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Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products From Canada into the United States

Final Environmental Assessment, December 2004

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I. What is this document and why is it being prepared?

Consistent with the National Environmental Policy Act of 1969 (NEPA) (42 United States Code 4321 *et seq*.) and the Council on Environmental Quality (CEQ) implementing regulations (40 Code of Federal Regulations (CFR) Parts 1500–1508), as well as the implementing procedures of the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) (7 CFR Part 372), this environmental assessment (EA) explores potential environmental effects associated with a rulemaking to allow some currently prohibited ruminants,[1] ruminant products, and ruminant by-products to be imported from other countries where there is a minimal risk that bovine spongiform encephalopathy (BSE, also known as "mad cow disease") could thereby become prevalent in the United States. Available evidence discussed in risk analyses indicates that BSE is unlikely to become prevalent in the United States as a result of protection measures developed to prevent the spread and further introduction of the disease.

II. What is the purpose of and need for the proposed action?

The purpose of the proposed action is to modify import regulations in order for the United States to allow the importation of ruminants, ruminant products, and ruminant by-products that do not substantially increase the risk of BSE entering the country. The need for the proposed action is to allow trade of certain live ruminants and ruminant products and by-products while removing unnecessary prohibitions on low-risk commodities.

On May 20, 2003, the Canadian Food Inspection Agency (CFIA) reported a case of BSE in a beef cow in northern Alberta. The United States immediately added Canada to the list of regions where BSE is known to exist (9 CFR § 94.18(a)(1)). This action prohibited the importation of ruminants, ruminant products, and ruminant by-products that have been in Canada. After the U.S. import prohibition, Canada conducted an epidemiological investigation and implemented additional risk mitigation measures. Thereafter, Canada requested that the United States allow the

[1] Any of various hoofed, even-toed, usually horned mammals such as cows, sheep, goats, deer, giraffes, and camels. They characteristically have a stomach divided into four compartments and chew cud.

importation of certain low-risk live ruminants and ruminant products and by-products.

Among responsibilities related to U.S. animal and plant health, APHIS enforces regulations to prevent, control, and/or eliminate animal diseases and monitors and promotes animal health and productivity. Other Federal agencies, namely the U.S. Department of Health and Human Services' (DHHS) Food and Drug Administration (FDA) and USDA's Food Safety and Inspection Service (FSIS), have roles and responsibilities that serve to protect human health and safety with regard to imported meat, meat by-products, and meat food products. As a Federal agency that must also comply with NEPA, APHIS, in complying with the CEQ NEPA implementing regulations, must consider, among other issues, "the degree to which the proposed action affects public health or safety" (40 CFR 1508.27(b)(2)). Hence, in this environmental assessment we refer to FSIS and FDA requirements that are designed to protect human and animal health from BSE agent exposure.

III. What alternatives are considered?

A. No action

The no action alternative would maintain the continued regulatory prohibition of the importation of ruminants, ruminant products, and ruminant by-products from Canada and from any other country or region that could eventually be classified as a BSE minimal risk region pursuant to the proposed rulemaking The current regulations in 9 CFR Parts 93, 94, 95, and 96 prohibit the importation of live ruminants and most ruminant products and by-products from (1) regions where BSE exists (9 CFR § 94.18(a)(1)) and (2) regions that present an undue risk of introducing BSE into the United States via live ruminant or ruminant products or by-products because of inadequate surveillance or import requirements that are less restrictive than would be allowed for importation into the United States (9 CFR § 94.18(a)(2)).

B. Proposed action

The proposed rulemaking would allow for the importation of certain live ruminants and ruminant products and by-products, provided the requesting country or region seeking recognition as a minimal risk region demonstrates that it meets certain factors similar to the criteria

recommended by the Office International des Epizooties (OIE).[2] This proposed rulemaking is designed to protect against the further introduction and spread of BSE in the United States while removing unnecessary prohibitions on certain low-risk commodities from these BSE minimal risk regions. Both the original APHIS risk analysis (USDA, APHIS, VS, 2003) and the updated analysis of risk (USDA, APHIS, VS, 2004a) prepared for this rulemaking discuss factors that a region would have to meet, through an evaluation, including whether the region has complied with the following:

(1) Maintains and, in the case of regions where BSE was detected, had in place prior to the detection of BSE in an indigenous ruminant, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:
    (a) Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;
    (b) Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE; and
    (c) A ban on the feeding of ruminant protein to ruminants that is in place and effectively enforced.
(2) In regions where BSE is detected, an epidemiological investigation is conducted sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and such measures are continued; and
(3) In regions where BSE is detected, additional risk mitigation measures, based on risk analysis, are taken as necessary following the BSE outbreak, and such measures are continued.

CFIA has requested the United States to recognize Canada as a minimal risk BSE region, thus allowing imports of certain live ruminants and ruminant products and by-products into the United States. For the list of low-risk products and discussions about specific risk-reduction strategies associated with CFIA's request, refer to the risk analysis, "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States,"(hereby incorporated by reference) prepared by APHIS in October 2003 (USDA, APHIS, VS, 2003) and "Analysis of Risk – Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of

[2] An organization that establishes international standards to facilitate trade for countries that are signatories to international trade agreements, while minimizing the risk of introducing diseases.

