction in the number of cattle marketed. This example abstracts from the wide range in size for small beef cow herds, but gives an indication of a possible average price effect of the rule for these operators in 2005. It should be recognized that while the decline in price would be a loss for producers, it would represent a gain for small-entity feedlot operators.

Beyond the net welfare gains as summarized in Table 1, there will likely be regional impacts not captured in the analysis. Among comments received on the proposed rule were ones that pointed out the historical reliance of some northern U.S. meat processing plants (and the communities they support) on cattle imports from Canada to maintain necessary throughput volumes. Historical dependence of these processing facilities on cattle imports from Canada exemplifies economic ties with Canadian entities that existed prior to the prohibition on ruminant imports. Resumption of imports will enable trade relationships involving small-entity operations to be reestablished.

Alternatives to the rule, whether leaving the regulations unchanged or modifying the commodities and/or import requirements specified in the rule, would benefit certain categories of small entities while harming others. For example, a continued prohibition on the importation of Canadian feeder cattle would benefit small-entity suppliers of feeder cattle, but at the expense of small-entity feedlot operators. Estimated price declines, particularly in the near term, will cause economic losses for some entities and at the same time benefit other entities. Overall, the analysis indicates the rule will have a net positive effect for the United States.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule has been designated by the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, as a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801–808). Accordingly, the effective date of this rule has been delayed the required 60 days pending congressional review.

Executive Order 12988

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

National Environmental Policy Act

In October 2003, APHIS prepared an environmental assessment to consider potential impacts to the human environment from implementation of the proposed rulemaking. During the comment period for the proposed rulemaking, comments were received from the public regarding the environmental assessment. As a result of those comments, APHIS revised the environmental assessment to discuss in more detail the potential impacts of concern for the human environment.

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 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

APHIS sent copies of the revised environmental assessment to those who commented on the October 2003 environmental assessment, in accordance with 7 CFR 372.9(a)(3). In a separate notice in today's issue of the **Federal Register**, APHIS is announcing the availability of the revised assessment and is requesting comments on the revised assessment for 30 days.

Paperwork Reduction Act

This final rule includes certain regulatory provisions that differ from those included in the November 2003 proposed rule. Some of those provisions involve changes from the information collection requirements set out in the proposed rule. These changes include

the following regarding ruminants from Canada:

- Bovines, sheep, and goats moved from a U.S. port of entry to a feedlot before being moved to slaughter must be accompanied by an APHIS Form VS 17–130, rather than an APHIS Form VS 1–27 as proposed.
- Those animals moved to a feedlot before being moved to slaughter must be permanently identified in Canada as being of Canadian origin with a distinct and legible mark, properly and humanely applied with a freeze brand, hot iron, or other method. This is a change from the proposed requirement that permanent identification be done by tattooing the animal.
- Those animals moved to a feedlot must be individually identified in Canada by an official Canadian eartag. This requirement was not in the proposed rule.
- The owners of feedlots wishing to be considered designated feedlots must sign an agreement with APHIS. This requirement was not in the proposed rule.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0234.

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 rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at 301–734–7477.

References

1. Office International des Epizooties, Terrestrial Animal Health Code, ''Bovine Spongiform Encephalopathy,'' Chapter 2.3.13, available at *http://www.oie.int.*

2. Office International des Epizooties, Terrestrial Animal Health Code, available at *http://www.oie.int.*

3. Harvard Center for Risk Analysis—Harvard School of Public Health, and Center for Computational Epidemiology—College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,'' (2001), available at *http://www.aphis.usda.gov/lpa/issues/bse/risk_assessment/mainreporttext.pdf;* Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States'' (2003), available at *http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf.*

4. USDA and FDA, ''A Case of Bovine Spongiform Encephalopathy (BSE) in the United States'' (March 2004), available at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_tr_ban%20_ltr_enc_1.pdf.*

5. USDA, FSIS Notice 5–04, ''Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination'' (January 12, 2004), available at *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/rdad/fsisnotices/5–04.pdf;* USDA, FSIS Notice 7–04, ''Questions and Answers for FSIS Notice 4–04 Regarding FSIS BSE Regulations'' (January14, 2004), available at *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/rdad/fsisnotices/7–04.pdf;* USDA, FSIS Notice 9–04, ''Verification Instructions for the Interim Final Rule Regarding Specified Risk Materials (SRMs) in Cattle'' (January 23, 2004), available at *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/rdad/fsisnotices/9–04.pdf;* USDA, FSIS Notice 10–04, ''Questions and Answers, Regarding the Age Determination of Cattle and Sanitation'' (January 29, 2004), available at *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/rdad/fsisnotices/10–04.pdf*

6. FDA, ''CVM Update: July 2004 Update on Ruminant Feed (BSE) Enforcement Activities,'' (July 29, 2004), available at *http://www.fda.gov/cvm/index/updates/bse72004up.htm.*

7. Research Triangle Institute, ''Review of the Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States'' (October 31, 2002), available at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_Peer_Review.pdf.*

