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# Analysis of Bovine Spongiform Encephalopathy (BSE) Risk to the U.S. Cattle Population from Importation of Whole Cuts of Boneless Beef from Japan

Veterinary Services

Animal and Plant Health Inspection Service  
United States Department of Agriculture

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## **Glossary**

**Affected cattle:** Bovine infected with the BSE agent that is at the end of the incubation period and test positive for BSE on post-mortem examination.

**Air-injection stunning:** An 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 organs and tissues (e.g., the liver) (FSIS 2004e).

**Ante-mortem inspection:** The examination prior to slaughter of livestock or poultry by inspection program personnel to ensure that the livestock and poultry are fit for human consumption.

**Boneless beef:** For the purposes of this risk assessment and of APHIS' proposed rule, whole cuts of boneless beef, or meat derived from the skeletal muscle of a bovine carcass, excluding all parts of the animal's head and diaphragm.

**BSE-affected regions:** Regions that currently have or have ever had BSE in indigenous animals.

**Equivalency determination:** FSIS determination of eligibility of foreign countries for importation of products into the United States (FSIS, 2004c).

**ID<sub>50</sub>:** The amount of infectious tissue that would be expected to cause 50 percent of exposed cattle to develop BSE.

**Incidence:** The number of new cases or outbreaks of a disease that occur in a population at risk in a particular geographical area within a defined time interval.

**Mechanically separated meat (MSM):** FSIS regulations in 9 CFR 319.5 define mechanically separated beef (MS[Beef]) as a meat food product that is a finely comminuted product that results from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses (FSIS, 2004f).

**Pithing:** The laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

**Post-mortem inspection:** an inspection after the death of the animal.

**Prevalence:** The total number of cases or outbreaks of a disease that are present in a population at risk, in a particular geographical area, at one specified time or during a given period. Prevalence is a static measure of population proportion that is diseased;

prevalence includes new cases that occurred during a given time period as well as previous cases.

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

**Specified risk materials (SRMs):** (as defined by FSIS in 9 CFR 310.22) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle for product for domestic use in the United States (FSIS, 2004a).

**World Organization for Animal Health (OIE):** The OIE is located in Paris, France, and holds a mandate under the World Trade Organization Sanitary and Phytosanitary Agreement to play a role in safeguarding world trade by publishing health standards for international trade in animals and animal products (OIE 1924-2004).

## Executive Summary

As of September 10, 2001, when bovine spongiform encephalopathy (BSE) was confirmed in a native animal in Japan, the Animal and Plant Health Inspection Service (APHIS) has prohibited the importation into the United States of ruminants that have been in Japan, as well as meat, meat products, and most other products and byproducts of ruminants that have been in Japan. Since then, the Government of Japan has taken a series of measures to detect and control BSE in Japan, and recently requested that APHIS consider allowing the resumption of trade in beef from Japan to the United States. Prior to the 2001 ban on the importation of ruminants and ruminant products from Japan, Japan primarily exported to the United States boneless cuts of beef from cattle born raised and slaughtered in Japan. Therefore, in response to Japan's request, APHIS considered allowing the importation of whole cuts of boneless beef derived from cattle that were born, raised, and slaughtered in Japan. This risk analysis qualitatively evaluates the animal health risks associated with that product and the likelihood that this product imported from Japan would introduce BSE into the United States and expose the U.S. cattle population.

Products discussed in this risk analysis reflect the product requested by Japan for approval. Whole cuts of boneless beef (referred to in the remainder of this risk analysis as boneless beef) are an inherently low risk commodity. Boneless beef from Japan would have to be processed in plants included on a list of foreign slaughter plants authorized to export meat and meat products to the United States. USDA's Food Safety and Inspection Service (FSIS) has conducted an equivalency determination recognizing the equivalence of the Japanese meat inspection system to that in the United States.

The most critical control for maintaining the low risk of the commodity under consideration pertains to the removal of specified risk materials (SRMs) during slaughter processing in a manner that avoids SRM cross-contamination of the tissues of concern. Because SRMs have been identified as the materials posing the greatest risk of containing the BSE agent, their proper removal and segregation at slaughter will ensure that potential sources of infectivity are excluded, thus avoiding potential contamination of edible meat with BSE infectivity. In addition to SRM removal, a second control measure to avoid contamination is that the beef will come from cattle that were not subjected to air injection stunning or a pithing process. A third control measure is the mitigations related to carcass splitting.

This analysis uses the approach recommended by the OIE (OIE, 2003) for trade-related animal health risk analyses, which focuses on determining likelihood of release (i.e., introduction of the disease agent), likelihood of exposing susceptible animals given release, and the magnitude of consequences given exposure. The analysis determined that the release of BSE is not likely because: (1) muscle tissue *per se* has not been shown to contain infectious levels of the BSE agent, even if derived from infected cattle; and (2) SRM removal and segregation are conducted in a manner that avoids contamination of the beef.

Furthermore, APHIS has concluded that even if product containing the BSE agent were imported, exposure of the U.S. cattle population is unlikely because: (1) meat and bone meal (MBM) derived from rendered meat and meat products is prohibited from ruminant feed (FDA, 1997); (2) very little to none of the imported material will enter the cattle feed chain; and (3) even if some portion of the material were rendered and incorporated into animal feed, partial inactivation of the BSE agent occurs during rendering.

Given the mitigations to prevent the importation of BSE-infected products, APHIS concludes that the risk of BSE release is extremely unlikely. Furthermore, APHIS concludes that the proposed provisions are sufficient to safely reinstate trade in boneless beef from Japan.

## **I. Purpose, Scope, and Format**

### *Purpose*

This document analyzes the likelihood that boneless beef imported from Japan would: (1) contain infectious levels of the BSE agent, and thereby release or introduce the BSE agent into the United States; and (2) expose U.S. cattle to BSE, if the imported beef was contaminated with BSE. The analysis will be used in determining whether and under what conditions boneless beef should be allowed to be imported into the United States from Japan. Under the Animal Health Protection Act (AHPA) of 2002, the Secretary of Agriculture is authorized to regulate the importation of animals and animal products as necessary, to prevent the introduction or dissemination of livestock pests and diseases in the domestic livestock population.

### *Scope*

The scope of this analysis is limited to BSE in boneless beef. The analysis does not address other transmissible spongiform encephalopathies (TSEs) such as chronic wasting disease (CWD) or scrapie. The analysis is limited to boneless beef derived from cattle that were born, raised, and slaughtered in Japan. The analysis includes consideration of the conditions in Japan as they relate to the risk of the commodity.

APHIS' authority under the AHPA does not extend to human health. However, because the action under consideration has implications for food safety and human health, APHIS consulted with FSIS during the development of the APHIS risk assessment. FSIS addressed human health considerations relative to the action under consideration, which are discussed in Appendix B. Currently, FSIS regulations include an equivalency determination recognizing the equivalence of the Japanese meat inspection system to that of the United States and establish a list of foreign slaughter plants authorized by the Japanese Government to export meat and meat products to the United States (FSIS, 2004c). Boneless beef from Japan would have to be processed in plants included on a list of foreign slaughter plants authorized to export meat and meat products to the United States.

### *Format*

As recommended by OIE guidelines for import risk analysis (OIE 2003b), this analysis includes a hazard identification, release assessment, exposure assessment, consequence assessment, and risk estimation.

## **II. Hazard identification**

This analysis focuses solely on animal health effects that might result from the importation of boneless beef from a region that has had indigenous cases of BSE. The agent of interest in this analysis is the agent that causes BSE in cattle. The commodity of interest is boneless beef (as defined in the glossary).

BSE is a progressive neurological disorder of cattle that research indicates is caused by a pathogenic form of a normally occurring protein known as a prion (PrP) (Bolton, et al, 1982; Prusiner, 1994). BSE belongs to a family of diseases known as TSEs. In addition to BSE, TSEs include, among others, scrapie in sheep and goats, CWD in deer and elk, transmissible mink encephalopathy, and Creutzfeldt-Jakob disease (CJD) in humans.

The pathogenic form of the prion protein (PrP<sup>Sc</sup>) is both less soluble and more resistant to degradation than the normal form (Taylor, 2000; Taylor et al, 1995). The PrP<sup>Sc</sup> is extremely resistant to heat and to normal sterilization processes, making it difficult to inactivate with standard methods used to process human food and animal feed. Although rendering and other processes can partially inactivate PrP<sup>Sc</sup>, the risk mitigation strategies (for meat and meat products) rely mainly on the elimination of tissues and organs known to carry infectivity.

The sole commodity considered in this analysis is boneless beef derived from Japanese cattle. Historically, Japan's beef exports have been comprised primarily of high value cuts of meat derived from cattle that were born, raised entirely, and slaughtered in Japan. The following paragraphs detail the characteristics, including tissue distribution and age studies of the localization of the BSE agent in cattle that demonstrate that muscle meat, such as the boneless beef considered in this risk assessment, is inherently a low risk commodity when subjected to appropriate process control measures.

### *II.A. Incubation period*

BSE has a long incubation period. Epidemiological data from the United Kingdom (UK) epidemic has demonstrated that, on average, cattle develop clinical signs four to six years after infection (Bradley, 1991; Anderson, 1996), though the incubation period can be longer or shorter than four to six years. In BSE, as in other TSEs, the total amount of infectivity in an animal increases throughout the incubation period reaching the highest load at the end, very close to the death of the animal. Infectivity is considered to increase exponentially after exposure, reaching 3 logs less than clinical cases by 70 percent of the incubation period, and 4.5 logs less than a clinical case at 50 percent of the incubation period (Comer and Huntley, 2003).

The incubation period is inversely related to dose (e.g., low dose exposures have long incubation periods before clinical signs of disease become apparent) (Matthews, 2004)<sup>1</sup>.

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<sup>1</sup> The Department for Environment Food and Rural Affairs' (DEFRA) Veterinary Laboratories Agency (VLA) in the UK has carried out cattle oral challenge studies to determine the incubation period for a range of doses of BSE infected cattle brain. In the first attack rate experiments, groups of 10 calves were dosed orally with 3 X100g (100g on 3 successive days), 100g, 10g or 1g of brain tissue from clinically sick animals. All animals in the two higher dose categories (3x100 and 100gr, respectively), 7 out of 9 in the 10 g and 7 out of 10 in the 1g trial groups developed BSE. The incubation period (ip) for the 3X100g ranged between 33 and 42 months. The ip for the 100g was 33 to 61 months; for the 10g was 42 to 75 months; and for the 1g was 45 to 75 months. The remaining animals in this experiment were killed at 110 months after exposure and showed no pathological evidence of disease.

The agent does not evoke a traditional immune response or inflammatory reaction (Khalili-Shirazi et al., 2005), thus reliable ante-mortem diagnostic tests based on host reaction are not available. Definitive diagnosis requires post-mortem microscopic examination of brain tissue or detection of PrP<sup>Sc</sup> in tissue samples.

### *II.B. Tissue distribution and infectivity*

Most of the information on the development and distribution of tissue infectivity in BSE-infected cattle has been derived from experimental pathogenesis studies conducted in the UK (Wells, et al. 1994; Wells, et al. 1998; Wells, et al. 1999). In these studies, cattle were deliberately infected with BSE through oral exposure to the brain tissue of cattle with confirmed BSE. The experimentally infected cattle were killed at regular intervals as the disease progressed. At each interval the tissues of the infected cattle were examined for histopathological changes consistent with BSE and for abnormal prion proteins. Also, at each interval, a mouse assay was done – i.e., tissues of the BSE infected cattle were injected into the brain of mice to identify those tissues of cattle capable of transmitting the disease.

The pathogenesis studies involved 30 animals, each of which received a large, uniform dose of the BSE agent at a very young age (4 months) (Wells, et al. 1994; Wells, et al. 1998; Wells, et al. 1999). The studies demonstrate that in cattle infected with BSE, the total amount of infectivity in the animal, as well as the distribution of infectivity in the animal's body, change over time (Wells, et al. 1994; Wells, et al. 1998; Wells, et al. 1999). The highest levels of infectivity were detected in the brain and spinal cord at the end stages of disease. Some cattle exhibited clinical signs of BSE as early as 35 months post oral exposure to the BSE agent. By 37 months post oral exposure, all of the five animals that were still alive demonstrated clinical evidence of BSE. Infectivity was found in cattle with clinical signs of BSE in the brain, spinal cord, DRG<sup>2</sup>, trigeminal ganglia, and the distal ileum of the small intestine.

BSE infectivity was demonstrated in the brain, spinal cord, and DRG as early as 32 months post oral exposure to the BSE agent in some cattle (Wells, et al. 1994; Wells, et al. 1998; Wells, et al. 1999). Infectivity was demonstrated in these tissues three months before animals began to develop clinical signs of the disease. Infectivity was demonstrated in the distal ileum of cattle 6 to 18 months post oral exposure to the BSE agent and again at 38 months and 40 months post oral exposure.