Commodities: Animal and Plant Health Inspection Service, December 2004" (USDA, APHIS, VS, 2004a).

IV. What is BSE?

BSE, commonly referred to as "mad cow disease" is a slowly progressive, degenerative disease that affects the central nervous system (CNS) of adult cattle. BSE belongs to a family of diseases known as transmissible spongiform encephalopathies (TSE). TSEs share some common characteristics, including a prolonged incubation period ranging from a few months to years and progressively debilitating neurological illnesses, which are always fatal. The typical incubation period for BSE in animals is 2 to 8 years (USDA, APHIS, 2004a). Following the onset of clinical signs, the animal's condition deteriorates until it either dies or is destroyed; this process usually takes from 2 weeks to 6 months (USDA, APHIS, 2004a).

Scientific literature suggests that the origin of BSE remains unknown and may never be known with certainty (Prince *et al.*, 2003). Currently, the most accepted theory is that the causative agent of BSE is an abnormal, self-replicating, prion protein. The BSE agent is extremely resistant to heat, ultraviolet light, ionizing radiation, and common disinfectant processes, and it also does not evoke any detectable immune response or inflammatory reaction in host animals. The original APHIS risk analysis states that scientific evidence (Wilesmith *et al*., 1988; 1991; 1992) has shown that contamination of animal feed results from the incorporation of ingredients that contain ruminant protein derived from TSE infected animals. Tissues of particular risk include, but are not limited to, the brain, spinal cord, and eyes. BSE does not appear to be transmitted via contact between cattle or between cattle and other TSE-affected species. Some evidence suggests that maternal transmission may occur at an extremely low level (Wilesmith *et al.*, 1997).

V. What are the risks that the prevalence of BSE could be increased in this country?

A. Under the current regulatory system

To prevent BSE from entering the United States, since 1989, APHIS has restricted importation of live ruminants and ruminant products and by-products (*e.g.*, fetal bovine serum, meat-and-bone meal, bonemeal,

bloodmeal, offal, fats, and glands) from countries where BSE has been diagnosed. The Food and Drug Administration (FDA), in 1997, established regulations that prohibit the feeding of most mammalian proteins to ruminants in the United States because the primary source of transmission of BSE has been shown to be proteins derived from BSE-infected cattle in feed. Because of concerns about cross-contamination of rendered products of nonruminant origin with the BSE agent, APHIS, since 2000, has prohibited all imports of rendered animal protein products, regardless of species, from BSE-infected countries.

A risk assessment (Cohen *et al.*, 2003), "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," by the Harvard Center for Risk Analysis and Tuskegee University (hereafter referred to as the Harvard risk assessment), found that, owing to the already ongoing Federal programs, the United States is highly resistant to the spread of BSE in cattle herds and humans. The Harvard risk assessment regarded the feed ban as the United States' most effective means of BSE prevention.

On December 23, 2003, USDA, APHIS announced a preliminary diagnosis of BSE in a single dairy cow in Washington State. On December 25, 2003, the United Kingdom Veterinary Laboratories Agency, which serves as an international reference laboratory for diagnosis of BSE, confirmed the diagnosis. USDA immediately initiated a recall of the meat (FDA, 2004) and APHIS, in collaboration with CFIA, traced the birth of the BSE-positive cow to a dairy farm in Alberta, Canada. Thus, the BSE-positive cow was not indigenous to the United States but rather was a cow imported from Canada. The cow was moved to the United States in September 2001 along with 80 other cattle from the Alberta, Canada, dairy farm. A total of 255 "Animals of Interest" (animals that were or could have been from the source herd in Alberta, Canada) were identified on 10 premises in Washington, Oregon, and Idaho. All 255 animals were depopulated and examined for the presence of BSE, and all were negative (USDA, OC, 2004).

B. Under the proposed action

The rulemaking includes factors that address the same issues addressed by the criteria of OIE for minimal risk classification. Specifically, the OIE code (OIE, 2002) provides for countries with indigenous cases of BSE to be categorized as minimal, moderate, or high risk based on established criteria. The primary differentiating standard for these designations is the incidence rate of indigenous cases. For a minimal risk country, the incidence rate must have been less than two cases per million during each

of the last four consecutive 12-month periods within the cattle population more than 24 months of age. The incidence rate for Canada has been 0 for 3 years and two animals in 5.5 million over the last 12-month period. This is within the parameters for a minimal risk country, and well below the parameters for a moderate risk country.

OIE criteria currently require that a country has had an effective feed ban in place for 8 years. The feed ban in Canada has been in place since August 1997, less than the 8 years recommended by OIE. However, Canada has submitted evidence to show a history of stringent import control measures since 1990, a strong surveillance system since 1992, and appropriate additional mitigation actions taken as necessary. Canada recently added an additional measure, in response to the BSE find, to enhance food safety controls regarding BSE. The new measure requires that specified risk materials (SRMs) be removed from cattle at time of slaughter. SRMs are tissues that are considered at particular risk of containing the BSE agent in BSE-infected cattle. Most of the SRMs associated with Canadian imports will be removed and disposed of by slaughterhouses in Canada over which the Food Safety and Inspection Service (FSIS) has oversight authority, as implemented through a review and audit of the Canadian inspection by FSIS in determining that the Canadian inspection system is equivalent to the system of the United States. In addition, Canada has had a regulatory system for beef slaughter and processing that has been deemed equivalent to the U.S. system by FSIS.

