Federal Register

Tuesday,

January 9, 2007

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; Importation of Live Bovines and Products Derived From Bovines; Proposed Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 96

[Docket No. APHIS–2006–0041]

RIN 0579–AC01

Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived From Bovines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations regarding the importation of animals and animal products to establish conditions for the importation of the following commodities from regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States: Live bovines for any use born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export; blood and blood products derived from bovines; and casings and part of the small intestine derived from bovines. We are proposing these amendments after conducting a risk assessment and comprehensive evaluation of the issues that concluded that such bovines and bovine products can be safely imported under the conditions described in this proposed rule.

DATES: We will consider all comments that we receive on or before March 12, 2007.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*, select ''Animal and Plant Health Inspection Service'' from the agency drop-down menu, then click ''Submit.'' In the Docket ID column, select APHIS–2006–0041 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS 2006–0041, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS 2006–0041.

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

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

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

For information concerning live ruminants, contact Dr. 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 proposed rule, contact Dr. Lisa Ferguson, Senior Staff Veterinarian, National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737–1231; (301) 734–6954.

SUPPLEMENTARY INFORMATION:

I. Background

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

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

Chronology of APHIS Federal Register Publications Regarding BSE Minimal-Risk Regions

We added the § 94.18(a)(3) category (BSE minimal-risk regions) to the regulations in a final rule published in the **Federal Register** on January 4, 2005 (70 FR 459–553, Docket No. 03–080–3). In the final rule, we specified which commodities may be imported from BSE minimal-risk regions and under what conditions, and recognized Canada as a BSE minimal-risk region. (At this time, Canada is the only recognized BSE minimal-risk region.)

The January 2005 final rule was based on a proposed rule we published in the **Federal Register** on November 4, 2003 (68 FR 62386–62405, Docket No. 03–080–1). On December 25, 2003, less than 2 weeks before the close of the comment period for our proposed rule, a case of BSE in a dairy cow of Canadian origin in Washington State was verified by an international reference laboratory.

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 this development, 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.

On January 5, 2005, along with the final rule, we published in the **Federal Register** a notice (70 FR 554, Docket No. 03–080–4) announcing the availability of, and requesting comments on, a final 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 the final rule. On January 21, 2005, we published in the **Federal Register** a

notice (70 FR 3183–3184, Docket No. 03–080–5) announcing the availability of a corrected version of the EA for public review and comment. On April 8, 2005, we published in the **Federal Register** a finding (70 FR 18252–18262, Docket No. 03–080–7) that the provisions of the final rule would not have a significant impact on the quality of the human environment.

On March 11, 2005, we published a document in the **Federal Register** that gave notice that the Secretary of Agriculture was delaying until further notice the implementation of certain provisions of the final rule with regard to certain commodities (70 FR 12112–12113, Docket No. 03–080–6).

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

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

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

Scope of the January 2005 Final Rule

The regulations established by the January 2005 final rule and subsequent amendments allow the importation from BSE minimal-risk regions of live bovines that are under 30 months of age when imported and when slaughtered and that have been subject to a ruminant feed ban equivalent to that in place in the United States. The risk analysis we conducted for that rule found that, because of the nature, incubation period, and progression of BSE infectivity, young cattle exposed to low levels of BSE will accumulate very little BSE infectivity within the first few years of life, and that cattle under 30 months of age from a BSE minimal-risk region are highly unlikely to have accumulated significant amounts of BSE infectivity even if infected. We concluded, therefore, that the risk to U.S. livestock presented by the importation of such bovines was low.

We did not attempt, for that rulemaking, to assess the BSE risk associated with the importation of live bovines 30 months of age or older from a BSE minimal-risk region. Our March 8, 2004, notice that reopened and extended the comment period on the November 2003 proposed rule stated that APHIS was evaluating the appropriate approach with regard to the importation of live animals 30 months of age or older from BSE minimal-risk regions, and would address that issue in a supplemental rulemaking proposal in the **Federal Register**. The provisions in this proposed rule regarding live bovines are the result of that evaluation.

The regulations established by the January 2005 final rule also allow the importation of the following commodities derived from bovines of any age: (1) Meat, meat food products, and meat byproducts; (2) whole or half carcasses; (3) offal; (4) tallow composed of less than 0.15 percent insoluble impurities that are not otherwise eligible for importation under § 95.4(a)(1)(i) of the regulations; and (5) gelatin derived from bones of bovines that is not otherwise eligible for importation under § 94.18(c) of the regulations.

The January 2005 final rule and subsequent amendments did not change the regulations concerning the importation of blood and blood products from regions listed in § 94.18(a); the requirements for the importation of blood and blood products from BSE minimal-risk regions remain the same as the requirements for importation of blood and blood products from other regions listed in § 94.18(a)—only serum and serum albumin are eligible for importation. The January 2005 final rule also did not change the regulations concerning the importation of bovine casings (defined as intestines, stomachs, esophagi, and urinary bladders) from regions listed in § 94.18(a); the requirements for the importation of bovine casings from BSE minimal-risk regions remain the same as the requirements for importation of bovine casings from other regions listed in § in 94.18(a)—only bovine stomachs are eligible for importation.

The January 2005 final rule and subsequent amendments allowed trade to resume in many, but not all, of the commodities that had been prohibited importation from Canada following detection of a BSE-infected cow in Canada in May 2003. We have continued to consider the BSE risk associated with older bovines and other bovine products from BSE minimal-risk regions—and Canada in particular—including bovine blood and blood products, bovine small intestine other than the distal ileum, and bovine casings, which are the subject of this proposed rule.

Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture may prohibit the importation of any animal or article if the Secretary determines that the prohibition is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. The Secretary has determined that it is not necessary to continue to prohibit the importation from BSE minimal-risk regions (currently only Canada) of live bovines born after the date a feed ban was effectively enforced in the region of export, bovine blood or blood products, bovine small intestine other than the distal ileum, or bovine casings, provided that the conditions described in this proposal are met.[1] This determination is based on a number of factors, which are discussed in this document and, in greater detail, in the risk assessment prepared for this rulemaking. The risk assessment, and the peer review plan and charge for this assessment may be viewed on the Regulations.gov Web site or in our reading room. Instructions for accessing Regulations.gov and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the

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

individuals listed under **FOR FURTHER INFORMATION CONTACT**.

II. BSE and the Government's Role in Protecting Human and Animal Health

A. Nature of BSE

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

The agent that causes BSE has yet to be fully characterized. The theory that is most accepted in the international scientific community is that the agent is an abnormal form of a normal protein known as cellular prion protein. The BSE agent does not evoke a traditional immune response or inflammatory reaction in host animals. BSE is confirmed by post-mortem 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 resistant to heat and to normal sterilization processes.

BSE is not a contagious disease, and therefore is not spread through casual contact between animals. (The possibility of maternal transmission (*i.e.*, from a bovine dam directly to her offspring) was suggested by a 1997 study (Ref 1) conducted in the United Kingdom. However, subsequent studies have shown that it is unlikely that maternal transmission of BSE occurs at any epidemiologically significant level, if it occurs at all (Ref 2)). Scientists believe that the primary route of transmission requires that cattle ingest feed that has been contaminated with a sufficient amount of tissue from an infected animal. This route of transmission can be prevented by excluding potentially contaminated materials from ruminant feed.

B. U.S. Government's Role in Protecting Human and Animal Health

Because variant Creutzfeldt-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, APHIS collaborates with other Federal agencies to implement a coordinated U.S. response to BSE.

Protecting human and animal health from the risks of BSE is carried out on the Federal level primarily by APHIS regarding animal health and the Department's Food Safety and Inspection Service (FSIS) regarding the food safety of meat and poultry, in coordination with the following Centers of the Food and Drug Administration (FDA), U.S. Department of Health and Human Services: The Center for Veterinary Medicine regarding animal feed and animal drugs; the Center for Food Safety and Applied Nutrition regarding foods other than meat, poultry, and egg products; the Center for Biologics Evaluation and Research regarding blood and blood products and other products; the Center for Drug Evaluation and Research regarding drugs containing bovine material; and the Center for Devices and Radiological Health regarding devices containing bovine material.

APHIS recognizes that, although Federal agencies may differ somewhat in their specific mandates, it is necessary to conduct a coordinated Federal effort to safeguard human and animal health. We consider it important to base APHIS' regulatory actions on the best scientific evidence. Additionally, as the agencies make BSE-related documents available for public comment, or otherwise solicit public response, the agencies share and discuss information received.

Of recent note is information solicited and received by FSIS between July and October 2006 regarding the 2005 updated Harvard Risk Assessment of BSE associated with public health exposure. FSIS discussed with APHIS and FDA public comments it received in response to a notice of availability (71 FR 39282–39283, Docket No. FSIS–2006–0011, published in the **Federal Register** July 12, 2006) and a public technical meeting regarding the risk assessment and the potential of BSE exposure and animal health. APHIS has taken relevant comments received into consideration with regard to its risk assessment for this proposed rule.

III. Commodities Covered by This Proposed Rule

This rule would amend the APHIS regulations as they apply to the importation of the following commodities from BSE minimal-risk regions:

- Live bovines;
- Blood and blood products derived from bovines;
- Small intestine, other than the distal ileum, derived from bovines; and
- Casings derived from bovines.

This part of the Supplementary Information section of this proposed rule discusses the risks associated with each commodity, mitigations that address the risk, and how we propose to amend the regulations to allow the importation of these commodities.

A. Live Bovines

BSE Transmission

As noted above under ''Nature of BSE,'' oral ingestion of feed contaminated with the BSE agent is the only documented route of field transmission of BSE (Ref 2 and 3). Several steps must take place for BSE to be transmitted to cattle in the United States from a bovine imported live from another country. A BSE-infected bovine must be imported into the United States; the infected bovine must die or be slaughtered; tissues from that animal that contain the infectious agent must be sent to a rendering facility; the infectivity present in these tissues must survive inactivation in the rendering process; the resulting meat-and-bone meal containing the abnormal prion protein must be incorporated into feed; and this feed must be fed to cattle at a level adequate to infect the cattle. (The amount of infectious material required in feed for cattle to become infected is dependent on the age of the cattle; younger cattle are more susceptible to BSE and require less BSE-contaminated feed to become infected (Ref 4).)

Proposed Regulatory Change; OIE Guideline

The first step that must occur for BSE to be transmitted to cattle in the United States from a BSE-infected bovine imported live into this country from a BSE minimal-risk region is that such a bovine must enter the United States. Under our current regulations, the risk of such a bovine entering the United States is already very low because of the APHIS regulatory standards for importation from BSE minimal-risk regions.

In this document, we are proposing to allow the importation of live bovines from BSE minimal-risk regions if the animals were born on or after a date determined by APHIS to be the date on and after which a ruminant-to-ruminant feed ban in the region of export has been effectively enforced. Experience around the world in countries with BSE has demonstrated that feed bans are

effective control measures, and that the incidence of BSE worldwide continues to decline because of these measures (Ref 5 and 6).

Because of the demonstrated efficacy of an effectively enforced feed ban in reducing the possibility of exposure of cattle to the BSE agent, the World Organization for Animal Health (OIE) provides guidelines for trade in live cattle from regions that have reported BSE if such regions have an effective feed ban in place, provided the cattle were born after the date when the feed ban was effectively enforced (OIE *Terrestrial Animal Health Code*, Chapter 2.3.13). The condition in this proposed rule for the importation of live bovines from BSE minimal-risk regions is consistent with the OIE guideline.

Importance of a Feed Ban in Reducing the Likelihood of BSE Transmission

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

Experience in the United Kingdom demonstrates that implementation of a ruminant-to-ruminant feed ban causes BSE prevalence to decrease. Animal feed restrictions were implemented in the United Kingdom in 1988, when the use of ruminant meat-and-bone meal (MBM) in ruminant animal feed was banned. In September 1990, the use of specified bovine offals was banned for use in any animal feed. This ban prohibited the use in any animal feed of bovine tissues with the highest potential concentration of infectivity. In 1994, the use of mammalian protein—not just ruminant protein—was banned from ruminant feed. In 1996, feeding of any farmed livestock, including fish and horses, with mammalian MBM was completely banned. As a result of reducing the recycling of infectivity, the annual incidence of BSE fell by 99.4 percent, from 36,680 in 1992 to 203 in 2005 (Ref 7).

Although the data presented in the following figure and table represent the specific situation in Great Britain during the years identified in the graph, there is every reason to expect downward pressure on the prevalence of BSE in any country that implements a feed ban.

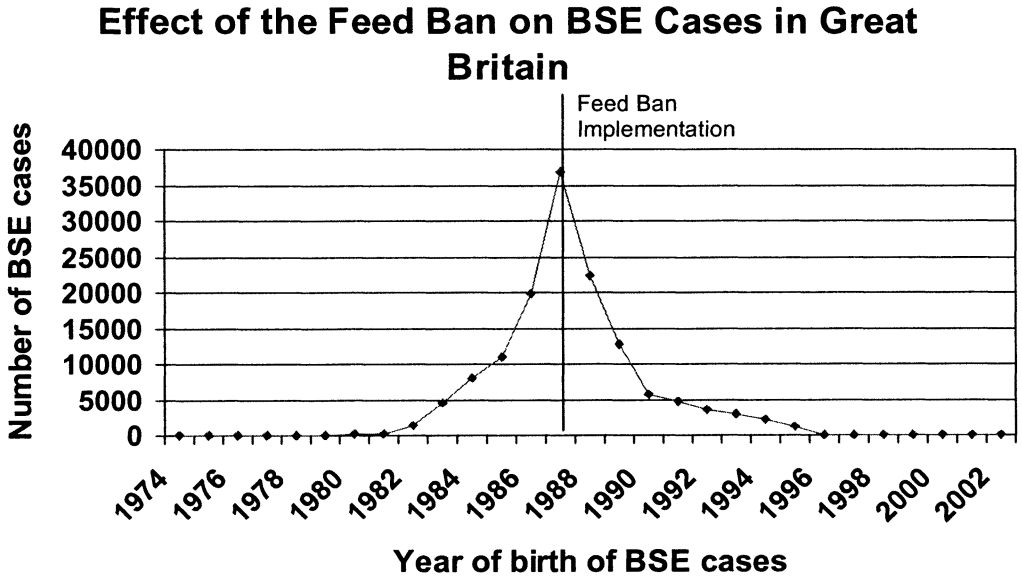

Figure 1. Confirmed cases in cattle in Great Britain born after feed ban implementation. Note: The first feed ban was implemented in the summer of 1988 (before fall calving) (Ref 8).

The raw data that provided the basis for Figure 1 are reproduced in Table 1:

TABLE 1.—CONFIRMED CASES IN GREAT BRITAIN BY YEAR OF BIRTH, WHERE KNOWN

Year	Cases
1974	1
1975	0
1976	2
1977	10
1978	6
1979	41
1980	102
1981	262
1982	1,394
1983	4,463
1984	8,069
1985	11,071
1986	19,752
1987	36,935
1988	22,266
1989	12,748
1990	5,748
1991	4,779
1992	3,531
1993	2,997
1994	2,182
1995	1,100
1996	67
1997	45
1998	37
1999	24
2000	6
2001	5
2002	1
Unknown birth year	43,342
Total	180,986

(Ref 8)

Determining a Date of Effective Enforcement of a Feed Ban

Under the current regulations, one of the conditions that must be met for a region to be recognized by APHIS as a BSE minimal-risk region is that the region must have in place a ruminant-to-ruminant feed ban that is effectively enforced. APHIS bases its determination

of whether a region has in place an effectively enforced ruminant-to-ruminant feed ban on an evaluation of the laws and regulations in place in the region, the adequacy of the infrastructure to implement the regulations, and the evidence of effective implementation and monitoring (*i.e.*, compliance inspections, training and records).