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The second attack rate experiments extend these findings with lower doses. As of September, 2004, at approximately 6 years post exposure, have confirmed 3 of 5 in the 1g trial group (ip 59-73 months), 3 out of 15 animals in the 0.1g group (ip 55-62 months), 1 out of 15 in the 0.01g group (ip 67 months), and 1 out of 15 in the 0.001g group (ip 69 months) positive for BSE.

<sup>2</sup> DRG are clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column. “DRG” as used in this document has the same meaning as the term “dorsal spinal nerve root ganglia.” Trigeminal ganglia are clusters of nerve cells connected to the brain that lie close to the exterior of the skull.

A second phase of the pathogenesis studies, which uses a cattle bioassay as an endpoint, is being conducted to ensure that low levels of infectivity that may not have been detected in the first phase using the mouse bioassay are not missed (UK FSA 2002; EC SSC 2002a). The second phase of the study is still underway and is not expected to be completed for several more years. The cattle bioassay, in which tissues from cattle deliberately infected with BSE are injected directly into the brain tissue of BSE-free cattle, is considered to be several hundred-fold more sensitive in detecting BSE infectivity than the mouse bioassay. Preliminary results from the cattle bioassay study demonstrate that, in addition to the materials that were found to contain infectivity when the mouse bioassay was used, the tonsils of calves 10 months post oral exposure to the BSE agent contain infectivity. However, because only one of five animals injected with infected tonsil material developed clinical BSE at 45 months post-inoculation, the level of infectivity in the tonsils appears to be very low. Infectivity studies have also been conducted in cattle exposed to BSE under field conditions. In these animals, at the end stages of the incubation period with demonstrated clinical signs, BSE infectivity has been confirmed only in the brain, spinal cord, and retina of the eye.

The amount and distribution of infectivity in specific tissues from an infected cow have been estimated by Comer and Huntley (Comer and Huntley 2003) in their evaluation of the available literature. Those summary results, presented in Table 1, describe distribution of infectivity in various tissues, i.e., brain, spinal cord, DRG, trigeminal ganglia, tonsil, and distal ileum, of a BSE-infected cow. The table uses an estimated weight of each tissue in grams, the number of estimated cattle oral ID<sub>50</sub>/gram, and the total number of cattle oral ID<sub>50</sub> attributed to each tissue to estimate a percentage of cattle oral ID<sub>50</sub> for each tissue.

**Table 1. Infectivity in a clinical case of BSE (bovine oral ID<sub>50</sub>)**

Tissue	Weight g/animal	Infectivity		%
		ID <sub>50</sub> /g	ID <sub>50</sub> /animal	
Brain	500	50	25,000	60.2
Spinal cord	200	50	10,000	24.1
Dorsal root ganglia	30	50	1,500	3.6
Trigeminal ganglia	20	50	1,000	2.4
Tonsil	50	0.005	0.25	0.0
Distal ileum	800	5	4,000	9.6
<b>TOTAL</b>	<b>1,600</b>		<b>41,500</b>	

Source: Comer and Huntley 2003.

Table 1 shows that 90 percent of the infectivity is associated with central and peripheral nervous system tissues, i.e., brain, spinal cord, DRG, and trigeminal ganglia. About 10 percent was associated with the distal ileum. Minimal infectivity was associated with tonsils in a clinically affected animal.

### *II.C. Infectivity in bovine muscle*

BSE infectivity in the muscle tissue of cattle examined in either the mouse bioassay or the cattle assays has not been demonstrated to date. Nevertheless, some reports have identified the presence of prions in muscle tissue from rodents, humans, and small ruminants infected with TSEs other than BSE (Bosque 2002, Prusiner 2004). Those findings are consistent with differences in the transmission, host range, genetic susceptibility, infectivity distribution, and epidemiology found in different TSEs that affect animals and humans.

The international scientific community largely considers that bovine muscle tissue from animals infected with BSE does not contain detectable amounts of BSE infectivity. For example, the UK's Spongiform Encephalopathy Advisory Committee (SEAC, 2001) and the European Commission's (EC) Scientific Steering Committee (SSC) evaluated the implications of the findings of the presence of infectivity in muscle for other TSEs in different species in relation to human food safety. EC SSC concluded that there was no reason to revise their opinions regarding the safety of meat, given the consistent negative results in BSE infectivity experiments (EC SSC, 2002a; Statement available online at: [http://europa.eu.int/comm/food/fs/sc/ssc/out254\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/ssc/out254_en.pdf)). SEAC concluded that the findings could not be directly applied to BSE in cattle and did not change the assessment of the risk to humans of consumption of beef.

In its new BSE chapter, the OIE recommends allowing unrestricted trade in boneless meat from cattle 30 months of age or less (excluding mechanically separated meat [MSM]) that were not subjected to air-injection stunning or pithing regardless of the BSE risk status of cattle in the exporting country. The OIE's new chapter was adopted by member countries in May 2005.

### *II.D. Infectivity in bovine blood*

Pathogenesis studies of natural and experimental BSE in cattle have not demonstrated detectable infectivity in the blood of cattle. These studies are based on assays of various bovine tissues and fluids injected into mice and calves.

In sheep, transmission of BSE was demonstrated by transfusion of a large volume of blood drawn from a sheep experimentally infected with the BSE agent to healthy sheep (Houston, et al., 2000; Hunter, et al., 2002). The UK's Spongiform Encephalopathy Advisory Committee (SEAC, 2000) and the Scientific Steering Committee (EC SSC, 2002) *ad hoc* groups evaluated the implications of these findings in relation to human food safety. SEAC concluded that the finding did not represent grounds for recommending any changes to the current controls of bovine products. The EC SSC considered that the research results do not support the hypothesis that bovine blood or lean meat constitutes a risk for humans.

## *II.E. Cross-contamination*

The BSE risk from boneless beef is derived primarily from the potential for cross contamination during slaughter and/or processing. Controls can be established that ensure that contamination of the beef with infectious levels of the BSE agent is unlikely to occur. These controls are prohibitions on air-injection stunning and pithing and procedures for removal of specified risk materials (SRMs).

## **III. Release Assessment**

A release assessment as defined by OIE (OIE 2004b) evaluates the pathways and controls that affect the risk that the hazardous agent will enter the importing country and estimates the likelihood of such an introduction occurring. Depending on the commodity under consideration in the assessment, the various factors may be more or less significant in a release assessment. For example, in this assessment evaluating boneless beef, since the commodity itself presents low BSE risk, more consideration may be given to factors necessary to control contamination of the product.

APHIS also considered the BSE conditions in Japan in light of OIE guidelines. That information, which is included in Appendix A, discusses measures that Japan has implemented to control BSE and protect animal and human health.

### *III.A. Factors of concern: contamination during the slaughter process*

Because of the nature of BSE, specifically the tissue distribution and infectivity, boneless beef in and of itself is an inherently low risk commodity for BSE. However, beef could become contaminated during the slaughter process. The following paragraphs describe these possibilities for cross-contamination and measures to avoid such contamination.

#### III.A.1. SRM removal

Specific tissues (SRMs) that pose the greatest risk of containing infectious levels of the BSE agent must be handled in ways that prevent contamination of the carcass with the BSE agent if the animal were infected with BSE. Considerable evidence exists that SRMs from infected cattle may contain BSE infectivity (Wells, 2003, Wells et al, 1994) at different points of the incubation period. Although muscle tissue is inherently a low-risk commodity, careful removal and segregation of SRMs will prevent cross contamination during processing. Given the evidence, APHIS considers SRM removal to be the most critical risk measure preventing contamination of edible meat with BSE infectivity.

##### III.A.1.a. SRM removal in Japan

Removal of SRMs has been mandatory since October 2001. Japan's Food Safety Commission has conducted a Food Safety Risk Assessment, completed in May 2005, and this assessment noted the following points related to SRM removal. As of March 2005

(at the time of the report), such removal is being carried out in all slaughterhouses in Japan. Japan's Ministry of Health, Labour and Welfare (MHLW) conducted a nationwide survey to verify compliance with the regulation requiring removal of SRMs. The results of the survey showed that Sanitation Standard Operating Procedures (SSOP) for SRM removal had been established and were being followed in approximately 90 percent of the slaughterhouses in Japan (JFSC, 2005).

### III.A.2. Air-injection stunning and pithing

Generally speaking, there are two types of captive bolt stunners used worldwide on livestock at slaughter: penetrative and non-penetrative. Most U.S. slaughter establishments use penetrative captive bolt stun guns to render cattle unconscious, quickly and painlessly prior to slaughter. Penetrative captive bolt stun guns have steel bolts, powered by either compressed air or a blank cartridge. The bolt is driven into the animal's brain. In the past, captive bolt stun guns were often built or modified to inject compressed air into the cranium of cattle, so as to disrupt the brain structures and induce total and prolonged unconsciousness. Studies have shown that penetrative captive bolt stunners that incorporate air-injection can force visible pieces of brain and other central nervous system (CNS) tissue into the circulatory system of stunned cattle. These studies prompted a prohibition on the use of air-injection stunning in the United States as well as in other countries.<sup>3</sup>

The frequency with which CNS tissue enters the circulatory system of stunned cattle, and the size of the CNS tissue emboli, depend on the method of stunning used. Fragments of CNS tissue that can be detected visually are referred to as CNS macro-emboli, while pieces of CNS tissue that can only be detected microscopically or with the use of CNS tissue markers are referred to as micro-emboli. Studies have found that when air-injection pneumatic stunners are used, CNS tissue emboli can be identified visually in the pulmonary artery and in the right ventricle of the heart and microscopically in the jugular venous blood (Garland, et al., 1996; Schmidt, et al., 1999; Anil, et al., 1999). Air-injection pneumatic stunning has also been found to result in a high incidence of visually observed blood clots in the right ventricle of the heart (Schmidt, et al., 1999).

Other types of penetrative captive bolt stunners besides those that use air injection include pneumatically operated stunners that do not inject air and standard cartridge-fired captive bolt stunners. However, in general, studies have not demonstrated that penetrative captive bolt stunning without air injection results in CNS tissue macro-emboli in the blood or other tissues of stunned cattle (Anil, et al., 1999).

Although not documented in the published studies, in addition to the heart and lungs, FSIS inspection program personnel have reported observing CNS tissue macro-emboli in the liver and kidney of cattle stunned with pneumatic powered air-injection stunners.

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<sup>3</sup> See FSIS' interim final rule entitled, "Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter" (Docket No. 01-0331F, 69 FR 1885-1891), published on January 12, 2004, for further information.

Pithing is another slaughter process that could introduce contamination. It involves the insertion of an elongated rod-shaped instrument into the cranial cavity of a stunned animal to further lacerate the CNS tissue. This process could cause dissemination of CNS tissue throughout the body during slaughter. Pithing is banned in the EU and has never been used in the United States. Prohibitions of air injection stunning and pithing reduce risk of contamination.

#### III.A.2.a. Stunning and pithing in Japan

Japan's Food Safety Commission's risk assessment noted that stunning of cattle occurs at 93.1 percent of the slaughterhouses in Japan, as of December 2004. Pithing is carried out at 71.9 percent of the slaughterhouses in Japan (used on approximately 80 percent of all slaughtered cattle), as of December 2004 (JFSC, 2005).

#### III.A.3. Splitting of carcasses

Cross-contamination events represent potential pathways to contaminate boneless beef. One potential event is cross-contamination of carcasses with spinal cord during carcass splitting (Helps, et al., 2004).

Spinal cord contamination can arise as a result of the splitting process as the saw cuts the carcass in half. Helps, et al. (2004) demonstrated tissue transfer (from female to male carcasses using a PCR assay for sex determining regions) from one carcass to subsequent carcasses during the splitting process. In the study, they then used an enzyme-linked immunosorbent assay (ELISA) test to convert the amount of tissue debris into spinal cord tissues. Up to 2.5 percent of the tissue was recovered from each of the five subsequent carcasses by swabbing the split vertebral face that came from the first split carcass; approximately 9 mg was spinal cord tissue. This study reported that under controlled conditions in an experimental abattoir, between 23 and 135 g of tissue accumulated in the saw after splitting five to eight carcasses. Of the total tissue recovered, between 10 and 15 percent originated from the first carcass, and between 7 and 61 mg was spinal cord tissue from the first carcass. This study demonstrates the potential for contamination of the subsequent carcass, including, potentially, low risk boneless beef. It should be noted that the boneless beef considered in this analysis is trimmed further, and the surface contamination that may reside on the product is greatly reduced.

#### III.A.3.a. Carcass splitting in Japan

Japan's Food Safety Commission risk assessment noted the following points related to carcass splitting. As of January 2005, 154 out of a total of 160 slaughterhouses conduct carcass splitting and from 99.4 to 100 percent of them implement some means to prevent the spattering of tissue. Furthermore, 125 facilities carry out suction removal of spinal cord tissue prior to carcass splitting, which is between 52.5 and 99.1 percent effective. Washing the dressed carcass and removing the spinal cord dura matter after splitting results in the carcass appearing to be 100 percent free of any visual evidence of

contamination by spinal cord fragments. Inspectors confirm this at slaughter (JFSC, 2005).

