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Importation of Certain Commodities From BSE Minimal-risk Regions (Canada)

Environmental Assessment, October 27, 2006

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I. Introduction

A. Need for the Proposed Action

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. Until May 2003, U.S. regulations allowed live ruminants[1] and ruminant products and byproducts to be imported from Canada with no restrictions related to bovine spongiform encephalopathy (BSE). At that time, the United States imposed regulatory restrictions on Canada with regard to the importation of these commodities because of the first diagnosed case of BSE, also known as "mad cow disease," in a cow in Alberta, Canada.

On January 4, 2005, APHIS published a final rule[2] (hereafter referred to as the Minimal-risk Regions (MRR) rule) that (1) established a BSE minimal-risk region category, (2) set forth conditions for the importation of certain live ruminants and ruminant products and byproducts from such regions, and (3) added Canada to the category of BSE minimal-risk regions. The criteria for a minimal-risk region include the following: a minimal-risk region must have had in place, prior to the detection of BSE, risk mitigation measures—such as import restrictions, a ruminant-to-ruminant feed ban, and surveillance—adequate to prevent widespread exposure and/or establishment of the disease. The region also conducts epidemiological investigations and risk assessments when BSE cases are identified and imposes additional risk mitigation measures as necessary. On July 15, 2005, APHIS implemented the regulations specified in the MRR rule.

The MRR rule allows, under certain conditions, the importation of the following commodities from Canada:

(1) bovines[3] for feeding or immediate slaughter, as long as they are less than 30 months of age when slaughtered;
(2) ovines and caprines (sheep and goats), for feeding or immediate slaughter, as long as they are slaughtered at less than 12 months of age;
(3) cervids (deer, elk, caribou, moose, and reindeer);
(4) camelids (llamas, alpacas, guanacos, and vicunas);
(5) meat from bovines, ovines, caprines, and cervids; and
(6) certain other products and byproducts, including bovine livers and tongues, gelatin, and tallow.

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[1] Any of various hoofed, even-toed, usually horned mammals such as cows, bison, sheep, goats, deer, giraffes, and camels. They characteristically have a stomach divided into four compartments and chew cud.
[2] 70 FR 459-553, January 4, 2005.
[3] *Bos taurus* (domestic cattle), *Bos indicus* (zebu cattle), and *Bison bison* (American bison).

Although implementation of the MRR rule resumed trade with Canada in certain ruminant commodities, the prohibition on live bovines 30 months of age and older and other associated commodities, such as bovine blood and blood products and bovine casings,[4] continued. As a result, bovine blood and blood products and the 2004 and 2005 U.S. supplies of bovine casings derived from the small intestine were constrained by BSE-related restrictions on the use of the bovine small intestine for human food. The requirement for the removal and disposal of the entire small intestine established in the MRR rule was consistent at the time with the USDA, Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services, Food and Drug Administration (FDA) regulations. However, FSIS and FDA have since modified their regulations to allow the use of the small intestine, except for the distal ileum,[5] for human food and cosmetic use.

The proposed action is needed to allow importation of the commodities and to allow trade when there is no scientific basis for trade restriction. The conditions for allowing trade of the bovine commodities would be consistent with the 2005 World Organization for Animal Health (commonly referred to as the Office International des Epizooties (OIE))[6] Terrestrial Animal Health Code for BSE (chapter 2.3.13.).[7] Therefore, USDA, APHIS is proposing to amend the regulations that establish conditions for the importation of live ruminants and ruminant products from minimal-risk regions[8] into the United States. The proposed action would amend the current regulations to allow, under certain conditions, the following additional commodities from minimal-risk regions: live bovines for unrestricted use born after the date of an effective feed ban, bovine blood and blood products, and bovine small intestine with the exception of the distal ileum. Currently, Canada is the only country that has been recognized as a minimal-risk region.

For purposes of this document, bovines include cattle and bison. Although the proposed rulemaking for this matter addresses the importation of live bovines, only a small amount of the bovines from Canada under consideration for the proposed action would be bison (about 0.2 percent or 2,500 of 1.3 million bovines per year); thus, when this document refers to the term "bovines," it mostly pertains to cattle.

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[4] According to 9 Code of Federal Regulations (CFR) § 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."

[5] The distal ileum is the very straight, terminal portion of the small intestine, ranging in length from 12 to 18 inches, depending upon the size of the animal.

[6] The World Trade Organization (WTO) recognizes the OIE as the international organization for development of standards, guidelines, and recommendations with regard to animal health and zoonoses (diseases that are transmissible from animals to humans).

[7] Available on the Internet at http://www.oie.int/eng/normes/mcode/en_chapitre_2.3.13.htm.

[8] 9 CFR § 94.18(a)(3).

B. Purpose of This Document

This environmental assessment will be used to help determine whether or not to prepare an environmental impact statement, a more comprehensive study of the proposed action and alternatives considered in this document. This environmental assessment will be used as a decisionmaking tool together with the associated risk assessment (USDA, APHIS, 2006a) and economic analysis (USDA, APHIS, 2006b) in determining whether to implement the proposed rulemaking.

C. Alternatives Considered

As a Federal agency subject to compliance with the National Environmental Policy Act (NEPA),[9] APHIS must prepare an environmental assessment to consider the environmental effects under a proposed action and alternatives to that action consistent with NEPA regulations.[10] In addition to the proposed rulemaking alternative, this document discusses the No Action alternative—the current regulations for importation of live ruminants and ruminant products from minimal-risk regions—because it is considered as the environmental baseline for discussing the proposed action.

1. No Action

Under this alternative, no change would occur to the MRR regulations published on January 4, 2005, that (1) established the criteria for a BSE minimal-risk region, (2) determined that Canada meets those criteria, and (3) specified the commodities allowed for importation from a BSE minimal-risk region. Commodities listed on page 1 of this document would continue to be allowed into the United States from regions that have been designated as minimal-risk regions. In addition, casings made from bovine small intestines from BSE minimal-risk regions and bovine blood and blood products would continue to be prohibited under this alternative.

2. Proposed Action

APHIS is proposing to add certain commodities to the list of those commodities that would be allowed under the import regulations for a minimal-risk region, specific to the consideration of Canada.[11] The proposed rulemaking would amend the current regulations to allow the entry of the following commodities from regions that present a minimal-risk of introducing BSE into the United States:

[9] 42 United States Code (U.S.C.) 4321 *et seq.*
[10] 40 CFR parts 1500–1508, 7 CFR 1b, and 7 CFR part 372.
[11] 9 CFR parts 93–96.

(1) live bovines born on or after March 1, 1999,[12] with no restrictions on their use, destination, or time of slaughter;
(2) bovine blood and blood products; and
(3) bovine small intestine (with the exception of the distal ileum).

The proposed amendment to allow bovine small intestine would be consistent with FSIS and FDA regulations[13] that allow the use of the small intestine with the exception of the distal ileum.

3. Other Alternatives Considered but Dismissed From Further Consideration

A third alternative, Remove All BSE-related Restrictions, was considered. This alternative would provide that live bovines of any age, bovine blood and blood products, and bovine small intestines would be allowed to be imported from Canada with no restrictions related to BSE much like the conditions that existed prior to May 2003, when BSE was discovered in Canada. However, FSIS and FDA regulations regarding the use of the small intestine with the exception of the distal ileum have changed since 2003, so trade in these commodities would not entirely return to the pre-May 2003 conditions that were in place before APHIS implemented regulatory restrictions. This alternative is not considered further in this document because returning to pre-May 2003 conditions (without implementing additional requirements to prevent potential BSE-exposure pathways considering that several BSE cases have been diagnosed in Canada) would not be consistent with OIE guidelines for BSE. As a member of OIE, the United States, represented by APHIS, has been actively involved in the development of OIE guidelines and fully supports and is committed to maintaining consistency with the OIE guidelines as much as possible.

II. Potential Environmental Impacts[14]

The NEPA implementing regulations set forth criteria that Federal agencies should evaluate in an environmental document.[15] NEPA criteria that are considered in this section of the document include potential effects on public health, effects on the physical environment, highly uncertain or unique or unknown risks on the human environment,[16] adverse effects on federally listed endangered or threatened species, and cumulative impacts.

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[12] APHIS determined that cattle born on or after March 1, 1999, are unlikely to have been exposed to the BSE agent by animal feed (USDA, APHIS, 2006a).

[13] 7 CFR § 310.22(a)(3) and (21 CFR § 189.5(b)(2)), respectively.

[14] A summary of potential environmental impacts considered in this environmental assessment by commodity and alternative is provided in table 7 of this document.

[15] 40 CFR § 1508.27(b).

[16] Under NEPA regulations, the "human environment" includes the natural and physical environment and the relationship of people with that environment" (40 CFR § 1508.14).

The potential environmental impacts addressed in this document would result from effects to public health from BSE exposure pathways and effects on the physical environment from allowing the importation of bovines from Canada into the United States. Public health could be affected by human exposure to bovine-derived products that contain the BSE-infective agent. It is important to note that other agencies, specifically FSIS and FDA, have direct authority over public health issues, including those related to the use of bovine-derived products. These agencies have regulations in place that are designed to prevent adverse impacts on public health. FSIS and FDA have been consulted during the development of the proposed rulemaking associated with the proposed action.

Although protection of animal health from BSE exposure is the disease concern related to the scope of the proposed rulemaking and its associated documents, other potential risks associated with the importation of cattle and associated meat products that could adversely impact public health include foodborne pathogens. FSIS has established requirements that are designed to prevent and reduce microbial pathogens (e.g., *E. coli* O157:H7 and *Listeria monocytogenes*) on raw products that can cause illness.[17] Further, the Centers for Disease Control (CDC) has attributed the implementation of FSIS' requirements for foodborne pathogens as an important factor in the overall decline in bacterial foodborne illnesses from 1996 through 2001 (USDA, FSIS, 2004). This matter will not be assessed further in this environmental assessment as a potential environmental impact as a result of the proposed rulemaking. This document does consider impacts on the physical environment that are unrelated to BSE exposure but that result from activities associated with the transport, holding, and slaughter of bovines.

