BSE Food Safety Assessment Report

United States of America

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Strategic Science, International and Surveilance Section

Food Standards Australia New Zealand

Executive summary

Food Standards Australia New Zealand (FSANZ) is the regulatory body responsible for conducting Bovine Spongiform Encephalopathy (BSE) food safety assessments of countries that seek to export beef or beef products to Australia. FSANZ analyses the information provided by applicant countries and assigns them a BSE risk status. The requirements detailed in the *Australian Questionnaire to Assess BSE Risk*[1] are based on those of the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code* (2009)[2]. The United States of America (USA) made a submission in 2010 to be assessed under the current BSE policy.

The World Organisation for Animal Health (OIE) upgraded the USA to negligible risk status in May 2013.

FSANZ has conducted an assessment of legislative measures in the USA concerning control and prevention of BSE, and an in-country assessment of the application and enforcement of these legislative measures. Five main control areas were examined:

(1) ***Import controls*** to prevent the release into the country of the BSE agent through imports of animals or animal-derived products.

(2) ***Feed ban controls*** to prevent entry of and recycling in the animal feed supply by the BSE agent.

(3) ***Food safety controls*** to prevent contamination of the human food supply with the BSE agent.

(4) ***Traceability and animal identification systems*** to ensure animals and animal-derived products can be effectively identified and recalled if required.

(5) ***Surveillance programs*** to ensure that BSE affected animals are identified and removed from the feed and food production systems.

The release of the BSE agent into the USA through imports of live bovines or products of bovine origin is extremely unlikely. Live animals are only imported from countries that have not reported cases of BSE or from Canada. Restrictions on live cattle coming from Canada since 2003 have minimised the possibility of BSE infectivity coming from this source. Bovine products are only imported from countries considered not to pose a BSE risk, or from countries under permit for specific uses only. Since 2000, regulations have prohibited the entry of any processed animal proteins, or feed products containing animal proteins, from countries with reported BSE or considered to present an undue risk of BSE.

Animals at the highest risk for BSE are identified through rigorous ante-mortem inspection procedures through prohibiting non-ambulatory animals or those animals showing clinical signs consistent with BSE, from entering the slaughter chain and rendering system. Disposal of such animals is through incineration and/or landfill. In addition, the brain and spinal cord of older animals and other high risk cattle materials prohibited in animal feed (CMPAF) are prohibited from being rendered and used for animal feed. Audit results from both the BSE feed inspection program and the BSE feed testing program in the USA since 2005 show an extremely high level of compliance with the BSE feed regulations. Feed manufacturers are required to have procedures in place to prevent cross-contamination and it is estimated that over 98 per cent of feed manufacturers in the USA meet this requirement through dedicated facilities—that is, feed mills that do not use prohibited material where they produce feed for ruminant animals. The USA has demonstrated, through an appropriate level of audit and

controls for more than eight years, that neither MBM nor greaves derived from ruminants is likely to have been used to feed ruminants. Consequently there is a very limited possibility that BSE would enter and recycle in the animal feed system within the USA.

Compliance with regulations ensures that good hygienic practices are employed throughout the beef production and supply chain so that the risk of cross-contamination of edible product with potential BSE infected materials is minimised. BSE disease contingency plans for BSE are well established with defined responses across federal and state agencies. Food industries, including slaughterhouses, are required to establish and maintain traceability and food recall processes and these processes are audited and tested for effectiveness and efficiency through annual mock recalls. As a result of these system requirements, it is considered that the recovery of contaminated beef and beef products could be achieved in a timely and effective manner.

The United States takes an active approach with its BSE awareness programs, notification requirements, and laboratory diagnostic procedures. Significant resources are dedicated to: train animal health inspectors; prepare laboratory diagnosticians; educate livestock producers, renderers, and private practitioners; and alert the public about BSE. BSE has been a reportable disease in the USA since 1986. The USA has extensive national laboratory services for the testing of BSE and together with the national coordination, training activities and reference testing undertaken by the National Veterinary Surveillance Laboratories, has the field and laboratory expertise and capability to detect, accurately diagnose, and confirm BSE.

Trace back and cohort identification in the event of a BSE case investigation is achieved by Federal authorities working closely with State Departments to coordinate activities and to utilise a number of private and public sources of information so that animal movements are tracked and risk animals identified and managed. This has been effectively demonstrated in the active investigations undertaken by authorities as a result of the one imported Canadian and three indigenous atypical BSE cases in the USA. In addition the recently commenced national animal disease traceability system will strengthen the ability to consistently trace cattle when moved inter-state. To ensure the traceability of imported cattle, APHIS requires that imported cattle must be accompanied by a permanent form of individual identification, and APHIS keeps records of the number and source of imported cattle in the APHIS Import Tracking System.

The United States has conducted BSE surveillance since 1990, finding three positive indigenous animals reported in 2005, 2006 and 2012 and an imported Canadian case reported in 2003. All indigenous cases were subsequently shown to be atypical forms of BSE and were born more than eleven years ago. From 2006 to 2012, surveillance results show that the United States has accumulated 7,433,447 surveillance points, which exceeds the OIE requirements for Type A surveillance by over 20 times. This high level of surveillance is expected to continue within the USA.

BSE controls were observed to be operating effectively during the in-country assessment with a high degree of official government oversight by the United States Department of Agriculture and the Food and Drug Administration, and coordination with State authorities. Appropriate monitoring and inspection procedures were verified across the beef production chain. Auditing of establishments (feed mills, slaughterhouses, farms and rendering plants) by the competent authority occurs regularly, and major non-compliances around official BSE controls have not been detected for many years.

In conclusion, the United States has comprehensive and well established controls to prevent the introduction and amplification of the BSE agent within the cattle population and to prevent

contamination of the human food supply with the BSE agent. This BSE food safety risk assessment concludes that imported beef and beef products sourced from the USA are safe for human consumption and recommends **Category 1 status** for the USA.

Acronyms

ABCCC	Australian BSE Country Categorisation Committee
ADT	Animal Disease Traceability
APHIS	Animal and Plant Health Inspection Service; an agency of the United States Department of Agriculture
BSE	Bovine Spongiform Encephalopathy
CFR	Code of Federal Regulations
CMPAF	Cattle materials prohibited in animal feed
CNS	Central nervous system
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry
FAO	Food and Agriculture Organisation of the United Nations
FDA	Food and Drug Administration of the United States
FFDCA	The Federal, Food, Drug, and Cosmetic Act of the United States
FMIA	The Federal Meat Inspection Act (FMIA) of the United States
FSANZ	Food Standards Australia New Zealand
FSIS	Food Safety and Inspection Service, an agency of the United States Department of Agriculture
HACCP	Hazard analysis and critical control points
ICP	Incident command post
ICVI	Interstate certificate of veterinary inspection
MBM	Meat-and-bone meal
NVSL	National Veterinary Services Laboratories
OIE	Office International des Epizooties (World Organisation for Animal Health)
PCR	Polymerase chain reaction
SOP	Standard operating procedure
SRM	Specified risk material
TSE	Transmissible spongiform encephalopathy
UK	United Kingdom of Great Britain and Northern Ireland
USA	United States of America
USDA	United States Department of Agriculture

Glossary

Accredited veterinarians operating under the United States Department of Agriculture's (USDA) system of accreditation can perform a range of animal health related functions on behalf of the government and include: clinical examinations of animals and herds for communicable diseases; recognize USDA animal identification systems and apply USDA-recognized identification; estimate the age of livestock using dentition; complete certificates for domestic and international movement of animals; apply and remove official seals; perform necropsies on animals; and recognize and report clinical signs and lesions of exotic animal disease.

Australian Questionnaire refers to the *Australian Questionnaire to Assess BSE Risk* which lists the data requirements for countries wishing to export beef or beef products to Australia and seeking to be assessed for BSE risk.

BSE agent is the infectious mis-folded protein, or prion, that causes BSE.

Cattle materials prohibited in animal feed (CMPAF) are defined as: the entire carcass of BSE-positive cattle, the brains and spinal cords from cattle 30 months of age and older, the entire carcass of cattle not inspected and passed for human consumption (unless the cattle are less than 30 months of age or the brains and spinal cords have been effectively removed), and tallow or mechanically separated beef from any of the above materials (except tallow containing no more than 0.15% insoluble impurities).

Cohorts, for the purpose of Section 4 of the Australian Questionnaire are all cattle which, during their first year of life, were reared with cattle in their first year of life that subsequently developed BSE, and which investigation shows consumed the same potentially contaminated feed during that period, or if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE cases.

Specified risk material (SRM) as defined by United States legislation is: the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, transverse processes of the thoracic and lumbar vertebrae, and wings of the sacrum), and dorsal root ganglia from cattle 30 months of age and older, and the distal ileum of the small intestine and the tonsils from all cattle.

Table of Contents

Introduction

Food Standards Australia New Zealand (FSANZ) is the regulatory body responsible for assessing the BSE food safety risk of, and assigning a status to, countries that seek to export beef or beef products to Australia. Individual countries are responsible for submitting comprehensive data to FSANZ around their BSE risk and associated risk management and controls. FSANZ assesses the information and data submitted by the applicant country in accordance with requirements set out in the *Australian Questionnaire to Assess BSE Risk*[1](the Australian Questionnaire). Legislation and standards underpinning BSE controls are also examined as part of the food safety assessment and these were provided as appendices to USA's response to the Australian Questionnaire.

In general, data requirements in the Australian Questionnaire are based on those of *Chapter 11.5 – Bovine Spongiform Encephalopathy* of the OIE *Terrestrial Animal Health Code* (2009)[a]. The Australian Questionnaire also seeks additional information on animal traceability and identification, and animal slaughtering and processing systems.

The United States of America (USA) submitted an application to FSANZ for assessment of BSE food safety risk on 14 June 2010. The initial application included documentation submitted to the OIE in 2009 and a later addendum was provided in early 2013 that included information submitted to the OIE in 2012. The in-country verification visit was conducted in August 2013. This report describes the BSE food safety risk assessment conducted by FSANZ to determine the risk that the BSE agent is present in beef and beef products imported from the USA.

Overview of the BSE Regulatory System in the USA

Responsibility for food safety controls across the beef and beef products industry are largely the responsibility of the United States Department of Agriculture (USDA), through both the Food Safety and Inspection Service (FSIS) and the Animal and Plant Health Inspection Service (APHIS). The United States Food and Drug Administration (FDA) administer and enforce the animal feed ban regulations and regulate processed foods with small proportions of beef content.

United States Department of Agriculture

Regulations for meat and meat products fall mainly under the jurisdiction of the USDA with responsibilities divided between two agencies:

(1) The FSIS, acting under the Federal Meat Inspection Act (FMIA), is responsible for inspecting domestic and imported meat products. FSIS sets standards for food safety and inspects and regulates all raw and processed meat products in interstate commerce, including imported products. The FSIS is also responsible for issuing foreign-meat-inspection certification following audits of the meat production facilities in the exporting country.

(2) The APHIS is responsible for issuing import permits for and verifying veterinary certification of animal products for import and export. Under the Animal Health Protection Act APHIS is also responsible for aspects relating to live animal controls including the establishment and enforcement of import and export certification

[a] The OIE Terrestrial Animal Health Code was most recently revised in 2013, but the data requirements with regard to BSE remain substantially the same and the Australian Questionnaire has therefore not been revised

requirements, animal disease surveillance and risk assessment, including BSE, and together with State agriculture and animal health counterparts, animal disease outbreak investigations, control and eradication, emergency response management and veterinarian accreditation.

State enforcement agencies are key USDA partners. Formal working relationships are reflected in Cooperative Agreements between FSIS and affected State agencies. State Meat Inspection (MPI) Programs are an integral part of the nation's food safety system. All of the establishments under MPI programs are small or very small. State MPI programs are characterized as providing more personalized guidance to establishments in developing their food safety oriented operations and operate under a cooperative agreement with FSIS. Under the agreement, a State's program must enforce requirements "at least equal to" those imposed under Federal Meat Inspection. In States with inspection programs, establishments have the option to apply for Federal or State inspection. However, product produced under State inspection is limited to intrastate commerce.

Food and Drug Administration

The United States Food and Drug Administration (FDA) administers and enforces the ruminant feed ban regulations with a strong cooperative effort from FDA's State counterparts that are responsible for the regulation of feed and feed ingredients in their respective States. The FDA is empowered to enforce these activities under the Federal Food Drug and Cosmetic Act (FFDCA) and the food safety aspects of the Public Health Service Act. FDA regulates under the adulteration and misbranding provisions of the FFDCA (Sec 402 and 403).

All inspections, investigations, and enforcement actions are closely coordinated among FDA and State feed control officials, as well as with other State regulatory officials involved with animal health. The ruminant feed ban regulation is enforced through close coordination of inspections, investigations and enforcement actions between the FDA and State and regional feed control and animal health bodies (State Agriculture Departments). The latter may have contractual or cooperative agreements with the FDA to inspect and sample feed establishments on behalf of the FDA. The FDA itself has the equivalent of 67 full-time employees exclusively devoted to field and laboratory investigations of the ruminant feed ban.

The FDA is also responsible for the regulation, including that related to imports, of food products consisting of: 3% or less raw meat; less than 2% cooked meat or other portions of the carcass; or less than 30% fat, tallow or meat extract, alone or in combination.

Laws and Regulations in the United States

Federal Laws in the United States are passed as an Act by the House and Senate and signed by the President. The Laws are then implemented (codified) in the Code of Federal Regulations (CFR) following:

- Notice and comment – notice of public rulemaking published in the Federal Register
    - Initial notice of proposed rule containing preamble (background and request for comments) and proposed codified language
    - Followed by notice of final rule containing preamble (background and response to comments) and codified language (regulation) to be added to the Code of Federal Regulations.

BSE History

In January 2010 the United States' cattle herd was 93.7 million head with the herd widely distributed across the country but generally more concentrated in the central states. The domestic market consumes 93% of cattle slaughtered in the United States and only about 7% is exported. In 2008, there were 956,500 United States properties carrying cattle, 757,000 held beef cattle, 82,170 held cattle in feedlots and 67,000 held dairy cows. Small cattle operations (1-49 head) accounted for 67.6% of all operations but only 11.5% of the national cattle herd. In contrast, large operations (500 or more head) accounted for 3.1% of all operations but 47.6% of the national cattle herd. Further information is provided in Appendix 1.

The USA has reported four cases of BSE since 2003 – one imported case of classical BSE from Canada in 2003 and three atypical BSE cases, one case in each of the years 2005, 2006 and 2012. Further details on the investigations of these cases are provided in Appendix 2.

Potential for release of the BSE agent through imported materials

Release of the BSE agent into a country's cattle population can occur through the importation of infected live animals or specific commodities contaminated with the BSE agent and subsequent exposure to these by susceptible animals. Avenues that could potentially introduce BSE include live cattle, meat-and-bone meal (MBM) or animal feed containing MBM, fresh meat, or food products of bovine origin — particularly if specified risk materials (SRM) are not removed or cross contamination has occurred during processing or SRM removal.

Section 1.1 of the Australian Questionnaire requests information on annual volumes of MBM that have been imported into a country during the last eight years. If applicable, countries are also required to provide evidence that rendering parameters are sufficient to inactivate the BSE agent should it be potentially present.

Section 1.2 of the Australian Questionnaire requires details of live cattle that have been imported during the last seven years. Evidence of the origin of the cattle must be supplied, as well as the BSE risk status of the exporting countries. Similarly, section 1.3 of the Australian Questionnaire requires data concerning the origin and annual volumes of products of bovine origin (beef and beef products) that have been imported during the past eight years.

This chapter addresses the above requirements by describing the history of introduction of MBM, live cattle, and beef products into the USA, as well as relevant legislation, certification and other controls that underpin the integrity of the system.

1 Introduction of MBM or greaves

1.1 Overview

Introduction into a country of animal protein sourced from ruminants in other countries poses a risk of exposing cattle to BSE infectivity, with consequent food safety risk to human beings who consume products form those cattle. Imports of products of ruminant origin (or containing products of ruminant origin) into the USA have been banned from BSE risk countries since 1989. Although data provided in the submission suggest that there are a number of exceptions to this regulation, such products are only allowed from BSE risk countries under permit and if used for cosmetics or enter the USA in transit to another country. However, all materials are subject to inspection, and imports that may contain mammalian protein are subject to multiple inspection steps involving Customs, FDA and APHIS, to ensure that import conditions are met before entry into the USA is permitted.

1.2 Legislation

Importation of MBM, greaves, or other products containing ruminant protein is subject to controls specified in Title 9 of the *Code of Federal Regulations* (CFR). Importation of products of ruminant origin, and those containing products of ruminant origin, has been prohibited since 1989 from countries in which BSE is considered to be present and from countries considered to present an undue risk of introduction of BSE into the USA. The current list of country status as classified in *9 CFR 94.18* is presented in **Table 1**.