We are proposing in this rule to require that bovines from a BSE minimal-risk region intended for importation into the United States have been born on or after the date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export. In determining the date of effective enforcement of a feed ban, we believe it is first necessary to consider the amount of time, if any, between the regulatory establishment of the feed ban in the region of export and the practical implementation of the ban. The period of practical implementation can be determined by evaluating implementation guidance and policies, such as allowing grace periods for certain aspects of the industry. In addition, the time necessary for initial education of industry and training of inspectors must be considered.

After the practical implementation period is determined, we believe it is then necessary to consider whether, in the region being evaluated, an additional period of time was needed to allow most feed products to cycle through the system, given the management practices in the country.

Feed Ban in Canada

In conjunction with the rulemaking that resulted in the January 2005 final rule, APHIS conducted a risk analysis in 2003 and 2004 to evaluate the BSE risk from ruminants and ruminant products imported from regions presenting a minimal BSE risk, and to evaluate whether Canada could be classified as a minimal risk region (Ref 9 and 10). As part of the risk analysis, USDA evaluated a series of measures introduced in Canada to prevent the feeding of ruminant proteins to ruminant animals. USDA considered the compliance activities reported by the Canadian Food Inspection Agency (CFIA) as well as epidemiological information in concluding that compliance with the feed ban was good, and that the feed ban was effectively enforced. In response to the detection of two additional BSE cases in Canada, in January 2005, USDA reassessed the oversight of Canada's feed ban. Based on review of inspection records and on-site observations, USDA confirmed that Canada has a robust inspection program, that overall compliance with the feed ban is good, and that the feed ban is reducing the risk of transmission of BSE in the Canadian cattle population (Ref 11). In addition to the USDA audit of the Canadian feed ban, CFIA conducted its own review in 2005, and concluded that the ban is providing an effective mitigation that is contributing to reducing the BSE risk in the country to an extremely low level (Ref 12).

Components of the Canadian Feed Ban

Canada's feed ban came into force on August 4, 1997, when CFIA issued regulations prohibiting the use of mammalian protein in ruminant feeds as follows: ''Any feed that is, or that contains any prohibited material originating from a mammal (with exceptions) shall not be fed to a ruminant'' (Ref 12). The ban provided exceptions for milk, blood, gelatin, and protein derived solely from porcine or equine sources. Canadian feed regulations also prohibit the use of plate waste and poultry litter in ruminant feed.

The feed ban includes requirements for labeling and recordkeeping. Feed manufacturers, renderers, retailers, and livestock producers must document their production procedures and feeding practices to verify their compliance with the feed ban. Feed manufacturers must keep records regarding the composition, identity, and distribution of all feeds for the species named in the regulations. Renderers, feed manufacturers and farmers must take steps to prevent the material prohibited under the feed ban from being incorporated into or contaminating ruminant feed. To prevent the misfeeding of prohibited material to ruminants, users of livestock feed must keep labels or invoices from all purchased feeds containing prohibited material; these records must be kept for 2 years.

Measures Required at Rendering Facilities

The rendering industry is important in reducing the risk of transmitting BSE infectivity, not only because of its role in inactivation of the BSE agent, but also because it serves as a control point for the redirection of ruminant protein away from cattle feeds. Since 1998, all Canadian rendering facilities have been subject to annual inspections and permitting (Ref 11). Three types of permits are issued, allowing companies to produce either non-prohibited material only, prohibited material only, or both non-prohibited and prohibited material (Ref 11). Permitting requires implementation of manufacturing controls (such as Good Manufacturing Practices and a risk-based Hazard Analysis and Critical Control Point (HACCP) plan, recordkeeping (for both production and distribution) and labeling requirements (*i.e.*, ''Do not feed to cattle, sheep, deer or other ruminants'' on labels and invoices for all prohibited material) directed at preventing cross-contamination or misfeeding.

Measures to Prevent Contamination of Feed

As mentioned earlier, renderers, feed manufacturers, and farmers must take steps to prevent material prohibited under the feed ban from being incorporated into or contaminating ruminant feed. Such incorporation or contamination can be prevented by having dedicated processing lines or facilities that use only prohibited or non-prohibited material. If a facility handles both prohibited and non-prohibited material, procedures must be established and maintained to conduct flushing and/or clean-out between batches of product to prevent cross-contamination.

The feed industry in Canada has also taken a number of aggressive steps to comply with measures in the feed ban designed to reduce the risk of contamination of feed for cattle with prohibited material. Recently both the United States and Canada reviewed the changes made to industry procedures and governmental inspectional oversight. (Ref 11 and 12). These reviews demonstrated, for example, that the Canadian rendering industry has moved toward establishment of dedicated facilities or dedicated processing lines within rendering facilities (Ref 11 and 12). Of the 29 rendering facilities in Canada, 6 handle both prohibited and non-prohibited material, compared to 13 that initially handled both types of material. Of the six, four use dedicated processing lines (Ref 12). According to CFIA's reports, the feed manufacturing industry has also moved toward dedicated facilities. According to the most recent review (March 2005), 94 (17%) of the 550 commercial feed mills in Canada handled prohibited material and also manufactured feeds for ruminants, compared to 120 (22%) in 2002–2003 (Ref 12). These actions, in addition to the labeling and recordkeeping requirements for all products containing prohibited material, decrease the likelihood of contamination of ruminant feeds with prohibited material.

Inspections and Compliance

Following establishment of the feed ban in 1997, CFIA broadened its communications with the affected industries and implemented an inspection program. This program was introduced in phases. From 1997–2000, inspection activities focused on integrating the feed ban's requirements into standard industry practices. For example, starting in 1998, rendering facilities were required to pass an annual inspection in order to renew their permits to operate. In 2000 and 2001, CFIA modified its compliance programs by increasing the frequency of inspections of commercial feed mills from once every 3 years to every year and by continuing the annual inspection and permitting of all rendering facilities. Since 2002, CFIA has been conducting annual inspections of all rendering and commercial feed mill facilities and some ruminant feeders and retail feed distributors.

Recent Regulatory Amendments in Canada

In June 2006, CFIA issued amendments to the feed ban regulations in Canada to enhance the feed ban in that country. Those amendments require, among other things, the removal of potentially BSE-infective tissues (specified risk materials, or SRMs) from all animal feeds, pet food, and fertilizer. The amendments will not be effective until July 12, 2007, and, therefore, they are not included in this discussion.

Date of Effective Enforcement of Ruminant-to-Ruminant Feed Ban in Canada

For the purposes of this proposed rule, we have determined a date we consider to be the date of effective enforcement of ruminant-to-ruminant feed ban in Canada, the only country currently recognized by APHIS as a BSE minimal-risk region. Although the regulations establishing the feed ban in Canada came into force upon their publication in August 1997, full implementation and effective enforcement was a gradual process. In determining a date when the feed ban could be considered to be effectively enforced, we carefully considered information drawn from the epidemiological investigations to date and the reports noted above under the heading ''Feed Ban in Canada.''

From the outset, CFIA recognized that a phase-in period would be required before prohibited materials that were already in feed channels would be exhausted and labeling and recordkeeping requirements would be met. CFIA estimated that it would take approximately 30 days for feed mills and retailers to use up and distribute existing supplies of ''old'' product; 60 days to add a caution statement to the necessary documents; and 60 days for farms to use up their stores of ''old'' product (Ref 13). All retailers were given until September 3, 1997, to use or distribute feed already produced. Feed manufacturers received a grace period until October 3, 1997, to comply with labeling requirements. Livestock producers were given a grace period until October 3, 1997, to use the feed manufactured and purchased prior to the feed ban. However, feed tracing associated with one of the Canadian BSE cases suggested that feed produced prior to implementation of the feed ban may have been available at feed stores beyond the grace period. Therefore, a period of 6 months has been estimated for practical implementation of the feed ban, making February 1998 a more reasonable baseline from which to assess effective implementation (Ref 13).

However, based on our evaluation of the situation in Canada, we believe that the feed ban there achieved full efficacy only at some time after the practical implementation period. We believe that additional time was necessary to allow for most old feed to cycle through and out of the system. To evaluate the duration of this time frame in Canada, we considered on-farm feeding practices in that country. Most cattle producers in Canada do not hold extensive long-term inventories of purchased feeds on their farms due to limited storage space and expense. These practices make it unlikely that feeds containing prohibited material were available for more than a few months after practical implementation of the feed ban. The possible exception is mineral mixes produced before the feed ban that may have contained ruminant MBM. Mineral mixes are typically fed daily but in very small quantities (grams rather than pounds per day) (Ref 14 and 15) and may be stored on the farms for longer periods of time. We believe, however, that they are not likely to have been purchased for use for periods longer than a year.

Both beef and dairy cattle production can be considered to have an annual, or 12-month, calving cycle, in that a cow on a beef or dairy farm will generally give birth once a year. Calving occurs among cows year-round on Canada's dairy farms to ensure a constant supply of fluid milk. Most dairy farms in Canada produce their own forage and grains (Ref 16). Forages produced seasonally are stored on the farm to provide the basis for the diet fed to dairy cattle of all ages and production stages. Protein supplements and specialty feeds, such as mixed calf feeds, are typically purchased commercially in quantities to be fed out over a few months, because these supplemental feeds are expensive to purchase, costly to store, and may deteriorate with time. Typically, purchased feeds are available throughout the year with only moderate price variations, so there is little incentive for producers to maintain large on-farm inventories (Ref 17). The Canadian beef production cycle is very seasonal in that cows are bred so that calving occurs at the same time of year, generally in the spring (Ref 16). Producers are not likely to carry extensive feed inventories from season to season (Ref 16 and 18). Therefore, in both Canadian dairy and beef production, a 12-month period would generally be sufficient to allow purchased feed products that may contain MBM to be completely used.

We arrived at our determination that the Canadian feed ban was fully implemented and effectively enforced as of March 1, 1999, by adding this additional 12-month period to the 6-month ''practical implementation period'' following the August 1997 establishment of the feed ban in Canada. We believe that prohibiting the importation of bovines from Canada that were born before March 1, 1999, would provide an appropriate additional mitigation to what is an already extremely low risk of the introduction of BSE from Canada.

Assessment of Risk From Cattle of Canadian Origin

As noted above, Canada is currently the only country recognized by APHIS as a BSE minimal-risk region. In conjunction with this rulemaking, we have conducted an assessment that both quantitatively and qualitatively addresses the potential BSE risk of importing live bovines from Canada.

Arriving at an estimation of risk begins with laying out the risk pathway (a series of occurrences or steps necessary for disease to enter and become established). Next, the likelihood of each of the multiple steps must be estimated. In our risk assessment, although we analyze the likelihood of each individual step in the process occurring, we interpret its significance in the context of the entire process.

BSE Prevalence in Canada

One of the conditions for being recognized by APHIS as a BSE minimal-risk region is that the region have in

place and maintain risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. In classifying Canada as a BSE minimal-risk region in our January 2005 final rule, we determined that such mitigation measures are in place and are maintained in Canada. For the risk assessment for this proposed rule, we have made a quantitative estimate of the prevalence of BSE among Canadian cattle, using data available to us through August 15, 2006, and have used this estimate as part of our quantification of the risk of transmission of BSE to U.S. livestock as a result of this rule. Our estimate indicates a very low level of BSE prevalence in Canada.

From the time of detection of the first native case of BSE in Canada in 2003, nine cases of Canadian-born BSE-infected cattle have been identified, as follows:

- In May 2003, BSE was confirmed in a cow in the Province of Alberta. The cow was determined to have been born in March 1997.
- In December 2003, BSE was confirmed in a cow of Canadian origin in Washington State. The cow was determined to have been born in April 1997.
- In January 2005, BSE was confirmed in two cows in the Province of Alberta. One of the cows was determined to have been born in October 1996. The other cow was determined to have been born in March 1998.
- In January 2006, BSE was confirmed in a cow in the Province of Alberta. The cow was determined to have been born in April 2000.
- In April 2006, BSE was confirmed in a cow in the Province of British Columbia. The cow was determined to have been born in April 2000.
- In June 2006, BSE (of a different phenotype than that in the other diagnoses) was confirmed in a cow in the Province of Manitoba. The cow was determined to have been born in approximately 1991.
- In July 2006, BSE was confirmed in a cow in the Province of Alberta. The cow was determined to have been born in April 2002.
- In August 2006, BSE was confirmed in a cow in the Province of Alberta, which, according to preliminary information available to APHIS, was born in 1996.

Of the nine Canadian-born cows diagnosed with BSE, three were born after March 1, 1999, the date we are proposing as the date of effective enforcement of a ruminant-to-ruminant feed ban in Canada. This is not unexpected, nor do we consider such diagnoses in any way to undercut our conclusion that March 1, 1999, can be considered the date of effective enforcement of the feed ban in Canada. Experience worldwide has demonstrated that, even in countries with an effective feed ban in place, BSE has occurred in cattle born after a feed ban was implemented. No regulatory effort can ensure 100 percent compliance. Isolated incidents, such as feed made from non-prohibited material being contaminated with prohibited material during processing, can occur due to human error. However, such isolated incidents are not epidemiologically significant and do not contribute to further spread of BSE, especially when considered in light of the entire risk pathway and its attendant risk mitigations.

Based on our determination that Canada has had in place since March 1, 1999, an effectively enforced feed ban that continues at a robust level, and the demonstrated effectiveness of a feed ban in reducing the likelihood of BSE transmission, our expectation is that the prevalence of BSE in Canada will continue to decline from its present minimal level. As we discuss in our risk assessment for this rulemaking, such a decline would decrease any possibility of BSE being introduced into the United States by Canadian cattle, and therefore decrease the negligible risk of the spread of BSE to U.S. cattle.

However, in our risk assessment, we also evaluated scenarios that are less likely than the one we expect, including no decrease in BSE prevalence in Canada over the next 20 years. Even using this extremely unlikely scenario, which would mean the continued detection of additional BSE—infected Canadian cattle born after March 1, 1999, our conclusion is that the BSE risk to U.S. livestock due to implementation of this proposed rule would be negligible.

We used a mathematical model to approximate the proportion of BSE—infected, but not necessarily clinically diseased, cattle in Canada. Our mathematical model is discussed in detail in the risk assessment we conducted in conjunction with this proposed rule. Using this mathematical model, we estimated that the prevalence of BSE in Canada, based on data available as of August 15, 2006, is 6.8 animals per every 10 million adult cattle. (The current adult cattle population in Canada is approximately 5.9 million animals.) In comparison, the same model was recently used to estimate the prevalence of BSE in the United States. The findings of that analysis supported a conclusion that BSE prevalence in the United States is below 1 case per million adult cattle, with a most likely estimate for the United States of 1 infected animal per 10 million adult cattle (Ref 19).[2]

Our estimate of BSE prevalence in Canada incorporates the United Kingdom data on the effectiveness of a feed ban. However, it should be noted that the actual prevalence of BSE in Canada is most probably lower than our estimate. This is because, where we needed to incorporate simplifying assumptions in our calculations, due to data uncertainty or the constraints of the mathematical model itself, we chose assumptions that, if anything, erred on the side of assuming greater prevalence.

An example of this is the data we used related to the diagnosis of BSE in a cow of Canadian origin in Washington State in December 2003. Although we incorporated that case into the number of Canadian-born cattle that have been diagnosed with BSE—which increased the estimate of overall BSE prevalence in Canada—we did not numerically increase the total Canadian cattle population by including in that country's number of cattle those animals of Canadian origin that had been imported into the United States and that tested negative for BSE. If those animals had been included in the figure used for the total Canadian cattle population, the estimated BSE prevalence would have been reduced. Additionally, we did not include in our calculations cows that were tested in Canada with negative results as part of investigations conducted after the diagnosis of BSE in cows of Canadian origin.