A. Public Health

BSE is a progressive neurological disorder of cattle. BSE belongs to a family of diseases known as transmissible spongiform encephalopathies (TSE). Research suggests that BSE is caused by an abnormal form of a normally occurring protein known as a prion (Bolton *et al.,* 1982, and Prusiner, 1994, as cited in USDA, APHIS, 2006a). The abnormal prion protein is both less soluble and more resistant to degradation than the normal prion protein. The abnormal prion protein also is extremely resistant to heat and to normal sterilization processes, making it difficult to inactivate with standard methods used to process human food and animal feed. Further, the BSE infectious agent does not evoke any apparent immune response or inflammatory reaction.

The public health concern associated with the importation of live bovines and bovine products from a BSE minimal-risk region is the potential for human exposure to BSE-infected materials. Human exposure to the BSE agent can result in the development of variant Creutzfeldt-Jakob disease (vCJD) (CDC, 2005a). Such exposure could occur through the consumption of bovine-derived products

[17] 61 FR 38805, July 25, 1996.

(such as meat or meat products) contaminated with BSE-infected tissues. Various studies suggest that the infectious agent may be 10 to 10,000 times less pathogenic in humans than in cattle (EC SSC, 2000). To put infectivity differences between humans and cattle in perspective, during the BSE epidemic in the United Kingdom, it was estimated that there were approximately 1 million infected animals. Worldwide, as of November 2005, there have been a total of 185 probable and confirmed cases of vCJD (CDC, 2005b). Of these, 158 cases were reported in the United Kingdom, with 27 cases reported in other countries. In some of the cases reported as occurring outside of the United Kingdom, the actual exposure to the BSE agent was likely to have occurred in the United Kingdom. Human exposure to the BSE agent or BSE infectivity most likely occurred before mitigation measures, such as specified risk material (SRM)[18] removal, were in place to prevent such exposures. These widely differing numbers—more than 1 million infected animals, with high infectivity present before control measures were introduced, and less than 200 vCJD cases—demonstrates the substantial species barrier for BSE transmission between cattle and humans.

1. Live Bovines

a. Background

For the purpose of this environmental assessment, the main concern with regard to potential BSE exposure is how the human environment, including public health, in the United States could be affected by allowing the importation of live bovines from Canada. The primary source of BSE transmission in bovines is feed contaminated with the infectious agent. Mitigations, such as ruminant-to-ruminant feed bans, are designed to decrease the possibility that animals will be infected, and, therefore, decreases the subsequent possibility that humans will be exposed to the BSE agent via products from infected animals. Canada and the United States employ several mitigation measures that are designed to protect animal health but also protect human health, for example, the ruminant-to-ruminant feed bans and handling and processing of SRMs, which are discussed in the following sections.

Transmission of the BSE agent can be prevented by excluding the tissues that could carry the BSE infective agent from ruminant feed. Experience in the United Kingdom demonstrates that implementation of a ruminant-to-ruminant feed ban results in a decrease in the prevalence of BSE (DEFRA, 2006, as cited in USDA, APHIS, 2006a). A ban on the feeding of ruminant protein to ruminants is one of the most important barriers to the dissemination of the BSE agent. Thus, the primary barrier to curtail BSE exposure of cattle to BSE infectivity that may

[18] SRMs are tissues that are considered at particular risk of containing infectious levels of the BSE agent in BSE-infected cattle. The following tissues are designated as SRMs: the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the distal ileum of the small intestine and tonsils from all cattle (9 CFR § 310.22(a)).

have entered the United States is FDA's ruminant feed ban. In addition, as discussed in the risk assessment for the proposed rulemaking, the interrelated feed ban measures in place in Canada have resulted in an incremental reduction in the risk that Canadian cattle will be exposed to the BSE agent (USDA, APHIS, 2006a).

Both FSIS and FDA have implemented regulations that prohibit the use of SRMs in human food and other products, including dietary supplements and cosmetics. On January 12, 2004, FSIS implemented a series of three interim final rules[19] to minimize human exposure to materials that scientific studies have demonstrated contain the BSE agent in cattle infected with BSE. Through these regulations, FSIS designates certain materials from cattle as SRMs, declares that SRMs are inedible, prohibits the use of these materials for human food, and requires that all nonambulatory[20] disabled cattle presented for slaughter be condemned. Proper removal, segregation, and disposal are required in order to mitigate any potential risks to public health. Processes for removal, segregation, and disposal of SRMs are designed to prevent these potentially infectious materials from entering into the human food supply. FSIS[21] requires SRMs to be rendered as "unfit for human food" within the meaning of section 1(m)(3) of the adulteration provisions of the Federal Meat Inspection Act.[22] Regardless of the selected SRM disposal method, slaughter establishments must develop Standard Operating Procedures (SOPs) that detail the method(s) by which SRMs will be disposed. These FSIS regulations are intended to ensure that SRMs are not used in human food and that SRMs do not cross-contaminate edible meat products.

Similarly, on July 14, 2004, to address the potential risk of BSE in human food, FDA issued an interim final rule[23] to designate certain materials from cattle, including the entire small intestine, as "prohibited cattle materials" and banned the use of such materials in human food, including dietary supplements and cosmetics. Among the materials FDA designated as prohibited cattle material are SRMs, the small intestine from all cattle, and material from cattle not inspected and passed for human consumption. Through their January and July, 2004 regulations, both FSIS and FDA, respectively, prohibited the use of the entire small intestine for human food; subsequently, on September 7, 2005, both FSIS[24] and FDA[25] issued interim final rules amending these regulations and currently designates only the distal ileum of the small intestine from cattle as an SRM.

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[19] 69 FR 1862, January 12, 2004.

[20] Nonambulatory disabled livestock is defined by FSIS as livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions (69 FR 1861, January 12, 2004).

[21] In accordance with 9 CFR part 314.

[22] 21 U.S.C. 601(m)(3).

[23] 69 FR 42256, July 14, 2004.

[24] 70 FR 53043, September 7, 2005.

[25] 70 FR 53063, September 7, 2005.

b. No Action (Live Bovines)

Under the No Action alternative, the current import regulations for the MRR rule would continue, as implemented in July 2005. Currently, Canada is the only country that has been approved as a minimal-risk region under APHIS regulations.[26] It is assumed that Canada would continue to meet the conditions of a BSE minimal-risk region and that APHIS would make no change to the regulation that allows importation of the following commodities:

(1) bovines for feeding or immediate slaughter, as long as they are slaughtered at less than 30 months of age;
(2) ovines and caprines (sheep and goats), for feeding or immediate slaughter, as long as they are slaughtered at less than 12 months of age;
(3) cervids (deer, elk, caribou, moose, and reindeer);
(4) camelids (llamas, alpacas, guanacos, and vicunas);
(5) meat from bovines, ovines, caprines, and cervids; and
(6) certain other products and byproducts, including bovine livers and tongues, gelatin, and tallow.

The "Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products From Canada into the United States, Final Environmental Assessment, December 2004"[27] (also referred to as the MRR EA; USDA, APHIS, 2004a) considered the potential impacts associated with potential BSE exposure from implementing the MRR rule (also referred to as the No Action alternative for the purposes of this document). The MRR EA addressed safeguards that had been implemented in the interest of protecting animal health, such as the ruminant-to-ruminant feed ban in place in both Canada and the United States since 1997, and safeguards that had been implemented to protect public health from potential BSE exposure, such as proper removal and disposal of ruminant SRMs at slaughter. The MRR EA referred to the associated risk assessments for the MRR rule (USDA, APHIS, 2003; USDA, APHIS, 2004a; and USDA, APHIS, 2004b) that analyzed risk-reduction strategies and requirements of the rulemaking that provide multiple safeguards against BSE exposure from imported Canadian cattle. The MRR EA concluded that the risk of introducing BSE into the United States as a result of the rulemaking was low based on past and more recent mitigation measures and safeguards implemented in Canada and the United States.

The MRR EA process concluded with a Finding of No Significant Impact[28] (FONSI) that implementation of the rule would not have a significant effect on the human environment, considering the multiple and overlapping safeguards in the United States, implemented and enforced by APHIS, FSIS, and FDA. These

[26] 9 CFR § 94.18(a)(3).
[27] Available at http://www.aphis.usda.gov/lpa/issues/bse/risk_assessment/03-080-3_ea.pdf.
[28] 70 FR 18252, April 8, 2005.

safeguards, as well as the additional risk mitigation measures required in the MRR rule, are designed to protect animal health and public health. The FONSI for the MRR EA addressed these issues, in addition to environmental issues, regarding the transport and holding of cattle.

b. Proposed Action (Live Bovines)

The proposed action would allow the importation of live bovines born on or after March 1, 1999, bovine small intestine other than distal ileum, and bovine blood and blood products from Canada into the United States. According to the risk assessment, Canadian cattle born on or after March 1, 1999, can be imported into the United States with a very low likelihood that they have been exposed to the BSE agent (USDA, APHIS, 2006a). This alternative would include certain mitigations that together with other requirements, including the APHIS, FSIS, FDA, and Canadian regulations, are designed to control the risk of BSE introduction into the United States.

USDA, Economic Research Service (ERS), provided projections of bovine imports from Canada based on previous import data and the availability of cattle in Canada. These projections forecast that up to 82 percent of the imported cattle (including steers/heifers, cows, bulls, stags, and calves) from Canada would be intended for immediate slaughter; approximately 14 percent as feeder animals;[29] and approximately 4 percent of cattle imports are expected for breeding (dairy heifers/cows,[30] beef heifers/cows, and bulls) purposes (as reported in USDA, APHIS, 2006a).

Although most of the live bovines expected to enter the United States following implementation of the proposed action would be cattle, it is anticipated that some bison will enter as well. USDA, ERS also estimates that 80 percent of bison from Canada are likely to be imported for immediate slaughter, approximately 10 percent as feeder animals, and approximately 10 percent of bison imports are expected for breeding purposes (USDA, APHIS, 2006a). ERS estimates that 4,000 and 3,150 bison will enter the United States in 2007 and 2008, respectively. After 2008, ERS estimates that 2,500 bison will enter the United States annually under this proposed rulemaking. In the absence of evidence to the contrary, the risk assessment (USDA, APHIS, 2006a) assumes that the prevalence of BSE in bison is the same as that in cattle. Since no cases have been reported in North American bison, this assumption likely overestimates the risk associated with importation of this species. Further, the risk assessment assumes that the

[29] Feeder cattle are destined for feedlot finishing and slaughter but may be placed on pasture for several months of gain before feedlot placement. Feeder cattle are generally placed on feed for 120 days to more than 200 days before being slaughtered at a quality grade of select or higher (USDA, APHIS, 2006b).

