BSE Food Safety Risk Assessment Report

Brazil

Last Update: May 2014

Risk Assessment Production Process 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's (OIE) *Terrestrial Animal Health Code* (2009).[2] Brazil made a submission in 2011 to be assessed under Australia's BSE policy.

Brazil was previously assessed by the Australian BSE Country Categorisation Committee for Human Food Products (ABCCC) in 2003 for the purpose of country categorisation. Brazil was assigned to Category A, meaning that beef and beef products from Brazil were regarded as posing a negligible risk to human health.

FSANZ has carried out an assessment of legislative measures concerning control and prevention of BSE in Brazil, and an in-country assessment to verify the application and enforcement of these measures. Five main control areas were examined:

(1) Import controls to prevent the release of the BSE agent through imports of animals or animal-derived products.
(2) Feed ban controls to prevent contamination of the animal feed supply with 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 risk of the BSE agent being released into the Brazilian cattle population through imports of MBM, live cattle, or beef and beef products is effectively managed.

Importation of MBM, or animal feed containing mammalian proteins, from countries with BSE was first banned in 1991, with updates and refinements to the ban in successive legislation. Brazil neither produces nor imports greaves. Since 2003, pet foods and finished animal feeds containing animal proteins have been accepted for import into Brazil only if they originated from countries with no history of BSE.

Importation of live cattle from countries in which BSE has occurred has been prohibited since 1990. Since 2001, cattle imported from countries that subsequently reported BSE have been subject to tracing and monitoring, cannot be sent to slaughter, and can be sold to another farmer only with approval of the Official Veterinary Service (OVS). When these cattle die, they are sampled for BSE prior to incineration and burial of the body on the farm. Countries of origin have been categorised according to the incidence of BSE since 2004. In 2008, Brazil adopted the category system of the OIE**.**

Importation of bovine products since 2003 has been limited to bovine pancreas and casings, originating exclusively from countries classified by the OIE as being at negligible risk of BSE.

The frequent revision of legislation related to imports of cattle and products derived from cattle illustrates that Brazil has been diligent in monitoring the BSE status of other countries, and in monitoring growing scientific knowledge concerning BSE.

The risk of introducing and recycling BSE infectivity through ruminant feed is regulated at multiple control points in Brazil, and the risk of BSE entering and recycling within the bovine feed system or entering the human food supply in Brazil is negligible.

Brazil relies principally on extensive, pasture-based cattle-farming systems, and 94% of the national cattle herd is never fed processed feeds. A ban on feeding mammalian proteins to ruminants has been in place since 2001 and is subject to enforcement including sampling of feed, both at feed mills and on farms, for prohibited material.

Specific requirements for feed mills producing both feed for ruminants and feed for non-ruminants, include: separate production lines, GMP implementation, validated procedures to prevent cross-contamination at all stages of production, and laboratory analysis of at least 10% of batches of ruminant feed. Feed containing animal protein must be prominently labelled to indicate that the feed must not be fed to ruminants, and may not be transported with feed for ruminants. A national program to detect cross-contamination at feed mills has been in place since 2003. There are also on-farm controls to ensure that purchased feed meets specifications, and that records of feed purchases are kept.

Control of slaughterhouse procedures is effectively applied by on-site federal inspection personnel and by regular internal and external audits. Any bovine animal showing clinical signs suggestive of BSE, or any bovine animal that dies in transit to a slaughterhouse, must be destroyed by incineration. Slaughterhouses must comply with mandatory procedures at stunning and slaughter to ensure SRM are removed and that there is no contamination of edible meat by SRM. SRM are destroyed by incineration or another approved method. Although it contains no SRM, MBM must be prominently labelled to indicate that it must not be fed to ruminants.

Brazil has appropriate control programs for the identification and notification of BSE clinical suspects, and for the laboratory diagnosis of cattle infected with BSE. There is a network of four laboratories for the diagnosis of BSE. All the laboratories perform the initial examination by histopathology. The second examination by immunohistochemistry is performed only at the federal LANAGRO laboratory. Diagnostic procedures are compliant with the OIE *Manual of Standards for Diagnostic Tests and Vaccines for Terrestrial Animals* (Manual of Standards)[3]. All four laboratories participate in international proficiency tests with OIE reference laboratories.

The federal veterinary service has been promoting technical training on BSE prevention and surveillance since 1997. There is a comprehensive program of training and continuing education on BSE directed at veterinarians and other field workers providing services to cattle farms. There are a wide range of publications and other materials distributed within the veterinary profession, as well as to farmers, livestock technicians and the general public. BSE has been a notifiable disease in Brazil since 1997, and a contingency plan for use in the event of a diagnosis of BSE has been established, published and distributed.

All cattle in Brazil must be marked by brand, tattoo or similar means to indicate the farm of origin and properties on which they were subsequently kept. Brazil also has a mandatory system for recording the movement of all cattle, and particularly rigorous movement control for cattle in municipalities adjacent to national borders. The Brazilian federal identification system for individual identification of cattle and buffaloes, SISBOV, is voluntary, but is required for beef producers who wish to supply markets requiring traceability that includes individual identification. This system includes an online database and a comprehensive inspection program.

Comprehensive food safety controls exist in Brazil to allow effective protection of the human

food supply from potential BSE contamination. Measures to prevent SRM contaminating the domestic and export food supply are in place. All establishments producing or supplying products of animal origin must have a comprehensive recall plan and must conduct simulations to ensure that the recall plan is effective. The recall plan and simulations are subject to audit by the Federal Inspection Service.

All beef and beef products produced in Brazil are traceable to the day of slaughter by reference to the GTA and invoices. Cattle are then able to be traced back to the farm of origin electronically (if within the SISBOV system) or by a review of slaughterhouse records. For the supply of export markets that require traceability of individual animals, export slaughterhouses will only accept cattle registered in SISBOV, a system which features individual lifetime traceability. Brazil exports beef to numerous countries that demand a high standard of traceability, and export slaughterhouses are experienced in meeting the requirements of export markets.

Brazil carries out active surveillance in compliance with the guidelines in Articles 11.5.20 to 11.5.22 of the OIE's *Terrestrial Animal Health Code*. Current surveillance practices have been in place since 2002. Brazil's total points for the seven years 2006-2012 inclusive were well in excess of the points target specified by the OIE for Type A surveillance.

In conclusion, robust controls to prevent BSE from entering and recycling within the bovine feed system or entering the human food supply in Brazil have been in place for at least eight years. The FSANZ BSE food safety assessment of Brazil recommends **Category 1** status for Brazil.

Acronyms

ABCCC	Australian BSE Country Categorisation Committee
AISIPOA	Industrial and Sanitary Inspector for Animal Origin Products
BND	National Database of bovine and bubaline animals
BSE	Bovine Spongiform Encephalopathy
CAO	Community Assistance Office
CNS	Central nervous system
DIA	Animal Identification Document
DPDC	Department of Consumer Protection and Defence
DSA	Animal Health Department (a department of MAPA)
EFSA	European Food Safety Authority
ERAS	Rural Establishment Approved by SISBOV
FMD	Foot and mouth disease
FSANZ	Food Standards Australia New Zealand
FPNC	Manufacturer of Non-Edible Products
GBR	Geographical BSE Risk
GMP	Good Manufacturing Practice
GTA	Animal Transit Guide
LVU	Local Veterinary Unit
MAPA	Ministry of Agriculture, Livestock and Food Supply
OIE	Office International des Epizooties (World Organisation for Animal Health)
OVS	Official Veterinary Service
SCAD	Scientific Commission for Animal Diseases
SDA	Secretariat of Animal and Plant Health and Inspection
SFA	Federal Superintendence of Agriculture, Livestock and Food Supply
SID	Official Inspection Service(s) of District(s)
SIE	Official Inspection Service(s) of State(s)

SIF	Federal Inspection Service
SIM	Official Inspection Service(s) of municipality/municipalities
SISBOV	System of Identification and Certification of Cattle and Buffaloes
SRM	Specified risk material
SUASA	Unified System of Agricultural Health
TSE	Transmissible spongiform encephalopathy
UF	Federative Unit
UK	United Kingdom of Great Britain and Northern Ireland
USA	United States of America

Glossary

Australian Questionnaire is 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 misfolded protein, or prion, that causes BSE.

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

Specified risk material[a] (SRM) as defined by Brazilian legislation comprises brain, eyes, spinal cord, tonsils, and distal 70 cm of ileum of all cattle and buffaloes regardless of age.

[a] The Australian BSE policy defines BSE risk materials are tonsils and distal ileum from bovine animals of any age; brains, eyes, spinal cord, skull and vertebral column of bovine animals over 30 months of age.

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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]. Legislation and standards underpinning BSE controls are also examined as part of the food safety assessment and these were provided as appendices to Brazil'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)[2]. The Australian Questionnaire also seeks additional information on animal traceability and identification, and animal slaughtering and processing systems.

Brazil submitted an application to FSANZ for country categorisation of BSE food safety risk in 2011. 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 Brazil.

BSE History

Brazil is a member of the OIE. At the OIE's 80th General Session in May 2012, the OIE recognized Brazil as a Member Country having a Negligible Risk for BSE in accordance with Article 11.5 of the *Terrestrial Animal Health Code.*

Importation of beef and beef products from Brazil to Australia is currently permitted by the Australian Government Department of Agriculture subject to certification requirements that have been in operation since 2003, when Brazil was classified as a Category A country under Australia's previous BSE policy.

A finding of the BSE agent in an aged cow in Brazil was reported to the OIE on 7 December 2012. The cow was a 13-year old beef cow that had been reared in an extensive grazing system in the state of Parana. The cow was kept throughout its productive life on pasture with mineral supplements. The owner notified the Official Veterinary Service (OVS) on 18 December 2010 that the cow was recumbent and showing limb stiffness. The OVS visited the holding the next day, by which time the cow was dead. Central nervous tissue was sampled for surveillance for rabies and BSE, and the cow was buried in a deep ditch on the holding. The central nervous tissue was negative for rabies and a negative histopathological result for BSE was obtained by an OVS-accredited laboratory on 11 April 2011. The sample was sent to the National Reference Laboratory and tested positive for BSE by immunohistochemistry on 15 June 2012. The sample was sent to the OIE Reference Laboratory in Weybridge, UK, for confirmatory diagnosis and tested positive for BSE by immunohistochemistry on 6 Dec 2012.

The case is considered to be atypical BSE, which occurs sporadically and appears to arise spontaneously. The delay between the histopathological examination and the immunohistochemical examination was due to overload in Brazil's network of accredited laboratories, as a result of a fire in a laboratory. Brazilian authorities undertook a comprehensive review of the case, including exhuming the cow to verify age by dentition,

and tracing surviving cohort animals that were terminated and tested for BSE. All cohort cows were negative for BSE. Laboratory systems to ensure that samples sent for BSE confirmatory testing are processed in a timely way have also been implemented.

Following the report of the atypical BSE case, the Scientific Commission for Animal Diseases (SCAD/OIE) reaffirmed the classification of Brazil as a country with negligible risk for BSE in February 2013 and again in May 2013. A second case of atypical BSE was confirmed on 9 May 2014 and was in a 12-year old beef cow. This animal was born and raised on a single farm under extensive pasture.

Potential for release of the BSE agent through imported materials

The importation of specific commodities is a possible avenue through which the BSE agent can be released into a country's cattle population. Commodities that could introduce BSE, if contaminated, include: MBM, live cattle, and a range of products of bovine origin.

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 present.

Section 1.2 of the Australian Questionnaire requires details of live cattle that have been imported during the past 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 importation of MBM, live cattle, and beef products into Brazil, as well as relevant legislation, certification and other controls that underpin the integrity of the system.

1 Importation of MBM

1.1 Overview

Importation of animal protein sourced from ruminants poses a potential food safety risk as it is the primary route through which cattle are exposed to BSE infectivity. Importation of MBM into Brazil since 2003 has been restricted to MBM from other South American countries and from New Zealand, none of which have had cases of BSE. Brazil neither produces nor imports greaves.

1.2 Legislation

The Ministry of Agriculture, Livestock and Food Supply (MAPA) administers and enforces legislation regarding the importation of animal protein, including MBM, into Brazil (see Appendix 2).

Importation of products of bovine origin, including but not limited to 'bone, meat or blood meal destined to animal feed' and 'animal feed made with protein originating from domestic or wild ruminant animals' from countries with a high incidence of BSE was first prohibited in

Normative Instruction No. 2 of July 1, 1991. At that time, only the UK was considered by Brazil to have a high incidence of BSE. France, Ireland and Switzerland were considered to have a low incidence of BSE and importation of some bovine products was permitted, but MBM, or animal feeds containing MBM, were not included in the list of permitted products from those countries. The legislation has been refined and updated through a number of subsequent Normative Instructions, Administrative Decrees, and Service Instructions, reflecting increasing scientific knowledge of BSE, as summarised in **Appendix 3.**

Administrative Decree No. 516 of December 9, 1997, made BSE a notifiable disease and imposed a ban on the use of ruminant proteins in ruminant feed, with the exception of proteins derived from milk. The feed ban was extended and refined to a ban on the production, importation, marketing or use of any source of protein or fat from mammals for the purpose of feeding ruminants, with the exceptions of milk protein and calcined bone flour, under *Normative Instruction No. 6 of February 1, 2001.*The same legislation also prohibited the import, from countries in which BSE has occurred, of any source of protein or fat from mammals for the feeding of other animal species. *Normative Instruction No. 6 of February 1, 2001* was superseded later that year by *Normative Instruction No. 15 of July 17, 2001*, which kept the same restrictions but added a prohibition on the importation of ruminants, embryos and other ruminant products from countries that had reported cases of BSE. This legislation also prohibited the production and commercialization of mammalian proteins and fats in Brazil when intended for ruminant consumption. When Canada registered its first case of BSE in 2003, MAPA published the *Normative Instruction no. 58 of July 21, 2003*, prohibiting the importation of any product containing ruminant protein, regardless of its destination. Items of ruminant origin exempt from the importation ban, under *Normative Instruction No. 7 of March 17, 2004*, included milk, dairy products, semen and embryos, protein-free tallow and derivatives, dicalcium phosphate, hides and skins, and gelatine or collagen produced from hides or skins. Prohibition on the production of products, destined to be fed to ruminants, which contain proteins or fat of animal origin was reiterated under *Administrative Decree No. 8 of March 25, 2004*.

Normative Instruction no. 15 of October 29, 2003 specified that animal residues must be rendered at minimum conditions of 133°C and 3 bar for 20 minutes, the minimum conditions recommended by the OIE in order to minimise BSE infectivity. Imported MBM and imported feedstuffs containing MBM must be accompanied by certification of compliance with these conditions, and must also originate from countries with negligible risk of BSE. The same minimum rendering conditions were reiterated in *Regulatory Instruction No 34, May 28, 2008*, which is the current legislation in force.

A classification system for countries, on the basis of their BSE history, was adopted under *Service Instruction DDA No. 22/02 of September 23, 2002*. The list of risk and non-risk countries has since been updated by successive pieces of legislation, copies of which were provided with the submission. The current list is found in *Normative Instruction no. 49 of September 15, 2008.*

1.3 Details of MBM imports

Quantities and countries of origin of imported meat meal of farm animal or poultry origin, from 2005 through to 2010 inclusive, are shown in **Table 1**. All the countries from which meat meal has been imported in the last eight years are classified by the OIE as having a negligible BSE risk.

Quantities and countries of origin of other non-edible animal waste from farm animals or poultry, and fat meal, imported into Brazil from 2005 through 2010 are shown in Table 2.

Table 1: Metric Tons of Meat Meal of Farm Animal or Poultry Origin Imported into Brazil, 2005-2012									
Country	2005	2006	2007	2008	2009	2010	2011	2012	**Total**
Chile	0	0	0	43.4	86	200	174.5	225.6	**729.5**
New Zealand	100	20	0	0	0	0	0	0	**120.0**
Uruguay	243	351	0	0	27	54	54	0	**729.0**
Total	**343**	**371**	**0**	**43.4**	**113**	**254**	**228.5**	**225.6**	**1578.5**

Table 2: Metric Tons of Non-edible Animal Waste and Fat, of Farm Animal or Poultry Origin, Imported into Brazil, 2005-2012									
Country	2005	2006	2007	2008	2009	2010	2011	2012	**Total**
Argentina	0	0	0	25	50	0	0	0	**75.0**
Paraguay	6964.5	3643	0	0	0	0	0	0	**10607.5**
USA	19.75	39.5	0	0	0	0	0	0	**59.3**
Total	**6984.3**	**3682.5**	**0**	**25**	**50**	**0**	**0**	**0**	**10741.8**

Argentina and Paraguay are classified by the OIE as having a negligible BSE risk. The OIE classification of the USA was upgraded to 'negligible' in 2013, but was previously 'controlled'. Brazil prohibited importation of meal containing ruminant protein from the USA in December 2003 in response to the reporting of the first case of BSE in the USA. All imports from the USA shown in **Table 2** were of swine origin.