8. Joshua T. Cohen and George M. Gray, Harvard Center for Risk Analysis, Harvard School of Public Health, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States: Response to Reviewer Comments submitted by Research Triangle Institute (RTI project number 07182.024)'' (October 31, 2003), available at *http://www.hcra.harvard.edu/pdf/ResponsetoComments.pdf.*

9. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,'' pg. 111 (2003), available at *http://www.hcra.harvard.edu/pdf/madcow.pdf.*

10. Joshua T. Cohen and George M. Gray, Harvard Center for Risk Analysis—Harvard School of Public Health, ''Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada'' (2003) available at *http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf.*

11. Evans, Brian, Chief Veterinary Officer, Memo to Dr. John Clifford, Deputy Administrator at APHIS (July 30, 2004).

12. Morley, R.S., S. Chen, and N. Rheault, ''Assessment of the Risk Factors Related to Bovine Spongiform Encephalopathy,'' *Revue Scientifique et Techique Office International des Epizooties* 22(1):157–78 (2003), available at *http://www.oie.int/eng/publicat/rt/2201/10.%20Morley.pdf;* Canadian Food Inspection Agency, Science Branch, Animal Health Risk Analysis, ''Risk Assessment on Bovine Spongiform Encephalopathy in Cattle in Canada'' (2002), available at *http://www.inspection.gc.ca/english/sci/ahra/bseris/bserise.shtml.*

13. Canadian Food Inspection Agency, ''Summary of the Report of the Investigation of Bovine Spongiform Encephalopathy (BSE) in Alberta Canada'' (2003), available at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/evalsume.shtml.*

14. International Review Team, ''Report on Actions Taken by Canada in Response to the Confirmation of an Indigenous Case of BSE'' (2003), available at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/internate.shtml.* See also Government of Canada, ''News Release: Minister's Comment on International Report on BSE'' (June 26, 2003), available at *http://www.inspection.gc.ca/english/corpaffr/newcom/2003/20030626e.shtml.*

15. Canadian Food Inspection Agency, ''BSE in North America; Specified Risk Materials,'' *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/srmmrse.shtml.*

16. Canadian Food Inspection Agency, ''BSE in North America; Surveillance and Animal Tracking,'' *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/surv/protecte.shtml.*

17. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States'' (2003), pg. 53, available at *http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf.*

18. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States'' (2003), Appendix 1, pg. 29, available at *http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/appendix_1.pdf.*

19. Office International des Epizooties, Terrestrial Animal Health Code, ''Guidelines for Risk Analysis,'' Chap. 1.3.2, Art. 1.3.2.3, available at *http://www.oie.int.*

20. USDA, ''News Release: Veneman Announces Expanded BSE Surveillance Program'' (March 15, 2004), available at *http://www.usda.gov/Newsroom/0105.04.html.*

21. USDA, APHIS, Veterinary Services, ''Analysis of Risk—Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004,'' available at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.*

22. Kirkwood, J. K. and A. A. Cunningham, ''Epidemiological Observations on Spongiform Encephalopathies in Captive Wild Animals in the British Isles,'' *Veterinary Record* 135:296–303 (1994).

23. Office International des Epizooties, Terrestrial Animal Health Code, ''Bovine Spongiform Encephalopathy,'' Chap. 2.3.13, Art. 2.3.13.15 and Art. 2.3.13.19, available at *http://www.oie.int.*

24. Prince, M.J., et. al., ''Bovine Spongiform Encephalopathy,'' *Revue Scientifique et Techique, Office International des Epizooties* 22(1):37–60 (2003).

25. Brown, Paul, et. al., ''Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease: Background, Evolution, and Current Concerns,'' *Emerging Infectious Diseases* 7(1):6–16 (2001), available at *http://www.cdc.gov/ncidod/eid/vol7no1/brown.htm.*

26. USDA, ''Official United States Standards for Grades of Slaughter Lambs, Yearlings and Sheep'' (1992), available at *http://www.ams.usda.gov/lsg/stand/standards/sl-lamb.pdf.* See also, e.g., ''Labeling Standards for Ovine Carcasses, Parts of Carcasses, Meat and Meat Food Products,'' Docket No. 97–030A, November 21, 1997; 62 FR 62271–62273.

27. Comer, P.J. and P.J. Huntley, ''Exposure of the Human Population to BSE Infectivity over the Course of the BSE Epidemic in Great Britain and the Impact of Changes to the *Over Thirty Month Rule,'' Over Thirty Month Rule (OTMR) Review Paper* (June 2003), available at *http://www.food.gov.uk/multimedia/pdfs/otmcomer.pdf.*

28. European Union Scientific Steering Committee, ''Revised Opinion and Report on: The Safety of Tallow Obtained from Ruminant Slaughter By-Products'' (adopted June 28–29, 2001), available at *http://europa.eu.int/comm/food/fs/sc/ssc/out228_en.pdf.*

29. European Union Scientific Steering Committee, ''Listing of Specified Risk Materials: A Scheme for Assessing Relative Risks to Man'' (adopted December 9, 1997), available at *http://europa.eu.int/comm/food/fs/sc/ssc/out22_en.pdf.*

30. Brown, P., R. G. Rohwer, B. C. Dunstan, C. MacAuley, D. C. Gajdusek, and W. N. Drohan, ''The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy,'' *Transfusion* 38:810–816 (1998); Manuelidis, E. E., E.J. Gorgacz, L. Manuelidis, ''Transmission Creutzfeldt-Jakob Disease with Scrapie-Like Syndromes to Mice,'' *Nature* 271:778–779 (1978).