[30] Milk and milk products are internationally recognized (according to OIE guidelines) to present a negligible risk of transmitting the BSE agent. FDA's interim final rule of September 7, 2005, (amending provisions in FDA's July 14, 2004, interim final rule) clarified that milk and milk products are not prohibited cattle materials (21 CFR § 189.5(a)(1) and 700.27(a)(1)).

conclusion of an extremely low likelihood of BSE infectivity release for cattle also applies to bison (USDA, APHIS, 2006a).

SRMs are required to be removed from cattle at slaughter. FSIS[31] and FDA[32] have regulations that ensure the proper processing and handling of SRMs removed from cattle. These regulations for SRM removal ensure that materials potentially infected with BSE do not enter human food supplies. Thus, this proposed action is not likely to be a risk to public health as a result of human consumption of food contaminated with SRMs.

Estimates of Potentially Available BSE Infectivity to Humans from Importing Live Bovines

Both qualitative and quantitative methods were used in the risk assessment prepared for the proposed rulemaking (USDA, APHIS, 2006a). As part of the release assessment, quantitative methods were used to estimate the current prevalence of BSE in the standing adult cattle population in Canada. Qualitative methods were then used to describe the most likely scenario considered in the release assessment, which was that release is unlikely due to the mitigations imposed and the expectation that the low prevalence in Canada will decrease. Less likely scenarios were also considered in the release assessment, based on the assumption that prevalence stays constant in Canada over the next 20 years.

Both qualitative and quantitative methods were also used in the exposure assessment to evaluate the likelihood of exposing susceptible animals given the release of infectivity via imported animals. The most likely scenario of the release assessment included the assumption that the prevalence of BSE in the standing adult cattle population will continuously decrease from the current estimate over 20 years (2007–2026). This expected decrease could not be incorporated into the quantitative methods in the release or exposure assessment. In this instance, where either the expected scenario cannot be numerically represented or where the numbers would be so low as to prevent their use in further calculations, the risk assessment qualitatively assesses the possible exposures. This qualitative exposure assessment, building on the most likely scenario of the release assessment, demonstrated that the likelihood of BSE exposure and establishment in the U.S. cattle population is negligible.

Even though the risk assessment concluded that it is most likely that the prevalence of BSE in Canada will decrease continuously over the next several years, the assessment considered less likely scenarios and quantitatively analyzed the impact of an assumed constant prevalence in Canada to simulate potential BSE exposure in U.S. cattle. Therefore, the quantitative exposure model and its results by necessity include the less likely assumption that Canadian BSE prevalence remains constant through 2026. Thus, as reported in the risk

[31] 69 FR 1862, January 12, 2004, and 70 FR 53043, September 7, 2005.
[32] 69 FR 42256, July 14, 2004, and 70 FR 53063, September 7, 2005.

assessment, the low estimates included in the quantitative exposure model for infected and clinically affected animals are over-estimates. Further, based on evidence, not presented in the quantitative exposure model, that BSE prevalence continues to decrease following implementation of a ruminant-to-ruminant feed ban, it is estimated that prevalence, 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. The quantitative exposure model simulations provided results for a base case scenario and a sensitivity analysis (which examines the relative importance of assumptions made for several uncertain parameters), both of which represent pessimistic values.[33] More detail about the models and the assumptions is described in the associated risk assessment prepared for the proposed rulemaking (USDA, APHIS, 2006a).

Assuming the less likely scenario of constant BSE prevalence in Canada under the base case scenario, the estimated number of infected cattle in the United States over a 20-year period amounts to 21. The majority of the 21 cattle would be imported, while approximately 2 of the cattle would represent secondary (native) cases resulting from exposure of cattle in the United States to the BSE infective agent introduced via the imported cattle. From the 21 cattle, the exposure model estimates that the potential infectivity available for human exposure over the 20-year period could amount to 45 cattle oral infectious dose (oral ID_{50}) units. BSE infectivity is expressed in terms of cattle oral infectious dose-50 units (ID_{50}). A cattle oral ID_{50} is defined as the amount of infectivity required to cause infection in 50 percent of an exposed cattle population (USDA, APHIS, 2006a).

In the sensitivity analysis, the relative importance of five uncertain parameters was determined by setting each of these parameters (e.g., mislabeling and contamination of feed, the rate of on-farm misfeeding of prohibited feed to cattle, render reduction factor, the proportion of poultry litter (which could contain prohibited ruminant materials) that is used in cattle feed, and Canadian BSE prevalence), individually, to its higher plausible (pessimistic) level, while keeping all other parameters at the base-case level. Even when simultaneously setting all uncertain parameters to their pessimistic values, the estimated number of infected cattle occurring in the United States over a 20-year period is approximately 150. The majority of these cattle would be imported, while approximately 42 of the cattle would represent secondary cases resulting from exposure of cattle in the United States to the BSE infective agent from the imported cattle. With these combined pessimistic assumptions, the exposure model estimates that the potential infectivity available for human exposure over the 20-year period could amount to 290 cattle oral ID_{50} units (see attachment 2 of USDA, APHIS, 2006a).

[33] In order to be consistent with the historic use of the term “pessimistic” in the Harvard model and Attachment 2 of the risk assessment, the term “pessimistic values” is used in this context to refer to the plausible higher values used in the sensitivity analysis.

Comparison of the Exposure Model Results to Human Exposure and the UK Experience

The significance of cattle oral ID_{50} units to human exposure and susceptibility is not known; however, various studies suggest that the infectious agent may be 10 to 10,000 times less pathogenic in humans than in cattle due to a species barrier (EC SSC, 2000). Thus, if the cattle−human species barrier were 100, it would mean that 100 times more infective material would be required in order to have a similar probability of infecting a human as a bovine. Comer and Huntly (2003) estimated, after an evaluation of available literature, that 54 million bovine oral ID_{50} units were available for human consumption in Great Britain[34] from 1980 to 2003. This extremely large amount of available infectivity has resulted in 158 cases of vCJD identified in the United Kingdom through November 2005, plus a few additional cases identified in other countries but attributed to exposure in the United Kingdom. Thus, when compared to the United Kingdom's BSE experience and the associated estimate of available bovine oral ID_{50} units, the expected, or average value of 45 cattle oral ID_{50} units as estimated by the exposure model for the base case scenario, and the average value of 290 cattle oral ID_{50} units as estimated by the exposure model for the combined pessimistic assumptions in the sensitivity analysis would result in a miniscule amount of the BSE infective agent that could possibly be available for potential human exposure over a 20-year period (USDA, APHIS, 2006a).

Based on the qualitative exposure assessment for the most likely scenario, the likelihood of human exposure is even lower than that estimated for cattle. Even in the less likely scenarios used in the quantitative exposure model (USDA, APHIS, 2006a), while the model estimates that there is potential infectivity available for human exposure over a 20-year period, the potential exposure amount is negligible. We note that the potential for human exposure under the base case scenario is estimated at 1,200,000[35] times less in the United States than what the United Kingdom experienced during its BSE epidemic. The estimated potentially available cattle oral ID_{50} units for the base case scenario and the sensitivity analysis are much lower than what occurred in the United Kingdom because of the low BSE prevalence in Canada[36] and the numerous mitigation measures that both Canada and the United States have implemented because of the science on BSE that has evolved as a result of the United Kingdom's experience.

[34] BSE in cattle was first diagnosed in Great Britain in 1986; from then til the end of 2002 there were more than 178,000 confirmed clinical cases (Comer and Huntly, 2003).

[35] 54,000,000/45 = 1,200,000.

[36] A total of 9 Canadian-born BSE cases have been identified as of October 27, 2006, compared to the United Kingdom which has detected 184,453 cases by passive and active surveillance through September 2006 (OIE, 2006).

2. Products

The proposed action would allow the importation of bovine small intestines other than the distal ileum and blood and blood products from Canadian bovines. This section will discuss the potential environmental impacts associated with the importation of these commodities.

a. Bovine Small Intestines, With the Exception of the Distal Ileum

i. Background

Transmission of the BSE agent to humans is believed to occur via ingestion of cattle products contaminated with the BSE agent (CDC, 2005a). The contamination of beef products would be the result of improper slaughter and processing (e.g., segregation, removal, and disposal of SRMs, including the distal ileum). However, slaughter and processing mitigations in the United States and in Canada have been designed to prevent contamination of beef products intended for human consumption. As discussed above, FDA and FSIS have determined that if the distal ileum is removed from the small intestine of cattle, the remainder of the small intestine can be used for human food. Further, the distal ileum is the only portion of the small intestine for which OIE recommends any trade restrictions because of BSE (OIE, 2005).

On July 14, 2004, FDA issued an interim final rule entitled, "Use of Materials Derived from Cattle in Human Food and Cosmetics" (also referred to as "interim final rule"),[37] to address the potential risk of BSE in human food and cosmetics. Through this rule, FDA prohibited the use of the entire small intestine in human food and cosmetics even though the agency (at the time the interim final rule was issued) considered, and currently considers, that only the distal ileum portion of the small intestine is an SRM.

After considering the public comments submitted on the removal of the distal ileum, FDA issued an interim final rule[38] on September 7, 2005, amending the July 14, 2004, FDA interim final rule discussed in the preceding paragraph, which became effective October 7, 2005. FDA concluded that processors have the technology to effectively remove the distal ileum portion from the remainder of the small intestine. These amendments to FDA's interim final rule are consistent with amendments that FSIS made to its interim final rule[39] (discussed in the following paragraph) regarding the use of beef small intestine.