2 Importation of pet food and finished animal feed

There were a number of importations of pet food and finished animal feed into Brazil from 2005 through 2012. Imported pet food or finished animal feed may contain animal protein only if it is imported from a country with negligible risk of BSE. Importation of pet foods from BSE risk countries was permitted only if they contained no animal protein. Details of pet food imports are presented in **Table 3.**

Table 3: Metric Tons of Pet Food Imported into Brazil, 2005-2012									
Country	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**Total**
BSE Negligible Risk Country									
Argentina	4240.5	4648.9	226.8	2841.4	2413.71	3656.35	3288.01	27.42	**21343.09**
Uruguay	0	26.8	12.65	0.5	6.54	1.96	3.06	0.25	**51.76**
BSE Risk Country (imported product cannot contain animal protein)									
Austria	0	92.38	188.3	134.36	149.07	156.24	395.49	392.56	**1508.4**
China	0	0	0	0	15.99	15.48	43.65	14.58	**89.7**
France	0	0	0.48	0	0	0	0	0	**0.48**
Germany	0	0	0	0	0	35.35	53.47	0	**88.82**
Italy	0	0	0	0	0	0	19.36	0	**19.36**
Norway	0	0.15	0	0	0	0	0	0	**0.15**
Poland	0	0	0	0	0	0	0	0.16	**0.16**
US	352.18	206.34	245.2	189.2	231.11	408.76	539.01	990.96	**3162.76**
Total	**4592.68**	**4974.57**	**673.43**	**3165.46**	**2816.42**	**4274.14**	**4342.05**	**1425.93**	**26264.68**

Details of finished animal feed imports are presented in **Table 4.**

Table 4: Metric Tons of Finished Animal Feed Imported into Brazil, 2005-2012									
Country	2005	2006	2007	2008	2009	2010	2011	2012	Total
BSE Negligible Risk Country									
Argentina	0	34.57	2146.8	53.53	0	0	2607.39	6056.75	**10899.04**
Chile	84	75	27	0	0	0	0	0	**186.00**
Mexico	0	0	0.12	0	0	0	0	0	**0.12**
Paraguay	435	0	0	480	180	0	0	0	**1095.00**
Uruguay	0	0.45	0.63	9.48	0.72	0	0	0	**11.28**
BSE Risk Country (imported product cannot contain animal protein)									
Belgium	19.04	147.85	233.94	47.19	38.07	12.95	40.55	17.61	**557.20**
Canada	0	0	0	1.3	5	6	0	86.47	**98.77**
Cuba	0	1.12	4.13	4.33	3.61	3.19	2.06	0	**18.44**
Germany	33.77	43.35	50.57	62.83	60.41	96.27	56.99	90.11	**494.30**
France	8.87	0	47	468.79	182.3	312.83	188.27	101.53	**1309.59**
Japan	0	0.06	0	0	0	0	0	0	**0.06**
Malaysia	16.73	8.16	262.04	10.1	0	9.1	0	0	**306.13**
Poland	0	0	0	0	0	0	8.11	5.65	**13.76**
South Korea	0	0	0.5	0	3	0	0	0	**3.50**
Spain	0	0	0	0	0.25	0.37	0.37	0.93	**1.92**
Switzerland	0.25	0	0	0.43	0.5	0	0	0	**1.18**
Netherlands	3647.6	5120.3	5958	5817	4003.19	4468.97	2985.00	1539.70	**33539.76**
USA	111.19	95.75	437.01	66.54	130.11	109.33	172.21	124.50	**1246.64**
Total	**4356.45**	**5526.61**	**9167.74**	**7021.52**	**4607.16**	**5019.01**	**6060.95**	**8023.25**	**49782.69**

3 Importation of live cattle

3.1 Overview

Importation of live cattle represents a potential food safety risk if imported cattle are sourced from countries that do not have adequate control programs in place to minimise the risk of BSE exposure.

3.2 Legislation

Prevention of BSE in Brazil is the responsibility of the Animal Health Department (DSA) of MAPA. DSA develops the legislation applicable to imports, based on available knowledge of BSE.

The first BSE-related legislation in Brazil was *Service Instruction no. 1, July 31st, 1990*, which prohibited the importation of live cattle from countries that had confirmed or suspect cases of BSE. This was followed by the *Normative Instruction no. 15 of July 17th, 2001*, which prohibited the importation of live cattle from countries that had registered indigenous cases of BSE. At that time, North America had not reported any BSE cases, but Canada reported its first BSE case in 2003. As a result, *Normative Instruction no. 58 of July 21st, 2003*, was issued, prohibiting the importation of live cattle, ruminant products or embryos from Canada.

Normative Instruction no.8 of February 18, 2001 prohibited the commercialization and transference to other farms of cattle imported from BSE risk countries, without prior authorization of the OVS. Cattle imported from BSE risk countries cannot be sent for slaughter, and upon their death or their owner's intention to destroy them, the veterinary service must be notified. A brain sample is collected for BSE testing before the animal is destroyed and either buried or incinerated on the farm.

Service Instruction no. 22 of September 23rd, 2002, established tracing and monitoring of imported cattle from countries at risk for BSE, the definition of animals considered to be clinical suspects for BSE, and a list of countries from which live cattle and products of bovine

origin could not be imported into Brazil.

In response to the growing number of countries that had notified BSE cases, MAPA published *Normative Instruction no. 07 of March 17th, 2004*, which prohibited the importation of ruminants, their products and by-products, and veterinary products containing ruminant protein from countries that had reported indigenous cases of BSE or that were considered to be countries at risk of BSE. In the same year, MAPA published *Normative Regulation no. 25 of April 6, 2004*, which established lists of countries assigned to categories on the basis of BSE risk.

Mandatory inclusion of all imported cattle and buffaloes (bubalines) in the Brazilian System of Identification and Certification of Bovine and Bubaline Origin (SISBOV) was established in *Normative Instruction no. 59 of July 30, 2003*. Legislative requirements of SISBOV were further specified in *Normative Instruction No. 17 of 13 July 2006*.

The OIE risk categories for BSE were adopted by Brazil under *Normative Instruction No. 49, September 15, 2008,* which is the currently applicable legislation. This legislation prohibited importation of live cattle or bovine products from Category III countries, whereas importation from Category 1 or Category II countries was permitted, subject to conditions or restrictions dictated by MAPA. Category I countries are those assessed by OIE as having negligible risk and Category II countries are those assessed as having controlled risk. Both classifications indicate that the country has legislation prohibiting the feeding of mammalian protein to ruminants, and a surveillance system to detect the occurrence of BSE in the country.

3.3 Details of live cattle imports

Importations of live cattle from 2005 through 2012 are summarized in **Table 5**.

Table 5: Live Cattle Imports into Brazil, 2005-2012

Country	2005	2006	2007	2008	2009	2010	2011	2012	Total
Cattle imported for breeding purposes									
Argentina	0	0	0	0	213	108	22	17	**360**
Australia	27	0	0	3	0	0	0	0	**30**
New Zealand	0	2	0	7	0	0	0	0	**9**
Paraguay	0	93	167	0	0	0	0	0	**260**
Uruguay	1082	1494	5928	34148	2280	1087	1296	256	**47571**
Total	**1109**	**1589**	**6095**	**34158**	**2493**	**1195**	**1318**	**273**	**48230**
Cattle imported for slaughter									
Uruguay	0	0	4059	35383	517794	66846	3944	0	**628026**
Total	**0**	**0**	**4059**	**35383**	**517794**	**66846**	**3944**	**0**	**628026**

A total of 676,256 cattle were imported into Brazil from 2005 to 2012 inclusive, of which 48,230 were for breeding and 628,026 for slaughter. Since 2003, all cattle imported into Brazil have originated from countries in South America or Oceania that are classified by the OIE as having negligible BSE risk. In 2003, 23 cattle were imported from Canada and 453 from the USA. All of these North American imports were for breeding purposes, and are considered to be unlikely to have been infected with BSE in their herd of origin. Of the total 476 cattle imported from North America in 2003, 85 have not been traced. However, if sent for slaughter these cattle will be tested for BSE on the grounds of their age, and they will be ineligible for export to countries requiring individual traceability because they are not registered in SISBOV (see **Section 17**).

All imported cattle must be accompanied by certification to show that they were born and reared in the country of origin or in a country with similar or better BSE risk classification.

Cattle in border municipalities must be identified in compliance with approved identification systems (see also Section 17 for further information). The same applies in border municipalities in neighbouring countries, and the mandatory ear-tags are readily distinguishable by colour. All roads and properties in border municipalities are geo-registered and both fixed and mobile checkpoints are used for movement control. Police and the military assist IAGRO with border biosecurity. GTAs for moving cattle in the border zone must be filed from the office on the farm concerned.

4 Importation of bovine products

4.1 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, or that may be administered to human beings.

4.2 Legislation

Importation of products of bovine origin, from countries with a high incidence of BSE was first prohibited in *Normative Instruction No. 2 of July 1, 1991* as described in Section 1.2, and the legislation has been refined and updated through a number of subsequent Normative Instructions, Administrative Decrees, and Service Instructions. The currently applicable legislation is *Normative Instruction No. 49, September 15, 2008,* under which importation of bovine products, subject to conditions or restrictions dictated by MAPA, is permitted only from countries assessed by OIE as having negligible BSE risk or controlled BSE risk.

4.3 Type of imported bovine products

4.3.1 Bovine pancreas intended for pharmaceutical use

Quantities of bovine pancreas, in metric tons, have been imported into Brazil for pharmaceutical use since 2003. Data on these imports were included in the submission. All imports of pancreas were sourced from Australia or New Zealand, both countries assessed by the OIE as having negligible risk of BSE, or from the USA, which was classified by the OIE as having controlled risk until 2013, when it was upgraded to negligible risk. The imported pancreas was for use in human pharmaceuticals and extremely unlikely to enter the bovine food supply and pancreas is not a tissue considered to be a risk material for BSE transmission. The imports of bovine pancreas are therefore not considered to be of concern with regard to introduction of BSE.

4.3.2 Bovine casings for human consumption

Quantities of bovine casings, in metric tons, imported into Brazil from 2003 through 2010 inclusive are presented in **Table 6**. Imported casings were fresh, refrigerated, frozen, salted or smoked.

All importations of casings were from countries in which BSE has not been recorded, and which have been assessed by the OIE as having negligible BSE risk.

Table 6: Metric Tons of Bovine Casings for Human Consumption Imported into Brazil, 2003-2010									
Country	2003	2004	2005	2006	2007	2008	2009	2010	Total
Argentina	122.8	545.3	549.6	158.3	269.2	1577.7	1748.5	2595.7	**7567.1**
Australia	312.8	253.8	117.3	145.4	119.4	148.6	150.8	156.2	**1404.3**
Chile	0	0	36.5	67.7	56.5	9.2	9.2	11.5	**190.6**
Paraguay	280.4	261.4	325.9	189.9	451.4	151.1	76.3	228.9	**1965.3**
Uruguay	0	99.7	1.3	0.5	0	0	36	83.7	**221.2**
Total	**716**	**1160.2**	**1030.6**	**561.8**	**896.5**	**1886.6**	**2020.8**	**3076**	**11348.5**

5 Summary: potential for release of the BSE agent through imported materials

The documentation submitted by Brazil supports a conclusion that the risk of the BSE agent being released into the Brazilian cattle population through imports of MBM, live cattle, or bovine products is controlled.

Importation of MBM, or animal feed containing mammalian proteins, from countries with BSE was first banned in 1991, with updates and refinements to the ban in successive legislation. Brazil neither produces nor imports greaves.

In the period beginning 2003, pet foods and finished animal feeds containing animal proteins have been accepted for import into Brazil only if they originated from countries with no history of BSE. Pet foods and finished animal feeds were imported from countries considered to be at risk of BSE only if the products contained no proteins of animal origin.

Importation of live cattle from countries in which BSE has occurred has been prohibited since 1990. Since 2001, there has been a ban on commercializing, transferring or sending to slaughter cattle imported from BSE risk countries. Cattle from BSE risk countries are subject to tracing and monitoring, and when these cattle die or are terminated on the farm they are sampled for BSE prior to disposal of the body by incineration and burial. Countries of origin have been categorised according to the incidence of BSE since 2004. In 2008, Brazil adopted the category system of the OIE.

Land border programs that include mandatory identification and rigorous movement control for cattle in municipalities adjacent to national borders ensure that there is no illegal introduction of cattle through this avenue.

Importation of bovine products since 2003 inclusive has been limited to bovine pancreas for pharmaceutical use and bovine casings for human consumption. Importation of bovine pancreas from the USA was halted after the occurrence of BSE in the USA in 2003, and since then, all imports have been from Australia or New Zealand, both of which are negligible risk BSE countries. Importations of bovine casings since 2003 inclusive have all originated from negligible risk BSE countries, including Australia and a number of South American countries.

The frequent revision of legislation related to imports of cattle and products derived from cattle illustrates that Brazil has been diligent in monitoring the BSE status of other countries, and in monitoring growing scientific knowledge concerning BSE.

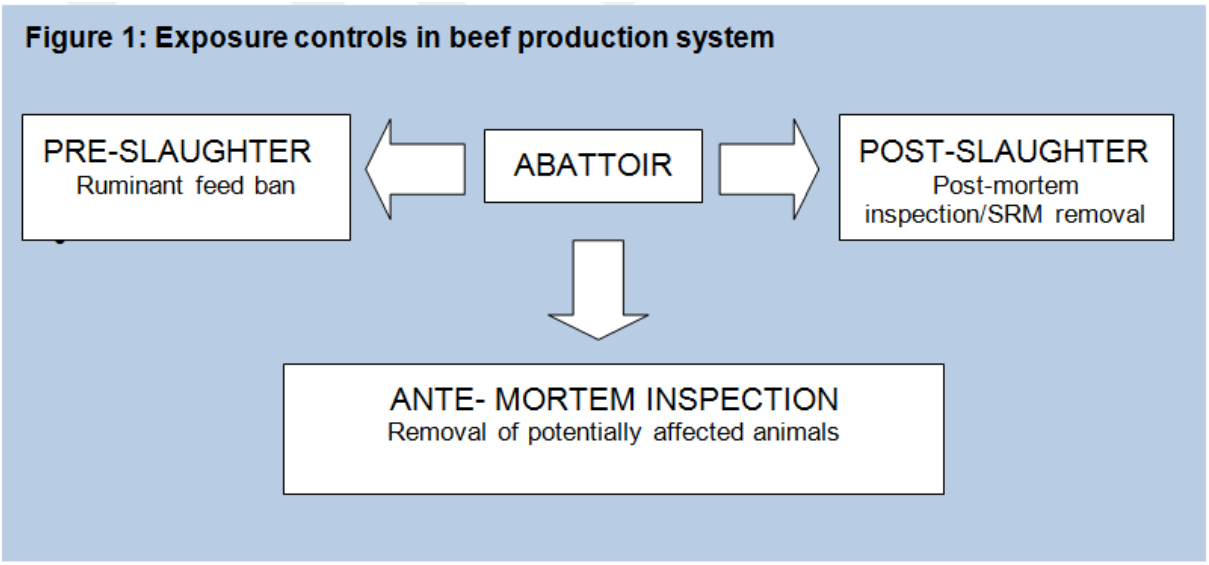
Exposure control

The exposure of cattle to BSE infectivity and amplification within the feed system is controlled by preventing the feeding of ruminant-derived protein to ruminants. 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[4-7] 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 (Specified Risk Material or 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 Brazil 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.

6 Pre-slaughter controls: ruminant feed ban

6.1 Overview

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

6.2 Legislation

The first feed ban to address BSE prevention in Brazilian legislation was *Decree No. 365 of July 3, 1996*, which prohibited the use of protein or ruminant MBM in ruminant feed. *Administrative Decree No. 516 of December 9, 1997* imposed a ban on the use of ruminant proteins in ruminant feed, with the exception of proteins derived from milk. The feed ban was extended and refined to a ban on the production, importation, marketing or use of any source of protein or fat from mammals for the purpose of feeding ruminants, with the exceptions of milk protein and calcined bone flour, under *Normative Instruction No. 6 of February 1, 2001.* Prohibition on the production of products, destined to be fed to ruminants, which contain proteins or fat of animal origin was reiterated under *Normative Instruction No. 8 of March 25, 2004*.

Normative Instruction no 15 of October 29, 2003, specified hygiene and sanitary requirements for construction and operation, and a requirement for Good Manufacturing Practice (GMP), for plants that process animal residues for animal feed. It mandated that animal residues must be reduced to particle sizes not exceeding 5 cm prior to sterilization at 133°C and 3 bar for at least 20 minutes, and must then be ground. This legislation was superseded by *Regulatory Instruction no 34 of May 28, 2008* which retained the same sterilization criteria, but further defined standards for all parts of the production process including collection, residues reception, processing, quality control, packaging, storage, destination and transportation. In addition, *Regulatory Instruction No 17 of April 7, 2008* prohibited the manufacture of ruminant and non-ruminant feed in the same plant unless the plant meets certain conditions including separate production lines, GMP implementation, validated procedures to prevent cross-contamination at all stages of production, and laboratory analysis of at least 10% of batches of ruminant feed. Although this legislation was published in April 2008, it was not enforced until April 2009, to allow animal feed plants time to make necessary changes.

Under *Normative Instruction 41 of October 8, 2009*, any bovine animal known to have been fed protein of mammalian origin must be sent for slaughter within 30 days, with removal and destruction of SRM at slaughter. The Animal Transit Guide (GTA) accompanying the animals to slaughter must specify that they ingested feed containing prohibited proteins. If they are not slaughtered within 30 days they will be killed and the carcass destroyed on the farm.

6.3 Use of bovine materials in animal feedstuffs

Most MBM produced in Brazil is used in feed for poultry, pigs and domestic pets. It is estimated that 54% of all MBM in Brazil is of bovine origin. MBM typically represents 6% (w/w) of broiler feed, 4.8% of pullet feed, 6% of pig feed and 6% of feed for other domestic animals.

Cattle represent a relatively small percentage of consumers of animal feed, because 94% of the national cattle herd in Brazil is kept in extensive, pasture-based farming systems in which processed feed is not used. Further information on bovine production systems in Brazil is provided in **Appendix 1**. Total quantities of finished feed consumed by different species in 2009, and relative percentages, are shown in **Table 7**.