Table 1: Country BSE risk classification according to 9 CFR 94.18

Countries in which BSE is considered to be present		
Austria	Belgium	Czech Republic
Denmark	Finland	France
Germany	Greece	Republic of Ireland
Israel	Italy	Japan
Liechtenstein	Luxembourg	Oman
The Netherlands	Poland	Portugal
Slovakia	Slovenia	Spain
Switzerland	United Kingdom	

Countries presenting an undue risk of introduction of BSE into the USA		
Albania	Andorra	Bosnia-Herzegovina
Bulgaria	Croatia	Federal Republic of Yugoslavia[a]
Hungary	Macedonia	Monaco
Norway	Romania	San Marino
Sweden		

Countries regarded as minimal-risk with regard to BSE
Canada

[a] Countries that were part of the Federal Republic of Yugoslavia at the time *9 CFR 94.18* was published are Serbia, Montenegro and Kosovo

Imports from countries not listed in *9 CFR 94.18* are not subject to any BSE-related prohibitions or restrictions.

Prohibition of processed animal proteins and materials including offal, tankage (rendered protein), fat, glands, tallow, blood and other products from countries listed in *9 CFR 94.18* is addressed in *9 CFR 95.4,* although there are certain specified exceptions, including exceptions applicable to Canada because it has been assessed by APHIS as posing a minimal-risk with regard to BSE. Exceptions permitted by *9 CFR 95.4* are consistent with OIE recommendations (OIE 2012), and are summarized in Appendix 3. Conditions applying to transit of prohibited materials through a United States territory are also specified in *9 CFR 95.4*.

Canada is recognised as a BSE minimal risk region because it meets the criteria defined in *9 CFR 94.0*. These criteria include the maintenance of risk mitigation measures to prevent establishment and spread of BSE, and are described in greater detail in Appendix 3. The status of minimal-risk indicates that APHIS has conducted a comprehensive risk assessment to establish that the country meets certain conditions to ensure that imported live ruminants or ruminant products present minimal risk of introducing BSE into the United States.

Since 1989, the importation of any rendered protein product that cannot be clearly defined as solely non-ruminant in origin has been prohibited if the country is listed as restricted in *9 CFR 94.18.* In December 2000, the regulations were revised to prohibit the entry of any processed animal proteins, or products containing animal proteins, from countries on the restricted list.

Single-species non-ruminant protein such as fishmeal may be imported under permit. In addition, rendered animal protein products may be allowed entry under permit if they are for purposes which preclude any opportunity for animals to be exposed to the products.

In January 2001, the USA added an additional level of review of processed animal products arriving from BSE-restricted countries when the FDA issued *Import Alert 99-25*, titled "Detention without Physical Examination of Animal Feed, Animal Feed Ingredients and Other Products for Animal Use Consisting or Containing Ingredients of Animal Origin and Not the Subject of a Valid USDA Import Permit". This alert covers the detention of imports of animal feeds, animal feed ingredients or other products for animal use that contain or may contain ingredients of animal origin, originating from BSE risk countries, unless the products are the

subject of a valid USDA import permit. The FDA modified its procedures at the port so that Customs receives an electronic reminder to alert the FDA of products entering under certain FDA codes from BSE risk countries. The FDA reviews the information concerning the shipment and if it is determined that the shipment may contain animal protein, it is referred to APHIS for assessment. Products rejected for import are either refused entry or destroyed.

Restrictions on imported shipments do not end at the border. Restrictions may also be applied to destination and end-use, in order to ensure that there is no risk of consumption of prohibited animal proteins by ruminants.

1.3 Details of MBM imports

Countries from which materials or products that possibly include MBM or other sources of ruminant proteins have been imported since 2004 inclusive are listed in Appendix 4, together with the classification, if any, of those countries according to the OIE and according to *9 CFR 94.18.* In essence most imports of animal-derived materials for feeding are of non-ruminant origin or from countries considered to present a low risk of BSE. Of the animal based materials that are imported, most are of porcine or non-mammalian origin and mostly used in pet food or as pet treats. However slaughterhouse offal or ground beef may be imported from Canada for pet food production, being principally from bovine animals less than 30 months of age.

The potential BSE risk presented by MBM imports is effectively mitigated by the USA's import restrictions as detailed in Appendix 4.

2 Introduction of live cattle

2.1 Overview

Importation of live cattle represents a potential food safety risk if imported cattle are sourced from countries which do not have adequate control programs in place to minimise the risk of BSE exposure. The United States has imported cattle in the last seven years from Australia, New Zealand, Canada and Mexico – all countries in which BSE has not occurred or where animal and food production systems are established to ensure that the cattle are not exposed to BSE.

2.2 Legislation

Importation of live cattle to the United States is regulated by APHIS and is restricted under *9 CFR 93 Subpart 4* which covers rules for importation of ruminants. Under *9 CFR 93.401*, live cattle imports are prohibited from countries listed in *9 CFR 94.18(a)(1) or (a)(2)*, that is, the countries listed in Table 1, with the exception of Canada. This ban carries the proviso that the Administrator may permit import of ruminants in specific cases, under prescribed conditions if it is determined for a specific case that the importation will not endanger the livestock of the USA.

Ruminants may be imported into the USA only through ports specified in *9 CFR 93.403.* Imported ruminants must be accompanied by an import permit issued by the USDA, as specified in *9 CFR 93.404,* and an official health certificate issued by a veterinarian accredited by the government of the country of origin to issue such certificates. Details of the health certificate are provided in *9 CFR 93.405*.

The USA prohibited live cattle imports from Canada in May 2003. This was altered in July 2005 when Canada was recognised as a BSE minimal-risk region. As a result of this regulatory change, importation of live cattle from Canada was permitted provided they were

imported for fattening and were to be slaughtered at less than 30 months of age.

In 2007, the USA enacted further regulatory changes that allowed the import of live cattle from Canada provided the cattle were born after March 1, 1999, the date regarded by APHIS as being the date of effective enforcement of the Canadian ban on feeding ruminant proteins to ruminants.

Unless destined for immediate slaughter, Canadian bovines must be marked with a brand, mark or tattoo. This may be a legible permanent brand or mark reading 'CAN' high on the right hip, or a tattoo reading 'CAN' applied within the left ear. All bovines must also have an official ear tag of the country of origin, providing individual identification that allows the animal to be traced to the premises of the animal's birth. This official identification may not be removed or tampered with while the bovine is in the USA, with the exception that it may be removed at slaughter. Conveyances carrying cattle from Canada must have an official Canadian government seal that may only be broken by a USDA representative. Cattle imported from Canada that go to a feedlot in the USA must subsequently be sent to slaughter as a group in vehicles sealed by the USDA, and accompanied by documentation including individual identification and a copy of the official Canadian health certificate. Thus, cattle imported from Canada for fattening prior to slaughter remain traceable to slaughter.

2.3 Details of importation of live cattle

Data dating back to 2001 show cattle have been imported only from Canada, Mexico, Australia and New Zealand. Numbers of cattle and the purpose of import are shown in Table 2. Cattle described as imported for 'commercial' purposes are intended for breeding, but are often not purebred. Cattle described as imported for 'feeding' are weanling or yearling animals destined for feedlot finishing, followed by slaughter. These animals are generally slaughtered before they reach 24 months of age. Cattle imported 'for transit, in bond, and competition purposes' did not remain in the USA. They were either in transit to another port or entered the country temporarily for competitions such as cattle shows or rodeos. 'Other' purposes of import include research, diagnostic or unspecified purposes. Cattle imported into the mainland USA from Hawaii are sometimes imported through Canada.

No cases of BSE have been identified in Australia, New Zealand or Mexico to date. BSE has been confirmed in 20 indigenous Canadian cattle. Nineteen were reported in Canada and one was reported in the USA. A further case in Canada was detected in a cow imported from the United Kingdom. The OIE recognizes Australia and New Zealand as having negligible BSE risk and Mexico and Canada as having controlled BSE risk.

Table 2: Cattle imports into the USA, 2005 - 2012									
Country of Origin	Purpose of import	2005	2006	2007	2008	2009	2010	2011	2012*
Canada	Breeding	0	0	9130	52899	13848	8454	12513	4110
	Commercial	0	0	562	3043	1099	182	0	0
	Feeding	235101	305597	546333	617668	274382	152266	76021	77085
	Immediate slaughter	322712	728535	858591	908082	774690	510478	598245	283413
	Transit, bond or competition	0	0	19	4467	2619	1469	1280	473
	Other	0	0	0	227	38	24	0	14
	In transit from Hawaii	6928	10480	12320	2480	0	0	0	0
	Country Total	**564741**	**1044612**	**1426955**	**1588866**	**1066676**	**672873**	**688059**	**365095**
Mexico	Breeding	313	85	40	83	106	72	226	0
	Commercial	22	0	0	911	365	66	0	0
	Feeding	1212960	1224662	1022697	779982	859439	668226	1487956	603258
	Immediate slaughter	34	1	5	4	1	1	0	0
	Transit, bond or competition	21650	19748	14783	11810	10357	7731	10977	11920
	Other	855	0	0	88	45	0	0	0
	Country Total	**1235834**	**1244496**	**1037525**	**792878**	**870313**	**676096**	**1499159**	**615178**
Australia	Breeding	11	22	598	4	25	0	18	0
	Country Total	**11**	**22**	**598**	**4**	**25**	**0**	**18**	**0**
New Zealand	Breeding	0	0	0	6	0	0	0	0
	Other	0	0	0	80	0	0	0	0
	Country Total	**0**	**0**	**0**	**86**	**0**	**0**	**0**	**0**
Overall imports		**1800586**	**2289130**	**2465078**	**2381834**	**1937014**	**1348969**	**2187236**	**980273**

*First six months only

3 Importation of bovine products

3.1 Overview

This section focuses on the risk of releasing the BSE agent through the importation of products containing bovine protein that are intended for human consumption. Importation of bovine products is subject to strict regulation by the USA. Imports are restricted from countries in which confirmed cases of BSE have occurred or for which other risk factors have been identified. Most imports of beef or beef-containing food products originate from Canada, Mexico, Australia, and New Zealand.

3.2 Legislation

Regulatory Agencies

Regulations for imports of bovine products fall mainly under the jurisdiction of the USDA with responsibilities divided between two agencies: (1) The APHIS Veterinary Service enforces restrictions on the importation of bovine products by issuing import permits and verifying veterinary certification; (2) FSIS acting under the Federal Meat Inspection Act, and in accordance with *9 CFR 327,* inspects imported products at United States borders and ports. The FSIS is also responsible for issuing foreign-meat-inspection certification following audits of the meat production facilities in the exporting country.

The Food and Drug Administration (FDA) has some jurisdiction over imported products containing less than three percent bovine material, such as canned soups or stews. All bovine products imported into the United States may be subjected to inspection by either the USDA or FDA.

Legislation

Since 1989, the USA has restricted imports of high-risk commodities of bovine origin from countries in which BSE has been found. All imports of bovine products for human consumption are subject to regulations that enforce the statutory laws established under the FFDCA and the FMIA. Both these Acts are part of Title 21 of the United States Code.

Under the FMIA, countries exporting bovine products into the USA must comply with the same standards of slaughterhouse construction, pre- and post-mortem inspection, sanitary processing, quality control, species verification and residue standards as those required within the USA. Countries wishing to export bovine products to the USA must obtain certification from the USDA. The FSIS maintains a list of foreign companies eligible to export bovine products to the USA

Imports of bovine products are prohibited from countries in which BSE is considered to exist, and from those countries considered to present an undue risk of introduction of BSE into the USA. The countries are those listed in Table 1, with the exceptions of Japan and Canada. These regulations, in place since 2000, are specified in *9 CFR 94.18*. An exception is made for gelatin under 9 CFR 94.18, subject to permit and provided it is destined for a use that will not result in it coming into contact with ruminants in the USA.

3.3 Type of imported bovine products

Fresh or frozen beef

In terms of exposure of cattle to BSE infectivity through imported bovine products destined for human consumption, the main risk is the improper disposal of waste material or by-products through the processing of whole or half carcasses or bovine cuts with included bone. Canada is the main exporter of these types of bovine products to the USA and under current restrictions all imports must be derived from animals which are considered to pose minimal risk of exposing the USA's cattle population to BSE infectivity. Details on the controls for handling bovine waste and by-products, which would include those from imported carcasses, half-carcasses and cuts, are covered under Section 5.

Small quantities of fresh or frozen bovine products have also been imported from Australia, New Zealand and some Central American countries. For the latter, much of this is boneless beef that results in a minimal BSE risk. In addition, for countries without an OIE classification the USDA has utilised its own assessment methodology to determine country BSE status before allowing imports. The USDA methodology is based on the OIE criteria for country assessment and additionally includes an in-country inspection component that verifies the effectiveness of controls.

The quantities of imported bovine products from 2005 to April 2012 inclusive are shown in Appendix 5. Small amounts of offal has also been imported from some restricted countries but restrictions mean that such imports can only be used for cosmetics or be imported when transiting to another country.

Processed bovine products

The USA has imported edible gelatin from a large number of countries. Gelatin from bovine hides may be imported as it is not considered to pose a risk of transmission of BSE (OIE, 2012). Gelatin from bovine bones is acceptable provided the cattle of origin came from BSE negligible risk countries and had no clinical signs of neurological disease, and SRM were removed at slaughter. Edible offal has been imported from a range of countries in the last eight years, including some imports from Denmark, a country in which BSE is considered to

be present under *9 CFR 94.18*. The data on imports are recorded under a trade code that includes edible offal from swine and beef and the United States advised that the imports from Denmark were from a porcine source. Determination of the type of products that are imported is determined through FSIS inspection of foreign establishments exporting the products to the United States, or through certification by a foreign inspection system that has been approved by FSIS. Audit reports of APHIS-inspected foreign establishments from which animal products exported to the United States are publicly published.

4 Summary: potential for release of the BSE agent through materials or animals imported into the USA

The assessment of imported materials supports the conclusion that the risk of the BSE agent being released into the USA cattle population through imports of live cattle, or bovine products, including MBM, is controlled and unlikely to occur.

The USA has prohibited the importation of live cattle and other ruminants from countries where BSE is known to exist since 1989 and this prohibition was extended in 1997 to a category of regions that pose an undue risk of introducing BSE into the USA. In 2005, APHIS amended its regulations to recognize a category of regions that present a minimal risk of introducing BSE that included Canada. In establishing the regulation, a combination of factors, focusing on the overall effectiveness of control mechanisms in place to prevent the introduction of BSE within a country, were considered.

In 1989, the USA began to restrict imports of high-risk bovine commodities from countries with reported indigenous cases of BSE. Since then, imports of ruminants and ruminant products from countries considered at risk for BSE have been either banned or subjected to a permit process requiring specific conditions. To obtain a permit, importers are required to adhere to restrictions intended to prevent ruminants in the USA from being exposed to products that could potentially carry the BSE agent.

Restrictions on the source, species, composition, and end-use for imported processed animal products minimize any BSE release potential. The products are either imported from countries that are not listed in regulations as having reported a case or presenting an undue risk of BSE, or are imported under permit for specific uses. Furthermore, most of the imported feed ingredients entering the United States do not contain ruminant-derived material.

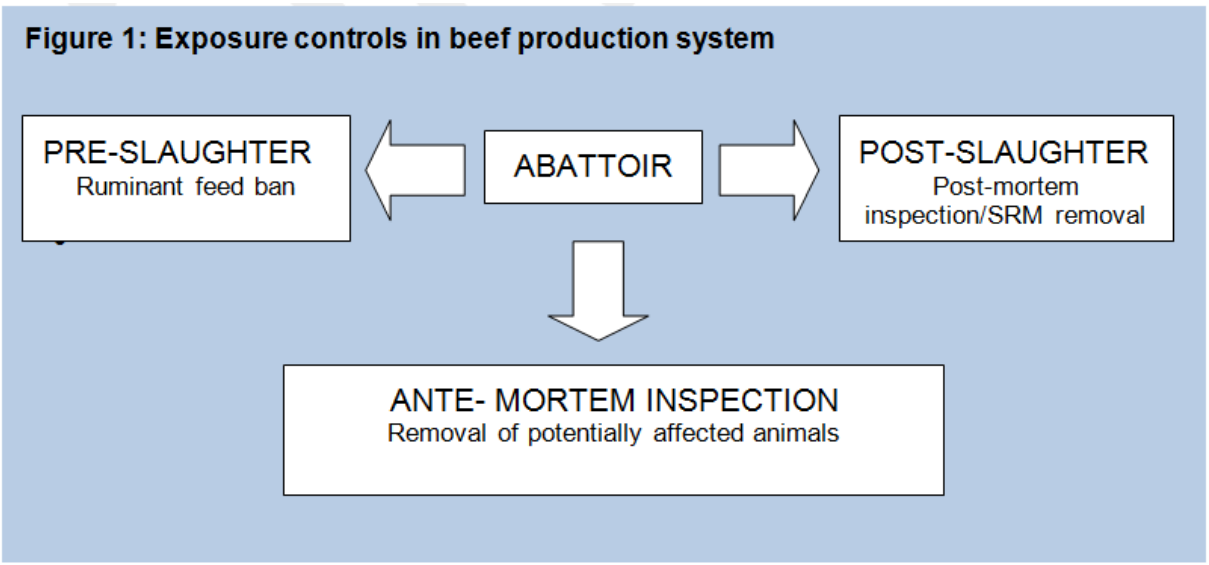
Exposure control

The exposure of cattle to BSE contaminated material and amplification of the infective agent within the feed system is controlled by preventing the feeding of ruminant-derived protein to ruminants. Depending on the BSE status of a country, such as whether a case of BSE has occurred and/or risk factors for BSE exist, prevention is achieved through regulations in three key areas across the beef production system:

- ***Pre-slaughter*** controls which prevent the feeding of ruminant protein to ruminants
- ***At slaughter*** controls which cover animal inspection procedures to ensure potentially affected animals are removed from the animal feed and food production systems
- ***Post-slaughter*** controls which ensure that potentially infected tissues are removed and do not enter the animal feed and food production systems

Scientific evidence[5-8] published since the BSE epidemic in the UK has established that feed ban regulations and procedures to prevent cross-contamination of ingredients used for cattle feed are critical control measures for preventing the recycling and amplification of BSE. Measures to prevent non-ambulatory (downer) cattle from entering the animal feed and human food chain should also be adopted. For countries where BSE has occurred or risk factors exist, controls should also extend to exclusion of potentially infectious tissue (SRM) from animal feed including pet food and human food products. Controls throughout the beef production chain to prevent exposure to BSE are summarised in **Figure 1**.