On September 7, 2005, FSIS issued an interim final rule[40] prohibiting the use of SRMs for human food and requirements for the disposition of nonambulatory

[37] 69 FR 42256, July 14, 2004.
[38] 70 FR 53063, September 7, 2005.
[39] 70 FR 53043, September 7, 2005.
[40] Ibid.

disabled cattle, amending the January 12, 2004, FSIS interim final rule.[41] This interim final rule became effective October 7, 2005. In this interim final rule, FSIS amended the January 12, 2004, SRM interim final rule to permit, for use as human food, beef small intestine, excluding the distal ileum, derived from cattle slaughtered in official U.S. establishments[42] or in certified foreign establishments in countries listed by FSIS[43] as eligible to export meat products to the United States. This is a requirement that all meat and meat food products must comply with in order to be eligible for use as human food in the United States. In addition, FSIS regulations do not permit natural casings derived from beef small intestine (minus the distal ileum) to be used as containers for meat food products unless the casings are derived from cattle that have been inspected and passed in an official U.S. establishment or in a certified foreign establishment.
BSE infectivity has not been confirmed in any portion of the intestinal tract of cattle other than the distal ileum. FSIS concluded that bovine intestinal tissues, other than the distal ileum, are either unlikely to contain BSE infectivity or contain infectivity below the level of detection using mouse bioassay studies.[44] Furthermore, the fact that infectivity has been confirmed only in the distal ileum indicates that the distal ileum, as opposed to the entire small intestine, has the most significant implications for public health.

The FSIS regulation amendment also requires establishments that process beef small intestine for human food to have in place procedures to ensure that the distal ileum is effectively removed. As provided in FSIS regulations,[45] the establishment must incorporate these procedures into its Hazard Analysis and Critical Control Point plan or Sanitation SOPs or other prerequisite program. FSIS also has requirements for the removal of at least 80 inches of the uncoiled and trimmed small intestine. This standard is sufficiently conservative to ensure removal of the distal ileum despite differences in length of the intestinal tract or its segments between breeds or variations from animal to animal of the same breed. This proposed rulemaking also would require the removal of the distal ileum, in accordance with these FSIS regulations (e.g., the removal of at least 80 inches of the uncoiled and trimmed small intestine) as discussed above, from all small intestines imported from Canada. However, establishments may propose alternative standards if they can demonstrate that such standards are as effective as the standards described above in ensuring that the entire distal ileum is completely removed.[46]

[41] 69 FR 1862, January 12, 2004.
[42] 9 CFR § 301.2.
[43] 9 CFR § 327.2(b).
[44] 70 FR 53043, September 7, 2005.
[45] 9 CFR § 310.22(d)(1).
[46] 70 FR 53043, September 7, 2005.

ii. No Action

Bovine small intestines (excluding distal ileum) were not considered in the MRR rule because at that time they were prohibited along with the distal ileum portion of the small intestine and other SRMs for use in human food. The SRM rule implemented by FSIS on January 12, 2004, prohibited the small intestine for use in human food, and a rule implemented by FDA on July 14, 2004, extended the measures to FDA-regulated human food and cosmetics. However, both FSIS and FDA implemented rules on September 7, 2005, that amended their rules to permit beef casings derived from small intestine, excluding the distal ileum, to be used for human food and cosmetics. As discussed earlier, these amendments were made after further research was conducted and FDA and FSIS evaluated these issues and received public comments on them.

iii. Proposed Action

The release assessment section of the risk assessment for this proposed action states that "[b]ecause bovine intestinal tissue, excluding the distal ileum, has not been shown to contain infectious levels of the BSE agent, even if derived from infected cattle, and because the distal ileum can be removed at slaughter in a manner to avoid contamination, APHIS concludes that it is highly unlikely that any BSE infectivity would be released into the United States via bovine intestines imported from Canada" (USDA, APHIS, 2006a). In addition to this low likelihood of release, regulations and controls implemented by FSIS and FDA are in place to mitigate risks to public health. FSIS has concluded that, "when the distal ileum is effectively removed, beef small intestine that complies with the requirements of this interim final rule presents no greater risk of introducing the BSE agent into the human food supply than do other beef products permitted for use as human food in the United States."[47]

b. Blood and Blood Products

i. Background

The potential effects of the consumption of bovine blood on the human environment will not be analyzed in this section. The consumption of bovine blood has been discussed within the context of consuming any bovine product, and that discussion has already taken place earlier within the public health section of this document. Blood is not classified as an SRM and is not prohibited from bovine products meant for consumption. The main concern with the use of bovine blood is its use in vaccinations and thus will be discussed in more detail below.

[47] 70 FR 53043, September 7, 2005.

Bovine blood and blood products may be used in a variety of ways. Fetal bovine serum (FBS), also known as fetal calf serum (FCS), and bovine serum albumin (BSA) are the primary products derived from cattle blood for use in animal vaccine and drug production. FBS is derived from the plasma of blood from a fetal bovine (a calf *in utero*) and BSA is derived from the plasma from a calf or adult bovine. These products are potentially used as components in growth media in the production of animal and human vaccines and drugs. BSA can also be used potentially as a stabilizer or protein carrier in these products.

BSE infectivity has never been found in cattle blood. Studies conducted specifically in cattle infected with BSE detected no infectivity in cattle blood or any tested derivatives (EC SSC, 2002). There is evidence that BSE infectivity was transmitted to sheep by transfusion of whole blood from sheep experimentally infected with BSE (Houston *et al.,* 2000, and Hunter *et al*., 2002, as cited in USDA, APHIS, 2006a). The Scientific Steering Committee of the European Commission examined these studies and determined that the finding of BSE infectivity in the blood of sheep could not be related to BSE in cattle (EC SSC, 2002 as cited in USDA, APHIS, 2006a).

Blood easily coagulates and produces two parts, a cellular component and a plasma component. Most products utilizing cattle blood are derived from the plasma as opposed to the cellular component. In animals infected with TSEs that do develop infectivity in the blood, studies have suggested that the infectivity is higher in the cellular component of the blood rather than in the plasma component (Brown, 1998; Brown, 1999; EC SSC, 2002; and Comer, 2004, as cited in USDA, APHIS, 2006a). Although BSE has never been detected in any bovine blood or blood product, should cattle with BSE have some undetected low amount of infectivity in the blood, products derived from the plasma component of the blood, such as FBS and BSA, would be expected to have a lower infectivity level than the cellular component of blood (USDA, APHIS, 2006a). When FBS and BSA are harvested for use in the preparation of vaccines and drugs, both the red and white cells are excluded from these products (USDA, APHIS, 2006a).

As APHIS' authority related to the proposed rulemaking is to protect animal health, the associated risk assessment evaluates the risk of the blood and blood products used in the production of veterinary vaccines and drugs and the pathways that may influence animal health. FDA evaluates human health concerns relating to the use of blood and blood products in human products. APHIS has involved FDA in discussions during the development of the proposed rulemaking.

ii. No Action

Under the No Action alternative, bovine blood and blood products would continue to be prohibited from importation into the United States from Canada. Prior to the 2003 ban on Canadian bovine and bovine products, some of the U.S. import

supply of blood and blood products was generated in Canada by the collection of such products from cattle, then imported from Canada. Currently, the United States receives blood and blood products from other countries that are not restricted due to animal disease concerns.

Blood and blood products were not addressed in the original MRR rule because APHIS did not have adequate information necessary to evaluate the risks of allowing blood and blood products into the United States from Canada. Since then, APHIS has been working with FDA to coordinate regulatory efforts.

iii. Proposed Action

Under the proposed action, APHIS would allow bovine blood and blood products from Canada to enter the United States according to certain mitigations. Bovine blood and blood products for animal health uses are regulated by APHIS. As APHIS' regulations with regard to animal diseases are for the purpose of protecting animal health, the risk assessment prepared for the proposed rulemaking evaluates the animal health risks associated with the imported commodities and the likelihood that these commodities from a minimal-risk region would introduce BSE infectivity into the United States and expose the U.S. cattle population.

The risk assessment analyzes the pathways of exposure and the mitigations that would be required to prevent the likelihood of introduction of BSE into the United States via blood and blood products used for animals. The mitigations are intended to prevent cross-contamination of the blood with SRMs, such as central nervous system tissue. These mitigations, as discussed in the risk assessment, include the following:

For all blood:

1. the blood is collected in a closed system.

For blood collected at slaughter, the slaughtered animal:

2. must have passed ante-mortem inspection and
3. was not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

For fetal bovine serum:

4. the dam must have passed ante-mortem inspection and was not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, and
5. the uterus is removed from the dam's abdominal cavity intact and taken to a separate area away from the kill floor.

For blood collected from live donor animals:

6. the donor must be free of clinical signs of disease.

The BSE prevalence in Canada is very low and is expected to decrease further over time. Even if one of the very few potentially infected animals were a source

for blood or blood products, additional steps in the production of blood products help to diminish the infectivity (USDA, APHIS, 2006a).

Although BSE infectivity has never been found in cattle blood (EC SSC, 2002), a possibility of cross-contamination with high-risk materials exists during the slaughter process. However, the mitigations described above minimize this potential.

The risk assessment states that "bovine blood is highly unlikely to contain BSE infectivity . . . and that USDA-specified mitigations will prevent cross-contamination." Thus, it is unlikely that BSE-infected blood will be imported or used to make blood products that will be imported (USDA, APHIS, 2006a).

Animal Products Derived From Bovine Blood and Blood Products

The risk assessment identified animal vaccinations as one potential pathway for BSE exposure. The risk assessment determined that multiple steps in the risk pathway act as safeguards against the release of BSE infectivity through the importation of blood and blood products. Canadian bovines, from which blood is collected, are unlikely to be infected with BSE due to the low prevalence of BSE in Canada. BSE infectivity has not been detected in cattle blood. In addition, blood collected at slaughtering establishments is unlikely to have BSE infectivity because of the mitigations imposed for the collection of blood. Moreover, the steps in the production and use of products manufactured with bovine blood or its derivatives are likely to further reduce any possible infectivity USDA, APHIS, 2006a).

The risk assessment concluded that "Given both the negligible release of BSE and exposure of bovines to any such introduced infectivity via the importation of bovine blood and blood products from Canada, we conclude that extremely few or no U.S. cases of BSE would result. Therefore, the consequences and resulting risk of their importation are negligible." (USDA, APHIS, 2006a).

FDA Oversight of Products Derived From Bovine Blood and Blood Products

Bovine blood and blood products used for human medical products are regulated by FDA. FDA oversees the safety of vaccines and drugs given to consumers and continually reviews the potential risk of products in relation to new entities, including the BSE agent. FDA has looked at the benefit of vaccines and the risk of contamination of vaccines with the BSE agent. Both FDA and FDA's joint advisory committees, Transmissible Spongiform Encephalopathy Advisory Committee and Vaccines and Related Biological Products Advisory Committee, have considered the risks posed by bovine materials in vaccines and concluded that the risk that anyone will acquire vCJD from a vaccine is remote and theoretical (USDHHS, FDA, 2004). This conclusion was based on the inherent low risk of the bovine materials involved (e.g., type and amount of tissues used,

specific time, and country or herd of origin) and/or the dilutions of materials during manufacture (USDHHS, FDA, 2004).