Table 7: Production, in metric tons x 1000, of animal feed in Brazil in 2009		
Species consuming	Thousand tons	Percentage of total production
Poultry	32614.24	55.88%
Pigs	15330.00	26.27%
Dairy cattle	4436.04	7.60%
Beef cattle	2368.73	4.06%
Others (pets, horses etc.)	3611.75	6.19%
Total	**58360.76**	**100.00%**

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

Technical regulation of hygiene-sanitary conditions, a requirement for Good Manufacturing Practices (GMP) and general measures to prevent cross-contamination were established under *Normative Instruction No. 1 of February 18, 2003*. This legislation was superseded by *Normative Instruction No. 4 of February 23, 2007*, which kept the requirements of the earlier legislation but broadened the scope of measures to prevent cross-contamination, and introduced requirements that raw materials and finished products must be transported and stored separately.

Normative Instruction no 15 of October 29, 2003 specified that animal residues could only be received from an authorised establishment, and that slaughtering establishments should separate animal residues by species. If such separation was impossible, the final product should be identified as mixed meal and the species used in it recorded on the sanitary certificate. The same piece of legislation specified that all animal feeds containing animal proteins, other than milk proteins, must be labelled with the words “ATTENTION – USE FORBIDDEN IN FEED FOR RUMINANTS”. Transport of processed feed meals together with feed meant for feeding ruminants was prohibited.

The *Normative Instruction no 15 of October 29, 2003* was superseded by the *Regulatory Instruction no. 34 of May 28, 2008* which retained the same requirements relevant to prevention of cross-contamination. In addition, this legislation prohibited the use of specified BSE risk materials (SRM) for production of MBM or fatty products. An exemption from sterilization requirements was added for establishments processing only non-ruminant residues, but they are required to prove that raw materials are not contaminated by ruminant residues or ruminant meal. Ruminant-derived blood, calcium-enriched bone meal and protein-free tallow were also exempted from sterilization requirements. The *Regulatory Instruction no. 34 of May 28, 2008* included, in its list of Bibliographic References, legislation related to BSE such as the *Nominative Instruction no. 8 of March 25, 2004*, which bans the use of animal proteins and fats in ruminant feeds.

Regulatory Instruction No 17 of April 7, 2008 prohibited the manufacture of ruminant and non-ruminant feed in the same plant unless the plant meets certain conditions including separate production lines, GMP implementation, validated procedures to prevent cross-contamination at all stages of production, and laboratory analysis of at least 10% of batches of ruminant feed.

Feed mills may choose not to include animal proteins in their products for non-ruminants, in order to avoid the cost of implementing the procedures to prevent cross-contamination. This choice must be communicated to MAPA, and does not exclude the feed mill from being inspected and sampled to ensure that there is no animal protein in ruminant feed.

Control of cross-contamination of feed with proteins of animal origin is principally performed

during production. However, in addition, the veterinary service performs on-farm inspections to ensure that ruminants are not fed animal protein, either deliberately or inadvertently as a result of cross-contamination. Samples are collected as part of active surveillance in risk areas, or in response to passive surveillance.

Geographically, there is little overlap between areas of cattle production and areas in which poultry and swine are produced, and this reduces the risk of cross-contamination through inappropriate use of feed.

6.5 Evaluation of the ruminant feed ban

Control of the feed ban was assessed by FSANZ personnel in the course of the in-country visit in June 2013.

Slaughterhouses

Two slaughterhouses were visited, both of which produce MBM from cattle. However, MBM is only produced from cattle that are assessed at ante-mortem and post-mortem inspections as being fit for human consumption, and tissues likely to contain BSE infectivity (specified risk materials or SRM) are not included in MBM but are removed and destroyed by incineration. Bags of MBM were observed to be clearly marked with prominent warnings that the contents were not to be fed to ruminants.

Feed Mill

The feed mill included in the in-country inspection produces a variety of feeds for domestic animals, including feed for ruminants and feeds that contain animal proteins and which are formulated for fish, poultry or swine. The production line for feeds that contain animal proteins is physically separate from the production line for ruminant feed. Raw materials for the different production lines come into the facility by different entrances and are stored separately prior to use. There are separate storage facilities for finished products from the two production lines. An auditable document trail is maintained from sourcing of raw material through manufacturing to dispatch of the final product.

Raw materials are purchased only from pre-approved suppliers. All raw materials are subject to sampling and analysis of every batch.

Prior to the building of separate production lines, which became mandatory in 2008, all batches of ruminant feed produced were subject to in-house analysis for animal protein. Since the separate production lines were completed, the company has adopted a practice of testing 10% of all batches of ruminant feed for animal protein by microscopy. The company's analyses of feed batches are in addition to those conducted by MAPA, which makes unannounced visits for auditing and inspection purposes.

The company sells animal feed both in bulk and in bags. Bagged feed that contains animal protein carries a prominent warning message that the product is not to be fed to ruminants. When feed is sold in bulk, the warning against feeding to ruminants is included on the invoice.

Raw materials and finished products are transported by contractors. Arriving and departing trucks are subject to verification, and there is a checklist used to ensure that trucks are clean, to ensure that there is no cross-contamination through transit.

The feed mill operates under Good Manufacturing Practices (GMP) which requires full

traceability, documented Standard Operating Procedures (SOPs) and a Hazard Analysis and Critical Control Point (HACCP) program. A simulated recall is conducted every month. There is a computerised document control system, and all documents that could be required by the federal government are archived for not less than five years. The feed mill is part of a company that has eight geographically separate production plants. The feed mill has an internal audit every two months, the company has a company-wide audit once a year, and MAPA conducts a full audit at least once a year.

Farms

Two beef production farms were included in the in-country assessment.

The first farm visited, located in the state of Goiás, breeds young stock, and includes a feedlot for preslaughter fattening of stock for up to 90 days. Prior to being placed in the feedlot, calves are raised on pasture and their mothers' milk, with minerals as the only supplements. The fodder used in the feedlot is entirely plant-based. Records, including those of purchased feed, are kept indefinitely. Fallen stock are subject to necropsy, and BSE testing if appropriate, by the veterinarian employed full-time on the farm, and are then burnt and buried. Farms that do not employ a veterinarian can call an Agrodefesa (Agrodefence) veterinarian to fallen stock. Agrodefesa is the Animal and Plant Health Agency of the state of Goiás and includes the state veterinary service. Agrodefesa veterinarians are accredited by MAPA.

The second farm inspected, located in the state of Mato Grosso do Sul, is one of five properties belonging to one owner. The property is used exclusively for pasture fattening young cattle bred on one of the other four properties. No hay or other feed is produced on the property. Feed is only purchased occasionally if there is a lack of pasture, such as in the event of drought.

Because the farming enterprise participates in SISBOV, the national cattle identification scheme, the property is inspected by a certifying company every six months, although it would be subject to inspections every two months if feedlots were used. When it is necessary to buy feed, the farm manager keeps records including the invoice, batch number and date of manufacture of the feed, and sends copies of these records to the certifier. Producers joining SISBOV are required to sign a declaration that the feed ban will be observed, withdrawal periods will be observed, and the farmer will not use prohibited substances such as growth promotants.

Deaths of cattle are rare on this property because animals are generally under three years of age. Dead cattle are subject to veterinary examination prior to being burnt and buried. The certifier is notified of the death, the cause of death and the method of carcass disposal.

On both farms, property owners and managers showed good awareness of the importance of the feed ban. They were aware that if a producer used cattle feed containing animal protein, all the cattle on the property would be slaughtered and the producer would be fined.

7 Ante-mortem slaughter controls

7.1 Overview

Older cattle that are non-ambulatory (downer cattle, fallen stock) and/or showing signs of neurological disease consistent with an established BSE case definition present the highest likelihood of infection with the BSE agent. Such animals should be targeted and prevented

from entering the ruminant feed and human food chains.

7.2 Legislation

BSE was made a notifiable disease in Brazil under the *Administrative Decree No. 516 of December 9, 1997.* The official definition of a suspect animal is “Cattle over 24 months old showing clinical signs of neurological or debilitating progressive disease that persists for more than 15 days”. Notification may be made by veterinarians, veterinary pathologists, farmers or third parties.

Brazilian farmers usually bury or incinerate fallen stock on the farm. Delivery of dead animals to rendering plants would not be cost-effective for the farmer. Furthermore, under *Normative Instruction No. 34 of May 28, 2008*, rendering plants cannot accept raw materials that have not been inspected.

7.3 Ante-mortem procedures

Ante-mortem inspection is carried out by an official veterinarian, who is a federal employee, employed and trained by MAPA. Cattle are inspected at unloading the day prior to slaughter, and again on the day of slaughter. The inspector is required to observe the cattle at rest and when moving.

Each truckload of cattle sent for slaughter must be accompanied by a GTA which provides, among other details, the property of origin, so cattle can be traced back to the farm of origin. The GTA is inspected on arrival of the truck at the slaughterhouse.

The holding yards at export slaughterhouses include a Sanitary Slaughterhouse and necropsy facility. While these are frequently in the same building as each other, they are physically separate from the main slaughterhouse building. If an animal was found dead on arrival at the slaughterhouse or died suddenly during the holding period prior to slaughter, it would be subject to necropsy in the necropsy facility. If an animal is found to be abnormal on ante-mortem inspection, it will be slaughtered in the Sanitary Slaughterhouse.

7.4 Slaughtering methods

Stunning and slaughtering methods are specified in *Normative Proceeding no 3 of January 17, 2000*. The preferred stunning method is mechanical stunning with a non-penetrating stunning device. This hits the skull without penetrating, thus avoiding dispersion of brain tissue to the environment. Use of a penetrating bolt pistol (cartridge-fired captive bolt stunner) that does directly damage the brain is permitted, but if this is used, any brain remnants dispersed outside the carcass must be collected and later put together with the brain. This includes the provision of an SRM collection container at the point of separation of head from carcass so that the operator at that point can collect any brain remnants that may have been missed earlier. The legislation specifies that the penetrating bolt pistol must not inject air into the cranial cavity. This is important because it can drive brain tissue into the circulation with consequent contamination of the carcass.

7.5 Evaluation of ante-mortem inspection, stunning and slaughter

Ante-mortem procedures were reviewed at both slaughterhouses during the in-country assessment. Holding yards, Sanitary Slaughterhouse facilities and necropsy facilities were observed, and procedures related to receiving cattle at the slaughterhouses, verifying

documentation and conducting ante-mortem inspections were reviewed.

MAPA personnel explained that cattle exhibiting neurological abnormalities on the farm of origin are unlikely to be transported to a slaughterhouse, because truck drivers who transport cattle are trained in animal welfare through their own companies. The training is provided by an international organisation. Truck drivers are trained to refuse to load cattle with neurological signs, and to advise the owner to seek veterinary attention for the animal.

Of the two slaughterhouses visited during the in-country inspection, the first uses a non-penetrating concussive stunning device, and the second uses a penetrating captive bolt that does not inject air into the cranial cavity. After the effectiveness of stunning has been verified by testing for blink reflex, slaughter is by exsanguination.

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

8.1 Overview

Brazil has had procedures for SRM removal and destruction in place since 2005, and has implemented rendering conditions recommended by the OIE to minimise BSE infectivity since 2003.

8.2 Legislation

Post-mortem procedures related to BSE are specified in *Circular Memo CGI/DIPOA no. 1 of January 23, 2007*.

The removal of SRM was first mandated in *Circular Memorandum no 2 of April 7, 2005,* but this legislation was superseded by *Circular Memorandum no 1 of January 1, 2007*, under which spleen was removed from the list of organs and tissues considered to be SRM. The current definition of SRM in cattle and buffaloes is: brain, eyes, spinal cord, tonsils, and distal 70 cm of ileum. SRM are removed from all cattle and buffaloes regardless of age.

The skull and mechanically separated meat of cattle and buffaloes, and the backbone of any ruminant, are not considered to be SRM with regard to the domestic market in Brazil. However, slaughter establishments accredited for export to the USA and European Union are required to comply with Annex II of *Memorandum no 463/DCI/DIPOA of August 5, 2004*. This legislation includes the following requirements with regard to SRM removal:

- The skull, brain, trigeminal ganglia, eyes, tonsils and terminal ileum are SRM and must be condemned.
- The head must be removed to prevent contamination of the carcass and other edible parts with SRM.
- Specific, colour-coded knives must be used for spinal cord removal from cattle.
- The tongue and cheek meat must be removed as soon as possible after decapitation and washed thoroughly, while the rest of the head is put in a receptacle for SRM.
- The exhaust water system of the saw used for carcass splitting must be ducted away from carcasses and other edible products.
- Slaughter effluents must be trapped and disposed of as SRM.
- The operator must ensure that no remnants of spinal cord are present before marking a carcass as having been subject to meat inspection.

- To ensure complete removal of dorsal root ganglia, the vertebral column of cattle ≥ 30 months, excluding tail vertebrae, dorsal and transverse processes of thoracic and lumbar vertebrae, and sacral wings, must be removed and disposed of as inedible product.
- SRM must be contained in dedicated containers.
- A HACCP system must be in place to ensure control of SRM.

8.3 Post-mortem procedures

An official veterinarian is present during all working hours at federally inspected slaughterhouses, so monitoring of correct procedures is permanent and continuous.

After heads are separated from carcasses, they are submitted for inspection by the Industrial and Sanitary Inspector for Animal Origin Products (AISIPOA). After the head is inspected, the tonsils are removed and placed in a properly identified container as SRM. The tongue is removed and the head is sent to the Head Section, where the eyes are removed and the cranium opened to remove the brain. Both eyes and brain are placed in marked containers as SRM.

After skinning and evisceration, the carcass is split lengthwise. The exposed spinal cord is removed and stored in a marked container as SRM. Spinal cord fragments, backbone sawdust and marrow that fall around the sawing platform are also collected as SRM.

The terminal 70 cm of the ileum is removed in the Offal Room, and is also placed in a container labelled to indicate that it contains SRM.

SRM not destined for human consumption must be either incinerated or buried. Prior to this disposal, reducing the total volume of material by such processes as autoclaving is permitted, but there must be controls in place to avoid cross-contamination of other materials through the equipment used.

Destruction of SRM by incineration occurs on a daily basis and is usually performed in a furnace on the slaughterhouse premises. Incineration furnaces must be approved by the competent authority within the local environmental agency. There are 88 establishments in Brazil that slaughter ruminants but do not process the residues in their own industrial facilities. They sell the residues to Manufacturers of Non-Edible Products (FPNC) for processing.

Depending on the intended destination of their products, slaughterhouses in Brazil may be inspected by municipal, state or federal authorities. All slaughterhouses producing products for export are controlled by the Federal Inspection Service (SIF). Slaughterhouses producing products only for the domestic market may also be controlled by SIF, or be under the Official Inspection Services of the States (SIE), municipalities (SIM) or Districts (SID). All slaughterhouses producing product for either the domestic or export market must remove, segregate and dispose of SRM.

Slaughterhouses under SIF represent 26% of the total of slaughterhouses in Brazil (not including poultry slaughterhouses) and were responsible for 80% of bovine slaughters in 2008. State-inspected slaughterhouses were responsible for a further 13.4% and municipally-inspected slaughterhouses were responsible for the remaining 6.6%.

All SRM destinations must be registered. All rendering plants and FPNC that process residues from ruminants must have auditable programs in place for control and destruction of all SRM and material that may be contaminated with SRM. Establishments that process only

non-ruminant residues must have a control program to ensure that ruminant residues are not allowed to be processed. All rendering plants that process animal waste and residues for production of animal feed are subject to federal inspection. Renderers attached to a slaughterhouse under Federal Inspection are continuously inspected by the federal veterinary authority. FPNC are inspected by the Official Service at least once a year, but the frequency of inspection may be adjusted according to the operational conditions of these establishments. Data on monitoring and enforcement were provided with the submission, and showed that a very high degree of compliance is present in Brazil.

8.4 Handling of suspect diseased cattle

Any bovine animal showing clinical signs suggestive of BSE is terminated and the carcass destroyed after sampling for BSE. Cattle that die during transportation to a slaughterhouse are subject to necropsy in the dedicated necropsy facility to determine cause of death, and the brain is sampled for BSE testing. The cattle are then incinerated. Clinical suspects observed in holding yards of a slaughterhouse are slaughtered in the Sanitary Slaughterhouse, which is separate from the main slaughterhouse building, and sampled before being condemned and destroyed by incineration.

8.5 Rendering processes

Rendering conditions sufficient to destroy BSE infectivity have been in place since 2003, when *Normative Instruction no. 15 of October 29, 2003* was issued. This legislation laid down detailed requirements for the construction and operation of establishments that process animal residues destined for animal feed, to ensure hygiene and quality control standards. Animal residues must be reduced to particles not larger than 5 cm before being sterilised for at least 20 minutes at temperature and pressure not less than 133°C and 3 bar, respectively. The legislation was superseded by *Normative Instruction no 34 of May 28*, *2008*, which is the current legislation.

8.6 Evaluation of post-mortem inspection, SRM removal and SRM destruction

These procedures were summarized by MAPA and observed at the two slaughterhouses included in the in-country assessment.

Post-mortem inspection procedures and all SRM removal processes were observed. Personnel and equipment involved in the removal of SRM are identified with colour-coding of uniforms, equipment and knife hilts. SRM were collected into clearly marked containers.

After collection into an appropriately marked container, all the SRM of a given organ type from one batch of cattle are weighed at the completion of slaughter of that batch. The weight is recorded and the SRM are sent to the incinerator, which is on the same premises. Prior to incineration the SRM container is weighed again and the weight recorded, so that delivery of all the SRM to the incinerator can be verified.

Prevention of cross-contamination was facilitated by one-way flow of carcasses from the slaughter floor, through the chilling process and to the boning room.

Management of downer cows was reviewed with slaughterhouse personnel. Brainstem samples are collected and submitted for testing from any cow that becomes non-ambulatory (downer) prior to slaughter. Collection is performed by a MAPA veterinarian and the carcass is held until the result of testing is received. The submission form for brainstems includes

information on the property of origin. In addition, the State Animal and Plant Health Agency office is notified and visits the property of origin.

