USDA

Veterinary Services

Safeguarding Animal Health

Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States

Animal and Plant Health Inspection Service
(APHIS)

Veterinary Services

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Glossary of terms

Air injected stunning: Immobilization process in which a captive bolt gun drives a bolt into the head and fractures the skull, followed by the injection of pressurized air into the cranial cavity, sometimes resulting in emboli that can contaminate various tissues, most importantly and selectively, the liver.

Bovid (bovine): A member of the family bovidae, including cattle, oxen.

Cervid (cervine): A member of the family Cervidae, which includes (but is not limited to) deer, elk, reindeer, moose.

Commercial use: Intended for sale and/or further distribution.

Mechanically separated meat: Process for separating meat from bone using pressurized equipment in which bone fragments can contaminate meat.

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

Office International des Epizooties (OIE): The world organization for animal health, located in Paris, France.

Personal use: Items intended only for personal consumption or display and not distributed further or sold.

Rendering: A cooking and drying process that breaks down discarded animal tissues into a protein fraction (e.g., meat-and-bone meal) and a fat fraction (e.g., tallow or lard).

Ruminant: Member of the mammalian suborder Ruminatia; an animal that has a stomach with four complete cavities and that characteristically regurgitates undigested food from the rumen and masticates it when at rest. Such animals include cattle, deer, and oxen.

Segregated facility: A facility that either slaughters only cattle less than 30 months of age or sheep and goats less than 12 months of age or complies with a segregation process approved by the national veterinary authorities of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.

Shooter bulls or shooter bucks: Bulls or bucks harvested by hunters on a game farm or similar facility.

Specified risk materials (as defined in Canada's Health of Animals Regulation): The skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord and dorsal root ganglia of cattle aged 30 months or older; and the distal ileum of cattle of all ages.

Tallow: Solid fat derived through a rendering process from cattle, sheep, etc., used to make candles, soaps, etc.

Traceback: Epidemiological investigation procedure in which efforts are made to identify animals that have been in contact with infected animals or herds in which an infected animal may have resided prior to confirmation of disease.

Traceforward: Epidemiological investigation procedure in which efforts are made to identify animals that have moved out of a herd in which an infected animal resided.

Traceout: Epidemiological investigation procedure in which movement of products and/or animals that might have been exposed to infection is traced.

Trim: Boneless meat cuts (muscle) intended for further processing into a product other than the native form (e.g., hamburger).

Veal calves: Calves that are raised for slaughter at 36 weeks of age or less, the age that represents the industry standard, as a source of veal.

Viscera: Large interior organs in any of the great body cavities, especially those in the abdomen.

Executive Summary

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) is conducting a risk analysis as a decision-making tool for a proposal to reinitiate trade in designated ruminants and ruminant products from Canada. Trade in ruminants and ruminant products was banned after bovine spongiform encephalopathy (BSE) was confirmed in a six-year-old cow on May 20, 2003. USDA immediately closed its borders through administrative action and followed that with an interim rule, published May 29, 2003, that added Canada to the list of regions where BSE is known to exist.

Despite the single case of BSE, VS considers Canada as a country that presents a minimal BSE risk for import purposes. The risk assessment provides the rationale for that conclusion, based both on OIE criteria for a minimal risk BSE region and on factors that VS has defined that it will use to address OIE recommendations for a minimal risk region. VS and OIE address the same issues.

The analysis describes the epidemiological characteristics of BSE that are relevant to the risk of imported ruminants and ruminant products from Canada and describes mitigations appropriate to that risk. The commodities discussed in this analysis were relatively freely traded prior to the ban and include feeder cattle and cattle for immediate slaughter less than 30 months of age, cervids and non-cervine ruminants for immediate slaughter, and meat and other products. The mitigations under consideration included a ban on the feeding of material of ruminant origin to ruminants, age restrictions on imported or source animals to an age at which infectious levels of the agent would be unlikely, feed source control, various processing and movement controls, and Canadian Food Inspection Agency (CFIA) verification that the mitigations were applied appropriately.

VS concluded that the surveillance, prevention, and control measures implemented by Canada are sufficient to minimize the risk of importing BSE into the United States, provided that additional mitigation measures are implemented as described. Furthermore, VS concludes that the mitigations that VS proposes are sufficient to allow resumption of trade in these animals and animal products.

Hazard Identification

This is an analysis of the BSE risk that might be posed by importation of designated commodities and animals into the United States from Canada. The only hazardous agent considered in this analysis is BSE. The analysis does not address other transmissible spongiform encephalopathies (TSEs) like chronic wasting disease (CWD) and scrapie that might be endemic in Canada and are also endemic in the United States.

In fact, prior to the confirmation of BSE in Canada and the subsequent implementation of the U.S. ban on ruminants and ruminant products, the United States and Canada traded extensively in animals that were susceptible to BSE, CWD, and scrapie, and products derived from those animals. The U.S. ban on Canadian ruminants and ruminant products was implemented solely because of the change in BSE status in Canada. No such change has occurred in CWD or scrapie status that would warrant their inclusion in this analysis.

BSE is a progressive neurological disorder of cattle that results from infection by an unconventional transmissible agent. Currently, the most accepted theory is that the agent is a modified form of a normal cell surface component known as prion protein, although other types of agents have been implicated, including virinos. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is extremely resistant to heat and to normal sterilization processes. It does not evoke any detectable immune response or inflammatory reaction in host animals (APHIS 2003c). The disease has been difficult to define experimentally with precision, although risk factors that are independent of the causative agent have been identified and can be mitigated.

Objective

This analysis is being conducted to assess the risk of resuming trade in designated ruminants and ruminant products from Canada to the United States in view of the confirmation of a single case of BSE in Canada in 2003.

On May 29, 2003, USDA published an interim rule adding Canada to the list of countries that are considered to be affected with BSE (APHIS 2003a). On August 26, 2003, based on a thorough scientific analysis, USDA began issuing import permits for certain ruminant derived products from Canada (APHIS 2003b). This analysis is being conducted to determine if, and under what conditions, trade in designated ruminants and ruminant products may be resumed without the need for an import permit. This analysis describes the risk factors associated with those animals and animal products as well as the applicable mitigations.

Because this analysis is conducted to support APHIS rulemaking and because the regulatory authority of APHIS, VS, is limited to animal health issues, the focus of this analysis will be BSE risk to U.S. livestock. The analysis will assess the likelihood that BSE infected animals or animal products would enter the United States from Canada and

expose U.S. livestock by the most likely pathway, that is, through feeding of infected materials to susceptible animals (Prince, et al. 2003; Wilesmith 2001, 2002, 2003).

Because of the limited scope of its regulatory authority, this APHIS analysis will not focus on human health issues, with one exception. Human health issues will be addressed solely in the context of potential exposure of and consequences to humans should BSE-infected material enter the United States AND enter the human food supply. Relevant to this, an evaluation conducted in the context of both human and animal health by the Harvard Center for Risk Analysis (Harvard Center for Risk Analysis et al., 2001) concluded that the United States is highly resistant to spread and establishment of BSE in the unlikely event of its entry into the United States.

Although outside of the regulatory authority of APHIS, the discussion of human health issues is included to maintain compliance with recommendations of the OIE (OIE 2002b), which recommend that animal health import risk analyses address consequences to human health.

Format of the Analysis

This analysis is composed of four components, the release assessment, the exposure assessment, the consequence assessment, and the risk estimation. These components are defined in OIE guidelines and represent the international recommended components for animal health import risk analysis (OIE 2002b).

Release Assessment

The ultimate import risk from imported Canadian animals and products to U.S. livestock is a function of the epidemiological characteristics of the disease and the development and implementation of mitigations to address that risk. This release assessment addresses the following issues:

- Country factors relevant to Canada as a minimal risk country for BSE;
- Epidemiological factors relevant to BSE risk possibly resulting from ruminant trade with Canada;
- Relevant risk mitigations that VS is proposing to apply and the rationale for their use;
- Mitigations that are appropriate to the risk factors identified; and
- Application of these risk mitigation measures on a commodity basis.

