BSE Food Safety Assessment Report



Last Update: December 2013 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. According to the BSE food safety policy (FSANZ 2010a), FSANZ analyses the information provided by applicant countries and assigns them a BSE risk status. Information provided must address the requirements detailed in the Australian Questionnaire to Assess BSE Risk (Australian Questionnaire)(FSANZ 2010b) which are based on those of the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code (OIE 2012). Imported beef and beef products are only permitted from countries which have been assessed and are assigned a favourable BSE risk status (Category 1 or Category 2). Countries seeking market access for fresh beef products are also subject to an assessment of animal quarantine risks by the Australian Department of Agriculture.

The Republic of Chile made a submission to FSANZ in June 2011 to be assessed for BSE food safety risk. Chile was previously assessed by FSANZ for BSE risk status in 2004 under the former BSE food safety policy and assigned Category A status¹. Chile currently exports bovine-derived natural sausage casings and retorted beef products to Australia under the Category A requirements. Chile currently has been assigned BSE 'negligible' risk status from the OIE.

FSANZ has carried out an assessment of legislative measures concerning control and prevention of BSE in Chile, and an in-country assessment to verify the application and enforcement of these measures was conducted. 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 animalderived 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 Chilean cattle population through imports of MBM, live cattle, or beef and beef products is effectively managed. In the past ten years the only live bovine animals imported into Chile were ten water buffalo from Australia. Bovine derived meat and bone meal (MBM) is only imported from OIE designated BSE 'negligible' risk countries of South America and beef imports are imported only from countries with BSE 'negligible' or 'controlled' risk status. Beef imports originate predominantly from South American countries, followed by Australia and the United States of America (USA).

The risk of introducing and recycling BSE infectivity through ruminant feed is addressed at multiple control points in Chile. A ruminant feed ban has been in place since December 2000 and audit, inspection and sampling procedures are in place to ensure that contamination of ruminant feedstuffs with prohibited mammalian proteins is prevented during production, storage and transport.

¹ Source: DAFF Imported Food Notice 02-12 - BSE Certification requirements for imported beef and beef products. Available at: <u>http://www.daff.gov.au/biosecurity/import/food/notices/2009/2012/ifn-02-12</u> [accessed: 4 July 2013].

Controls have been in place since 2002 to ensure that bovine animals that could be infected with BSE do not enter the human food supply. Competent authority oversight of slaughter processes, defined instructions and quality assurance systems for both ante- and post-mortem activities ensure that BSE suspect animals are not processed for animal feed or human consumption.

Traceability requires both animal identification programs to monitor cattle movements and enable tracing of cattle back to farm of origin, and food traceability programs to trace beef or beef products back to the source animal. Both systems are well-established in Chile. Animal identification systems were first introduced in 2004. Procedures to register livestock establishments, register cattle births and deaths, individually identify animals and monitor movements are now well developed with modifications legislated in 2008, 2012 and 2013. The animal identification and traceability system is underpinned by an information system that enables the competent authority to reliably and quickly trace animals to farm-of-origin. Beef and beef products intended for human consumption are traceable through the food supply chain and food businesses are required to have an effective recall protocol in place for the recovery of product if required.

Chile has appropriate systems in place for the identification and notification of BSE suspect cases, and for the laboratory diagnosis of BSE should it occur. BSE has been a notifiable disease in Chile since 1996, and comprehensive measures ensure that there is sufficient BSE awareness among official and private veterinarians, animal holders, slaughterhouse personnel and stock transporters. The official Veterinary Diagnostic Laboratory Service is the Chilean reference laboratory for TSEs and uses diagnostic tests compliant with the OIE Standards. Participation in a regional proficiency testing program and quality control of sample collection and submission ensures that laboratory testing and reporting are maintained at a high standard.

BSE cases have not been reported in Chile. Active surveillance for BSE has been in place since 2005 and Chile's programs are in line with OIE recommendations. Currently, surveillance is conducted such that the points acquired from testing animals across the recommended sub-populations, meet the target for both Type A and Type B surveillance. Chile has had a comprehensive BSE contingency plan, with accompanying procedural manuals, in place since 2005 for responding to a suspect BSE event.