Projected Future Prevalence Rates in Canada

Our qualitative conclusion is that, due to the feed ban in Canada, BSE prevalence rates will progressively decline in that country over the next 20 years. However, because we could not provide an accurate prediction for the rate at which we would expect prevalence to decrease, we did not attempt to numerically represent the actual expected annual release over the 20 years of our analysis. For example, it would be guesswork to attempt to estimate exactly what the prevalence of BSE in Canada will be in the year 2012 and to use that figure in our mathematical model, even though, qualitatively, we consider it very likely that the prevalence will be less than it was in August 2006. Therefore, when creating a scenario for our quantitative

[2] The current adult cattle population in the United States is approximately 42 million animals.

calculations, we assume that the prevalence of BSE in Canada will remain the same for each of the next 20 years as it was in August 2006.

BSE Risk From Live Bovines From Minimal-Risk Regions

BSE prevalence, however, is just one factor that must be considered when determining the risk of BSE transmission. Requiring, as this rule would do, that live bovines imported into the United States from a BSE minimal-risk region be born after the date of effective enforcement of a feed ban, would mitigate the risk of exposure of U.S. livestock to the BSE agent. As discussed above, such a requirement would be consistent with the OIE recommendation to allow trade in live cattle from regions that have reported BSE if such regions have an effective feed ban in place.

Moreover and importantly, however, if an infected bovine from a BSE minimal-risk region were to be imported into the United States, for that bovine to transmit infection to a U.S. cow, each in a series of additional mitigations against such transmission would have to fail or be breached. The effect of such mitigations, discussed in greater detail in our risk assessment, was also discussed in the APHIS risk assessment that was conducted for our January 2005 final rule establishing the category of BSE minimal-risk regions (Ref 9). In the risk assessment for this rulemaking, we assess with regard to imports of live bovines from Canada (currently the only region recognized by APHIS as a BSE minimal-risk region), using updated data and assumptions, the likelihood of that series of mitigations failing if this proposed rule were implemented.

The mitigations that would have to be breached include:

- Slaughter controls and dead animal disposal;
- Rendering inactivation;
- Feed manufacturing and use controls;
- Biologic limitations to susceptibility.

As discussed in our risk assessments, these mitigations work in a series and are multiplicative in their risk-reduction effects; *i.e.*, however small the chances that BSE infected material would make it past the first mitigation, the likelihood of the material eventually infecting a U.S. animal would shrink to a significantly smaller level with each subsequent mitigation. The risk assessment for this proposed rule simulated the impact of these mitigations on the likelihood of exposure, establishment, and spread of BSE infectivity in the United States if this proposed rule were to be implemented, and quantified those impacts where possible.

Both qualitative and quantitative methods were used in the exposure assessment to evaluate the likelihood of exposing susceptible animals, given the release of infectivity via imported bovines. The most likely scenario of the release assessment included the assumption that the prevalence of BSE in the standing adult cattle population in Canada will continuously decrease. As explained earlier, this expected decrease could not be incorporated into the quantitative methods and, therefore, the possible exposures were assessed qualitatively. This qualitative exposure assessment of the most likely scenario of the release assessment—decreasing Canadian prevalence—indicates that the likelihood of BSE exposure and establishment in the U.S. cattle population as a consequence of infectivity in the United States introduced via imports from Canada is negligible.

Even though we concluded that it is most likely that Canadian prevalence will decrease, we also considered the less likely scenarios and quantitatively analyzed the impact of an assumed constant prevalence in Canada to simulate potential BSE exposure in U.S. cattle. The quantitative model used in the exposure assessment and its results include the much less likely scenario that Canadian BSE prevalence remains constant through 2026. Because we believe this situation is much less likely to occur, we have concluded that prevalence and release and, therefore, the number of infected animals occurring in the United States would be lower than the values derived from the quantitative exposure model.

Using a base-case assumption that the August 2006 BSE prevalence rate in Canada remains the same over the next 20 years, our quantitative model predicts the importation of a total of approximately 19 infected bovines over that period under the provisions of this proposed rule. (As discussed above, however, as a result of implementation of an effective feed ban, we expect the already low prevalence in Canada to decline over time.) The model further predicts that, if 19 infected bovines were imported over a 20-year period, approximately 2 U.S. animals would consequently be infected during that period due to such importations. (For purposes of comparison, the standing U.S. cattle population in 2006 is approximately 97 million animals, which would be multiplied over a 20-year period.)

Of the total number of infected animals predicted over the next 20 years (*i.e.*, the total of infected imported animals and infected U.S. cattle), only a small fraction (numerically, fewer than 1 (0.67)) would live long enough to develop clinical signs and be likely to contain significant levels of infectivity, due to the lengthy incubation period for BSE and the fact that most U.S. cattle are slaughtered before reaching the age when infectivity is manifested in clinical signs. Even assuming the unlikely event of no decline in the Canadian BSE prevalence rate over the next 20 years, the predicted results from our risk assessment indicate that, given the nature of BSE and the mitigations in place that prevent its transmission in the United States, it is highly unlikely that BSE would become established in the United States due to implementation of this proposed rule. And, as noted, we believe the quantitative component of our risk assessment overestimates the likely number of infected animals that would be present in the United States over the next 20 years as a result of importing cattle from Canada under the provisions of this proposed rule.

Sensitivity Analysis to Account for Uncertain Parameters

In reaching the conclusions discussed above, we used what we consider base-case conditions. In order to account for uncertainty, however, and to allow for possible divergence from those expected base case conditions, we have also done ''sensitivity analyses.'' Sensitivity analysis evaluates the degree to which changes in the data used in a model affect the model's results. Even assuming a combination of pessimistic values (*i.e.*, those generating greater risk than base-case conditions) for every model parameter used, we concluded that factors mitigating BSE risk in the United States (*e.g.*, at slaughter, during rendering, regarding feed manufacturing and use, and biological factors (the effect of an animal's age on its BSE susceptibility)) would prevent BSE amplification in the United States, and that any imported infectivity would disappear from the U.S. cattle population. A detailed discussion of the sensitivity analyses is contained in our risk assessment.

Proposed Regulatory Changes Regarding Live Bovines

Based on the information available to us, we believe that allowing the importation from a BSE minimal-risk region of live bovines born on or after the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export would continue to

protect against the introduction and spread of BSE in the United States, while removing unnecessary restrictions on the importation of such animals, and are proposing to amend § 93.436(a) of the regulations to allow such importations. The regulations would specify March 1, 1999, as the date of the effective enforcement a ruminant-to-ruminant feed ban in Canada, currently the only country recognized by APHIS as a BSE minimal-risk region.

We would remove the requirement in § 93.436(a)(1) of the current regulations that live bovines imported from BSE minimal-risk regions be less than 30 months of age when imported into the United States and when slaughtered. We would additionally remove the requirement in § 93.436(a)(1) and (b)(1) that such bovines not be pregnant when imported into the United States and the provisions in § 93.436 that limit importation to those bovines imported either for immediate slaughter or for movement to a feedlot and then to slaughter.

Identification and Movement of Live Bovines From BSE Minimal-Risk Regions

Section 93.436 also includes movement restrictions to help ensure that all bovines imported from BSE minimal-risk regions are slaughtered in the United States before they are 30 months of age. If we remove the requirement that the bovines be less than 30 months of age when slaughtered, certain of the movement restrictions in § 93.436 would no longer be necessary. We are proposing to remove those restrictions that would be unnecessary, as discussed below.

Permanent Identification of Bovines Moving to Other Than Immediate Slaughter

Current § 93.436(b)(3) requires that bovines imported from a BSE minimal-risk region for other than immediate slaughter (*i.e.*, for movement to a feedlot in the United States and then to slaughter) be permanently and humanely identified before arrival at the port of entry with a distinct and legible mark identifying the exporting country. The permanent identification required by the current regulations can be either a freeze brand, a hot iron brand, or some other method of identification applied to each animal's right hip. In this proposal, we retain the requirement that bovines imported from a BSE minimal-risk region for other than immediate slaughter be permanently marked to identify the exporting country. In the event a bovine from a BSE minimal-risk region were to be diagnosed in the United States with BSE, such marking would expedite initial identification of the animal's country of export. Traceback to the animal's premises of origin would then be facilitated by the animal's unique individual identification, which is currently required under § 93.436(b)(4) and which would continue to be required under the provisions of this proposed rule. However, we are proposing to specify an alternative to the requirement that the animal be marked on the right hip by freeze brand, hot iron, or some other method. (The current regulations allow in a general way for alternative means of identification with the Administrator's approval, but don't include any specifications for such alternative means of identification.)

We are proposing to specify in § 93.436(b)(2) that, in addition to the options for permanent identification already included there, the permanent identification of bovines imported from BSE minimal-risk regions can be in the form of a tattoo on the inside of one ear of each animal that identifies the exporting country. Bovines imported from Canada that are identified by tattoo would have to be identified with the letters ''CAN''.

We proposed in our November 2003 proposed rule to limit the country-of-export permanent identification to a tattoo. However, comments from the public on that proposed rule expressed concern that tattoos might become illegible over time, could not be effectively monitored without restraining the animal, might become obscured by dirt and hair, and are not readily visible—particularly on animals with dark-skinned ears. In our January 2005 final rule, we agreed that tattoos might not provide readily visible identification of the country of origin of bovines, and set forth instead the requirement described above.

We continue to believe that tattoos might not be the most readily visible means of identification of live animals in groups of animals. However, as noted above, the purpose of requiring permanent identification of the animal's country of export in this proposed rule is to expedite initial identification of an animal's country of export in the event the animal is diagnosed with BSE. Such a diagnosis cannot be confirmed on a live animal. Once the animal has been euthanized or has otherwise died, an ear tattoo would be an effective means of identification.

Sealing of Means of Conveyance and Movement as a Group; Bovines Imported for Movement to a Feedlot

We are proposing to remove the requirement in § 93.436(b)(6) that live bovines imported from a BSE minimal-risk region for feeding and then slaughter be imported in a means of conveyance sealed in the region of origin with seals of the national government of the region origin, and be moved directly from the port of entry as a group to a feedlot identified on the APHIS movement documentation currently required for such animals. Under this proposed rule, the importation of bovines from a BSE minimal-risk region would not be dependent on whether the animals are less than 30 months of age when imported and when slaughtered, but, rather, would be governed by whether the animals were born on or after the date of effective enforcement of a ruminant-to-ruminant feed ban in the exporting region. Once imported, the bovines would be handled in the same way as U.S. bovines. Therefore, we do not believe it would be necessary to retain the provisions in the regulations that were designed to help ensure that bovines from a BSE minimal-risk region are moved directly to a feedlot and are handled as an easily identifiable group.

Sealing of Means of Conveyance and Movement as a Group; Bovines Imported for Immediate Slaughter

We are also proposing to remove the requirement in § 93.436(a)(6) that the bovines imported from BSE minimal-risk regions for immediate slaughter be slaughtered as a group. However, we would continue to require that bovines from Canada imported for immediate slaughter be moved directly as a group from the port of entry in a sealed means of conveyance. We would require that the means of conveyance be sealed at the port of entry with seals of the U.S. Government, rather than requiring the sealing to occur in the region of export with seals of the national government of the region of export, as required in the current regulations. We explain our rationale for these proposed provisions in the following paragraphs.

With regard to BSE, the purpose of requiring in the current regulations that bovines from BSE minimal-risk regions that are imported for immediate slaughter be moved to the slaughtering establishment in a sealed means of conveyance is to guard against diversion of any of the animals between the port of entry and the slaughtering establishment, in order to ensure that the animals are slaughtered as a group

before 30 months of age. Because this proposed rule would not require that the animals be slaughtered before 30 months of age, there would be no BSE-related reason to require sealing of the means of conveyance.

However, we believe it is necessary to continue to require sealing of means of conveyance transporting bovines from Canada to immediate slaughter as a mitigative measure against diseases other than BSE. Cattle imported from Canada for immediate slaughter are not subject to tuberculosis and brucellosis testing requirements that would otherwise be applied to animals imported into the United States. Therefore, we would continue to require that such cattle be moved directly to slaughter in a sealed means of conveyance. (APHIS had been requiring such sealing at the port of entry even before our November 2003 proposal regarding BSE. However, the requirement for sealing was being done as APHIS policy, and was not specified in the regulations.)

Where Sealing Must Take Place

We are proposing to remove the requirement that the sealing of the means of conveyance be done in the region of export. That requirement was included in the January 2005 final rule in response to comments from members of the public who expressed concern that requiring sealing at the port of entry could be harmful to the welfare and quality of the animals, due to delays at the port of entry. Under the provisions of this proposed rule, however, we do not expect undue delays of shipments at the port of entry. When a means of conveyance carrying bovines for immediate slaughter arrives at the U.S. port of entry, APHIS inspectors would confirm that the animals are as described on the certificate that must accompany the animals being imported, but generally would not require that the animals be offloaded from the means of conveyance. Therefore, requiring that the sealing of the means of conveyance take place at the port of entry would not cause measurable delay of the shipment. Further, sealing at the port of entry rather than in the region of export will reduce the time the animals will need to be contained in a sealed means of conveyance and reduce the likelihood that a seal will need to be broken between the time it is applied and the arrival of the animals at a slaughtering establishment.

APHIS Form VS 17–130

Currently, § 93.436(b)(8) requires that bovines imported from BSE minimal-risk regions for movement to feeding and then slaughter 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 the animal. Because, under this proposed rule, bovines imported from a BSE minimal-risk region that are not moved for immediate slaughter would not be limited to moving to a feedlot and then slaughter, it would no longer be necessary to require that the bovines be accompanied by a VS Form 17–130 that identifies the feedlot of destination. The other necessary information on the VS Form 17–130–*e.g.*, the individual responsible for the movement of the animals and the individual identification of the animal-is already required on the health certificate that must accompany the animals under § 93.405. Therefore, we are proposing to remove the requirement that live bovines imported from BSE minimal-risk regions for other than immediate slaughter be accompanied by VS Form 17–130.

Transport From Feedlots to Slaughter

We are proposing to remove the requirement in § 93.436(b)(9) that the bovines imported from BSE minimal-risk regions for other than immediate slaughter remain at a feedlot until transported from the feedlot to a recognized slaughtering establishment for slaughter, and we are proposing to remove the requirement in § 93.436(b)(10) that the bovines be moved directly from the feedlot to a recognized slaughtering establishment in conveyances sealed at the feedlot with seals of the U.S. Government. We are also proposing to remove the requirement in § 93.436(b)(11) that the bovines be accompanied from the feedlot to a recognized slaughtering establishment by APHIS Form VS 1–27 or other movement documentation deemed acceptable by the Administrator, identifying the physical location of the recognized slaughtering establishment, the individual responsible for the movement of the animals, and the individual identification of the animal. This requirement would not be necessary because, under this proposed rule, cattle imported for other than immediate slaughter would not be limited to those less than 30 months of age that are moved directly to a feedlot and then to slaughter.

Immediate Slaughter

Section 93.420 contains provisions regarding the importation of ruminants from Canada for immediate slaughter, and applies to all ruminants from Canada imported for immediate slaughter, including sheep, goats, bovines, and other types of ruminants. However, as applied to sheep, goats, and bovines, many of the requirements in § 93.420 are duplicative of provisions set forth in § 93.419 for sheep and goats and in § 93.436 for bovines. Because the majority of provisions in the current regulations regarding the importation of bovines and sheep and goats from Canada for immediate slaughter are contained in § 93.436 and § 93.419, respectively, we are proposing to rewrite § 93.420 so that it applies only to ruminants imported from Canada for immediate slaughter other than bovines, sheep, and goats. Any provisions of current § 93.420 that are still applicable to bovines, sheep, and goats under this proposed rule and that do not already appear in § 93.436 or § 93.419 would be moved to those sections. 9 CFR 93.405.