MAPA employees, including veterinarians and technical staff, at the slaughterhouse received training from MAPA in BSE recognition. All employees at the slaughterhouses receive training at induction. In addition there is an annual schedule of training and refresher courses, and training records were presented. Training of slaughterhouse staff to different tasks is based on requirements. Both slaughterhouses are approved to export beef and bovine products to numerous other countries.

Daily verification inspections are carried out in all areas in the slaughterhouses, and the companies are required to respond with action plans to findings by onsite federal staff. Action plans must include corrective actions, preventative actions and the time within which the actions must be done. Both companies conduct their own internal audits, and in addition are subject to audits by both SIPOA, which is the state-based federal inspection service and DIPOA, which is the MAPA inspection service based in the federal capital Brasilia. Auditing visits by SIPOA are termed 'supervisions' and occur every two months. The DIPOA audit occurs at least once a year and is unannounced. There are also market-driven audits which may be conducted by auditors from a particular country or by auditors from a particular multinational restaurant company. Records that could be required for an audit are kept for at least five years.

9 Compliance with legislation

9.1 Feed ban

Collection of samples from establishments producing ruminant feed has been in place since 2001. Until 2003, samples were collected only at non-compliant plants during inspections, or when there was a suspicion of fraud. However, since 2003 a monitoring plan has been in place which includes routine testing. Positive findings of contamination of ruminant feed with animal protein have been progressively decreasing, as shown in **Table 8**.

Table 8: Results of testing of samples of ruminant feeds collected at processing plants, 2001-2012

Year	Number of feed samples analysed	Number of positive results for mammalian protein	Percentage of positive results
2001*	200	17	8.5%
2002*	622	65	10.5%
2003*	470	115	24.5%
2004	1014	120	11.8%
2005	561	56	10.0%
2006	519	30	5.9%
2007	640	48	7.5%
2008	624	38	6.1%
2009	423	19	3.9%
2010	451	8	1.8%
2011	456	11	2.4%
2012	495	9	1.8%

*In these years, collection was only made when there was known non-compliance or a suspicion of fraud.

In the event that a sample of ruminant feed is found to contain animal protein, the plant is subject to litigation. Any part of the batch that is still present at the plant is seized, and the establishment is required to recall the batch from the market. All cattle feed present in the plant is seized and tested for animal protein. Production of cattle feed by the plant is suspended until the plant is in compliance with the legislation. Power to impose these

procedures is provided by the *Decree no 6296 of December 11, 2007* and the *Circular Memorandum DFIP no 22 of September 29, 2008*.

Testing of animal feed for prohibited proteins is conducted only in official laboratories. Currently there are laboratories in five states that are responsible for all sample testing. Until 2002, samples were analysed by mass spectrometry. Since then, the method used is a microscopy technique developed by the reference laboratory (LANAGRO-MG). The limit of detection is 0.1% contamination.

Data were provided with the submission to show that rendering plants and feed mills processing ruminant material, or mixed-species material that may include ruminant material have all been regularly inspected since 2001.

9.2 Ante-mortem inspection, stunning, slaughter, post-mortem inspection, SRM removal and SRM disposal

Compliance with legislation related to slaughterhouse activities is enforced by MAPA employees that include veterinarians and technical personnel. Critical tasks including ante-mortem inspections, post-mortem inspections and SRM removal are conducted, supervised and audited by MAPA personnel.

10 Summary: exposure control

In Brazil, the risk of introducing and recycling BSE infectivity through the ruminant feed system is controlled by:

- Reliance on extensive, pasture-based cattle-farming systems, with the result that 94% of the national cattle herd is never fed processed feeds.
- A ban on feeding mammalian proteins to ruminants that has been in place since 2001 and is subject to enforcement including sampling of feed for prohibited material.
- Procedures in place to ensure that if ruminants were inadvertently fed protein of mammalian origin the animals would be destroyed and safely disposed.
- Procedures in place to prevent cross-contamination of ruminant and non-ruminant material, including prominent labels on feed containing mammalian proteins to indicate that the feed must not be fed to ruminants, as well as a prohibition on the transport of MBM with feed for ruminants.
- Specific requirements for feed mills producing both feed for ruminants and feed for non-ruminants, including separate production lines, GMP implementation, validated procedures to prevent cross-contamination at all stages of production, and laboratory analysis of at least 10% of batches of ruminant feed.
- On-farm controls to ensure that purchased feed meets specifications and that records of feed purchases are kept.
- The requirement that all rendering plants that produce ingredients for animal feed can only accept inspected materials. Cattle that die on farms are incinerated and buried on-site.
- The processing of SRM for production of MBM or fat-based products is prohibited, and MBM must be prominently labelled to indicate that it must not be fed to ruminants.
- Termination and destruction, by incineration, of any bovine animal showing clinical

signs suggestive of BSE, or any bovine animal that dies in transit to a slaughterhouse.

- Control of slaughterhouse procedures by on-site federal inspection personnel and by regular internal and external audits.
- A ban on the slaughter of cattle imported from countries that later reported cases of BSE. These cattle must be buried or incinerated on-farm.
- A national monitoring program to detect cross-contamination in feed mills that produce both feed for ruminants and feed for non-ruminants, that has been in place for all feed mills since 2003.

BSE food safety controls

The Australian Questionnaire requires countries to have in place effective controls during the slaughtering process so that food for human consumption is prevented from becoming contaminated with materials that may be BSE-infected. 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 Brazil.

11 Beef production systems

11.1 Hygiene practices for the minimisation of cross-contamination

Stunning methods are specified in *Normative Proceeding no 3 of January 17, 2000*. The preferred stunning method is the use of a non-penetrating captive bolt, which avoids dispersal of brain tissue. Use of a penetrating bolt is permitted, but if this method is used, any brain remnants dispersed outside the carcass must be collected. The legislation specifies that the penetrating bolt pistol must not inject air into the cranial cavity.

Post-mortem procedures related to BSE are specified in *Circular Memo CGI/DIPOA no. 1 of January 23, 2007*. SRM must be removed and placed in appropriately marked containers. SRM include bone-dust from the vertebral column, spinal cord fragments and fragments of vertebral marrow that are produced when the carcass is split longitudinally. Destruction of SRM is performed daily. Many slaughterhouses have an incinerator on the premises for this purpose. Some slaughterhouses send the SRM to FPNC for destruction. FPNC that receive material from the slaughter of ruminants must have auditable programs in place to ensure the destruction of all SRM and material that may have been contaminated with SRM.

Mandatory conditions for the pre-sterilization grinding, and the sterilization, of animal residues have matched the recommendations of the OIE for the reduction of BSE infectivity in MBM since 2003.

SRM must not be used for production of by-products under any circumstances. All slaughterhouses that slaughter ruminants must have written operational procedures, covering all stages of production, to include:

- Removal and segregation of SRM during slaughter
- Auditable records on the amount of SRM produced on each day of slaughter, and verification that it corresponds in weight to the total number of animals slaughtered on that day
- Destruction of SRM by incineration or denaturation, followed by burial in an approved location.

Each company must also set preventative and corrective measures to address possible deviations that may occur. All controls in place must provide auditable outcomes.

12 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.

12.1 Legislation

Unique individual identification and lifetime traceability of cattle and buffaloes is voluntary for farmers in Brazil, but participation in SISBOV is mandatory for farmers producing cattle intended for markets that require traceability that includes individual identification. Further details on SISBOV are provided in **Section 17**.

When an animal certified through SISBOV is sent to a SIF-inspected slaughterhouse, the slaughterhouse has access to the National Database of bovine and bubaline animals (BND) and inputs information regarding the slaughter and inspection of each animal, which enables traceability of carcasses. The BND also shows a record of all properties on which the animal was kept, and the destination of other cattle that were on those properties.

The OVS keeps transit records of all rural properties in Brazil and issues the GTAs. In the event that a positive BSE case was identified at a slaughterhouse, the GTA provides information on the animal's origin. Based on the data stored at the Local Veterinary Units and the information contained in GTA files, it is possible to identify properties through which the animal may have passed, and to identify other animals potentially at risk.

Traceability of bovine and buffalo meat is the subject of *Law No. 12.097 of November 24, 2009*. Under this law, traceability is implemented on the basis of:

- brand, tattoo or other animal marking for the identification of the property of origin
- the GTA
- the invoice
- official registers of inspection services of animal products, which may be at the federal, state or municipal level
- registers of animals and products by private sector businesses involved in production and distribution.

Details of the requirements pertaining to identification of live bovine animals under this law are provided in **Section 17.2**.

Under *Law No. 12.097 of November 24, 2009* slaughterhouses may not accept cattle that do not have identification, or that are not accompanied by a GTA which describes the identification. Invoices, as referred to in this legislation, must be issued from an invoice book that has previously been registered by a rural authority. Further details of the traceability system mandated by *Law No. 12.097 of November 24, 2009* are laid out in *Decree No. 7.623 of November 22, 2011.*

The legislation that regulates the recall of products from the consumer market is *Ordinance no. 789 of August 24, 2001*. Specifics of the recall plan for establishments producing and/or supplying products of animal origin are covered in *Circular Letter no. 41 of November 17, 2010*, and key points are summarized in **Section 13.1**.

12.2 Evaluation of traceability of beef and beef products

Traceability of beef was assessed as part of the in-country inspection, during inspection visits to two export slaughterhouses. When cattle with individual SISBOV identification are sent to a slaughterhouse, the GTA with the shipment includes barcodes of all the SISBOV numbers of the cattle on the truck. The slaughterhouse scans these barcodes to notify the BND that the cattle are scheduled to be slaughtered, and also maintains its own records of the ear-tag numbers for purposes of traceability. The GTA also includes information on the property of origin and the specific export markets. Shipments of cattle are also accompanied by a declaration from the producer describing their condition, that they have been fed only pasture or that fodder has contained only plant protein, and that they have not been given any hormones, antibiotics or growth promotants.

Ear-tags of cattle are inspected on arrival at the slaughterhouse, and the recorded age of the animal is compared to the dentition after the animal is slaughtered. If an animal did not match its BND record in age, sex or other characteristic, but was otherwise fit for human consumption, the carcass would be diverted from the export market to the domestic market. SISBOV ear-tags are collected at slaughter and retained by the slaughterhouse for at least five years, after which they are destroyed by incineration or another approved method.

The individual identification number of each SISBOV-registered animal is maintained through slaughter and chilling in both slaughterhouses. In addition, all cattle have a slaughter number based on the order of slaughter. Each half- carcass is clearly marked on the hindquarter and the forequarter, and at one slaughterhouse an additional identification tag was attached to the abdominal musculature.

Individual identification ceases at boning, but exported beef is still identified by batch. At the first slaughterhouse visited, a batch comprises all the cattle that were slaughtered on a given day. At the second slaughterhouse, a batch comprises all the cattle from a specific producer that were slaughtered on a given day. Trace-forward of a randomly selected individual animal, and trace-back of boned beef, were effectively demonstrated at both slaughterhouses.

13 Recall systems

13.1 Legislation

The legislation that regulates the recall of products introduced into the consumer market is *Ordinance No. 789 of August 24, 2001*. This Ordinance regulates communication between the Department of Consumer Protection and Defence (DPDC), suppliers and consumers. Suppliers who become aware of hazard associated with their product must immediately notify the DPDC, the Department of Economic Law of the Ministry of Justice, and the Consumer Orientation and Protection Programs, as well as all other responsible authorities. The Ordinance lays out the information that must be provided. The supplier must also immediately inform consumers through a media campaign including press, radio and television. The supplier must provide interim and final reports on the recall to the DPDC.

Circular Letter no. 41 of November 17, 2010 provides the guidelines for certification of the recall plan adopted by establishments producing and/or supplying products of animal origin for human consumption. The following are mandated:

- The existence of a recall plan that specifies, in detail, all actions that will be carried out once a decision to implement the recall is made
- Immediate reporting, to authorities and consumers, of any non-conformity in the product that may imply a risk to consumers

- Identification, by name, of all individuals involved in the recall activities, and up-to-date information of their contact details including address, telephone number, and email address.
- Specified functions and responsibilities of each individual in the team involved in the recall plan
- The establishment shall provide mechanisms for the collection and analysis of data on risks posed by consumption of any product, in order to project the scope of the recall to be implemented
- Coding of products to permit rapid identification of consignments, in order to facilitate rapid withdrawal
- Establishment of mechanisms to streamline communication to consignee companies, consumers and health authorities

The philosophy of 'one step forward, one step backward' should be applied throughout. Records of production and marketing must be maintained until the product expiry date is reached. Establishments must periodically assess the plan by conducting tests and simulations to verify the traceability of products. These simulations should always include at least one step beyond the corporate structure of the establishment, such as a step involving a distributor or retailer. Records of simulations must be maintained. The SIF may request at any time that a company conducts a recall simulation.

13.2 Food recall process

Law no 8.078 of September 11, 1990, states that the supplier who becomes aware of any harmfulness of products and services already released to the market must report the matter immediately to authorities and must also notify consumers via press, radio and television.

In the event of any recall, the SIF acts to assess whether the procedures taken are consistent with the level of harmfulness identified. Specifically, the SIF will strive to verify that:

- All consignees of adulterated consignments were notified
- The establishment has ensured that the consignees tracked, recovered and returned targeted consignments
- The establishment has monitored consignee compliance with instructions (e.g. whether to destroy or return consignments)
- If the consignment or consignments reached the commercial market, that the establishment has announced the recall to the public through press, radio and television
- The establishment has proposed appropriate measures to mitigate the risk of noncompliant consignments (e.g. reprocessing, sterilization, destruction).

14 Summary: BSE food safety controls

Food safety controls are established in Brazil to allow effective protection of the human food supply from potential BSE contamination. Measures to prevent SRM contaminating the domestic and export food supply are effectively in place.

Beef and beef products can be traced back to the day of slaughter, and often to the farm of origin, by reference to the GTA and invoice. When the beef is sourced from cattle registered within SISBOV and sourced from ERAS, individual animals can be traced until the carcass is boned. Brazil exports beef to numerous countries that require this level of traceability, and export slaughterhouses are experienced in meeting the requirements of export markets.

All establishments producing or supplying products of animal origin must have a comprehensive recall plan and must conduct simulations to ensure that the recall plan is effective. The recall plan and simulations are subject to audit by the Federal Inspection Service.

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 Brazil's cattle identification and traceability system which serves to underpin any BSE case investigation.

15 BSE Education and Awareness

The federal veterinary service in Brazil has been promoting meetings and technical training on BSE prevention and surveillance since *Administrative Decree no. 516 of December 9, 1997* was enacted. The Decree declared Brazil free of BSE and incorporated BSE detection into the existing rabies surveillance system. Researchers and faculty from teaching institutions and veterinary research institutions were trained to act as trainers throughout the country, including BSE in the regular curriculum in veterinary schools, and bringing knowledge of BSE to veterinarians and other field workers who provide services to cattle farms.

Since 2002, in order to be certified to perform brucellosis and tuberculosis tests, practicing veterinarians have been obligated by law to receive training which includes a six-hour program on TSEs, with an emphasis on BSE. The curriculum includes clinical diagnosis of TSEs, the obligation to notify and procedures for doing so, and collection and submission of samples for BSE diagnosis. As of 2010, 14,323 veterinarians had completed this training.

The procedures to be followed in the event of detection of a positive BSE case are specified in the *Procedures Handbook upon the Occurrence of BSE*, a handbook for official veterinarians. This handbook has been distributed to all state veterinary services in order to keep all veterinarians working at the LVUs prepared for an outbreak.

The *Handbook of Procedures to Diagnose Diseases of the Bovine Central Nervous System*, first published in 2001, contains technical information on BSE, including the procedure for collecting brainstem samples. This handbook has been distributed to veterinarians in all states. As of August 2005, over 25,000 copies had been distributed. The governments of South Africa, Colombia, Paraguay and Bolivia have requested copies to use as models for their own surveillance programs.

In 2005, 5,000 copies of a *Handbook for Collection of Feed Samples for Testing the Presence of Animal Protein* were distributed to veterinary services in all states. Identification of risk areas is the responsibility of each state. Each state is required to report to MAPA on which areas have been identified as risk areas, and to justify those choices. If MAPA does not approve of the selected areas, or if the state does not perform the identification, MAPA will take over the process.

MAPA released a technical publication entitled Bovine Spongiform Encephalopathy in 2008, and distributed 3,000 copies to official veterinarians, veterinary students and technicians in charge of animal feed plants.

Most of the Handbooks are available for download from MAPA's website http://www.agricultura.gov.br , and other information on BSE is also available on the same website. MAPA also uses seminars, handbooks, radio, magazines, DVDs and CDs to raise awareness of BSE among cattle producers and the general public, as appropriate.

16 Disease notification and diagnoses

16.1 Overview

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

16.2 Legislation

BSE became a notifiable disease in Brazil in 1997, under *Administrative Decree no. 516 of December 9, 1997*. The official definition of an animal to be considered a BSE suspect is 'cattle over 24 months old showing clinical signs of neurological or debilitating disease that persists for more than 15 days'.

16.3 Identification and handling of BSE suspects

Notification of suspect cases may occur through practicing veterinarians, through veterinary pathologists at universities, or through farmers or third parties. There are over 90,000 practicing veterinarians registered with the Federal Board of Veterinary Medicine in Brazil. There are 199 veterinary schools with diagnostic laboratories and teaching hospitals that provide extension services.

When notification of a BSE suspect case is received at the Local Veterinary Unit (LVU) of the official veterinary service, the veterinarian in charge of the LVU registers the notification and provides primary instructions to the notifier. A visit to the property must be made within 24 hours of notification. If, after initial clinical and epidemiological investigation, there is reason to support the suspicion, the animal is terminated and the appropriate brainstem sample collected for testing, after which the rest of the carcass is incinerated and buried. The brainstem sample is submitted to an accredited laboratory. While the results of laboratory testing are pending, the property is closed to prevent the removal of products and animals, and an epidemiological investigation is begun. If the result of laboratory testing is negative, actions on the property are suspended.