APHIS conducted a risk analysis that was published before the finding of the cow of Canadian origin in the State of Washington. The Explanatory Note (USDA, APHIS, VS, 2004b) describes why the detection of the BSE-infected cow in the United States does not affect the conclusion of the original risk analysis:

- Both of the BSE cases of Canadian origin occurred in cattle born before the Canadian feed ban was implemented. They were both older than 30 months of age when they were diagnosed as infected. Infection presumably occurred prior to or around the time the Canadian feed ban was enacted in August 1997.

- The finding of an imported case in a cow greater than 30 months of age has little relevance to an analysis of risk under the proposed mitigation measures beyond the implications for BSE prevalence in Canada.

- The proposed rule was not in effect in 2001 when the imported case, which was more than 4 years old at the time, entered the United

States. Under the proposed conditions, the animal would not have been allowed entry into the United States.

The APHIS risk analyses (USDA, APHIS, VS, 2003 and 2004a) describe the risk-reduction strategies that would provide multiple safeguards against BSE and determined that with the surveillance, prevention, and control measures implemented by Canada, and the existing and proposed mitigation measures for specific animals and animal products intended for import, the risk of BSE-infected cattle being imported into the United States from Canada would be low. The Explanatory Note considered the factors discussed in the original risk analysis and the existing and proposed risk mitigation measures and determined that an additional BSE case of Canadian origin does not significantly alter the original risk estimate. Both the original risk analysis and the Explanatory Note conclude that the risk is low. The updated analysis of risk concludes that the initial risk estimate for the introduction and establishment of BSE from Canadian sources is appropriate (USDA, APHIS, VS, 2004a).

VI. What are the nature and extent of environmental effects that could be expected from BSE from the implementation of the rulemaking in this country?

According to the NEPA implementing regulations, criteria set forth in 40 CFR § 1508.27(b) should be considered in this environmental assessment. Not all criteria are applicable; those that are applicable will be considered below, principally for the proposed action. The NEPA criteria that will be considered in the subsequent sections include effects on public health or safety, unique or unknown risks, precedence for future actions, and cumulative effects. The degree to which the no action alternative potentially could adversely affect all aspects of environmental quality being considered, while not zero, is less than that associated with the proposed action. Further discussion will focus only on potential environmental effects associated with the rulemaking proposal.

A. The degree to which the proposed action affects public health or safety (40 CFR § 1508.27(b)(2))

The primary consequence to human health that would occur from ingesting the BSE agent is variant Creutzfeldt-Jakob disease (vCJD).

There appears to be a causal link between vCJD, a TSE that affects humans, and the consumption of beef products contaminated with the BSE agent. Cases of vCJD have been reported, primarily in the United Kingdom, occurring in people who consumed beef that may have been contaminated. As of December 2003, a total of approximately 153 cases of vCJD have been reported worldwide (Centers for Disease Control, 2003). The one reported case of vCJD in the United States was of a woman who contracted the disease while residing in the United Kingdom. The symptoms appeared years later after the woman moved to the United States.

As reported in the original APHIS risk analysis (USDA, APHIS, VS, 2003), there are many unknown factors relative to development of vCJD, including definition of an infectious dose or the length of an incubation period. Available information compiled from various studies suggests that the infectious agent may be 10 to 10,000 times less pathogenic in humans than in cattle (summarized in Cohen *et al.*, 2003; EUSSC, 2000). The original APHIS risk analysis further states, "Risk of such public health consequences should be extremely low in the context of importation of BSE infected commodities from Canada." Canada's situation with BSE exposure in cattle is very different from the situation that existed in the United Kingdom and certain other European countries in the early 1990s where there was widespread BSE exposure or establishment in cattle. The United Kingdom imposed stringent control measures after BSE was detected there. The peak of widespread BSE exposure in cattle in the United Kingdom was 30,000 cases per year in 1992-1993. The situation improved dramatically with the stringent control measures that were imposed, as has been the case in other European countries that were considered to have widespread exposure. The situation with Canada is different in that (1) control measures were in place before the detection of the disease, (2) only two animals of Canadian origin have been confirmed with BSE, (3) both were born before implementation of Canada's feed ban, and (4) Canada has maintained other protective measures (including import restrictions) that would help preclude a high level of infectivity from being transmitted to the cattle population.

Additionally, various safeguards have been implemented in the United States by FDA, FSIS, and APHIS and abroad that are designed to prevent the introduction of the BSE pathogen into the human food supply and to protect animal health from the BSE pathogen. The proposed rule should not pose any consequential risk to public health and safety based upon the current safeguards in place and the additional safeguards in the proposed rule.