<u>BSE detection in Canada</u>

Prior to May 20, 2003, there were no restrictions on trade between the United States and Canada because of BSE. On May 20, CFIA reported a case of BSE in a six-year-old beef cow in northern Alberta (CFIA 2003a). USDA immediately closed its borders through administrative action and followed that action with an interim rule published May 29, 2003 (APHIS 2003a). This rule added Canada to the list of regions where BSE is known

to exist and prohibited importation of Canadian ruminants and most products derived from ruminants into the United States.

Canadian response to the incident

Canada conducted an extensive epidemiological investigation after the confirmation of the BSE case on May 20, 2003 (CFIA 2003). The investigation included a consideration of several options for the possible source of exposure to BSE (CFIA 2003), including spontaneous mutation of normal protein to a pathogenic (resistant) form of prion protein or exposure to prions associated with another transmissible spongiform encephalopathy, such as scrapie of sheep and goats or CWD of deer and elk. However, despite exhaustive investigations, CFIA concluded that the scientific evidence to date did not support any of these theories. Furthermore, CFIA noted that the prion associated with the index case was characterized by molecular analysis at the international reference laboratory in the United Kingdom (UK) as BSE, not CWD. Therefore, although it has not been confirmed, the most likely explanation is that the one case resulted from exposure to contaminated feed. The infected animal was born prior to the implementation of a feed ban within Canada and could have been fed contaminated feed at an early age. It is unlikely that a definitive source will ever be firmly established.

Canada as a minimal risk country

Despite the single case of BSE, VS considers Canada as a country that presents a BSE risk for import purposes similar to a minimal risk country as defined by the criteria set by OIE. VS bases this opinion on its evaluation of Canada's basic infrastructure and the control measures which Canada has implemented.

The OIE categorizes countries with indigenous cases of BSE as minimal, moderate, or high risk for BSE, based on established criteria (OIE 2002a). 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 one case per million during each of the last four consecutive 12 month periods within the cattle population over 24 months of age. Canada's adult cattle population is approximately 5.5 million animals, and only one animal was confirmed with BSE in the last 12 month period. Over the entire preceding three consecutive years, the incidence rate was 0 (zero). This incidence rate is within the parameters for a minimal risk country, and well below the parameters for a moderate risk country.

The only other case of BSE diagnosed in Canada was reported in December 1993 in the Province of Alberta (CFIA 2002). This animal was imported from the UK prior to the ban, so it does not count as an indigenous case that would affect classification is a minimal risk region.

Additional factors relevant to the OIE risk classification include an implementation of an effective ruminant-to-ruminant feed ban, awareness and education programs, compulsory

notification of suspect BSE cases, surveillance and monitoring program, an appropriately conducted risk assessment (CFIA 2002), a competent diagnostic capacity, and an appropriate slaughter/culling program to address risk animals when a positive case is identified. Canada fully meets or exceeds all of these factors, with the exception of duration of the feed ban.

Canada has maintained prevention and control measures that were instituted in 1990 to minimize possible exposure and/or amplification of the BSE agent (CFIA 2002; Morley, Chen, and Rheault 2003). Canada has maintained stringent import restrictions since 1990, prohibiting the import of meat-and-bone meal from countries other than the United States, Australia, and New Zealand. Import of live ruminants and most ruminant products have also been restricted to minimize Canada's external risk exposure to BSE. Canada has maintained an active targeted surveillance program in cattle at highest risk for BSE since 1992. Since 1997, Canada has maintained a mammalian to ruminant feed ban, with requirements similar to the feed ban in place in the United States (DHHS).

The single OIE criterion that Canada did not meet at the time this analysis was conducted was duration of the feed ban. The current OIE recommendation (OIE 2002a) is that a minimal risk country should have had an effective feed ban in place for eight years. The current feed ban in Canada has been in place for six years. A strict reading would, therefore, classify Canada as a moderate risk country because the current feed ban has been in place for six years.

VS considers the six year length of the feed ban in Canada as sufficient to classify Canada as a minimal risk region for BSE. The OIE recommendation of eight years may be set at a conservative level to account for the wide range that has been reported for the incubation period of BSE. Because of the variability of current estimates associated with the incubation period for BSE, VS chose not to specify an amount of time that a feed ban should be in place for a minimal risk country. Rather, VS considered the sum total of the control mechanisms (e.g., effectiveness of surveillance, import controls, and feed ban) in place at the time of the diagnosis and the actions taken after it (e.g., epidemiological investigations, depopulation), thereby allowing the actions CFIA took in other elements to compensate for a shorter feed ban. As an example relevant to this point and discussed in more detail elsewhere in this document, the level of surveillance conducted in Canada exceeded the OIE recommendations. In addition, Canada's surveillance was both active and targeted in such a manner as to exceed the OIE recommendations. VS considers Canada to exhibit minimal risk for BSE even though the feed ban has not been in place for eight years because Canada has compensated in the areas of surveillance and control.

VS considers OIE recognition of status in developing trade policies. However, VS is aware that OIE recommendations are evolving. In fact, VS has proposed revisions of the OIE recommendations for BSE and has made comments to reflect this through official channels. VS is concerned that some OIE criteria may be too general and others too specific. At one end of the spectrum, the OIE criterion stating that "a risk assessment…has been conducted and it has been demonstrated that appropriate measures

have been taken for the relevant period of time to manage any risk identified" (OIE 2002a) appears to be extremely general. On the other end of the spectrum, as discussed previously, the requirement that "the ban on feeding ruminants with meat and bone meal and greaves derived from ruminants has been effectively enforced for at least 8 years" may be too restrictive when other factors are considered.

VS definition of BSE minimal risk region

Therefore, VS has developed a list of factors that a country or region should address that VS will use to evaluate whether the region exhibits minimal risk for BSE. These factors address the same issues as OIE recommendations and include two categories of regions:

- Regions in which a BSE-infected animal has been diagnosed but in which measures have been taken that make it unlikely that BSE would be introduced from the region into the United States, and
- Regions in which BSE has not been detected but which cannot be considered BSE free. For example, such regions might have exhibited some level of risk resulting from factors like limitations in the surveillance program or import requirements that are less restrictive than those of the United States. However, the region took sufficient measures to be considered minimal risk, such as increasing its level of surveillance or import restrictions to the point that risk of BSE introduction from the region is unlikely. However, the region has not had the mitigations in place long enough to be considered BSE-free.

Specifically, VS proposes that a BSE minimal-risk region is a region that:

(1) Maintains, and, in the case of regions in which BSE was detected, had risk mitigation measures in place prior to the detection of BSE in the region that were adequate to prevent widespread exposure and/or establishment of the disease.

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

> (a) The region had restrictions on the importation of animals that were sufficient to minimize the possibility of infected ruminants being imported into the region and restrictions on importation of animal products and animal feed containing ruminant protein that were sufficient to minimize the possibility of ruminants in the region being exposed to BSE.
>
> This factor addresses whether the region faces a high risk of initial or recurrent

BSE outbreaks from multiple importations of animals or products that may spread BSE. In those regions in which BSE has been detected, it addresses whether the region's BSE outbreak was more likely to be the result of a point failure in its import controls or possible exposure prior to the implementation of such import controls. Because the incubation period for BSE is generally measured in years (OIE 2002a), the finding of a case of BSE reflects an exposure that occurred several years in the past.

(b) The region conducted surveillance for BSE at levels that meet or exceed OIE recommendations;

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

(c) The region has a ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent in place, and compliance with the ban appears to be good.

This factor distinguishes between regions with effective feed bans and those without them. If an animal with BSE were born after a feed ban was implemented, the observation suggests that the feed ban may not have been effectively enforced.

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

This factor addresses whether a region adequately investigates a case of BSE to determine if any of the risk factors have changed. If there have been any significant changes in risk factors, there might be a possibility of increased incidence of BSE.