BSE controls were observed to be operating effectively during the in-country assessment with a high degree of official veterinary oversight. Appropriate monitoring and inspection procedures were verified across the beef production chain. Auditing of establishments (feed mills, slaughterhouses, farms and rendering plants) by the competent authority occurs regularly, and unmanaged adverse findings with respect to official BSE controls have not been identified.

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

Acronyms

BSE	Bovine Spongiform Encephalopathy
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry
DIIO	Dispositivo Identificacion Individual Oficial (Official Individual Identification Device)
FMA	Formulario de movimiento animal (Animal movement form)
FSANZ	Food Standards Australia New Zealand
GBR	Geographical BSE Risk
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Point
ISO	International Organization for Standardisation
MBM	Meat and bone meal
МоН	Ministry of Health
OIE	Office International des Epizooties (World Organisation for Animal Health)
PABCO	Planteles Animales Bajos Certificación Oficial (Official Certification Program for Livestock Establishments)
PCR	Polymerase chain reaction
RFD	Radiofrequency device
RUP	Rol Único Pecuario (Livestock establishment number)
SAG	Agriculture and Livestock Service
SIPEC	Sistema de Información Pecuaria (Animal Information System)
SRM	Specified risk material
TSE	Transmissible spongiform encephalopathy
USA	United States of America
VDLS	Veterinary Diagnostic Laboratory Service

Glossary

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

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

BSE rapid test is a high-through-put screening test to detect the BSE agent in brain samples. Most BSE rapid test kits employ enzyme-linked immunosorbent assay (ELISA) methodology which has been validated by numerous international reference laboratories.

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

PABCO or *Planteles Animales Bajos Certificación Oficial* (Certification of Herds under Official Control) refers to a voluntary quality control program for the management of animal health and chemical residues. The program is managed by SAG and specifies farm level requirements for facilities, animal management, anabolic substance use, veterinary supervision and records management (which includes animal registration, traceability and feed supply). Farms that supply export markets must be PABCO certified.

PCR or polymerase chain reaction is a laboratory test used to amplify and identify DNA.

Prions are infectious agents of proteinaceous nature, causing transmissible spongiform encephalopathies (TSEs) in mammals. Among the TSE diseases are the various forms of Creutzfeldt-Jakob disease in humans, BSE in cattle, and scrapie in sheep and goats.

Specified risk material (SRM) The Australian BSE food safety policy (FSANZ 2010a) defines BSE risk materials as 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. According to Chilean regulations, cattle born and raised in a 'negligible' BSE risk country are defined as being free of SRM.

Veterinary Diagnostic Laboratory Service (VDLS) refers to the official SAG laboratory where feed testing for mammalian protein and detection of transmissible spongiform encephalopathies (TSEs) in brain stem samples is conducted.