FDA prepared a risk estimation for the use of FCS in the production of human vaccines. The estimate was based on the high infectivity levels in the UK cattle population during the UK BSE epidemic in the mid-1980s. In calculating the risks, FDA used the highest estimate consistent with infectivity experiments. The risk estimate did not include steps that would probably remove infectivity, and disregarded any species barrier that may exist between cattle and humans because this has not been quantified. The estimate also assumed a 10 percent rate of maternal transmission. However, the risk assessment prepared for the proposed rulemaking states that although there was a suggestion that maternal transmission can occur, more recent work has failed to demonstrate evidence of maternal transmission (Hill, 2005, as cited in USDA, APHIS 2006a).

Even with these overestimates of the risks, FDA was aware that, because blood used to create FCS is pooled from approximately 1,500 calves, any amount of infectivity in the blood would be diluted to lower levels. In addition, they knew that the amount of FCS (4 milliliters) used to produce a viral culture is a small fraction from the pooled blood that produces approximately 500,000 doses of vaccine, limiting the amount of infectivity given to a single person. Using these numbers, FDA concluded that the risk to humans is about one case of vCJD arising every 5,000 years. FDA further concluded that "because of the assumptions used, this is an overestimate of the risk and the true risk is likely to be significantly less" (USDHHS, FDA, 2001).

FDA reviews drugs and vaccines on a product by product basis. Each product must be approved by FDA before it can be marketed. FDA not only looks at the product itself but also the processes involved in making the product. It is during this overview process that risks are evaluated and mitigations may be placed on these processes to ensure the product is safe for humans to use or consume.

Although Canada and the United States have reported BSE cases and USDA has placed Canada on the list of regions that present a minimal-risk of introducing BSE into the United States via live ruminants and ruminant products, FDA has not recommended that manufacturers find a new source for bovine-derived materials obtained from Canada or the United States for use in manufacture of drugs or biological products. FDA has expressed that the control measures in place, such as the ruminant-to-ruminant feed ban that is similar in the United States and Canada, assure the safety of bovine-derived materials originating from these countries for use in the manufacture of vaccines (USDHHS, FDA, 2004).

B. Impacts on the Physical Environment

1. Transport of Bovines

a. Background

Cattle imported from Canada to the United States must transit through 1 of 20 approved ports of entry at the Canada-U.S. border. [48] Cattle are transported by heavy-duty trucks that vary in size. The number of cattle transported on a truck depends upon the truck size and the size of the animals.

Environmental impacts from the transport of cattle would stem from pollutants that result from truck transport. The types of pollutants from heavy-duty trucks that would impact air quality include nitrous oxide emissions and particulate matter. Heavy-duty commercial trucks are believed to be responsible for 40 percent of nitrous oxide emissions and 60 percent of particulate matter emissions from all vehicles, although studies have been implemented to determine the amount of emission pollutants released under different transport scenarios.

Efforts Regulating Pollutants of the Physical Environment From Truck Transports

Since the Clean Air Act of 1970, emissions standards for cars and trucks, forcing improved engine technology and reformulated gasolines, have greatly reduced the amount of air pollution. Today's truck engines emit nearly 70 percent less nitrous oxide and 90 percent less particulates than in 1987. Environmental quality issues related to commercial truck transport are being studied and addressed at Federal, State, and local levels. For example, the U.S. Environmental Protection Agency (EPA) is addressing the increase in emissions from the growth in transport freight within the United States. EPA developed a strategy to reduce diesel emissions by requiring new diesel engine standards beginning in 2004 vehicle models and by initiating a program requiring U.S. refiners to provide cleaner diesel fuels. Similar to the United States, Canadian environmental protection laws have vehicle emissions requirements that are designed to prevent harmful air emissions from vehicles, including transport trucks. Truck transport activities are subject to comprehensive environmental regulation in both the United States and Canada.

b. No Action

Shortly after the issuance of the final MRR EA for the MRR rule, a litigant filed a complaint challenging the rule in the United States District Court for the District of Montana. In the complaint, the litigant alleged that the final MRR EA failed to assess the environmental effects of transporting an estimated 2 million head of cattle from farms and feedlots in Canada to feedlots and slaughter establishments

[48] Eastport, ID; Houlton and Jackman, ME; Detroit, Port Huron, and Sault Ste. Marie, MI; Baudette, MN; Opheim, Raymond, and Sweetgrass, MT; Alexandria Bay, Buffalo, and Champlain, NY; Dunseith, Pembina, and Portal, ND; Derby Line and Highgate Springs, VT; and Oroville and Sumas, WA (9 CFR 93.403(b)).

in the United States, as well as the environmental impacts of holding the additional feeder cattle until slaughter.

The FONSI[49] that concluded the MRR EA process addressed the allegations and concluded that the issues raised did not pose potentially significant impacts on the environment, as follows.

The FONSI for the MRR EA based its consideration of the allegation of environmental impacts from the transport of cattle on an estimated number of 2 million cattle (provided by the economic analysis for the MRR rule) that could be imported in 2005, provided implementation would occur in January 2005.[50] Based on 2 million cattle being imported, the litigant estimated that the resumption of limited trade in live cattle would result in 35,000 truck round-trips between Canada and the United States. According to data, truck crossings from Canada into the United States for 2001 totaled approximately 6.8 million, for 2002 totaled 6.9 million, and for 2003 totaled 6.7 million (U.S. Department of Transportation, Bureau of Transportation Standards (U.S. DOT, BTS), 2006).[51]

As presented in the allegation, an additional 2 million cattle would result in 35,000 truck round-trips (averaging 57 animals per truckload) annually. In comparing the overall truck transport totals for recent years, 35,000 truck round-trips equates to approximately 0.5 percent (½ of 1 percent) of the overall average annual truck crossings (6.9 million) and about 0.6 percent (less than 1 percent) of the annual truck crossings (5.6 million) through the 20 ports of entry authorized for importation of ruminants under the MRR rule.

Table 1. Truck Crossings From Canada to the United States (in millions) for 2001-2003

Truck Crossing Year:	All U.S.-Canadian Border Truck Crossings	Total Truck Crossings at Approved Ports of Entry for Cattle
2001	6.8	5.5
2002	6.9	5.7
2003	6.7	5.6

More recent projections by APHIS of bovine imports under the age of 30 months for a 20-year period (2007 through 2026) (USDA, FAS, 2005), considering that no bovines of 30 months of age and older were imported, gave a range of

[49] 70 FR 18252, April 8, 2005.

[50] This amount was based on historical import data from 2001 and 2002, an estimated backlog of cattle in Canada as a result of the temporary closure of the border to live cattle in 2003, and an estimated number of cattle under 30 months of age that would have been available for importation into the United States because of an increase in the number of older cattle that would be slaughtered in Canada for the export of beef to the United States. The estimated backlog of cattle was later adjusted downward to 900,000 when the Secretary announced that implementation of part of the MRR rule that would allow for importation of beef from cattle 30 months of age or older would be delayed; this estimated decrease in imports reflected an increase in Canadian slaughter capacity during 2004.

[51] Confirmation with the U.S. Department of Transportation revealed that the categories of loaded and unloaded truck containers should not be included for truck transport calculations, as was done for the Finding of No Significant Impact (FONSI) for the MRR environmental assessment. In revising the information discussed in the FONSI and using the truck transport category only, the percentage of annual truck transports for cattle under 30 months of age changes from 0.25 percent to 0.5 percent.

approximately 1.1 to 1.3 million animals from Canada annually. Using a conservative number of 50 animals per transport truck, this equates to 22,000 to 26,000 round-trip truck crossings from Canada to the United States. This is about 0.3-0.4 percent of the overall average annual truck crossings (6.8 million) for 2001 through 2003 and about 0.4-0.5 percent of the average annual truck crossings (5.6 million) at the 20 ports of entry authorized for importation of ruminants under the MRR rule. The truck crossings resulting from transport of bovines under 30 months of age do not represent a significant increase to the overall annual truck transport traffic from Canada to the United States.

c. Proposed Action

The proposed rulemaking to allow bovines 30 months of age and older from Canada would restore trade in this commodity to historical import amounts prior to the United States' prohibition of these animals in May 2003. Based on ERS-projected annual cattle imports from Canada under the proposed rulemaking (see table 5, Projected imports of various cattle use types for years 2007 through 2026, in the risk assessment (USDA, APHIS, 2006a)) for the years 2007 through 2026, the annual number of bovines imported at 30 months of age and older is expected to increase by 0.30–0.34 million (fluctuating between 303,000 and 343,000 head), restoring trade in imported bovines to their average annual imports prior to May 2003.

Using a conservative number of 50 bovines per transport truck, a range of 303,000 to 343,000 annual head of bovines 30 months of age and older (the lowest and highest projected numbers during the 20-year period), the number of round-trip truck transports would increase by a range of 6,060 to 6,860. This represents an increase of about 0.1 (1/10 of 1 percent) when considering the overall average annual truck transports from Canada to the United States (5.6 million annually for 2001-2005) at the approved ports of entry; the increase in truck transports from the proposed action is *de minimus* by measure.

The addition of 0.30–0.34 million bovines resulting in 6,060 to 6,860 additional round-trip truck transports through the 20 possible ports of entry at the Canada-U.S. border will not result in an unmanageable burden on U.S. Customs Border Patrol or the APHIS inspectors who oversee animal imports at the border. The amount of truck transports for the imported Canadian bovines under the proposed rulemaking added to the current situation (the MRR rule) would return the inspection load at the border to nearly the same amount that occurred before May 2003.