31. Center for Disease Control, ''Bovine Spongiform Encephalopathy in a Dairy Cow— Washington State, 2003,'' *MMWR Weekly* 52(53):1280–1285 (2004).

32. Codex Alimentarius Commission, ''Principles and Guidelines for the Conduct of Microbiological Risk Assessment,'' Section 4—Guidelines for Application, CAC/GL–30 (1999), available at *http://www.codexalimentarius.net/web/standard_list.do?lang=en.*

33. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States'' (2003), pg. 2, available at *http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf.*

34. USDA, ''Report of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases: Measures Relating to Bovine Spongiform Encephalopathy in the United States'' (February 13, 2004), available at *http://cofcs66.aphis.usda.gov/lpa/issues/bse/bse_sec_adv_comm.pdf.*

35. The Secretary's Foreign Animal and Poultry Disease Advisory Committee's Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Encephalopathy or International Review Team (IRT), ''Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States'' (2004), available at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_tr_ban_ltr%20_enc_2.pdf.*

36. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,'' pg. vii-viii (2003), available at *http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf.*

37. Gray, G. Cohen, J., Harvard Center for Risk Analysis, Harvard School of Public Health, ''Response to Comments Submitted in Response to USDA's Proposed Rule on Importing Beef and Beef Products from Canada'' (June 18, 2004).

38. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,'' Section 4.4.1—Switzerland (2003), available at *http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf.*

39. Yamakawa, Y., K. Hagiwara, K. Nohtomi, et al, ''For the Expert Committee for BSE Diagnosis, Ministry of Health, Labour and Welfare of Japan: Atypical Proteinase K-Resistant Prion Protein (PrPres) Observed in an Apparently Healthy 23-Month-Old Holstein Steer,'' *Jpn J Infect Dis* 56:221–222 (2003), available at *http://www.nih.go.jp/JJID/56/221.pdf* and Casalone, C., G. Zanusso, PL. Acutis, et al, ''Identification of a Novel Molecular and Neuropathological BSE Phenotype in Italy: International Conference on Prion Disease: From Basic Research to Intervention Concepts,'' 8–10 (October, 2003).

40. Scientific Steering Committee, ''Opinion on TSE Infectivity Distribution in Ruminant Tissues (State of Knowledge, December 2001)'' (Adopted January 10–11, 2002),

available at *http://europa.eu.int/comm/food/fs/sc/ssc/out241_en.pdf.*

41. Wilesmith, JW et. al., ''A Cohort Study to Examine Maternally-Associated Risk Factors for Bovine Spongiform Encephalopathy,'' *Veterinary Record* 141:239–243 (1997).

42. FSIS, ''Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter; Bovine Spongiform Encephalopathy Surveillance Program; Interim Final Rules and Notice,'' Docket No 03–025IF, 69 FR 1861–1874 (January 12, 2004).

43. Mulkey, David and Alan W. Hodges, ''Using IMPLAN to Assess Local Economic Impacts,'' (last visited December 6, 2004), available at *http://hortbusiness.ifas.ufl.edu/usingimplan.pdf.*

44. OMB, ''Circular A–4: Regulatory Analysis'' (September 17, 2003).

45. USDA Economic Research Service, ''Dissecting the Challenges of Mad Cow and Foot-and-Mouth Disease,'' *Agricultural Outlook* 4–5 (Aug. 2001), available at *http://www.ers.usda.gov/publications/AgOutlook/aug2001/AO283c.pdf.*

46. United States Meat Export Federation,—Methodology and Results of the Value of Beef Exports,'' pp. 8–9 (2002), available at *http://www.cattle-fax.com/special/files/beefvalue_method_02.pdf.*

47. FDA, ''Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed,'' Docket No 02N–0273, 67 FR 67572–67573 (November 6, 2002).

48. The guidelines are discussed in WHO, ''Joint WHO/FAO/OIE Technical Consultation on BSE: Public Health, Animal Health and Trade'' (June 11–14, 2001), available at *http://www.who.int/emc-documents/tse/docs/whocdscsraph20018.pdf.*

49. Prince, M.J., et. al., ''Bovine Spongiform Encephalopathy,'' *Revue scientifique et technique, Office International des Epizooties* 22(1) 37–60 (2003); Wilesmith, J.W., ''The Epidemiology of Bovine Spongiform Encephalopathy,'' *Seminars in Virology* 2:239–45 (1991); Wilesmith, J.W., et. al., ''Bovine Spongiform Encephalopathy: Epidemiological Studies,'' *Veterinary Record* 123:638–644 (1988).