Figure 1: Exposure controls in beef production system



This chapter describes the control measures that are in place in the USA that prevent the contamination and recycling of the BSE agent in cattle feed as well as assuring that food for human consumption is free of BSE.

5 Pre-slaughter controls: ruminant feed ban

5.1 Overview

Under the Australian BSE Questionnaire countries must demonstrate that an effective ruminant feed ban has been effectively implemented. More specifically, evidence is required to support that ruminant-derived MBM has not been fed to cattle for the last eight years.

5.2 Legislation

The ruminant feed ban was first introduced in 1997 by means of *21 CFR 589.2000*. This regulation prohibited the use of any protein derived from mammalian tissues in feed for ruminants, with specific exceptions such as dairy proteins. Renderers that produce products containing mammalian proteins are required to take measures to ensure that those products do not enter the ruminant feed supply, including placing a warning label on the products and maintaining distribution records of the products for at least one year. These records may be audited by the FDA. The regulation also covers requirements to prevent cross-contamination of ruminant feed with mammalian protein intended for feed for non-ruminants, such as requiring separate production equipment or using appropriate written clean-out procedures. Establishments responsible for feeding ruminants are required to maintain copies, for at least one year, of purchase invoices and labelling for all feeds received that contain animal protein products. These records may be subject to FDA inspection.

The feed ban was refined, effective October 26 2009, through *21 CFR 589.2001*, titled *Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy.* This regulation defines cattle materials prohibited in animal feed or CMPAF to include:

- the entire carcass of BSE-positive cattle
- the brains and spinal cords from cattle 30 months of age and older
- the entire carcass of cattle not inspected and passed for human consumption, unless the cattle are less than 30 months of age or the brains and spinal cords have been effectively removed
- tallow or mechanically separated beef from any of the above materials, with an exception made for tallow containing no more than 0.15% insoluble impurities, as measured by an approved AOCS method.

Cattle not inspected and passed for human consumption are defined in this regulation as those that fail ante-mortem inspection, and includes cattle that are unable to rise or unable to walk for any reason. If renderers choose to remove brains and spinal cords from such cattle, or to separate them on the basis of whether or not they are 30 months of age or older, then renderers must maintain adequate written procedures on how these procedures are carried out.

5.3 Measures to prevent cross-contamination of ruminant and non-ruminant protein

CFR 589.2001 specifies the following measures to prevent cross-contamination of animal feed with cattle materials that are prohibited from use in animal feed*:*

- Use of separate equipment or containers
- Labelling, in a conspicuous matter, of prohibited material with the words “Do not feed to animals”
- Marking of the prohibited materials with an agent that can be readily detected on visual inspection
- Maintenance of records sufficient to track cattle materials. These records must be available to the FDA for inspection.
- Renderers receiving material from other establishments, such as slaughterhouses, must have records to demonstrate that the suppliers have procedures in place to effectively exclude prohibited cattle materials from the cattle materials supplied. This documentation must include a description of the segregation procedures used,

documentation that the segregation procedures were in place prior to the supplying of the material, and records that the renderer periodically reviews the supplier's documentation.

Records and other documentation must be retained and available to the FDA for at least one year.

In addition, there are a range of different State enforcement measures that prevent the introduction of feed that could contain prohibited material. These include:

- Firms importing animal products and fertilizers are required to be licensed with the State.
- State authorities review the label of the product and send an inspector to the consignee to determine if the product is properly labelled,
- Use of approved feed ingredients and licensing for the product. Products are subjected to sampling.
- Interstate feed movements are monitored by other State agencies including State Police.
- All firms that manufacture feed or feed products utilizing prohibited materials must be licensed. State inspections include a thorough review of good management practices (GMPs), cleanout procedures, labelling, inventory control procedures, and adequate receiving records.
- States encourage facilities to utilize a truck cleanout form or "Ingredient Transporter Questionnaire Form," which requires the transporter to declare the previously used load and the cleanout, and an "Ingredient Receiving Log."
- During inspection, product labels are reviewed for the presence of animal protein products. Many suppliers send out an annual letter verifying that they do not handle prohibited material at their facility. The inspected firms retain this documentation, which is reviewed by State inspectors.

5.4 Feed production practices

5.4.1 Commercially produced animal feeds

The commercial animal feed industry produces approximately 117,753,000 metric tons of products, including complete feeds, supplements and concentrates, each year. Most of these products are destined for species other than cattle, as shown in **Table 3**.

Table 3: Products of the Commercial Feed Industry by Livestock Type

Livestock for which product is produced	Annual production in metric tons x 1000	Per cent of total
Chickens: Starter/Grower/Layer/Breeder	16478	14
Chickens: Broiler	40834	35
Turkey	4667	4
Dairy Cows	13922	12
Beef/Sheep	16704	14
Hog	16834	14
All other	8314	7
Total	**117753**	**100**

Feed manufacturers may prevent cross-contamination either by using separate equipment or by instituting adequate cleanout procedures to prevent carryover of prohibited material into

ruminant feed. Most feed mills use either separate facilities or separate equipment within a facility. Separation must include manufacture, processing and storage. If separate equipment is used, it must be clearly identified to ensure that accidental cross-contamination does not occur. Fewer than 2% of feed mills use cleanout rather than separation. Firms that do use cleanout procedures must have written SOPs that cover all aspects of cleanout and related practices, from receipt of raw materials to shipping of the finished product. Documentation must include identification of the responsible personnel, and must state how the adequacy of the cleanout procedure is verified. Cleanout procedures must apply to transport such as trucks and railcars in addition to facilities within the feed mill itself.

The feed mill visited during the in-country verification visit produced a range of animal feed products as well as sourcing and distributing finished pet food products. The feed mill had-Facility Certification Institute (FCI) certification and was HACCP approved. Separate lines were used for feed with and without animal proteins to avoid cross-contamination. Suppliers of feed ingredients needed to be approved and to certify that ingredients were animal-protein free and suppliers were re-approved every two years and needed to provide a letter of compliance for quality assurance. Every load of incoming raw product was inspected, documentation verified and not released into the facility until a range of analytical tests (including tests on feed for animal protein) were shown to be negative. The State Agriculture Department conducted ongoing sampling of feeds destined for ruminants for animal proteins. Appropriate labelling of products that contain mammalian protein indicating that they are not to be fed to ruminants was seen and this information also accompanied bill of sale documentation.

5.4.2 Animal feeds blended on-farm

Commercially manufactured feed represents only a small proportion of blended feed fed to cattle in the USA. Most feed used in dairy and beef production in the USA is blended on-farm from ingredients that are purchased individually. The USA produces abundant, cheap plant protein that is readily available for animal feed production. As a result, plant proteins make up most of the protein sources in animal rations.

Appendix 6 **describes** typical feed uses within the beef and dairy production industries in the United States.

Most farms and those farms visited during the in-country verification visit utilised feed supplier assurance programs that certify the absence of animal proteins in feed ingredients that are purchased.

5.5 Enforcement of the ruminant feed ban

5.5.1 Inspection framework

Feed inspection efforts place a priority on establishments that process or manufacture animal feed and feed ingredients, such as renderers, protein blenders and feed mills and farms. Inspections are also conducted on pet food manufacturers, pet food salvagers, and animal feed distributors and transporters. The *FDA Compliance Program Guidance 7371.009 (BSE/Ruminant Feed Ban Inspections)* is used to assist both FDA and State investigators determine compliance with the feed ban. The feed inspection program is risk-based. Facilities are selected for inspection based on an algorithm that takes into account: time since last inspection, outcome of inspection, type of firm, potential of cross contamination, and other factors. Inspection is a comprehensive process which involves plant audits, visual inspection, verification of MBM use and sourcing, review of records, clean-up procedures, and training of employees. Renderers and feed mills that process with prohibited (ruminant) material are considered performance goal firms and all of them are inspected annually.

In the 2012 financial year on a national level there was a total of 7099 BSE feed related inspections; 1700 were performed by the FDA and 5399 were performed by the States. 4702 of the latter were conducted under contract to the FDA and 697 were through cooperative agreement arrangements. Of the more than 6000 feed mills registered in the United States less than three per cent now use ruminant (prohibited) material in their manufacturing process. Although it is not mandatory to have separate manufacturing lines when using prohibited material and manufacturing feed for both ruminants and non-ruminants, in practice the vast majority of feed mills employ separate lines. It is estimated that of the three per cent of manufacturers that use prohibited material, less than five per cent do not employ separate lines but manage this through clean out processes. These are mostly small mills and the rate continues to decrease with time

Details of the audit and sampling findings in rendering plants and feed mills processing ruminant materials, dating from 2003 to 2012, was provided by the USA. Numerical data show a very low incidence of infractions that has been declining over time.

From 1998 to May 2013 inclusive, more than 46,000 inspections of feed mills, feed transporters, distributors, on-farm mixers and rendering plants were conducted, and approximately 0.2% violations were found and mainly related to a lack of appropriate documentation. This indicates a high level of compliance with the ruminant feed ban.

5.5.2 Testing of feeds

The FDA began a feed testing program in 2001. This program initially used microscopy to inspect feed, and was directed at imported feed and feed ingredients. All feeds and feed ingredients of animal origin, including those containing poultry or fishmeal, were subject to sampling if they originated from countries identified as having BSE or as having inadequate systems in place to prevent BSE. In 2003 the feed testing program was expanded so that, starting in fiscal year 2004, domestically produced animal feed and feed ingredients were subject to greater inspection. In 2006 the use of PCR was introduced to improve the capability to detect prohibited material. The domestic sampling program is intended to audit commercially distributed feeds as well as providing a source of information to target firms for follow up investigation and inspection. Samples are collected from feed or feed ingredients in commercial distribution channels and from products arriving at feed manufacturers' premises rather than from outgoing products.

FDA's sampling assignments specify that the highest priority for sample selection should be given to finished products intended for ruminants, and feed ingredients that may reasonably be expected to be later used in ruminant feed. At least half of all samples come from these categories. Because most firms that use prohibited material do not make ruminant feed, fewer samples from such firms are collected. However, samples may be collected to support regulatory action if inspections indicate potential cross-contamination or mislabelling. The next level of priority is directed to animal feed or feed ingredients labelled as containing animal protein, but not labelled with a caution statement "Do not feed to cattle or other ruminants". The third priority is given to animal feed or feed ingredients that do not list mammalian protein in the product name or ingredient list. The FDA asks field personnel to select products for sampling from a range of different sources, processors or manufacturers.

Data on the number of feed samples submitted for testing for prohibited animal proteins are shown in **Table 4**. There have been no positive results to sample testing since 2006.

Table 4: Domestic and imported feed samples submitted for testing for prohibited proteins			
Fiscal year	Domestic samples	Import samples	Annual total
2002	27	171	198
2003	13	138	151
2004	651	460	1111
2005	967	479	1446
2006	886	352	1238
2007	807	290	1097
2008	813	207	1020
2009	625	183	808
2010	782	215	997
2011	555	139	694
2012	612	102	714

5.6 Evaluation of compliance with the feed ban

The risk of accidentally feeding ruminants on rations intended for other species ('mis-feeding') is low in the USA. In the USA relatively few cattle farms also raise pigs or poultry. The 2007 Census of Agriculture showed that of 963,669 cattle farms, only 81,204, or 8.4%, also had pigs, poultry or both. A risk analysis conducted by the Harvard Center for Risk Analysis concluded that the risk of mis-feeding on multispecies farms is 1.6%, where the probability that any cattle being raised on a farm with pigs and/or poultry that are fed prohibited mammalian proteins is 5%. Further, only 23% of dead-stock cattle are rendered; the other non-rendering disposal options used in the United States prevent recycling of any potential infectivity. Finally, the average age of the cattle population in the United States is relatively young. Most animals are slaughtered at less than 30 months of age.

Animal protein feed ingredients derived from either ruminant or non-ruminant sources combined make up less than 1 per cent of processed feedstuffs used in the USA due to the abundance of affordable grain and oilseed crops grown in the country. This allows for feed formulation without the need to rely on animal protein sources for supplementation. This alone significantly reduces any potential exposure to prohibited materials in the feed (see Appendix 6 for feed use patterns).

As reflected in the information received from the USA, audit results from both the BSE feed inspection program and the BSE feed testing program continue to show an extremely high level of compliance with the BSE feed regulation. This assessment concludes that from the point of widespread feed testing starting in the USA from 2004, together with ongoing inspection and enforcement measures around the ruminant feed ban regulations, an effective ruminant feed ban has been in place in excess of eight years.

6 Ante-mortem slaughter controls

6.1 Overview

Older cattle which are non-ambulatory (downer cattle, fallen stock) and/or showing signs of neurological disease consistent with an established BSE case definition present the highest risk of infection with the BSE agent. Such animals are targeted and prevented from entering the ruminant feed and human food chain.

6.2 Legislation

Ante-mortem inspection regulations for official slaughter establishments are specified in *9 CFR 309*, titled *Ante-mortem Inspection*. Key details of this legislation with relevance to BSE include the following:

- All livestock are to be examined prior to slaughter on the day of slaughter
- Any livestock suspects of having any disease that may cause condemnation of the carcass must be handled so that its identity is retained through to final post-mortem inspection
- Non-ambulatory disabled cattle are not slaughtered for human food. Non-ambulatory disabled cattle are animals that cannot rise from a recumbent position or that are disabled or cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions
- Animals identified as US Suspects must be: identified with an official device that may only be removed by an authorised official; and must be set apart and slaughtered separately to other livestock
- Livestock showing symptoms of neurological disorders that may be consistent with BSE, must be condemned and may not be taken into any part of the establishment that is used for edible products
- Dead or dying animals, as well as comatose or semi-comatose animals, must be identified as US Condemned and disposed of by rendering.

The exclusion of non-ambulatory cattle and other BSE clinical suspects from the animal feed production process is achieved through these materials being classified as CMPAF and as such must go to landfill or be incinerated.

6.3 Ante-mortem procedures

FSIS inspectors examine animals before and after slaughter, preventing diseased animals from entering the food supply and examining carcasses for visible defects that can affect safety and quality.

Ante-mortem inspection is carried out by FSIS veterinarians and must include inspection of animals at rest and in motion. Non-ambulatory or dead animals and those with suspect neurological signs are separated into dedicated pens and are condemned. The brains from these animals are sampled by USDA veterinary officers and submitted to a designated laboratory for BSE testing. The carcasses are classified as CMPAF material and disposed of through landfill or incineration.

6.4 Slaughtering methods

Methods considered to be humane for slaughtering cattle are specified in *9 CFR 313*, and include captive bolt, gunshot, electrocution and, for calves only, carbon dioxide gas. *9 CFR 313.15(b)(2) (ii)* specifically prohibits the use on cattle of captive bolt stunners that deliberately inject compressed air into the cranium.

Injecting compressed air into the skulls of cattle in conjunction with a captive bolt stunner is prohibited as stated in *9 CFR 310.13(b)(2).*

6.5 Evaluation of ante-mortem slaughter controls

In order to operate, slaughterhouse establishments must be approved and registered with the USDA and meet a minimum set of requirements. FSIS veterinary medical officers onsite have overall responsibility for ante-mortem and post-mortem inspection and certification of meat being fit-for-human-consumption. Ante-mortem activities are verified internally on a

regular basis. Official veterinary oversight is complemented by a set of quality assurance and HACCP processes within each establishment to ensure compliance with regulations. Information from the in-country verification visit indicated that audits from the USDA occur every three months and internal verification of procedures occurs at least three times per day. External audits from commercial companies occur several times per year. The export facilities inspected during the in-country verification visit were certified for ISO 9001: Quality Management Systems.