2. Holding of Bovines in Feedlots

a. Background

The types of environmental impacts associated with holding cattle in feedlots include air and water pollutant discharges and emissions, such as nutrients, organic matter, pathogens, and odorous/volatile compounds, such as ammonia, associated with holding feeder cattle in feedlots. Pollutants from animal feeding operations can impact surface water, groundwater, air, and soil (EPA, 1997). Waste disposal practices used by animal feeding operations can contribute to water quality degradation. Many of these operations collect manure from animal confinement areas in solid or liquid form and apply it to farmland as a nutrient for crops or simply as a disposal method (EPA, 1997). In groundwater, pathogens and nitrates from manure can impact public health and animal health via drinking water (EPA, 1997). Nitrate contamination is more prevalent in ground waters than in surface waters (EPA, 1997). In addition to adverse impacts, animal manure has environmental benefits; if applied under proper conditions, animal manure is a valuable fertilizer and soil conditioner.

The processing of cattle results in waste products that are potentially damaging to the environment. Animal byproducts and waste products become available through the slaughter process. These byproducts and products include manure, contents of rumen (the first stomach compartment of ruminants) and intestines, edible products such as blood and liver, inedible products such as bones, fat recovered from waste water, and waste water. The annual total cattle slaughter for 2002 through 2005 averaged 34 million head (USDA, ERS, 2006b).

Efforts Regulating Pollutants of the Physical Environment From Livestock Impacts

Potential impacts on air and water quality associated with livestock are addressed under an array of existing environmental statutes, regulations, and guidelines in the United States. Some of the Federal regulatory efforts related to controlling pollutants resulting from livestock and slaughter operations are discussed below.

Since 1974, EPA has promulgated effluent guidelines for more than 50 industrial categories. Effluent guidelines are national regulations that control the discharge of pollutants from industrial facilities to surface waters (EPA, 2004). These regulations include the National Pollutant Discharge Elimination System Permit regulations and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFO) under the Clean Water Act, as well as State environmental regulations for proper management of waste water and manure from animal feedlot operations.

EPA also has established requirements for CAFOs under the Clean Water Act and, with regard to nitrate contamination of underground sources of drinking

water, under the Safe Drinking Water Act. In February 2004, EPA established new waste water discharge standards for the meat and poultry products industry, including slaughter establishments that slaughter more than 50 million pounds of meat per year and, further, meat processors that generate more than 50 million pounds per year of finished products (such as bacon or sausage). State and Federal regulations in the United States are designed to encourage sound management practices for animal feeding operations and discourage polluting activities.

Additionally, USDA's Environmental Quality Incentive Program (EQIP), administered by the Natural Resources Conservation Service, can help CAFOs meet manure application standards proposed by EPA (USDA, ERS, 2003). This program provides technical and financial assistance in developing nutrient management plans, cost-share payments for waste management structures, and incentive payments to assist crop and livestock producers with environmental and conservation improvements on the farm. EQIP also provides financial help to transport manure to off-farm locations (USDA, ERS, 2003).

In addition to State laws and regulations for air emissions, a variety of provisions under the Clean Air Act address air emissions relating to animal feedlot activities. In January 2005, EPA announced an air quality compliance agreement to address emissions from certain animal feeding operations. This agreement is part of a national farm air emissions study, which is a part of EPA's ongoing effort to minimize air emissions from animal feeding operations and to ensure that those operations comply with applicable provisions under the Clean Air Act, the Comprehensive Environmental Response, Compensation and Liability Act, and the Environmental Planning and Community Right-to-Know Act. The agreement will help in gathering scientific data that EPA needs to make informed regulatory and policy determinations and will establish an industry-funded emissions monitoring program that will help provide information, leading to better tools to help the farm industry, USDA, and EPA determine the compliance status of animal feeding operations (EPA, 2006).

The array of environmental laws and their regulations—Federal, State, and local—are intended to protect the human environment in the United States.

b. No Action

The number of cattle imported from Canada annually for slaughter represents a minor amount of the overall annual slaughtered head of bovines in the United States each year, thus, is unlikely to contribute to a significant increase toward any potential environmental effects. The average annual cattle imports for 2001 and 2002 totaled nearly 1.5 million head of bovines (USDA, APHIS, 2004c). The average annual number of bovines under the age of 30 months projected for importation from Canada during the years 2007 through 2026 ranges

between 1.1 million to 1.3 million (USDA, ERS, 2006a).[52] The United States is fourth in the world in cattle population with nearly 96 million cattle. As stated above, the average U.S. annual commercial cattle slaughter (for 2002 through 2005) is about 34 million. The average number of cattle that were projected to be imported annually for slaughter from Canada under the MRR rule (1.3 million) is less than 4 percent of the overall total U.S. cattle population slaughtered annually, not a significant increase to the overall annual commercial cattle slaughter.

c. Proposed Action

As mentioned previously, total cattle slaughter in the United States averaged 34 million head annually for 2002 through 2005. The proposed rulemaking to allow cattle 30 months of age and older would increase the annual slaughtered number of bovines by 0.30–0.34 million (303,000–343,000) head of animals, a minimal increase (about 1 percent) to the overall slaughter total. There is no evidence indicating that waste and disposal systems for feedlots or slaughter establishments would not be able to accommodate 0.30–0.34 million bovines 30 months of age and older from Canada. As a result of the availability of these additional animals for trade if the rulemaking is implemented, U.S. businesses would likely not request more cattle than they can process.

Prior to the import prohibition to allow bovines from Canada in May 2003, the feedlots and slaughter establishments were able to handle the imports that were available from Canada. As a result of the decrease in imported animals, some businesses that processed bovines were affected and had to adjust their labor forces to accommodate for the decrease in business. The amount of bovines that a feedlot or slaughter establishments requests for processing would likely not be more than their capacity for handling them; thus, the supply of bovines going to feedlots and slaughter establishments most likely would not exceed the demand for them, nor is there evidence that their systems for handling of waste would be overwhelmed by the amount of animals they request from producers in Canada.

3. SRMs Generated

a. Background

The amount of SRMs that would be generated from the importation of live bovines leads to the need to assess potential impacts on the human environment (which includes the natural or physical environment) from their disposal. An allegation made after the issuance of the MRR EA claimed that APHIS did not attempt to assess the environmental impacts of disposing of SRMs from imported Canadian cattle, indicating that an analysis of the amount of SRMs generated was warranted. While the MRR EA discussed the number of live cattle expected to be

[52] The number of bovines to be imported from Canada that was originally cited in the MRR EA has been updated based on current projections.

imported to the United States from 2005 until 2009 under the MRR rule,[53] the MRR EA did not address the amounts of SRMs these animals would generate and whether the amount generated would present any environmental impacts attendant to their disposal. Therefore, this section of the document estimates the amount of additional SRMs generated from bovines under the No Action and the Proposed Action alternatives and compares the SRM amounts generated under each alternative with the overall annual SRM amount generated in the United States. Information for arriving at the estimated amounts is provided below, and a discussion on the estimate specific to each alternative is provided in the appropriate alternative section.

In order to calculate how many pounds of SRMs would be generated under both the No Action and the Proposed Action alternatives, one must know how many pounds of SRMs are generated by each individual animal. According to FDA, "cattle not over 30 months of age" (in other words, cattle 30 months of age and under) generate approximately 28.3 pounds of SRMs while cattle over 30 months of age generate approximately 88.5 pounds of SRMs (USDHHS, FDA, 2005). For these calculations FDA included the entire small intestines. However, as previously discussed, BSE infectivity has not been confirmed in any portion of the intestinal tract of cattle other than the distal ileum. FSIS regulations permit beef small intestines, excluding the distal ileum, to be used for human food.[54] The FDA regulations permit the manufacture and use of beef casings derived from beef small intestines, excluding the distal ileum, for human food and cosmetics.[55] Therefore, for APHIS' purposes, it is inappropriate to consider the entire small intestines when calculating the weight of SRMs generated during slaughter.

According to industry sources, the distal ileum comprises roughly 10 percent[56] of the small intestine by weight (USDA, FSIS, 2005). By multiplying FDA's estimate for the weight of the small intestines[57] (which includes the distal ileum) by 10 percent, cattle under 30 months would generate approximately 2.8 pounds of distal ileum, while cattle over 30 months would generate approximately 3.5 pounds of distal ileum. Using these weights for the distal ileum instead of the weight of the entire small intestine, cattle under 30 months of age would generate approximately 3.1 pounds of SRMs[58] while cattle over 30 months of age would generate approximately 57.0 pounds of SRMs.[59] FDA estimates that cattle

[53] The number of bovines that was originally cited in the MRR EA has been updated based on current projections.

[54] 70 FR 53043, September 7, 2005.

[55] 70 FR 53063, September 7, 2005.

[56] The weight of the distal ileum is highly variable from one animal to the next. However, the estimate that the distal ileum comprises 10 percent of the entire small intestine is a conservative estimate.

[57] 28.0 pounds in cattle under 30 months and 35.0 pounds in cattle over 30 months.

[58] 2.8 pounds of distal ileum + 0.3 pounds of tonsils (USDHHS, FDA, 2005) = 3.1 pounds of SRMs.

[59] 3.5 pounds of distal ileum + 0.3 pounds of tonsils (USDHHS, FDA, 2005) + 0.936 pounds of brain (USDHHS, FDA, 2005) + 0.374 pounds of spinal cord (USDHHS, FDA, 2005) + 0.22 pounds of eyes (USDHHS, FDA, 2005) +15.2 pounds of skull (including trigeminal ganglia) (USDHHS, FDA, 2005) + 36.5 pounds of vertebral column (USDHHS, FDA, 2005) = 57.0 pounds of SRMs.

30 months of age would generate the same amount of SRMs as cattle under 30 months of age. However, as per the definition of SRMs in 9 CFR § 310.22(a) (see footnote number 18), cattle 30 months of age would generate an equal amount of SRMs as cattle over 30 months of age.

b. No Action

USDA's Economic Research Service (ERS) estimated the number of cattle that would enter the United States from Canada under the No Action alternative from 2007 to 2026 (USDA, ERS, 2006a). Based on their projections, a range of 1,099,000 to 1,290,000 live cattle would enter the United States each year from 2007 to 2027[60], which would generate about 3,407,000[61] to 3,999,000 [62] pounds of SRMs annually. See table 2 below.