1. Actions to protect public health and safety from BSE

APHIS and FSIS developed a step-by-step action plan in the event a case of BSE were to be detected in the United States. The plan outlines those events that should take place, including identification of a suspect animal, confirmation, the epidemiologic investigation, animal and herd disposition activities, and communication of information. The plan has been shared with other government agencies that have developed their own plans to coordinate with those of APHIS. A summary of the BSE response plan is available on the Internet at the following web site: http://www.aphis.usda.gov/lpa/issues/bse/bsesum.pdf. The BSE Emergency Disease Guidelines detail acceptable disposal methods that should be used to dispose of BSE-suspect carcasses.

BSE-infected carcasses or tissue must be disposed of in such a way as to inactivate, to the extent possible, the pathogen and eliminate the spread of disease and risk of transmission to other animals, wildlife, and humans. The disposal method chosen also should be the most environmentally acceptable in regard to the local geography, topography, type of animal and disease, numbers of carcasses to be disposed, and disposal options available.

APHIS operational guidelines discuss disposal options for diseased animal carcasses (USDA, APHIS, 2003; USDA, APHIS and FSIS, 2001). Before a method of disposal is selected, there are many factors that must be considered. Field personnel should inquire with environmental authorities concerning Federal, State, and local regulations that may impose restrictions on the selected disposal method (USDA, APHIS and FSIS, 2001). APHIS, as appropriate, will comply with all applicable local and State environmental regulations to minimize any environmental effects from these methods of disposal. Disposal methods include:
(1) incineration, (2) alkaline hydrolytic tissue digestion, (3) landfill disposal, and (4) burial. The APHIS recommended disposal method for carcasses and materials contaminated with the BSE agent and other TSE agents is the use of an alkaline hydrolysis tissue digester (USDA, APHIS, 2003).

a. Incineration

Incineration can be used to dispose of BSE-infected carcasses when other more preferred methods are not practical. The optimal way is through the use of commercial incinerators designed to handle animal carcasses. This might require moving the infected carcasses over some distance to where this type of incinerator is located. However, a portable air curtain incinerator can be used on site if there is an adequate supply of fuel, usually wood, and the ancillary equipment and labor are available. Further, if fuel is easily obtainable, burning a small number of carcasses

on the infected premises is feasible. Good management of the incineration process is also necessary to assure a thorough incineration of the infected material (USDA, APHIS, 2003). The choice of the disposal method is dependent on local and/or State regulations or laws that require specific compliance. Permits and clearances to incinerate will likely be required to comply with State and local environmental laws.

b. Alkaline Hydrolytic Tissue Digestion

The use of alkaline hydrolysis tissue digesters currently is the preferred method for disposal of BSE-contaminated carcasses. Research has demonstrated that alkaline hydrolysis is effective in significantly reducing the infectivity of the abnormal prion causing BSE. Alkaline hydrolysis involves the use of sodium hydroxide or potassium hydroxide, under heat and pressure, as the agent that digests (breaks down) carcass tissue, leaving only effluent and the mineral portion of bone and teeth. The effluent has a pH level ranging from 11.4 to 11.7 and, therefore, in most cases, can be discharged into municipal sewage systems. If potassium hydroxide is used, the effluent can be dehydrated and used as fertilizer. The bone and teeth easily can be crushed into a fine powder and sent to a landfill (USDA, APHIS, 2003).

Although alkaline hydrolysis involves a low operational cost per pound of tissue disposed, the equipment is expensive to purchase. Therefore, this method of carcass disposal would have limited application in a disease outbreak. The commercially available equipment for alkaline hydrolysis is designed for permanent installation in a building with a temperature-controlled environment. Portable units are expanding the options for use of this disposal method (USDA, APHIS, 2003).

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c. Landfill Disposal

The primary environmental concerns about landfills relate to their ability to contain any remaining infective prions or other potentially hazardous substances associated with the carcasses and to prevent any runoff to surface water or any leaching to groundwater. The linings of landfills are such that movement of prions or other substances is largely precluded.

Before landfills can be used, several criteria need to be satisfied, including meeting local/State environmental requirements (*e.g.*, water table levels,

leachate management, and gas treatment regimes) and obtaining the necessary permits. As with other tissue samples and carcasses, handling and transport of potentially infected BSE tissue samples and carcasses to the disposal sites require care to prevent any cross-contamination of vehicles or other potential fomites.

d. Burial

A burial site may be on the affected farm or at the diagnostic laboratory where the carcass is examined. The site should be inaccessible to animals, away from populated areas, not used for agricultural purposes, clearly marked, and properly protected. Burial sites also should be located a sufficient distance from underground utility lines, septic systems, water wells, and surface water (USDA, APHIS and FSIS, 2001).