(3) In regions in which BSE was detected, additional risk mitigation measures were taken, as necessary, following the BSE outbreak. These were based on risk analysis of the outbreak, and the region continues to take such measures. The additional measures reflect lessons learned during the outbreak and incorporation of policies developed from consideration of new or additional technical information into existing programs.

This factor addresses whether a region implements all necessary risk mitigation measures to prevent further exposure to BSE. It distinguishes between those regions that thoroughly analyze their situation and that address the relevant problems from regions that do not impose risk mitigation measures, thus prolonging possible exposure to BSE.

Each factor of this definition is repeated below, and the observations relevant to Canada as a minimal risk country are discussed.

(1) A region maintains in which BSE was detected had risk mitigation measures in place adequate to prevent widespread exposure and/or establishment of the disease prior to the detection of BSE in the region, and it continues to maintain these restrictions.

(a) The region had restrictions on the importation of animals that were sufficient to minimize the possibility of infected ruminants being imported into the region and restrictions on importation of animal products and animal feed containing ruminant protein that were sufficient to minimize the possibility of ruminants being introduced into the region or ruminants in the region being exposed to BSE.

Canada has maintained stringent import restrictions since 1990 (CFIA 2002; Morley, Chen and Rheault 2003). These restrictions prohibited the importation of live ruminants and most ruminant products from countries that had not been recognized as free of BSE by the United States, Canada, or Mexico. These countries have had an agreement to recognize country evaluations conducted by any of the others.

Canada prohibited the importation of live cattle from the UK and the Republic of Ireland starting 1990, and subsequently applied the same prohibitions to other countries as those additional countries identified native cases of BSE. In 1996, Canada's policy became even more restrictive and it prohibited the importation of live ruminants from any country that it had not recognized as free of BSE.

Some animals were imported into Canada from high risk countries prior to the imposition of these import restrictions. A total of 182 cattle was imported into Canada from the UK between 1982 and 1990. In actions similar to those taken in the United States, efforts were made in Canada to trace these animals. In late 1993, after Canada identified a case of BSE in one of the imported cattle, all cattle imported from the UK or the Republic of Ireland that remained alive at the time were killed (CFIA 2002).

Import restrictions have also been imposed on ruminant products, including the one that was imposed on meat-and-bone meal in 1978 (CFIA 2002). In general, Canada has prohibited the importation of most meat-and-bone meal from countries other than the United States, Australia, and New Zealand. Limited amounts of specialty products of porcine or poultry origin were allowed to be imported into Canada under permit for use in aquaculture feed products. No meat-and-bone meal for livestock feed-associated uses has been imported, except from the United States, Australia, and New Zealand.

(b) The region conducts surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE.

OIE recommendations are recognized by the World Trade Organization as international

recommendations for animal disease control. One OIE criterion for a BSE minimal risk region is that surveillance for BSE must have been conducted for at least seven years (CFIA 2002a). Canada has conducted such surveillance since 1992. The OIE Code (OIE 2002c) provides guidelines for surveillance and monitoring systems for BSE, identifying the minimum number of annual investigations recommended based on the adult cattle population of a country. To meet this recommendation, Canada would have to test a minimum of 336 samples annually since the country has a population of 5.5 million adult cattle. Canada has tested more than this minimum number of samples for the past seven years (CFIA 2002). Therefore, Canada exceeds the basic requirements for this criterion. In addition, Canada exceeds other OIE criteria by conducting active targeted surveillance, rather than routine surveillance. In this regard, active targeted surveillance involves sampling animals at risk for BSE, even if there is no evidence of clinical signs.

(c) The region has implemented a ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent. There is no evidence of significant non-compliance with the feed ban.

Canada implemented its feed ban in 1997 (CFIA 2002a). The ban prohibits the feeding of most mammalian protein to ruminants. The conditions of the ban are such that VS considers them to exceed minimal recommendations for a feed ban prohibiting feeding of ruminant material to ruminants. Under the ban in place in Canada, mammalian protein may not be fed to ruminants with certain exceptions. These exceptions include pure porcine or equine protein, blood, milk, and gelatin. The feed ban is essentially the same as the feed ban in place in the United States (DHHS). Relevant to the date of implementation of Canada's feed ban, the animal in which BSE was diagnosed in May 2003 was a six-year-old native-born beef cow from the Province of Alberta that was born before implementation of the feed ban (CFIA 2003a).

Canadian government authorities inspect rendering facilities, feed manufacturers and feed retailers to ensure compliance with the feed ban (CFIA 2003a). Rendering facilities are regulated under an annual permit system, and compliance with the regulations is verified through at least one inspection each year. Feed manufacturers or mills, feed retailers, and farms have been inspected on a routine basis. These inspections have revealed that the level of compliance is good, and there is no evidence of significant noncompliance with the feed ban (CFIA 2003a).

(2) In a region in which BSE has been detected, the epidemiological investigation following detection of BSE was sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and the region continues to take such measures.

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

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

The investigation included a consideration of several possibilities for the source of exposure to the infected cow (CFIA 2003). Although it has not been confirmed, CFIA assumed, based on the age of the cow, that the animal was exposed through contaminated feed. The infected animal was born prior to implantation of the feed ban in Canada and could have been exposed to contaminated feed at an early age (CFIA 2003a).

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

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

Following the detection of BSE in Canada, a broad eradication program was initiated during the epidemiological investigation. More than 2,700 head of cattle were culled. As part of the culling activity, more than 2,000 animals that were 24 months of age or older were tested. The 700 that were not tested were less than 24 months of age. No further evidence of BSE was detected in any of these animals.

In addition, Canada prohibited the use of certain tissues, which have been called specified risk materials, in the human food supply (CFIA 2003). These are tissues in which the infectious agent has been shown experimentally to localize.

As noted previously, Canada has maintained an effective mammalian-to-ruminant feed ban, with requirements similar to the feed ban in place in the United States (DHHS), since 1997. Since compliance with the feed ban appears to have been good (CFIA 2003a), it is unlikely that the animal recently confirmed with BSE ingested contaminated feed during the period covered by the ban. This suggests that the ban has been effective. All of these actions will further reduce the already minimal risk of the spread of BSE.

Because we believe that regions such as Canada, that can effectively address the factors listed above, pose a minimal risk of introducing BSE into the United States, we believe it is warranted to allow the importation of designated commodities from such regions. These are prohibited importation from regions in which BSE exists and regions that present an undue risk of BSE under our current regulations (APHIS 2003). However, because BSE was diagnosed in at least one animal in the region, we believe it is necessary to continue to take precautions to further mitigate the chance that BSE might be introduced into the United States from the region. The precautions appropriate for specific commodities intended for importation would be determined by the presence or absence of factors that make it more or less likely the commodity might be contaminated or infected with the BSE.

We are conducting this analysis based on our consideration of Canada as a minimal risk region for BSE. We are addressing individual commodities in this analysis because the BSE commodity import requirements that we intend to propose based on this analysis, while similar to the OIE recommendations (OIE 2002a), are somewhat more stringent than those of OIE.

Risk Factors

As previously mentioned, the nature of the BSE infectious agent has not been confirmed with certainty. However, it has been possible to define risk factors that contribute to establishment and spread of BSE. These factors are based on technical knowledge and disease epidemiology and do not require definition of the nature of the agent. Therefore,

the mitigation approaches described in this document should be effective regardless of the nature of the BSE agent.

The following discussion will address risk factors that are relevant to BSE contamination of commodities (both animals and products) that might be exported from Canada to the United States. The overall risk concern is whether the imported commodities are likely to contain infectious levels of the agent, enter the U.S. animal feed supply, and be able to infect animals.

BSE is a difficult disease to define experimentally with precision because of the long incubation period and limitations in experimental models. Controlled studies are often difficult to conduct because of the studies take so long to complete. Much of the data originate from epidemiological observations made during BSE outbreaks. The time necessary to conduct epidemiological studies in animal may be years.