Table 2. The Range (Lowest and Highest Amounts) of SRMs Generated in the United States From Cattle Entering From Canada Under the No Action Alternative

Year	Number of Cattle Entering the United States from Canada	Pounds of SRMs Generated
2007	1,099,000	3,407,000
2016–2026	1,290,000	3,999,000

To put into perspective the amount of SRMs generated from cattle entering from Canada under the No Action alternative, the United States slaughtered an average of 28.4 million steers and heifers and an average of 5.69 million cull beef and dairy cows annually during the period ranging from 2002 to 2004 (USDA, ERS, 2006b). Assuming that all steers and heifers were under 30 months of age and all cull beef and dairy cows were 30 months of age and older, and assuming that SRMs were required to be removed of and disposed of in 2002 and 2003, which they were not, the average amount of SRMs generated annually would have been about 412 million pounds.[63] The amount of SRMs that is estimated to be generated from cattle imported from Canada under the No Action alternative would be approximately 1 percent[64] of the total amount estimated to have been generated[65] in the United States. A 1 percent increase in the amount of SRMs generated is not expected to overburden U.S. disposal facilities.

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[60] The number of bovines to be imported from Canada that was originally cited in the MRR EA has been updated based on current projections.

[61] 1,099,000 cattle under 30 months of age × 3.1 pounds of SRMs = 3,407,000 pounds of SRMs.

[62] 1,290,000 cattle under 30 months of age × 3.1 pounds of SRMs = 3,999,000 pounds of SRMs.

[63] 28.4 million cattle × 3.1 pounds of SRMs + 5.69 million cattle × 57 pounds of SRMs = 412 million pounds of SRMs.

[64] 4 million pounds of SRMs generated under the No Action alternative during the years from 2016 through 2026 (2016 to 2026 data was used in the calculation since these years would generate the greatest amount of SRMs) ÷ 412 million pounds of SRMs estimated to have been generated annually from 2002 to 2004 = 0.01 (1 %).

[65] Since SRMs were not required to be disposed of in 2002 and 2003, the amount of SRMs that would have been generated from 2002-2004 is theoretical.

c. Proposed Action

Similar to the No Action alternative for the importation of live cattle, ERS estimated the number of cattle that would enter the United States from Canada under the proposed rulemaking from 2007 to 2026 (USDA, ERS, 2006c). Based on ERS projections, a range of 1,160,000[66] to 1,310,000[67] feeder, fed, and cull cattle[68] born after the effectively enforced feed ban date would enter the United States in 2007 for slaughter. We estimate that these cattle would generate about 19,928,000[69] to 23,196,000 [70] pounds of SRMs. See table 3 below.

Table 3. The Range (Lowest and Highest Amounts) of SRMs Generated in the United States From Cattle Entering From Canada Under the Proposed Action Alternative.

Year	Number of Cattle Entering the United States	Pounds of SRMs Generated
2009	1,160,000	19,928,000
2007 & 2021	1,310,000	23,196,000

To put into perspective the amount of SRMs generated from cattle under the proposed action, the average amount of SRMs that would have been generated from cattle annually in the United States between 2002 and 2004 was about 412 million pounds (see footnote number 59 and 61 for an explanation of this estimate). The amount of SRMs that is predicted to be generated from cattle imported from Canada under the Proposed Action alternative is approximately 6 percent[71] of the total amount estimated to have been generated in the United States.

The additional amount of SRMs generated from cattle imported from Canada from 2008 to 2026 ranges from 16,161,000 [72] to 19,789,000[73] pounds. The additional SRMs comprise less than 5 percent of the total amount of SRMs estimated to have been generated from cattle slaughtered in the United States (see table 4).

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[66] 2009: A total of 1,211,000 cattle imported (USDA, ERS, 2006c) – 51,000 breeding cattle imported (USDA, ERS, 2006c) = 1,160,000 feeder, feed, and cull cattle.

[67] 2021: A total of 1,368,000 cattle imported (USDA, ERS, 2006c) – 58,000 breeding cattle imported (USDA, ERS, 2006c) = 1,310,000 feeder, feed, and cull cattle.

[68] This number does not include about 58,000 head of cattle forecast to be imported into the United States from Canada for breeding in 2007. Over a period of 2008 to 2026, the number of breeding cattle assumed to be imported from Canada, ranges from 51,000 to 58,000 cattle per year.

[69] 303,000 cattle 30 months of age and over × 57.0 pounds of SRMs + 857,000 cattle under 30 months of age × 3.1 pounds of SRMs = 19,928,000 pounds of SRMs.

[70] 355,000 cattle 30 months of age and over × 57.0 pounds of SRMs + 955,000 cattle under 30 months of age × 3.1 pounds of SRMs = 23,196,000 pounds of SRMs.

[71] 23.0 million pounds of SRMs generated under the Proposed Action alternative during 2007 and 2021 (2007 and 2021 data was used in the calculation since this year would generate the greatest amount of SRMs) ÷ 412 million pounds of SRMs estimated to have been generated annually from 2002 to 2004 = 0.06 (6 percent).

[72] 19,928,000 pounds of SRMS under the Proposed Action – 1,215,000 cattle × 3.1 pounds per head = 16,161,000 pounds of SRMs.

[73] 23,196,000 pounds of SRMs under the Proposed Action – 3,407,000 pounds of SRMs under the No Action alternative = 19,789,000 pounds of SRMs.

Table 4. The Range (Lowest and Highest) of the Difference in the Amount of SRMs Generated in the United States From Cattle Entering From Canada Under the No Action and Proposed Action Alternatives

Year	Pounds of SRMs Generated Under Proposed Action	Pounds of SRMs Generated Under No Action	Difference in Pounds of SRMs Generated	Difference as a Percent of Total SRMs Disposed (2002–2004)
2009	19,928,000	3,767,000	16,161,000	3.9%[74]
2007	23,196,000	3,407,000	19,789,000	4.8%[75]

A less than 5 percent increase in the amount of SRMs is not expected to overburden U.S. disposal facilities. In addition, the live bovines expected to be imported into the United States under the proposed rulemaking may reduce the supply of U.S.-sourced slaughter cattle. Therefore, some of the additional SRMs generated from Canadian imports under the proposed rulemaking may be offset by a decrease in SRMs generated domestically.

C. Highly Uncertain or Unique or Unknown Risks

The NEPA implementing regulations require consideration of the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risk.[76]

The exact relationship between human exposure to BSE agents and the likelihood that humans will develop vCJD cannot be quantified in terms of risk because the human oral infectious dose (the dose able to cause infection) is not known at this time (EC SSC, 2000). Although there are still some unknown facts with regard to the infective BSE agent, there is a great deal now known about BSE.[77] While it is known that the control of SRMs is a measure designed to protect public health, there are other unknown issues that could arise in the future.

Future research has been recommended by the European Union Scientific Steering Committee, which includes cattle bioassay and more sensitive prion detection testing of many of the cattle tissues. Stored tissue is available for this purpose in the United Kingdom. A pathogenesis study underway in Germany will also provide tissue from cattle incubating BSE for additional testing. Funds for BSE research will be used for newly funded BSE projects and facilities. Many of these newly funded projects involve international collaboration with researchers from the United Kingdom and other European countries. While the primary tissues of concern for spreading the BSE agent have been identified, the research results of future studies on BSE may further refine this determination and inform

[74] 16,161,000 pounds of SRMs ÷ 412,000,000 pounds of SRMs estimated to have been generated = 0.039 (3.9%).
[75] 19,789,000 pounds of SRMs ÷ 412,000,000 pounds of SRMs estimated to have been generated = 0.048 (4.8%).
[76] 40 CFR § 1508.27(b)(5).
[77] 70 FR 18252, April 8, 2005.

policies with regard to BSE.[78] The Department of Health and Human Services also has issued a department-wide action plan outlining steps to improve scientific understanding of BSE and other TSEs (CDC, 2005b).

There is strong scientific consensus about the BSE agent, the mechanisms for its spread, and the tissues that are most likely to harbor the infective agent. Scientific research, backed by practical experience, has resulted in a defined series of measures that countries can use to keep the BSE agent out of the food and feed chain and thus ensure the safety of animal and public health.[79]

Gaps exist in the knowledge about the BSE agent. However, based on current knowledge about the BSE agent, the APHIS proposed rulemaking for which this environmental analysis is prepared and earlier rulemakings by APHIS, FSIS, and FDA include mitigations that are designed to protect animal health and public health from the possibility of exposure to the BSE agent. Although our knowledge of BSE is not complete, our current understanding allows us to conclude that the described uncertainties will not have a significant adverse impact on the human environment.

D. Endangered or Threatened Species

Section 7 of the Endangered Species Act (ESA) and ESA's implementing regulations require Federal agencies to ensure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of critical habitat. TSEs have been reported in European zoos in wild ruminants, cats, and monkeys (Cunningham *et al.*, 2004) and are believed to have resulted from BSE-contaminated feed. Thus, for both alternatives, six endangered ruminant species were considered as potentially at risk as a result of the possibility of ingestion of contaminated ruminant feed (see table 5).

Table 5. Endangered Wild Ruminant Species in the United States Potentially At Risk From Transmissible Spongiform Encephalopathies.

Common Name	Scientific Name	Listing Status
Woodland caribou	*Rangifer tarandus caribou*	Endangered
Columbian white-tailed deer	*Odocoileus virginianus leuceurus*	
Key deer	*Odocoileus virginianus clavium*	
Sonoran pronghorn	*Antilocapra americana sonoriensis*	
Bighorn sheep	*Ovis Canadensis*	
Sierra Nevada bighorn sheep	*Ovis canadensis californiana*	

[78] 70 FR 53043, September 7, 2005.
[79] 70 FR 18252, April 8, 2005.

Also, for both alternatives, one threatened and six endangered wild cats were considered for risk of infection from BSE because of the possibility that they could feed on BSE-infected bovine or bovine carcasses (see table 6).

Table 6. Listed Wild Cats Known to Feed on Bovine Carcasses.

Common Name	Scientific Name	Listing Status
Canada lynx	*Lynx Canadensis*	Threatened
Eastern puma (=cougar)	*Puma (=Felis) concolor cougar*	Endangered
Florida panther	*Puma (=Felis) concolor coryi*	
Gulf Coast jaguarundi	*Herpailurus (=Felis) yagouaroundi cacomitli*	
Jaguar	*Panthera onca*	
Ocelot	*Leopardus (=Felis) pardalis*	
Sinaloan jaguarundi	*Herpailurus (=Felis) yagouaroundi tolteca*	

Impact of the No Action alternative on endangered and threatened species was analyzed in the MRR EA (USDA, APHIS, 2004a). In that environmental analysis, APHIS determined that the importation of certain ruminants and ruminant products (the No Action alternative in this environmental analysis) would have no effect on federally listed wild cats or ruminants.