Burial trenches should be at least 9 feet deep with floor dimensions of 7×2 feet per adult bovine carcass. "The carcasses should be covered with at least 6 feet of soil to avoid attracting wildlife that could possibly spread the disease. The soil should not be tightly packed because gas formation may cause a tightly packed trench to crack and leak" (USDA, APHIS and FSIS, 2001).

e. Disposal of SRMs Removed from Ruminants

The Resource Conservation and Recovery Act (RCRA) of 1976 provided the U.S. Environmental Protection Agency (EPA) the authority to develop and establish regulatory programs to manage solid waste, hazardous waste, medical waste, and underground storage tanks. Although, EPA has coordinated efforts with FSIS for the establishment of safeguards designed to prevent SRMs from entering the human food chain, EPA does not have specific regulations for SRMs with regard to disposal and does not classify SRMs as hazardous waste. However, there may be State and local regulations that regulate the disposal of SRMs.

On January 12, 2004, FSIS issued a interim final rule requiring establishments that slaughter cattle and establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs (9 CFR § 310.22(d)(1); FSIS Docket No. 03-025IF; 69 FR 1862-1874). FSIS has declared that SRMs are inedible and prohibits their use for human food; therefore, FSIS requires SRMs to be removed from the human food chain and disposed of in accordance with 9 CFR 314 such that the condemned material is sufficiently denatured and handled to prevent the use in human food. The FSIS regulations for SRM removal, segregation, and disposition are intended to ensure that SRMs are not used in human food

and that SRMs do not cross-contaminate edible meat products. The FSIS regulation for SRM removal, segregation, and disposition is summarized below from the FSIS interim final rule.

(1) FSIS Regulations

FSIS does not prescribe in its interim final rule specific procedures establishments must follow, believing that establishments should have the flexibility to implement the most appropriate procedures that will best achieve the requirements of this rule. Establishments are responsible for ensuring that SRMs are completely removed from the carcass, segregated from edible products, and disposed in an appropriate manner. Establishments must address their control procedures in their HACCP (Hazard Analysis and Critical Control Point) plans, Sanitation SOPs (Standard Operating Procedures), or other prerequisite programs. FSIS will ensure the adequacy and effectiveness of the establishment's procedures (FSIS Docket No. 03-025IF; 69 FR 1869). Section 310.22(d)(4)) also requires establishments that slaughter cattle and establishments that process the carcasses or parts of cattle to maintain daily records that document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and that the establishments make these records available to FSIS personnel on request. FSIS will assess whether additional guidance or requirements are necessary.

FSIS amended the regulations that prescribe requirements for dead, dying, disabled, or diseased and similar livestock in 9 CFR § 309.3 to require that nonambulatory disabled cattle be condemned and disposed of in accordance with 9 CFR § 309.13. Unless another provision in 9 CFR part 309 applies, under § 309.13, condemned livestock must be killed by the establishment, if not already dead. Such animals cannot be taken into the establishment to be slaughtered or dressed or conveyed into any department of the establishment that is used for edible products. Under 9 CFR § 310.22(b) and (c), it states that SRMs are inedible and shall not be used for human food and shall be disposed of in accordance with 9 CFR § 314.1 and 314.3. The carcasses of condemned livestock must also be disposed of in the manner provided for in 9 CFR part 314. Under 9 CFR part 314, condemned carcasses must be disposed of by “tanking,” *i.e.*, inedible rendering (9 CFR § 314.1; FSIS Docket No. 03-025IF; 69 FR 1871). For those establishments that do not have facilities for tanking, condemned carcasses may be disposed of by incineration or denatured by crude carbolic acid, cresylic disinfectant, or any other proprietary material approved by the Administrator of FSIS (9 CFR § 314.3; FSIS Docket No. 03-025IF; 69 FR 1871). In addition, the FSIS Administrator recognizes the use of activated charcoal to denature inedible materials

(FSIS Docket No. 03-025IF; 69 FR 1871). While FSIS recommends the use of disinfectants, EPA regulates disinfectants under FIFRA. Prior to 2003, prions were not considered pests, and therefore their treatment with disinfectants was not regulated. In September of 2003, EPA classified prions as a pest (Hazen, 2004) and, therefore, the agency was required to regulate the "microorganisms" under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The only direct impact to human health and safety by the proposed rulemaking relates to noncompliance with regard to the removal of the tonsils and distal ileum from all cattle less than 30 months of age imported from a minimal risk region. As described in the preceding pages, the current safeguards established by APHIS and FSIS for the disposal and handling of condemned carcasses and SRMs are designed to minimize any potential impacts to human health and safety.

(2) International Recommendations

The OIE, in joint consultation with the World Health Organization (WHO) and the Food and Agriculture Organization (FAO), states, "Whenever the possibility that slaughtered animals may be infected with BSE cannot be excluded, all tissues that have been proved capable of carrying BSE infectivity should be removed and destroyed" (OIE, 2001). According to APHIS's proposed rule, all tonsils and distal ileum are to be removed from all cattle, and no cattle 30 months of age or older may be imported into the United States. Whenever there is the possibility that the animal, and therefore, the SRMs (the tonsils and distal ileum) may be infected, these SRMs and animal carcasses need to be properly "destroyed." This will help to prevent the introduction of the BSE infectious agent into the human food supply.