### III.A.3.b. Japan's additional mitigation measure

During the FSIS equivalency determination, FSIS noted that in the certified Japanese slaughter establishments eligible to export beef to the United States, the spinal cord is removed by suction before splitting the carcass (Craver, personal communication, 2005), which is believed to be an effective mitigation that could further reduce the already low possibility of cross-contamination of carcasses. Further, like the U.S. system of processing beef, the Japanese establishments remove the vertebral column as a unit and further reduce the likelihood of the DRG contaminating boneless meat. Together, these practices further reduce the likelihood that infectivity could be transferred to the carcass and further to processed boneless beef. Given that the Japanese meat inspection system is equivalent to that of the United States, the slaughter mitigations applied in both systems would work similarly to reduce the potential for contamination of the boneless beef.<sup>4</sup>

### *III.B. Mitigations*

In accordance with FSIS regulations, boneless beef imported from Japan would have to be prepared in an establishment eligible to have its products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the regulations in 9 CFR 327.2 (FSIS, 2004c), and the boneless beef would have to meet all other applicable requirements of the Federal Meat Inspection Act and regulations thereunder (9 CFR chapter III) (FSIS, 2004d), including the requirements for removal of SRMs and the prohibition on the use of air-injection stunning devices prior to slaughter on cattle from which the beef is derived (FSIS, 2004b). The prohibition on air-injection stunning would address the potential risk posed by stunning devices that may force visible pieces of brain into the circulatory system of stunned cattle. To address that same risk, APHIS should not accept boneless beef derived from cattle that were subject to a pithing process at slaughter.

The requirement for preparation in an export-eligible establishment will ensure that plants approved for export to the United States follow adequate procedures for SRM removal and processing of beef, specifically that the SRMs of the cattle were removed in

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<sup>4</sup> As a matter of reference, in situations in which the carcass is split down the middle, such as in the United States, during the slaughter process some spinal cord may be aerosolized and can contaminate edible meat. This is not considered to be a significant risk, as the Harvard-Tuskegee study (Harvard Tuskegee, 2001; 2003) estimates that the fraction of spinal cord that could contaminate muscle during the splitting process is only 0.00108 percent.

A mis-split can occur when the cut veers off the vertical and terminates at a point short of the cervical vertebrae (carcasses are split caudal to cranial). The rate and extent of mis-splitting influences the potential for spinal cord from an infected animal to contaminate human food, primarily through mechanical separation processes such as advanced meat recovery systems. It is not relevant in the deboning process to produce whole cuts of boneless beef, and, therefore, is not an issue to be addressed in this analysis.

a manner to avoid contamination of the beef, i.e., (a) the tonsils and distal ileum were completely removed from the animal at slaughter in accordance with FSIS regulations in 9 CFR 310.22 and (b) if the beef came from cattle 30 months of age or older, the brain, eyes, spinal cord, skull, dorsal root ganglia, trigeminal ganglia, and vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum) were completely removed from the animal at slaughter in a manner to avoid contamination of the beef with the tissues, in accordance with FSIS regulations in 9 CFR 310.22.

SRMs as defined by FSIS (9 CFR 310.22) (FSIS, 2004e) include the brain, skull, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and wings of the sacrum), and DRG of cattle 30 months of age and older. In addition, FSIS requires the removal of tonsils and distal ileum from cattle of all ages (FSIS, 2004e). Ante- and post-mortem inspections are required in FSIS regulations appearing in 9 CFR Parts 309 and 310 and are a factor in FSIS equivalency determinations. Japanese regulations on inspection also contain requirements regarding ante- and post-mortem inspections.

Although carcass-splitting methods may contribute to risk, FSIS' regulations and guidance on SRM removal include provisions related to the proper care and cleaning of saws. As part of FSIS' equivalency determination, establishments must be consistent with these regulations in order to be eligible to export beef to the United States. Based on FSIS' finding of Japan's system equivalency, the measures implemented in Japan are sufficient to prevent contamination and no additional mitigations would be necessary.

### *III.C. Verification of slaughter conditions in Japan*

#### III.C.1. FSIS equivalency determination

As required under the Food Meat Inspection Act, FSIS ensures that imported meat in the U.S. marketplace is safe, wholesome, unadulterated, and properly labeled by: (1) determining if foreign countries and their establishments have implemented food safety system and inspection requirements equivalent to those in the United States; and (2) reinspecting imported meat and poultry products from those countries through random sampling of shipments. The FSIS regulations in 9 CFR 327.2 (FSIS, 2004) provide that countries eligible to export meat to the United States must have a meat inspection system determined by FSIS to be equivalent to the U.S. meat inspection system. The FSIS equivalency determination is based on a review of the foreign country's relevant laws and regulations and an on-site audit of the foreign country's inspection system. Please see Appendix B for a discussion of FSIS' equivalency determination of Japan's food safety system and inspection requirements.

#### III.C.2. Certification by veterinary official of Japan

APHIS is considering requiring that an authorized veterinary official of the Government of Japan certify on an original certificate that the any requirements for the importation of

boneless beef from Japan have been met. This certification would ensure that conditions in Japan meet the standards that APHIS and FSIS consider appropriate for safe trade in the commodity being assessed (boneless beef) from a region meeting the OIE guidelines for controlled risk.

Verification by the Government of Japan is necessary to ensure compliance with requirements for risk mitigation approaches. Verification can be provided by the Government of Japan through endorsement of certificates that document the nature of the commodity (e.g. whole cuts of boneless beef); the risk mitigations that have been applied (e.g. appropriate SRM removal, no air injection stunning or pithing); and review of procedures and/practices applicable to risk (e.g., FSIS equivalence).

## **IV. Exposure Assessment**

### *IV.A. Exposure pathways*

This section of the risk assessment evaluates the pathways by which boneless beef imported from Japan might expose U.S. cattle to BSE if the product contained the BSE agent. Cattle could be exposed in two ways:

1. Direct exposure to contaminated product; and
2. Indirect exposure to the processed product.

For the disease to develop in cattle, animals have to be exposed to a sufficient amount of infectivity at a particular time of their lives (age related-susceptibility), and live long enough to develop clinical signs of the disease.

The barriers to these types of exposures are discussed in the following sections. Implicit in this discussion is the assumption, albeit unlikely, that infected product is exported to the United States.

### *IV.B. Barriers to direct exposure*

The primary barriers to exposing U.S. cattle to imported Japanese beef are the product characteristics and the distribution channels for this product.

The primary factors limiting the likelihood that whole cuts of boneless beef imported from Japan would expose the U.S. cattle population to BSE are the inherently low risk of the product, measures to prevent contamination, and the fact that the product is unlikely to be fed to cattle. Although the product is not intended for animal consumption, APHIS evaluated pathways by which some small fraction of the product might inadvertently be fed to cattle. Possible pathways include restaurant trimmings and plate waste, and the direct feeding of human food waste to cattle.

In addition to the fact that boneless beef is an inherently low risk commodity, it is anticipated that the amount of beef that would be imported from Japan is relatively small.

In fact, when the U.S. market was open to Japanese beef, the amount imported was approximately 15 metric tons annually. Since the amount of material likely to be disposed of is even smaller, any infectious agent, if present, would be highly diluted upon disposal.

Home food waste is rarely if ever fed directly to cattle; likewise it is rarely if ever rendered. Food waste from restaurants is likewise rarely if ever fed to cattle, nor is it rendered. Such waste becomes municipal garbage and is landfilled (Meeker, 2005 personal communication).

Although some of the boneless beef could become plate waste, which is allowed to be incorporated into ruminant feed, the amount of meat in the plate waste would be insignificant (Harvard Tuskegee 2001; 2003). Furthermore, since the U.S. Food and Drug Administration (FDA) requires that the plate waste be further heat processed for feed, it would most likely be subject to rendering processes that will inactivate significant levels of the agent, further reducing the level of infectivity in MBM (Harvard Tuskegee 2001; 2003).

We are unable to identify any epidemiologically significant pathway for exposure of the U.S. cattle population to BSE infectivity in products imported under this rule, even if those products contain infectivity. In addition, because we anticipate that the amount of beef that would be imported from Japan is relatively small and the amount of material likely to be disposed of is even smaller, any infectious agent, if present, would be highly diluted upon disposal. Therefore, we conclude that it is extremely unlikely that imported material containing an infectious level of the BSE agent will enter the animal feed chain.

#### *IV.C. Barriers to indirect exposure*

An alternative exposure pathway for cattle to the BSE agent is via the feeding of prohibited rendered ruminant protein to non-ruminant animals. This pathway assumes subsequent misdirection, mislabeling, misfeeding, or cross-contamination in feed processing – all violations of the FDA feed ban. The FDA regulations for implementing the feed ban require firms to keep specific records on the manufacture of feed, have processes in place to prevent commingling of ruminant and non-ruminant feed containing prohibited materials, and ensure that non-ruminant feed containing materials prohibited in ruminant feed is labeled conspicuously with the statement, “Do not feed to cattle or other ruminants.”

Furthermore, most imported beef is 90 percent lean and boneless and is not trimmed prior to cooking for human consumption (Cook, 2004 personal communication) and therefore is not available for rendering. Given that the product under consideration is boneless beef only, APHIS expects that little or no product imported under this rule will be trimmed and rendered and, thereby, enter the feed chain. APHIS concludes that the rendering of trimmings from processing plants, butcher shops, or restaurants for use in non-ruminant feed is not an epidemiologically significant pathway for exposure of U.S.

cattle products to the BSE agent in products imported under this rule, even if the products contained the agent.

## **V. Consequence Assessment**

Consequence assessments evaluate the consequences of a disease, given release and exposure. APHIS did not formally evaluate the potential consequences of BSE to the U.S. cattle population. APHIS recognizes that the consequences of widespread BSE establishment, however unlikely, would be severe for the economic health of the cattle industry.

## **VI. Risk Estimation and Conclusion**

APHIS recognizes that there are potential pathways of risk from boneless beef from Japan that need mitigation. However, APHIS considers that the measures identified in Section III.B. of the Release Assessment section of this document are sufficient to mitigate that risk.

The total effect of mitigations reflects the combined results of the mitigations defined in the Release Assessment and the mitigations described in the Exposure Assessment. Conceptually, APHIS considers these as a series of interlocking, overlapping, and sequential risk barriers inserted at critical control points, each of which reduces the risk to the U.S. cattle population. Although we refer to the information considered in the release and exposure assessments in the discussion below, we do not repeat it.

In order for the importation of infected product from Japan to transmit infection to a U.S. cow, several barriers must be crossed:

1. U.S. import restrictions
2. Rendering inactivation
3. Feed manufacturing controls
4. Dose limitations

APHIS considers it unlikely that infected product will be exported if the mitigation measures identified in the Release Assessment are applied because boneless beef is considered a low risk commodity for the reasons outlined in the Hazard Identification section and because the mitigation measures identified would mitigate the risks of contamination during slaughter.

If, however, infected product were to be exported, then each of the remaining barriers outlined above reduces the level of infectivity in the system. As discussed in the Exposure Assessment, rendering, feed manufacturing controls lower the likelihood that contaminated MBM would be incorporated into feed prepared for ruminants.

If, despite these measures, some remaining infectivity were fed to cattle, the amount of infectivity present would have to be adequate to infect an animal ingesting that feed. Animals consuming the infectivity that are older than four months of age are less susceptible than younger animals (susceptibility declines exponentially at a rate of 0.85 annually after the age of 4 months leveling off at 10 percent of the peak value [De Koeijer, 2004]).

Ultimately, however, in the extremely unlikely event that an animal should become infected from contaminated feed, it is unlikely that infectious levels of the agent from that animal would be transmitted to other cattle because infectivity from that animal must also by-pass or circumvent all of the barriers discussed.

Thus, these factors make it highly implausible that infected boneless beef imported from Japan could create an infection in the U.S. cattle herd. Many of the same barriers to this infection make it highly unlikely that if an animal did become infected that it would sustain a cycle of infection through rendering and feeding contaminated MBM.

Although APHIS recognizes that the consequences of BSE establishment in the United States would be severe, we conclude that the risk to animal health associated with the action under consideration is low.

Given the mitigations to prevent the importation of BSE-infected products, APHIS concludes that the risk of BSE release is extremely unlikely.

We are unable to identify any epidemiologically significant pathway for exposure of the U.S. cattle population to BSE infectivity in the product being considered for importation,, even if those products contain infectivity. Based on the evidence, we conclude that it is extremely unlikely that imported boneless beef from Japan containing an infectious level of the BSE agent will enter the animal feed chain.

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APHIS’ Considerations of Japan in Light of the World  
Organization for Animal Health’s (OIE) Guidelines

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Veterinary Services

Animal and Plant Health Inspection Service  
United States Department of Agriculture

## APPENDIX A – APHIS’ consideration of Japan in light of the World Organization for Animal Health’s (OIE) guidelines

The information contained in this appendix describes the conditions existing in Japan in the context of the new 2005 World Organization for Animal Health (OIE) guidelines for BSE.