In accordance with § 93.405 of the regulations, bovines, sheep, and goats imported from BSE minimal-risk regions must be accompanied by a health certificate. Among the information that must be recorded on the health certificate is the specific physical location of the feedlot or recognized slaughtering establishment where the ruminants are to be moved after importation. Because, under this proposed rule, bovines imported from BSE minimal-risk regions would not be limited to moving to a feedlot or slaughtering establishment, we are proposing to change that provision in § 93.405(a)(4) to refer to ''destination,'' rather than to ''feedlot or recognized slaughtering establishment.''

B. Bovine Blood and Blood Products

Blood and blood products can be divided into two main groups:

1. In addition to whole blood, those products derived from blood that are composed of cells, such as red cell concentrate and platelets; and

2. Plasma (that portion of blood that is cell-free) and products derived from plasma, such as serum (plasma with fibrinogen and clotting factors removed), clotting factors, immunoglobins and albumin (Ref 20).

Fetal bovine serum (FBS) is the most commonly imported blood-derived commodity. FBS is serum derived from blood of bovine fetuses. As serum, it is the cell-free portion of blood with fibrinogen and clotting factors removed. It is used in tissue culture media,

including those used to produce pharmaceuticals and biological products, such as vaccines, and cannot be derived synthetically.

BSE Risk Associated With Bovine Blood and Blood Products From BSE Minimal-Risk Regions

Our January 2005 final rule did not include provisions for the importation of bovine blood and blood products from BSE minimal-risk regions. We considered it advisable at the time to continue to prohibit the importation of blood and blood products from such regions (with the exception of those commodities that were already allowed to be imported for restricted use from BSE-affected regions under § 95.4(b) and (d)).

In consultation with FDA, we have continued to assess the risk of BSE from blood and blood products from BSE minimal-risk regions. Based on the conclusions of our assessment, we are proposing to amend the regulations in § 95.4 to allow the importation of blood and blood products from such regions under specified conditions, which we discuss below.

Consistent with the approach of the risk assessment conducted for this proposed rule with regard to live animals and bovine small intestine, the risk estimation for blood and blood products relies on a comprehensive understanding of the multiple steps in the risk pathway. Thus, to understand the likelihood of BSE spreading and becoming established in the United States as a result of importing blood and blood products from a BSE minimal-risk region (currently only Canada), we examine the entire risk pathway. We evaluate the evidence from research to date—including research that has not detected infectivity in bovine blood and research in other species where infectivity has been detected—in the context of this larger risk pathway. Analysis of this risk pathway, discussed below, is the basis for our proposal to allow, under specified conditions, the importation of blood and blood products derived from bovines from BSE minimal-risk regions.

One of the conditions for being recognized by APHIS as a BSE minimal-risk region is that the region have in place and enforce risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease, so that, even if one of the very few infected bovines in a BSE minimal-risk region were a source of imported blood or blood products, additional factors would act to further diminish the likelihood of the BSE agent's entering the United States in bovine blood or blood products.

Perhaps the most important factor is that, in research using infected bovines, infectivity has not been detected in cattle blood or any tested derivatives (Ref 21). This finding is applicable to clotted blood and fetal calf blood, and to products derived from whole blood, such as serum or buffy coat (the white cell fraction of centrifuged whole blood). As noted below, research in other species with BSE or other TSE agents has demonstrated infectivity in blood, and we use these studies to further inform our risk assessment. In addition, because blood components—such as FBS and bovine serum albumin (BSA)—are used in the manufacture of vaccines, it is worthwhile to address injection vs. oral consumption as a route of exposure.

Injection presents a different risk pathway than does oral consumption of BSE-contaminated bovine materials. The route of exposure can affect the risk of disease transmission. The relative efficiencies of different transmission routes of BSE have been reported to be, in decreasing order, intracerebral (injecting directly into the brain), intravenous (injecting directly into a vein), intraperitoneal (injected directly into the abdominal cavity), subcutaneous/intramuscular (injecting below the skin and/or into a muscle), and oral. It is estimated that the subcutaneous/intramuscular route of transmission requires 10 times the dose of a TSE agent to cause infection as does the intracerebral route and that oral/intragastric transmission requires 10 times the dose needed for subcutaneous/intramuscular transmission. In other words, injection of a BSE agent into an animal is a more efficient way of transmitting the disease agent to that animal than getting it into the animal through its food.

The difficulty in examining the possibility of BSE transmission through injection is that BSE infectivity has not been detected in unprocessed bovine blood. We generally avoid extrapolating from studies of TSEs other than BSE in species other than bovines; however, in order to consider the only available evidence, we elected to use such studies as potential indicators of the behavior of BSE in cattle blood if, contrary to current evidence, it were to be present at previously undetectable levels. These studies are discussed in detail in our risk assessment.

It is important to restate that no studies have demonstrated BSE infectivity in bovine blood and that we considered studies that involved TSEs other than BSE and species other than bovines. If, contrary to current research, BSE infectivity were to be distributed in bovine blood, research indicates that the BSE infectivity would likely be highest in the cellular components of the blood. These cellular fractions of the whole blood, both red and white cells, are excluded from the blood when harvesting FBS and BSA for use in the preparation of vaccines and drugs.

Another component of the pathway of interest consists of the ways in which bovine blood that is collected might in some way become contaminated with SRMs at the time of collection, particularly in a slaughter environment. To guard against such possible contamination, it would be necessary to collect the blood in a closed system (a system in which the blood is conveyed directly from the animal in a closed conduit to a closed receptacle) or in an otherwise hygienic manner. Additionally, to prevent blood collected from a fetal calf from becoming contaminated with SRMs, the uterus from a slaughtered dam should be removed intact and taken to a separate area away from the slaughtering area of the facility. Further, pithing or use of air injection stunning devices at slaughter could cause macro-emboli from higher risk tissues from the animal's central nervous system to be introduced into the animal's circulatory system. Prohibiting the use of these processes is necessary to prevent contamination of the blood.

Proposed Regulatory Changes Regarding Blood and Blood Products

Currently, the regulations in § 95.4 specify that only the following blood products for the following uses are eligible for importation from any region listed in § 94.18(a) (including (a)(1) through (a)(3)), based on the fact that the manner in which they are used makes it highly unlikely they will come in contact with ruminants in the United States:

- Under § 95.4(b), serum derived from ruminants that have been in any region listed in § 94.18(a) may be imported into the United States for scientific, educational, or research purposes if the APHIS Administrator determines that the importation can be made under conditions that will prevent the introduction of BSE into United States. Such serum is allowed importation into the United States only if it is accompanied by an import permit issued by APHIS in accordance with 9 CFR 104.4 (a U.S. Veterinary Biological Product Permit), and must be moved and handled as specified on the permit.
- Under § 95.4(d), serum albumin (a blood plasma protein) derived from

ruminants that have been in any region listed in § 94.18(a) may be imported into the United States for use as an ingredient in cosmetics (provided FDA import requirements are also met), if the person importing the article obtains a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors, which states the intended use of the article and the name and address of the consignee in the United States.

All other serum and serum albumin from regions listed in § 94.18(a) is prohibited importation into the United States.

The regulations in § 95.4 regarding BSE do not specifically reference blood and blood products other than those described above—either to prohibit or to allow their importation—largely because commercial interest in importing blood products from regions listed in § 94.18(a) has focused on serum and serum albumin. By policy, however, APHIS has prohibited the importation of any blood and blood products from § 94.18(a) regions, other than those described above.

Based on our evaluation of the BSE risk associated with bovine blood and blood products from BSE minimal-risk regions, we believe that bovine blood and blood products may be imported from BSE minimal-risk regions if properly protected against contamination. We are, therefore, proposing the following changes to the regulations at § 95.4(e).

In general, blood collected from bovines can be obtained in one of three ways: It can be collected from an animal that has been slaughtered, it can be collected from a live donor animal (similar to human blood collection), and it can be collected from the fetal calf of a bovine dam that has been slaughtered.

For all of the above three manners of collection, we would require that the blood be collected in a closed system or in an otherwise hygienic manner that prevents contamination of the blood with SRMs. This requirement is necessary to ensure that the blood is not contaminated after collection.

Prohibited Methods of Stunning

When a bovine is slaughtered as part of the process of blood collection, we would require in § 95.4(e)(1)(ii) and (e)(2)(ii) that the slaughtered animal was not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or subjected to a pithing process. Either of those processes create the possibility that macro-emboli from higher risk tissues from the animal's central nervous system might be introduced into the animal's circulatory system.

Fetal Calves

For blood collected from a fetal calf, we would require in § 95.4(e)(2)(iii) that the uterus be removed from the slaughtered dam's abdominal cavity intact and taken to a separate area sufficiently removed from the slaughtering area of the facility to ensure that the fetal blood is not contaminated with SRMs when collected.

Animal Health Requirements

Also, although it is extremely unlikely that any given bovine in a BSE minimal-risk region would be infected with BSE, because of the often undifferentiated clinical signs of BSE (*i.e.*, clinical signs that could be attributed to either BSE or some other disease(s)), we consider it prudent to disqualify from importation into the United States blood and blood products drawn from live bovines showing signs of any type of disease. Therefore, we would require in § 95.4(e)(1)(ii) and (e)(2)(ii) that bovines slaughtered as part of the process of collection (*e.g.*, when blood is collected directly from the slaughtered animal or from the fetal calf of a slaughtered dam) have passed ante-mortem inspection to ensure that the animals are clinically normal and have no obvious signs of disease. If the blood is collected from a live bovine donor, the donor animal must be free of clinical signs of disease.

We are proposing to add language to § 95.4 to prohibit the importation of the blood and blood products and derivatives of blood and blood products, except as specifically provided in § 95.4. This would codify current policy.

Required Certification

We would require in § 95.4 that the shipment of blood or blood products to the United States be 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, attesting that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the applicable requirements of § 95.4 have been met.

C. Small Intestine of Bovines

The requirement established in the January 2005 final rule for removal of the entire small intestine of bovines from BSE minimal-risk regions was consistent with the FSIS regulations at that time, which govern the slaughter of animals in the United States for meat and meat products for human consumption. The FSIS regulations also apply to slaughtering establishments in other countries that wish to export meat to the United States. FSIS regulations (9 CFR 327.2) provide that a country can be considered eligible to export meat and meat products to the United States only if it maintains a meat inspection program equivalent to that of the United States. A country must demonstrate ''equivalence'' by implementing measures that provide the same level of protection against food hazards as is achieved domestically. FSIS conducts audits of eligible foreign countries' meat inspection systems at least annually. At the time of our January 2005 final rule, FSIS required that the entire small intestine be removed and be disposed of as inedible, in order to ensure removal of the entire distal ileum.

Research Regarding BSE and the Gastrointestinal System of Cattle

As discussed in our risk assessment for this proposed rule, in studies regarding the pathogenesis of BSE in the gastrointestinal system of cattle experimentally and naturally exposed to the BSE agent, no BSE infectivity was detected at any time in the esophagus, reticulum, rumen, abomasum, proximal small intestine, proximal colon, distal colon, and rectum (Ref 21). The studies demonstrated that, if infectivity in intestinal tissues of bovines (other than distal ileum) exists, it is below the level of detection by mouse bioassay (*i.e.*, the insertion of tissue with infectivity from a bovine into a mouse). Based on these studies, we have concluded that intestine other than the distal ileum is highly unlikely to contain epidemiologically significant levels of infectivity, if any infectivity is present at all.

These studies have been compelling to the international scientific community, and the OIE has based international trade guidelines on the likelihood that the distal ileum, but not the remainder of the bovine intestine, is a potential source of BSE infectivity. The distal ileum is the only portion of the bovine intestine for which OIE recommends any trade restrictions because of BSE.

FSIS and FDA Regulations Regarding the Small Intestine

On September 7, 2005, FSIS published in the **Federal Register** an interim final rule that allowed for use as human food, under certain conditions, beef small intestine, excluding the distal ileum, derived from cattle slaughtered in official U.S. establishments or in

certified foreign establishments in countries listed by FSIS in 9 CFR 327.2(b) as eligible to export meat products to the United States (Ref 22). FSIS also provided that it will permit casings derived from beef small intestine, excluding the distal ileum, to be used as containers of meat food products only if the casings are derived from cattle that have been inspected and passed in an official U.S. establishment or a certified foreign establishment.

Also on September 7, 2005, FDA published an interim final rule (Ref 23) and request for comments in which it provided that small intestine is not considered a prohibited cattle material if the distal ileum is removed by a qualifying procedure. FSIS imposed a similar requirement in its interim rule.

The small intestine of cattle attaches at its most proximal end (closest to the mouth) to the most distal (closest to the anus) chamber of the ruminant stomach. The most proximal segment of small intestine is the duodenum. Distal to the duodenum is the very long jejunum. The duodenum and jejunum are used for natural beef casings. Distal to the jejunum is the ileum, which is estimated to be 2- to 3-feet long (Ref 24). The distal-most portion of the ileum, or ''distal ileum,'' is estimated to be 12- to 18-inches long. It attaches at the most proximal portion of the large intestine, the cecum, at what is termed the ''ileocecal junction'' or ''ileocecal orifice.'' Just distal to the ileocecal junction is the cecocolic junction.

FSIS and FDA have determined that the distal ileum can be effectively removed from the rest of the small intestine (Ref 22 and 23). They have also determined that the remaining small intestine can be used as human food if the distal ileum is removed (Ref 22 and 23). To ensure complete removal of the distal ileum, both FSIS and FDA require the removal of at least 80 inches of the uncoiled and trimmed small intestine as measured from the cecocolic junction, unless the processing establishment has demonstrated that an alternative method is effective in ensuring complete removal of the distal ileum. Based on bovine anatomy as described above, we concur that removal of at least 80 inches of the uncoiled and trimmed small intestine as measured from the cecocolic junction will remove the distal ileum.

Proposed Regulatory Changes Regarding Bovine Small Intestine

In our January 2005 final rule, we provided in § 94.19 that one of the conditions for the importation of meat, meat byproducts, and meat food products derived from bovines from BSE minimal-risk regions is that the commodity have been derived from bovines from which the SRMs were removed at slaughter. This same condition is set forth in § 95.4(g) with regard to offal derived from bovines from BSE minimal-risk regions.

The regulations at § 94.19 also require, in addition to the removal of SRMs, the removal of the entire small intestine, even though only part of the small intestine (the distal ileum) has been determined to be an SRM.

Because it is possible to effectively separate and remove the distal ileum from the remainder of a bovine's small intestine, we are proposing to remove the requirements in § 94.19(a)(2), (b)(2), and (f) that bovine meat, meat byproducts, meat food products, and whole or half carcasses intended for importation from BSE minimal-risk regions be derived from animals from which the entire small intestine was removed at slaughter. We would require instead only that SRMs have been removed. (Under FSIS regulations, in effect, the distal ileum SRM includes 80 inches of the uncoiled and trimmed small intestine as measured from the cecocolic junction, unless the processing establishment has demonstrated that an alternative method is effective in ensuring complete removal of the distal ileum.) Similarly, we are proposing to remove the importation condition in § 95.4(g)(1)(i) (which we are proposing in this document to redesignate as § 95.4(h)(1)(i)) that offal derived from bovines from BSE minimal-risk regions be derived from animals from which the small intestine was removed, and would provide instead that the offal must have been derived from bovines from which SRMs were removed.

D. Bovine Casings

Currently, § 96.2(b) prohibits 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), which includes BSE minimal-risk regions. In § 96.1, *animal casings* are defined as intestines, stomachs, esophagi, and urinary bladders from cattle, sheep, swine, or goats that are used to encase processed meats in foods such as sausage.

As explained above, only the distal ileum of the small intestine of bovines presents a BSE risk, and FSIS and FDA have established procedures for effective removal of the distal ileum from the remainder of the small intestine. There is no scientific evidence of BSE infectivity in ruminant esophagi or urinary bladders.