Therefore, although risk factors can be identified with some certainty, individual risk mitigation measures may be difficult to apply precisely. For example, the discussion in this document will identify contaminated feed as the most likely pathway of BSE transmission. However, it has not been established with certainty that contaminated feed is the only pathway. Furthermore, it cannot be assumed that there is complete compliance with a feed ban, which is the most effective mitigation for contaminated feed. Therefore, VS considered it necessary to mitigate risk arising from alternative pathways or lack of compliance with a feed ban.

Feed source and exposure

The primary source of BSE infection is commercial feed contaminated with the infectious agent. Scientific evidence (Wilesmith, et al. 1988; 1991; 1992) shows that feed contamination results from the incorporation of ingredients that contain ruminant protein derived from infected animals. Standard rendering processes do not completely inactivate the BSE agent. Therefore, rendered protein such as meat-and-bone meal derived from infected animals may contain the infectious agent. Bans prohibiting incorporation of mammalian or ruminant protein into ruminant feed are imposed to mitigate risk.

Oral ingestion of feed contaminated with the abnormal BSE prion protein is the only documented route of field transmission of BSE (Prince, et al. 2003; Wilesmith, et al. 1988; 1991; 1992), although other routes have been considered. In fact, CFIA considered other alternatives for source of the infectious agent such as spontaneous mutation of normal prion protein to a pathogenic form and exposure to prions associated with other TSEs in its epidemiological investigations. CFIA attributed the source of animal found infected in 2003 to feed.

Based on the scientific evidence available to date, animals that have not ingested contaminated feed are unlikely to harbor the agent, so feed exposure influences risk.

Animals are unlikely to have infectious levels of the agent and will present a lower risk if they were (a) born after the implementation of an effective feed ban, or (b) not fed risk material (e.g., wild animals or farmed animals that are not fed feeds containing meat-and-bone meal).

The risks associated with feed source and exposure can be mitigated by accepting for import only animals or products derived from animals that have not been fed commercial feed that is likely to be contaminated with infectious levels of the agent. If the feed ban were completely effective, this measure should be sufficient, by itself, to mitigate risk. However, as previously mentioned, factors like unrecognized lack of compliance with the feed ban or disease transmission by alternative pathways may contribute to risk. Such risk can be mitigated further by additional risk mitigation measures. Such mitigation measures and the risk factors they are intended to address are described subsequently.

Levels of infectious agent: effect of animal age

Levels of infectious agent in certain tissues vary with the age of animal, so age of the animal influences risk. Pathogenesis studies, where tissues obtained from orally infected calves were assayed for infectivity, have shown that infectivity was not detected in most tissues until at least 32 months post-exposure (Wells, et al. 1998; Wells, et al. 1994; EU SSC 2002). The exception to this is the distal ileum, the distal portion of the small intestine, where infectivity was confirmed from experimentally infected animals as early as 6 months post-exposure.

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

Research demonstrates that the incubation period for BSE is apparently linked to the infectious dose received, i.e., the larger an infectious dose received, the shorter the incubation period (EU SSC 2002). While some cases have been found in animals less than 30 months of age, these have been relatively few and have occurred primarily in countries with significant levels of circulating infectivity. Specifically, BSE has been found in animals less than 30 months of age in the UK in the late 1980's to early 1990's, when the incidence of BSE was extremely high. This research also suggests that a calf must receive an oral dose of 100 grams of infected brain material containing high levels of the infectious agent to produce disease within a minimum of approximately 30 months (EU SSC 2002; DEFRA 2003; EC 2002, 2003).

BSE testing in the European Union (EU) was conducted throughout the year 2001. This testing revealed only two positive animals that were younger than 30 months of age in a total of 2,147 positive cases. Of note is that these animals were 28 and 29 months of age. For reference, in 2001, a total of 8,516,227 tests were conducted within the EU, and, of those, 1,366,243 tests were conducted on animals less than 30 months of age. In 2002, there were no animals less than 30 months of age that were positive in the EU testing

scheme. Approximately 10.2 million tests were conducted in EU Member States in 2002, and, of these, 1.6 million were conducted on animals less than 30 months of age. The average mean age of positive animals in the EU in 2002 was 96.9 months, an increase from 85.9 months in 2001 (EC 2002, 2003).

This suggests a useful dividing line for purposes of mitigating risk. Infected cattle over 30 months of age or sheep and goats over 16 months of age may have levels of the abnormal prion in affected tissues that are sufficient to infect other animals fed protein derived from these tissues. Infected cattle younger than 30 months of age or sheep and goats less than 16 months of age are unlikely to have infectious levels of the prion protein (EU SSC 2002; Wells, et al. 1994; Wells, et al. 1998). The 30 month age limit is accepted internationally in BSE standards set by various countries and is consistent with OIE recommendations (OIE 2002a).

The risks associated with age can be mitigated by accepting for import only animals or commodities derived from animals of an age where even high risk tissues are unlikely to have infectious levels of the agent. However, restrictions applicable to age alone may not be sufficient. In this regard, there are circumstances in which the age of the animal is unknown. A case in point is wild cervids. Since age can not be used to mitigate risk from these animals, alternative risk mitigation measures, which will be described subsequently, are justified. There are also circumstances in which restricting age of animal imported or source animal for a product to a particular age for a given species may not be sufficient to mitigate risk. A case in point is the requirement for removal of intestine from cattle, even those that are less than 30 months of age, the rationale for which is discussed subsequently.

Tissue localization

Some bovine tissues have demonstrated infectivity, whereas others have not (Wells, et al. 1994; Wells, et al. 1998; Wrathall, et al. 2002). Tissues that have confirmed infectivity, and thus are likely to contain the infectious agent in infected cattle, are brain, tonsil, spinal cord, eyes, trigeminal ganglia, dorsal root ganglia, and distal ileum. Affiliated tissues or structures such as skull or vertebral column are considered risk materials because of the difficulty in separating out small tissues such as dorsal root ganglia from the vertebral column.

Possibilities for cross contamination from risk materials must also be considered. For example, tonsils are directly and tightly attached to tongues, so removal of tonsil from tongues should mitigate risk. Similarly, distal ileum is a part of the intestine so removal of intestine should mitigate risk associated with infectious agent localization in the distal ileum. However, even cattle carrying the infectious agent are unlikely to carry that agent in tissues that have not had demonstrated infectivity (e.g., muscle, liver, skin, hide, milk, embryos) or products derived from these tissues (Wells, et al. 1994; Wells, et al. 1998; Wrathall, et al. 2002).

The risks associated with tissue localization can be mitigated by accepting only tissues that are unlikely to have infectious levels of the agent or commodities derived from those organs or tissues. Alternatively or in addition, if justified, risk materials can be removed. Of note in this regard is that while muscle (meat) from cattle is not, by itself, a risk tissue, it can be contaminated with vertebral column or spinal cord, and intestines from cattle younger than 30 months of age (i.e., as early as six months of age) may have infectious levels of the agent. Therefore, removal of intestine in order to remove the distal ileum from cattle less than 30 months of age is justified to mitigate risk.

Source species

Tissue distribution of the agent varies with species. No natural infections with BSE have yet been confirmed in sheep, although testing is ongoing in Europe. However, results from experimental infections of sheep have shown that the BSE prion is distributed more widely in sheep tissues than in cattle (Foster, et al. 1996; Foster, et al. 2001). This distribution is similar to the distribution of scrapie infections in sheep. In scrapie, the agent may be found in the lymphoreticular system and in peripheral nerves (Foster, et al. 1996; Foster, et al. 2001). It is assumed, based on analogy with scrapie, that, if it infected sheep naturally, BSE would distribute similarly.

Similarly, no natural infections with BSE have been confirmed in goats, although actual experiments have not been conducted in the species. In the absence of actual data, assuming that the agent did infect goats, distribution of the agent in goat tissues has been assumed to be similar to distribution of the agent in sheep tissues because of the overall species similarities.

Similarly, natural infection with BSE of cervids (deer and elk species) has not been documented, and no challenge studies on cervine susceptibility have been conducted. In the absence of experimental data, distribution of the infectious agent in cervids (if it were to infect cervids) is assumed to be similar to the distribution of CWD, a naturally occurring TSE in cervids.