### International Guidelines on BSE

International guidelines for trade in animals and animal products are developed by the OIE, which is recognized by the World Trade Organization (WTO) as the international organization for the development and periodic review of standards, guidelines, and recommendations with respect to animal health and zoonoses (diseases that are transmissible from animals to humans). The OIE guidelines for trade in terrestrial animals (mammals, birds, and bees) are detailed in the Terrestrial Animal Health Code (available on the internet at <http://www.oie.int>). The guidelines on bovine spongiform encephalopathy (BSE) are contained in Chapter 2.3.13 of the Code and supplemented by Appendix 3.8.4 of the Code.

The 2005 OIE guidelines identify certain commodities that do not require any BSE-related restrictions, regardless of the BSE status of the exporting country or zone. For example, the guidelines do not recommend any restrictions in the trade of deboned skeletal muscle meat derived from cattle under 30 months of age or blood and blood products from cattle of any age (among other products), provided that the product meets certain other conditions, regardless of the BSE status of the exporting region.

The 2005 OIE guidelines also contain recommended conditions for trade in other products and live animals based on the BSE risk status of a country, zone, or compartment (referred to in this appendix as a region).

There are three possible BSE classifications for an exporting region: Negligible risk, controlled risk, and undetermined risk. Under the OIE guidelines, regions may qualify for negligible risk status when either (1) there have been no indigenous cases of BSE or any imported cases of BSE have been completely destroyed, or (2) the last indigenous case of BSE was reported more than 7 years ago. Other criteria also apply, but those are the starting points. Regions that have had indigenous cases of BSE within the past 7 years may qualify for controlled risk status if, in addition to the criteria listed above for both negligible and controlled risk regions, it can be demonstrated through an appropriate level of control and audit that meat-and-bone meal (MBM) and greaves derived from ruminants have not been fed to ruminants, but it cannot be demonstrated that feed controls have been in place for 8 years or that other criteria have been complied with for 7 years. Additionally, the following animals, if alive in the region, must be permanently identified and their movements controlled and, when slaughtered or at death otherwise, must be completely destroyed: all BSE cases, as well as the progeny of all female cases born within 2 years prior to or after clinical onset of BSE; all cattle which, during their first year of life, were reared with BSE cases during their first year of life when investigation shows they consumed the same potentially contaminated feed during that

## APPENDIX A – APHIS’ consideration of Japan in light of the World Organization for Animal Health’s (OIE) guidelines

period, or, if investigation is inconclusive, all cattle born in the same herd as, and within 12 months of, the birth of the BSE cases.

Also, for both negligible and controlled risk status, a risk assessment must have been conducted that identifies all potential factors for BSE occurrence and their historic perspective, and the region must have demonstrated that appropriate measures, as recommended for either negligible or controlled risk status, have been taken for the relevant period of time. In addition, the region must have an on-going awareness program for veterinarians, farmers, and workers involved in transportation, marketing, and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Appendix 3.8.4 of the OIE guidelines for BSE. The regions must also require notification and investigation of all cattle showing clinical signs consistent with BSE and examine in an approved laboratory brain or other tissues collected within the framework of the region’s surveillance and monitoring system. To increase the likelihood of detecting BSE, the OIE recommends surveillance that targets cattle displaying clinical signs compatible with BSE and cattle that have died or been killed for reasons other than routine slaughter. The guidelines recommend different surveillance strategies based on the BSE risk status of the region. For controlled risk status, the guidelines recommend surveillance designed to detect BSE at a level of least one case per 100,000 in the adult cattle population of the region, at a confidence level of 95 percent.

The OIE guidelines for undetermined risk regions apply to those regions that do not meet the criteria for negligible or controlled risk status.

The recommended export conditions contained in the OIE guidelines are increasingly stringent as the status of a region moves from negligible risk through controlled risk to undetermined risk. For example, the following conditions for export of beef are recommended:

- **From negligible risk regions:** The beef should be accompanied by an international veterinary certificate stating that the region complies with the OIE conditions for negligible risk status.
- **From controlled risk regions:** The cattle from which the beef is derived were not subjected to air-injection stunning or pithing and received ante- and post-mortem inspections; the beef does not contain specified risk materials (SRMs) or mechanically separated meat (MSM) from the skull and vertebral column of cattle over 30 months of age, all of which have been completely removed in a manner to avoid contamination of the beef with SRMs.
- **From undetermined risk regions:** The cattle from which the beef is derived were not subjected to air-injection stunning or pithing, received ante-and post-mortem inspections, and were not suspect or confirmed cases and either: (1) the cattle have not been fed meat and bone meal (MBM) or greaves, and the beef does not contain SRMs, nervous and lymphatic tissues exposed during the deboning process, or MSM from the skull and vertebral column of cattle over 12 months of age, all of which have been completely removed in a manner to avoid contamination of the beef with SRMs;

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or (2) the meat is deboned skeletal meat (excluding any MSM) from cattle 30 months of age or less.

The mitigation measures that the Animal and Plant Health Inspection Service (APHIS) has identified as appropriate for whole cuts of boneless beef from Japan are as follows:

1. The beef must be prepared in an establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the regulations in 9 CFR 327.2 and the beef meets all other applicable requirements of the Federal Meat Inspection Act and regulations thereunder (9 CFR chapter III). This requirement would ensure that establishments processing beef for export to the United States employ processes for carcass splitting and SRM removal that would avoid contamination of the carcass, and that air-injection stunning devices are not used on cattle from which the beef is derived. Although not specifically required in the APHIS proposal, ante- and post-mortem inspections are required in FSIS regulations appearing in 9 CFR Parts 309 and 310 and are a factor in FSIS equivalency determinations. Japanese regulations on inspection also contain requirements regarding ante- and post-mortem inspections.
2. The cattle from which the beef is derived must not have been subjected to a pithing process.
3. An authorized veterinary official of the Government of Japan must certify on an original certificate that the above conditions have been met.

These conditions are consistent with the 2005 OIE guidelines for trade in meat and meat products from regions of controlled risk. APHIS believes this is appropriate, given that Japan has reported indigenous cases of BSE within the last 7 years and has measures in place to control BSE risks, but that these measures have not been in place long enough for Japan to be considered a negligible risk region.

### The BSE Situation in Japan

This section discusses the BSE situation in Japan in more detail. The discussion is based on information provided by the Government of Japan, including a risk assessment prepared by the Japanese Food Safety Commission’s Prion Expert Committee (JFSC, 2005), as well as information the Government of Japan provided in response to specific questions from the U.S. Department of Agriculture, and information that APHIS obtained during a site visit conducted in January 2005. The information is organized according to OIE guidelines.

## **I. Risk assessment conducted to identify potential factors for BSE occurrence and their historic perspective**

In conducting our risk analysis, we reviewed a risk assessment conducted by the Japanese Food Safety Commission’s Prion Expert Committee. The Food Safety Commission is an organization that conducts risk assessments independently of MAFF and the Ministry of Health, Labour and Welfare (MHLW). The Food Safety Commission then makes recommendations, based on the results of its risk assessments, to the relevant government agencies. Several expert committees work on more specific areas of food safety. The Prion Expert Committee began an assessment in March 2005 and released the final assessment in May 2005. The report, entitled “Food Safety Risk Assessment Related to Measures Against Bovine Spongiform Encephalopathy (BSE) in Japan,” is available on the internet at: [http://www.fsc.go.jp/sonota/measure\\_bse\\_injapan170520.pdf](http://www.fsc.go.jp/sonota/measure_bse_injapan170520.pdf). This assessment was an update to an Interim Report completed in September 2004, intended to help address specific questions about risk management measures.

Among other issues, the committee evaluated, from a risk management viewpoint, the revision of the current Japanese policy of testing all animals at slaughter to exclude cattle aged 20 months and younger from mandatory testing. Therefore, the assessment considered cattle born in or after July 2003, which would include all cattle aged 20 months or younger as of March 2005, as the main focus of the report. Risk mitigation measures, such as the feed ban or SRM removal, had been in place since 2001, prior to the July 2003 date considered in Japan’s assessment. Since the focus of the Japanese assessment was on the revision of the testing requirement, an evaluation of the effectiveness of these measures prior to July 2003 was not addressed in this document. However, these measures did not change significantly in the time frame between 2001 and 2003.

The risk assessment reviewed Japan's overall strategies and measures concerning BSE in order to evaluate the risk in Japan of humans becoming infected with BSE and examined the effectiveness of measures to reduce such risks. The committee’s risk assessment examined proposed changes in four areas of BSE measures: (1) BSE testing at slaughterhouses; (2) ensuring complete removal of SRMs; (3) reinforcement of securing feed ban effectiveness; and (4) promoting further BSE research studies. The committee conducted both a qualitative and quantitative risk assessment and consolidated the results.

### *I.A. Applicability to animal health*

Although the Japanese risk assessment focuses on human health issues, it addresses the same issues that would be considered in a risk assessment related to animal health, i.e., age and tissue distribution in animals, animal traceability, feed bans, SRM removal, testing, and potential for contamination through processing (JFSC, 2005). The animal health risk to the United States was estimated from the probability that boneless beef containing infectious levels of the agent would be exported to the United States and enter the animal feed supply.

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### *I.B. Factors considered in Japan’s assessment*

The assessment considered potential factors for BSE occurrence and their historic perspective including the feed ban, BSE testing, cross-contamination, and animal traceability. Following are some of the key findings of the risk assessment.

#### (1) Effectiveness of feed ban

Japan relies on imports for approximately 90 percent of its concentrate feeds, such as feed grains, which are used as raw material in the domestic production of compound and mixed feed. There has been a complete ban on importing MBM since October 2001. The committee assumed that compound and mixed feed produced overseas and imported into Japan do not present a high risk.

Since October 2001, on-the-spot inspections have been carried out on feed importers, feed dealers, manufacturers, and cattle-raising farms, to check for MBM contamination of compound feed. MBM was detected in only one case (in February 2005, poultry-origin protein was detected in cattle feed at a compound feed plant where cattle feed and poultry/pig feed containing chicken meal were produced on the same production line).

Prior to October 2001, compound feed for cattle and feed for chickens/pigs containing MBM derived from cattle were manufactured on the same production lines in some factories. The committee concluded therefore that the possibility of cross-contamination of feed cannot be denied. However, the feed ban imposed in October 2001 prohibits the use of ruminant-derived MBM in animal feed, and additional requirements were established that mandate the use of separate production lines used exclusively for cattle feed. All manufacturing facilities were expected to have such exclusive lines by March 31, 2005.

#### (2) BSE Testing

Japan began testing high-risk cattle in April 1996. Beginning in October 2001, BSE testing became mandatory for all cattle that exhibited clinical signs for BSE and all dead cattle aged 24 months or older (MHLW, 2001). The committee concluded that the delay in establishing a system for testing dead cattle created difficulties in determining the true state of the prevalence of BSE in Japan and had a major impact on the results of the present risk assessment.

In May 2001, Japan initiated testing of at-risk cattle in slaughterhouses. The testing program was expanded later that year. Since October 2001, all cattle slaughtered in Japan undergo an ELISA screening test, followed by a confirmation test using the Western blot method and a microscopic pathological/immunohistochemical examination (MHLW, 2001). At the time the risk assessment was released, Japan was considering removing the slaughter testing requirement for cattle aged 20 months or younger, which, based on the date of the report, would have been cattle born during or after July 2003). The committee considered it likely that even if BSE infection were detected in cattle born

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during or after July 2003, the amount of accumulation would be close to the detection limit of the ELISA test, which is a very low level.

### (3) SRM Removal/contamination prevention

Removal of SRMs has been mandatory since October 2001, and as of March 2005 (at the time the risk assessment was released), such removal was being carried out in all slaughterhouses in Japan. MHLW conducted a nationwide survey to verify compliance with the regulation requiring removal of SRMs. The results of the survey showed that SSOP (Sanitation Standard Operating Procedures) had been established and were being followed in approximately 90 percent of the slaughterhouses in Japan.

As of January 2005, 154 out of a total of 160 slaughterhouses conduct carcass splitting and from 99.4 to 100 percent of them implement some means to prevent the spattering of tissue. Furthermore, 125 facilities carry out suction removal of spinal cord tissue prior to carcass splitting, which is between 52.5 and 99.1 percent effective. Washing the dressed carcass and removing the spinal cord dura matter after splitting results in the carcass appearing to be 100 percent free of any visual evidence of contamination by spinal cord fragments. Inspectors confirm this at slaughter.

### (4) Stunning and pithing

Stunning of cattle occurs at 93.1 percent of the slaughterhouses in Japan, as of December 2004. Although there have been reports that stunning causes tissue from the central nervous system (CNS) to migrate into the cow’s blood, no quantitative data have been reported indicating the contamination rate or the amount of contamination in meat from SRMs through this process.