MAPA currently operates a network of four laboratories for the diagnosis of BSE. All these laboratories are part of public institutions and are subject to audits. Accreditation and monitoring rules for laboratories performing BSE diagnosis were published in *Normative Instruction no. 15 of February 15*, *2002*. General rules for laboratory accreditation were reviewed in *Normative Instruction no. 1 of January 17, 2007*. Of the four laboratories in the network, three are credentialed laboratories belonging to State governments, and one is a LANAGRO laboratory belonging to MAPA. Geographical locations of the laboratories are shown in **Figure 2.**

Figure 2: Geographical distribution of laboratories performing BSE diagnosis in Brazil

16.4 Contingency plan in the event of a diagnosis of BSE

The operative procedures in the event that a positive BSE case is detected are published in the *Procedures Handbook upon the Occurrence of BSE*.

If a laboratory confirmation of BSE by an accredited laboratory within Brazil was to occur, this would initiate declaration of a Sanitary Emergency. The property or properties involved would remain closed and an Emergency Group would be formed. The Emergency Group's initial responsibility would be to carry out identification activities of the origin of the affected herd and its progeny. These activities would occur while confirmation from the world reference laboratory in the UK was pending.

In the event of a BSE diagnosis confirmed by the world reference laboratory, MAPA would announce the existence of the disease, the state and municipality of the outbreak and the emergency measures to be taken to restrict it. Notification would also be made to the National Congress, the OIE and the embassies of all countries that buy meat and animal by-products from Brazil. The veterinarians of the Federal Agriculture Agencies of the whole country, veterinarians of state services, the Ministry of Health and other pertinent institutions

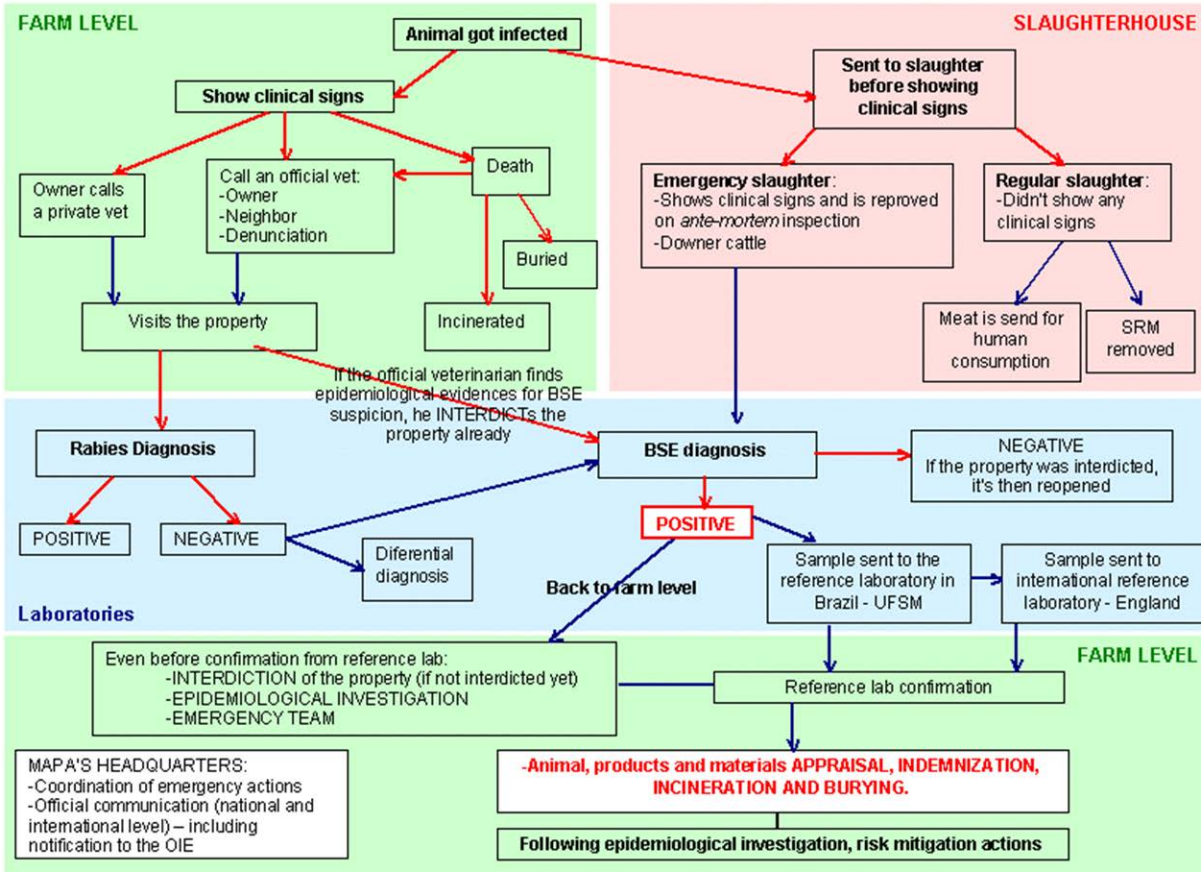
would be notified by teleconference. Daily updates, including details of restriction measures adopted, would be posted on the website of the official veterinary service. Access to technical assistance for the public would be provided through a toll-free 0800 telephone number.

Measures to be taken on the property or properties where the outbreak occurred would include appraisal of animals to be indemnified, sanitary slaughter of animals suspected of being affected, and total destruction of carcasses to ensure elimination of the BSE agent. The property would remain closed until sanitary emergency actions have been completed. In addition to animals, products and materials might require destruction. All animals and materials to be destroyed would be subject to appraisal for compensation purposes.

Epidemiological investigation would be carried out with the aim of identifying the infection source of the affected animal, tracking the herd from which the animal originated, and tracking any progeny of the animal.

Notification and emergency steps are summarized in **Figure 3**. In this figure, 'or' is signified by red arrows; 'and' by blue arrows.

Figure 3: **Notification and emergency flow chart.**



16.5 Diagnostic tests

According to Chapter 2.4.6 of the OIE *Manual of Standards for Diagnostic Tests and Vaccines for Terrestrial Animals* (Manual of Standards), there are multiple methods for detecting BSE in brain or other CNS tissue including:

- Histopathological examination of brain or CNS tissue, which detects characteristic neuropathological changes such as spongiform and other characteristic changes
- Immunohistochemistry, which detects abnormal prion accumulation in the brain tissue
- Western blot rapid tests, which detect the abnormal prion protein from fresh (unfixed) tissue
- Other rapid tests such as ELISA that detects the abnormal protein.

Procedures compliant with the OIE Manual of Standards have been in place in Brazil since 2002. Methods for TSE diagnosis specified in the OIE Manual of Standards have been incorporated into Brazilian legislation through Normative Instructions. *Normative Instruction no. 15 of February 2002* approved accreditation and monitoring rules for TSE diagnostic laboratories, and specified the processing of samples for histopathology. *Normative Instruction no. 18 of February 27, 2004* approved the quality requirements for monitoring for TSEs through immunohistochemistry, and specified the processing of samples for immunohistochemistry. *Normative Instruction no. 36 of October 5, 2007* established the accreditation of TSE diagnostic laboratories in regard to diagnosis by immunohistochemistry.

Brainstem samples submitted from farms are examined by histopathology at any of the four laboratories in the network. Samples are then sent to the official LANAGRO laboratory for additional testing by immunohistochemistry. Brainstem samples from slaughterhouses are sent directly to the official laboratory and tested only by immunohistochemistry.

Brazil does not currently use rapid tests but intends to introduce both ELISA and western blot rapid tests. Diagnostic material must be archived for at least seven years. The responsible expert at each accredited laboratory is a recognized expert in veterinary pathology.

16.6 Laboratory assurances and auditing

All four laboratories in the network are required to be accredited with ISO IEC 17.025 by 14/7/2014. The LANAGRO laboratory is expected to have achieved this accreditation by the end of 2013. All four laboratories participate in international proficiency tests with OIE reference laboratories in Argentina and Canada.

16.7 Penalties and reporting incentives

A decree listing all notifiable diseases of livestock has been in place, and subject to regular updating, since 1934. Under the decree, failure of an owner to notify authorities of animals with clinical signs of notifiable diseases will lead to a fine, and sanitary supervision of the property. The property is interdicted and seen by federal and state authorities as a high risk property.

Any veterinarian who fails to report a suspect case of BSE may be prosecuted under civil or criminal law in accordance with the Brazilian Civil Code or Criminal Code. In addition, the Federal Board of Veterinary Medicine may sue the veterinarian and cancel their professional permit.

Compensation is paid for imported cattle that cannot be sent to a slaughterhouse, but which are euthanized, incinerated and buried on the farm where they are kept. There is no compensation for cattle born in Brazil that are destroyed as clinical suspects. If cattle born in Brazil are destroyed as part of a BSE investigation, compensation may be paid if laboratory results are negative, but there would be no compensation for confirmed cases.

17 Cattle identification and traceability

17.1 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 that effective and timely identification, tracing and removal of beef and beef products from markets and the distribution chain is feasible.

17.2 Legislation

The national identification system in Brazil for cattle and buffaloes is SISBOV. SISBOV was created by MAPA in 2002, and is currently ruled by *Normative Instruction no. 17 of July 13, 2006*. In general, this identification and traceability system is voluntary for farmers of cattle or buffaloes, but it is mandatory for animals intended for export. SISBOV requires individual identification of cattle intended for meat exports to markets that require traceability.

Branding or tattooing of all cattle, regardless of whether the producer participates in SISBOV, is mandatory under *Law no.12.097 of November 24, 2009*, which mandates minimum standards of traceability for meat from cattle and buffaloes. Cattle and buffaloes must have at least a brand or tattoo, which must indicate the property of birth and subsequent properties on which the animal was kept. These brands and tattoos must be registered with state or municipal entities, or with the local office of the federal Unified System of Agricultural Health (SUASA). However, cattle are exempt from branding or tattooing if an electronic identification device is used instead. Cattle are also exempt from branding or tattooing if they are pedigree animals registered with a breed society that is approved by MAPA. Slaughter establishments will not accept cattle that do not have any identification or that are not accompanied by a GTA which describes the identification.

Importation of cattle or buffaloes, or products of bovine origin, is conditional on the importer being able to show that the country of origin has equivalent standards of bovine identification and traceability, and that these standards are enforced.

Further details of the traceability system mandated by *Law No. 12.097 of November 24, 2009* are laid out in *Decree No. 7.623 of November 22, 2011.* If a farmer who uses brands to identify cattle purchases branded cattle, the new brand must be placed to the right of the existing one, or if there is no space to the right, above the existing one. Tattoos can be letters, numbers or combinations of letters or numbers, but if a tattooed animal is transferred to a new owner, the new owner must adopt an identification system other than tattoo for that animal.

Registers for the purposes of identification and traceability must be archived for not less than five years.

17.3 Current identification systems for cattle

Farmers interested in participating in SISBOV hire a certifying company, accredited by MAPA. The certifying company may be a private company or one operated by the State in which the farm is located. The certifying company takes responsibility for identifying the

animals and gathering the documentation required for the property to meet the requirements to be a 'Rural Establishment Approved by SISBOV (ERAS)'. Each ERAS is subject to periodic inspections, at least every six months, by the responsible certifying company. At inspection, the certifying company verifies certification and maintenance procedures of the property and registered animals.

The SISBOV system is anchored to the BND, managed by MAPA, which contains records on the farmer, the holding, the individual registration of all bovine and/or bubalines on the farm, and records of the movements of those animals.

Types of bovine identification include: ear-tags, ear-tag with button on the other ear, electronic devices on ear-tags or intra-ruminal boluses, tattoos for cattle registered with Breed Associations, a fire-brand of the individual number plus an ear tag, and other identification systems subject to approval by MAPA. For ERAS compliance, the first identification of the animal should be at weaning or prior to its first movement, but in either case before the age of 10 months.

When a certified animal is sent to a slaughterhouse that is subject to federal inspection, the slaughterhouse has access to the BND and inputs information regarding the slaughter and inspection of each animal, which enables traceability of carcasses. The BND also shows a record of all properties on which the animal was kept, and the destination of other cattle that were on those properties.

For cattle that are not entered in SISBOV, age is most commonly assessed by the records kept by producers. In addition, females born after 2001 have the year of birth marked on the left side of the face, as part of a compulsory brucellosis vaccination program. When there is no other source of information, age is estimated from dentition by a veterinarian.

The practical application of SISBOV for traceability purposes was assessed as part of the in-country inspection visit.

Competent Authority

A presentation on SISBOV was included in the opening meeting, and further information was obtained from MAPA personnel during the course of visits to slaughterhouses and farms.

All cattle on ERAS establishments must be entered into SISBOV. The SISBOV identification remains with the animal for the whole of its life and does not change if the animal is moved to another property. Cattle brought onto an ERAS establishment from a non-approved holding must go through a quarantine process consisting of 40 days before movement and 90 days after movement, before being tagged.

Tags are usually ordered and applied by the farmer. The companies that make and distribute ear tags are registered and accredited with MAPA. If a farmer orders ear tags that are not used prior to the next visit by the certifier, the farmer must be able to produce the ear tags and explain why they were not used. Ear tags that are not used within two years of receipt must be destroyed. The original ear tag of a domestically-born animal is yellow, but if it is lost, the replacement tag is orange. Imported animals have a white tag. Slaughterhouses archive ear tags of slaughtered animals for five years, and then destroy them. In the event that an animal dies on a farm, the farmer is responsible for destroying the tag and for notifying the certifier, who updates the national database.

Placement of ear tags is recorded in triplicate. One copy of the form remains on file on the farm, one copy is given to the certifier who updates the online database and then files the form, and one copy is provided to the LVU. When the farmer sends information on births,

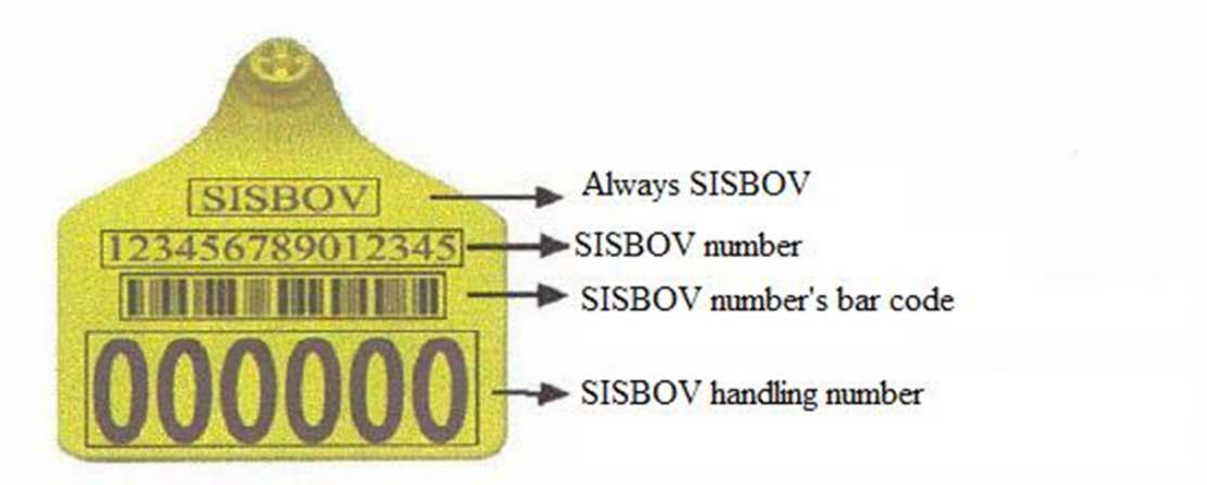
deaths or movements to the certifier, the certifier is required to update the national database within seven days. If there is more than one livestock producer on a property, each producer will have their own registration number for the purposes of SISBOV.

When a certifier conducts an inspection of the property, a certificate is issued that expires after six months, or sooner if inspections are more frequent. The certifier also informs MAPA of the outcome of the inspection visit via the internet.

MAPA audits at least 10% of ERAS properties annually. If any noncompliance is found on audit, the certification of the property is suspended immediately. Audits may be on a random basis or may be in response to concerns raised at a slaughterhouse. Properties filing a large number of GTAs, indicating a high number of movements of animals, are likely to be audited more frequently. MAPA also audits at least 20% of SISBOV certifiers each year. Audits are principally on a random basis but may be driven by concerns about compliance. To avoid conflicts of interest, MAPA cannot act as a certifier itself, and State governments cannot audit certifiers, because State governments can be certifiers. There are 42 certifying agencies in Brazil but only twelve are currently active.

The appearance of a SISBOV ear-tag is shown in **Figure 4**

Figure 4: Appearance and format of a SISBOV ear-tag. The handling number is the 9th, 10^{th}, 11^{th}, 12^{th}, 13^{th} and 14^{th} digits of the full 15-digit SISBOV number.



If a SISBOV-registered animal does not also have an electronic chip, then the animal must have an Animal Identification Document (DIA), which functions like a passport, in addition to the SISBOV ear-tag. A DIA and corresponding SISBOV ear-tag are shown in **Figure 5**.

Figure 5: SISBOV ear-tag and DIA

Farms

Both farms included in the visit were registered with SISBOV. Cattle were mustered into the yards, and the ear-tags demonstrated, at the first farm. Some of the cattle on this farm were pedigree Zebus; pedigree animals have a tattoo, their number is recorded, and their registration certificate is issued by the breed association of which forms part of their identification. Cattle breed associations are approved by MAPA

SISBOV certification at the second farm is managed by a private company, and representatives of the company were present at the inspection visit. Because the farm does not use feedlots, the certifiers visit every six months. If a farm has feedlots, certifiers visit every two months. In addition to verifying all arrivals, departures and deaths on the property, and cross-checking the records of these with the national database, the certifiers also monitor vaccinations and antibiotic use. Brazil has nationwide control programs for rabies, foot and mouth disease (FMD) and bovine brucellosis, and vaccinations are mandatory in many areas. Details of births and deaths on the property are also sent to the state animal and plant health agency.