7 Post-slaughter controls: post-mortem inspection, SRM removal, and rendering procedures

7.1 Overview

This section describes regulations for processing and handling of bovine carcasses and by-products to ensure that BSE infectivity cannot enter the human food supply or be fed to cattle.

7.2 Legislation

The controls for the handling of condemned carcasses and bovine waste material are under the jurisdiction of the FSIS.

SRM are defined in *9 CFR 310.22* as the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, transverse processes of the thoracic and lumbar vertebrae, and wings of the sacrum), and dorsal root ganglia from cattle 30 months of age and older, and the distal ileum of the small intestine and the tonsils from all cattle. *9 CFR 310.22* requires establishments that slaughter or process cattle to implement procedures to remove SRM, addressing the risk of cross-contamination of edible parts of the carcass with SRM, and incorporate the removal and disposal procedures for SRM into their HACCP plans, sanitary SOPs or other prerequisite programs.

FSIS (USDA) *9 CFR 319.5* defines mechanically separated meat and prohibits the use of mechanically separated beef in human food.

Regulations concerning removal of SRM are specified in *9 CFR 310.22.* Slaughterhouses and processing establishments must develop, implement and maintain written procedures for the removal and disposal of SRM. The procedures must address the risk of cross-contamination of edible materials with SRM, and must be incorporated into the establishment's HACCP program, sanitary SOPs or other prerequisite programs. The procedures must be subject to ongoing evaluation of their effectiveness, and the establishment must institute appropriate corrective actions if the procedures are found, by the establishment itself or by FSIS, to be inadequate. Daily records of SRM removal, that may be electronic, must be kept for at least one year and must be accessible to FSIS. SRM must be removed using dedicated equipment, or equipment that is cleaned and sanitized before use on cattle younger than 30 months of age. Strict controls apply to the shipping of carcasses of cattle 30 months of age or older that still contain vertebral columns to another establishment for further processing. The carcasses must remain under the control of the shipping establishment or FSIS, must be accompanied by documentation to state that the carcasses are of cattle 30 months or older, and must maintain records identifying the receiving establishment and verifying that the receiving establishment removed the vertebral columns and disposed of them as SRM.

7.3 Post-mortem procedures

Post-mortem procedures are supervised and monitored by the official FSIS veterinary

inspectors. Procedures monitored include:

- Carcass identification
- Verification of animal age by examining teeth or by documentation
- Removal of tongue and masseter muscles from the head and disposal of remaining head parts
- Inspection of the carcass, head, viscera and edible and inedible offal and disposal of inedible parts
- Carcass splitting and removal of spinal cord
- Results of ante-mortem and post-mortem inspection are recorded
- Final certification of passed and inspected product being fit-for-human-consumption by the application of the mark of inspection.

7.4 Rendering processes

Destruction of inedible material, including SRM, is covered in *9 CFR 314*. Besides rendering, with or without prior crushing, condemned and inedible materials may be incinerated or thoroughly chemically denatured. *9 CFR 314* includes numerous clauses on segregation of condemned and inedible materials and their derivatives, in order to prevent contamination of edible products.

Application of *21 CFR 589 'Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy'* is the subject of a Guidance of Industry document issued by the FDA on 6 May 2009, and directed to renderers. Prohibited materials or CMPAF include brain and spinal cord from cattle 30 months of age and older, and materials that contain these tissues. Unlike SRM, CMPAF does not include the skull or vertebral column if the brain and spinal cord are effectively removed.

Renderers who pick up dead cattle must remove the brain and spinal cord of dead cattle 30 months or older, and must have written procedures on how the age of the dead animal is determined, as well as written procedures on how the brain and spinal cord are removed and disposed. These procedures must be available for FDA inspection. Renderers who receive CMPAF must establish and maintain records that are sufficient to show that the CMPAF are not used in animal feed. Renderers who receive other bovine materials from other establishments must verify that the supplier has adequate procedures in place to ensure that the materials do not contain CMPAF.

Separated CMPAF must be marked to allow easy visual recognition. Acceptable markers include Patent Blue V (E131) and a number of marking inks. CMPAF must be recovered from wastewater in rendering plants. Any non-CMPAF tissues caught during the same process become CMPAF.

Rendering processing parameters are not mandatory and the USA relies on an effective feed ban and removal of CMPAF from the feed system to prevent potential BSE infectivity entering animal feed. Other aspects of beef production in the USA help to reduce the risk of BSE transmission in feed. It is estimated that in 2005, approximately 45% of dead cattle were picked up and processed by rendering companies, but after FDA required removal of the brain and spinal cord from cattle 30 months of age and older in 2009, that percentage declined to an estimated 23% in 2011. The remainder of dead stock cattle are disposed of on the farm where they died, or are sent to land fill. Recycling of infectivity via the latter two disposal mechanisms is unlikely. The majority of cattle slaughtered annually are younger than 30 months and therefore are at low risk of harbouring BSE infectivity. For example, in

2005, 84% of cattle slaughtered in the USA were less than 30 months of age. These and other factors suggest that if BSE was introduced into the USA, it would not amplify and spread.

Although rendering parameters are not mandatory, the United States submission cites evidence from the 2003 Harvard risk assessment for BSE ('Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States'[4]) estimating that 95 per cent of ruminant MBM is produced using processes that result in at least 1 log reduction in BSE infectivity. A summary of inactivation and rendering in the United States is as follows:

- 5 per cent of ruminant MBM is rendered using a batch system that reduces infectivity by 3.1 logs
- 45 per cent of MBM is rendered using a continuous flow system to which fat is added that reduces infectivity by 2 logs
- 45 per cent of MBM is rendered using a continuous flow system without fat added that reduces infectivity by 1 log.

Only 5 per cent of ruminant MBM is rendered using a vacuum system that results in no reduction in BSE infectivity if it were present. Based on this evidence, the expected (average) reduction in infectivity from rendering is calculated to be 1.4 logs. Thus, in the event BSE infectivity were hypothetically introduced into the United States rendering system, the risk assessment shows that roughly 96 per cent would be destroyed during rendering.

The rendering facilities that were visited during the in country verification visit confirmed that when removal of CMPAF is required, the cattle are aged by dentition, the brain and spinal cord removed according to written SOPs and the prohibited material labelled as CMPAF and disposed of through landfill.

7.5 Compliance with regulations

The audit program for compliance with regulations pertaining to post-mortem inspections and SRM removal are the same as for ante-mortem inspection (section 6.5). The rendering process conforms to the rendering industry's code of practice and operates under a registered HACCP program. The process is externally audited every three years by the American Feed Industry Association, which is ISO accredited. In addition to internal company audits, FDA inspections at firms rendering ruminant material occur at least annually. There is appropriate labelling on MBM products (including a requirement for imported feeds to have similar labelling) and their bill of sale information that complies with the ruminant feed ban requirements. Audits cover all aspects of rendering along the supply chain; including site and equipment inspection, receival and handling of raw ingredients, supplier list of raw materials, production line operations, storage facilities, product labelling, client list and dispatch records. Documentation on audits was observed during the in-country inspection.

8 Summary: exposure control

Animals at the highest risk for BSE are identified through rigorous ante-mortem inspection procedures through prohibiting non-ambulatory animals or those animals showing signs consistent with BSE, from entering the slaughter chain and rendering system. Disposal of such animals is through incineration and/or landfill. In addition, the brain and spinal cord and other high risk CMPAF tissues are prohibited from being rendered and used for animal feed. Audit results from both the BSE feed inspection program and the BSE feed testing program in the USA since 2005 show an extremely high level of compliance with the BSE feed regulations. The USA has demonstrated, through an appropriate level of audit and controls for more than eight years, that neither MBM nor greaves derived from ruminants is likely to

have been used to feed ruminants. There is therefore a very limited possibility that exposure of cattle to BSE would occur through contaminated feed in the United States.

The abundance and lower price of grains and other crops grown in regions of the USA where livestock are raised also influences the risk associated with ruminant feeding practices. Only about one per cent of feedstuffs utilise mammalian derived ingredients. The FDA's 1997 BSE feed regulation requires that feed manufacturers have procedures in place to prevent cross-contamination. Over 98 per cent of feed manufacturers meet this requirement through dedicated facilities—that is, feed mills that do not use prohibited material where they produce feed for ruminant animals.

BSE food safety controls

The Australian Questionnaire requires countries to document the controls they have in place during the slaughtering process to prevent food for human consumption from becoming contaminated with materials that may contain BSE. It also requires a country to demonstrate effective and timely systems for the accurate identification, traceability and recall of meat and meat products in the event of a food safety issue. The following chapter addresses these requirements within the USA.

9 Beef production systems

9.1 Legislation

FSIS is responsible for ensuring the safety, wholesomeness, and correct labelling and packaging of meat. FSIS operates under the authority of the Federal Meat Inspection Act and sets standards for food safety and inspects and regulates all raw and processed meat products sold in interstate commerce, including imported products. These functions are complimented by State enforcement programs for some domestic-only slaughterhouses.

9.2 Hygiene practices for the minimisation of cross-contamination

9 CFR 310.22(e) requires that establishments that slaughter cattle and establishments that process carcasses and parts of cattle develop and maintain written procedures for the removal, segregation, and disposition of SRMs. These regulations specify that these procedures must address potential contamination of edible material with SRMs before, during and after entry into the establishment. In addition, 9 CFR 310.22(f) prescribes requirements for the sanitation of equipment used to cut through specified risk materials. Under these regulations, establishments must either: 1) use dedicated equipment to cut through SRMs; or 2) clean and sanitize equipment used to cut through SRMs before it is used on carcasses or parts from cattle younger than 30 months. If establishments segregate the slaughter of cattle 30 months of age and older from cattle younger than 30 months, they are permitted to use routine operational sanitation procedures on equipment for SRMs if it processes cattle younger than 30 months first.

Materials condemned as unfit for human consumption, including SRMs, must be disposed of in accordance with the requirements in 9 CFR 314 for the handling and disposition of condemned or other inedible products at official establishments. Inedible and condemned material from slaughter establishments is generally rendered for non-ruminant feed use at packer-associated rendering plants or at independent rendering plants that collect this material from slaughter establishments.

10 Traceability systems for beef and beef products

In the event of a BSE case, traceability systems should demonstrate that they can achieve timely and effective identification, tracing and recall of beef and beef products from all BSE affected animals. The system should be able to identify and trace beef and beef products from the point of retail sale back to the point of manufacturing and (where applicable) to the point of slaughter. The system should integrate with cattle identification and traceability measures such that the origin of contaminated beef or beef products can be traced back to any animals of interest if required.

10.1 Legislation

There are recordkeeping requirements in the Federal Meat Inspection Act that require all persons, firms and corporations to maintain records of all transactions of any cattle or related products. The requirements apply to the following:

> (1) Any persons, firms, or corporations that engage, for commerce, in the business of slaughtering any cattle, or preparing, freezing, packaging, or labelling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food
>
> (2) Any persons, firms, or corporations that engage in the business of buying or selling (as meat brokers, wholesalers or otherwise), or transporting in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any such animals
>
> (3) Any persons, firms, or corporations that engage in business, in or for commerce, as renderers, or engage in the business of buying, selling, or transporting, in commerce, or importing, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules, or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter.

The above requirements mean that persons and establishments are essentially required to have records that facilitate the tracing of animals and/or product one step forwards and one step back along the supply chain. These records are the subject of regular audits.

9 CFR 320 offers additional information as to the types of records that need to be maintained and 9 CFR 418 (see Appendix 3) provides information about the written recall procedures that need to be maintained by FSIS inspected facilities (discussed in Chapter 11 and see Appendix 3).

10.2 Details of the traceability system

Cattle arriving at the slaughterhouse are required to have an owner-shipper statement that documents the number and types of animals, the owner/shipper of the animals and the property of origin and health status of the herd. Most animals have some form of individual identification in the form of ear tags, tattoos, brands, or back tags and these are cross referenced to the carcass. Slaughterhouses have known suppliers of cattle and many receive cattle from the company's feedlot establishments.

Transporters of cattle must carry manifests or bills of lading that accompany livestock shipments arriving at slaughterhouses. Documentation includes information about the number and type of livestock carried and the origin and destination of the movement. Compliance with this documentation may be checked at any stage by FDA or regional Agriculture inspectors and is verified upon reaching the slaughterhouse.

Within both slaughterhouses that were visited during the in country verification visit, up to the point of deboning, carcasses are traced on a lot basis. A lot is a group of animals coming from a single property. In addition, production companies utilize a numeric identification system to trace a carcass and its' parts from the slaughter line through fabrication and packaging and retain all records of this information, often stored in computers. In the event of a product recall, companies can narrow down the source of the animals to a particular time interval during the slaughter production day. Deboned packaged meat is identified by the batch, date, age of animal and quality parameters. Meat can be traced back to the day's batch and within this further discrimination can be achieved to a group of animals by the time

that they went through the slaughter process. Slaughterhouse records are linked to supplier records to determine the farm origin.

11 Recall systems

11.1 Legislation

9 CFR 418 provides information about the written recall procedures that need to be established and maintained by FSIS inspected facilities under the FMIA. Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, or product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall and how the establishment will implement the recall, if it decides that one is necessary. All records, including records documenting recall procedures, must be available for official review and copying.

Procedures for conducting recalls of meat and poultry products are described in FSIS Directive 8080.1, 'Recall of Meat and Poultry Products[5]'. Meat and meat processing establishments are required to have effective recall programs under this directive that are integrated into HACCP and quality assurance systems, and to test the effectiveness of recall systems through regular audits and mock recalls.

11.2 Food recall process

FSIS enforces the need for a recall program and coordinates recalls for federally inspected slaughterhouses and meat processing establishments. It ensures meat establishments have established and effective programs and conducts audits regularly. FSIS is also responsible for identifying and removing recalled product from commerce and verifying the effectiveness of the firm's recall activities, as well as notifying the public about product recalls. For recalls conducted by State-inspected firms or retail establishments, the appropriate State agency verifies the recall in most cases. If requested to do so, FSIS will provide the State agencies with appropriate assistance and information.

12 Contingency plan for the investigation and response to a suspect BSE event

APHIS has developed and continuously reviews its contingency plan for BSE and animal diseases. A copy of the current BSE Response Plan was included with the USA's submission. An official response would begin on receipt of an inconclusive BSE test result from a designated State laboratory (see Chapter 15 for BSE testing details). The National Veterinary Services Laboratories (NVSL) laboratory in Iowa then undertakes confirmatory testing and if it confirms a positive diagnosis, this triggers a full-scale response. Actions include the following:

- Notifications to the Centers for Epidemiology and Animal Health (CEAH), personnel within the Veterinary Services (VS), State Veterinarians, APHIS, FSIS, FDA and OIE.
- VS deploys a Regional Incident Analysis Team
- The carcass is disposed of as well as any rendered product that may be derived from the animal
- At-risk cattle are traced, based on the OIE definition of at-risk cattle which includes progeny, birth cohort and feed cohort.
- FDA takes responsibility for feed investigations
- A hold order or quarantine is placed on the last known premises of residence. This will initially apply to all bovines on the property but is modified as at-risk cattle and

cattle of interest are identified
- At-risk cattle are terminated and tested
- Cattle of interest will be further evaluated to eliminate those that are not possible at-risk cattle from further investigations. Those that cannot be eliminated as possible at-risk cattle will be terminated and tested.
- SOPs are developed and documented for all routine procedures required for carrying out the response, in consultation with State animal health officials and environmental protection agencies.

The response is handled through an Incident Command Post (ICP) which is initially located in the State where the last known premises of the animal is located, although additional ICPs may be established if the investigation extends to other States.

The baseline ICP Organisational Structure is as shown in Appendix 7**.**

13 Summary: BSE food safety controls

Food safety controls across the beef and beef products industry are the responsibility of the FSIS and State based animal health authorities. FSIS inspectors examine animals before and after slaughter, preventing diseased animals from entering the food supply and examining carcasses for visible defects that can affect safety and quality. 250,000 different processed meat and poultry products fall under FSIS inspection. In addition to inspecting these products during processing, FSIS evaluates and sets standards for food ingredients, additives, and compounds used to prepare and package meat and poultry products.

Compliance with regulations ensures good hygienic practices are employed throughout the beef production and supply chain so that the risk of cross-contamination of edible product with potential BSE infected materials is minimized. Animal disease contingency plans, including for BSE, are well established with defined responses across federal and state agencies. Food industries, including slaughterhouses, are required to establish and maintain traceability and food recall processes and these processes are audited and tested for effectiveness and efficiency through annual mock recalls. As a result of these system requirements, it is considered that the recovery of contaminated beef and beef products and tracing of at-risk animals could be achieved in a timely and effective manner.

BSE Control Programs and Technical Infrastructure

The following chapter addresses the requirements in the Australian Questionnaire to have appropriate control programs that support a capability to adequately identify, notify, and diagnose cattle that display signs meeting the case definition of BSE. This assessment covers systems focused on the notification and disease investigation of clinical suspects, diagnostic methods to detect the presence of the BSE agent in infected tissues, and BSE awareness programs and education. This chapter also assesses the cattle identification and traceability system in the USA, which serves to underpin any BSE case investigation.