Table of Contents

EXECL	JTIVE SUMMARY	II
ACRO	NYMS	IV
GLOSS	SARY	v
INTRO	DDUCTION	1
OVER	VIEW OF CHILE'S BSE REGULATORY SYSTEM	2
BSE H	ISTORY	2
POTE	NTIAL FOR RELEASE OF THE BSE AGENT THROUGH IMPORTED MATERIALS	3
1 2 3 4	IMPORTATION OF MBM IMPORTATION OF LIVE BOVINE ANIMALS IMPORTATION OF BOVINE PRODUCTS SUMMARY: POTENTIAL FOR RELEASE OF THE BSE AGENT THROUGH IMPORTED BOVINE MATERIALS	4 5
EXPO	SURE CONTROL	7
5 6 7 8	PRE-SLAUGHTER CONTROLS: RUMINANT FEED BAN ANTE-MORTEM SLAUGHTER CONTROLS POST-SLAUGHTER CONTROLS: POST-MORTEM INSPECTION, SRM REMOVAL, AND RENDERING PROCEDURES SUMMARY: EXPOSURE CONTROL	. 10 . 12
BSE FO	OOD SAFETY CONTROLS	. 14
9 10 11 12	BEEF PRODUCTION SYSTEMS TRACEABILITY SYSTEMS FOR BEEF AND BEEF PRODUCTS RECALL SYSTEMS SUMMARY: BSE FOOD SAFETY CONTROLS	. 14 . 16
BSE C	ONTROL PROGRAMS AND TECHNICAL INFRASTRUCTURE	. 18
13 14 15 16	BSE EDUCATION AND AWARENESS Disease notification and diagnoses Cattle identification and traceability Summary: BSE control programs and technical infrastructure	. 18 . 21
BSE SI	URVEILLANCE	. 25
17 18 19	Chile's BSE surveillance program Chile's BSE surveillance points data Summary: BSE surveillance	. 26
CONC	LUSIONS AND BSE RISK CATEGORISATION	. 29
REFER	RENCES	. 31
APPE	NDICES	. 33
Арр Арр	Pendix 1: Overview of the cattle population and beef production in Chile Pendix 2: Key legislation for BSE control Pendix 3: Structure of the Agriculture and Livestock Service (SAG) and key responsibilities for BSE control . Pendix 4: Timeline of diagnostic capacity at the official Veterinary Diagnostic Laboratory Service	. 36 . 38

Introduction

Food Standards Australia New Zealand (FSANZ) is the government agency responsible for assessing the food safety risk of bovine spongiform encephalopathy (BSE), and assigning a status to countries that seek to export beef or beef products to Australia. FSANZ evaluates BSE food safety risk according to scientifically recognised and internationally accepted practices for the control and prevention of BSE. Although FSANZ sets a number of joint food standards for both Australia and New Zealand, it is not responsible for setting hygiene and primary production-related standards concerning BSE controls for New Zealand.

Under the BSE food safety policy, introduced in March 2010 (FSANZ 2010a), individual countries submit applications to FSANZ that include comprehensive data relevant to their BSE risk and associated risk management and controls, in accordance with requirements set out in the *Australian Questionnaire to Assess BSE Risk (*the Australian Questionnaire)(FSANZ 2010b). In general, data requirements in the Australian Questionnaire are based on those of *Chapter 11.5 – Bovine Spongiform Encephalopathy* of the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code* (OIE 2012). The Australian Questionnaire also seeks information on animal traceability and identification, animal slaughtering and processing systems.

FSANZ assesses the information and data submitted by the applicant country through: (1) a desk assessment of legislative measures concerning controls around the introduction, spread and prevention of BSE; and (2) an in-country assessment to verify the application and enforcement of these measures.

In addition to submitted documentation, legislation and standards underpinning BSE controls are examined as part of the desk assessment. Publically available documentation issued by other statutory bodies may also be reviewed.

Countries that submitted an application for a BSE risk assessment retain their existing BSE status until the risk assessment is complete or the application withdrawn. Chile submitted an application to FSANZ for country categorisation of BSE food safety risk in June 2011 and an in-country verification visit was undertaken in March 2013 in the major cattle and dairy production areas of Chile, including Los Lagos, Los Rios and Santiago Metropolitan regions (Appendix 1). This report describes the BSE food safety risk assessment conducted by FSANZ to determine the risk of the BSE agent being present in beef and beef products imported from Chile.

This report describes the findings of the BSE food safety risk assessment and concludes with the assignment of a country BSE risk category that indicates the risk that the BSE agent may be present in beef and beef products imported from Chile.

Overview of Chile's BSE regulatory system

The Republic of Chile is a unitary state and has three levels of government – national, regional and sectoral. The central Veterinary Authority in Chile is the Servicio Agrícola y Ganadero (SAG), a division of the Ministry of Agriculture, and has its headquarters in Santiago. There are 15 SAG regional offices located in the capitals of each region. There are also 64 local ('sectoral') SAG offices in towns throughout Chile.