When the certifiers visit the farm, at least 600 cattle are brought into the yards. The certifiers read the tags of at least 300 of the cattle and verify the recorded details of sex, age and colour of the cattle. The certifiers also verify that the other 300 cattle have ear-tags. Animals are not subject to checking if they have arrived on the farm within the previous 30 days or, on breeding farms, if they have not been weaned.

On both farms, documentation was well-organised and could be readily accessed. All records are kept for five years, as required by law, by both the producer and the certifier.

The state animal and plant health agency in Mato Grosso do Sul is IAGRO. As part of the approval process for the establishment of a cattle farming business, IAGRO personnel visit the property and provide training on animal health issues such as mandatory vaccinations. IAGRO approval is required before a farmer can move animals. Farmers may register movements of cattle via the internet, or may visit their local IAGRO office to do so. IAGRO tracks all arrivals and departures of cattle through GTAs, and may pay special attention to properties that register a high number of cattle movements, as well as those that miss mandatory vaccinations. Vaccination campaigns for foot and mouth disease occur every six months.

Border programs

Brazil shares a border with ten other countries. Some of these borders are land borders, while others are natural barriers to cattle such as rivers or mountains. Management of cattle in municipalities close to a land border was discussed during the visit to the second farm. There are eleven border municipalities in Mato Grosso do Sul, and these are regarded as high-risk areas by IAGRO, which administers FMD vaccinations on cattle farms in these areas rather than permitting farmers to do so themselves. Cattle in border municipalities must be identified in compliance with an IAGRO identification system. The same applies in border municipalities in the neighbouring countries, and the mandatory ear-tags are readily distinguishable by colour. All roads and properties in border municipalities are geo-registered and both fixed and mobile checkpoints are used for movement control. Police and the military assist IAGRO with border biosecurity. GTAs for moving cattle in the border zone must be filed from the office on the farm concerned. The loading of the truck or trucks is supervised, and there must be a checkpoint on the route the truck is to take. This will be achieved by setting up a mobile checkpoint on the route if necessary.

If a cattle farm purchases even one animal from one of the eleven border municipalities, the property is interdicted and cannot send any cattle for slaughter for export beef production for 90 days. The interdiction is entered into the GTA and slaughterhouses are notified. If the interdicted property sells cattle to another farm during the interdiction period, the purchasing farm is also interdicted, because the interdiction applies to the whole herd rather than to specific animals.

If a property was suspected of being involved in smuggling animals over the national border, it would be interdicted for any transit and the herd count would be audited by IAGRO. The property owner would be fined if found guilty, and any animal that had crossed a border illegally would be seized and slaughtered in a Sanitary Slaughterhouse.

18 Summary: BSE control programs and technical infrastructure

Brazil has appropriate control programs for the identification and notification of BSE clinical suspects, and for the laboratory diagnosis of bovines infected with BSE.

The federal veterinary service has been promoting technical training on BSE prevention and surveillance since 1997. There is a comprehensive program of training and continuing education on BSE directed at veterinarians and other field workers providing services to cattle farms. Handbooks and publications on BSE recognition, brainstem sampling for BSE, procedures to be followed upon detection of a BSE case, and collection of feed samples, are widely distributed and understood within the veterinary profession. A variety of other education sources including DVDs, magazine, radio and advertising material are distributed to farmers, livestock technicians and the general public.

BSE has been a notifiable disease in Brazil since 1997, and a contingency plan to be followed in the event of a diagnosis of BSE has been established, published and distributed. Both farmers and veterinarians face penalties for failure to report BSE suspect cases.

There is a network of four laboratories for diagnosis of BSE in Brazil and all of the laboratories perform screening for BSE via histopathology. All samples also undergo subsequent testing by immunohistochemistry that is performed only at the federal LANAGRO laboratory. Diagnostic procedures are compliant with the OIE Manual of Standards. All four laboratories participate in international proficiency tests with OIE reference laboratories.

The Brazilian federal identification system for cattle and buffaloes, SISBOV, is voluntary, but is required for beef producers who wish to supply export markets that require traceability that includes individual identification. This system includes an online database and a comprehensive inspection program. Brazil also has a mandatory system for recording the origin and movement of all cattle, and mandatory identification and rigorous movement control for cattle in municipalities adjacent to national borders.

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 of Chapter 11.5 of OIE's *Terrestrial Animal Health Code*.[2] 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.

The BSE surveillance program in Brazil complies with the guidelines in Articles 11.5.20 to 11.5.22 of the OIE's *Terrestrial Animal Health Code.* This Chapter provides further details of Brazil's surveillance activities and historical data.

19 Brazil's BSE surveillance program

The National BSE Prevention Plan includes both passive and active surveillance for BSE. BSE clinical suspects are defined as "Cattle over 24-months old showing clinical signs of neurological or debilitating progressive disease that persists for more than 15 days".

In addition to cattle meeting the definition to be clinical suspects, the following cattle are tested for BSE:

- Cattle over 24 months that are suspect rabies cases but test negative for rabies
- Cattle imported from countries in which there have been cases of BSE. These cattle must be destroyed on farm and the brainstem submitted for BSE testing. However, for the purpose of surveillance, they are classified as routine slaughter samples
- Cattle subject to emergency slaughter
- Fallen stock.

On farms, veterinary practitioners collect samples from cattle that show neurological signs, as well as from cattle found dead without a known cause. Samples may be sent directly for rabies diagnosis or for differential diagnosis of other neurological diseases. Samples submitted for rabies that test negative for rabies are submitted for BSE testing. Samples submitted for differential diagnosis of neurological syndrome are also tested for BSE.

Laboratories register the results of submissions from farms in the database in one of three categories:
Category 1: Animals that tested negative for rabies
Category 2: Animals that showed clinical signs for 15 days or longer
Category 3: Animals that were found dead, or had chronic or debilitating disease.

Samples submitted from slaughterhouses are those from animals that were dead on arrival at the slaughterhouse, were sent for emergency slaughter, or that showed neurological signs during ante mortem inspection. Results from slaughterhouse samples are categorised as follows:
Category 2: Animals that showed neurological signs
Category 3: Animals that were found dead
Category 5: Animals sent for emergency slaughter.

Category 4 is reserved for test results from imported cattle from countries considered to pose a risk for BSE. These cattle may not be sent for slaughter, and may only be moved between properties if authorised by the OVS. When one of these cattle reaches the end of its useful

life, it is terminated on the farm, and the brainstem sample must be collected prior to destruction of the carcass. Likewise if the animal dies spontaneously, a brainstem sample is collected prior to destruction of the carcass.

The OIE surveillance categories are considered to correspond to Brazil's as follows:

OIE *clinical suspect*	Categories 1 (rabies negative) and 2 (clinical signs > 15 days)
OIE *fallen stock*	Category 3 (found dead or chronic debilitation)
OIE *casualty slaughter*	Category 5 (emergency slaughter)
OIE *routine slaughter*	Category 4 (imported cattle from countries with BSE risk)

The incidence of rabies has declined since 2006 in Brazil, with a resultant decrease in the number of *clinical suspect* samples submitted for BSE testing.

The number of samples submitted directly for BSE testing because of neurological signs or debilitation of ≥14 days duration has fluctuated around 100/year since 2002.

A finding of the BSE agent in an aged cow in Brazil was reported to the OIE on 7 December 2012. The cow was a 13-year old beef cow that had been reared in an extensive grazing system in the state of Parana. The case is considered to be atypical BSE, which occurs sporadically and appears to arise spontaneously. A second case of atypical BSE was confirmed in a 12-year old cow on 9 May 2014.

20 Brazil's BSE surveillance points data

From 2006 through 2012 inclusive, 21,659 bovine brain samples were tested for BSE. Of these, 4207 samples were from clinical suspects. The total corresponded to 1566936.4 points according to the OIE surveillance points scoring system. There have been two positive results, both atypical BSE cases in aged cows reported to the OIE on 7 December 2012 and 9 May 2014. The cases did not alter the OIE's assessment of Brazil as being negligible BSE risk.

Surveillance points data from 2006 to 2012 inclusive are shown in **Tables 10A to 10G**.

Table 10, A-G: Surveillance points data, 2006-2012

Table 10A: Surveillance points data for 2006

Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>2 to <4	426	110,760	50	5	1,432	572.8	38	7.6
>4 to <7	175	131,250	32	6.4	494	790.4	18	16.2
>7 to <9	46	10,120	25	2.5	33	23.1	10	4
>9	43	1,935	154	0	23	4.6	3	0.3
Totals	**690**	**254,065**	**261**	**13.9**	**1,982**	**1,390.9**	**69**	**28.1**

Table 10B: Surveillance points data for 2007

Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>2 to <4	238	61,880	1	0.1	2,101	840.4	45	9.0
>4 to <7	104	78,000	16	3.2	635	1,016	29	26.1
>7 to <9	26	5,720	5	0.5	28	19.6	18	7.2
>9	22	990	92	0	85	17	8	0.8
Totals	**390**	**146,590**	**114**	**3.8**	**2,849**	**1,893**	**100**	**43.1**

Table 10C: Surveillance points data for 2008								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>2 to <4	343	89,180	5	0.5	2,663	1,065.2	3	0.6
>4 to <7	129	96,750	16	3.2	718	1,148.8	1	0.9
>7 to <9	23	5,060	38	3.8	51	35.7	0	0
>9	31	1395	84	0	43	8.6	0	0
Totals	**526**	**192,385**	**143**	**7.5**	**3,475**	**2,258.3**	**4**	**1.5**

Table 10D: Surveillance points data for 2009								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>2 to <4	822	213,720	12	1.2	2399	959.6	36	7.2
>4 to <7	267	200,250	4	0.8	673	1076.8	37	33.3
>7 to <9	52	11,440	11	1.1	45	31.5	8	3.2
>9	27	1,215	53	0	18	3.6	3	0.3
Totals	**1,168**	**426,625**	**80**	**3.1**	**3,135**	**2,071.5**	**84**	**44.0**

Table 10E: Surveillance points data for 2010								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>2 to <4	607	157820	8	0.8	1893	757.2	28	5.6
>4 to <7	245	183750	4	0.8	535	856.0	21	18.9
>7 to <9	38	8360	9	0.9	46	32.2	4	1.6
>9	25	1125	49	0	39	7.8	7	0.7
Totals	**915**	**351055**	**70**	**2.5**	**2513**	**1653.2**	**60**	**26.8**

Table 10F: Surveillance points data for 2011								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>2 to <4	193	50180	0	0	749	74.9	34	6.8
>4 to <7	67	50250	2	0.4	304	60.8	6	5.4
>7 to <9	17	3740	1	0.1	13	1.3	0	0
>9	11	495	26	0	6	0	6	0.6
Totals	**288**	**104665**	**29**	**0.5**	**1072**	**137**	**46**	**12.8**

Table 10G: Surveillance points data for 2012								
Age in years	Clinical suspect	Points	Routine slaughter	Points	Casualty slaughter	Points	Fallen stock	Points
>2 to <4	104	27040	0	0	580	232.0	8	1.6
>4 to <7	50	37500	0	0	713	1140.8	1	0.9
>7 to <9	72	15840	0	0	26	18.2	0	0
>9	4	180	5	0	32	6.4	0	0
Totals	**230**	**80560**	**5**	**0**	**1352**	**1397.4**	**9**	**2.5**

Total points by year, for 2006-2012 inclusive, are summarized in **Table 11**.

Table 11: Cumulative points data by year for 2006 - 12 inclusive					
Year	Clinical Suspect	Routine Slaughter	Casualty slaughter	Fallen Stock	Total points for year
2006	254065	13.9	1390.9	28.1	255497.9
2007	146590	3.8	1893.0	43.1	148529.9
2008	192385	7.5	2258.3	1.5	194652.3
2009	426625	3.1	2071.5	44.0	428743.6
2010	351055	2.5	1653.2	26.8	352737.5
2011	104665	0.5	137.0	12.8	104815.3
2012	80560	0	1397.4	2.5	81959.9
					1566936.4

The number of cattle over 24 months of age in Brazil in 2012 was 121,353,046, comprising 31,851,417 males and 89,501,629 females. The cattle population of Brazil has remained fairly stable over the last seven years, so this means that the points target under Type A surveillance would be 300,000, and under Type B surveillance would be 150,000. Brazil's points total in the interval 2006-2012 inclusive is well in excess of both values.

Data were provided in the submission, and following the in-country assessment, to show that surveillance of bovine brain samples is conducted in all regions of Brazil, in numbers approximately proportional to the proportion of the national cattle herd in each region.

21 Summary: BSE surveillance

Brazil carries out active surveillance in compliance with the guidelines in Articles 11.5.20 to 11.5.22 of the OIE's *Terrestrial Animal Health Code*. Current surveillance practices have been in place since 2002. Brazil's total points for the period 2006 to 2012 inclusive added up to over 1.5 million**,** well in excess of the OIE points target for Type A surveillance. Two atypical BSE cases have been reported, one in December 2012 and a second in May 2014. Both of these cases were animals born more than 11 years ago so that Brazil continues to be classified as negligible BSE risk status under OIE guidelines. Additionally it indicates the high level and rigor of the BSE surveillance system operating in Brazil in being able to detect atypical cases; such cases have been estimated to only occur spontaneously at a very low prevalence in the range of one in 2.5 to 3.0 million head of cattle.

Conclusions and BSE risk categorisation

Brazil has legislative controls and systems to prevent the introduction and amplification of the BSE agent within the Brazilian cattle population and contamination of the human food supply with the BSE agent. In-country assessment by FSANZ personnel confirmed that legislative requirements relevant to BSE prevention and control are effectively implemented.

The risk of the BSE agent being released into the Brazilian cattle population through imports of MBM, live cattle, or beef and beef products is effectively managed. Importation of MBM, or animal feed containing mammalian proteins, from countries with BSE was first banned in 1991, with updates and refinements to the ban in successive legislation. Brazil neither produces nor imports greaves. Since 2003, pet foods and finished animal feeds containing animal proteins have been accepted for import into Brazil only if they originated from countries with no history of BSE.

Importation of live cattle from countries in which BSE has occurred has been prohibited since 1990. Since 2001, cattle imported from countries that subsequently reported BSE have been subject to tracing and monitoring, cannot be sent to slaughter, and can be sold to another farmer only with approval of the OVS. When these cattle die, they are sampled for BSE prior to incineration and burial. Countries of origin have been categorised according to the incidence of BSE since 2004. In 2008, Brazil adopted the category system of the OIE**.**

Importation of bovine products since 2003 has been limited to bovine pancreas and casings, originating exclusively from countries classified by the OIE as being at negligible risk of BSE. The frequent revision of legislation related to imports of cattle and products derived from cattle illustrates that Brazil has been diligent in monitoring the BSE status of other countries, and in monitoring growing scientific knowledge concerning BSE.

The risk of introducing and recycling BSE infectivity through ruminant feed is regulated at multiple control points in Brazil, and the risk of BSE entering and recycling within the bovine feed system or entering the human food supply in Brazil is negligible. Brazil relies principally on extensive, pasture-based cattle-farming systems, and 94% of the national cattle herd is never fed processed feeds. A ban on feeding animal proteins to ruminants has been in place since 2001 and is subject to enforcement including sampling of feed, both at feed mills and on farms, for prohibited material.

There are specific requirements for feed mills producing both feed for ruminants and feed for non-ruminants, including separate production lines, GMP implementation, validated procedures to prevent cross-contamination at all stages of production, and laboratory analysis of at least 10% of batches of ruminant feed. Feed containing animal protein must be prominently labelled to indicate that the feed must not be fed to ruminants, and MBM may not be transported with feed for ruminants. A national program to detect cross-contamination at feed mills has been in place since 2003. There are also on-farm controls to ensure that purchased feed meets specifications, and that records of feed purchases are kept.

Control of slaughterhouse procedures is effectively applied by on-site federal inspection personnel and by regular internal and external audits. Any bovine animal showing clinical signs suggestive of BSE, or any bovine animal that dies in transit to a slaughterhouse, must be terminated and destroyed by incineration. Slaughterhouses must comply with mandatory procedures at stunning and slaughter to ensure SRM are removed and that there is no contamination of edible meat by SRM. SRM are destroyed by incineration or another approved method. Although it contains no SRM, MBM must be prominently labelled to indicate that it must not be fed to ruminants.

Brazil has appropriate control programs for the identification and notification of BSE clinical suspects, and for the laboratory diagnosis of BSE. There is a network of four laboratories for diagnosis of BSE. All the laboratories perform the initial examination by histopathology. The second examination by immunohistochemistry is performed only at the federal LANAGRO laboratory. Diagnostic procedures are compliant with the OIE Manual of Standards and all four laboratories participate in international proficiency tests with OIE reference laboratories. Although Brazil has reported two atypical BSE cases, both animals were born more than 11 years ago, allowing Brazil to remain classified as negligible BSE risk status under OIE

The federal veterinary service has been promoting technical training on BSE prevention and surveillance since 1997. There is a comprehensive program of training and continuing education on BSE directed at veterinarians and other field workers providing services to cattle farms. There are a wide range of publications and other materials distributed within the veterinary profession, as well as to farmers, livestock technicians and the general public. BSE has been a notifiable disease in Brazil since 1997, and a contingency plan for use in the event of a diagnosis of BSE has been established, published and distributed.

All cattle in Brazil must be marked by brand, tattoo or similar means to indicate the farm of origin and properties on which they were subsequently kept. Brazil also has a mandatory system for recording the movement of all cattle, and rigorous movement control for cattle in municipalities adjacent to national borders. The Brazilian federal identification system for individual identification of cattle and buffaloes, SISBOV, is voluntary, but is required for beef producers who wish to supply export markets requiring traceability that includes individual identification. This system includes an online database and a comprehensive inspection program.