Proposed Regulatory Changes Regarding Bovine Casings

Therefore, we are proposing to amend § 96.2 of the regulations to allow the importation of casings derived from bovines from BSE minimal-risk regions if the casings are derived from that part of the small intestine that is eligible for use as human food in accordance with the requirements established by FSIS at 9 CFR 310.22 and FDA at 21 CFR 189.5 and 21 CFR 700.27. We are also proposing to allow the importation from BSE minimal-risk regions of casings derived from bovine esophagi and urinary bladders.

Executive Order 12866 and Regulatory Flexibility Act

This proposed 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 if he or she determines that the regulations are necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.

This proposed rule would amend the regulations by establishing conditions for the importation of the following commodities from regions that present a minimal risk of introducing BSE into the United States: Live bovines for any use born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export (for live bovines from Canada, that date is March 1, 1999); blood and blood products derived from bovines; and casings and part of the small intestine derived from bovines.

In accordance with Executive Order 12866 and the Regulatory Flexibility Act, we assessed the potential economic costs and benefits of this rule and potential effects on small entities. Below is a summary of our economic analysis. The full economic analysis may be viewed on the Regulations.gov Web site or in our reading room. (Instructions for accessing Regulations.gov and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individuals listed under **FOR FURTHER INFORMATION CONTACT**.

We do not have enough data for a comprehensive analysis of the potential

economic effects of this proposed rule on small entities. Therefore, in accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis for this proposed rule. We are inviting comments about this proposed rule as it relates to small entities. In particular, we are interested in determining the number and type of small entities that would incur benefits or costs from the implementation of this proposed rule and the economic effect of those benefits or costs.

The Proposed Rule and This Analysis

The purpose of this proposed rule is to remove certain restrictions on the importation of certain bovine commodities from BSE minimal-risk regions. APHIS has determined that the restrictions are unwarranted to prevent the introduction and dissemination of BSE into the United States from such regions.

The risk assessment for this proposed rule analyzes the likelihood that importing those commodities from Canada would introduce and disseminate BSE into the U.S. cattle population. The likelihood of release (introduction of the disease agent), the likelihood of exposure for susceptible animals given release, and the magnitude of consequences given release and exposure are evaluated either quantitatively or qualitatively. The risk estimation that combines these components concludes that the BSE risk posed by the proposed rule would be negligible.

This preliminary regulatory impact analysis addresses expected economic effects of allowing resumption of imports from Canada of the commodities listed above. Expected benefits and costs are examined in accordance with Executive Order 12866. Expected economic impacts for small entities are also considered, as required by the Regulatory Flexibility Act. Effects for Canadian and other foreign entities are not addressed in this analysis. However, the Agency expects reestablished access to U.S. markets to benefit Canadian producers and suppliers of commodities included in the proposed rule and, for at least one commodity, cull cattle/processing beef, to result in partial displacement of processing beef imports from other sources.

Analytical Approach

We expect the proposed rule to have effects for several different categories of commodities, and benefits to exceed costs overall. Using projected baseline data for the United States and projected imports from Canada with and without the rule, we compute impacts for four commodity categories: Cull cattle/processing beef would be the commodity primarily affected, due to the resumption of cull cattle imports from Canada; and feeder cattle, fed cattle, and fed beef would be affected secondarily, as Canada's slaughter mix adjusts to reestablished exports of culled cows, bulls, and stags to the United States.

The demand for cull cattle is derived from the demand for processing beef, and only a small portion of the U.S. supply of processing beef would come from imported Canadian cull cattle. Therefore, cull cattle and processing beef are combined into a single commodity category. Processing beef refers to lean, boneless beef that is mixed with trimmings from grain-fed cattle to produce ground beef, thereby complementing the domestic production of fed beef. Demand for processing beef is high, as reflected in robust ground beef sales. Despite higher domestic cull cattle slaughter in past months in response to drought conditions, U.S. production of processing beef is currently trending low because the industry is in the early stages of the expansion phase of the cattle cycle.

Historically, Canada has been a major trading partner of the United States in livestock and meat. In 2002, prior to the discovery of BSE in Canada, the United States imported 1.7 million live bovines from Canada, valued at more than $1.1 billion and accounting for more than 67 percent of U.S. total bovine imports. That same year, the United States imported from Canada 382,110 MT of bovine meat, also valued at $1.1 billion, which comprised about 44 percent of bovine meat imports from all sources. U.S.-Canadian cattle and beef trade changed dramatically following Canada's May 2003 BSE discovery. Canada's cattle population increased rapidly following the loss of export markets for its cattle and beef. Its excess cow population and the strong U.S. demand for cull cattle/processing beef underlie imports of Canadian cull cattle expected to occur with this rule.

We evaluate welfare impacts of the proposed rule for cull cattle/processing beef, feeder cattle, fed cattle, and fed beef using a net trade, non-spatial partial equilibrium model.[3] Present and annualized values of welfare gains and losses for the 5-year period, 2007–2011, are computed using 3 percent and 7 percent discount rates. The present and annualized values are expressed in 2006 and 2001 dollars.

For five other commodity categories—breeding cattle, vealers and slaughter calves, bison, bovine casings and small intestine products, and bovine blood and blood products—we do not quantitatively model expected effects of the proposed rule. For the first three of these categories, changes in import quantities projected under the proposed rule are very small, suggesting that impacts for U.S. entities would not be significant. For bovine casings, small intestine products, and blood and blood products, insufficient information about the commodities and quantities that would be imported and levels of U.S. production and consumption prevents us from modeling expected effects of the rule.

Price and Quantity Impacts for the Modeled Commodities

The proposed rule is expected to result in the resumption of cull cattle imports from Canada. In addition, declines in imports of feeder cattle, fed cattle, and fed beef are expected to occur as a result of the resumption of cull cattle imports affecting the slaughter mix in Canada. The baseline, along with the projected changes, are presented in Table VIII, below. Relative prices highlight the different situations for the Canadian and U.S. cull cattle markets. For example, in September, 2006, the price of slaughter cows in Canada was only 70 percent of the comparable U.S. price.

Cull cattle/processing beef. With the rule, imports of cull cattle from Canada would result in price declines for processing beef. Over the period of analysis, the annual decrease in the price of processing beef, all things equal, is expected to average about 4.3 percent, ranging from declines of $5 per cwt (hundredweight, 100 pounds) in 2007, to $3 per cwt in 2009. In response to this price effect, wholesale demand for processing beef would increase by an average of about 114 million pounds per year over the period of analysis, and domestic supply would decrease by an annual average of about 131 million pounds.

Feeder cattle, fed cattle, and fed beef. Imports of feeder cattle, fed cattle, and fed beef are projected to decrease because of the rule. Of these commodities affected secondarily, the

[3] A complete description of the model is provided in: Forsythe, K.W. ''An Economic Model for Routine Analysis of the Welfare Effects of Regulatory Changes.'' V3.00. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health, April 20, 2005 (draft). It can be found at *http://www.aphis.usda.gov/peer_review/content/printable_version/bas_model_econOnly_apr20.pdf.*

largest impacts would be for feeder cattle. We estimate that the price of feeder cattle would increase in 2007 by about 0.3 percent, from $733 to about $735 per head in 2006 dollars. Over the 5-year period of analysis, the annual increase in feeder cattle prices attributable to the proposed rule, all things equal, is expected to average about 0.6 percent, ranging from about $2.20 per head in 2007, to about $4.60 per head in 2010. In response to these price increases, there would be an average annual decrease in the demand for feeder cattle of about 152,000 head over the period of analysis, and an average annual increase in domestic supply of about 66,000 head.

For fed cattle, our analysis indicates that the price would increase by less than 0.1 percent in 2007. Over the 5-year period, the annual increase in fed cattle prices attributable to the proposed rule, all things equal, is expected to average less than 0.2 percent, ranging in 2006 dollars from 35 cents per head in 2007, to about $1.90 per head in 2009. We estimate that these small changes in price would cause the demand for fed cattle to decrease by an average of about 33,000 head per year and the domestic supply of fed cattle to increase by an average of 26,000 head per year.

Impacts of the proposed rule for fed beef are expected to be very small, with the price increasing in 2007 by less than 0.3 percent, or about 36 cents per cwt carcass weight equivalent from a base price of $142. Over the 5-year period of analysis, the increase in fed beef prices, all things equal, is expected to average less than 0.1 percent, with no effect projected for the last 3 years.

Clearly, the largest price effects would result from the resumption of cull cattle imports from Canada, an expected outcome matched by estimated welfare impacts.

Welfare Effects for the Modeled Commodities

In this analysis, consumption and production have commodity-specific definitions that differ from their commonly understood meanings. These definitions are central to interpreting the changes in welfare, and are shown in Table I. They imply that the proposed rule may have mixed effects for at least some entities in the affected industries.

TABLE I.—DEFINITIONS OF CONSUMERS AND PRODUCERS FOR THE MODELED COMMODITY CATEGORIES

Commodity category	Consumers	Producers
Feeder cattle	Buyers of cattle for feedlot feeding in the United States.	Sellers of U.S.-raised cattle for feedlot feeding in the United States.
Fed cattle	Buyers of fed cattle for slaughter in the United States.	Sellers of U.S.-sourced fed cattle for slaughter in the United States.
Cull cattle/processing beef	U.S. buyers of processing beef at the wholesale level.	Sellers of U.S.-produced processing beef at the wholesale level.
Fed beef	U.S. buyers of fed beef at the wholesale level	Sellers of U.S.-produced fed beef at the wholesale level.

Cull cattle/processing beef. Projected cull cattle imports from Canada are converted to their processing beef equivalent using projected carcass weights for cows, bulls, and stags, as shown in the note to Table II. Consumers (buyers of processing beef at the wholesale level) can be expected to benefit from welfare gains and producers (sellers of processing beef at the wholesale level) can be expected to bear welfare losses due to the cull cattle imports. The present value of the welfare changes in 2006 dollars when using a 3 percent discount rate would be $1.24 billion in consumer gains, $657 million in producer losses, for a net benefit of about $587 million. Annualized values over the 5 years, in 2006 dollars when using a 3 percent discount rate, would be consumer gains of $271 million, producer losses of $143 million, and net benefits of $128 million.

TABLE II.—CULL CATTLE/PROCESSING BEEF: PRESENT AND ANNUALIZED VALUES OF WELFARE CHANGES WITH THE PROPOSED RULE, 2007–2011

	Discount rate (percent)	Changes in welfare		
		Consumer	Producer	Net
		(Thousand dollars)		
Present value:				
2006 Dollars	3	1,243,147	−656,540	586,607
	7	1,120,778	−590,070	530,708
2001 Dollars	3	1,080,856	−570,814	510,043
	7	974,488	−513,038	461,450
Annualized value:				
2006 Dollars	3	271,447	−143,358	128,089
	7	273,347	−143,912	129,435
2001 Dollars	3	236,010	−124,640	111,370
	7	237,669	−125,125	112,544

Note: Consumers are U.S. buyers of processing beef at the wholesale level; producers are sellers of U.S.-produced processing beef at the wholesale level. Cull cattle imports from Canada in thousand head are converted to processing beef in million pounds carcass weight equivalent by multiplying by the following carcass weights (pounds) for cows and bulls/stags, respectively: 2007, 576 and 888; 2008, 579 and 893; 2009, 583 and 899; 2010, 586 and 904; and 2011, 590 and 909 (Source: Expert opinion, USDA Economic Research Service, Market and Trade Economics Division, Animal Products, Grains, and Oil Seeds Branch).

Welfare changes for the cull cattle/processing beef category dominate the modeled effects. The relatively large impacts are not unexpected, given that this is the one modeled commodity category for which imports from Canada would be newly reestablished. The numbers of cull cattle that would be imported with the rule, projected to average 545,000 cows and 66,000 bulls and stags per year, 2007–2011, are much larger than the projected average annual declines in feeder cattle (218,000 head) and fed cattle (59,000 head).

Feeder cattle, fed cattle, and fed beef. Fewer feeder cattle and fed cattle and less fed beef are projected to be imported from Canada with the rule than would enter without the rule, and the model indicates for these commodities gains in producer welfare (higher prices and less competition from Canadian suppliers) and losses in consumer welfare (higher prices and fewer feeder, fed cattle, and less fed beef available for purchase). Of these three commodities, the largest impact would be for feeder cattle, with estimated producer welfare gains of $494 million and consumer welfare losses of $518 million, for a net loss of $24 million (2006 dollars, discounted at 3 percent).

Combined welfare effects. Effects of the proposed rule for cull cattle/processing beef, feeder cattle, fed cattle, and fed beef are summed in Table III.

TABLE III.—PRESENT AND ANNUALIZED VALUES OF COMBINED WELFARE CHANGES FOR THE MODELED COMMODITIES WITH THE PROPOSED RULE, 2007–2011

	Discount rate (percent)	Changes in welfare [1]		
		Consumer	Producer	Net
		(Thousand dollars)		
Present value:				
2006 Dollars	3	444,740	111,662	556,401
	7	407,740	96,136	503,876
2001 Dollars	3	386,246	97,526	483,775
	7	302,447	133,266	435,714
Annualized value:				
2006 Dollars	3	97,110	24,384	121,494
	7	99,452	23,457	122,908
2001 Dollars	3	84,339	21,296	105,634
	7	86,339	20,514	106,851

[1] Combined welfare changes for cull cattle/processing beef, feeder cattle, fed cattle, and fed beef.

The analysis tells us that the present value of the combined welfare changes in 2006 dollars when using a 3 percent discount rate, for example, would be $445 million in consumer gains, $112 million in producer gains, for a total welfare benefit of $556 million. Annualized values over the 5 years, in 2006 dollars when using a 3 percent discount rate, would be consumer gains of $97 million and producer gains of $24 million, yielding benefits of over $121 million.

Our analysis shows producer welfare changes to be negative in 2007 and positive in each of the following 4 years, 2008–2011. In 2007, producer welfare losses for the cull cattle/processing beef category would be larger than the combined producer welfare gains for the other three commodities. For the years 2008–2011, the opposite would occur. This is largely due to the fact that, given Canada's excess cull cattle supply, the largest annual number of cull cattle would be imported in 2007, with imports diminishing thereafter. Table III shows positive changes in producer welfare because the discounted producer welfare gains in 2008–2011 would exceed producer welfare losses in 2007.

By far, the largest effects of the proposed rule would be due to resumption of Canadian cull cattle imports. As shown in Table IV, the present value of consumer welfare gains for the cull cattle/processing beef category outweighs the combined consumer welfare losses for the other three categories ($1.24 billion in consumer benefits, compared to $798 million in combined consumer losses, in 2006 dollars and discounted at 3 percent). Producer welfare losses attributable to resumption of cull cattle/processing beef imports are smaller in magnitude than the combined producer welfare gains for the other three categories ($657 million in producer losses, compared to over $768 million in combined producer gains).

We invite public comment on these estimates of welfare changes. In particular, we welcome informed opinion regarding the price elasticities we use in the analysis for cull cattle/processing beef (price elasticity of supply, 0.84; price elasticity of demand, −0.40) that result in the welfare gains for buyers of processing beef being so much larger than the welfare losses for sellers of processing beef.