Pithing is carried out at 71.9 percent of the slaughterhouses in Japan (used on approximately 80 percent of all slaughtered cattle), as of December 2004. While it is generally accepted that the contamination rate of meat from SRMs as a result of pithing cannot be completely ignored, the committee concluded that the amount of contamination can be presumed to be small (JFSC, 2005).

### (5) Traceability

The traceability system was initiated in January 2002 and made mandatory at the production stage in December 2003 and the distribution stage a year later. Traceability in the production stage has proved effective in identifying and eliminating BSE case cohorts. Traceability in the distribution stage has yet to be verified.

## **II. Ongoing awareness program for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting**

Japan began public awareness programs on BSE in 1996, including mass media presentations, training courses, and BSE publications (Ozawa, 2003). Japan continues to

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educate veterinarians and farmers in the early detection of BSE using clinical signs in order to prevent BSE-infected cattle from entering the animal feed and human food chains. According to Japan’s risk assessment (JFSC, 2005), efforts are currently being made to ensure that all farmers are informed of, and provided guidance on the relevant laws and regulations. Information and guidance are provided through field inspections carried out on cattle, pigs, and poultry by regional agricultural administration offices and on-the-spot inspection conducted by prefectural authorities. Regional agricultural administration offices carry out the field inspections on a rotating basis. The number of farms, the contents of the inspection, and other details of the on-the-spot inspections are left up to the discretion of the prefectural authorities.

### **III. Compulsory notification and investigation of all cattle showing clinical signs consistent with BSE**

BSE has been a notifiable disease in Japan since April 27, 1996, by amendment of the Domestic Animal Disease Control Law (Law No. 166 of 1951) (MAFF, 2002). All veterinarians, owners, or persons transporting animals are required to report the disease. If there is no veterinarian involved, the owner, or, in the case of a transporter, the agent, is responsible for notifying the proper authorities.

According to Article 63 of the Domestic Animal Disease Control Law, the penalties for not reporting are: up to 3 years in prison and a fine of up to 1 million yen (U.S. \$8,919)<sup>1</sup> (MAFF, 1997). Japan has also had a compensation policy for suspected BSE cases since 1996 (Ozawa, 2003).

In addition, the Japanese Law on Special Measures Against Bovine Spongiform Encephalopathy (MAFF, No. 70 dated July 2002 amendment to Animal Infectious Disease Control Law No. 166 dated May 1951) specifies that, upon death of any cattle over 24-months-of-age, the veterinarian who conducts a necropsy on the cattle body (or, in cases where the body has not been autopsied by a veterinarian, the owner) shall, without delay, report such death to the Governor of the prefecture having jurisdiction over the location of such cattle body, unless notification shall be given pursuant to the provisions of Article 13, Paragraph 1 of the Domestic Animal Infectious Disease Control Law or otherwise designated by MAFF. The Governor of the prefecture who received the report shall order the owner of the cattle body so reported to submit the cattle body to inspections by livestock disease prevention and control officers at prefecture Livestock Hygiene Service Centers; provided, however, that this does not apply to cases designated by MAFF Ordinance as those in which such inspections are difficult to conduct due to such reasons as the geographical conditions.

#### *III.A. BSE incidence in Japan*

Japan detected its first BSE-infected animal in September of 2001. As of June 17, 2005, a total of 20 cases of BSE were reported by Japan, two of which warrant further

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<sup>1</sup> Using the rate of exchange (1 U.S. dollar = 112.118 Japanese yen) current as of July 2005.

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discussion. Fifteen were found during slaughter surveillance, and five during on-farm surveillance (Table 1). All 20 reported cases were either Holstein cows or Holstein steers.

**Table 1. Reported BSE Cases in Japan 2001 – March 2005** <sup>1</sup>

	2001	2002	2003	2004	2005	Total
<i>Slaughter Surveillance</i>						
Animals with clinical signs <sup>2</sup>	0	3	1	0	0	4
w/o clinical signs > 30 months	2	1	0	3	3	9
w/o clinical signs, < 30months	0	0	2	0	0	2
Subtotal	2	4	3	3	3	15
<i>On-Farm</i>						
Fallen stock <sup>3</sup>	1	0	0	0	1	2
Animals with clinical signs <sup>2</sup>	0	0	1	2	0	3
Subtotal	1	0	1	2	1	5
Total	3	4	4	5	4	20

**Source: MAFF, 2004.**

<sup>1</sup> Japanese fiscal year from April 1 – March 31. Data for FY 2004 is through March 1, 2005.

<sup>2</sup> Nervous system symptoms (dyskinesia, perceptual disorder, reflex or consciousness disturbance, etc.) and those showing symptoms for the entire body.

<sup>3</sup> Fallen stock include dead, dying, and downer cattle.

Two of the 20 cases of BSE detected in and reported by Japan warrant further investigation. These two cases were reported in 2003 in a 21-month old steer and a 23-month old steer. Neither of these animals displayed clinical signs of the disease. Following initial enzyme-linked immunosorbent assay (ELISA) screening tests, which yielded weak positive results, confirmatory tests were conducted. The animals tested positive on a confirmatory Western blot (Japanese version) test, but negative on the confirmatory immunohistochemistry (IHC) test (Yamakawa, 2003). Currently, the officials are conducting mouse bio-assays, which involve injecting tissue derived from the cattle into a mouse panel, to see if infection occurs and help characterize the agent present. The average incubation period before standard mouse panels develop clinical symptoms with typical BSE is estimated to be approximately 230 days. As of January 2005, this ongoing study was in excess of 300 days in duration with no evidence of infectivity detected.

At the time of this analysis, the relevance of the presence of the atypical cases is not known, especially given the lack of findings in the mouse assays. However, the OIE expert *ad hoc* review of “atypical” BSE cases reported by Japan and Italy (OIE opinion, December 2003, available online at [http://www.oie.int/eng/press/en\\_031208.htm](http://www.oie.int/eng/press/en_031208.htm)) concluded that there was no basis for suggesting that the risk to humans or animals had changed, and that current surveillance strategies and measures taken to protect human health are able to detect cases and mitigate the risk.

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### III.A.1. Epidemiological investigations of confirmed BSE cases

#### Source of exposure

Following the first confirmed case of BSE in Japan (a 5 year, 5-month-old Holstein cow) on September 10, 2001, comprehensive investigations were conducted of all beef and dairy farms in Japan and the 142 “major formula feed manufacturers” to determine the likely source(s) of BSE infectivity and possible routes of exposure (BSE Technical Committee, 2003). These investigations included tracing potentially exposed animals and tracing the disposition of MBM and other products imported from countries known to have BSE. No violations by the major formula feed manufacturers were found, but 165 out of 140,000 farms (0.1 percent) with a total of 5,129 cattle were identified as having blood meal and/or bone meal in their cattle rations. The herd mates and other non-cohort animals that potentially consumed blood and/or bone meal were put under quarantine and kept alive under surveillance to determine if any of these animals had been infected with BSE. As of March 2005, approximately 2,010 cattle were still alive and under surveillance by prefecture veterinarians; no clinical signs of BSE have yet been observed in any animals under surveillance. None of these 2,010 cattle are cohorts of any of the positive BSE cases in Japan. The remaining (approximately 3,100) cattle, which were condemned, slaughtered, or dead on the farm tested negative for BSE.

In September 2002, MAFF formed a BSE Epidemiological Study Group (the Group) within its BSE Technical Committee. The Group’s assignment was to identify and assess all feasible routes of BSE introduction and exposure to cattle in Japan. The Group published its final report in September 2003 regarding the first seven cases of BSE confirmed in Japan (BSE Technical Committee, 2003). The Group concluded that cattle imported from Britain in 1982 or 1987 may have been infected with BSE, their remains rendered, and the resulting contaminated MBM then incorporated into cattle feed. Japanese cattle may have been exposed to the BSE agent through contaminated feed via this pathway. In addition, contaminated MBM imported from Italy in the 1980s and early 1990s may have been contaminated and could have been a source of the infection. Results of epidemiological studies suggest that cattle in Japan may have been infected through one or both of these routes, the remains of infected cattle rendered after slaughter or death, and this infected domestic MBM then incorporated into cattle feed, thus leading to the cases that began appearing in 2001. The Group further concluded that infected MBM may have cross-contaminated cattle feed at the manufacturing and delivery stages.

The Group’s investigation found many combination feed production companies in which the same facilities (production lines) produced feed for cattle, pigs, and chickens. MBM in such facilities intended for use in pig and chicken feed might accidentally be incorporated into cattle feed. To address this risk, MAFF required that all facilities producing feed for cattle, pigs, and chickens have dedicated feed manufacturing lines by April 1, 2005. (For a more detailed discussion of Japan’s actions related to a feed ban, see Section VI of this Appendix.)

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The Group also investigated milk replacer and calf starter as sources of the BSE agent (BSE Technical Committee, 2003). The Group found that milk replacer produced in a single factory was fed in seven of the cases of BSE-infected dairy cattle. A detailed epidemiologic investigation found no evidence that MBM was used as an ingredient in this milk replacer. However, powdered fat (animal fat mixed with casein or other lactoproteins and pulverized) imported in 1995 or 1996 from The Netherlands (which had BSE in its cattle population) was used to make milk replacer fed to dairy calves. MAFF sent specialists to The Netherlands to investigate the origin of the animal fat ingredients, to evaluate the manufacturing processes, and to address other issues relevant to identifying possible sources of BSE infectivity. The Group found no evidence of bovine protein contamination in the powdered fat. An investigation of calf starter ration as a possible source of BSE found there was no formula feed manufacturer common to all seven cases of BSE. Two cases had never been fed a calf starter ration. The Group concluded that there was no *direct* evidence to indicate that imported powdered animal fat or ingredients of calf starter were the source of the BSE agent that caused the Japanese outbreak.

Prior to the outbreak of BSE in Japan, MBM was traditionally used as an ingredient of fertilizer, poultry and swine feed, and pet food. Relatively small amounts were used in ruminant feed. For example, use of MBM for ruminant feed before 1996 was reported to be less than 250 tons/year (representing less than 0.05 percent of the total amount of MBM used for feed). Use of MBM was banned for animal feed in 2001 (BSE Working Group, 2004).

Epidemiological investigations of the BSE outbreak revealed that most of the MBM imported from European countries was likely to be used in feed for non-ruminant species. Mixed farms with both ruminants and non-ruminants are not common in Japan. In 2000, 0.03 percent of the dairy farms and 0.08 percent of the beef farms reported having non-ruminant animals (Sigura, et al, 2003). However, since ruminant and non-ruminant feed productions shared lines and facilities, MAFF concluded that cross contamination of ruminant feed in the feed mills with MBM from Italy was the likely source of exposure.

### Actions taken as a result of epidemiological investigations

In accordance with OIE standards, as a result of the completed epidemiologic investigation of the initial seven cases of BSE, Japan destroyed all affected animals and quarantined and destroyed 361 suspected animals that were cohorts to these cases (all cohorts were negative to BSE testing) (BSE Technical Committee, 2003). An epidemiologic investigation is conducted following the detection of every BSE case. Since the seventh case, the investigations of the subsequent cases have involved more than 250 cohorts (MAFF, 2005a).

### **IV. Examination of brain or other tissues in an approved laboratory**

Japan uses two rapid screening ELISA tests for BSE. Official veterinarians are responsible for obtaining tissue samples and running the initial screening test on tissues

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in local meat inspection laboratories and Prefecture Livestock Hygiene Service Centers. The Western blot test and immunohistochemical (IHC) examinations are used as confirmatory tests. Confirmatory testing is conducted at the National Institute of Infectious Diseases, Obihiro University of Agriculture and Veterinary Medicine, and Hokkaido University, and the National Institute of Animal Health (NIAH) which is affiliated with MAFF. The Prion Research Unit of the National Institute of Animal Health is an OIE Reference Laboratory for BSE.

### **V. Type A surveillance**

#### *V.A. Implementation of type A surveillance in Japan*

According to OIE guidelines, a country or region must demonstrate an adequate level of surveillance for BSE for it to be classified as controlled risk. The surveillance program must use good quality data concerning the age distribution of its adult population and the number of BSE cases stratified by age and by subpopulation. The program should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them. The approach used and the assumptions made should be fully documented, and the documentation retained for 7 years. The surveillance program should be designed to detect BSE at a level of least one case per 100,000 in the adult cattle population, at a confidence level of 95 percent in the country, zone, or compartment of concern. “Point values” are assigned to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled (Table 3). The total point accumulation is then periodically compared to the target number of points for a country, zone, or compartment (Table 2). Surveillance points remain valid for 7 years (the 95th percentile of the incubation period). Overall, surveillance in Japan is consistent with OIE guidelines for type A surveillance, which include collection of samples that represent national herd demographics.