Comprehensive food safety controls exist in Brazil to allow effective protection of the human food supply from potential BSE contamination. Measures to prevent SRM contaminating the domestic and export food supply are in place. All establishments producing or supplying products of animal origin must have a comprehensive recall plan and must conduct simulations to ensure that the recall plan is effective. The recall plan and simulations are subject to audit by the Federal Inspection Service.

All beef and beef products produced in Brazil are traceable to the day of slaughter by reference to the GTA and invoices. Cattle destined for markets that do not require traceability of individual animals are often, but not invariably, traceable to the farm of origin by the same means. For the supply of export markets that d traceability of individual animals, export slaughterhouses will only accept cattle registered in SISBOV, a system which features individual lifetime traceability. Brazil exports beef to numerous countries that demand a high standard of traceability, and export slaughterhouses are experienced in meeting the requirements of export markets.

Brazil carries out active surveillance in compliance with the guidelines in Articles 11.5.20 to 11.5.22 of the OIE's *Terrestrial Animal Health Code*. Current surveillance practices have been in place since 2002. Brazil's total points for the 7 years 2006-2012 inclusive were well in excess of the points target specified by the OIE for Type A surveillance.

In conclusion, robust controls to prevent BSE from entering and recycling within the bovine feed system or entering the human food supply in Brazil have been in place for at least eight years. The FSANZ BSE food safety assessment of Brazil recommends **Category 1** status for Brazil.

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Appendix 1: Background information on Brazilian bovine production systems

(Source of information in this Appendix: Ministry of Agriculture, Livestock and Food Supply, Brazil).

The predominant production system in Brazil is based on grazing and relying on native and cultivated pastures, which are grazed at continuous stocking all year round. Forage conservation is only utilized in intensive dairy production systems and some rare feed-lot systems. Of the approximate 212,000,000 cattle in 2013, approximately 75% are beef cattle and 20% dairy cattle.

1. Feeding pattern

1.1. Beef Systems

The considerable geographical size of Brazil, the variety of ecosystems and the diversity of regions and farmers result in a wide range of beef production systems across the country. The presence of practicing veterinarians on the farms increases as the production systems are intensified. According to the feeding processes, the production systems can be grouped as follows.

a) Extensive systems in which grazing is the only source of food. This system accounts for 94% of the total beef cattle herd. Extensive systems are characterized by native and cultivated pastures as the only source of food. Mineral supplements can be given to the cattle. The sources of these supplements are monocalcium, dicalcium and monoammonium phosphates. This type of system usually carries out all production phases (rearing until fattening).

b) Semi-intensive systems in which there is a combination of grazing and food supplementation on pasture. Around 5% of the total beef cattle herd is found in these systems. Animals are kept in feeding stables, but also on pastures for grazing, and are supplemented with minerals and protein/energy supplements. The aim is to achieve a shorter production period than in the extensive systems, by supplementing the grazing animals during their growth period (suckling, growing and finishing). The amount of supplementary feed supplied varies according to the production targets of each individual system.

Creep feeding

Creep feeding is the practice of providing nursing calves with the opportunity to eat supplements to which cows do not have access. Most beef cows will produce enough milk only during the first 60 - 90 days of lactation, when additional nutrients start to be given to the calf. Note that this is the only beef system in which the animals are fed concentrates in the first 12 months of age.

Protein supplement

The use of protein supplement (also called multiple mixture) is characterized by the low daily offering (1g/kg live weight/day), since it does not aim to fulfil directly the demands for protein of the grazing cattle, but to prevent nitrogen deficiency for the rumen bacteria.

Concentrate

The purpose of feeding of concentrate is to guarantee weight gain, regardless of the season. Amounts offered vary from 2 to 12 g/kg of live weight/day, depending on the target weight gain.

c) Intensive systems in which feeding systems include grazing, food supplementation on pasture and feedlot. Around 1% of the total cattle herd are found in intensive systems. Basically, these systems consist of finishing steers in feedlots. During the time in the feedlot the concern is to reduce feeding costs by using diets with a proportion of roughage: concentrate close to 60:40%. Corn and sorghum silage, and chopped fresh sugar cane, predominate among roughage sources.

1.2. Dairy Systems

In contrast to many dairy producing countries, Brazil features a wide range of milk production systems. Most of the herds are composed of European (*Bos primigenius taurus*) x Zebu (*Bos primigenius indicus*) crossbred animals.

a) Extensive systems

In these systems, animals are kept on pasture and supplemented only with mineral salt, attaining a level of productivity lower than 1,200 litres of milk/cow/year. Cows are milked once a day and calves suck their dams after milking throughout lactation up to 6 to 8 months of age. Male calves are sold after weaning to beef cattle growers, or kept on the farm up to slaughter. Estimates indicate that this type of system is adopted by 89.5% of dairy farmers and responsible for 32.8% of total Brazilian milk production.

b) Semi-extensive systems

In these systems, animals are kept on pasture and supplemented with different kind of forages and/or concentrates during periods of pasture shortage. Cows are fed concentrates according to milk production level over their first stage of lactation. Cows are milked twice a day and calves suck their dams after milking throughout lactation up to 7 to 10 months of age. Male calves are sold after weaning. Heifers and cows are usually culled for slaughter, but active exchange of animals is common among farmers in the same region. These systems are adopted by 8.9% of the dairy farmers and account for 37.7% of total Brazilian milk production.

c) Intensive grazing systems

In these systems, animals are kept on high quality pastures with forage supplementation during pasture shortages or, in some cases, throughout the year. Concentrates are offered to cows throughout lactation according to milk production level, and also to calves and heifers. Cows are milked twice a day. Calves are artificially reared and weaned at 2 to 3 months of age. Male calves are sold as soon as possible after birth for slaughter. Heifers and cows are usually sold for slaughter, but active exchange of productive animals is common. Estimates indicate that these systems are adopted by 1.6% of the dairy farmers and account for 24.9% of total Brazilian milk production.

d) Intensive confinement systems

In these systems, animals fed with forage rations based exclusively on silage and hay. Concentrates are fed to cows according to milk production level throughout their entire lactation, as well as to calves and heifers. Calves are artificially reared on milk replacers and weaned at 2 to 3 months of age. Most male calves are sold as soon as possible after birth for slaughter, although a few of them are raised as young bulls. Heifers and cows are usually sold for slaughter, but sales of productive animals represent an important income to the dairy

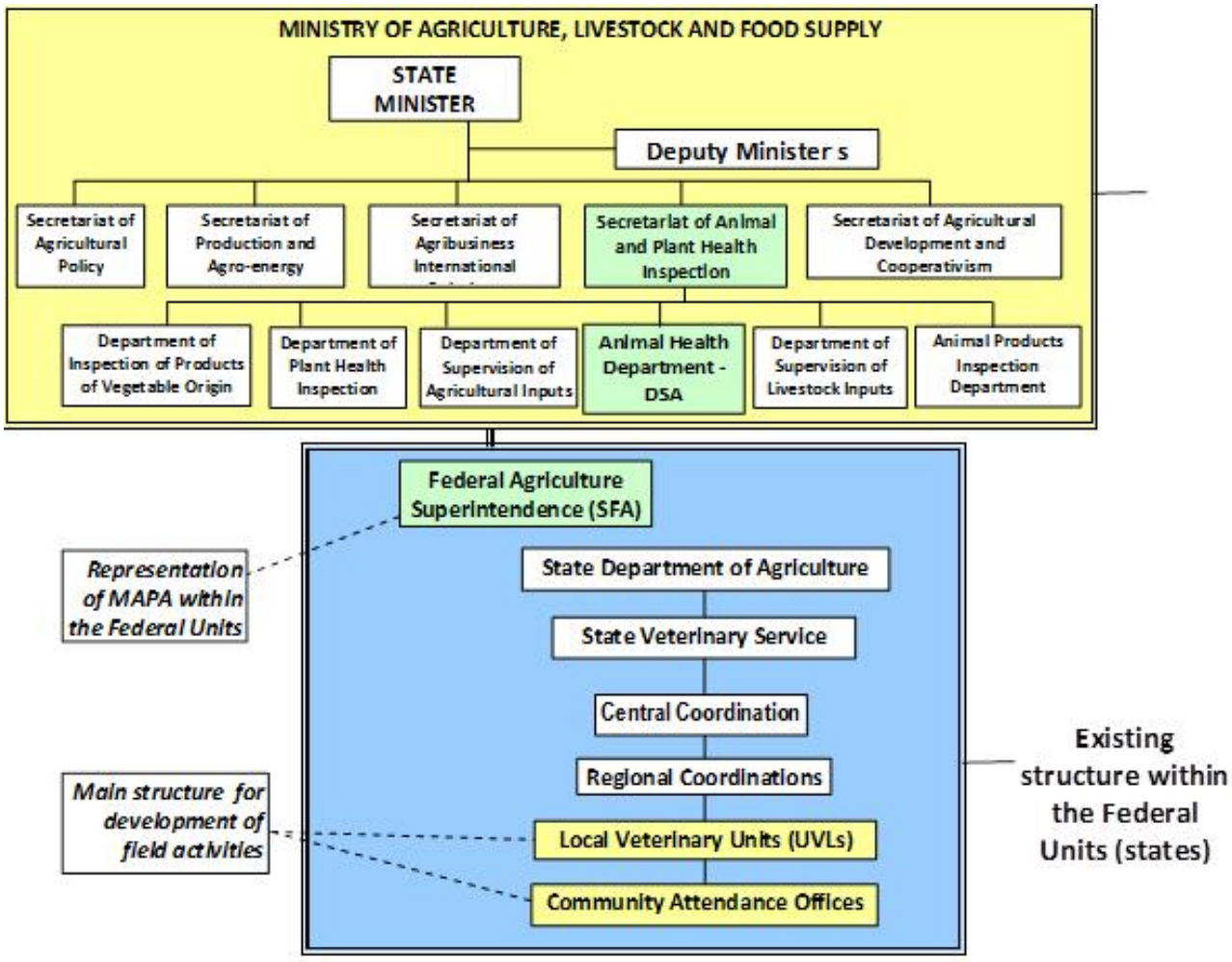
farmers. Estimates indicate that this type of system is adopted by 0.1% of the dairy farmers and accounts for 4.6%of total Brazilian milk production.

Appendix 2: Structure and organisation of veterinary services in Brazil

(Source of information in this Appendix: Ministry of Agriculture, Livestock and Food Supply, Brazil).

The structure of official veterinary services in Brazil is summarised in **Figure 6.** The federal Ministry of Agriculture, Livestock and Food Supply (MAPA) have a central office in Brasilia, the federal capital, and also have offices in each of Brazil's Federative Units (UF), or states. MAPA has an office in each state capital called Federal Superintendence of Agriculture, Livestock and Food Supply (SFA). MAPA also has offices in other cities, depending on factors such as territory size, animal population, kind of agriculture and livestock use. SFAs communicate with departments of the Secretariat of Animal and Plant Health and Inspection (SDA), which is responsible for inspection of animal and plant health, products of animal origin, and livestock input. Each state is responsible for developing animal health with the assistance of state veterinary services, which maintain a technical liaison with SFA.

Figure 6: Structure of official veterinary services in Brazil

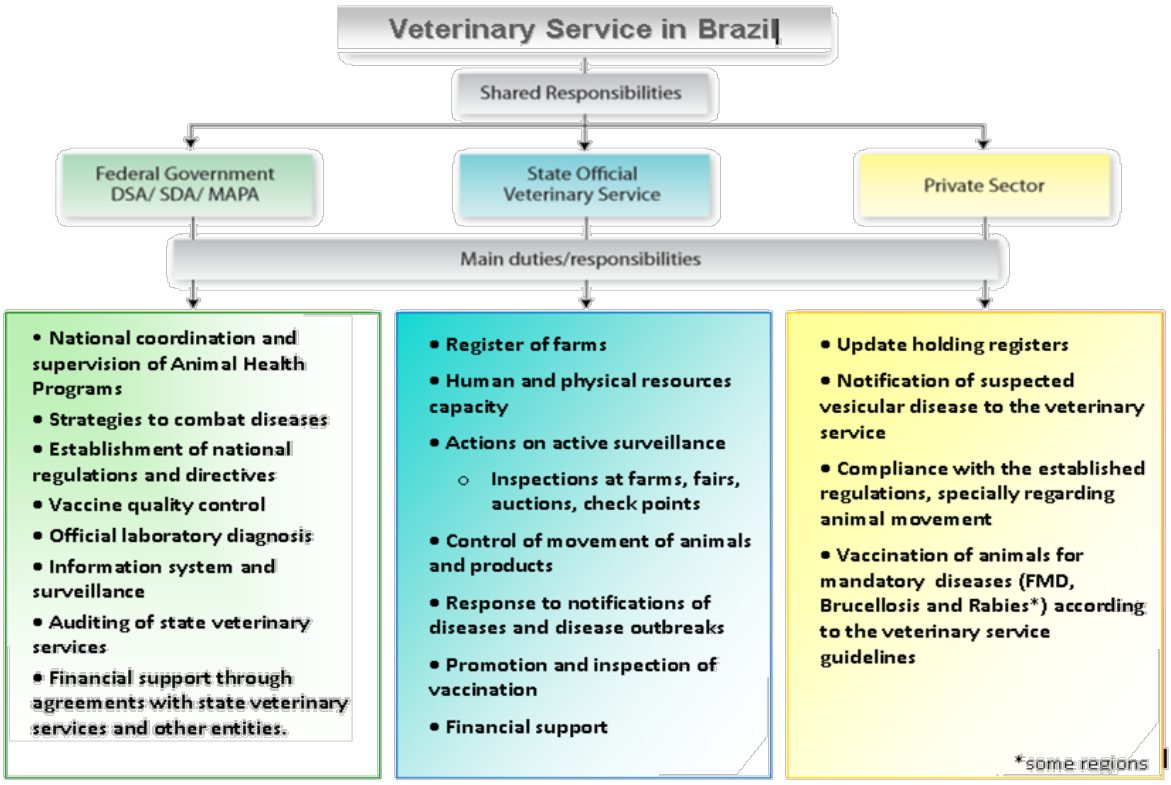


States are administratively divided into municipalities. State veterinary services are also

organized in other levels, as follows: a central coordination unit, regional coordination units responsible for managing several municipalities, and the Local Veterinary Units (LVU), in which field veterinarians are responsible for field activities and for submitting information to the coordination units. In some states in which making an LVU available in each municipality is not possible, Community Assistance Offices (CAO) are installed, staffed by technical and administrative personnel who provide assistance to the population. LVU veterinarians in neighbouring municipalities are responsible for managing and supporting these offices, and are summoned in the event of a sanitary emergency.

The roles of the different parts of the veterinary service in Brazil are summarised in **Figure 7**.

Figure 7: **Roles within the Veterinary Service in Brazil.**



Appendix 3: Brazilian Legislation and Official Documents Concerning or Relevant to BSE Control

Table 12: Brazilian Legislation and Official Documents Concerning or Relevant to BSE Control	
Title/identification	Comments
Legislation and documents concerning importation of cattle or bovine products	
Service Instruction N. 1 of July 31, 1990	Prohibited the importation of any live cattle originating from countries with registered or suspected BSE cases. At that time, BSE had been registered in the UK, Ireland and Oman.
Normative Instruction No. 2 of July 1, 1991	Prohibited the importation from countries with a high incidence of BSE of any live ruminants, bovine or ovine semen or embryos, offal meats, MBM or blood meal, animal feed containing ruminant proteins, or organs, glands, tissues or fluids from ruminants. Milk and dairy products were permitted if from licenced establishments, and leather and skins were permitted subject to health guarantees. From countries with low incidence of BSE, the following imports were permitted subject to authorization: Ruminant semen and embryos, boneless frozen beef free of nervous or lymphatic tissue, bone-in frozen beef to be deboned and processed to remove lymphatic and nervous tissues in a Brazilian export slaughterhouse, milk and dairy products from licenced establishments, leather and skins. At the time of this legislation, the UK was considered a country of high BSE incidence and France, Ireland and Switzerland to be countries of low BSE incidence.
Normative Instruction No. 1 of November 24, 1992	Reiterated *Normative Instruction No. 2 of July 1, 1991*, but with the following changes: Permitted importation of bovine serum from countries with high BSE incidence, subject to certain conditions; permitted importation of ruminants from countries with low BSE incidence, subject to certain conditions; added Denmark to the list of countries with low incidence of BSE
Administrative Decree No. 516 of December 9, 1997	Declared Brazil BSE-free, and made BSE and scrapie notifiable. Prohibited the use of ruminant proteins, except dairy proteins, in ruminant feed. Required that countries of origin of ruminants and ruminant-derived products must comply with the surveillance measures for TSEs in the *International Animal Health Code.*
Normative Instruction No. 6 of February 1, 2001	Banned the production, importation or marketing of any source of protein or fat from mammals destined for feeding of ruminants, with the exception of dairy proteins and calcined bone flour. Prohibited the importation, from countries with registered cases of BSE, of mammalian protein or fat for the feeding of any animals. Mandated that animal feed containing any mammalian protein must carry a highlighted warning label prohibiting the use of the feed for ruminants. Mandated laboratory