Risks associated with differences in tissue distribution among species can be mitigated by accepting only tissues which are unlikely to have infectious levels of the agent or commodities derived from those tissues. These tissues may differ with species of origin because of differences in tissue localization among species. Although the tissue distribution of the TSEs in these species may be wider than in cattle, no specific risk tissues have been identified that justify removal in sheep, goats or cervids from Canada.

Prevalence of disease in region of origin

The possible prevalence of disease in the region of origin will influence the risk. Prevalence of disease will be lower in a country with adequate prevention and control measures; thus animals from such a region will be at lower risk of being exposed to infection.

The risks associated with prevalence can be mitigated by accepting commodities only from a country with a low prevalence, such as one that that can be considered minimal risk.

Potential for contamination at slaughter

There may be risks associated with contamination through processing. For example, certain tissues derived from animals killed by air injection stunning or processed using mechanically separated meat recovery systems may contain emboli or fragments from high risk tissues like brain and spinal cord, posing risk by contamination (Garland, Bauer, and Bailey 1996; Grandin 1997; Anil, et al. 1999).

Potential for mixing or inappropriate diversion

High and low risk commodities might be mixed and diverted inappropriately in slaughter facilities in which commingling is allowed. Similarly, animals from a single source, such as Canada, might be separated and diverted inappropriately if the vehicles are not sealed.

Vertical transmission

Vertical transmission (i.e., maternal transmission) may occur (Prince 2003; Wilesmith 1997; Donnelly 1997); however, experimental evidence suggests that maternal transmission is not a significant pathway for disease transmission so it will not be factored into the risk assessment.

Mitigations

Various mitigations have been applied to reduce BSE risk of spread (e.g., feed bans) and introduction into a region (e.g., restrictions defined in import certifications). The rationale by which VS has applied these mitigations to animals and products is explained. Some of the mitigations may appear to be applied in a relatively conservative fashion. By applying multiple risk mitigation measures for specified commodities, VS intends to address the potential for multiple risk factors to be associated with the commodity. However, VS feels that this approach is justified in view of the lack of precise data concerning many of the risks associated with BSE.

Feed bans

Feed bans prohibiting ruminant protein from being used in ruminant feed reduces risk of spread and amplification of the BSE agent to animals through feed by eliminating a potential source of infectious agent.

Verification and compliance

Verification by CFIA is necessary to ensure compliance with requirements for risk mitigation approaches. Verification can be provided by CFIA through endorsement of certificates that document the nature of the commodity and the risk mitigations that have been applied, inspection of facilities (e.g., dedicated or segregated slaughter facilities), review of procedures and/practices applicable to risk (e.g., feeding practices), and controlling transport conditions and route (e.g., sealing of trucks for entry through designated ports).

Contamination at slaughter

Slaughter methods that might result in contamination of low risk materials with high risk materials (e.g., air injection stunning for animals or mechanically separated meat recovery systems) can be prohibited.

Mixing or inappropriate diversion

Facilities that are dedicated to the use of low risk animals or products or in which high and low risk materials can be segregated adequately can be designated to ensure that low risk commodities are not mixed and diverted inappropriately or contaminated by high risk materials. Transport of animals from a designated origin to a designated destination in sealed vehicles can prohibit separation of the group and inappropriate diversion of animals.

Certification requirements for live animals

Certification requirements for live animals have been developed by VS to ensure that risk mitigation options are applied appropriately. These requirements, which will be defined in the proposed rule, include various forms of verification and inspection by CFIA to provide confidence that animals meet acceptable risk criteria. These standards are based on the risk considerations discussed previously and include those that follow.

VS will require certification for animals to address risks that might be presented by animal age, species, feed source, feed exposure, movement conditions, and contamination at slaughter:

- *Animals are less than a certain age*. Animals that are young enough to be unlikely have infectious levels of the agent include cattle that are less than 30 months of age and veal calves (generally defined by industry standards as less than 36 weeks of age). Also, because of their age, sheep and goats, which are defined by industry standards as less than 12 months of age would be unlikely to have infectious levels of the agent;
- *Animals are born after a feed ban was implemented.* Animals that were born after a feed ban was implemented are unlikely to be exposed to the infectious agent;

- *Animals are not known to have been fed ruminant proteins.* Animals born before a feed ban was implemented, but which were not fed risk material, are unlikely to have been exposed to the infectious agent. Animals unlikely to have been fed risk materials or exposed to the agent include wild ruminants that have not been maintained on ranches or farms. Other animals in this class include domestic ruminants fed solely on materials that are unlikely to contain the infectious agent;
- *Animal transport is controlled*. (1) Animals enter the United States through designated border crossings. Identification of designated entry points can provide control of animal movement flow and a control point where inspectors may check certifications, and, potentially, facilitate traceback, should that be necessary, and (2) Animals are transported in trucks sealed at the port of entry and the transport conditions are verified at the destination by U.S. authorities.
- *Animals are moved as a group.* Movement of animals as a group serves to maintain the identity of the shipment and ensure arrival at the intended destination for appropriate processing.

Certification requirements for products

VS will require certification for products to verify that the products originate from low risk sources and/or that high risk materials are either not present or have been removed. Certification requirements address organ or tissue localization, species differences, intended use, slaughter method, and cross-contamination, and include the following:

- Potentially high risk materials (e.g., intestine containing distal ileum for cattle) are removed during processing, so the product is unlikely to contain the infectious agent;
- The tissue being exported is not likely to contain the infectious agent (e.g., liver);
- The tissue being exported is derived from an animal that is unlikely to contain infectious levels of the agent (e.g., meat from bovids less than 30 months of age or sheep and goats less than 12 months of age).
- Possibilities for cross-contamination are minimized. For example, for bovids, the slaughter plant operates in such a manner as to prevent commingling with potentially infectious materials by being dedicated to processing of animals less than 30 months of age; processing lines for commodities are segregated so as to prevent contact between high and low risk material; or plants are dedicated to use for materials that are eligible for export to the United States;
- Product is intended for industrial applications or personal use/display (e.g., trophies). This reduces the likelihood that the product will enter the animal food chain;
- Verification by CFIA inspection ensures that various conditions meet established criteria;
- Inspection of products and approval of processes and facilities is performed in the United States. Such approvals include inspection to ensure that intestines are removed from Canadian cattle slaughtered in the United States by personnel from the Food Safety and Inspection Service (FSIS).

Commodities under consideration for importation from Canada

VS considered the likelihood that various animals and animal products might have infectious levels of the agent. Since this analysis focuses on risk originating from Canada, the commodities discussed reflect animals and products that were being imported into the United States from Canada prior to the ban, and, for which trade may be reinitiated.

Risk considerations for individual commodities are grouped as live ruminants (Table 1) or ruminant products (Table 2) from minimal risk regions. The information is presented in tabular form. Listed in the first column of the table are individual commodities. The second column contains mitigations that APHIS intends to apply. The third column contains a summary of the mitigations affecting the likelihood that the commodity will contain infectious levels of the agent, including factors relating to the nature of the commodity (e.g., age of animal, tissue of origin) and external mitigations that APHIS will require (e.g., feed source, verification).

Risk considerations are discussed and mitigations to address that risk are assigned to animals and animal products that might be imported from Canada. The mitigations assigned to individual commodities were based on extensive discussion of the risk factors and mitigations described previously in this document and a consideration of the likelihood that the material might contain infectious levels of the BSE agent.

Risk deliberations were undertaken by a permanent technical advisory team of experts within APHIS, the TSE Working Group. This group is composed of 13 members, one or two from each of the following APHIS units: Centers for Epidemiology and Animal Health, National Veterinary Services Laboratories, National Center for Animal Health Programs, VS Regional Offices, Center for Veterinary Biologics, National Center for Import and Export, Plant Protection and Quarantine, and Legislative and Public Affairs. The group was formed several years ago to address and make policy recommendations regarding issues associated with TSEs.