14 BSE Education and Awareness

Since 1990, the USA has had an active BSE awareness program that is aimed at a wide range of audiences including producers, processing plant operators, veterinarians, animal health educators, slaughterhouse inspectors, federal and state officials, and the general public. Documentation was provided with the submission. Examples of the awareness program include the following:

- Press releases, information on BSE, APHIS surveillance program activities and training information (available at www.aphis.usda.gov)
- Satellite seminars are provided by APHIS to communicate the latest policies and procedures to the public, industries, State officials and other interested parties
- Articles on BSE, written by experts from various USDA agencies, are regularly published in scientific journals, trade/industry publications and farmers' magazines
- FDA maintains a BSE information page at www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/BovineSpongiformEncephalopathy/default.htm
- APHIS and FSIS regularly provide training and workshops on BSE. Numerous examples were provided in the submission
- State Agriculture Departments develop, publish and disseminate education on BSE and guidance on how to comply with BSE regulations is directed to cattle producers, feed manufacturers, handlers, transporters and renderers.

Information is disseminated by a wide range of media including workbooks, CDs, DVDs, online documents and courses, video seminars, telephone hotlines, fact sheets, brochures, manuals and in-person training.

15 Disease notification and diagnoses

15.1 Overview

This section focuses on procedures for notification and diagnoses of animals that are tested under the BSE surveillance and monitoring program in the USA.

15.2 Legislation

BSE has been a reportable disease in the USA since 1986. Government authority to control the movement of animals with reportable diseases and to slaughter them is covered by *9 CFR 53 and 9 CFR 71*. The powers and responsibilities of accredited veterinarians related to the control and prevention of reportable diseases are covered in *9 CFR 161*. Accredited veterinarians are responsible for notifying State and Federal animal health officials of any suspected or confirmed cases of animal diseases for which the USDA has a control or eradication program. The obligations include reporting any suspect cases of BSE. In addition to veterinarians, animal health officials, slaughterhouse inspectors and others working with

livestock are required to immediately notify State or Federal health authorities of suspected cases of BSE.

APHIS maintains the National Animal Health Reporting System (NAHRS) on its website that lists national reportable diseases and includes all OIE-reportable diseases for cattle, small ruminants, horses, swine, poultry, and aquaculture. Each year, small modifications are made to the OIE disease list and the NAHRS reportable disease list is modified accordingly at the beginning of the next calendar year.

Powers for the USDA to control and respond to a disease outbreak, including provisions for quarantine and slaughter of affected or suspect animals, are provided by the *Animal Health Protection Act.*

15.3 Identification and handling BSE suspects

Detailed instructions for the identification and handling of BSE suspects are provided in the *Procedures Manual: Bovine Spongiform Encephalopathy Ongoing Surveillance Program* (the Procedures Manual). This document is produced by APHIS Veterinary Services. Cattle subject to sampling include cattle of any age with progressive behavioural changes or with clinical signs of central nervous system (CNS) dysfunction, including rabies suspects that test negative for rabies, and cattle of 30 months of age or older that fall into any of the following categories:

- Cattle condemned at slaughter
- Cattle that are non-ambulatory (downer cattle) regardless of apparent reason
- Cattle that are severely weakened, even if able to stand and walk for short periods
- Cattle that are terminated, or die spontaneously, as a result of moribund conditions, infectious disease, emaciation or injuries
- Cattle found dead, with the exception of those known to have died from acute conditions unrelated to CNS disorder, such as lightning strike, trauma, gunshot, or dystocia.

If documentation of the age of the animal is lacking, it is judged to be 30 months or older if at least one permanent second incisor has erupted. Cattle may be located on farms, or at veterinary diagnostic laboratories, public health laboratories, slaughterhouses, collection facilities, or rendering facilities.

The Procedures Manual provides detailed instructions, accompanied by photographs, on how to collect the appropriate sample of brainstem at the level of the obex, and how to transport and to electronically notify the laboratory of the arrival of the sample.

15.4 Diagnostic tests

The NVSL coordinates the National Animal Health Laboratory Network (NAHLN), a nationwide strategy to coordinate the work of all organizations providing animal disease surveillance and testing services. With respect to BSE, the NVSL and six other State-based laboratories form the network that undertakes BSE testing (Appendix 8). The NVSL Pathobiology Laboratory performs surveillance and confirmatory testing on all samples identified as suspect (potential positive) for BSE by the NAHLN laboratories. Confirmatory testing is through both Western Blot (WB) and Immunohistochemistry (IHC).The seven regional laboratories listed in Appendix 8 use an enzyme-linked immunosorbent assay (ELISA) test to screen brainstem samples. Diagnostic procedures and methods used by testing laboratories are conducted according to Chapter 2.4.6 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

If a sample is reactive on a 1-well ELISA BSE test, the screening test is repeated in a 2-well ELISA. If the result is reactive in either or both wells, the sample is then shipped to the NVSL, the reference diagnostic laboratory. The flow chart for testing and decision-making is shown in Appendix 9. Carcasses and offal from tested animals must be held until laboratory results are received. After a negative laboratory result is received, the carcass and offal may be rendered, buried, incinerated or destroyed by alkaline digestion.

15.5 Laboratory assurances and auditing

The NVSL maintains the records of all BSE tests, together with slides and blocks for histopathology and information on the identity of the tested animal for three years. Regional laboratories responsible for screening tests also maintain records, and regularly provide raw test data to NVSL for consistency review. Laboratory records are summarized on the APHIS website.

All BSE testing laboratories have recognised quality management systems and are accredited to ISO Standards 17025, 17043, and ISO Guide 34. Accreditation is through the American Association of Veterinary Laboratory Diagnosticians (AAVLD). Ongoing quality assurance activities include internal audits, management review, corrective and preventive actions, and proficiency tests. Various external audits are conducted on a regular basis, including audits by the AAVLD and USDA. NVSL provides training and proficiency testing for BSE testing on an annual basis and makes inspections and reviews records of NAHLN laboratories. All tests throughout the NAHLN have documented SOPs.

15.6 Penalties and reporting incentives

Penalties may be imposed on veterinarians who fail to comply with rules and regulations around the reporting of animal diseases. Possible penalties include fines, temporary suspension of accreditation, and complete revocation of accreditation.

Livestock owners whose animals are taken or destroyed by national authorities as part of disease investigation and control are eligible for compensation.

16 Cattle identification and traceability

16.1 Overview

Cattle traceability systems should enable effective and efficient identification, tracing and recall of beef and beef products from all BSE affected animals in the event that BSE has occurred. The system should be able to identify and trace beef and beef products from the point of retail sale back to the point of manufacturing and where applicable to the point of slaughter. The system should integrate with cattle identification and traceability measures such that the origin of contaminated beef or beef products can be traced back to any animals of interest if required. The system should ensure capability for effective and timely identification, tracing and removal of beef and beef products from markets and the distribution chain.

16.2 Legislation

The USDA began implementing the National Animal Identification System (NAIS) in 2004. However the NAIS met with some resistance, and was abandoned in 2010. The USDA proposed a new rule on animal disease traceability in August 2011, and issued a Final Rule, *78 FR 2042* on December 20, 2012. The discussion of costs and benefits in this rule

specifically states that it is not intended to 'provide for a full-scale farm-to-plate traceability system, which would be beyond the scope of our statutory authority'. The Rule specifically applies to interstate movement, excluding movement within Tribal lands that straddle a state line, or if the movement is to a custom slaughter facility. Livestock moved interstate must, with some exceptions, be officially identified and accompanied by an interstate certificate of veterinary inspection (ICVI) which lists the species, the number of animals, the addresses of origin and destination, and the names of the consignor and consignee. The ICVI will generally also list, or be accompanied by, a list of the official identification numbers of all the animals in the shipment, with exceptions for some species and some classes of livestock. ICVIs for movement of cattle and bison must be retained by the consignee for five years.

Official identification is required for the following classes of cattle and bison:

- All sexually intact cattle and bison 18 months of age or over;
- All female dairy cattle of any age and all dairy males born after March 11, 2013;
- Cattle and bison of any age used for rodeo or recreational events; and
- Cattle and bison of any age used for shows or exhibitions.

An ICVI is not required in the following circumstances:

- Cattle are moved directly to a recognized slaughter establishment, or directly to an approved livestock facility from which they are shipped to a recognized slaughter establishment. In these cases, an owner-shipper statement suffices in place of an ICVI
- Cattle are moved directly from the farm of origin for veterinary medical examination or treatment and then returned to the farm of origin without a change of ownership
- Cattle are loaded in one State, transported through another State and then unloaded in the original State
- They are moved as a commuter herd. A commuter herd is defined as a herd of cattle or bison moved interstate between two premises during the course of normal livestock management operations and without change of ownership. For this exception to be made, a commuter herd agreement must exist. This is a written agreement between the owner or owners of the cattle and the animal health officials of the States or Tribes of origin and destination. The commuter herd agreement specifies the conditions required for movement, and must be renewed annually. A copy of the commuter herd agreement must accompany the cattle
- The animal health officials in the shipping and receiving States or Tribes agree on another form of identification.

Cattle and bison that are moved interstate must be identified by at least one of the following:

- An official individual ear tag
- A brand registered with a recognized brand inspection authority. The animal or animals must also be accompanied by an official brand inspection certificate, and the use of identification by brand must be with the agreement of the shipping and receiving State or Tribal authorities
- A tattoo or other identification method acceptable to a breed association for registration purposes, when accompanied with a breed registration certificate. The use of this method of identification must be with the agreement of the shipping and receiving State or Tribal authorities
- A group or lot identification.

Cattle may also be moved interstate with a USDA-approved back tag if their destination is a recognized slaughtering establishment or federally approved livestock facility. Additionally such animals are required to be slaughtered within three days of their movement to the slaughter plant. An official identification number is not required on the ICVI if the cattle are under 18 months of age, or spayed heifers, unless they are being shipped for rodeo, exhibition or recreational purposes.

16.3 Current identification systems for cattle

The new animal identification and traceability system is more flexible and does not mandate a particular form of identification. It is owned, led, and administered by the States and Tribal Nations with Federal support focused entirely on animal disease traceability. Until the new national system is fully implemented cattle identification and traceability systems across States will be disparate in terms of the methods that are used. For example, some States have a relatively high coverage of radio frequency identification devices for cattle, whereas others still largely rely on branding and tattooing. Most States have databases of animal holdings, but these are not nationally consistent. When trace back and cohort identification are required, State Departments utilise a number of sources of information including: owner/livestock producers; auction/market records; accredited veterinarians and health certificates; tuberculosis/brucellosis control program statistics, brand inspection records; livestock transporters' manifests; and official identification devices.

To ensure the traceability of imported cattle, APHIS requires that imported cattle must be accompanied by a permanent form of individual identification, and APHIS keeps records of the number and source of imported cattle in the APHIS Import Tracking System.

17 Summary: BSE control programs and technical infrastructure

The United States takes an active approach with its BSE awareness programs, notification requirements, and laboratory diagnostic procedures. Significant resources are dedicated to train animal health inspectors; prepare laboratory diagnosticians; educate livestock producers, renderers, and private practitioners; and alert the public about BSE. BSE has been a reportable disease in the USA since 1986. The USA has extensive national laboratory services for the testing of BSE and together with the national coordination, training and reference testing undertaken by the NVSL, has the field and laboratory expertise and capability to detect, properly diagnose, and confirm BSE.

Although individual identification of domestic cattle is not uniform across States within the USA, in the event of a need for trace back and cohort identification, Federal authorities work closely with State Departments to utilise a number of sources of information including: owner/livestock producers; auction/market records; accredited veterinarians and health certificates; tuberculosis/brucellosis control program statistics, brand inspection records; livestock transporters' manifests; and official identification devices. The USA has demonstrated through its investigations of the four reported cases of BSE that these mechanisms have been able to effectively trace back and identify animal cohorts when needed. The various methods of trace-back were effectively demonstrated in Nebraska and Colorado during the in-country verification visit.

BSE Surveillance

Section 3 of the Australian Questionnaire requires countries to provide evidence of the number of BSE-related samples collected for each cattle subpopulation, with data stratified by year and age group. Such data are then used to derive BSE surveillance point calculations using the recommendations from the OIE's *Terrestrial Animal Health Code*. The degree and quality of surveillance for BSE within the cattle population of a country, combined with other systems for BSE control, helps to determine the BSE risk status of the country. This chapter provides details of the United States' surveillance activities and historical data.

18 The BSE surveillance program in the USA

The United States has conducted BSE surveillance since 1990. Following the confirmation of BSE in an imported cow in December 2003, the USDA designed and implemented an enhanced BSE surveillance program to estimate the prevalence of the disease in the USA's cattle population. The enhanced surveillance began in June 2004 and had the goal of testing as many cattle as possible over a limited period. The USDA collected nearly 750,000 samples during a 2-year period and detected two US-born animals that were positive for atypical BSE.

At the end of the enhanced surveillance period the USDA initiated an ongoing surveillance program for BSE that was implemented by September 2006. The design and implementation of the ongoing program is compliant with the recommendations of the OIE guidelines in Articles 11.6.20 to 11.6.22 of the OIE *Terrestrial Animal Health Code.* Sampling of apparently healthy animals at routine slaughter has been discontinued because these animals are the least likely to be infected and have the lowest surveillance point values. Sampling of carcasses at rendering plants and slaughter facilities dedicated to diseased, disabled, dying or dead animals has been limited because they provide less surveillance information than other classes of cattle. However they provide the bulk of the samples tested. The emphasis has been placed on sampling animals that have at least one pre-defined clinical sign compatible with BSE, which include the following:

- Cattle of any age with progressive behavioural changes
- Cattle of any age with clinical signs of CNS dysfunction
- Cattle of any age that are rabies suspects but test negative for rabies
- Cattle of 30 months of age or older that are condemned at slaughter
- Cattle of 30 months of age or older that are non-ambulatory (downer cattle) regardless of apparent reason
- Cattle of 30 months of age or older hat are severely weakened, even if able to stand and walk for short periods
- Cattle of 30 months of age or older that are terminated, or die spontaneously, as a result of moribund conditions, infectious disease, emaciation or injuries
- Cattle of 30 months of age or older found dead, with the exception of those known to have died from acute conditions unrelated to CNS disorder, such as lightning strike, trauma, gunshot, or dystocia.

The Centre for Epidemiology and Animal Health (CEAH) in Fort Collins, Colorado is a national unit established to help APHIS strengthen animal health infrastructures both nationally and internationally through surveillance, monitoring, risk analysis, spatial epidemiology, and modelling. It forms part of the National Animal Health Surveillance System that integrates animal health monitoring and surveillance activities conducted by many federal and state government agencies into a comprehensive and coordinated system. A

national surveillance unit for BSE was established under the CEAH in 2005 to design and integrate surveillance for BSE and better analyse the surveillance data. Through the national BSE surveillance program, SOPs for reporting have been established and monthly statistics and reports on BSE testing are generated and analysed. The CEAH also generate reports on samples that are inappropriate for sampling due to autolysis or a failure to sample the obex region of the brain stem. On a national level approximately 2% of samples are lost due to not being testable and feedback is given to the regions if trends are observed. The CEAH examines the regional distribution and target sub-populations from which BSE samples are generated and develops recommendations for future surveillance.