	testing of animal feed to determine the origin of proteins. Mandated the application of HACCP principles to inspection of animal feed manufacture.
Normative Instruction No. 8 of February 18, 2001	Prohibited the commercialization, transfer to another breeding establishment or slaughter of cattle imported from countries with BSE or at risk of BSE. Deaths of imported animals must be reported to the authorities and permission received to burn and bury the carcass. Intention to slaughter these animals must be likewise notified, and the brain sampled, with burning and burial of the carcass. The owner receives financial compensation.
Normative Instruction No. 15 of July 17, 2001	Reiterated the existing import bans, changed prohibited countries of origin to those having registered BSE cases. Extended ban to various poultry-derived products, but added semen, and collagen derived from skins, to permitted imports. Reiterated the national ban on using protein or fat from mammals for use in ruminant feed, with the exceptions of dairy proteins and calcined bone flour. Reiterating the warning label requirement on animal feeds, the requirement for testing of animal feeds and the application of HACCP principles.
Service Instruction DDA No. 22/02 of September 23, 2002	Adopted and described an interim classification of countries' risk of BSE until the OIE risk ratings were established. Established a definition for BSE clinical suspects. Prohibited the import of cattle or bovine products from countries classified as being in risk categories III and IV under the interim classification scheme. Reiterated the requirement for tracing of imported cattle, and mandated that calving dates of imported cows must be documented.
Normative Instruction of No. 58 of July 21, 2003	Prohibited the importation from Canada of live cattle, embryos, and bovine products. The prohibition included meat and offal, blood products, blood meal, meat meal, meat and bone meal, autoclaved bone meal; butcher waste meal; poultry viscera meal; poultry feather and viscera meal; poultry slaughterhouses waste meal, as well as any ingredient or raw material containing viscera of animals fed with protein or fat of ruminants. However exceptions were specified for semen, milk and dairy products, collagen derived from skins and calcined bone meal.
Normative Instruction of No. 59 of July 30, 2003	Mandated the inclusion of all imported cattle and bubalines in SISBOV. An attachment specifies details of import permits and the process to be followed at the port of entry, as well as quarantine procedures.
Normative Instruction No. 15 of October 29, 2003	Specified the sanitary conditions and GMP practices for rendering plants, inspection procedures and monitoring of quality of products. Covers all procedures including reception of the non-edible animal residues, processing, quality control, packing, storage, destination and transportation. Among numerous other provisions, mandated the sterilization conditions recommended by the OIE to minimize TSE infectivity, and the

	labelling of products to indicate that they are not to be used for feeding ruminants. Mandated documentation requirements, SOPs and Manual of Procedures. Specimen forms, including inspection checklists, included.
Normative Instruction No. 7 of March 17, 2004	Prohibited the importation, from countries having registered cases of BSE, of ruminants, their products or their by-products, as well as any animal products intended for ruminant feed. Exemptions were made for milk and dairy proteins, semen and embryos, protein-free tallow, dicalcium phosphate, hides, skins, and gelatin or collagen made exclusively from hides or skins.
Administrative Decree No. 8 of March 25, 2004	Forbade the use of products destined for ruminant feed that contain fat or protein of animal origin. These include poultry bedding and 'residues of swine breeding'. Prohibited the use of veterinary treatments containing ruminant products in ruminants. Exemptions were made for milk, dairy products, and gelatin or collagen made exclusively from hides or skins. Mandated the use of warning labels on animal feeds containing animal proteins or fats, to state that they must not be fed to ruminants. Mandated analysis of ruminant feeds to determine the origin of protein therein.
Normative Instruction No. 25 of April 6, 2004	Established a BSE risk characterisation of countries. Countries in Category I, having highly remote risk, were Argentina, Australia, Botswana, Brazil, Chile, Singapore, Costa Rica, El Salvador, Namibia, New Zealand, Nicaragua, Norway, Panama, Paraguay, Swaziland, Uruguay. Countries in Category II, having remote risk, were Colombia, Mauritius, India, Pakistan and Sweden. Countries in Category III, having confirmed or likely low levels (<10 cases/million) of BSE included Albania, Austria, Germany, Belgium, Canada, Cyprus, Denmark, Slovenia, Spain, Estonia, The USA, Finland, France, Greece, The Netherlands, Hungary, Falkland Islands, Ireland, Israel, Italy, Japan, Lithuania, Liechtenstein, Luxemburg, Oman, Poland, Romania, Slovakia Republic, Czech Republic, Switzerland and Russia. Countries in Category IV, having a confirmed high levels of BSE, were Portugal and the UK. All countries not named above were classified in Category V, having unknown risk of BSE.
Normative Instruction No. 17 of July 13, 2006	Established SISBOV and laid out all the conditions for registration and participation, including movement tracing, and documentation requirements, and how the system is controlled and audited. Included details on control and traceability of imported animals.
Regulatory Instruction No. 34 of May 28, 2008	Specified the regulation of sanitary and technological inspection of plants processing animal residues, and the document requirements for transportation of animal residues
Normative Instruction No. 49 of September 15, 2008	Introduced a classification system of the BSE risk of countries based on the OIE system, and using the same categories. Prohibited the importation from Category III countries of ruminants, their products and by-products

	including veterinary pharmaceuticals, and any products or ingredients of animal origin destined for animal feed. Specified that importations from Category I or II countries are subject to SDA sanitary requirements being met. Exemptions such as milk, dairy products, deproteinated tallow, skins, hides and gelatin or collagen from skins or hides reiterated. A mandatory Decision Matrix for importations of cattle and bovine products was included in this legislation.
Legislation and documents relevant to exposure control through feed ban	
Decree No. 365 of July 3, 1996	Prohibited the use of *in natura* protein or ruminant MBM in ruminant feed.
Administrative Decree No. 516 of December 9, 1997	Declared Brazil BSE-free, and made BSE and scrapie notifiable. Prohibited the use of ruminant proteins, except dairy proteins, in ruminant feed. Required that countries of origin of ruminants and ruminant-derived products must comply with the surveillance measures for TSEs in the *International Animal Health Code.*
Normative Instruction No. 6 of February 1, 2001	Banned the production, importation or marketing of any source of mammalian protein or fat destined for feeding of animals, if originating from countries with registered cases of BSE. Exemptions were specified for milk protein and calcined bone flour. Mandated the labelling of animal feed containing mammalian protein or fat with a warning that the product is not to be fed to ruminants. Instituted mandatory laboratory analysis to identify the source of proteins in ruminant feed. Mandated that the inspection system for animal feed producers must be based on HACCP principles.
Normative Instruction No.1 of February 18, 2003	Established technical regulation of hygiene-sanitary conditions, a requirement for Good Manufacturing Practices (GMP) and general measures to prevent cross-contamination in feed mills; superseded by *Normative Instruction No. 4 of February 23, 2007*
Normative Instruction No. 15 of October 29, 2003	Specified the sanitary conditions and GMP practices for rendering plants, inspection procedures and monitoring of quality of products. Covers all procedures including reception of the non-edible animal residues, processing, quality control, packing, storage, destination and transportation. Among numerous other provisions, mandated the sterilization conditions recommended by the OIE to minimize TSE infectivity, and the labelling of products to indicate that they are not to be used for feeding ruminants. Mandated documentation requirements, SOPs and Manual of Procedures. Specimen forms, including inspection checklists, included.
Administrative Decree No. 8 of March 25, 2004	Forbade the use of products destined for ruminant feed that contain fat or protein of animal origin. These include poultry bedding and 'residues of swine breeding'. Prohibited the use of veterinary treatments containing ruminant products in ruminants. Exemptions were made for milk, dairy products, and gelatin or collagen made exclusively from hides or

	skins. Mandated the use of warning labels on animal feeds containing animal proteins or fats, to state that they must not be fed to ruminants. Mandated analysis of ruminant feeds to determine the origin of protein therein.
Normative Instruction No. 4 of February 23, 2007	Mandated hygiene and sanitation conditions and GMP conditions for companies that manufacture animal feed, as well as an Inspection Guide to enforce these. The Normative Instruction gave feed mills 545 days to become compliant with the specified conditions. The comprehensive requirements include prevention of cross-contamination, and recall capability. A specimen checklist for official inspections was included.
Decree no. 6296 of December 11, 2007	Provided for the obligatory inspection and surveillance of products meant for animal feed. Required feed mills to be registered with MAPA, and each product must also be registered. Products must meet the label and registration descriptions. Specified label information; standards of storage and transport; inspection and surveillance; quality control and record keeping; and obligations. Specified administrative sanctions for noncompliance, including fines, suspension and revocation or cancellation of registration.
Regulatory Instruction No. 17 of April 7, 2008	Prohibited the manufacture of non-ruminant feed and ruminant feed in the same plant unless there are separate production lines, Best Manufacturing Procedures are followed, validated procedures for prevention of cross-contamination are used throughout the process, and at least 10% of batches of ruminant feed are tested to ensure that they contain no animal protein. An exemption was made for feed mills that do not use any ingredients of animal origin. The Regulatory Instruction gave feed mills 365 days to achieve compliance.
Regulatory Instruction no.34 of May 28, 2008	An updated version of *Normative Instruction no. 15 of October 29, 2003,* this specified the regulation of sanitary and technological inspection of plants processing animal residues, and the document requirements for transportation of animal residues. It retained the existing requirements relevant to prevention of cross-contamination, and prohibited the use of SRM for production of MBM or fat-derived products. An exemption was provided for established for blood meal, calcium-enriched bone meal and protein-free tallow, and also for establishments not processing ruminant residues.
Circular Memorandum DFIP no. 22 of September 29, 2008	Together with *Decree no. 6296 of December 11, 2007*, empowers authorities to exercise inspection and surveillance of feed mills, and to apply administrative sanctions against feed mills.
Normative Instruction No. 41 of October 8, 2009	Specifies the procedures for collecting samples of ruminant feed for testing for prohibited proteins, for identifying animals that are likely to have eaten prohibited feed, and for disposal of animals suspected of having been fed prohibited proteins.
Legislation and documents relevant to exposure control through slaughterhouse	

and rendering procedures	
Administrative Decree No. 516 of December 9, 1997	Declared Brazil BSE-free, and made BSE and scrapie notifiable. Prohibited the use of ruminant proteins, except dairy proteins, in ruminant feed. Required that countries of origin of ruminants and ruminant-derived products must comply with the surveillance measures for TSEs in the *International Animal Health Code.*
Normative Proceeding No. 3 of January 17, 2000	Specified acceptable methods for stunning and slaughter of livestock
Normative Instruction No. 15 of October 29, 2003	Specified the sanitary conditions and GMP practices for rendering plants, inspection procedures and monitoring of quality of products. Covers all procedures including reception of the non-edible animal residues, processing, quality control, packing, storage, destination and transportation. Among numerous other provisions, mandated the sterilization conditions recommended by the OIE to minimize TSE infectivity, and the labelling of products to indicate that they are not to be used for feeding ruminants. Mandated documentation requirements, SOPs and Manual of Procedures. Specimen forms, including inspection checklists, included.
Memorandum No. 463/DCI/DIPOA of August 5, 2004	Defined SRM, mandated and described their removal. Described the use of dentition to identify cattle 30 months or older. Mandated the training of all staff about BSE and its risks to human beings.
Circular Memorandum No.2 of April 7, 2005	Advised of the mandatory requirement for removal, denaturation and destruction of SRM
Circular Memorandum No. 1 of January 1, 2007	Revised *Circular Memorandum No.2 of April 7, 2005* to remove spleen from the list of SRM, and was itself superseded by *Circular Memo CGI/DIPOA No.1 of January 23, 2007*
Circular Memo CGI/DIPOA No.1 of January 23, 2007	Accompanied the document establishing the guidelines for removal and destruction of SRM. Defined SRM as brain, eyes, tonsils, spinal cord and distal ileum (last 70 cm). Required the keeping of records of the amount of SRM removed, and checking of this against the number of animals slaughtered. Included details of when and where SRM should be removed and expected weights of different SRM organs.
Normative Instruction No. 34 of May 28, 2008	Specified the regulation of sanitary and technological inspection of plants processing animal residues, and the document requirements for transportation of animal residues
Legislation and documents relevant to food safety controls	
Law No. 8.078 of September 11, 1990	Mandated that any supplier who becomes aware of any harmfulness of products and services already released to the market must report the matter immediately to authorities and must also notify consumers via press, radio and television
Ordinance No. 789 of August 24, 2001	Regulated recall of products from the consumer market, and communication between the Department of Consumer Protection and Defence (DPDC), suppliers and consumers. Suppliers who become aware of hazard associated with their product must immediately notify The DPDC, the Department

	of Economic Law of the Ministry of Justice, and the Consumer Orientation and Protection Programs, as well as all other responsible authorities. The Ordinance specified the information that must be provided. The supplier must also immediately inform consumers through a media campaign including press, radio and television, and must provide interim and final reports on the recall to the DPDC
Law No. 12.027 of November 24, 2009	Mandated minimum standards of traceability of bovine and buffalo meat. All cattle and buffalos must have at least a registered brand or tattoo indicating property of birth and subsequent properties on which it lives. or other animal marking for the identification of the property of origin. Electronic identification or pedigree documents from an approved breed society are also acceptable identification. Slaughterhouses are prohibited from accepting cattle that do not have identification. Cattle going to slaughter must be accompanied by a GTA which describes the identification. Invoices for cattle must be issued from an invoice book that has been registered by a rural authority. Importers of cattle or buffaloes, or products of bovine origin, must be able to show that the country of origin has equivalent standards of bovine identification and traceability, and that these standards are enforced
Circular Letter No. 41 of November 17, 2010	Provided the guidelines for certification of the recall plan adopted by establishments producing and/or supplying products of animal origin for human consumption. Mandates a recall plan that specifies, in detail, all actions that will be carried out once a decision to implement the recall is made. Requires the establishment to immediately report, to authorities and consumers, any non-conformity in the product that may imply a risk to consumers. All individuals to be involved in recall activities must be named, up-to-date contact details listed, and their responsibilities specified. Establishments must have mechanisms for the collection and analysis of data on risks posed by consumption of any product, in order to project the scope of the recall to be implemented. Products must be coded to permit rapid identification of consignments. Product distribution registers must be maintained. The final destination of recalled products must be specified, coordination of recall with regulatory agencies must be described. Recall simulations must be conducted and records kept of these. Records of production and marketing must be maintained, at least until the product expiry date is reached.
Decree No. 7.623 of November 22, 2011	Provides details of the application of *Law No. 12.027 of November 24, 2009.*These details include how to add additional brands to an animal, and how to re-mark tattooed animals.
Legislation and documents relevant to control programs and technical infrastructure	
Administrative Decree No. 516 of December	Declared Brazil BSE-free, and made BSE and

9, 1997	scrapie notifiable. Prohibited the use of ruminant proteins, except dairy proteins, in ruminant feed. Required that countries of origin of ruminants and ruminant-derived products must comply with the surveillance measures for TSEs in the *International Animal Health Code.*
Normative Instruction No. 15 of February 15, 2002	Established the rules for the credentialing and monitoring of laboratories testing for BSE.
Joint Service Regulation DDA/DIPOA No. 02 of August 15, 2003	Specified that all cattle subject to casualty slaughter must be tested for BSE.
Normative Instruction No. 18 of February 27, 2004	Specified the quality requirements for accreditation and monitoring by MAPA of laboratories for the diagnosis, by IHC, of TSEs in ruminants. Included the requirement that the laboratory must have a Responsible Technician (RT) with a degree in veterinary medicine and proven experience with veterinary pathology and IHC expertise.
Normative Instruction No. 17 of July 13, 2006	Established SISBOV and laid out all the conditions for registration and participation, including movement tracing, and documentation requirements, and how the system is controlled and audited. Included details on control and traceability of imported animals.
Normative Instruction No. 1 of January 17, 2007	Reviewed the rules for laboratory accreditation first established in Normative Instruction No. 15 of February 15, 2002.
Normative Instruction No. 36 of October 5, 2007	Established the accreditation of TSE diagnostic laboratories for diagnosis by immunohistochemistry.
Law No. 12.027 of November 24, 2009	Mandates minimum standards of traceability of bovine and buffalo meat. All cattle and buffalos must have at least a registered brand or tattoo indicating property of birth and subsequent properties on which it lives, or other animal marking for the identification of the property of origin. Electronic identification or pedigree documents from an approved breed society are also acceptable identification. Slaughterhouses are prohibited from accepting cattle that do not have identification. Cattle going to slaughter must be accompanied by a GTA which describes the identification. Invoices for cattle must be issued from an invoice book that has been registered by a rural authority. Importers of cattle or buffaloes, or products of bovine origin, must be able to show that the country of origin has equivalent standards of bovine identification and traceability, and that these standards are enforced.
Decree No. 7.623 of November 22, 2011	Provides details of the application of *Law No. 12.027 of November 24, 2009.*These details include how to add additional brands to an animal, and how to re-mark tattooed animals.
Procedures Handbook upon the Occurrence of BSE (undated)	Title is self-explanatory
Handbook of Procedures to Diagnose Diseases of the Bovine Central Nervous System (first published 2001)	Describes clinical signs of BSE, differential diagnoses, sampling, shipping of samples, and histopathology
Handbook for Collection of Feed Samples for Testing the Presence of Animal Protein (first published 2005)	Title is self-explanatory

Bovine Spongiform Encephalopathy (first published in 2008)	Title is self-explanatory

Historical summary of key legislative measures for the prevention of BSE in Brazil

General Measure	Initial adoption
1. Restriction on imports of live cattle from BSE risk countries	1990 (last updated in 2013)
2. Restriction on imports of meat-and-bone meal from ruminants	1991 (last updated in 2013)
3. Prohibition of feeding ruminants with animal proteins ("feed-ban")	1996 (last updated in 2004)
4. Mandatory surveillance of TSEs	1997 (last updated in 2002)
5. Organization of laboratory network for TSEs diagnosis	2001 (last updated in 2007)
6. Tracing and prohibition of slaughtering of imported cattle from BSE risk countries	2001 (last updated in 2009)
7. Sterilization of ruminants-derived MBM (133º/20min/3bar process)	2003 (last updated in 2008)
8. Removal and destruction of SRM	2005 (last updated in 2007)

OIE Code and Scientific Advisory Committee on TSEs (Portaria 69/2004)