TABLE IV.—PRESENT VALUES OF SEPARATE AND COMBINED WELFARE CHANGES WITH THE PROPOSED RULE FOR CULL CATTLE/PROCESSING BEEF, FEEDER CATTLE, FED CATTLE, AND FED BEEF, IN 2006 DOLLARS AND DISCOUNTED AT 3 PERCENT, 2007–2011

	Cull cattle/processing beef	Feeder cattle	Fed cattle	Fed beef	Combined
	(Thousand dollars)				
Change in consumer welfare	1,243,147	518,352	176,136	−103,919	444,740
Change in producer welfare	−656,540	494,483	171,791	101,928	111,662
Net change	586,607	−23,870	4,345	−1,991	556,401

Displacement of Processing Beef Imports From Other Countries

The net impact of cull cattle imports from Canada would depend upon the extent to which they would displace (substitute for) processing beef imports from other countries. About 35 percent of cull cattle imports from Canada over the period of analysis are projected to displace processing imports from other countries and the remainder are projected to contribute to an increase in the U.S. supply of processing beef (respectively, 5-year averages of 132 million pounds and 245 million pounds, carcass weight equivalent).[4] We consider here the effects of extreme displacement possibilities, that is, if either none or all of the Canadian cull cattle imports were to displace processing beef imports from other countries.

Projected imports of cull cattle from Canada are shown in Table V, together with changes in the U.S. supply of processing beef under the three displacement scenarios: None of the Canadian imports displacing imports from other countries; projected displacement; or all of the Canadian imports displacing imports from other countries. In the third scenario, we assume that the cull cattle imports from Canada would have no impact on the U.S. supply of processing beef.

Table VI compares the present and annualized values of welfare changes and average annual price changes for the cull cattle/processing beef category under the three displacement scenarios, in 2006 dollars. Discounting at 3 percent, the present value of net welfare benefits for the cull cattle/processing beef category would be about $927 million when no displacement is assumed to occur, compared to net benefits of about $587 million when projected levels of displacement occur, and zero benefits or costs when we assume all imported Canadian processing beef would displace imports from other countries. Annualized net values for the three scenarios, discounted at 3 percent, range from $203 million, to $128 million, to no impact. Over the 5-year period, annual declines in prices would average about $6 per cwt if no displacement were to occur, and about $4 per cwt with projected levels of displacement. There would be no price effect if all processing beef imports from Canada were to displace imports from other countries.

TABLE V.—PROJECTED IMPORTS OF CULL CATTLE FROM CANADA WITH THE PROPOSED RULE AND CHANGES IN THE U.S. SUPPLY OF PROCESSING BEEF IF (I) NONE OF THE CULL CATTLE IMPORTED FROM CANADA DISPLACE PROCESSING BEEF IMPORTED FROM OTHER COUNTRIES, (II) PROJECTED DISPLACEMENT OCCURS, OR (III) ALL OF THE CULL CATTLE IMPORTED FROM CANADA DISPLACE PROCESSING BEEF IMPORTS FROM OTHER COUNTRIES, 2007–2011, IN MILLION POUNDS CARCASS WEIGHT EQUIVALENT

	2007	2008	2009	2010	2011
Projected cull cattle imports from Canada	458	403	333	343	346
Projected processing beef imports from Canada	0	0	0	0	0
Projected displacement of processing beef imports from other countries by processing beef imports from Canada	170	149	128	106	106
Change in U.S. supply if none of the processing beef imports from Canada displace imports from other countries	458	403	333	343	346
Change in U.S. supply of processing beef if projected displacement occurs	288	254	205	237	240
Change in U.S. supply if all the processing beef imports from Canada displace imports from other countries	0	0	0	0	0

Note: Cull cattle (slaughter cows, bulls, and stags) are converted from thousand head to million pounds carcass weight equivalent by multiplying by the following carcass weights (pounds) for cows and bulls/stags, respectively: 2007, 576 and 888; 2008, 579 and 893; 2009, 583 and 899; 2010, 586 and 904; and 2011, 590 and 909 (Source: Expert opinion, USDA Economic Research Service, Market and Trade Economics Division, Animal Products, Grains, and Oil Seeds Branch).

TABLE VI.—PRESENT AND ANNUALIZED VALUES OF WELFARE CHANGES AND AVERAGE ANNUAL PRICE CHANGES FOR CULL CATTLE/PROCESSING BEEF IF (I) NONE OF THE CULL CATTLE IMPORTED FROM CANADA DISPLACES PROCESSING BEEF IMPORTED FROM OTHER COUNTRIES, (II) PROJECTED DISPLACEMENT OCCURS, OR (III) ALL OF THE CULL CATTLE IMPORTED FROM CANADA DISPLACE PROCESSING BEEF IMPORTS FROM OTHER COUNTRIES, IN 2006 DOLLARS, 2007–2011

Discount rate (percent)	Amount of imports from Canada assumed to displace imports from other countries [1]	Changes in welfare		
		Consumer	Producer	Net
		(Thousand dollars)		
Present value:				
3	None	1,928,548	−1,001,140	927,408
3	Projected	1,243,147	−656,540	586,607
3	All	0	0	0
7	None	1,742,482	−901,619	840,864
7	Projected	1,120,778	−590,070	530,708
7	All	0	0	0
Annualized value:				
3	None	421,107	−218,603	202.504
3	Projected	271,447	−143,358	128,089

[4] These projections are based on the expert opinion of staff of the USDA Economic Research Service, Market and Trade Economics Division, Animal Products, Grains, and Oil Seeds Branch.

TABLE VI.—PRESENT AND ANNUALIZED VALUES OF WELFARE CHANGES AND AVERAGE ANNUAL PRICE CHANGES FOR CULL CATTLE/PROCESSING BEEF IF (I) NONE OF THE CULL CATTLE IMPORTED FROM CANADA DISPLACES PROCESSING BEEF IMPORTED FROM OTHER COUNTRIES, (II) PROJECTED DISPLACEMENT OCCURS, OR (III) ALL OF THE CULL CATTLE IMPORTED FROM CANADA DISPLACE PROCESSING BEEF IMPORTS FROM OTHER COUNTRIES, IN 2006 DOLLARS, 2007–2011—Continued

Discount rate (percent)	Amount of imports from Canada assumed to displace imports from other countries [1]	Changes in welfare		
		Consumer	Producer	Net
3	All	0	0	0
7	None	424,975	−219,896	205,079
7	Projected	273,347	−143,912	129,435
7	All	0	0	0
Average annual price change and percentage price change:		(Dollars per cwt)	(Percentage)	
	None	−6.00	−6.57	
	Projected	−4.00	−4.26	
	All	−0	0	

Note: Prices are in carcass weight equivalent.

[1] Projected displacement quantities for the 5 years, 2007–2011, in million pounds carcass weight equivalent, are 170, 149, 128, 106, and 106. Displaced quantities for the 5 years, if all cull cattle imported from Canada were to displace processing beef imports from other countries, would be 458, 403, 333, 343, and 346 (Source: Expert opinion, USDA Economic Research Service, Market and Trade Economics Division, Animal Products, Grains, and Oil Seeds Branch).

It is evident that the extent of import displacement would influence impacts of the proposed rule for the cull cattle/processing beef category. Table VII shows the significance of the displacement assumption for the combined welfare effects. The larger the quantity of processing beef imports from other countries that would be displaced, the smaller the net benefits. The difference between consumer gains and producer losses would exceed $897 million (discounted at 3 percent) if no displacement of processing beef imports from other countries were to occur. The present value of net benefits would be about $556 million with projected displacement, and there would be a net welfare loss of $30 million if all of the imported Canadian cull cattle were to displace imports from other countries. In the third scenario, the modeled effects of the rule would be due to changes in the supply of Canadian feeder cattle, fed cattle, and fed beef as a result of the cull cattle imports affecting the slaughter mix in Canada. In this case, consumer welfare losses for these commodities would exceed producer welfare gains, resulting in a net decline in welfare.

TABLE VII.—PRESENT AND ANNUALIZED VALUES OF COMBINED WELFARE CHANGES FOR THE MODELED COMMODITIES IF (I) NONE OF THE PROCESSING BEEF IMPORTS FROM CANADA DISPLACE IMPORTS FROM OTHER COUNTRIES, (II) PROJECTED DISPLACEMENT OCCURS, OR (III) ALL OF THE PROCESSING BEEF IMPORTS FROM CANADA DISPLACE IMPORTS FROM OTHER COUNTRIES, IN 2006 DOLLARS, 2007–2011

Discount rate (percent)	Amount of imports from Canada assumed to displace discount imports from other countries	Changes in welfare		
		Consumer	Producer	Net
		(Thousand dollars)		
Present value:				
3	None	1,130,141	−232.938	897,202
3	Projected	444,740	111,662	556,401
3	All	−798,407	768,202	−30,206
7	None	1,029,444	−215,413	814,032
7	Projected	407,740	96,136	503,876
7	All	−713,038	686,206	−26,832
Annualized value:				
3	None	246,770	−50,861	195,909
3	Projected	97,110	−24,384	121,494
3	All	−174,337	167,742	−6,595
7	None	251,080	−52,527	198,552
7	Projected	99,452	23,457	122,908
7	All	−173,895	167,369	−6,527

Multi-sector impacts. For a broader examination of impacts, we map interactions among the grain, animal, and animal products industries using a second model.[5] This model takes into account substitution among livestock products in response to relative price changes. It incorporates foreign trade and yields expected price and revenue effects, but does not allow for computation of welfare changes.

Our results show for the combined livestock, feed, and grain sectors, an estimated decline in gross revenues with the proposed rule of less than one percent in 2007. For the beef and cattle sectors, the gross revenue declines are also less than one percent. The analysis indicates declines of less than one percent, as well, in cattle and beef prices in 2007.

As expected, these simulated impacts are small because they describe effects for aggregated commodity groupings (all cattle production and all beef production are grouped within single categories) and because of the linkages specified between the livestock production and processing sectors that allow for greater flexibility in adjusting to supply shocks. The larger effects reported above for cull cattle/processing beef are subsumed within a combined beef sector in this multi-sector model. These results support our expectation that broader impacts of the proposed rule would be limited.

Effects for Commodities Not Modeled

Commodity categories not modeled that would be affected by the proposed rule are breeding cattle, vealers and slaughter calves, bison, bovine casings and small intestine products, and bovine blood and blood products.

Breeding cattle. We do not expect the resumption of dairy and beef breeding cattle imports from Canada to significantly affect the U.S. market for these animals. The number that would be imported under the proposed rule is small in comparison to projected cattle imports from Canada overall (4 percent) and even smaller in comparison to the number of replacement breeding heifers supplied on average by U.S. producers (0.5 percent). Breeding cattle imported from Canada would augment the U.S. breeding herd very slightly. Demand for these animals, like the demand for breeding cattle generally, would derive from management decisions based on herd composition and expected future net returns, with price variations influencing secondarily the quantity of breeding cattle purchased.

Vealers and slaughter calves. The proposed rule is expected to have a small effect on the number of vealers and slaughter calves imported from Canada. A decline in imports is projected in each year of the period of analysis, compared to quantities that would be imported without the rule, as Canadian slaughter patterns adjust to reestablished export opportunities for cull cattle. Over the 5-year period, an average of 11,800 fewer vealers and slaughter calves are projected to be imported annually with the proposed rule than would be imported without the rule.

For the 10-year period, 1994–2003, slaughter of vealers and calves in the United States averaged 1.3 million head per year. We expect annual U.S. vealer and calf slaughter during the period of analysis to be similar to this earlier average. On this basis, the average annual decrease in vealer and slaughter calf imports from Canada under the proposed rule would be equal to less than 1 percent of U.S. vealer and calf slaughter. Any effect on vealer and slaughter calf prices because of the smaller number expected to be imported under the proposed rule would not be significant.

Bison. Like the cattle industry, the commercial bison industry is comprised primarily of cow-calf operations that sell weaned calves to other operations for finishing and processing. Projected bison imports from Canada total 4,000 head in 2007, 3,150 head in 2008, and 2,500 head each year thereafter. Each year, 250 head of breeding bison are projected to be imported. The remainder would be mainly bison for immediate slaughter (2,500 head in 2007, 2,400 head in 2008, and 2,000 head in each of the following years), with a lesser number of feeders (1,250 head in 2007, 500 head in 2008, and 250 head in each year thereafter).

The 2,500 bison projected to be imported for immediate slaughter in 2007 would represent about 7 percent of the U.S. slaughter total in 2005. We assume that most if not all of these slaughter bison (as well as the 1,250 head projected to be imported in 2007 for feeding) would be slaughtered at less than 30 months of age, that is, they would be of the same age as Canadian bison that are currently allowed to be imported. Thus, the only change in bison imports in 2007, as well as in subsequent years, under the proposed rule would be imports of 250 head of breeding bison.

Yearly imports from Canada of 250 head of breeding bison would augment the U.S. bison breeding herd only slightly. They would annually represent only about two-tenths of one percent of the U.S. bison breeding herd, assuming the composition of the national bison herd is similar to that of the national cattle herd, with breeding stock (cows, replacement heifers, and bulls) constituting about 56 percent of the animals.

As the market for bison meat becomes better established, the demand for breeding stock will continue to strengthen. The projected imports of breeding bison under the proposed rule would help meet this growing demand. However, they would constitute a very small addition to the U.S. breeding herd. Any effects on bison prices and the welfare of U.S. bison producers are expected to be insignificant.

Bovine casings and small intestine products. The proposed rule may affect the supply of bovine casings and small intestine products in the United States in three ways: By allowing importation of bovine casings from Canada; by allowing importation of Canadian bovine small intestines, minus the distal ileum, that are used to make certain casings and variety meats; and by reducing restrictions on live bovine imports from Canada and thereby changing the U.S. supply of bovine products in general, including intestines and other material used to produce casings and variety meats.

We calculate that with the rule the annual supply of bovine casings and variety meats produced from small intestines would increase on average over the period of analysis by about 1.6 percent. The largest increase would occur in 2007, with production of 2.5 million pounds of additional small intestine for use as casings and variety meats. These supply projections presume a ready market for these products.

The proposed rule would allow importation from Canada of bovine small intestine minus the distal ileum that could then be processed into casings and variety meats in the United States. APHIS does not have information on the volume of bovine small intestine that may be imported from Canada because of the proposed rule. We welcome information that would enable us to evaluate effects on the U.S. supply of bovine small intestine of allowing their importation from Canada.

[5] Three examples of studies based on this type of model are: Paarlberg, P.L. ''Agricultural Export Subsidies and Intermediate Goods Trade,'' *American Journal of Agricultural Economics.* 77, 1 (1995): 119–128. Paarlberg, P.L., J.G. Lee, and A.H. Seitzinger. ''Potential Revenue Impact of an Outbreak of Foot-and-Mouth Disease in the United States,'' *Journal of the American Veterinary Medical Association. 220,* 7 (April 1, 2002): 988–992. Sanyal, K.K. and R.W. Jones. ''The Theory of Trade in Middle Products,'' *American Economic Review. 72* (1982): 16–31.

Current regulations prohibit the importation of bovine and other ruminant casings from BSE minimal-risk regions. The proposed rule would remove this prohibition, and therefore allow resumption of bovine casings imports from Canada. The Agency does not have information on levels of production or consumption of bovine casings in the United States, and trade data do not distinguish between bovine and ovine casings; import and export quantities and prices for bovine casings alone are unavailable from the U.S. Department of Commerce. We welcome information that the public may provide that would enable us to better understand the U.S. bovine casings industry and levels of historic trade in bovine casings between the United States, Canada, and the world.

Bovine blood and blood products. The proposed rule would allow resumption of imports of bovine blood and blood products from BSE minimal-risk regions, that is, of Canadian origin. The primary commodities affected would be products used in the manufacture of vaccines and drugs, of which fetal bovine serum (FBS) is the most important. It is the most widely used serum in the culturing of cells, tissues and organs.

Since the detection of BSE in Canada in 2003, imports of FBS from Canada have been restricted to either research samples of Canadian-origin FBS (limited to 1 liter per shipment), or FBS that is derived from animals that originate in the United States, Australia, Mexico, or Central America and is processed at a designated Canadian facility under USDA permit.