**Table 2. Point targets for different adult cattle population sizes in a country, zone, or compartment which has not identified any BSE cases.**

<b>Target points for country, zone or compartment with 0 cases, 95% confidence</b>		
<b>Adult Cattle Population Size (24 months and older)</b>	<b>DP<sup>1</sup> 1/100,000</b>	<b>DP<sup>1</sup> 1/50,000</b>
≥ 1,000,000	300,000	150,000
800,000 – 1,000,000	240,000	120,000
600,000 – 800,000	180,000	90,000
400,000 – 600,000	120,000	60,000
200,000 – 400,000	60,000	30,000
100,000 – 200,000	30,000	15,000
50,000 – 100,000	15,000	7,500

Source: OIE, 2005.

<sup>1</sup>DP is the maximum possible prevalence or “design prevalence.”

**Table 3. Surveillance point values for samples collected from animals in the given subpopulation and age category.**

<b>Surveillance subpopulation</b>			
<b>Routine slaughter <sup>1</sup></b>	<b>Fallen stock <sup>2</sup></b>	<b>Casualty slaughter <sup>3</sup></b>	<b>Clinical suspect <sup>4</sup></b>
<b>Age ≥ 1 year and &lt; 2 years</b>			
0.01	0.2	0.4	N/A
<b>Age ≥ 2 years and &lt; 4 years (young adult)</b>			
0.1	0.2	0.4	260
<b>Age ≥ 4 years and &lt; 7 years (middle adult)</b>			
0.2	0.9	1.6	750
<b>Age ≥ 7 years and &lt; 9 years (older adult)</b>			
0.1	0.4	0.7	220
<b>Age ≥ 9 years (aged)</b>			
0.0	0.1	0.2	45

Source: OIE, 2005

<sup>1</sup> See point 4) of Article 3.8.4.2.

<sup>2</sup> See point 3) of Article 3.8.4.2.

<sup>3</sup> See point 2) of Article 3.8.4.2.

<sup>4</sup> See point 1) of Article 3.8.4.2.

### *V.B. On farm surveillance*

In April 1996, MAFF began its surveillance efforts by recommending to all prefecture Livestock Hygiene Service Centers (178 Centers distributed among 47 Prefectures) that all dead or dying adult cattle, buffalo, sheep, and goats brought to them should be subjected to tissue sampling and histopathological examination for BSE (MAFF, 1996). This Cabinet Order gradually expanded into a law, effective as of April 2004, requiring mandatory testing of all dead cattle 24 months of age and older. MAFF has stated that

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this law, referred to as the “Law Concerning Special Measures on BSE,” (MAFF, 2002) was fully implemented on April 1, 2004. Between April 1996 and March 2005, 124,532 cattle identified on farms as dead or showing clinical signs consistent with BSE were subjected to laboratory testing; 4 cases of BSE were confirmed from those tested (Table 4). The mandatory reporting of dead cattle and cattle with symptoms consistent with BSE dramatically increased (18-fold) as the number of high-risk cattle tested for BSE rose from 3,755 in FY 2002 to 68,390 in FY 2004. This mandatory reporting requirement enhances the ability of regulatory officials to detect animals infected with BSE.

Any animal that tests positive for BSE upon confirmatory testing at NIAH is incinerated entirely. If confirmatory test results are negative, the carcass is released for rendering.

**Table 4. BSE Surveillance On Farms: Number of High-Risk Cattle Subjected to Laboratory Testing, Japanese FY 1996-2004.** <sup>1</sup>

Fiscal Year	96/97	97/98	98/99	99/00	00/01	½	02/03	03/04	04/05 <sup>2</sup>	Total
CNS Suspects	23	20	36	36	24	132 (1)	420	3,411 (1)	958 (1)	5,060 (3)
Fallen Stock	194	203	210	237	227	801	3,755	44,739	68,390 (1)	118,756 (1)
BSE Case Cohort						236	139	266	75	716
2005Total	217	223	246	273	251	1,169 (1)	4,314	48,416 (1)	69,423 (2)	124,532 (4)

Source: MAFF, 2005b.

<sup>1</sup>Figures in parentheses are number of confirmed BSE cases found. Japanese fiscal year is April 1-March 31.

<sup>2</sup>Number of cattle tested through November 2004.

*V.C. Slaughter surveillance*

Japan requires testing for BSE of all animals at slaughter (MHLW, 2004). As of October 2001, all cattle slaughtered in Japan must be tested for BSE as part of the post-mortem examination (MHLW, 2001). Cattle are slaughtered in 162 abattoirs which are staffed by over 2,600 meat inspectors (official veterinarians). As of December 28, 2004, over 4 million head of cattle had received post-mortem testing for BSE in the slaughter surveillance program (Table 5). During this surveillance, 10 confirmed cases of BSE were found at slaughter.

**Table 5. BSE Testing in Abattoirs, FY 2001-3<sup>rd</sup> Quarter FY 2004<sup>1</sup>**

<b>FY (April 1 – March 31)</b>	<b>2001<sup>3</sup></b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>Total</b>
Risk Cattle <sup>2</sup>	1,851	2,973 (3)	6,266 (1)	6,564	17,654 (4)
Cattle > 30 months without clinical signs	215,548 (2)	517,767 (1)	494,987	366,455 (1)	1,594,757 (4)
Cattle < 30 months without clinical signs	306,192	733,071	751,377 (2)	605,360	2,396,000 (2)
Total <sup>3</sup>	523,591 (2)	1,253,811 (4)	1,252,630 (3)	978,379 (1)	4,008,411 (10)

**Source: MAFF, 2005b.**

<sup>1</sup> In February and March of 2005 (4<sup>th</sup> Quarter of FY 2004), two additional BSE cases in cattle older than 30 months without clinical signs were confirmed during slaughter surveillance.

<sup>2</sup> Among cattle of 24 months or older, those suspected of having nervous signs (dyskinesia, perceptual disorder, reflex or consciousness disturbance, etc.) and those showing signs for the entire body. The figures in parenthesis are the number of BSE-positive cattle.

<sup>3</sup> BSE testing in abattoirs began on October 18, 2001. Figures in parenthesis are the number of BSE-positive cattle.

*V.D. Evaluation of Japan’s BSE surveillance in accordance with OIE guidelines*

APHIS evaluated whether Japan meets OIE guidelines for type A surveillance by considering the adult cattle population (24 months and older) in the country and the number of animals tested in each surveillance category.

In 2004, Japan reported 4.5 million head of cattle (FAOSTAT data, 2005, which can be accessed online at <http://faostat.fao.org/faostat/notes/citation.htm> and was last updated in February 2005). Approximately 1,587,000 beef and dairy cattle are 30 months of age or older (MAFF, 2004). OIE reports incidence rates for the age cohort over 24 months of age (OIE, 2004). The cohort of animals over 24 months of age accounts for 45 percent of the beef and dairy animals (**Note:** statistic based on OIE information related to incidence of BSE in Japan, which is available online at [http://www.oie.int/eng/info/en\\_esbincidence.htm](http://www.oie.int/eng/info/en_esbincidence.htm)). Applying this percentage to the 2003 population of dairy and beef animals yields a population of 2.05 million dairy and beef cattle over 24 months of age.

Based on the estimated number of adult cattle (older than 24 months of age) in Japan, and assuming a prevalence of 1/100,000, the minimum number of points required to meet type A surveillance would be 300,000 (see Table 2). These points could be accumulated over a 7-year period. Although additional specific data would be necessary to complete a detailed and accurate calculation, estimated the number of points using assumptions as described below. Table 6 below summarizes the pooled data for on-farm surveillance and slaughter surveillance for all cattle for years 2001-2004 (MAFF, 2005b). The data show nearly 4.2 million animals were tested for BSE, including nearly 142,000 high-risk

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animals (i.e., all cattle tested on-farm as BSE suspects, plus animals with CNS signs tested at abattoirs). APHIS assigned the lowest possible point value recommended by the OIE (see Table 3) to each surveillance category in Japan. The total number of points from all surveillance categories between 1998 and December 2004 was estimated to be 1,227,373 (see Table 6).

**Table 6. Summary of On-Farm and Abattoir BSE testing, 1998 – December 2004.**

Surveillance Location	Category	No. Animals Tested	Point Assigned	No. of Points
On-Farm	Clinical signs	5,017	45	225,765
	Fallen stock <sup>1</sup>	118,359	0.2	23,672
	BSE case cohort	716	0.1	71
	Subtotal	124,092		249,508
Abattoir	CNS Symptoms <sup>2</sup>	17,654	45	794,430
	Age > 30 months of age	1,594,757	0.1	159,475
	Age < 30 months of age	2,396,000	0.01	23,960
	Subtotal	4,008,411		977,865
Total		4,132,503		1,227,373

Source: Compiled from information provided by MAFF (MAFF, 2005b).

<sup>1</sup>As of October 2001, testing of all dead cattle 24 months of age or older became mandatory.

<sup>2</sup>Among cattle of 24 months or older, those suspected of having nervous signs (dyskinesia, perceptual disorder, reflex or consciousness disturbance, etc.) and those showing signs for the entire body (See Table 5).

As noted above, these calculations were based on certain assumptions. Although the definition of a clinical suspect is very specific in the OIE chapter, in Table 6, it appears that all cases Japan reported as on-farm CNS suspects and all cases reported as “risk cattle” in abattoir testing met the definition of a clinical suspect. When compared to U.S. surveillance experience, these numbers seem higher than expected for a country with an adult cattle population of approximately 2 million. If this assumption is changed significantly, and we assume that only half of those animals reported in these categories meet the definition of clinical suspect, the total number of points accumulated is 717,253. Taking this one step further, we can assume only one-third of the animals in these categories meet the definition of clinical suspect, and the total number of points accumulated is 547,198. Even with these conservative assumptions, the number of points exceeds the OIE recommendation.

The OIE Code notes that the goal of surveillance changes after a country has determined that BSE exists within its cattle population. At that time, the surveillance goal may change from detection of disease to monitoring the extent of the disease and the

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effectiveness of control measures. The Code notes that this may require more intensive surveillance efforts.

### **VI. MBM and greaves derived from ruminants have not been fed to ruminants**

Japan has had legislation in place since April 11, 1953 (Law Concerning Safety Assurance and Quality Improvement of Feeds, or Feed Safety Law), that enables enforcement of Japan’s feed ban. Those regulations are updated regularly (Feed Safety Law, 2003). The Feed Safety Law addresses, among other things, the production of feed and feed additives, official specifications for feed, and rules about testing for conformity with official specifications. There are also guidelines regarding the processing, transport, storage, manufacture and shipping of rendering materials (ruminant and non ruminant materials).

MAFF Ordinances (Chapter 2: Regulations about manufacture, etc. of feeds, Article 3 Standards and specifications) (Feed Safety Law, 2003) allocates regulatory authority to the Minister of MAFF. Subsequently, regulation of feed for cattle, sheep, goats, and deer that contain mammalian proteins was regulated by amending MAFF Ordinance No. 35, concerning Standards and Specifications for Feeds and Feed Additives, on July 24, 1976. The Ordinance requires keeping records on names, dates and place of usage of all feeds, the type of livestock being fed, the amount of feed used, and the date of purchase and distributor of the feed.

In April 1996, an administrative guidance was issued in the name of the Division Chief, Feed Distribution Division of the Livestock Bureau of the MAFF regarding the prohibition of the use of protein originating from ruminants as feed for ruminants (MAFF, 1996). Agricultural Administration Offices, prefecture and city governments, fertilizer and feed inspection services, related bodies (17 bodies) such as formula feed manufacturers’ associations, and all beef and dairy farmers received a booklet describing the specifics of the guidance.

On September 18, 2001, following the detection of the first BSE case, Japan prohibited ruminant MBM from use in ruminant feed. In October 2001, Japan issued an Ordinance (amended Ordinance No. 35; pertinent regulation contained in Article 1, Attachment No. 1, 1, (1), I) and implemented a complete ban on the use of mammalian protein, including blood products, as well as fish meal and poultry meal as feed for cattle, sheep, goats, and deer. The ban was fully implemented in January 2002. Use of ruminant-derived MBM is totally prohibited under the Feed Safety Law (Feed Safety Law, 2003). MBMs, which cannot be used either as fertilizer or livestock feed, are incinerated.

According to the Ministerial Ordinance concerning Standards and Specifications for Feeds and Feed Additives (Ordinance No. 35, Ministry of Agriculture and Forestry, July 24, 1976) as amended (Attachment No. 1, 1, (2), M), feed, raw materials, and ingredients used to produce feed for cattle, etc.<sup>2</sup> must be manufactured using processes completely

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<sup>2</sup> This language is taken directly from MAFF’s regulation. The “etc.” refers to sheep, goats, and deer.

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isolated from the manufacturing processes for feed (including raw materials and ingredients that are used to produce feed) containing mammalian, poultry, or fish proteins. Swine or equine blood meal or protein, chicken meal, feather meal, and poultry blood meal and protein can be used as feed for livestock<sup>3</sup> other than cattle, sheep, goats, and deer, only if processed in a dedicated line under conditions certified by MAFF.