Live animals from minimal risk regions

The technical group applied the general considerations listed in bullet form in assigning mitigations to live animals (Table 1). Specific considerations applied to each commodity are identified in the table.

Risk from

- Bovids less than 30 months of age intended for immediate slaughter is mitigated primarily by restrictions on age, feed source, movement controls, and removal of risk materials. With regard to age, it is unlikely that animals that are less than 30 months of age have infectious levels of the agent in most tissues. This applies not

only to cattle but also to veal calves less than 36 weeks of age and sheep and goats less than 12 months of age;

- Bovids for feeding is also mitigated by restrictions on feed source, removal of risk tissue, and movement (e.g., to designated feedlot, through specific ports of entry). In addition, since the animals will reside in the United States until slaughter they are identified as Canadian in origin by tattoo. Age is addressed by the requirement that they be slaughtered before they reach 30 months of age;
- Animals can be mitigated by limiting imports to animals that have not been fed ruminant proteins (other than milk protein) or, where there is not a maximum age at which the animals might be slaughtered, that were born after the feed ban or removing risk materials;
- Sheep or goats less than 12 months of age are considered to be mitigated by age restrictions because (a) there is no known natural infection with BSE of sheep and goats, and (b) although the species can be infected with the BSE agent experimentally, infectious levels of the agent have only been found in animals older than 16 months. Other mitigations are generally consistent with those for bovids;
- Cervids is mitigated by restricting imports to wild animals that are unlikely to have been exposed to contaminated feed or requiring that CFIA exercise oversight of feeding practices and potential for occurrence of TSE. For live animals, oversight of feeding practices is addressed by CFIA documented certification that the herd is one in which surveillance is conducted according to national or provincial standards by appropriate authorities. The herd is not known to be affected with or exposed to a TSE. At present, the TSE program for cervids in Canada is one that monitors for CWD. However, all sampling done to monitor for CWD would identify animals that might be affected with other TSEs such as BSE. This requirement provides assurance and verifies that CFIA is monitoring for TSE diseases, in general, and that there is no evidence of other TSE;
- Tissues of animals of any species can be mitigated by requiring that risk materials (e.g., intestine in bovids) are removed, either in the United States under FSIS supervision, or in Canada with CFIA certification. Because of evidence the infectious levels of the BSE agent may be present in the distal ileum of infected bovids as early as 6 months post-exposure, removal of intestines in a manner considered adequate to ensure that the materials are not fed to ruminants should further mitigate risk of cattle less than 30 months of age. No specific risk tissues have been identified that justify removal from sheep, goats, or cervids;
- Animals of any species can be mitigated by maintaining identity and controlling movement, e.g., requiring trucks to be sealed, entry to be through designated ports, shipments to be adequately documented with appropriate forms, animals to be moved as a group, movement to be directed to a designated destination, and animal origin to be identified (e.g., by tattoo). Movement of animals as a group is particularly relevant to movement of animals to a feedlot or to slaughter. Animals going to slaughter are moved and slaughtered as a group to maintain identity to ensure that their intestines are removed. Animals going to feedlots are identified by tattoo to insure that their identity is not lost at the feedlot and to ensure that their intestines are removed at slaughter;

- Animals of any species can be mitigated by requiring CFIA to certify or verify that the conditions are appropriate for the commodity;
- Diversion of animals going direct to slaughter, for which a health certificate is not required (APHIS 2004f)**,** is mitigated by requirement that truck be sealed and the contents documented direct to slaughter to be opened under supervised conditions.

Table 1 - Live animals from minimal risk regions

Commodity Description	**Required Risk Mitigations**	**Risk factor/mitigation summary**
Bovids imported for slaughter by 30 months of age, including veal calves (intended for immediate slaughter)	Trucks are sealed and contents documented to move direct to slaughter as a group; CFIA verifies that the animals were under 30 months of age and not known to have been fed ruminant proteins during their lifetime; intestine is removed at U.S. plant under FSIS supervision and disposed of appropriately; animals enter United States through VS designated ports of entry.	Source is young animals not known to have been fed ruminant proteins; CFIA and FSIS verify; risk materials are removed; movement is controlled.
Bovids imported for feeding in a U.S. feedlot prior to slaughter by 30 months of age or less.	CFIA verifies that the animals are less than 30 months of age and are not known to have been fed ruminant protein during their lifetime; animals must be moved to designated feedlot as a group and slaughter at less than 30 months of age; intestine is removed at U.S. plant under FSIS supervision and disposed of appropriately; cattle come in through VS designated ports of entry; ear tattoo identifies them as Canadian in origin.	Source is young animals not known to have been fed ruminant proteins; feedlot is designated; movement to feedlot is controlled; CFIA and FSIS verify; risk materials are removed; animals are identified as Canadian.
Sheep or goats imported for slaughter by 12	Trucks are sealed and contents documented to	Source is young animals not known to have been fed

months of age (intended for immediate slaughter)	move direct to slaughter as a group; CFIA verifies that the animals were under 12 months of age and are not known to have been fed ruminant proteins during their lifetime; animals enter United States through VS designated ports of entry.	ruminant proteins; CFIA verifies; movement is controlled;
Sheep and goats imported for feeding in a U.S. feedlot prior to slaughter by 12 months of age or less	CFIA verifies that the animals are under 12 months of age and are not known to have been fed ruminant protein during their lifetime; animals must be moved as a group to designated feedlot and to slaughter at less than 12 months of age; animals come through VS designated ports of entry; ear tattoo identifies them Canadian in origin.	Source is young animals not known to have been fed ruminant proteins; feedlot is designated; movement to feedlot is controlled; CFIA and FSIS verify; animals are identified as Canadian.
Cervids (intended for immediate slaughter)	Trucks are sealed and contents documented to move as a group direct to slaughter; CFIA verifies that the animals were born after the feed ban and are not known to have been fed ruminant proteins during their lifetime; cervids enter United States through designated ports of entry. Animals must be members of a herd participating in a nationally or provincially recognized TSE surveillance program; herd is not known to have been infected with or exposed to TSE.	Source is animals under surveillance for TSE, not known to have TSE, born after feed ban, and not known to have been fed ruminant proteins; CFIA verifies; movement is controlled.

Ruminant products from minimal risk regions

The technical group applied the general considerations listed in bullet form in assigning mitigations to ruminant products (Table 2). Specific considerations applied to each commodity are identified in the table.

Risk from

- Any material can be mitigated, in part, by requiring that mitigations be applied to the source animal as described for Table 1 (e.g., meat from cattle less than 30 months of age that have not been known to been fed ruminant proteins or veal from calves less than 36 weeks of age). In addition, for products, other mitigations for source animals would include requirements that they be wild animals, not farmed or ranched, that are unlikely to have been exposed to the infectious agent through feed;
- Any situation where high and low risk commodities might be mixed or improperly diverted can be mitigated by requiring that slaughter facility only kills animals less than a designated age (e.g., dedicated to bovids less than 30 months or sheep and goats less than 12 months) or complies with a facility segregation procedure approved by CFIA and endorsed by APHIS as sufficient to prohibit contamination or commingling of meat with products not eligible for importation into the United States;
- Meat can be mitigated by prohibiting processing conditions that might result in contamination (e.g., mechanically separated meat). The issue is addressed in the USDA definition of meat, which excludes mechanically separated meat or other products that contain bone or central nervous system tissue (FSIS 2003);
- Any product can be mitigated by requiring removal of relevant risk materials. For example, to ensure removal of distal ileum, intestine is removed from cattle and, because there is no age restriction for bovids constituting a source of tongues, tonsils are removed prior to export;
- Hunter harvested animals can be mitigated by requiring that the materials derived be imported only for personal use, which makes it highly unlikely that the item or its derivatives would enter the food chain for animals. Of relevance to imported materials from Canada are caribou and musk ox meat that are sold commercially after harvesting from wild animals on Nunavut lands;
- Animals in cervine herds can be mitigated by requiring them to originate from herds in which surveillance is conducted by national or provincial authorities. The herd is not known to be affected with or exposed to a TSE. In addition, surveillance for TSE in cervids is conducted according to national and/or provincial standards;
- Tallow may be mitigated by requiring that it contain less than 0.15 percent protein because tallow is primarily lipid material with a minimal cellular component. When it is derived from bovids less than 30 months of age and the level of protein is low, the material would be unlikely to contain prion protein;

- Liver is mitigated because the tissue unlikely to contain the agent in animals of any age, regardless of feed source, unless the liver is contaminated as a result of air-injected stunning which often drives emboli of brain tissue into the liver;
- Tongues are a low risk tissue in themselves. However, they may be derived from bovids older than 30 months and may be contaminated with adjacent tonsils which may pose a risk in animals older than 30 months of age. Therefore, risk is mitigated by control of the feed source and removal of tonsils.