The proposed rule may affect the supply of FBS in the United States in two ways: By allowing Canadian-origin FBS imports for commercial purposes, and by reducing restrictions on bovine imports from Canada and thereby changing the U.S. supply of pregnant cows presented for slaughter. We approximate that the proposed rule would allow for the importation of up to 24,000 liters of FBS derived from Canadian cows. Had this amount been imported in 2005, it would have represented about 13 percent of U.S. imports of FBS from all sources. In addition, the increase in pregnant cow slaughter projected with the proposed rule may provide an additional 23,000 to 32,000 liters. Other than for these upper-bound approximations, we are unable to project the extent to which the U.S. supply of FBS may be affected by the proposed rule. The additional supplies would benefit U.S. establishments that use FBS in their manufacturing processes.

Alternative to the Proposed Rule

An alternative to the proposed rule considered by APHIS would be to allow resumption of live bovine imports from BSE minimal-risk regions without restriction by date of birth. In other words, Canadian bovines could be imported for any destination or purpose without regard to their age.

Cattle imports from Canada. In Table VIII, projected imports under the alternative are compared to projected imports if no regulatory action were taken (baseline import quantities) and to projected imports under the proposed rule. The alternative would allow entry of bovines born before the date specified in the proposed rule as when a ruminant-to-ruminant feed ban in Canada was effectively enforced: March 1, 1999. For convenience, we refer to these animals as older cull cattle.

Under the proposed rule, cattle that are 8 years or older prior to March 1, 2007 would be prohibited. Each year thereafter, the prohibited older cull cattle would comprise a smaller age group: 9 years or older prior to March 1, 2008, 10 years or older prior to March 1, 2009, and so on. Within a few years, the proposed rule's requirement that bovines be born on or after March 1, 1999, would not limit bovine imports from Canada; bovine imports allowed under the proposed rule and the alternative would be the same.

TABLE VIII.—PROJECTED IMPORTS OF CANADIAN FEEDER CATTLE, FED CATTLE, CULL CATTLE/PROCESSING BEEF, AND FED BEEF: BASELINE, PROPOSED RULE, AND ALTERNATIVE OF NO RESTRICTION BY DATE OF BIRTH ON LIVE BOVINE IMPORTS, 2007–2011

	2007	2008	2009	2010	2011
Feeder cattle from Canada					
(Thousand head)					
Baseline	302	371	425	440	441
Proposed Rule	189	175	167	178	179
Alternative	189	175	167	178	179
Fed cattle from Canada					
(Thousand head)					
Baseline	742	731	729	755	756
Proposed Rule	728	673	644	685	688
Alternative	728	673	644	685	688
Cull cattle from Canada, net of imports assumed to displace processing beef imports from other countries					
(Million pounds carcass weight equivalent)					
Baseline	0	0	0	0	0
Proposed Rule	288	254	205	237	240
Alternative	360	318	205	237	240
Fed beef from Canada					
(Million pounds carcass weight equivalent)					
Baseline	446	425	420	419	419
Proposed Rule	371	390	420	419	419

TABLE VIII.—PROJECTED IMPORTS OF CANADIAN FEEDER CATTLE, FED CATTLE, CULL CATTLE/PROCESSING BEEF, AND FED BEEF: BASELINE, PROPOSED RULE, AND ALTERNATIVE OF NO RESTRICTION BY DATE OF BIRTH ON LIVE BOVINE IMPORTS, 2007–2011—Continued

	2007	2008	2009	2010	2011
Alternative	371	390	420	419	419

Source: Expert opinion, USDA Economic Research Service, Market and Trade Economics Division, Animal Products, Grains, and Oil Seeds Branch.

Note: For the cull cattle/processing beef category, cull cattle imports are converted from thousand head to million pounds carcass weight equivalent for 2007–2011 by multiplying by the following carcass weights (pounds) for cows and bulls/stags, respectively: 2007, 576 and 888; 2008, 579 and 893; 2009, 583 and 899; 2010, 586 and 904; and 2011, 590 and 909.

Projected imports of Canadian feeder cattle, fed cattle, and fed beef are the same under the proposed rule and under the alternative. In both cases, feeder and fed cattle imports would be fewer than would enter without the rule, and fed beef imports would be less in the first 2 years of the period of analysis. The only difference between imports under the proposed rule and under the alternative is with respect to cull cattle imports projected for 2007 and 2008. Under the alternative, imports of cull cattle are projected in these 2 years to be one-fourth greater, net of displaced processing beef imports, than they would be under the proposed rule. The older cull cattle that would be imported under the alternative would total 168,000 cows and 20,000 bulls and stags in 2007, and 147,000 cows and 18,000 bulls and stags in 2008. These older cull cattle would yield 72 million pounds and 64 million pounds of processing beef, carcass weight equivalent, for the 2 years.

Table IX shows the present and annualized values of welfare changes under the alternative for the cull cattle/processing beef category. The present value of the welfare changes (2006 dollars, 3 percent discount rate) would be $1.4 billion in consumer gains, $731 million in producer losses, for a net benefit of about $667 million. Annualized values over the 5 years would be consumer gains of $305 million, producer losses of $160 million, and net benefits of $146 million.

TABLE IX.—ALTERNATIVE OF NO RESTRICTION BY DATE OF BIRTH ON LIVE BOVINE IMPORTS: PRESENT AND ANNUALIZED VALUES OF WELFARE CHANGES FOR CULL CATTLE/PROCESSING BEEF, 2007–2011

	Discount rate (percent)	Changes in welfare		
		Consumer	Producer	Net
		(Thousand dollars)		
Present Value:				
2006 Dollars	3	1,397,680	−730,800	666,880
	7	1,267,061	−660,333	606,728
2001 Dollars	3	1,215,348	−635,446	579,902
	7	1,101,796	−574,189	527,606
Annualized Value:				
2006 Dollars	3	305,190	−159,573	145,617
	7	309,025	−161,049	147,976
2001 Dollars	3	265,377	−138,752	126,624
	7	268,718	−140,039	128,678

Note: Consumers are U.S. buyers of processing beef at the wholesale level; producers are sellers of U.S.-produced processing beef at the wholesale level. Cull cattle imports from Canada in thousand head are converted to processing beef in million pounds carcass weight equivalent by multiplying by the following carcass weights (pounds) for cows and bulls/stags, respectively: 2007, 576 and 888; 2008, 579 and 893; 2009, 583 and 899; 2010, 586 and 904; and 2011, 590 and 909.

To exemplify the differences in welfare effects between the alternative and the proposed rule for the cull cattle/processing beef category, we compare in Table X their present and annualized values in 2006 dollars when discounted at 3 percent. Compared to effects under the proposed rule, consumer welfare gains under the alternative would be 12.4 percent larger, producer welfare losses would be 11.3 percent larger, and net benefits would be 13.7 percent larger. The annual decrease in processing beef prices under the alternative over the 5-year period, all things equal, is computed to average $4.80 per cwt, compared to an average annual decrease of $4.00 under the proposed rule.

TABLE X.—PRESENT AND ANNUALIZED VALUES OF WELFARE CHANGES FOR CULL CATTLE/PROCESSING BEEF, WITH THE ALTERNATIVE AND WITH THE PROPOSED RULE, 3 PERCENT DISCOUNT RATE, 2006 DOLLARS, 2007–2011

	Changes in welfare		
	Consumer	Producer	Net
	(Thousand dollars)		
Present Value:			
Alternative	1,397,680	−730,800	666,880
Proposed Rule	1,243,147	−656,540	586,607
Difference	154,533	−74,260	80,273
Annualized Value:			
Alternative	305,190	−159,573	145,617
Proposed Rule	271,447	−143,358	128,089
Difference	33,743	−16,215	17,528
Difference as a percentage of welfare changes with the proposed rule	12.4%	11.3%	13.7%

When we compare present and annualized values of combined welfare changes under the alternative and under the proposed rule, we find that the net welfare benefits would be 15 to 16 percent larger under the alternative than would be realized under the proposed rule. For example, the annualized net benefit (2006 dollars, 3 percent rate of discount) would be $140 million under the alternative, compared to $121 million under the proposed rule. Impacts under the alternative and under the proposed rule would also differ for some of the commodities not modeled. For example, we would expect the supply of bovine casings to be larger with the alternative, due to larger projected slaughter numbers.

BSE risk. As described in the risk assessment for this proposed rule, transmission of BSE requires that bovines ingest feed that contains the infectious agent. Feed contamination results from the incorporation of ingredients that contain certain 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 remain contaminated. Prohibitions on the use of ruminant protein in ruminant feed are imposed by FDA to mitigate the risk of BSE transmission.

The OIE establishes standards for the international trade in animals and animal products. It recommends that cattle be imported from a region that has reported an indigenous case of BSE only if the cattle selected for export were born after the date from which a ban on the feeding of ruminants with meat-and-bone meal and greaves (the residue left after animal fat or tallow has been rendered) derived from ruminants had been effectively enforced.

On August 4, 1997, Canada issued regulations prohibiting the use of mammalian protein in ruminant feeds. Implementation of the feed ban was a gradual process, with producers, feed mills, retailers, and feed manufacturers given grace periods before they were required to be in full compliance with the regulations. It is estimated that this implementation period may have lasted several months, making February 1998 a more realistic date on which the ban can be considered to have been practically implemented.

The likelihood that Canadian cattle born after February 1998 would be exposed to the BSE agent continues to decrease over time. APHIS considers that a period of 1 year following the practical implementation of the feed ban allows sufficient time for the measures taken by Canada to have their desired effect. Therefore, APHIS concludes that cattle born on or after March 1, 1999, are unlikely to have been exposed to the BSE agent via feed and can be imported into the United States for any purpose with a low risk that they will be infected with the BSE agent.

We do not have a quantitative estimate of the additional risk posed by importation of Canadian cattle born before March 1, 1999. The importance of a feed ban as a risk mitigation measure is demonstrated in science and experience, and is incorporated into the OIE feed ban recommendation. We conclude that there may be some degree of increased risk of BSE introduction under the alternative, compared to the minimal risk posed by the proposed rule, because of the greater likelihood of the older cull cattle having been exposed to infectivity. While our analysis indicates larger net welfare benefits may be realized under the alternative of no restriction by date of birth on live bovine imports, the proposed rule is preferable because it would pose a lower risk of BSE introduction into the United States and would be consistent with demonstrated science, experience, and OIE guidance.

Expected Impacts Assuming Resumption of Processing Beef Imports From Canada

Current regulations require that imported Canadian cattle be slaughtered at less than 30 months of age and that imported Canadian beef come from cattle slaughtered at less than 30 months of age. Our analysis assumes no imports of processing beef from Canada. As a second scenario, we consider effects if imports of Canadian beef from cattle slaughtered at 30 months or older were to resume at the same time that the proposed rule is finalized.

Importation of ruminant products and byproducts was included in the BSE minimal-risk regions final rule, and this proposed rule would not change regulations regarding the importation of beef from Canada. However, in March 2005, APHIS gave notice in the **Federal Register** that the applicability of certain provisions of the rule pertaining to bovine meat, meat byproducts, whole and half carcasses, and certain other bovine products was being delayed until further notice. This partial delay of applicability of the BSE minimal-risk regions rule prohibits the importation of such products if derived from bovines 30 months of age or older at slaughter.

As discussed, the United States is a large importer of processing beef, with Australia, New Zealand, and Uruguay currently our primary suppliers. Over the period of analysis, total processing beef imports are projected to provide about 45 percent of U.S. consumption of processing beef (decreasing from 49 percent in 2007 to 42 percent in 2011). We assume annual imports of Canadian processing beef, 2007–2011, would average 240 million pounds carcass weight equivalent, of which about two-thirds would displace processing beef imports from other countries and about

one-third would represent a net increase in U.S. supply. It is further assumed under this scenario that the Canadian cull cattle imported would not displace processing beef imports from other countries.[6] The net addition of processing beef from Canada would be equivalent to 2.8 percent of projected baseline imports (without the rule) over the period of analysis, or 1.3 percent of U.S. supply. When the processing beef produced from projected cull cattle imports from Canada is included, the increase in the U.S. supply of processing beef under this scenario would be equivalent to 4.3 percent of projected imports without the proposed rule.

Projected imports of cull cattle and processing beef from Canada under this scenario are compared in Table XI to projected imports of cull cattle alone used to evaluate the proposed rule. Results of the analysis show the price of processing beef decreasing in 2007 by 6.3 percent under this scenario, from $99 to about $93 per cwt carcass weight equivalent in 2006 dollars. Over the period of analysis, the annual decrease in processing beef prices because of the proposed rule, all things equal, is expected to average about 5 percent, ranging from about $6.20 per cwt in 2007 to about $3.80 per cwt in 2009.

TABLE XI.—SCENARIO COMPARISON OF QUANTITIES OF (1) CULL CATTLE ALONE AND (II) CULL CATTLE AND PROCESSING BEEF PROJECTED TO BE IMPORTED FROM CANADA, NET OF DISPLACED PROCESSING BEEF IMPORTS FROM OTHER COUNTRIES, 2007–2011, IN MILLION POUNDS OF PROCESSING BEEF, CARCASS WEIGHT EQUIVALENT

Year	Cull cattle only	Cull cattle and processing beef
2007	288	339
2008	254	299
2009	205	242
2010	237	279
2011	240	282

Source: Expert opinion, USDA Economic Research Service, Market and Trade Economics Division, Animal Products, Grains, and Oil Seeds Branch.

Notes: Cull cattle are converted to processing beef by multiplying by the following carcass weights (pounds) for cows and bulls/stags, respectively: 2007, 576 and 888; 2008, 579 and 893; 2009, 583 and 899; 2010, 586 and 904; and 2011, 590 and 909. All of the quantities that follow are expressed in million pounds of processing beef, carcass weight equivalent. For the cull cattle imports only scenario, the quantities are based on projected imports of slaughter cows, bulls, and stags, and are equivalent to: 2007, 458; 2008, 403; 2009, 333; 2010, 343; and 2011, 346. These quantities are reduced by the following projected displaced processing beef imports from other countries: 2007, 170; 2008, 149; 2009, 128; 2010, 106; and 2011, 106. For the scenario that assumes importation from Canada of both cull cattle and processing beef, quantities of cull cattle imported are: 2007, 214; 2008, 199; 2009, 192; 2010, 204; and 2011, 207. Projected processing beef imports are: 2007, 325; 2008, 275; 2009, 200; 2010, 200; and 2011, 200. Combined cull cattle and processing beef imports are 2007, 539; 2008, 474; 2009, 392; 2010, 404; and 2011, 407. These quantities are reduced by the following projected displaced processing beef imports from other countries: 2007, 200; 2008, 175; 2009, 150; 2010, 125; and 2011, 125.

As shown in Table XII, the present value of the welfare changes in 2006 dollars when using a 3 percent discount rate would be $1.47 billion in consumer gains, $770 million in producer losses, for a net benefit of about $695 million. Annualized values over the 5 years, in 2006 dollars when using a 3 percent discount rate, would be consumer gains of $320 million, producer losses of $168 million, and net benefits of $152 million.

TABLE XII.—CULL CATTLE/PROCESSING BEEF: PRESENT AND ANNUALIZED VALUES OF WELFARE CHANGES ASSUMING CULL CATTLE IMPORTS AND PROCESSING BEEF IMPORTS FROM CANADA WOULD RESUME AT THE SAME TIME, 2007–2011

	Discount rate (percent)	Changes in welfare		
		Consumer	Producer	Net
		(Thousand dollars)		
Present Value:				
2006 Dollars	3	1,465,829	−770,389	695,440
	7	1,321,580	−692,393	629,187
2001 Dollars	3	1,274,467	−669,797	604,670
	7	1,149,081	−602,002	547,078
Annualized Value:				
2006 Dollars	3	320,071	−168,218	151,853
	7	322,321	−168,868	153,453
2001 Dollars	3	278,286	−146,253	132,033
	7	280,250	−146,823	133,427

Compared to impacts for the cull cattle/processing beef category when only cull cattle would enter, this scenario would result in consumer welfare gains larger by 17.9 percent, producer welfare losses larger by 17.3 percent, and net benefits larger by 18.6 percent.