50. AMS USDA, ''Country of Origin Labeling—Current Status of Country of Origin Labeling,'' available at *http://www.ams.usda.gov/cool/status.htm.*

List of Subjects

9 CFR Part 93

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

9 CFR Part 94

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

9 CFR Part 95

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

9 CFR Part 96

Imports, Livestock, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR parts 93, 94, 95, and 96 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 continues to read as follows:

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

■ 2. Section 93.400 is amended by revising the definitions of *flock* and *inspector* and adding definitions of *as a group, bovine, bovine spongiform encephalopathy (BSE) minimal risk region, camelid, cervid, designated feedlot, positive for a transmissible spongiform encephalopathy, premises of origin, State representative, suspect for a transmissible spongiform encephalopathy,* 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.

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

Bovine spongiform encephalopathy (BSE) minimal risk region. A region listed in § 94.18(a)(3) of this subchapter.

* * * * *

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

* * * * *

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

* * * * *

Designated feedlot. A feedlot that has been designated by the Administrator as one that is eligible to receive sheep and goats imported from a BSE minimal-risk region and whose owner or legally responsible representative has signed an agreement in accordance with § 93.419(d)(8) of this subpart to adhere to, and is in compliance with, the requirements for a designated feedlot.

* * * * *

Flock. Any group of one or more sheep maintained on common ground; or two or more groups of sheep under common ownership or supervision on two or more premises that are geographically separated, but among which there is an interchange or movement of animals.

* * * * *

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this subpart.

* * * * *

Positive for a transmissible spongiform encephalopathy. A sheep or goat for which a diagnosis of a transmissible spongiform encephalopathy has been made.

Premises of origin. Except as otherwise used in § 93.423 of this subpart, the premises where the animal was born.

* * * * *

State representative. A veterinarian or other person employed in livestock sanitary work by a State or political subdivision of a State who is authorized by such State or political subdivision of a State to perform the function involved under a memorandum of understanding with APHIS.

Suspect for a transmissible spongiform encephalopathy. (1) A sheep or goat that has tested positive for a transmissible spongiform encephalopathy or for the proteinase resistant protein associated with a transmissible spongiform encephalopathy, unless the animal is designated as positive for a transmissible spongiform encephalopathy; or

(2) A sheep or goat that exhibits any of the following signs and that has been determined to be suspicious for a transmissible spongiform encephalopathy by a veterinarian: Weight loss despite retention of appetite; behavior abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor

abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, ''star gazing,'' head pressing, recumbency, or other signs of neurological disease or chronic wasting.

* * * * *

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. Section 93.405 is amended as follows:

■ a. A new paragraph (a)(4) is added to read as set forth below.

■ b. In paragraphs (b)(2) introductory text, (c)(2), and (c)(3) the phrase ''Australia, Canada, and New Zealand'' is removed and the phrase ''Australia and New Zealand'' is inserted in its place.

■ c. In paragraph (c)(3), the phrase ''Australia, Canada, New Zealand, or the United States'' is removed and the phrase ''Australia, New Zealand, or the United States'' is added in its place.

■ d. The Office of Management and Budget citation at the end of the section is revised to read as set forth below.

§ 93.405 Certificate for ruminants.

(a) * * *

(4) If the ruminants are bovines, sheep, or goats from regions listed as BSE minimal-risk regions in § 94.18(a)(3) of this subchapter, the certificate must also include the name and address of the importer; the species, breed, and number or quantity of ruminants to be imported; the purpose of the importation; individual ruminant identification, which includes the eartag required under § 93.419(d)(2) or § 93.436(b)(4) of this subchapter, and any other identification present on the animal, including registration number, if any; a description of the ruminant, including name, age, color, and markings, if any; region of origin; the address of or other means of identifying the premises of origin and any other premises where the ruminants resided immediately prior to export, including the State or its equivalent, the municipality or nearest city, or an equivalent method, approved by the Administrator, of identifying the location of the premises, and the specific physical location of the feedlot where the ruminants are to be moved after importation; the name and address of the exporter; the port of embarkation in the foreign region; and the mode of transportation, route of travel, and port of entry in the United States.

* * * * *

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

■ 4. In § 93.419, new paragraphs (c) and (d) are added to read as follows:

§ 93.419 Sheep and goats from Canada.

* * * * *

(c) Any sheep or goats imported from Canada must be less than 12 months of age when imported into the United States and when slaughtered, and must be from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000. The animals must be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government that states that the conditions of this paragraph have been met. Additionally, for sheep and goats imported for other than immediate slaughter, the certificate must state that the conditions of paragraphs (d)(1) and (d)(2) of this section have been met. For sheep and goats imported for immediate slaughter, the certificate must also state that:

(1) The animals have not tested positive for and are not suspect for a transmissible spongiform encephalopathy.

(2) The animals have not resided in a flock or herd that has been diagnosed with BSE; and

(3) The animals' movement is not restricted within Canada as a result of exposure to a transmissible spongiform encephalopathy.