For the proposed action, bovine, bovine carcasses, or SRMs are unlikely to expose federally listed species to BSE because of the multiple mitigation measures in place, which include disposal methods that would prevent direct exposure of these materials to wildlife. The disposal of carcasses outside of slaughter channels is regulated by local and/or state requirements. In certain areas, disposal methods such as on-farm burial may be prohibited. Such carcasses could be rendered, landfilled, or composted. In the unlikely event that a carcass left lying in the field is infected with BSE, very few animals that would feed on a cattle carcass are capable of becoming infected with BSE. Therefore, such carcasses are not likely to transmit BSE to the human environment.

Exposure of listed species to ruminant feed containing BSE-contaminated SRMs, blood and blood products, or casings would also be extremely unlikely since these products are prohibited from being included in ruminant feed. Therefore, it would be unlikely that listed wild cats would be exposed to BSE-contaminated bovine or bovine carcasses and SRMs or that federally listed ruminants would be exposed to BSE-contaminated ruminant feed as a result of the implementation of this proposed action.

Based on the low prevalence of BSE in Canada and the multiple barriers in place to reduce the level of BSE infectivity in the system (USDA, APHIS, 2006a), implementation of the proposed action is expected to have no effect on federally listed wild cats or ruminants.

E. Cumulative Impacts

Under NEPA, Federal agencies must analyze the potential cumulative impacts of a proposed action. The Council on Environmental Quality (CEQ) defines cumulative impacts as impacts on the environment that result from the incremental impact of an action when added to other past, present, and reasonably foreseeable future actions. Actions resulting in a cumulative impact may or may not be generated by the same agency. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.[80]

Public Health

BSE-infected bovines may affect the human environment, which includes public health, if SRMs with infectious levels of the agent enter the food chain. Proper SRM removal and segregation are essential mitigation measures for preventing impacts on public health and has been discussed previously in this document as well as in the MRR EA. The cumulative impacts of importing live bovines and certain properly processed low-risk bovine products from BSE-affected countries into the United States under current regulations, the proposed action, and any future proposed actions should not have a significant impact on the human environment in the United States.

Multiple mitigation measures prescribed by the proposed action and previous actions would have to substantially fail in order for the BSE agent to find its way into the animal and human food supplies, and there is no evidence to conclude that such a significant breakdown in the system of interlocking and overlapping measures could occur. Even if SRMs from imported Canadian bovines were infected with BSE, any potential cumulative risk of removing and segregating these SRMs, combined with the removal and segregation of SRMs from U.S. bovines, would not increase potential public health risks from BSE exposure provided that U.S. facilities adhere to FSIS and FDA requirements.

Other Agency Regulations

FDA and FSIS contribute to the overlapping safeguards that are currently in place to protect animal health and to ensure that public health within the United States is not affected by minimizing human exposure to materials that could contain the BSE agent. These agencies' regulations are discussed in the MRR EA (USDA,

[80] 40 CFR § 1508.7.

APHIS, 2004a) as well as the Public Health section of this document. See the following bulleted list for a summary.

Overlapping safeguards:

- FDA ruminant-to-ruminant feed ban regulation.
- FDA and FSIS regulations for SRM removal, segregation, and disposition intended to ensure SRMs are not used in human food and do not cross-contaminate edible meat products.
- FSIS regulations on nonambulatory disabled cattle. These cattle must be condemned and may not be used for edible products. Their carcasses must be disposed of by tanking (i.e., inedible rendering), incineration, or denatured by the materials approved by the Administrator of FSIS.
- FSIS regulations that prohibit the incorporation of mechanically separated meat in human food.
- FSIS regulations that prohibit the use of certain stunning devices and pithing during slaughter.

FDA is currently proposing to amend its regulations[81] to prohibit the use of certain cattle-origin materials in the food or feed of all animals.[82] FDA stated that the purpose of the additional prohibitions and restrictions is to strengthen existing safeguards designed to help prevent the spread of BSE in U.S. cattle (USDHHS, FDA, 2005).

Additionally, the Canadian Food Inspection Agency, has implemented regulations that prohibit feeding most mammalian proteins and all plate waste and poultry litter to ruminants.

Physical Environment

BSE-infected bovines may affect the human environment, which includes the natural or physical environment, if the SRMs generated within the United States overwhelm the ability of facilities to properly dispose of the material. The actions that could contribute to an increase in the amount of SRMs generated from the U.S. bovine population are the importation of live bovines currently being imported under the MRR rule and the additional live bovines that APHIS is proposing to allow from Canada. In viewing each action and its incremental effect on the amount of SRMs to be disposed of, there is no evidence to suggest that the expected increase in the quantity of SRMs could not be appropriately handled by U.S. facilities.

Other aspects of the proposed action that may affect the physical environment include impacts that may result from the transport and holding of additional bovines. Since the cumulative impacts of this aspect of the proposed action has

[81] 21 CFR § 589.000
[82] 70 FR 58569, October 6, 2005.

previously been discussed in depth in this document, this section will focus on the impacts to the physical environmental that are related specifically to the amount of SRMs generated within the United States.

On July 15, 2005, the MRR rule went into effect. In December 2004, prior to finalizing the rule, an environmental assessment was prepared and made available to the public (USDA, APHIS, 2004a). The cumulative impacts section analyzed the amount of SRMs to be imported (SRMs are imported within live bovines) and the ability of the United States to handle any potential increase in the amount of SRMs disposed. The analysis relied on historical import quantities of cattle, as well as projected changes in U.S. importation and Canadian exportation trends. While the estimate of the number of cattle that would be imported from Canada was eventually revised downward,[83] the cumulative impacts analysis still found that there was no evidence to suggest that the United States would be unable to handle the projected increase in the amount of SRMs to be disposed and that risks to the human environment would not increase.

Under the proposed action, there exists the potential for an increase in the quantity of SRMs to be disposed of in the United States. Based on the data generated earlier in the physical environmental impact section of this document, an additional 16,161,000 to 19,789,000 pounds of SRMs would be imported from Canada each year from 2007 to 2026. The additional SRMs comprise less than 5 percent of the total amount of SRMs estimated to have been generated from cattle slaughtered in the United States. This amount of SRMs should not overburden the United States' ability to properly dispose of the material.

The cumulative impacts of importing live bovines from BSE-affected countries into the United States under current regulations and the proposed action should not have an additive impact on the natural or physical environment. Live bovines are currently not imported from any BSE-affected country other than Canada. If, in the future, APHIS were to recognize any other regions in addition to Canada as minimal-risk regions, there is no reason to believe that the mitigation measures and other requirements imposed in such a rulemaking would be any more likely to be breached and result in potential adverse impacts on the natural or physical environment. Additionally, the public would have the opportunity to participate in future rulemaking changes related to importing live bovines and bovine products from countries that present a risk of introducing BSE into the United States.

[83] 70 FR 18252, April 8, 2005.

F. Other Laws or Requirements

The CEQ NEPA regulations require Federal agency consideration of whether a proposed action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.[84]

While indirect environmental impacts, such as the addition of environmental pollutants from trucks transporting cattle, waste from imported live cattle held in feedlots and slaughtered in U.S. slaughter establishments, and SRM disposal from slaughter of imported cattle, could result from the proposed action, the action itself does not threaten a violation of laws or requirements that are designed to protect the environment. Potential indirect environmental impacts extend beyond the scope of the proposed rulemaking.

Some executive orders such as Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks, and Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, and departmental or agency directives require special environmental reviews in certain circumstances. In considering these additional review requirements, no circumstance that would trigger the need for special environmental reviews is involved in implementing the proposed action considered in this document.

III. Summary of Potential Environmental Impacts by Alternative

This section provides a summary table of the potential environmental impacts considered in this document to show a comparison of the impacts between the No Action alternative and the Proposed Action alternative by commodity.

[84] 40 CFR § 1508.27(b)(10).

Table 7. Summary of Potential Impacts by Commodity and Alternative

Environmental Impacts	No Action Alternative	Proposed Action Alternative
Public Health		
- Live cattle	Currently 1.1−1.3 million cattle under the age of 30 months imported annually. No adverse impacts on the human environment provided that mitigations and other requirements are adhered to.	Increase of 0.30−0.34 million cattle 30 months of age and older imported annually. Estimated potentially available 45−290 cattle oral ID_{50}s.* No adverse impacts on the human environment provided that mitigations and other requirements are adhered to.
- Bovine small intestines (except the distal ileum)	No adverse impacts on the human environment.[85]	No adverse impacts on the human environment provided that mitigations and other requirements are adhered to.
- Bovine blood and blood Products	No adverse impacts on the human environment.[86]	No adverse impacts on the human environment provided that mitigations and other requirements are adhered to.
Physical Environment		
- Transport of cattle	Air quality degradation from 22,000-26,000 truck transports annually.[87]	Slight increase in air quality degradation from an additional 6,060 to 6,860 truck transports annually.
- Holding of cattle in Feedlots	Air quality and water quality degradation. Beneficial increase in fertilizer and soil conditioner.	Slight increase in air quality and water quality degradation. Beneficial increase in fertilizer and soil conditioner.
- SRMs generated and Disposed	~ 1 % increase in the amount of SRMs estimated to have been previously generated in the U.S. This amount is not expected to overburden U.S. disposal facilities.	< 5 % increase in the amount of SRMs estimated to have been previously generated in the United States. This amount is not expected to overburden U.S. disposal facilities.
Federally listed endangered or threatened species	No effect.	No effect.
Cumulative impacts	No adverse impact on the human environment.	No adverse impact on the human environment.

*Based on less likely scenarios quantitatively analyzed through an exposure model.

[85] Bovine small intestines (except for the distal ileum) are not allowed for importation under the no action alternative.

[86] Bovine blood and blood products are not allowed for importation under the no action alternative.

[87] Compared to 5.6 million average annual truck crossings from Canada to the United States for 2001 through 2005 (through the 20 ports of entry authorized for importation of ruminants under the MRR rule).

IV. Agencies or Persons Contacted

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