Facilities must have separate lines to produce minerals, roll grains, and other materials that go into ruminant and nonruminant feeds (Feed Safety Law, 2003). However, the amended Ordinance did not take effect until April 1, 2005, for manufacturers who produce feed for cattle, sheep, goats, or deer. Further, feed containing mammalian, poultry, or fish proteins must be stored so that it will not contaminate feed (including raw materials or ingredients used to produce feeds) for cattle, etc. (Attachment No. 1, 1, (4), C). As of October 2004, 96 of the 136 formula feed companies had either built separate lines for ruminant and nonruminant feed or had chosen to produce only one type of feed. The remaining 40 firms were required to either build separate lines for ruminant and non-ruminant feeds or cease producing both types by April 1, 2005 (Feed Safety Law, 2003). MAFF does not require specific procedures for flushing except for requiring use of an appropriate material, usually corn, soy waste, etc. Ruminant MBM can be used in fertilizer only from BSE negative animals and after SRM removal (FFIS and MAFF, 2005).

### *VI.A. Feed ban compliance*

All feed manufacturers, rendering facilities, and farmers/ranchers are subject to Japan’s feed regulations. Penalties for violating the Feed Safety Law are outlined in Chapter 6, “Penal provisions,” Article 67, 1 of that law (Feed Safety Law, 2003). Any person who violates the Feed Safety Law faces imprisonment for up to three years or a fine of up to 1 million yen (U.S. \$8,919)<sup>4</sup>, or both. Further, Article 72, 1 and (1) states that where any representative, agent, employee, or other worker of a corporation, or an individual violates any of the provisions in the Feed Safety Law the corporation will also be subject to a fine up to 100 million yen (U.S. \$891,740)<sup>4</sup>. In accordance with Article 73, 1, members of the Board of Directors of an Inspection Station who violate the order also face fines of up to 200,000 yen (U.S. \$1,784)<sup>4</sup>.

If a feed manufacturer violates regulations pertaining to ingredient standards, production methods, record-keeping, storage methods, labeling methods, or methods of use, MAFF issues a binding order to the manufacturer to stop shipping the non-compliant product as well as instructions for disposal or recall of the product (Feed Safety Law, Articles 23 and 24, 2003). Following notification of a violation, MAFF personnel provide technical assistance to Feed and Fertilizer Inspection Service (FFIS) staff in investigating the cause of violation. If the manufacturer fails to comply, all further feed production, sale, and use

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<sup>3</sup> Under MAFF regulations, the definition of “livestock” includes: cattle, pigs, sheep, goats, deer, chickens, quail, bees, and fish that are widely produced through aquaculture for human consumption.

<sup>4</sup> Using the rate of exchange (1 U.S. dollar = 112 Japanese yen) current as of July 2005.

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from that facility is prohibited, and all feed manufactured at that facility is destroyed or recalled and subsequently destroyed. Additional measures, in accordance with feed safety regulations, include imprisonment and fines for owners and managers.

FFIS and Prefectural governments have jurisdiction to perform inspections for feed ban compliance. Since April 1, 2001, FFIS has operated as an Incorporated Administrative Agency under “The Incorporated Administrative Agency, Fertilizer and Feed Inspection Services Law.” The FFIS, which receives guidance for its operations from MAFF, is concerned with food safety. The FFIS head office in Saitama-City is staffed with 47 inspectors. The FFIS field staff work from five branch offices: Sapporo (12 inspectors), Sendai (12 inspectors), Nagoya (14 inspectors), Osaka (21 inspectors), and Fukuoka (16 inspectors).

FFIS inspectors perform unannounced on-site inspections of feed manufacturers and feed importers. Fertilizer, soil amendments, feed or feed additives, and their raw materials, are inspected as well as all records and business documents. FFIS collects samples, conducts physical and chemical analyses of these samples, as well as conducts potency tests, animal tests, and cultivation tests to determine if products contain the components indicated, if products are free from harmful components, and if products meet official specifications and standards. FFIS takes samples for feed microscopy analysis from all formula feed manufacturers. All inspection results are reported to MAFF; if violations occur, MAFF takes administrative action including issuing guidance or citing violators who may be held liable for civil and/or criminal penalties. FFIS provides technical guidance to manufacturers or importers to improve processes or areas where violations occur (MAFF, 2005b).

FFIS, under the guidance of MAFF, also conducts safety inspections at every rendering facility at least once per year. Of the 121 rendering facilities in Japan, 69 facilities handle ruminant material and have a total of 132 production lines for producing feed: 31 ruminant-only lines; 48 ruminant and other animal lines; and 53 non-ruminant animal only lines. Rendering facilities accept downer animals only if they are accompanied by a veterinary certificate verifying that the animals are not BSE-suspect (MAFF, 2005b).

Government inspectors from the 47 Prefectures in Japan visit wholesalers and farmers and are authorized to inspect the same manufacturers and other facilities that FFIS inspects, provided the facility is within the prefecture (MAFF, 2005b).

Results of inspection activity are summarized for fiscal years (FY) 2001, 2002, 2003, and through the third quarter of FY 2004 are detailed in the following paragraphs (MAFF, 2005b).

### FY 2001 (April 1, 2001-March 31, 2002)

During the period from September 12 to 21, 2001, as part of the epidemiological investigation of the first BSE case, FFIS conducted on-site inspections on approximately 142 major formula feed companies nationwide. The inspections did not find any

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violations of using ruminant MBM and greaves as ingredients in feed destined for ruminant (MAFF, 2005b).

FY 2002 (April 1, 2002-March 31, 2003)

FY 2002 was the first full year of inspections following implementation of the feed ban. FFIS listed 2,653 feed facilities in Japan.

**Table 7. Feed ban inspection activities in Japan, FY 2002.**

Facility Type	No. of Facilities	No. of Inspections
Major formula feed manufacturers	146	220
Other formula feed manufacturers	527	75
Fishmeal & rice bran plants	935	232
Other (warehouses, additives, etc.)	1,045	140
Total	2,653	667

Source: MAFF, 2005b.

Major formula feed companies are the entities that produce feed for livestock and are the group of facilities most closely scrutinized by FFIS inspectors for compliance to the feed ban. All major formula feed manufacturing companies are inspected at least once each fiscal year. For the remaining types of feed facilities, a sample of facilities is picked randomly to inspect. All inspections are unannounced.

For 2002, 1,618 samples of feed were collected during 667 inspections of the facilities selected. Out of the 1,618 samples, 536 samples of feed were taken specifically for BSE testing purposes (samples screened via microscopy for presence of mammalian protein; positive samples tested further using ELISA and/or PCR). No feed contaminated with ruminant protein was found. Of the 4 total violations that were identified, 3 were for the presence of an insoluble impurity (animal oil and fat) in excess of the level specified by the ingredient standards and 1 was for the presence of feather meal contamination in fish meal protein supplement (MAFF, 2005b).

FY 2003 (April 1, 2003 – March 31, 2004)

In FY 2003, 680 facilities were inspected out of 2653 facilities (25.6 percent), including all 140 major formula feed manufacturers. No violations for prohibited animal protein were found. The 8 violations that were found (0.7 percent) were either for antibiotic contamination or chemical contamination of feeds tested (MAFF, 2005b).

In addition, 1,962 out of 127,900 cattle farms (1.5 percent) were inspected for compliance with the feed ban. Three farms (2 dairies and 1 beef operation) were found to be feeding fish meal in their feed (MAFF, 2005b).

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### FY 2004 (April 1, 2004 – October, 2004)

As of October 2004, 136 formula feed companies existed in Japan. Inspections of these facilities are ongoing for this fiscal year. However, through the end of the third quarter, no violations for prohibited animal protein have been found.

Through the third quarter of 2004, approximately 1,000 inspections have been conducted on farms. No violations have been found (MAFF, 2005b).

### **VII. Animal identification and traceability**

According to Japan’s Special Measure Law, all animals that test positive for BSE are incinerated. In addition, if an animal is diagnosed with BSE, all offspring born to the affected animal within 2 years prior to, or after, clinical onset of the disease are destroyed. All birth cohorts of the affected animal are also destroyed.

The Japanese government and the livestock industry maintain an animal ID system that allows traceback of all animals to dam and herd of origin. In addition, a genetic registry is maintained that allows confirmation of breed origin by animal ID and can confirm purebred status by DNA testing to assure compliance with the provision of the proposed rule.

To ensure that measures to prevent the spread of BSE are implemented correctly, and to secure confidence in the safety of beef for domestic consumption in Japan, at all stages from production to distribution and consumption, the Law for Special Measures Concerning the Management and Relay of Information for Individual Identification of Cattle (Beef Traceability Law) (MAFF, 2003) was announced in June 2003. Enforcement activities for this law began in December 2003 for all livestock producers and also at the 162 slaughter plants in Japan. Processors, distributors, and retailers had until December 1, 2004, to provide traceability information from the slaughterhouse to the retail outlet.

#### *VII.A. Animal Identification at the Farm*

Animal ID at the production stage required the national government to prepare an Individual Identification Register. This was commissioned to the National Livestock Breeding Center (NLBC) located in Fukushima. The Center prepared an individual cattle identification register, in which the following individual ID data is recorded and managed:

- Individual 10-digit ID number
- Date of birth
- Gender
- Individual ID number of dam
- Raising location(s) and raising person(s) from birth to slaughter

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- Dates of outgoing and incoming transfers (buyer and seller are both responsible for providing this information)
- Date of slaughter or death (owner and slaughter plant responsible for providing this information)
- Other details (breed, location of abattoir, etc.)

When the program began, the initial livestock inventory was to be supplied to NLBC. NLBC supplied tags (numbers randomly generated) at government expense to each owner for the initial inventory. Tags were applied to both ears. Thereafter, owners were responsible for reporting births, deaths, and movements. Typically, on-farm inventory changes are reported within one week for dairy calves and within one to two months for beef calves. The required number of tags are then sent to the owner from stocks maintained at the national level. The cost of tags is borne by national government. All persons are prohibited from removing ear tags or transferring or receiving cattle without ear tags. Lost ear tag(s) must be reported to NLBC, which re-issues tag(s) with a duplicate 10-digit number. Regional Agriculture Bureau inspectors visit farms to assess compliance. Fines up to 30,000 yen (U.S. \$ 268)<sup>5</sup> can be levied against producers for non-compliance.

### *VII.B. Animal Identification at Slaughter*

Abattoirs are required to notify the NLBC of the date of slaughter of all animals. Individual Identification Numbers (IINs) must be relayed to each buyer of the carcass. A record of these data must be maintained on-premises.

Identification of each carcass is maintained as the carcass is processed into primal cuts. The 10-digit ID from the ear tag of the animal slaughtered is transferred to each primal cut. In addition, upon shipping, an additional 4-digit number identifying the abattoir is attached to the shipping boxes along with the 10-digit ID number(s) traceable to the animal(s).

Abattoirs and meat wholesalers are required to collect reference muscle tissue samples from all carcasses for future random DNA testing. Inspectors collect 10,000-20,000 meat samples annually in a random sample of meat retailers to verify the IINs corresponding to the meat items are from the same carcass traced to the abattoir where the animal was slaughtered. DNA from the carcass and meat item are compared to determine if identification is accurate.

### *VII.C. Animal Identification in Distribution Channels*

Beef for domestic consumption in Japan is subject to animal ID requirements. This “designated beef” is beef derived from cattle whose information is recorded in the Individual Cattle Identification Register maintained by NLBC. Manufactured or processed beef products, as well as certain fresh products such as “minced meat” or

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<sup>5</sup> Using the rate of exchange (1 U.S. dollar = 112.118 Japanese yen) current as of July 2005.

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“small cuts of meat,” are exempt from these requirements because in many cases the number of cattle involved would be quite high, thus tracking and listing the corresponding cattle IINs would be extremely time-consuming and costly.

Businesses subject to the Beef Traceability Law (MAFF, 2003) are businesses that sell beef (“Sellers”) and businesses that supply cuisine stipulated by Cabinet Order, based on beef as its principal ingredient (“yakiniku,” “sukiyaki,” “shabu-shabu,” and “steak”). Thus, sellers must relay IINs and other information to purchasers; IINs must be indicated on the container or package, on the invoice, or in an easily visible location in retail or other stores. Recording and management of these data must be available on-premises.

Collateral measures of the Beef Traceability Law include on-site inspections by MAFF (Director-General of the Regional Agricultural Administration Office) inspectors. Restaurants and retail establishments must make public the IINs of beef offered for sale. Individual ID data are disclosed to the public on the internet; the names and details of producers are excluded from the public record. Consumers, distributors, and producers can confirm individual ID data corresponding to cattle at any time, at every stage from production to distribution and consumption. The regulation does not apply to offal, trimmings, ground beef, or processed products. Penalties for non-compliance include warnings, fines, and publication of names of noncompliant processors, distributors, or retailers (MAFF, 2003).

To respond to Japanese consumers’ demands for accountability within the country’s meat distribution system, MAFF and the Japan Agricultural Standard Council (JAS) announced a traceability and certification system for domestic beef, beginning in April 2003. Beef Exporters can enroll in the program as well. Whereas the Beef Traceability Law is mainly concerned with facilitating the ability of governmental officials to track the movement and ownership changes in cattle via a mandatory ID system, the JAS certification program requires exporters to provide, in addition to mandatory 10-digit ID numbers, the following information for each animal: date of birth, sex, and breed; name and address of the owner; location of fattening site; date fattening commenced; date of slaughter; and names of all feeds and pharmaceuticals used in producing the animal.