(d) *Imported for feeding.* Any sheep or goats imported from Canada for feeding at a feedlot must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) in a means of conveyance sealed in the region of origin with seals of the national government of the region of origin, must be moved directly as a group from the port of entry to a designated feedlot, must not be commingled with any sheep or goats that are not being moved directly to slaughter from the designated feedlot at less than 12 months of age, and must meet the following conditions:

(1) The sheep and goats must be permanently and humanely identified before arrival at the port of entry with a distinct and legible ''C'' mark, properly applied with a freeze brand, hot iron, or other method, and easily visible on the live animal and on the carcass before skinning. The mark must be not less than 1 inch or more than 1¼ inches high. Other means of permanent identification may be used upon request if deemed adequate by the Administrator to humanely identify the animal in a distinct and legible way as having been imported from Canada;

(2) Each sheep and goat must be individually identified by an official Canadian Food Inspection Agency eartag, applied before the animal's arrival at the port of entry into the United States, that is determined by the Administrator to meet standards equivalent to those for official eartags in the United States as defined in § 71.1 of this chapter and to be traceable to the premises of origin of the animal. No person may alter, deface, remove, or otherwise tamper with the individual identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at the time of slaughter;

(3) The animals may be moved from the port of entry only to a feedlot designated in accordance with paragraph (d)(8) of this section and must be accompanied from the port of entry to the designated feedlot by APHIS Form VS 17–130 or other movement documentation deemed acceptable by the Administrator, which must identify the physical location of the feedlot, the individual responsible for the movement of the animals, and the individual identification of each animal, which includes the eartag required under paragraph (d)(2) of this section and any other identification present on the animal, including registration number, if any;

(4) The seals of the national government of Canada must be broken only at the port of entry by the APHIS port veterinarian or at the designated feedlot by an accredited veterinarian or a State or USDA representative or his or her designee. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the designated feedlot;

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

(6) The animals must be accompanied to the recognized slaughtering establishment by APHIS Form VS 1–27 or other documentation deemed acceptable by the Administrator, which must identify the physical location of the recognized slaughtering establishment, the individual responsible for the movement of the animals, and the individual identification of each animal, which includes the eartag required under paragraph (d)(2) of this section and any other identification present on the animal, including registration number, if any;

(7) The animals must be less than 12 months of age when slaughtered;

(8) To be approved to receive sheep or goats imported for feeding, a feedlot must have signed a written agreement with the Administrator stating that the feedlot:

(i) Will not remove eartags from animals unless medically necessary, in which case another eartag or other form of official identification, as defined in § 79.1 of this chapter, will be applied and cross referenced in the records;

(ii) Will monitor all incoming imported feeder animals to ensure that they have the required ''C'' brand;

(iii) Will maintain records of the acquisition and disposition of all imported sheep and goats entering the feedlot, including the Canadian Food Inspection Agency tag number and all other identifying information, the age of each animal, the date each animal was acquired and the date each animal was shipped to slaughter, and the name and location of the plant where each animal was slaughtered. For Canadian animals that die in the feedlot, the feedlot will remove its eartag and place it in a file along with a record of the disposition of the carcass;

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

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

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

(vii) Will designate either the entire feedlot or pens within the feedlot as terminal for sheep and goats to be moved only directly to slaughter at less than 12 months of age, and

(viii) Agrees that if inventory cannot be reconciled or if animals are not moved to slaughter as required the approval of the feedlot will be immediately withdrawn.

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

■ 5. Section 93.420 is revised to read as follows:

§ 93.420 Ruminants from Canada for immediate slaughter.

(a) Ruminants imported from Canada for immediate slaughter must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) in a means of conveyance sealed in Canada with seals of the Canadian Government, and must be moved directly as a group from the port of entry to a recognized slaughtering establishment for slaughter as a group. The seals must be broken only at the port of entry by the APHIS port veterinarian or at the recognized slaughtering establishment by an accredited veterinarian or a State or USDA representative or his or her designee. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the recognized slaughtering establishment. The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33, which shall include the location of the recognized slaughtering establishment. Such ruminants shall be inspected at the port of entry and otherwise handled in accordance with § 93.408.

(b) In addition to meeting the requirements of paragraph (a) of this section, sheep and goats imported from Canada for immediate slaughter must meet the requirements of § 93.419(c) as well as the following conditions:

(1) The animals have not tested positive for and are not suspect for a transmissible spongiform encephalopathy;

(2) The animals have not resided in a flock or herd that has been diagnosed with BSE; and

(3) The animals' movement is not restricted within Canada as a result of exposure to a transmissible spongiform encephalopathy.

■ 6. An undesignated center heading ''Additional General Provisions'' is added preceding reserved § 93.430.

■ 6a. A new § 93.436 is 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 and when slaughtered;

(2) The bovines must have been subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(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, and the certificate 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) in a means of conveyance sealed in the region of origin with seals of the national government of the region of origin, and must be moved directly as a group from the port of entry to a recognized slaughtering establishment. The seals must be broken only at the port of entry by the APHIS port veterinarian or at the recognized slaughtering establishment by a USDA representative. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the recognized slaughtering establishment;

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

(6) At the recognized slaughtering establishment, the bovines must be slaughtered as a group.