Most national and international documents are silent as to how potentially contaminated SRMs should be disposed of. The WHO recommends that infectious waste[3] "should be incinerated or treated by a method that is effective for the inactivation of TSE agents. In regions where no incineration facilities are available, it is recommended that these wastes be chemically disinfected then burnt [*sic*] in pits dedicated to final disposal. Residues should be checked for total combustion" (WHO, 2000). WHO's recommendations for the disposal of infectious wastes, which includes infected tissues, appear relevant to the disposal of SRMs.

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[3] WHO's recommendations relate to infectious healthcare waste, which they define as "the discarded materials that have been in contact with blood and its derivatives, or wastes from infection isolation wards. These include but are not limited to cultures, tissues, dressings, swabs or other items . . ."

Besides recommendations for disposal of infected tissues, the WHO also recommends that disposable gloves and aprons worn when dealing with the possibly infected material should be "disposed of by incineration," although they also indicate additional methods may be suitable, *i.e.*, autoclave and chemical methods (WHO, 2000). This sanitary practice serves to protect the health and safety of those individuals that use protective wear and others who could come into contact with the protective wear.

(3) Research

Research has shown that prions are very difficult to inactivate and require rigorous treatment. The higher the solids content of the waste, the more rigorous the treatment required. Evaluations conducted by EPA have reported prions ability to survive boiling and autoclaving. Chemical treatment and gamma irradiation can be used to inactivate prions[4]. The required irradiation dose is related to pathogen size. As the size decreases, the gamma dose increases because it is harder for the gamma irradiation to hit the specific sensitive targets in the smaller infectious agents (EPA, 2002). EPA also addresses the speculation in regards to the link between mineral deficiency, enhanced oral manganese (Mn) uptake, and Mn-catalyzed denaturation of copper-free prion protein to the pathogenic prion protein, which might explain the enhanced occurrence of some prion diseases in certain world regions (EPA, 2004).

Research on prions and TSEs is ongoing. The National Academy of Sciences has published a report, "2004 Advancing Prion Science: Guidance for the National Prion Research Program" (NPRP). In this report, the Institute of Medicine's (IOM) Committee on TSEs: Assessment of Relevant Science recommends research to close significant gaps in present knowledge of TSEs and techniques to strengthen the United States research infrastructure for studying these diseases. The committee determined that the scientific community must first answer fundamental questions about TSEs and prions to develop the tools necessary to protect human and animal health. Therefore, the committee recommends that NPRP fund basic biomedical research on the structural features of prions; the molecular mechanisms of prion replication; the

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[4] Chemical treatment and gamma irradiation are options for the inactivation of prions that have been characterized to date (e.g., scrapie). However, the BSE agent, not fully characterized, may not be as efficiently inactivated by chemical treatments and gamma irradiation as, for example, the scrapie prion protein. Any given prion will not necessarily be same as all other prions, thus, it is those unique differences that creates the emergence of new prion causing diseases. Chemical treatments and gamma irradiation are options for prion inactivation that have been discovered through advances in research; however, not necessarily specific to the BSE agent.

mechanisms of TSE pathogenesis; and the physiological function of prion protein, the normal form of the misfolded protein of prions. The committee also recommends that NPRP support research on the epidemiology and natural history of TSEs. This report fulfills a request of the U.S. Army's Medical Research and Materiel Command for advice from the IOM on the most effective research agenda for the NPRP, established by the U.S. Congress in 2002 (National Academy of Sciences, 2004).

Although gaps exist in the knowledge about the BSE agent, through the APHIS rulemaking for which this EA is prepared and earlier rulemakings by APHIS, FSIS, and FDA, the safeguards are designed to protect animal health and human health from the possibility of exposure to the BSE agent.

2. Additional safeguards to protect public health and safety

The Harvard risk assessment identified three pathways or practices that could contribute most either to increased human exposure to the BSE agent or to the spread of BSE if it should be introduced into the United States. The pathways or practices are (1) noncompliance with the feed ban, (2) rendering of downer cattle (cattle that cannot rise from a recumbent position or that cannot walk) including cattle that die on the farm, and (3) inclusion of high risk tissue, such as brain and spinal cord, in edible products.

Cattle sent for slaughter in the United States are evaluated by the FSIS for signs of neurologic disease. Cattle exhibiting neurological signs on antemortem inspection are condemned and are not used for human food. Central nervous system tissue from these animals is forwarded to APHIS laboratories for pathologic examination.

FSIS issued an interim final rule on January 12, 2004, requiring immediate implementation of the following safeguards for the purpose of eliminating the potential for BSE infective animal tissues from the human food supply:

- Prohibit any material from "nonambulatory disabled livestock" (downer cattle) for human food.

- Prohibit for use in human food of certain SRMs that are known to harbor the highest concentrations of the infectious BSE agent. The following tissues are designated as SRMs: skull, brain, 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. In addition, the tonsils and the distal ileum of the small intestine of cattle of all ages are designated as SRMs. To ensure the distal ileum is completely removed, the entire small intestine (although not a designated SRM except for the distal ileum) must be removed and disposed of as inedible.

- Prohibit the use for human food of products known as mechanically separated beef, a product that may contain SRMs.