[6] The import quantities and extent of displacement are projections made by staff of the USDA Economic Research Service (ERS), Market and Trade Economics Division, Animal Products, Grains, and Oil Seeds Branch, based on their expert opinion and reference to the ''USDA Agricultural Baseline Projections to 2015,'' United States Department of Agriculture, Interagency Agricultural Projections Committee, Baseline Report OCE–2006–1, February 2006.

Combined effects under this scenario for cull cattle/processing beef, feeder cattle, fed cattle, and fed beef are shown in Table XIII.

TABLE XIII.—PRESENT AND ANNUALIZED VALUES OF COMBINED WELFARE CHANGES FOR THE MODELED COMMODITIES, ASSUMING CULL CATTLE IMPORTS AND PROCESSING BEEF IMPORTS FROM CANADA WOULD RESUME AT THE SAME TIME, 2007–2011

	Discount rate (percent)	Changes in welfare		
		Consumer	Producer	Net
		(Thousand dollars)		
Present Value:				
2006 Dollars	3	669,191	2,387	671,578
	7	610,108	−2,145	607,963
2001 Dollars	3	581,395	2,519	583,917
	7	529,956	−1,342	528,614
Annualized Value:				
2006 Dollars	3	146,122	523	146,643
	7	148,808	−513	148,294
2001 Dollars	3	126,951	551	127,501
	7	129,252	−327	128,923

Removal of the delay of applicability, thereby allowing importation of Canadian beef from cattle slaughtered at 30 months or older, is a decision that will be taken at the discretion of the Secretary of the U.S. Department of Agriculture.

Expected Impacts for Small Entities

We have prepared an initial regulatory flexibility analysis that indicates that industries expected to be affected by the proposed rule are composed largely of small entities. Industries that may be affected, as categorized by the North American Industry Classification System, are Beef Cattle Ranching and Farming (NAICS 112111), Dairy Cattle and Milk Production (NAICS 112120), All Other Animal Production (NAICS 112990), Cattle Feedlots (NAICS 112112), Animal (except Poultry) Slaughtering (NAICS 311611), Meat Processed from Carcasses (NAICS 311612), Meat and Meat Product Merchant Wholesalers (NAICS 424470), Supermarkets and Other Grocery (except Convenience) Stores (NAICS 445110), Meat Markets (NAICS 445210), In-Vitro Diagnostic Substance Manufacturing (NAICS 325413), and Biological Product (except Diagnostic) Manufacturing (NAICS 325414).

Average effects for small entities would be small. As examples, we approximate that gross receipts for small-entity beef and dairy operations would increase, respectively, by $160 (0.6 percent of annual revenue) and $133 (less than 0.1 percent of annual revenue), due to the rule's projected impact on feeder cattle prices. We approximate that small-entity feedlots may incur a revenue loss of about $5,040 (less than 0.3 percent of annual revenue), due to the rule's expected effects on feeder cattle and fed cattle prices. Small-entity meat packing and processing establishments may benefit marginally with the rule, with estimated price increases for fed beef in 2007 and 2008 representing an increase in annual revenue of less than 0.2 percent. Effects of the proposed rule for packers and processors that utilize processing beef would be larger, due to the resumption of cull cattle imports from Canada. Annual prices of processing beef are expected to fall by an average of $4 per cwt over the period of analysis. The price declines would benefit establishments that use processing beef to produce ground beef for the wholesale market. Conversely, establishments that sell processing beef would be negatively affected by the expected price declines.

Currently, bovines imported from Canada are restricted to animals that are slaughtered at less than 30 months of age. Bovines not imported for immediate slaughter must be moved from the port of entry to a feedlot in a sealed means of conveyance and from the feedlot to a recognized slaughtering establishment again in a sealed means of conveyance. The animals may not be moved to more than one feedlot. Under the proposed rule, these movement restrictions would no longer be imposed. Canadian bovines imported other than for immediate slaughter could be moved any number of times to any destinations in unsealed means of conveyance.

Under the proposed rule, feeder bovines imported from BSE minimal-risk regions would not need to be accompanied by APHIS Form VS 17–130, which currently is used to identify the feedlot of destination. (The individual responsible for the movement of an imported animal and the individual identification of the animal would still be required information on the accompanying health certificate.) Also under the proposed rule, bovines of Canadian origin moved from a U.S. feedlot to a slaughtering establishment would not need to be accompanied by APHIS Form VS 1–27.

Removal of these movement and paperwork requirements would benefit buyers and sellers of Canadian-origin bovines. Many of the beneficiaries are likely to be small entities, given their predominance among cattle and dairy operations and feedlot establishments. Affected businesses would be able to take advantage of a broader range of transactional opportunities than under current regulations. For example, the sale of a young steer first for backgrounding, then for confined feeding at one or more facilities, and finally for slaughter may enable the original and subsequent owners of the animal to better maximize returns compared to current marketing possibilities. While we are not able to quantify impacts of removing current movement restrictions on Canadian cattle imports, we expect their removal would benefit the cattle industry across-the-board.

The Agency has found no significant alternatives to the proposed rule that would continue to protect against the introduction and dissemination of BSE into the United States while removing unnecessary prohibitions on the importation of certain commodities from Canada. Without the proposed rule, restrictions on U.S. importation of

certain Canadian bovine commodities that are without scientific merit would continue. With the proposed rule, importation of these Canadian commodities would be allowed to resume under certain conditions and the risk of introduction of BSE into the United States would remain minimal.

Executive Order 12988

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

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the importation of bovine and bovine products from Canada under this proposed rule, we have prepared an environmental assessment. The environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment may be viewed on the Regulations.gov Web site or in our reading room. Instructions for accessing Regulations.gov and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule. In addition, copies may be obtained by calling or writing to the individuals listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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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 proposing to amend 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 would continue to read as follows:

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

§ 93.405 [Amended]

2. In § 93.405, paragraph (a)(4) would be amended by removing the words ''feedlot or recognized slaughtering establishment'' and adding in their place the words ''destination''.

3. Section 93.419 would be amended as follows:

a. Paragraphs (b) and (c) would be revised to read as set forth below.

b. Paragraph (d) would be redesignated as paragraph (e).

c. A new paragraph (d) would be added to read as set forth below.

d. In newly designated paragraph (e)(2), the reference to ''paragraph (d)(7)'' would be removed and a reference to ''paragraph (e)(7)'' would be added in its place.

§ 93.419 Sheep and goats from Canada.

* * * * *

(b) If the sheep or goats are unaccompanied by the certificate required by paragraph (a) of this section, or if they are found upon inspection at the port of entry to be affected with or exposed to a communicable disease, they shall be refused entry and shall be handled or quarantined, or otherwise disposed of, as the Administrator may direct.

(c) Any sheep or goats imported from Canada must not be pregnant, must be less than 12 months of age when imported into the United States and when slaughtered, 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, and 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. The animals must be accompanied by the certification issued in accordance with § 93.405 that states, in addition to the statements required by § 93.405, that the conditions of this paragraph have been met. Additionally, for sheep and goats imported for immediate slaughter, the certificate must state that the conditions of paragraphs (d)(1) through (d)(3) of this section have been met, and, for sheep and goats imported for other than immediate slaughter, the certificate must state that the conditions of paragraphs (e)(1) and (e)(2) of this section have been met.

(d) *Sheep and goats imported for immediate slaughter.* Sheep and goats 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 sheep and goats shall be inspected at the port of entry and otherwise handled in accordance with § 93.408. The seals on the means of conveyance must be broken only at the port of entry by the APHIS port veterinarian or at the recognized slaughtering establishment by an authorized USDA representative. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the recognized slaughtering establishment. 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. Additionally, the sheep and goats must meet 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.

* * * * *

4. Section 93.420 would be revised to read as follows:

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

The requirements for the importation of sheep and goats from Canada for immediate slaughter are contained in § 93.419. The requirements for the importation of bovines from Canada for immediate slaughter are contained in § 93.436. All other ruminants imported from Canada for immediate slaughter, in addition to meeting all other applicable requirements of this part, must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) to a recognized slaughtering establishment for slaughter, in conveyances that must be sealed with seals of the U.S. Government at the port of entry. The seals may be broken only at a recognized slaughtering establishment in the United States by an authorized USDA representative. The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33, which must include the location of the recognized slaughtering establishment. Such ruminants shall be inspected at the port of entry and otherwise handled in accordance with § 93.408.

(Approved by the Office of Management and Budget under control number 0579–0277)

5. Section 93.436 would be amended as follows:

a. Paragraphs (a) and (b) would be revised to read as set forth below.

b. In paragraph (c), the reference to ''§§ 93.419(c) and 93.420'' would be removed and a reference to ''§§ 93.405 and 93.419'' would be added in its place.

§ 93.436 Ruminants from regions of minimal risk for BSE.

* * * * *

(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 have been born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export. For bovines imported from Canada, that date is March 1, 1999.

(2) 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 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 official identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at the time of slaughter;

(3) The bovines must be accompanied by a certificate issued in accordance with § 93.405 that states, in addition to the statements required by § 93.405, that the conditions of paragraphs (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). The bovines shall be inspected at the port of entry and otherwise handled in accordance with § 93.408;

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

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

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

(1) The bovines must have been born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export. For bovines imported from Canada, that date is March 1, 1999.

(2) 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. Acceptable means of permanent identification include the following:

(i) A mark properly applied with a freeze brand, hot iron, or other method, and easily visible on the live animal and on the carcass before skinning. Such a mark must be not less than 2 inches nor more than 3 inches high, and must be applied to each animal's right hip, high on the tail-head (over the junction of the sacral and first cocygeal vertebrae). Bovines exported from Canada so marked must be marked with ''CAN'';

(ii) A tattoo with letters identifying the exporting country must be applied to the inside of one ear of the animal. For bovines exported from Canada, the tattoo must read ''CAN'';

(iii) Other means of permanent identification upon request if deemed adequate by the Administrator to humanely identify the animal in a distinct and legible way as having been imported from the BSE minimal-risk exporting region.

(3) 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 § 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 official identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at the time of slaughter;

(4) 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 (a)(1) and (a)(2) of this section have been met; and

(5) The bovines must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f).

* * * * *

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

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

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

§ 94.19 [Amended]

7. In § 94.19, paragraphs (a)(2), (b)(2), and (f) would be amended by removing the words ''and small intestine'' each time they appear.

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

8. The authority citation for part 95 would continue to read as follows:

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

9. Section 95.4 would be amended as follows:

a. The heading and the paragraph (a) introductory text would be revised to read as set forth below.

b. Paragraphs (e) through (h) would be redesignated as paragraphs (f) through (i), respectively.

c. Paragraphs (a)(1)(ii) and (a)(1)(iv) would be revised to read as set forth below.

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

e. Paragraph (d) introductory text would be revised to read as set forth below.

f. New paragraph (e) would be added to read as set forth below.

g. In newly designated paragraph (h)(1)(i), the words ''and small intestine'' would be removed.

h. In newly designated paragraph (i) introductory text, the words ''paragraphs (h)(1) through (h)(3)'' would be removed and the words paragraphs ''paragraphs (i)(1) through (i)(3)'' would be added in their place.

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

(a) Except as provided in paragraphs (c) through (i) of this section, the importation of the following is prohibited:

(1) * * *

(ii) Glands, unprocessed fat tissue, and blood and blood products derived from ruminants;

* * * * *

(iv) Derivatives of glands and blood and blood products derived from ruminants;

* * * * *

(d) Except as provided in paragraph (e) of this section, the importation of serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ruminants that have been in any region listed in § 94.18(a) of this chapter, and collagen and collagen products that meet any of the conditions listed paragraphs (a)(1) through (a)(3) of this section, is prohibited unless the following conditions have been met:

* * * * *

(e) Bovine blood and blood products that are otherwise prohibited importation under paragraph (a)(1) or (d) of this section may be imported into the United States if they meet the following conditions:

(1) For blood collected at slaughter and for products derived from blood collected at slaughter:

(i) The blood was collected in a closed system in which the blood was conveyed directly from the animal in a closed conduit to a closed receptacle, or was collected otherwise in an hygienic manner that prevents contamination of the blood with SRMs.

(ii) The slaughtered animal passed ante-mortem inspection and was not subjected to a pithing process or to a stunning process with a device injecting compressed air or gas into the cranial cavity;

(2) For fetal bovine serum:

(i) The blood from which the fetal bovine serum was derived was collected in a closed system in which the blood was conveyed directly from the animal in a closed conduit to a closed receptacle, or was collected otherwise in an hygienic manner that prevents contamination of the blood with SRMs;

(ii) The dam of the fetal calf passed ante-mortem inspection and was not subjected to a pithing process or to a stunning process with a device injecting compressed air or gas into the cranial cavity;

(iii) The uterus was removed from the dam's abdominal cavity intact and taken to a separate area sufficiently removed from the slaughtering area of the facility to ensure that the fetal blood was not contaminated with SRMs when collected.

(3) For blood collected from live donor bovines and for products derived from blood collected from live donor bovines:

(i) The blood was collected in a closed system in which the blood was conveyed directly from the animal in a closed conduit to a closed receptacle, or was collected otherwise in a hygienic manner that prevents contamination of the blood with SRMs;

(ii) The donor animal was free of clinical signs of disease.

(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, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (e)(1), (e)(2), or (e)(3) of this section, as applicable, have been met.

* * * * *

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

10. The authority citation for part 96 would continue 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.

11. In § 96.1, new definitions of *Food and Drug Administration* and *Food Safety and Inspection Service* would be added, in alphabetical order, to read as follows:

§ 96.1 Definitions.

* * * * *

Food and Drug Administration. The Food and Drug Administration of the United States Department of Health and Human Services.

Food Safety and Inspection Service. The Food Safety and Inspection Service of the United States Department of Agriculture.

* * * * *

12. In § 96.2, paragraph (b) would be revised to read as follows:

§ 96.2 Prohibition of casings due to African swine fever and bovine spongiform encephalopathy.

* * * * *

(b) *Ruminant casings.* The importation of casings, except stomachs, from ruminants that originated in or were processed in any region listed in § 94.18(a) of this subchapter is prohibited, except as provided in paragraphs (b)(1) and (b)(2) of this section:

(1) Casings that are 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.

(2) Casings that are derived from bovines that were slaughtered in a region listed in § 94.18(a)(3) of this subchapter may be imported, provided, if the casings are derived from the small intestine, the casings are derived from that part of the small intestine that is eligible for use as human food in accordance with the requirements established by the Food Safety and Inspection Service at 9 CFR 310.22 and the Food and Drug Administration at 21 CFR 189.5.

(3) Casings imported in accordance with either paragraph (b)(1) or (b)(2) of this section must be accompanied by a certificate that:

(i) States that the casings meet the conditions of this section;

(ii) Is written in English;

(iii) Is signed by an individual eligible to issue the certificate required under § 96.3; and

(iv) Is presented to an authorized inspector at the port of entry.

(Approved by the Office of Management and Budget under control number 0579–0015)

13. In § 96.3, paragraph (d) would be revised to read as follows:

§ 96.3 Certificate for animal casings.

* * * * *

(d) In addition to meeting the requirements of this section, the certificate accompanying sheep casings from a region listed in § 94.18(a)(3) of this subchapter must state that the casings meet the requirements of § 96.2(b)(1) and the certificate accompanying bovine casings from a region listed in § 94.18(a)(3) of this subchapter must state that the casings meet the requirements of § 96.2(b)(2).

* * * * *

Done in Washington, DC, this 3rd day of January 2007.

Bruce Knight,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 07–17 Filed 1–4–07; 3:00 pm]

BILLING CODE 3410–34–P