(b) *Bovines for feeding.* Bovines from a region listed in § 94.18(a)(3) of this subchapter may be imported for movement to a feedlot and then to 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 have been subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(3) The bovines must be permanently and humanely identified before arrival at the port of entry with a distinct and legible mark identifying the exporting country, properly applied with a freeze brand, hot iron, or other method, and easily visible on the live animal and on the carcass before skinning. The mark must be not less than 2 inches nor more than 3 inches high, and must be applied to each animal's right hip, high on the tail-head (over the junction of the sacral and first cocygeal vertebrae). Other means of permanent identification may be used upon request if deemed adequate by the Administrator to humanely identify the animal in a distinct and legible way as having been imported from the BSE minimal-risk exporting region. Bovines exported from Canada must be so marked with ''CAN;''

(4) Each bovine must be individually identified by an official eartag of the country of origin, applied before the animal's arrival at the port of entry into the United States, that is determined by the Administrator to meet standards equivalent to those for official eartags in the United States as defined in § 71.1 of this chapter and to be traceable to the premises of origin of the animal. No person may alter, deface, remove, or otherwise tamper with the individual identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at the time of slaughter;

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

(6) The bovines must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) in a means of conveyance sealed in the region of origin with seals of the national government of the region of origin, and must be moved directly from the port of entry as a group to the feedlot identified on the APHIS VS Form 17–130 or other movement documentation required under paragraph (b)(8) of this section;

(7) The seals of the national government of the region of origin must be broken only at the port of entry by the APHIS port veterinarian or at the feedlot by an accredited veterinarian or a State or USDA representative or his or her designee. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the feedlot;

(8) The bovines must be accompanied from the port of entry to the feedlot by APHIS Form VS 17–130 or other movement documentation deemed acceptable by the Administrator, which must identify the physical location of the feedlot, the individual responsible for the movement of the animals, and the individual identification of each animal, which includes the eartag required under paragraph (b)(4) of this section and any other identification present on the animal, including registration number, if any;

(9) The bovines must remain at the feedlot until transported from the feedlot to a recognized slaughtering establishment for slaughter;

(10) The bovines must be moved directly from the feedlot identified on APHIS Form VS 17–130 to a recognized slaughtering establishment in conveyances that must be sealed at the feedlot with seals of the U.S. Government by an accredited veterinarian or a State or USDA representative. The seals may be broken only at the recognized slaughtering establishment by a USDA representative.

(11) The bovines must be accompanied from the feedlot to the recognized slaughtering establishment by APHIS Form VS 1–27 or other movement documentation deemed acceptable by the Administrator, which must identify the physical location of the recognized slaughtering establishment, the individual responsible for the movement of the animals, and the individual identification of each animal, which includes the eartag required under paragraph (b)(4) of this section and any other identification present on the animal, including registration number, if any; and

(12) The bovines must be less than 30 months of age when slaughtered.

(c) *Sheep and 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 conditions set forth in this subpart for such sheep and goats. The conditions for the importation of sheep and goats from Canada for immediate slaughter are set forth in §§ 93.419(c) and 93.420.

(d) *Sheep and goats for feeding.* Sheep and goats from a region listed in § 94.18(a)(3) of this subchapter may be imported for other than immediate slaughter under the conditions set forth in this subpart for such sheep and goats. The conditions for the importation of sheep and goats from Canada for other than immediate slaughter are set forth in §§ 93.405 and 93.419.

(e) *Cervids.* There are no BSE-related restrictions on the importation of cervids from a region listed in § 94.18(a)(3) of this subchapter.

(f) *Camelids.* There are no BSE-related restrictions on the importation of camelids from a region listed in § 94.18(a)(3) of this subchapter.

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

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

■ 7. The authority citation for part 94 continues 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; 7 CFR 2.22, 2.80, and 371.4.

■ 8. Section 94.0 is amended by revising the definitions of *authorized inspector* and *cervid* and adding new definitions of *bovine, bovine spongiform encephalopathy (BSE) minimal-risk region, Food Safety and Inspection Service, personal use, positive for a transmissible spongiform encephalopathy, specified risk materials (SRMs),* and *suspect for a transmissible spongiform encephalopathy,* in alphabetical order, to read as follows:

§ 94.0 Definitions.

* * * * *

Authorized inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

* * * * *

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

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 in an indigenous ruminant, 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 recommendations of the World Organization for Animal Health (Office International des Epizooties) for surveillance for BSE; and

(iii) A ruminant-to-ruminant feed ban that is in place and is effectively enforced.

(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.

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

* * * * *

Food Safety and Inspection Service. The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture.

* * * * *

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

* * * * *

Positive for a transmissible spongiform encephalopathy. A sheep or goat for which a diagnosis of a transmissible spongiform encephalopathy has been made.

* * * * *

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

Suspect for a transmissible spongiform encephalopathy. (1) A sheep or goat that has tested positive for a transmissible spongiform encephalopathy or for the proteinase resistant protein associated with a transmissible spongiform encephalopathy, unless the animal is designated as positive for a transmissible spongiform encephalopathy; or

(2) A sheep or goat that exhibits any of the following signs and that has been determined to be suspicious for a transmissible spongiform encephalopathy by a veterinarian: Weight loss despite retention of appetite; behavior abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, ''star gazing,'' head pressing, recumbency, or other signs of neurological disease or chronic wasting.