19 BSE surveillance points data

Table 4, A-G: United States BSE surveillance points data, 2006-2012

Table 4A: Surveillance points data 1 October 2005 to 30 September 2006								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>1 to <2	118	0	0	0	507	203	1607	321
>2 to <4	247	64220	116	11	3134	1254	43145	8629
>4 to <7	593	444750	790	158	11556	18489	184722	166250
>7 to <9	210	46200	38	4	2923	2046	28807	11523
>9	204	9180	19	0	2481	496	13916	1392
Totals	1372	564350	963	173	20601	22488	272197	188115

Table 4B: Surveillance points data 1 October 2006 to 30 September 2007								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>1 to <2	78	0	0	0	131	52	21	4
>2 to <4	553	143780	0	0	1299	520	3451	690
>4 to <7	1573	1179750	0	0	6266	10026	18485	16636
>7 to <9	474	104280	0	0	2592	1814	2980	1192
>9	617	27765	0	0	2428	486	2180	218
Totals	3295	1455575	0	0	12716	12898	27117	18740

Table 4C: Surveillance points data 1 October 2007 to 30 September 2008								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>1 to <2	73	0	0	0	196	78	29	6
>2 to <4	502	130520	0	0	1583	633	4774	955
>4 to <7	1164	873000	0	0	6598	10557	16800	15120
>7 to <9	320	70400	0	0	3086	2160	2449	980
>9	365	16425	0	0	2743	549	2415	241
Totals	2424	1090345	0	0	14206	13977	26467	17302

Table 4D: Surveillance points data 1 October 2008 to 30 September 2009								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>1 to <2	65	0	0	0	32	13	6	1
>2 to <4	364	94640	0	0	1655	662	5404	1081
>4 to <7	1071	803250	0	0	6668	10669	17458	15712
>7 to <9	392	86240	0	0	2898	2029	2687	1075
>9	460	20700	0	0	2792	558	2191	219
Totals	2352	1004830	0	0	14045	13931	27746	18088

Table 4E: Surveillance points data 1 October 2009 to 30 September 2010								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>1 to <2	83	0	0	0	12	5	9	2
>2 to <4	376	97760	0	0	1342	537	4730	946
>4 to <7	932	699000	0	0	6790	10864	18720	16848
>7 to <9	428	94160	0	0	2804	1963	3281	1312
>9	546	24570	0	0	2091	418	2079	208
Totals	2365	915490	0	0	13039	13787	28819	19316

Table 4F: Surveillance points data 1 October 2010 to 30 September 2011								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>1 to <2	56	0	0	0	12	5	12	2
>2 to <4	325	84500	0	0	1052	421	4618	924
>4 to <7	1038	778500	0	0	6182	9891	18426	16583
>7 to <9	373	82060	0	0	2193	1535	3151	1260
>9	473	21285	0	0	1390	278	1154	115
Totals	2265	966345	0	0	10829	12130	27361	18884

Table 4G: Surveillance points data 1 October 2011 to 30 September 2012								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>1 to <2	0	0	0	0	10	4	20	4
>2 to <4	429	111540	0	0	1148	459	4800	960
>4 to <7	1077	807750	0	0	5719	9150	20723	18651
>7 to <9	420	92400	0	0	1586	1110	3250	1300
>9	511	22995	0	0	1115	223	1370	137
Totals	2437	1034685	0	0	9578	10946	30163	21052

Table 5: Surveillance points by year and for cumulative period, 2006-2012

Table 5: Cumulative points data by year for 2006 - 12 inclusive					
Year	Clinical Suspect	Routine Slaughter	Casualty slaughter	Fallen Stock	Total points for year
2006	564350	173	22488	188115	775126
2007	1455575	0	12898	18740	1487213
2008	1090345	0	13977	17302	1121624
2009	1004830	0	13931	18088	1036849
2010	915490	0	13787	19316	948593
2011	966345	0	278	115	997359
2012	1034685	0	10946	21052	1066683
					7433447

20 Summary: BSE surveillance

The United States has conducted BSE surveillance since 1990, reporting three positive indigenous animals in 2005, 2006 and 2012. All cases were subsequently shown to be atypical forms of BSE. One imported BSE case born in Canada was also reported in 2003. For the last seven complete fiscal years, surveillance results show that the United States has accumulated 7,433,447 surveillance points, which exceeds the OIE requirements for Type A surveillance by over 20 times. At a national level the USA analyses BSE surveillance data quarterly for trends and representativeness and makes recommendations to the States for improvements. Based on the surveillance data from October 1, 2001, to September 30, 2008, the USA has estimated that the prevalence of BSE in its cattle population would be less than 1 infected animal in 1 million adult cattle with 95 per cent confidence.

Conclusions and BSE Risk Characterisation

The release of the BSE agent into the USA through imports of live bovines or products of bovine origin is extremely unlikely. Live cattle are only imported from countries that have not reported BSE cases, or from Canada. Restrictions on live cattle coming from Canada since 2003 have minimized the possibility of BSE infectivity coming from this source. Bovine products are only imported from countries that are not considered to pose a risk from BSE or from countries under permit for restricted uses only. Since 2000, regulations have prohibited the entry of any processed animal proteins, or feed products containing animal proteins, from countries with reported BSE or considered to present an undue risk of BSE.

Animals at the highest risk of exhibiting BSE are identified through rigorous ant-mortem inspection procedures through prohibiting non-ambulatory animals or those animals showing signs consistent with BSE, from entering the slaughter chain and rendering system. Disposal of such animals is through incineration and/or landfill. In addition, the brain and spinal cord of older animals and other high risk tissues are prohibited from being rendered and used for animal feed. Audit results from both the BSE feed inspection program and the BSE feed testing program in the USA since 2005 show an extremely high level of compliance with the BSE feed regulations. Feed manufacturers are required to have procedures in place to prevent cross-contamination and it is estimated that over 98 per cent of feed manufacturers in the USA meet this requirement through dedicated facilities—that is, feed mills that do not use prohibited material where they produce feed for ruminant animals. The USA has demonstrated, through an appropriate level of audit and controls for more than eight years, that neither MBM nor greaves derived from ruminants is likely to have been used to feed ruminants. There is therefore a very limited possibility that BSE would enter and recycle in the animal feed system within the USA.

Food safety controls across the beef and beef products industry are the responsibility of the FSIS and State based animal health authorities. FSIS inspectors examine animals before and after slaughter, preventing diseased animals from entering the food supply and examining carcasses for visible defects that can affect safety and quality. In addition, about 250,000 different processed meat and poultry products fall under FSIS inspection. In addition to inspecting these products during processing, FSIS evaluates and sets standards for food ingredients, additives, and compounds used to prepare and package meat and poultry products.

Compliance with regulations ensures good hygienic practices are employed throughout the beef production and supply chain so that the risk of cross-contamination of edible product with potential BSE infected materials is minimised. BSE disease contingency plans for BSE are well established with defined responses across federal and state agencies. Food industries, including slaughterhouses, are required to establish and maintain traceability and food recall processes and these processes are audited and tested for effectiveness and efficiency through annual mock recalls. As a result of these system requirements, it is considered that the recovery of contaminated beef and beef products and tracing to at-risk animals could be achieved in a timely and effective manner.

The United States takes an active approach with its BSE awareness programs, notification requirements, and laboratory diagnostic procedures. Significant resources are dedicated to train animal health inspectors; prepare laboratory diagnosticians; educate livestock producers, renderers, and private practitioners; and alert the public about BSE. BSE has been a reportable disease in the USA since 1986. The USA has extensive national laboratory services for the testing of BSE and together with the national coordination, training activities and reference testing undertaken by the NVSL, has the field and laboratory expertise and capability to detect, properly diagnose, and confirm BSE.

Trace back and cohort identification for a BSE case investigation in the USA is achieved by Federal authorities working closely with State Departments to coordinate activities and to utilise a number of private and public sources of information so that animal movements are tracked and risk animals identified and managed. This has been effectively demonstrated in the active investigations undertaken by authorities as a result of the one imported Canadian and three indigenous atypical BSE cases in the USA. In addition, the recently commenced national animal disease traceability system will strengthen the ability to consistently trace cattle when moved inter-state. To ensure the traceability of imported cattle, APHIS requires that imported cattle must be accompanied by a permanent form of individual identification, and APHIS keeps records of the number and source of imported cattle in the APHIS Import Tracking System,

The United States has conducted BSE surveillance since 1990, finding three positive indigenous animals reported in 2005, 2006 and 2012 respectively and one imported Canadian case reported in 2003. All indigenous cases were subsequently shown to be atypical forms of BSE and were born more than eleven years ago. From 2006 to 2012, surveillance results show that the United States has accumulated 7,433,447 surveillance points, which exceeds the OIE requirements for Type A surveillance by over 20 times. This high level of surveillance is expected to continue within the USA.

BSE controls were observed to be operating effectively during the in-country assessment with a high degree of official government oversight by FSIS, APHIS, FDA, and good coordination with State authorities. Appropriate monitoring and inspection procedures were verified across the beef production chain. Auditing of establishments (feed mills, slaughterhouses, farms and rendering plants) by the Federal or State authorities occurs regularly, and major non-compliances around official BSE controls have not been detected for many years.

In conclusion, the USA has comprehensive and well established controls to prevent the introduction and amplification of the BSE agent within the cattle population and to prevent contamination of the human food supply with the BSE agent. This BSE food safety risk assessment concludes that imported beef and beef products sourced from the USA are safe for human consumption and recommends Category 1 status for the USA.

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Appendix 1: Overview of Cattle and Beef Industry in the United States

As of January 2010 the United States' cattle herd was 93.7 million head, the smallest it has been in 24 years. It has declined overall since peaking at 130 million in 1975. The herd has not exceeded 97 million head since 2004. This decline is due primarily to the decrease in the number of small operations with fewer than 50 head of cattle. The United States herd is over three times the size of Australia's cattle herd of 27.9 million head. The United States herd is widely distributed across the country but generally more concentrated in the central states. The domestic market consumes 93% of cattle slaughtered in the United States and only about 7% is exported.

In 2008, there were 956,500 United States properties carrying cattle, 757,000 held beef cattle, 82,170 held cattle in feedlots and 67,000 held dairy cows. Small cattle operations (1-49 head) accounted for 67.6% of all operations but only 11.5% of the national cattle herd. In contrast, large operations (500 or more head) accounted for 3.1% of all operations but 47.6% of the national cattle herd.

Total annual slaughter numbers of cattle, calves and bison for 2007-9 derived from USDA Animal Health Report 2007 USDA slaughter statistics are shown in Table A1.

Table A1: Total Annual Slaughter Numbers for Cattle, Calves and Bison in the United States (2007-2009)

Species/Category	**2007**	**2008**	**2009**
Cattle	34 264 000	34 364 800	33 338 200
Calves	758 100	956 800	944 200
Bison	67 000	70 100	68 300
Total	**35 089 100**	**35 391 700**	**34 350 700**

According to the NASS summary data, most commercially slaughtered cattle and calves undergo federal inspection by the Food Safety and Inspection Service (FSIS). In 2009, 98.3% and 98.5% of slaughtered cattle and calves respectively were federally inspected. The 2008 figures were 98.4 % and 98.5% respectively.

As of June 2010 27 states maintain state inspection systems in addition to federal registration of plants for meat. All other states have transferred the responsibility of meat inspection to FSIS and no longer maintain a two tier system of inspection.

Beef Grazing Industry

Grazing beef cattle (cows, bulls, steers, heifers and calves) accounted for approximately 80 million head (including 'other heifers' category), 85.4 percent of the total cow inventory on 1 January 2010.

Like other livestock commodities, the trend in the beef grazing industry over the last decade has been towards fewer but larger enterprises, with 54.4 % of the 1 January 2009 United States beef cow inventory being held by 9.7% of all US beef cow operations.

In 2009, sale of cattle and calves was the top agricultural commodity worth over US$43.7 billion (15.4% of total commodity value).

Total national beef production was 26,068 million pounds (11.82 million tonnes) in 2009 and 26,663 million pounds (12.09 million tonnes) in 2008. The majority of beef production is for the domestic market with only 7.1% of total United States beef production exported in 2008.

Cattle on Feed (Feedlots)

Cattle on feed are those being fed a ration of grain or other concentrates in preparation for slaughter.

The total number of cattle in United States feedlots on 1 January 2010 was just over 13.64 million. The vast majority of these are in feedlots with over 1000 head capacity (10.8 million on 1 May 2009), 128 of these larger feedlots hold 39.9% of the feedlot. Of these large feedlots, two-thirds are in Kansas, Nebraska and Texas, States with large grain supplies. The feedlot industry follows a seasonal pattern with numbers on feed peaking in December to February, and commercial cattle slaughter typically peaking in May and June.

Dairy Cattle Industry

In January 2010 the number of milk cows and replacement heifers was 9.08 million and 4.5 million respectively, in total representing approximately 14.5% of the national herd. Most dairy cattle are in California, Wisconsin, Minnesota and north-eastern States. Dairy cow numbers have remained relatively stable over the last decade, whilst by 2008 the number of dairy operations had decreased by 57.2% from 1998 levels. In addition to this general increase in the size of individual dairy operations, annual milk production per cow has increased by 17% over the same period.

In 2009 dairy products were fourth highest earning agricultural commodity worth over US$24.3 billion (8.6% of total commodity value).

Appendix 2: BSE case investigations

Case 1 – Imported BSE case from Canada

On December 9, 2003, a non-ambulatory 6.5-year-old Holstein cow, born on April 9, 1997, arrived at a slaughter plant in Washington State. A brain sample was submitted to the National Veterinary Services Laboratories (NVSL) for testing. The carcass passed post-mortem inspection, and the plant processed it as usual. The plant sent offal, including potential high risk material, to inedible rendering. On December 23, 2003, a preliminary diagnosis of BSE was announced and on December 25, 2003, the Central Veterinary Laboratory in Weybridge, England, confirmed the diagnosis.

The United States Animal and Plant Health Inspection Service (APHIS) followed the OIE's guidelines and conducted a complete trace of progeny, birth cohorts, and feed cohorts. In collaboration with the Canadian Food Inspection Agency (CFIA), the index cow was traced to a dairy farm in Alberta, Canada, proving the BSE-positive cow was an imported animal from Canada. By tracing the index animal's history, APHIS and CFIA determined that the index cow was included in a shipment of 81 cattle exported on September 4, 2001, through the port of Oroville, Washington, to a dairy cattle finishing location in south-central Washington State. At the finishing premises, three animals were retained; seven animals were moved to a heifer raising operation 50 kilometres away; and 70 animals, including the index case, were purchased and relocated on October 16, 2001, to a dairy farm 80 kilometres south (the U.S. index herd location) from the finishing site.

APHIS attempted to trace all animals that had entered the United States from the Canadian source herd. This included birth cohorts as defined by OIE guidelines and all other animals that were or could have been from the identified source herd. Investigations located 255 animals of interest (animals that were or could have been from the source herd in Alberta, Canada) that were identified on ten premises in three States in the Pacific Northwest (Washington, Oregon, and Idaho). Officials slaughtered, destroyed, and tested all 255 animals for BSE; all results were negative.

As recommended in OIE guidelines, officials traced and located the index cow's two most recent calves. They located a heifer, born on November 9, 2002, on the index herd premises in Washington (one of the 255 animals of interest previously mentioned). They euthanized that heifer, which tested negative for BSE. They located a bull calf, born on November 29, 2003, at a nearby bull-calf-rearing facility. Because the bull calf entered the rearing facility without any identification and could not be positively identified, officials euthanized all calves on the premises (n=449).

The CFIA conducted a feed investigation and concluded that the affected animal could have consumed pellets made with MBM before Canada's July 1997 feed ban. FDA officials located and contained over 2,000 tons of MBM and other by-products that could have been derived from the carcass of the infected animal. None of this material entered the animal feed manufacturing process.

Following the confirmation of BSE in an imported cow in December 2003, the USDA designed and implemented an enhanced BSE surveillance program to estimate the prevalence of the disease in the USA's cattle population. The enhanced surveillance began in June 2004 and had the goal of testing as many cattle as possible over a limited period. The USDA collected nearly 750,000 samples during a 2-year period and detected two US-born animals that were positive for atypical BSE.

Case 2 – Atypical BSE case from Texas

On June 10, 2005, a 12 year old beef cow from Texas was confirmed to be BSE positive on a scrapie-associated fibrils (SAF) immunoblot (Western blot) test. The Central Veterinary Laboratory in Weybridge, England, confirmed these results on June 24. The case was subsequently characterized as high-type BSE based on the Western blot banding pattern.

Upon confirmation of the positive test results, officials DNA-tested animals in the suspected herd of origin of the index cow, located in Texas, and confirmed that this farm housed the index herd. Because the index farm maintained essentially no records, officials compiled the list of known birth cohorts using brucellosis vaccination (CV) tag numbers from the VS national Generic Database records.

The birth cohort included 121 animals from the index farm, identified through CV tag number or tattoos. Of those, officials accounted for 67 animals. Of those, officials euthanized 42 animals and tested them for BSE with negative results. Officials identified and traced 25 animals that left the farm. Of those, officials determined 13 animals were presumed dead; 11 animals were slaughtered; and one animal, found alive, was euthanized and tested for BSE with negative results. Animal health officials disposed of the carcasses of all euthanized animals by burial in an approved landfill facility.

Of the remaining 54 animals from the birth cohort, several may have died within the index herd, but most likely left the herd without identification and would have been either retagged at the livestock market or consigned directly to slaughter without identification. To account for these remaining birth cohorts, officials traced all adult cattle that left the index farm since 1990 as animals of interest.

Officials traced 200 animals of interest: 143 were reported slaughtered, 34 were presumed dead, 20 were untraceable and two were alive. From the latter, one birth cohort was euthanized and tested negative and the other was determined not an animal of interest due to her young age.

Officials determined the at-risk progeny were the index cow‘s 2003/2004 calf and her 2002/2003 calf. Both had been sold through the livestock market. Officials discovered early in the investigation that not only the index farm owner and his wife sold animals from the index farm, but other immediate family members also sold these animals. Therefore, officials included calves sold from the index farm by all pertinent family members in the trace work. Additionally, there were no herd records to indicate the gender of the two at-risk progeny. Therefore, officials traced all calves sold during the appropriate period.

Officials identified 213 calves of interest to trace: 208 calves were confirmed to have entered known feeding/slaughter channels and 1 calf was classified as untraceable. No calves were traced to farms outside of feeding and slaughter channels.