- Require additional process controls for meat derived by the process known as advanced meat recovery (AMR) and prohibit the use of AMR processes on vertebral column or skulls of cattle 30 months of age or older. Meat obtained by AMR may be used for human food, but sampling procedures must be in place to ensure that neither spinal cord nor dorsal root ganglia are present in the final product.

- Prohibit slaughter of bovines by the use of air-injected stunning (pneumatic stun guns).

- Develop procedures to verify that cross-contamination of edible tissue with SRMs is reduced to the maximum extent practical in facilities that slaughter cattle or process carcasses or parts of carcasses of cattle, both younger than 30 months of age and 30 months of age and older. The multiple risk mitigation measures implemented in the United States to prevent the spread of BSE have been designed to reduce to the maximum extent possible cross contamination of carcasses with high-risk tissues.

Additional information on USDA rulemaking and notices can be accessed at www.fsis.usda.gov/oa/news/2004/bseregs.htm .

APHIS is in the process of working to implement a national identification system to track animals of various species through the livestock marketing chain to enhance the speed and accuracy of the response to animal diseases, such as BSE (69 FR 64714, dated November 8, 2004).

3. Preventative measures for handling infected animal remains

EPA does not classify SRMs as hazardous waste. However, BSE-infected animals and animal remains are handled as hazardous waste in some States, such as Washington and Wisconsin. The Washington State Legislature defines animal waste as waste animal carcasses, body parts, and bedding of animals that are known to be infected with, or that have been inoculated with, human pathogenic microorganisms infectious to

humans. Biosafety level 4 disease waste is waste contaminated with blood, excretions, exudates, or secretions from humans or animals who are isolated to protect others from highly communicable infectious diseases that are identified as pathogenic organisms (Washington State Legislature, 2004).

The Explanatory Note states that "the consequences with regard to animal health, human health, and the environment continue to be minimal or low under the conditions described in the risk analysis and rule."

B. The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks (40 CFR § 1508.27(b)(5))

There are still unknown facts with regard to the infective BSE agent (prions) and its persistence in the environment. The ability of prions to persist in the environment under extreme conditions and the lack of BSE-related studies regarding disposal of SRMs are unclear about which disposal method can be considered to be definitively effective in inactivating or isolating the BSE agent.

The exact relationship between human exposure to BSE agents and the likelihood that humans will develop vCJD under various scenarios cannot be quantified in terms of risk because the human oral infectious dose (the dose able to cause infection) (SSC, 2000) is not known at this time. Similarly, potential human exposure to the BSE agent through products containing ingredients of bovine origin, such as some pharmaceuticals, gelatin, beef stocks, extracts, and flavorings was not analyzed. If BSE should enter the United States, the Harvard risk assessment indicates that, at most, probably only a small amount of potentially infectious tissues would reach the human food supply as a result of the BSE agent surviving the rendering process and/or the mislabeling and cross-contamination of meat and bone meal.

Concern about the possibility of prions in muscle tissue from cattle has been raised based on research studies. According to the updated analysis of risk (USDA, APHIS, VS, 2004a), "BSE infectivity has never been demonstrated in the muscle tissue of cattle examined in either the mouse bioassay or the cattle assays described in the previous paragraphs. Nevertheless, some reports have identified the presence of prions in muscle tissue from rodents, humans, and sheep infected with TSEs other than BSE [Bosque 2002, Prusiner, 2004]. Although these recent findings suggest the possibility that BSE infectivity might be present in cattle muscle tissue, no such infectivity has been demonstrated in ongoing

bioassays. Any theoretical level of infectivity defies quantification, and, if infectivity in muscle tissue occurs, it only represents a minuscule fraction of the total infectivity within affected cattle."

Although the Harvard risk assessment (Cohen *et al.*, 2003) concludes that it is unlikely that U.S. cattle would become infected from eating BSE-contaminated feed because of the FDA ban on feeding ruminant protein to other ruminants, the assessment states that in estimating the spread of BSE among cattle, the most influential sources of uncertainty are related to compliance with the feed ban. Some suggested cases associated with feed ban noncompliance include misfeeding prohibited feed to cattle on farms that have a variety of livestock or mislabeling of feed that contains ruminant protein. These cases would increase risk and tend to compromise the effectiveness of the feed ban. However, in the case of Canada, the risk analysis (USDA, APHIS, VS, 2003) indicates that the country "was one in which the feed ban appeared to be an effective barrier to dissemination of the infectious agent, and there is no subsequent evidence of significant non-compliance with the feed ban."

C. The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration (40 CFR § 1508.27(b)(6)) and whether the action is related to other actions with individually insignificant but cumulatively significant impacts (40 CFR § 1508.27(b)(7))

Implementation of the proposed rule will set a precedent for future actions by establishing criteria by which BSE-infected countries may request to be recognized as a minimal risk country and, after demonstrating that they meet certain conditions, may import certain live ruminants and ruminant products and byproducts. Importation of live ruminants from BSE minimal risk countries may increase the amount of SRMs disposed of in the United States. The increase in the quantity of tonsils and distal ileum to be disposed of from imported ruminants could affect the ability of disposal facilities to appropriately handle such disposal; however, there is no evidence to suggest that such an effect is likely to occur.