From SAG's central office through the regional and local levels to the official veterinarians in export approved establishments, SAG has the legal authority and responsibility to enforce the relevant laws, decrees and resolutions (Appendix 2). The Livestock Protection Division of SAG, headed by the Chief Veterinary Officer, manages animal health programs. The animal health subdepartment of the Livestock Protection Division manages disease surveillance; the safety and certification subdepartment manages process controls and certification of slaughter establishments; and the integrated management of animal health subdepartment manages the animal information system. The Laboratory and Quarantine Division of SAG manages the Veterinary Diagnostic Laboratory Service which has responsibility for testing samples submitted for BSE testing and ruminant feed samples (Appendix 3).

The Ministry of Health (MoH) in Chile has regulatory control of food for human consumption, including meat. Through an agreement between the MoH and SAG, the sanitary inspection of animals and their meat is delegated to SAG.

BSE History

The Chilean cattle population at the last census in 2007 was 3.7 million head and is comprised mostly of dairy breeds. Beef production is predominantly a by-product of the dairy industry and Holstein and Holstein cross progeny account for the majority of the slaughter population (refer to Appendix 1).

No BSE cases have been detected in Chile. In 2006, the OIE classified Chile as "provisionally free" from BSE until it was amended in 2007 to a *Controlled Risk* for BSE. In May 2009, the OIE re-classified Chile as having a *Negligible Risk* for BSE and Chile has maintained this status up to the most recent OIE General Session in May 2013.

The Food Safety Commission of Japan concluded in 2011 that the potential risk of BSE exposure and propagation in Chile is considered negligible, and the risk-reducing efficacy at the meat processing lines was considered "extremely effective" to "highly effective" (FSCJ 2011)

Importation of beef and beef products from Chile to Australia is currently permitted by the Australian Government Department of Agriculture subject to certification requirements that have been in operation since 2004, when Chile was classified as a Category A country under Australia's former BSE food safety policy.

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: meat and bone meal (MBM), animal feed contaminated with 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 Chile, 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 ruminant MBM into Chile since 2003 has been restricted to MBM from three other South American countries categorised as having negligible BSE risk by the OIE; Argentina, Brazil and Uruguay.

1.2 Legislation

The SAG has legislative control over the importation of bovine animals and bovine products, including MBM, into Chile. Imports of bovine animals and their products are controlled by *Resolution No. 5277/2004* that restricts imports to countries that have been assessed by SAG and have in place BSE controls in accordance with international standards set out by the OIE. This resolution revoked previous resolutions that established a list of countries that were permitted to export bovine animals and bovine products to Chile.

The particle size, temperature, cooking time and pressure requirements for the production of MBM and the by-products that could be used in MBM manufacture were established by *Resolution 5037/2005*. The importation of pet food containing MBM of ruminant origin is controlled by *Resolution No. 1113/2002* and establishes that processing requirements in the exporting country must be equivalent to those of Chile. Products that enter Chile must be supported by a certificate issued by the relevant authority in the country of origin, stating their compliance with such country's health conditions as well as the restrictive system or special control to which they have been subject.

1.3 Details of MBM imports

For the years 2003 to 2010, imports of MBM were solely from Argentina and Brazil. In 2010 one establishment from Uruguay was authorized and imports were received in 2011. The data in Table 1 summarises the volume of imports of MBM from Brazil, Argentina and Uruguay.

Pet food containing MBM or processed bovine protein is currently imported from Argentina and Brazil. The import data provided during the in-country visit and shown in Table 2 is a combination of pet food free of MBM and bovine proteins and pet food that contains MBM and/or bovine proteins.

Year	Argentina	Brazil	Uruguay	Total
2003	954.0	2975.0	0	3929.0
2004	76.6	7520.7	0	7597.3
2005	224.0	6857.7	0	7081.7
2006	4399.5	2978.8	0	7378.3
2007	1237.8	1159.8	0	2397.6
2008	1490.5	1315.3	0	2805.8
2009	583.8	2581.7	0	3165.5
2010	234.7	9065.9	0	9300.6
2011	263.3	8,891.4	54.0	9,208.7
2012	79.5	8,384.6	0	8,464.1
Total	9543.7	51,730.9	54.0	61,328.6

 Table 1 MBM imports in tonnes by country of origin for the years 2003-2012

Source: Agriculture and Livestock Service.