Table 2 - Ruminant products from minimal risk regions

Commodity Description	**Required Risk Mitigations**	**Risk factor/mitigation summary**
Bovine meat, fresh, chilled, or frozen (including veal), from animals less than 30 months of age that meets USDA definition of meat.	CFIA verifies that the animals were less than 30 months of age when slaughtered and are not known to have been fed ruminant proteins during their lifetime; slaughter plant only kills bovids less than 30 months of age or complies with a facility segregation procedure approved by CFIA and endorsed by APHIS for bovids older than 30 months of age; intestine is removed; meat processing must meet USDA standards.	Source is young animals not fed ruminant proteins; slaughter plant is segregated or dedicated to prevent commingling or diversion; intestine is removed, CFIA verifies.
Bovine whole or half carcasses from animals less than 30 months of age.	CFIA verifies that the animals were less than 30 months of age when slaughtered and are not known to have been fed ruminant proteins during their lifetime; intestine is removed at slaughter plant that only kills bovids less than 30 months of age or complies with a facility segregation procedure approved by CFIA and the Administrator.	Source is young animals not known to have been fed ruminant proteins; slaughter plant is dedicated or segregated to prevent commingling or diversion; CFIA verifies.
Fresh or frozen bovine liver	CFIA verifies that the product is pure liver and that no air-injected stunning process was used at slaughter.	Tissue of origin is not risk tissue; CFIA verifies.

Fresh or frozen bovine tongues	CFIA verifies that the animals were born after the feed ban and are not known to have been fed ruminant proteins during their lifetime; tonsils are removed.	Source is animals born after feed ban and not known to have been fed ruminant proteins; risk tissues are removed; CFIA verifies.
Sheep or goat meat, fresh or frozen, from animals under 12 months of age that meets USDA definition of meat	CFIA verifies that the animals were less than 12 months of age when slaughtered and are not known to have been fed ruminant proteins during their lifetime; slaughter plant only kills sheep or goats less than 12 months of age or complies with a facility segregation procedure approved by CFIA and the Administrator, meat processing must meet USDA standards.	Source is young animals not fed ruminant proteins; processing methods are restricted; slaughter plant is dedicated or segregated to prevent commingling or diversion; CFIA verifies.
Fresh lamb or kid carcasses	CFIA verifies that the animals were less than 12 months of age when slaughtered and were not known to have been fed ruminant proteins during their lifetime; slaughter plant only kills sheep or goats less than 12 months of age or complies with a facility segregation procedure approved by CFIA and the Administrator.	Source is young animals not known to have been fed ruminant proteins; slaughter plant is dedicated or segregated to prevent commingling or diversion; CFIA verifies.
Hunter-harvested ruminant, cervine, sheep or goat whole dressed carcass (eviscerated and the head removed) or meat of wild cervids, sheep, goats or other meat from ruminants for personal use	CFIA verifies that feeding processed feed to wildlife is not practiced in the province where the animal was harvested; hunter shows proof that animal was a legally harvested wild (not ranched) animal. Such proof will include the hunting license, tag or equivalent.	Source is wild ruminants not fed commercial processed feed; CFIA verifies; hunter verifies.

Cervine meat or other products from farmed animals (includes shooter bulls or shooter bucks) processed in a slaughterhouse; with or without bone, fresh or frozen; ground meat or sausage is allowable if it is derived from either (1) only cervine meat or (2) only cervine and non-ruminant meat	CFIA verifies that the animals were born after the feed ban and are not known to have been fed ruminant proteins during their lifetime. Animals must be members of a herd not known to be infected with or exposed to a TSE.	Source is animals born after feed ban and not fed ruminant proteins; herd not known to have TSE; CFIA verifies.
Caribou and musk ox meat from Nunavut lands, with or without bone, fresh or frozen (represents specialty commercial product derived from wild animals in the province)	CFIA verifies that feeding of processed feed to wildlife is not practiced and that meat is from wild animals harvested on Nunavut lands; that the processing facility either slaughters only cervids eligible for entry into the U.S. or complies with a facility segregation procedure approved by CFIA and the Administrator.	Source is wild ruminants not fed commercial processed feed; processing facility is dedicated; CFIA verifies.
Gelatin from bones of cattle less than 30 months of age.	CFIA verifies that source animals are less than 30 months of age that are not known to have been fed ruminant proteins.	Source is young animals not known to have been fed ruminant protein; CFIA verifies.
Tallow for unrestricted use from bovids less than 30 months of age.	CFIA verifies that the tallow is less than 0.15 percent protein and is derived only from bovids born after the feed ban, less than 30 months of age, and not known to have been fed ruminant proteins during their lifetime; intestines were removed.	Source is animals born after feed ban and not known to have been fed ruminant proteins; risk tissues are removed; animals are ambulatory; CFIA verifies.
Cervine offal (viscera or non-muscle tissues removed from a carcass at slaughter), fresh, chilled or frozen	CFIA verifies that the animals were born after the feed ban and are not known to have been fed ruminant proteins during their lifetime; animals must be members of a herd not known to be infected with or exposed to a TSE.	Source is animals born after feed ban and not known to have been fed ruminant proteins; herd is not known to be infected with TSE; CFIA verifies.

In summary, VS considers that Canada is a minimal risk region for BSE. However, in light of the recent positive animal, VS has analyzed BSE mitigations relevant to live animals and products that might be imported from Canada. These additional mitigation measures address epidemiological risk factors for disease transmission that VS has identified. VS concludes from this analysis that the requirements described in this analysis are adequate to mitigate BSE risk from Canadian imports of these products.

Based on these conclusions, and in compliance with OIE recommendations (OIE 2002b), adequate information was presented for VS to complete the risk assessment at this point. However, in the interests of thoroughness, VS continued its assessment to briefly address risk associated with exposure and consequence.

Exposure Assessment

VS considers it unlikely that infectious levels of BSE would be introduced into the U.S. from a minimal risk country like Canada with any of the commodities discussed in this assessment. Also, VS considers that, even if the BSE agent were introduced into the United States, it would be extremely unlikely to be introduced into commercial animal feed and thereby infect animals. That is a primary result of the nature of the products, none of which is likely to become a significant animal feed component.

Several specific observations are relevant in this regard. First of these is the low number of infected animals or products that might conceivably be imported into the United States from Canada, based on the low prevalence that was identified (i.e., only a single infected Canadian animal that has been identified). Second is the extremely low likelihood that an infected animal or product from an infected animal would enter the U.S. animal feed chain. Third is the extremely low likelihood that an animal or product would contain infectious levels of the agent. Fourth is the likelihood that the mitigations applied by VS would reduce the likelihood of all of the above.

These conclusions are consistent with the results of the Harvard study (Harvard Center for Risk Analysis et al. 2001). The analysts developed a probabilistic simulation model to characterize the consequences of introducing BSE into the United States. The model analyzed the effects of introducing hypothetical numbers of infected animals the United States. The model allowed predictions of the number of newly infected animals that would result from introduction of BSE, the time course of the disease following its introduction, and the potential for human exposure.