### **VIII. Ante- and post-mortem inspections**

Japanese regulations on inspection contain requirements regarding ante- and post-mortem inspections. Slaughter is prohibited for all cattle that present neurological signs compatible with BSE. If veterinarians (employed by the Prefectural government) diagnose cattle as suspect for BSE during an ante-mortem examination in an abattoir, official action is taken to prohibit the slaughter and processing of such cattle, and notification is sent to the cattle owner, the abattoir owner, and the Prefectural authority. The BSE-suspect animal is removed from the slaughter plant premises and relocated to a Livestock Hygiene Service Center within the prefecture for further observation, testing, and appropriate disposition.

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Based on Article 14, 1 of the Abattoir Law (MHLW, 2004), all animals must pass ante-mortem inspection before being slaughtered and must pass post-mortem inspection before their meat can be approved for consumption. These inspections are conducted by official veterinarians employed by the Prefectural governments under the supervision of MLHW (the agency responsible for food safety), which ensures BSE testing is carried out on all animals, regardless of their age, during the post-mortem examination. When BSE is suspected at post-mortem examination, all parts originating from that animal are identified by the respective 10-digit national ID number and held until results are confirmed.

Cattle diagnosed with BSE and all contaminated materials in abattoirs are incinerated. All SRMs removed at slaughter are either directly incinerated or incinerated after being rendered (to reduce volume). SRMs in dead stock or carcasses that are delivered directly to rendering facilities are also directly incinerated or incinerated after rendering processes. The owner or facility manager must thoroughly disinfect the facilities, equipment, instruments, and appliances that have been or may have been in contact with SRMs. The owner or manager of the abattoir must provide all information required for investigation.

### **IX. BSE-related import restrictions in Japan**

Japan has prohibited the importation of live cattle from the United Kingdom (UK) and other BSE-affected countries since 1990. This prohibition was extended to the European Union (EU), Switzerland, and Liechtenstein in January 2001. Currently, no imports of live cattle are allowed from any country where BSE has been diagnosed.

The policy addressing imported MBM has evolved over the years as a result of new knowledge on inactivation of the BSE agent during the rendering process. Japan’s policies closely mirrored decisions and recommendations of the European Commission that were issued over the period that new BSE cases in Member States were reported. Beginning in July 1990, Japan prohibited the importation of MBM from BSE countries except for MBM processed under specific standards (i.e., 133° C for 20 minutes at 3 bar). In 1996, all imports of MBM from the UK or from other countries using raw material from the UK, were completely banned. Subsequently, Japan banned imports of processed animal protein (such as MBM) from all Member States of the European Union. As of October 2001, based on a recommendation from the Japanese “Technical Meeting concerning BSE” held in September of that year, Japan banned the importation of MBM for use in feeds or fertilizers from all countries.

### ***APHIS’ evaluation of conditions in Japan***

APHIS evaluated all of the information discussed above when considering whether to propose allowing the importation of boneless beef from Japan. However, the only information that is directly relevant to our assessment of the risk associated with the importation of boneless beef is that information related to slaughter practices that could result in contamination of the beef. The pathways and mitigations to prevent

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contamination via these pathways are discussed in the main body of this risk analysis. APHIS believes that the risk associated with practices in Japan that could result in contamination of boneless beef are addressed by the mitigation measures we have identified, and APHIS considers MAFF competent to certify to those measures.

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APPENDIX B – Human Health Considerations: A Supplement to APHIS’ Analysis of Bovine Spongiform Encephalopathy (BSE) Risk to the U.S. Cattle Population from Importation of Whole Cuts of Boneless Beef from Japan

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Office of Public Health Science

Food Safety and Inspection Service  
United States Department of Agriculture

## APPENDIX B – Human Health Considerations: A Supplement to APHIS’ Analysis of Bovine Spongiform Encephalopathy (BSE) Risk to the U.S. Cattle Population from Importation of Whole Cuts of Boneless Beef from Japan

### **Introduction**

The Food Safety and Inspection Service (FSIS) is the United States Department of Agriculture's (USDA) public health regulatory agency responsible for ensuring the safety of the nation’s meat, poultry, and processed egg products supply. FSIS has developed this analysis titled “Human Health Considerations: A Supplement to Animal and Plant Health Inspection System’s (APHIS) Analysis of Bovine Spongiform Encephalopathy (BSE) Risk to the U.S. Cattle Population from Importation of Whole Cuts of Boneless Beef from Japan” to focus on the impact to human health. In this analysis FSIS considered the likelihood of human illness from BSE associated with whole cuts of boneless beef imported from Japan.

APHIS has developed the risk assessment titled “Analysis of Bovine Spongiform Encephalopathy (BSE) Risk to the U.S. Cattle Population from Importation of Whole Cuts of Boneless Beef from Japan” to inform a proposed rule that will establish conditions to allow entry of only whole cuts of boneless beef derived from cattle that were born, raised, and slaughtered in Japan. The APHIS risk assessment qualitatively evaluates the likelihood that whole cuts of boneless beef imported from Japan under certain conditions would introduce BSE into the U.S. cattle population. The risk assessment for whole cuts of boneless beef developed by APHIS covers all the relevant infectivity pathways from animal production through slaughter. FSIS has utilized the APHIS risk assessment and additional information to further analyze the implications to human health from the importation of boneless beef from Japan.

BSE infectivity has to date not been demonstrated in the muscle tissue of infected cattle examined in either the mouse bioassay or the cattle assays. The source of BSE infectivity to whole cuts of boneless beef is potentially through cross contamination from SRM tissues during slaughter. Although the likelihood of infectivity reaching boneless beef through cross contamination is low, slaughter practices such as carcass splitting, SRM removal, stunning and pithing can influence the extent and level of cross contamination to this product.

Currently, information on the human dose-response relationship for the BSE agent and variant Creutzfeldt-Jakob Disease (vCJD) is not available. As a result, exposure serves as a surrogate for estimating human health risk. When additional information becomes available, it may be considered to develop quantitative risk estimates.

### **Human Health – Variant CJD**

Variant CJD (vCJD) is a rare and fatal human neurodegenerative condition. In contrast to traditional forms of CJD, vCJD affects younger patients (average age 29 years, as opposed to 65 years); has a relatively longer duration of illness (median of 14 months as opposed to 4.5 months); and is linked to exposure, probably through consumption of products derived from BSE infected cattle (WHO, 2005).

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According to the International Society for Infectious Diseases, from October 1996 to April 2005, there were 155 confirmed or probable cases of vCJD reported in the United Kingdom (UK) (Department of Health, 2005). There were nine vCJD cases reported in France, two in Ireland, and one each in Canada, Hong Kong, the U.S., and Japan. The cases of vCJD that are reported from Canada, Hong Kong, the U.S., and Japan are due to exposure in the United Kingdom.

### **Infectivity in Muscle Tissues**

BSE infectivity has to date not been demonstrated in the muscle tissue of infected cattle examined in either the mouse bioassay or the cattle assays. The issue of BSE infectivity in relation to the muscle tissue has been reviewed and discussed further in the APHIS risk assessment (APHIS 2005). Cross-contamination during slaughter is a potential pathway through which BSE infectivity could contaminate the carcass and the boneless beef product.

#### ***Cross-contamination of whole cuts of boneless beef***

During slaughter, the source of BSE infectivity to whole cuts of boneless beef is potentially from infected SRMs. Although the likelihood of infectivity reaching boneless beef through cross contamination is low, certain slaughter practices may increase the likelihood of cross contamination. It should be noted that the pathogenic form of the prion protein (PrP<sup>Sc</sup>) is both less soluble and more resistant to degradation than the normal form (Taylor, 2000; Taylor et al., 1995). Additionally, PrP<sup>Sc</sup> is extremely resistant to heat and to normal sterilization processes, making it difficult to inactivate with standard methods used to process human food and animal feed. Hence, during slaughter, prevention of cross contamination is an important mitigation with reference to the cuts of boneless beef.

Japan has instituted safeguards over the years and continues to strengthen its mitigations for BSE control. The three pathways (i.e., stunning and pithing, carcass splitting, and improper SRM removal) and the mitigations that control potential cross contamination of the whole cuts of boneless beef have been reviewed and discussed further in the APHIS risk assessment (APHIS 2005). Stunning by air injection devices and pithing practices are not allowed in Japanese establishments certified by Japan/FSIS inspection system as being equivalent to that of the United States. Further information on these practices as they relate to the risk of BSE in other tissues may be obtained from FSIS interim final rule entitled, “Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter” (Docket No. 01-0331F, 69 FR 1885-1891), published on January 12, 2004 (FSIS, 2004a). Like the U.S. system of processing beef, in Japan, the SRMs are removed in ways to avoid contamination of the carcass and thus reduce the potential for contamination of beef products that will be consumed by humans. The Japanese establishments also remove the vertebral column as a unit to reduce the likelihood of the DRG contaminating boneless meat. These pathways and the likelihood of contamination of whole cuts of boneless beef are discussed adequately in the

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APHIS, 2005 risk assessment and will not be addressed in detail in this analysis. It is important to note that, when applied together at slaughter, the different safeguards provide an ample protection against the risk of cross-contamination of the whole cuts of boneless beef.

### **FSIS equivalency determination**

As required under the Food Meat Inspection Act, FSIS ensures that imported meat in the U.S. marketplace is safe, wholesome, unadulterated, and properly labeled by: (1) determining if foreign countries and their establishments have implemented food safety system and inspection requirements equivalent to those in the United States; and (2) re-inspecting imported meat and poultry products from those countries through random sampling of shipments. The FSIS regulations in 9 CFR 327.2 (FSIS, 2004b) provide that countries eligible to export meat to the United States must have a meat inspection system determined by FSIS to be equivalent to the U.S. meat inspection system. The FSIS equivalency determination is based on a review of the foreign country’s relevant laws and regulations and an on-site audit of the foreign country’s inspection system.

If FSIS determines that a foreign country’s meat inspection system is equivalent to the U.S. system, FSIS conducts a rulemaking to add that country to the list in 9 CFR 327.2 of countries eligible to export meat and meat products to the United States. Once a country is listed as eligible to export meat and meat products to the United States, it is responsible for certifying individual exporting establishments to FSIS and for providing annual recertification documentation.

FSIS has determined that Japan’s meat inspection system is equivalent and that Japan is eligible to export meat and meat products to the United States and a list of Japanese slaughter plants authorized to export meat and meat products to the United States has been already developed. The last two FSIS audits of Japan’s meat inspection system were conducted in August 2004 and January 2005. During the August 2004 audit, it was found that in one of four establishments audited, BSE was not considered in the HACCP hazard analysis as a hazard reasonably likely to occur. However, it was also found that all of the measures required by the United States, including specified risk material segregation, removal and disposal had been implemented and were being followed as required in all four establishments audited. During the January 2005 audit, it was found that Japan continues to employ all the U.S. BSE requirements, and none of the four establishments received a Notice of Intent to Delist (NOID) or were delisted by Japan (FSIS Audit Report 2005).

Additionally, in the certified Japanese slaughter plants the potential for SRM contamination of whole cuts of boneless beef is further reduced by adopting the practice of suction removal of spinal cord before the splitting of the carcasses (FSIS Audit Report 2005). This is believed to be an effective mitigation to address the potential source of infectivity that could lead to the cross-contamination of carcasses and the boneless products.

This analysis makes qualitative inferences rather than quantitative ones, due to the type of information available. Moreover, all human health risk assessments for BSE currently utilize

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human exposure as a surrogate for human illness because no scientific dose-response relationship has been established.

### **Conclusion**

Given the mitigations to prevent the importation of BSE-infected products, APHIS concludes that the risk of BSE release is extremely unlikely. The FSIS analysis further considered the potential for human exposure to BSE infectivity through imported whole cuts of boneless beef from Japan by evaluating the various infectivity pathways outlined in APHIS risk assessment, FSIS equivalency requirements, and relevant additional information for human exposure. Specifically, the FSIS analysis on human implications of importation of whole cuts of boneless beef derived from Japanese cattle found that there is no evidence to date of the BSE agent in muscle tissue of infected cattle. The Japanese meat inspection system has been determined by FSIS to be equivalent to the inspection system in the United States, and those establishments eligible to export beef to the United States are certified by the government of Japan and are audited by FSIS. Thus, the probability of cross-contamination of carcasses with spinal cord and DRG and the subsequent cross-contamination of whole cuts of boneless meat during trimming is very low. As such, FSIS concluded that mitigations from production through slaughter and processing provide an interlocking system of safeguards and reasonable certainty that whole cuts of boneless beef derived from Japanese cattle are safe for U.S. consumption and would pose similar and no greater level of risk as product produced for human consumption in the United States.

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