The feed history investigation identified 21 feeds or feed supplements that were used on the index farm since 1990. The FDA conducted in-depth investigations and site visits involving 3 retail feed stores, 9 feed manufacturers, 10 slaughter plants, 8 renderers, and 1 broker. Investigators collected information on formulations, shipping invoices, and use of ruminant MBM on the premises before and after the 1997 ruminant feed ban. The investigation found no feed or feed supplements used on the index farm since 1997 had been formulated to incorporate ruminant materials.

Case 3 – Atypical BSE case from Alabama

On March 15, 2006 NVSL completed IHC testing on a sample from a 10 year old beef cow from Alabama and confirmed the second native case of BSE in the USA. The case was subsequently confirmed to be H-type atypical BSE.

The index cow gave birth to a black bull calf around February or March 2005 on the index premises. The owner took the calf to a stockyard sale in July 2005 where it died before sale.

The most recent owner of the index farm purchased the index case at a stockyard in December 2004. The stockyard records for that day describe the farm buying a single animal that matches the appearance of the index case. Because the index cow had no permanent identification, officials used the following criteria in an attempt to trace the index case to its herd of origin:

Stockyard records identified the previous owner of the index cow. The index cow was one of 26 animals sold as part of a dispersal of the herd in December 2004. The 26 animals had been purchased between July and November 2004. Officials evaluated stockyard records of all 26 cattle purchased to determine where the index cow came from. Despite a thorough investigation of two farms known to contain the index cow, and 35 other farms that might have supplied the index cow to the farms where the index case resided, investigators were unable to locate the herd of origin.

Case 4 - Atypical BSE case from California

On April 24, 2012, the USDA announced a fourth case of BSE in the United States. The index animal was a 10 year and seven months-old Holstein cow from a central California dairy. The animal was sampled by a renderer and results from immunohistochemistry and Western blot tests at USDA's NVSL confirmed the animal positive for L-type atypical BSE.

Two offspring of the index animal were designated as at-risk cattle. One was traced out-of-State and depopulated with "not detected" BSE test results. The other offspring was stillborn. The carcass of the index animal (along with approximately 90 other carcasses being held at the renderer's transfer station), were disposed of in a landfill. The carcass of the index animal did not enter the human or animal food chain. In conjunction with USDA's investigation, the FDA and the California Department of Food and Agriculture (CDFA) conducted an extensive feed investigation. Twelve feed suppliers were identified to the index premises; one of which was no longer in business. The remaining 11 were found to be in compliance with FDA and CDFA feed regulations and requirements.

Appendix 3: Legislation and official regulations concerning or relevant to BSE control

Title	Summary of Relevant Content
Acts	
Animal Health Protection Act	Act of Congress conferring powers to the Secretary of Agriculture for the prevention and control of animal diseases. Powers include: • prohibition of import, quarantine or restriction of movement, or destruction of animals, articles or conveyances • order to disinfect potentially infective items • prohibition or restriction of export from the USA • prohibition or restriction of interstate movement • seizure, quarantine, destruction or other remedial action towards infected or suspect animals, articles or conveyances • payment of compensation at fair market value, less any compensation received from a State or other source • refusal of compensation if the owner has violated control measures • warrantless inspection of moving conveyances • inspection, with warrant, of premises • diagnostic and control measures applied to livestock • establishment of a veterinary accreditation program • maintain property and/or employees to carry out measures • apply criminal penalties to persons violating the Act • collection of required information • promulgation of regulations and orders • appropriation of funds
Federal Food, Drug and Cosmetic Act	Subchapter VIII, Imports and Exports, includes the following, relevant to import of meat and meat products: • The food safety programs, systems and standards of the country, territory or region of origin of imported food must be adequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed or held within the United States. • Each shipment of food must be preceded by notice of the article, the manufacturer, the shipper, the grower (if this information is available in a timely manner), the country of origin, the country from which the article is shipped, any country to which the shipment has been refused entry, and the anticipated port of entry. This certification must be issued by an agency or representative of the government of the country from which the food originated. • The Secretary of Agriculture may also require documentation accompanying a shipment that lists certified facilities that manufacture, process, pack or hold the food • There is provision in this Act for the US Secretary of Agriculture to identify the inadequacies that prevent food offered for import from reaching the required standard, and to establish a process by which the exporting country can inform the Secretary of improvements in food processing, and can demonstrate those improvements.
Federal Meat Inspection Act	This Act, in common with the Federal Food, Drug and Cosmetic Act, requires that meat imported in the USA meets the same standards of meat inspection, slaughterhouse building standards, slaughter, sanitary protection, freedom from residues and other measures to ensure food safety as those applicable to meet produced and marketed within the United States.
Rules and Regulations in the Code of Federal Regulations (CFR)	
9 CFR 93 (Subpart D)	Regulations pertaining to importation of ruminants into the USA, including inspection powers, ports of entry, permits and certifications required quarantine etc. **9 CFR 93.405(a)(4)** specifies general certification required for bovines from Canada **9 CFR 93.436** addresses general requirements for ruminants from regions of minimal risk for BSE. Under **9 CFR 94.18**, this currently means Canada. Regulations for cattle imported from Canada for immediate slaughter include the following: • Cattle must have been born after March 1, 1999, the date of an effective ruminant-to-ruminant feed ban in Canada • Each animal must have a unique individual identification that is traceable to the premises of origin • Cattle must have appropriate certification and enter by an approved port of entry,

	and be conveyed directly to the slaughter premises in conveyances sealed by US officials at the port of entry. The seal may only be broken at the slaughter premises by an authorized USDA representative. Regulations for cattle imported from Canada for other than immediate slaughter include the following: • Cattle must have been born after March 1, 1999, the date of an effective ruminant-to-ruminant feed ban in Canada • Cattle must be permanently marked with 'CAN' by a freeze brand or hot iron brand on the right hip, and must have the tattoo 'CAN' inside one ear, or other approved permanent legible marking to indicate the country of origin • Each animal must have a unique individual identification that is traceable to the premises of origin
9 CFR 94.0	Definition of a BSE minimal risk region. Such a region must: • Maintain risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease, including restrictions on import of potentially infected ruminants, restrictions of the import of animal products or feed containing ruminant protein, BSE surveillance measures that meet or exceed the OIE recommendations, and an effectively enforced ruminant feed ban • Have conducted an epidemiological investigation into any BSE base sufficient to confirm the adequacy of control and prevention measures • Have taken any necessary additional risk mitigation measures in response to any BSE outbreak, based on risk analysis of the outbreak, and must continue to take those measures.
9 CFR 94.18	Classification of countries by BSE status. • BSE considered to be present in Austria, Belgium Czech Republic, Denmark, Finland, France, Germany, Greece, Republic of Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Oman, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Switzerland and the UK • Presenting an undue risk of introduction into the USA of BSE are Albania, Andorra, Bosnia-Herzegovina, Bulgaria, Croatia, Yugoslavia, Hungary, Macedonia, Monaco, Norway, Romania, San Marino and Sweden • Canada classified as minimal-risk with regard to BSE Importation of ruminant-derived meat , meat products, and edible products (excluding gelatin, milk or milk products) from these countries is prohibited except as provided by **9 CFR 94.19** Gelatin may be imported from any of the listed countries, regardless of BSE risk classification, provided it is for a use that will not result in it coming into contact with ruminants in the USA. Permit required. Meat and other bovine products may transit the USA subject to permit and Customs control, but must be in sealed leak-proof containers.
9 CFR 94.19	Prohibition of importation of ruminant-derived meat , meat products, and edible products (excluding gelatin, milk or milk products) from countries in **9 CFR 94.18 (a)(3)**, which includes only Canada, except under specific conditions which include: • Presence of a certificate of compliance issued by a government veterinarian • Bovines, sheep or goats of origin must have been subject to a ruminant feed ban • Bovines of origin must not have been stunned by an air-injection method at slaughter • SRM of the bovines of origin must have been removed at slaughter • Sheep or goats of origin must not have had, been exposed to or been suspected of a TSE • Meat from sheep or goats must not have been able to be contaminated or mixed with meat ineligible for export to the USA
9 CFR 94.27	This regulation makes an exception to 9 CFR 94.18 for whole cuts of boneless beef from Japan, subject to the following conditions: • The beef is from calves that were born, raised and slaughtered in Japan • The beef is from a slaughterhouse that is eligible under the FMIA and the regulations in 9 CFR 327.2 , and the beef meets all other applicable requirements of the FMIA and regulations thereunder (9 CFR chapter III), including the requirements for removal of SRMs and the prohibition on the use of air-injection stunning. • The cattle of origin were not subject to a pithing process at slaughter • The shipment is accompanied by certification from an authorized veterinary official of the government of Japan that the specified conditions have been met.
9 CFR 95.4	Prohibitions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and blood and blood products, with

	specified exceptions. Ruminant serum may be imported for scientific, educational, or research purposes if the Administrator determines that the importation can be made under conditions that will prevent the introduction of BSE into the USA. Other exceptions that may apply include: • The material is from a non-ruminant, or from ruminants that have never been in countries listed in **9 CFR 94.18** • The material has been processed in a country listed in **9 CFR 94.18** but only in facilities in which no material from ruminants of a country listed in **9 CFR 94.18** has been processed, and the facility has demonstrated to APHIS that there is no risk of cross-contamination, and the facility is subject to APHIS inspections • Serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ruminants may be imported, with appropriate documentation and controls, for use in cosmetics • Blood from an animal fit for human consumption may be imported if it was collected into a closed system at slaughter and there was no possibility of contamination with SRM • Fetal bovine serum may be imported if collected under specified conditions. • Specific exceptions for insulin, tallow and offal are also included in this regulation, subject to stated restrictions Conditions applying to transit of prohibited materials through US territory are also specified in this regulation.
9 CFR 310.22	Defines SRM and specifies their handling and disposition. SRM are defined as the The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from cattle 30 months of age and older and the distal ileum of the small intestine and the tonsils from all cattle. SRM are prohibited for use as human food and must be removed from bovine carcasses, segregated from edible materials, and disposed of in accordance with **9 CFR 314.1** or **9 CFR 314.3**. Establishments that slaughter or process cattle must incorporate procedures for the removal, segregation, and disposition of SRM into their HACCP plans or Sanitation SOPs or other prerequisite programs. Daily records of the implementation and monitoring of these procedures must be maintained for at least one year. Dedicated equipment must be used for SRM removal, or equipment must be cleaned and sanitized before being used on other parts of the carcass. Carcasses or parts of carcasses of cattle over 30 months of age, that still include the vertebral column, may be transported between federally-approved facilities provided that appropriate documentation accompanies the carcasses, and provided appropriate records are kept.
9 CFR 314.1	Covers the secure control and handling of condemned material prior to rendering ('tanking'), unless it is crushed, to ensure that the material cannot be mistaken for edible material. Under **9 CFR 310.22**, SRM may be disposed of in this way.
9 CFR 314.3	Covers the destruction of condemned material at facilities that have no 'tanking' (rendering) capability. In such cases the material must be destroyed or made inedible in the presence of an inspector by incineration or by chemical denaturation. Some appropriate denaturing chemicals are listed. Under **9 CFR 310.22**, SRM may be disposed of in this way.
9 CFR 320	Covers the keeping, maintenance, retention and inspection of records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, giving the following information with respect to each transaction in which any livestock or carcass, part thereof, meat or meat food product is purchased, sold, shipped, received, transported, or otherwise handled with any business subject to the Act: (i) The name or description of the livestock or article; (ii) The net weight of the livestock or article; (iii) The number of outside containers (if any); (iv) The name and address of the buyer of livestock or article sold by such person, and the name and address of the seller of livestock or articles purchased by such person; (v) The name and address of the consignee or receiver (if other than the buyer); (vi) The method of shipment; (vii) The date of shipment; and (viii) The name and address of the carrier.
9 CFR 418	Covers requirements for the notification of food recalls and written recall procedures. Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official

	establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will affect the recall, should it decide that one is necessary. All records, including records documenting procedures required by this part, must be available for official review and copying.
21 CFR 189.5	21 CFR Part 189 covers substances prohibited in human food. 21 CFR 189.5 specifically addresses substances from cattle that are prohibited in human food. These include SRM as well as non-ambulatory disabled cattle, cattle that have not passed ante-mortem and post-mortem inspections, and mechanically separated beef. The definition of SRM is found here as well as in **9 CFR 310.22** (*q.v.*), and the conditions and exclusions applicable to tallow and tallow derivative are found here as well as in **21 CFR 589.2001** (*q.v.*) Manufacturers and processors of human food must maintain, for at least 2 years, records sufficient to show that no prohibited materials from cattle are present in their products. Importers of food for human consumption must also be able to demonstrate that no such materials are in the food they import.
21 CFR 589.2000	Lists Specific Substances Prohibited From Use in Animal Food or Feed. Protein derived from mammalian tissues mean any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; tallow containing no more than 0.15 percent insoluble impurities and tallow derivatives as specified in 589.2001; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein. Outlines requirements for renderers that manufacture products that contain or may contain protein derived from mammalian tissues and that are intended for use in animal feed and include: • Labelling • Record keeping • Test and manufacturing conditions • Good manufacturing processes Lists requirements for protein blenders, feed manufacturers, and distributors, including pet food manufacturers that contain or may contain protein derived from mammalian tissues that include: • Labelling • Record keeping • Good manufacturing practices • Avoidance of cross-contamination • Clean-out procedures.
21 CFR 589.2001	Prohibits the use of certain cattle origin materials in the food or feed of all animals. Prohibited cattle origin materials include: • Entire carcass of BSE-positive cattle • Brains and spinal cords of all cattle 30 months or older • Entire carcass of cattle 30 months or older if brain and spinal cord were not effectively removed • Mechanically separated meat • Tallow, except as defined by the regulation Specifies documentation and records that renderers must keep to show compliance with the feed ban. Mandates separation of prohibited materials from permitted materials through the use of separate equipment and containers. Mandates the labelling of prohibited materials, or products made with them, to indicate that they must not be fed to cattle. Mandates the maintenance of appropriate records of suppliers, including certification or documentation from the supplier to verify that supplied materials to not contain prohibited material. All records must be maintained for at least one year and available for FDA inspection.
21 CFR 700.27	Covers substances of bovine origin prohibited from use in cosmetic products and essentially applies the same restrictions and prohibitions as those applied by 21 CFR 189.5 for human food.

Appendix 4: Countries from which materials or products in HTS codes that could include MBM or other sources of ruminant proteins have been imported since 2004

Countries from which materials or products in HTS codes that could include MBM or other sources of ruminant proteins have been imported since 2004			
Country	HTS categories for products[a]	OIE BSE risk classification	US classification per 9 CFR 94.18
Argentina	A,C,F,G,H,K	Negligible	-
Australia	A,B,C,D,G,H,I,J,K,L	Negligible	-
Austria	I	Negligible	BSE present
Belgium/Luxembourg	C,D,H,I,J,K,L	Negligible/ Controlled	BSE Present/BSE Present
Brazil	A,C,H,I,J,K,L	Negligible	-
Bolivia	A,C,	-	-
Bulgaria	D	-	Undue risk
Canada	A,B,C,D,E,F,G,H,I,J,K,L	Controlled	Minimal risk
Cambodia	K	-	-
Chile	A,C,F,I,K,L	Negligible	-
China	A,C,D,E, F,G,H,I,J,K,L	-	-
Colombia	A,B,C,I,K	Negligible	-
Congo (Brazzaville)	I	-	-
Congo (Kinshasa)	I	-	-
Costa Rica	C,K	-	-
Cote d'Ivoire	I	-	-
Czech Republic	G,H,I	Controlled	BSE present
Denmark	C,F,G,I,J,K,L	Negligible	BSE present
Dominican Republic	D	-	-
Ecuador	B,C,J,K,L	-	-
Finland	D	Negligible	BSE present
France	B,C,D,E,F,G,H,I,J,K,L	Controlled	BSE present
Gabon	I	-	-
Germany	A,C,D,E,F,H,I,J,K,L	Controlled	BSE present
Hong Kong	C,I,J,K,L	-	-
Hungary	C	Controlled	Undue risk
Iceland	C,I,J,K,L	Negligible	-
India	A,B,C,D,E,G,H,I,J,K	Negligible	-
Indonesia	A,C,E,L	-	-
Ireland	D,F,G,H,I,J,K	Controlled	BSE present
Israel	F,G,L	-	BSE present
Italy	B,C,E,F,G,H,I,J,K,L	Controlled	BSE present
Japan	C,D,I,J,L	Controlled	BSE present
Korea, Republic of	A,C,G,H,I,J,K,L	Controlled	-
Kyrgyzstan	L	-	-
Macau	I,L	-	-
Malaysia	B,C,E,G,H,I,J,K,L	-	-
Marshall Islands	F	-	-
Mexico	A,B,C,D,E,F,G,H,I,K,L	Controlled	-
Moldova	K	-	-
Namibia	A,C	-	-
Nepal	K	-	-
Netherlands	A,B,C,D,E,F,G,H,I,J,K,L	Controlled	BSE present
New Zealand	A,B,C,I,J,K,L	Negligible	-
Nigeria	A,I	-	-
Norway	B,C,D,I	Negligible	Undue risk
Pakistan	A,C	-	-
Panama	C	Negligible	-
Paraguay	A,C,J,K	Negligible	-
Peru	B,C,I,K,L	Negligible	-
Philippines	J	-	-