For example, in a hypothetical scenario in which ten BSE-infected cattle were imported into the United States, the results suggested that an average of only three new cases of BSE would occur. These cases would occur primarily as a result of non-compliance with the feed ban. In the unlikely event that disease was introduced, it would be almost certain to be eliminated within 20 years under the conditions currently existing in the United States.

Reducing the hypothetical number of infected animals imported to one resulted in an estimate of less than one new BSE case in 20 years.

Of note in relation to the scenarios tested in the study is the hypothesis that one or ten animals are imported to the United States from Canada. In fact, there is no evidence to date that any infected animals have been imported, and only a single indigenous case of BSE has been detected in all of Canada, despite extensive surveillance and traceback efforts.

In summary, the scenarios presented in the Harvard study (Harvard Center for Risk Analysis 2001) assess the likelihood of BSE spread upon the unlikely event that it was introduced into the United States. The study results suggested that, should BSE be introduced, the disease is extremely unlikely to become established in the United States. Any new cases of BSE would be most likely a result of lack of compliance with the regulations enacted to protect animal feed.

The study concluded that the most effective U.S. measure preventing BSE spread is the feed ban instituted by the Food and Drug Administration (FDA) in 1997 (DHHS) to prevent recycling of potentially infectious cattle tissues. The FDA feed ban greatly reduces the chance that BSE will spread from a sick animal to other cattle through feed.

In summary, the fact that Canada has detected only a single indigenous case of BSE, the strong BSE controls Canada has in place, and the importation restrictions VS would impose before allowing these imports make it unlikely that BSE would be introduced from Canada. Additionally, the Harvard study suggested that the measures taken by the U.S. government and industry make the United States robust against the spread of BSE to animals should it be introduced into this country. These measures, which include ensuring compliance with the FDA feed ban and reducing the potential for infectious tissues to enter the animal food supply will ensure that these risks remain low.

Thus, considering all available data and scientific information, VS considers exposure risk to the agent to be low.

Consequence Assessment:

A consequence assessment describes the consequences of introduction of BSE into the United States. This consequence assessment addresses both direct and indirect consequences as recommended by the OIE (OIE 2002b). Direct consequences include animal infection, disease and production losses, and public health consequences. Indirect consequences include surveillance and control costs, compensation costs, potential trade losses, and adverse consequences to the environment.

Animal health

BSE is unlikely to have a major direct influence on animal health at the national level. Although the disease is devastating to the individual animal and its ultimate effect is death, it is very unlikely, based on the single occurrence of BSE in Canada, that a significant number of infected animals would be imported into the United States from Canada. If any infected animals did enter, the disease would be unlikely to spread to others and, essentially the infected animals should constitute dead end hosts.

Public health

As previously mentioned, although public health consequences are not issues under the regulatory authority of APHIS, we address the issue in this assessment. The primary public health consequences would appear as occurrences of variant Creutzfelt-Jacob Disease (vCJD), a neurological disorder in humans apparently associated with ingestion of BSE-contaminated meat products. Although there are many unknown factors relative to development of vCJD, including the definition of an infectious dose or the length of an incubation period, of significance to this analysis is that the available information compiled from a variety of studies suggests the infectious agent may be 10 to 100,000 times less pathogenic in humans than in cattle (summarized in Harvard Center for Risk Analysis 2001; EUSSC 2000).

Risk of such public health consequences should be extremely low in the context of importation of BSE infected commodities from Canada. The Harvard study found that even if BSE were to enter the United States, it would be unlikely to spread. Therefore, it would be unlikely to enter the human food chain. Third, is the extremely low likelihood that, should an infected carcass enter the food chain, the tissues that present the highest risk of infection would be available for human consumption. The Harvard study demonstrated that, even if BSE were to occur in the United States, little infectivity would be available for potential human exposure.

Surveillance, control, and indemnity

An Interagency Working Group formed by the Secretary of Agriculture issued a report on risks and economic impacts associated with the potential introduction of BSE into the United States (USDA 2002). In addition to the other costs, a BSE occurrence in the United States would cause economic costs due directly to costs of the government response to the disease. This would include both direct losses to BSE and depopulation of contact herds. A single case would be likely to necessitate the depopulation of several thousand animals along with associated indemnity costs. Additional costs would be incurred for surveillance, testing, and disposal of carcasses. Multiple cases could cause the loss of a substantial portion of the U.S. herd. Furthermore, the cost of the investigation into the source and causes of the incident could require large government expenditures. The report concluded that the response would depend on the nature of the outbreak, and, as such, the costs of such a program are difficult to predict.

Information relevant to potential costs to the U.S. government may be provided by the Canadian experience. VS presents data from the Canadian experience with BSE, which we believe reflects the type of scenario most likely to constitute a model for any experience the United States might have. In this regard, the Canadian experience reflects expenditures incurred as a result of BSE detection in a single animal, not the widespread disease that was observed in Europe (CFIA 2003b). Specifically, as of August 31, 2003, CFIA documented expenditures related to animal infection, disease, production losses, and surveillance and control costs of approximately $5.7 million (Canadian dollars) on salaries, $1.4 million on costs other than salaries, and $7.0 million on indemnities. The total estimated costs of BSE detection and the CFIA response in Canada were $14 million Canadian dollars, which is equivalent to approximately $19 million U.S. dollars. For reference, there are approximately 45 million adult cattle in the United States (USDA-NASS) in comparison to approximately 5.5 million in Canada (CFIA 2003a).

Effects on trade

Trade-related economic consequences of a BSE introduction from Canada would result if other countries refused to accept U.S. ruminant products. Again, the Canadian experience provides relevant information on trade consequences. In this regard, the United States could expect the spectrum of trading partners imposing restrictions on the U.S. because of BSE to be similar to the countries imposing restrictions on Canada. As of August 11, 2003, 49 countries had imposed restrictions on Canadian animals and products as a result of the BSE-infected animal.

Countries imposing restrictions on Canada included Japan, Mexico, and Korea (CFIA 2003). These three countries also constitute major U.S. export markets. The value of lost exports to these three U.S. ruminant markets alone would total $3 billion annually if trade restrictions were enforced against the United States: Japan ($1.2 billion); Mexico ($1.12 billion); and South Korea ($712 million). Indirect economic losses to U.S. firms that support ruminant exports to these three markets would equal an additional $2.5 billion annually. The magnitude of these values reflects both animal and product exports (Green and Grannis 2003).

More than 33 thousand full-time U.S. jobs, accounting for almost $1 billion in wages annually, could be jeopardized by loss of these three markets. In the longer term, if trade restrictions persisted and alternative export markets did not develop, the U.S. ruminant production sector could contract, allowing other supplying countries to establish trade relationships in the absence of U.S. supply (Green and Grannis 2003).

Effects on the environment

Environmental effects have been considered under all applicable environmental review laws in force in the United States. These are considered in a separate, but related, environmental assessment (APHIS 2003d). The environmental assessment was

conducted in compliance with the National Environmental Policy Act and implementing regulations (NEPA 1969).

Risk Estimation

VS concludes from this assessment that the surveillance, prevention, and control measures implemented by Canada are sufficient to minimize the risk of importing BSE into the United States, provided that additional mitigation measures are implemented as described. Furthermore, VS concludes that the animals and animal products under consideration in this analysis are of low or minimal risk in view of the certification requirements that will be implemented.

These conclusions are consistent with the 2001 Harvard study, which found that the measures taken by the U.S. government and industry make the United States robust against the spread of BSE, should it be introduced into the country. Of particular significance in this regard is the feed ban instituted by the FDA in 1997 to prevent the recycling of potentially infectious ruminant tissues (DHHS).

VS concluded from the consequence assessment that the consequences with regard to animal health, human health, and the environment were minimal or low. The major economic consequence of importing a BSE infected animal would be trade losses. Although these would be significant, it is important to note that the results of both the release and exposure assessment indicated that the risk of introduction and establishment of BSE was low.

In summary, VS considers the risk of BSE-imported animals or animal products entering the United States from Canada and exposing U.S. livestock through feeding of infected materials to susceptible animals, to be low.

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