* * * * *

§ 94.1 [Amended]

■ 9. In § 94.1, paragraph (b)(4) and the introductory text to paragraph (d) are amended by removing the reference to ''§ 94.21'' each time it appears and adding in its place a reference to ''§ 94.22''.

■ 10. Section 94.18 is amended as follows:

■ a. In paragraph (a)(1), the word ''Canada,'' is removed.

■ b. Paragraph (a)(3) is redesignated as paragraph (a)(4) and newly redesignated paragraph (a)(4) is revised to read as set forth below.

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

■ d. In paragraph (d), the introductory text and paragraph (d)(3) are revised and a new paragraph (d)(5) is added 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) of 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 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(f) have been met:

* * * * *

(d) *Transit shipment of articles.* Meat, meat products, and edible products other than meat that are prohibited importation into the United States in accordance with this section may transit air and ocean ports in the United States for immediate export if the conditions of paragraph (d)(1) through (d)(4) of this section are met. If such commodities are derived from bovines, sheep, or goats from a region listed in paragraph (a)(3) of this section, they are eligible to transit the United States by overland transportation if the requirements of paragraphs (d)(1) through (d)(5) of this section are met:

* * * * *

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

* * * * *

(5) The commodities must be eligible to enter the United States in accordance with § 94.19 and must be accompanied by the certification required by that section. Additionally, the following conditions must be met:

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

(ii) The commodities must not be transloaded while in the United States;

(iii) A copy of the import permit required under paragraph (d)(1) of this section must be presented to the inspector at the port of arrival and the port of export in the United States.

* * * * *

§§ 94.19 through 94.25 [Redesignated as §§ 94.20 through 94.26]

■ 11. Sections 94.19 through 94.24 are redesignated as §§ 94.20 through 94.26, respectively.

■ 12. A new § 94.19 is 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 meat, meat products, and edible products other than meat (excluding gelatin that meets the conditions of § 94.18(c), milk, and milk products), from bovines, sheep, or goats that have been in any of the regions listed in § 94.18(a)(3) is prohibited. The commodities listed in paragraphs (a) through (f) of this section may be imported from a region listed in

§ 94.18(a)(3) if the conditions of this section are met; if (except for commodities described in paragraph (e) of this section) 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; and if all other applicable requirements of this part are met.

(a) *Meat, meat byproducts, and meat food products from bovines.* The meat, meat byproduct, or meat food product, as defined by FSIS in 9 CFR 301.2—that those terms as applied to bison shall have a meaning comparable to those provided in 9 CFR 301.2 with respect to cattle, sheep, and goats—is derived from bovines that have been subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000 and meets the following conditions:

(1) The meat, meat byproduct, or meat food product is derived from bovines for which an air-injected stunning process was not used at slaughter; and

(2) The SRMs and small intestine of the bovines were removed at slaughter.

(b) *Whole or half carcasses of bovines.* The carcasses are derived from bovines for which an air-injected stunning process was not used at slaughter and that meet the following conditions:

(1) The bovines are subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000; and

(2) The SRMs and small intestine of the bovines were removed at slaughter.

(c) *Meat, meat byproducts, and meat food products from sheep or goats or other ovines or caprines.* The meat, meat byproduct, or meat food product, as defined by FSIS in 9 CFR 301.2, is derived from ovines or caprines that are from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000, that were less than 12 months of age when slaughtered, and that meet the following conditions:

(1) The animals 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;

(2) The animals did not test positive for and were not suspect for a transmissible spongiform encephalopathy;

(3) The animals have not resided in a flock or herd that has been diagnosed with BSE; and

(4) The animals' movement is not restricted within Canada as a result of exposure to a transmissible spongiform encephalopathy.

(d) *Carcasses of ovines and caprines.* The carcasses are derived from ovines or caprines that are from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000, that were less than 12 months of age when slaughtered, and that meet the following conditions:

(1) The animals 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;

(2) The animals did not test positive for and were not suspect for a transmissible spongiform encephalopathy;

(3) The animals have not resided in a flock or herd that has been diagnosed with BSE; and

(4) The animals' movement is not restricted within Canada as a result of exposure to a transmissible spongiform encephalopathy.

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

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

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

(f) *Gelatin other than that allowed importation under § 94.18(c).* The gelatin is derived from the bones of bovines subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000 and from which SRMs and small intestine were removed.

(g) *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

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

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

■ 14. Section 95.1 is amended by revising the definition of *inspector* and adding new definitions of *bovine, bovine spongiform encephalopathy (BSE) minimal-risk region, offal, positive for a transmissible spongiform encephalopathy, specified risk materials (SRMs), and suspect for a transmissible spongiform encephalopathy,* in alphabetical order, to read as follows:

§ 95.1 Definitions.

* * * * *

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

Bovine spongiform encephalopathy (BSE) minimal-risk region. A region listed in § 94.18(a)(3) of this subchapter.

* * * * *

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland

Security, to enforce the regulations in this part.

* * * * *

Offal. The inedible 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.

Positive for a transmissible spongiform encephalopathy. A sheep or goat for which a diagnosis of a transmissible spongiform encephalopathy has been made.