If there were any possible BSE infectivity of SRMs from imported Canadian ruminants, the cumulative risk of disposing of these SRMs combined with SRMs from U.S. ruminants would not increase potential human health risks of BSE exposure, provided that processing establishments dispose of all SRMs according to FSIS requirements in 69 FR 1862-1874.

Under the proposed rulemaking SRMs will be removed from ruminant products before they enter the United States; SRM disposal therefore is not an issue for ruminant products and the importation of this commodity does not need to be analyzed in the cumulative effects section.

In evaluating the cumulative effects of an action, the Council on Environmental Quality (CEQ) states that the historical context of an action is critical (CEQ, 1997). Based on historical import quantities, as well as projected changes in U.S. importation and Canadian exportation trends, APHIS predicted the total number of live cattle imports from Canada for the years 2005 until 2009 if the Canadian BSE Minimal Risk rule was enacted. APHIS hypothesized that a range of 1.5 to 2 million live cattle will enter the United States from Canada in the year 2005 (USDA, APHIS, 2004b). Importation of live cattle into the United States from Canada is expected to decrease over time with an approximate range as follows:

- 1,043,800 to 1,173,800 live cattle being imported in 2006,
- 953,800 to 1,033,800 in 2007,
- 873,800 to 903,800 in 2008, and
- 853,800 to 892,800 in 2009 (USDA, APHIS, 2004b).

While the projected importation of other ruminants was not analyzed, the historical importation of these animals is such a small number in relation to total U.S. supply (sheep from Canada represented 4.5 percent of the total U.S. supply while goats from Canada represented less than 2 percent of the total U.S. supply) (USDA, NASS, 2003) that their potential effect on the risk of BSE exposure is expected to be low.

Although it is speculative as to which or how many BSE-infected countries or regions will be able to request recognition and will be able to meet the minimal-risk requirements of the proposed rulemaking, the cumulative effects must be considered, even if that means speculating to a certain degree, “Cumulative effects analysis necessarily involves assumptions and uncertainties . . .” (CEQ, 1997). Currently, there are no countries other than Canada that qualify as a minimal risk country and are allowed to import ruminant and ruminant products under this rule. If and when other countries are added to the minimal risk category and qualify for importation, the importation of ruminants is not expected to increase considerably because most of the imports into the United States come from a small number of countries, mainly Canada and Mexico (USDA, ERS, 2004). Under the circumstances, any SRMs added to the waste stream as a result of importation of ruminants from countries other than Canada should not significantly affect the quality of the human environment.

D. The degree to which the action may adversely affect an endangered or threatened species or its habitat (40 CFR § 1508.27(b)(9))

Endangered Species Act. Section 7 of the Endangered Species Act (ESA) and ESA's implementing regulations require Federal agencies to insure 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 Europe in captive wild ruminants, cats, and monkeys and are believed to have resulted from BSE-contaminated feed. Six endangered ruminant species were considered as potentially affected as a result of the possibility of contact by these wild species with BSE-infected cattle or ingestion of contaminated feed (see table 1).

Table 1. Endangered wild ruminant species in the United States 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*	

No evidence is available to show that BSE is spread by contact between unrelated cattle or from cattle to other species. In addition, animal feed imported from Canada that might be fed to wild ruminants in the United States should not contain BSE-contaminated animal products. The FDA has established regulations that prohibit the feeding of most mammalian proteins to ruminants in the United States. Thus, the APHIS proposed rulemaking should have no effect on listed wild ruminant species potentially susceptible to TSEs.

One threatened and three endangered wild cats were considered for risk of infection from BSE because of the possibility that they could feed on BSE-infected cattle or carcasses of cattle (see table 2).

Table 2. Listed wild cats known to feed on domestic cattle or cattle 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*	
Jaguar	*Panthera onca*	

Based upon the effectiveness of the criteria and the mitigation measures included in the proposed rule to reduce BSE risk, implementation of the proposed rulemaking is not expected to have any effect on federally listed wild cats or their habitats.

VII. What are the conclusions?

The risk of introducing BSE into the United States as a result of the rulemaking is low based on past and more recent risk mitigation measures and safeguards implemented in Canada and the United States. According to the APHIS Explanatory Note (USDA, APHIS, VS, 2004b) prepared for this rulemaking, APHIS concluded that the“consequences with regard to animal health, human health, and the environment continue to be minimal or low under the conditions described in the risk analysis and rule.”

VIII. What agencies have been contacted for information and review?

Regionalization Evaluation Services
National Center for Import and Export
Veterinary Services, APHIS, USDA

Emergency Programs
Veterinary Services, APHIS, USDA

Office of Solid Waste, EPA

Food Safety and Inspection Service, USDA

Food and Drug Administration, DHHS

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USDA, APHIS, VS–See U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services.

USDA, ERS–See U.S. Department of Agriculture, Economic Research Service.

USDA, FSIS–See U.S. Department of Agriculture, Food Safety and Inspection Service.

USDA, NASS–See U.S. Department of Agriculture, National Agricultural Statistics Service.

USDA, OC–See U.S. Department of Agriculture, Office of Communications.

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