Poland	C,I,L	Controlled	BSE present
Portugal	H	Controlled	BSE present
Russian Federation	C,I	-	-
Sierra Leone	I	-	-
Singapore	J,K	Negligible	-
Slovenia	I,J,K,L	Controlled	BSE present
South Africa	I	-	-
Spain	B,C,G,I,J,K,L	Controlled	BSE present
Switzerland	A,C,H,I	Controlled	BSE present
Taiwan	A,C,D,F,H,I,J,K,L	Controlled	-
Thailand	A,C,E,G,H,J,K,L	-	-
Trinidad and Tobago	I	-	-
Tunisia	J	-	-
United Kingdom	C,D,F,G,H,I,J,K,L	Controlled	BSE present
Uruguay	A,C,I,J,K	Negligible	-
Venezuela	C	-	-
Vietnam	C,I,K	-	-

[a]Key:

A. Bones and horn cores; un-worked, defatted, prepared, treated with acid or degelatinized; powder and waste of the products
B. Flours, meals, and pellets of meat or meat offal; and greaves (cracklings)
C. Animal products not elsewhere specified or included; dead animals unfit for human consumption, which are chiefly used as food for animals or as ingredients in such food
D. Mixed poultry feeds or mixed poultry feed ingredients
E. Mixed dairy cattle feeds or mixed dairy cattle feed ingredients
F. Mixed other cattle feeds or mixed other cattle feed ingredients
G. Mixed swine feeds or mixed swine feed ingredients
H. Mixed other livestock feeds or mixed other livestock feed ingredients
I. Other mixed feed or mixed feed ingredients
J. Dog or cat food, put up for retail sale in airtight containers
K. Dog or cat good, put up for retail sale not in airtight containers
L. Other pet food, put up for retail sale

The class of import represented by A includes bone meal, bone ash, charcoal, degreased bone chips, and various pet food products. Permits have been issued for imports of bone ash or charcoal from the Netherlands and the UK for the manufacture of bone china. The imported shipments were consigned directly to the manufacturer with no opportunity for animal contact. Degreased bone chips are used in gelatin production. Degreased bone chips of bovine origin have been admitted from Canada under permit since 2005, subject to the condition that the animals of origin were less than 30 months of age at time of slaughter.

The class of import represented by B includes MBM of non-ruminant origin only. Exporters are required to demonstrate that any MBM is of porcine, avian or piscine origin.

The third class of import listed as C, includes a variety of animal products for use in pet food or as pet treats. Most imports made in this category can be shown to have been of porcine or non-mammalian origin. However slaughterhouse offal or ground beef may be imported from Canada for pet food production, being principally from bovine animals less than 30 months of age. The imports from Spain, France and Denmark were pig ears; the imports from Germany were pig ears, fish food and poultry by-products; the entries from the Netherlands were fish food, worms for fish food, and oyster shell for bird feed; entries from the UK were bloodworms or other marine by-products; and the entries from Japan were marine fish products for fish food.

The livestock feeds or feed ingredients represented by D to H were largely of non-animal origin. Most of these feeds were imported from Canada, which has very similar animal feed regulations to the US. Since August 1997, Canada and the USA have had closely harmonised regulations prohibiting the use of mammalian protein in ruminant feed.

The imports of mixed poultry feed ingredients from Japan and Germany were for salinomycin

- an antiprotozoal agent that acts on Coccidian parasites, while those from France include vitamin premixes, white millet and a specialty enzyme supplement that is not animal-derived. Imports of ingredients for dairy cattle feed from the Netherlands, France and Denmark were not of animal origin. Imports of swine feed from the UK were of finished swine feed containing no products of animal origin. Imports categorized as H or I include horse feed and supplements from the UK that contained no animal protein; fish food from the UK, the Netherlands, Germany and Japan; bird feeds from Belgium/Luxembourg, the Netherlands, Italy and Germany; and supplements, flavourings, vitamins and specialty pet foods from EU countries.

Dog and cat food imports classed as J, K or L include imports from BSE risk countries, but the shipments themselves did not contain proteins of ruminant origin. They included dental chews from Ireland; pig ears, salmon treats and other dog treats from Denmark; vegetable- or poultry-based dog treats, vegetable by-products and fish foods from Germany; pig ears from various European countries; and horse treats, fish foods, bird foods and rodent feeds from the UK. None of these included any prohibited proteins of bovine origin.

Appendix 5: Imports of beef or beef products into the USA, January 2005 – April 2012 inclusive, in metric tons

Imports of beef or beef products into the USA, January 2005 – April 2012 inclusive, in metric tons								
Carcasses and half-carcasses, fresh or chilled								
Country of origin	2005	2006	2007	2008	2009	2010	2011	2012
Canada	8592	7398	6522	5682	3853	2887	2794	917
Australia	0	0	0	0	1	0	0	0
New Zealand	0	9	0	0	0	0	0	0
Other Pacific Is.	0	0	0	0	1	0	0	0
Total	**8592**	**7407**	**6522**	**5682**	**3855**	**2887**	**2794**	**917**
Bone-in beef cuts, fresh or chilled								
Country of origin	2005	2006	2007	2008	2009	2010	2011	2012
Mexico	4089	7158	9159	8584	12681	19781	25414	10844
Canada	4714	16817	20387	15913	19576	26179	16482	4011
Australia	486	665	828	383	361	176	150	55
Nicaragua	14	57	135	19	0	0	81	19
New Zealand	19	2	21	20	3	1	11	2
Chile	0	0	7	0	2	5	0	0
Uruguay	10	0	0	0	0	0	0	0
Total	**9332**	**24699**	**30537**	**24919**	**32623**	**46142**	**42138**	**14931**
Boneless beef cuts, fresh or chilled								
Country of origin	2005	2006	2007	2008	2009	2010	2011	2012
Canada	334187	247047	227452	233073	237158	250464	199209	67791
Mexico	2499	4609	4896	4629	8924	17819	30101	14372
Australia	20626	32340	37369	29544	32304	26148	25343	8665
Nicaragua	4270	3332	6292	6257	5034	5579	8601	1611
Uruguay	19036	7394	8069	1685	2869	2087	1791	351
Honduras	0	0	19	131	37	363	1368	504
Costa Rica	2948	1825	2034	1636	1903	1442	836	201
New Zealand	4939	4988	3775	2087	1259	1493	815	523
Chile	0	0	253	271	24	170	129	1
Japan	0	174	545	149	141	41	0	0
Netherlands	0	0	0	19	0	0	0	0
Total	**388505**	**301709**	**290704**	**279481**	**289653**	**305606**	**268193**	**94019**
Carcasses and half-carcasses, frozen								
Country of origin	2005	2006	2007	2008	2009	2010	2011	2012
Australia	26	0	0	25	0	0	0	0
Canada	12	1409	236	182	0	0	0	0
New Zealand	5	22	0	0	0	0	0	0
Total	**43**	**1431**	**236**	**207**	**0**	**0**	**0**	**0**
Bone-in beef cuts, frozen								
Country of origin	2005	2006	2007	2008	2009	2010	2011	2012
Canada	872	1879	2497	2922	2526	3730	3362	1132
Mexico	17	0	10	297	1006	335	619	161
Australia	784	758	431	233	222	176	456	42
Nicaragua	87	37	60	48	84	108	228	87
New Zealand	885	511	356	130	22	98	101	0
Chile	0	0	9	1	16	69	58	17
Costa Rica	0	0	46	63	40	29	46	8
Honduras	0	8	0	0	1	0	0	0
Uruguay	60	0	0	7	0	0	0	0
Total	**2705**	**3193**	**3409**	**3701**	**3917**	**4545**	**4870**	**1447**

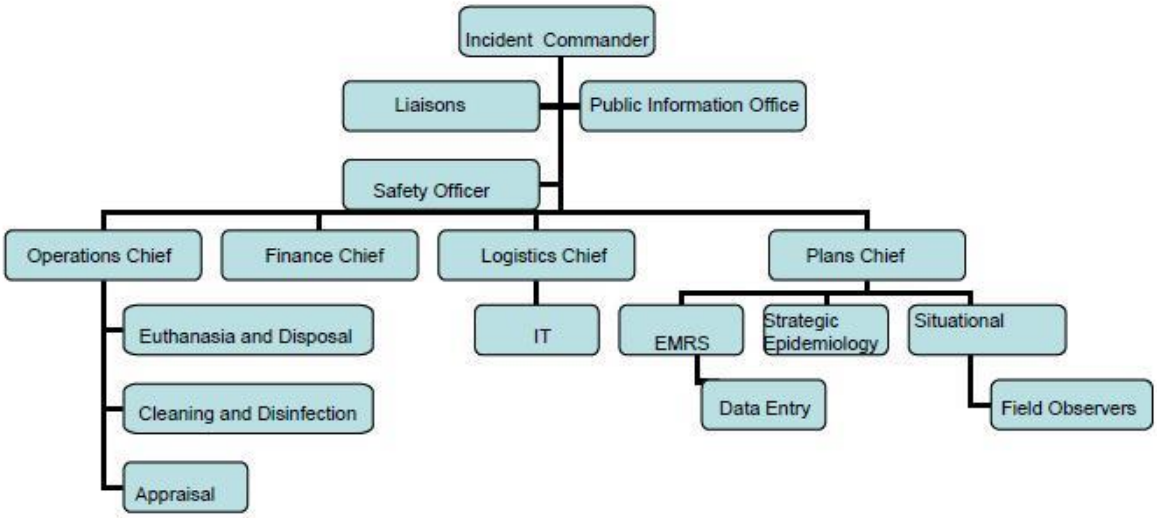
Imports of beef or beef products into the USA, January 2005 – April 2012 inclusive, in metric tons (continued from the previous page)								
Boneless beef cuts, frozen								
Country of origin	2005	2006	2007	2008	2009	2010	2011	2012
New Zealand	192371	181251	164068	171457	168313	152282	147308	58068
Australia	277631	261743	256986	190370	230332	161617	123842	62055
Nicaragua	16802	17285	22464	26659	24572	27739	32775	10374
Canada	18301	12978	13078	28204	13854	11713	12755	3960
Uruguay	154242	84273	96565	17804	19711	12793	9284	5630
Costa Rica	5630	4638	3919	4735	5744	6409	5682	1633
Honduras	191	87	133	2071	1541	1142	4764	2003
Mexico	2021	1868	2504	928	1537	698	1199	744
Chile	0	80	887	528	711	1170	776	39
Total	**667189**	**564203**	**560604**	**442756**	**466315**	**375563**	**338385**	**144506**
Sausages and similar products of beef, meat, meat offal or blood; food preparations based on these products								
Country of origin	2005	2006	2007	2008	2009	2010	2011	2012
Brazil	52724	66928	69241	52931	49686	15074	10837	6184
Argentina	26637	20553	16534	13498	10673	10514	10266	300
Uruguay	8683	7215	9604	1552	1867	2236	4628	1763
Mexico	3754	5739	6613	5783	3677	7078	3610	776
New Zealand	877	945	752	1632	2250	2851	3287	961
Canada	1910	1940	1987	1617	1345	1642	2402	1618
Australia	741	845	678	681	813	705	975	492
Chile	0	0	0	0	0	0	73	0
Croatia	97	81	66	23	7	13	13	0
Belgium/Luxembourg	0	0	0	42	16	0	0	0
Colombia	0	10	0	0	0	0	0	0
Denmark	0	0	58	0	0	0	0	0
Dominican Republic	5	0	0	0	0	0	0	0
France	1	3	3	4	3	4	0	0
Honduras	964	296	0	0	0	0	0	0
Italy	0	0	9	0	47	0	0	0
Netherlands	0	16	31	0	8	0	0	0
Nicaragua	0	133	400	114	3	0	0	0
Southern Asia NEC	147	0	0	0	0	0	0	0
Spain	0	0	0	2	3	1	0	0
Ukraine	0	1	0	0	0	0	0	0
United Kingdom	0	0	0	0	131	57	0	0
Vietnam	0	0	0	3	0	0	0	0
Total	**96540**	**104705**	**105976**	**77882**	**70529**	**40175**	**36091**	**12094**
Mixtures of pork and beef, prepared or preserved, offal or blood								
Country of origin	2005	2006	2007	2008	2009	2010	2011	2012
Mexico	0	0	67	211	396	293	355	104
Canada	1	4	3	0	0	0	14	3
Netherlands	33	0	0	3	0	0	0	0
Spain	0	1	4	0	0	0	0	0
Total	**34**	**5**	**74**	**214**	**396**	**293**	**369**	**107**
Meat and edible offal of bovine animals, salted, in brine, dried, or smoked: edible flours and meals of meat or meat offal								
Country of origin	2005	2006	2007	2008	2009	2010	2011	2012
Canada	129	151	183	180	117	122	141	43
Uruguay	252	238	356	190	222	152	78	39
Mexico	6	3	0	0	0	2	1	2
Australia	48	6	0	0	46	0	0	0
Brazil	0	0	740	956	4	0	0	0
China	0	0	2	0	0	0	0	0
Costa Rica	0	0	0	0	0	0	0	13
New Zealand	1558	57	157	53	0	0	0	0
Total	**1993**	**455**	**1438**	**1379**	**389**	**276**	**220**	**97**

Appendix 6: Typical feed use in dairy and beef production in the United States

Typical feed use in dairy production in the United States, by age and type of livestock			
Animal type	**Age or stage of life**	**Feed**	**Comments**
Calves, pre-weaning	0 – 4 weeks	Milk replacer or whole milk	Bull calves are generally fed only milk replacer or milk, and slaughtered for veal
	4 – 10 weeks	Milk replacer/milk + grain calf starter	
Replacement heifers, weaning to breeding	10 weeks to 15 months	Grain, forages, supplements. 6.2% of operations feed protein that is of animal, non-dairy origin.	Ration is initially primarily grain with forage fraction increased over time, with decrease in protein content of ration. Ingredients vary based on geographic availability
Heifers, breeding to first calf	15-24 months	Grain, forages, supplements	Ration is typically half grain and half forage. Ingredients vary based on geographic availability
Cows	Lactating	Grain, forages, supplements. Rarely pastured.	Greater volume and % protein compared to dry cow ration. 35% forage minimum.
	Dry (last 60 days of pregnancy)	Grains, forages, supplements. May be pastured.	~ half the volume, and lower protein content, compared to lactating ration

Feed use in beef production in the United States, by age and type of livestock			
Animal type	**Age or stage of life**	**Feed**	**Comments**
Calves, preweaning	0 to 7 months	Mother's milk and pasture	Calves are usually pastured with their mother until weaning
Calves, weaning to being sent to feedlot	7 to 10-12 months	Backgrounders: Grain, forage, supplements	Ration is initially primarily forage but concentrates are added over time, progressively increasing protein intake. Ingredients vary based on geographic availability.
		Stockers: Wheat pasture	
Feedlot	10/12 to 16-24 months	Grain, forage, supplements	Feedlot ration is typically high in concentrate and low in forage. Ingredients vary based on geographic availability
Cows		Pasture, ± grain	Beef cows are typically pastured but may receive a protein supplement in winter

Appendix 7: Baseline incident command post organisational structure



Appendix 8: Designated State BSE testing laboratories in the United States

Designated laboratories for BSE testing	
Designated laboratory	States from which samples are submitted
California Animal Health and Food Safety Laboratory University of California, School of Veterinary Medicine West Health Science Drive Davis, CA 95616	Arizona, California, Nevada
Colorado State University Veterinary Diagnostic Laboratory 300 West Drake, Rm. E-100 Fort Collins, CO 80523	Colorado, Illinois, Indiana, Kansas, Kentucky, Minnesota, Missouri, North Dakota, Ohio, South Dakota, Utah, Wyoming
Athens Veterinary Diagnostic Laboratory University of Georgia College of Veterinary Medicine, Building 1079 Athens, GA 30602	Alabama, Florida, Georgia, South Carolina, Virginia
USDA, APHIS, VS, NVSL 1800 Dayton Avenue Ames, IA 50010	Idaho, others as requested or redirected
Texas Veterinary Medical Diagnostic Laboratory Pathology Department 1 Sippel Road College Station, TX 77843	Arkansas, Louisiana, Mississippi, Oklahoma, Texas
Washington Animal Disease Diagnostic Laboratory Bustad Hall Room 155-N Pullman, WA 99164	Alaska, Hawaii, Iowa, Montana, Nebraska, New Mexico, Oregon, Washington
Wisconsin Veterinary Diagnostic Laboratory –TSE Laboratory University of Wisconsin -- Madison 445 Easterday Lane Madison, WI 53706	Tennessee, West Virginia, Wisconsin

Appendix 9: Flow chart for BSE testing