* * * * *

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

Suspect for a transmissible spongiform encephalopathy. (1) A sheep or goat that has tested positive for a transmissible spongiform encephalopathy or for the proteinase resistant protein associated with a transmissible spongiform encephalopathy, unless the animal is designated as positive for a transmissible spongiform encephalopathy; or

(2) A sheep or goat that exhibits any of the following signs and that has been determined to be suspicious for a transmissible spongiform encephalopathy by a veterinarian: Weight loss despite retention of appetite; behavior abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, ''star gazing,'' head pressing, recumbency, or other signs of neurological disease or chronic wasting.

* * * * *

■ 15. Section 95.4 is amended as follows:

■ a. In paragraph (a) introductory text, the words ''paragraphs (c) through (f)'' are removed and the words ''paragraphs (c) through (h)'' are added in their place.

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

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

■ d. Paragraph (c)(6) is revised to read as set forth below.

■ e. Paragraph (f) is redesignated as paragraph (h).

■ f. New paragraphs (f) and (g) are added to read as set forth below.

■ g. In newly redesignated paragraph (h), the introductory text, paragraph (h)(3) introductory text, and paragraph (h)(4) are revised 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 origin 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 § 94.18(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 derived from bovines that have not been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter;

(2) The tallow is composed of less than 0.15 percent insoluble impurities;

(3) After processing, the tallow was not exposed to or commingled with any other animal origin material; and

(4) 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)(3) of this section have been met; and

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

(g) Offal that is otherwise prohibited importation under paragraph (a)(1) of this section may be imported if the offal is derived from cervids or the offal is derived from bovines, ovines, or caprines from a region listed in § 94.18(a)(3) of this subchapter that have not been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter, and the following conditions are met:

(1) If the offal is derived from bovines, the offal:

(i) Contains no SRMs and is derived from bovines from which the SRMs and small intestine were removed;

(ii) Is derived from bovines for which an air-injected stunning process was not used at slaughter; and

(iii) Is derived from bovines that are subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(2) If the offal is derived from ovines or caprines, the offal:

(i) Is derived from ovines or caprines that were less than 12 months of age when slaughtered and that are from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(ii) Is not derived from ovines or caprines that have tested positive for or are suspect for a transmissible spongiform encephalopathy;

(iii) Is not derived from animals that have resided in a flock or herd that has been diagnosed with BSE; and

(iv) Is derived from ovines or caprines whose movement was not restricted in the BSE minimal-risk region as a result of exposure to a transmissible spongiform encephalopathy.

(3) 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) or (g)(2) of this section have been met; and

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

(h) *Transit shipment of articles.* Articles that are prohibited importation into the United States in accordance with this section may transit air and ocean ports in the United States for immediate export if the conditions of paragraphs (h)(1) through (h)(3) of this section are met. If such commodities are derived from bovines, sheep, or goats from a region listed in§ 94.18(a)(3) of this subchapter, they are eligible to transit the United States by overland transportation if the requirements of paragraphs (h)(1) through (h)(4) of this section are met:

* * * * *

(3) The person moving the articles notifies, in writing, the inspector at both the place in the United States where the articles will arrive and the port of export before such transit. The notification includes the following:

* * * * *

(4) The articles are eligible to enter the United States in accordance with this section and are accompanied by the certification required by this section. Additionally, the following conditions must be met:

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

(ii) The commodities are not transloaded while in the United States;

(iii) A copy of the import permit required under paragraph (h)(2) of this section is presented to the inspector at the port of arrival and the port of export in the United States.

* * * * *

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

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

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

■ 17. In § 96.1, a definition of *authorized inspector* is added in alphabetical order to read as follows:

§ 96.1 Definitions.

* * * * *

Authorized inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this subpart.

* * * * *

■ 18. In § 96.2, paragraph (b) is revised to read as follows:

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

* * * * *

(b) *Bovine or other ruminant casings.* The importation of casings, except stomachs, from bovines and other ruminants that originated in or were processed in any region listed in § 94.18(a) this subchapter is prohibited, except that casings derived from sheep that were slaughtered in a region listed in § 94.18(a)(3) of this subchapter at less than 12 months of age and that were from a flock subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000 may be imported, provided the casings are accompanied by a certificate that states that the casings were derived from sheep that met the conditions of this paragraph and that meets the following conditions:

(1) The certificate is written in English;

(2) The certificate is signed by an individual eligible to issue the certificate required under § 96.3; and

(3) The certificate is presented to an authorized inspector at the port of arrival.

* * * * *

■ 19. In § 96.3, a new paragraph (d) is added to read as follows:

§ 96.3 Certificate for Animal Casings.

* * * * *

(d) In addition to meeting the other requirements of this section, the certificate accompanying sheep casings from a region listed in § 94.18(a)(3) of this subchapter must state that the sheep from which the casings were derived were less than 12 months of age when slaughtered and were subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000.

* * * * *

Done in Washington, DC, this 27th day of December 2004 .

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 04–28593 Filed 12–29–04; 3:00 pm]

BILLING CODE 3410–34–P