Year	Argentina	Brazil	Uruguay	Total
2009	42.9	2.3	0.0	45.2
2010	40.4	0.6	0.0	41.0
2011	1352.6	914.0	0.0	2266.6
2012*	61519.1	1347.8	0.0	62866.9
Total	62955.0	2264.7	0.0	65219.7

* Note that data for 2012 includes all pet food imported from Argentina, Brazil and Uruguay, with and without MBM. For the years 2009 to 2011, the data only includes pet food containing MBM.

2 Importation of live bovine animals

2.1 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. Australia is the only country from which live bovine animals (water buffalo) have been imported into Chile since 2004.

2.2 Legislation

Imports of bovine animals and their products are controlled by *Resolution No. 5277/2004* that restricts imports to countries that have been assessed by SAG and have in place BSE controls in accordance with international standards set out by the OIE. This resolution revoked previous resolutions that established a list of countries that were permitted to export bovine animals and bovine products to Chile.

2.3 Details of live cattle imports

Ten water buffalo were imported into Chile from Australia in 2006. Chilean authorities continue to monitor the BSE status of Australia which is currently designated as a negligible BSE risk country by the OIE and has mandatory reporting of BSE cases. No cattle have been imported into Chile from 2004 to the present; six cattle were imported from the United States of America (USA) in 2003. These animals and their off-spring are subject to life-long quarantine and strict movement controls have been applied.

3 Importation of bovine products

3.1 Overview

This Section focuses on the risk of releasing the BSE agent through the importation of products containing bovine protein that are intended for human consumption.

3.2 Legislation

The importation of bovine products is also controlled by *Resolution No. 5277/2004 (refer to* Section 2.2 above). The following bovine products are exempted from the import restrictions if all general and specific health standards are fulfilled in each case: milk and dairy products, semen, in-vivo collected embryos (only if collection and handling are in compliance with the recommendations of the International Embryo Transfer Society), protein-free tallow (insoluble impurities may not exceed 0.15% w/w) and products derived from it, skins and leathers, jelly and collagen exclusively prepared from skins and leathers.

3.3 Type of imported bovine products

Data on beef imports were provided during the in-country verification visit for the period 2005 to 2012. In the reporting period most beef was imported from Paraguay, Argentina and Brazil. The proportion of beef imported from Australia and the USA has increased in the past two to three years (Table 3). Fresh chilled carcasses and half carcasses are imported from Australia and fresh chilled or frozen boneless and bone-in cuts are imported from Australia, USA, Brazil, Argentina, Paraguay and Uruguay.

Imports of edible bovine offal from Australia, USA and Uruguay account for the majority of edible bovine offal imported for human consumption (Table 4). Edible bovine offal, including tongue and liver, are imported fresh chilled or frozen.

2005-2	2012						
Year	Argentina	Australia	Brazil	Paraguay	USA	Uruguay	Total
2005	55,083	0	63,997	19,479	0	2,981	141,540
2006	26,319	0	195	31,093	0	24,949	82,556
2007	55,126	0	6,259	37,997	0.1	7,641	107,023
2008	25,714	9,717	2,685	44,823	67	44,890	127,896
2009	41,788	1,774	5,026	64,435	251	4,579	117,853
2010	17,555	3,897	19,288	80,418	3,166	10,987	135,311
2011	21,276	13,304	33,746	44,403	3,166	9,622	125,517
2012	25,325	14,687	58,399	0	7,145	14,450	120,006
Total	268,186	43,379	189,595	322,648	13,795	120,099	957,702

Table 3 Beef imports in tonnes for human consumption by country of origin for the period2005-2012

Source: Agriculture and Livestock Service.

Year	Argentina	Australia	Brazil	Paraguay	USA	Uruguay	Total
2005	23	0	0	12	0	0	35
2006	69	114	0	0	0	0	183
2007	22	95	0	0	0	0	117
2008	0	183	0	0	0	991	1,174
2009	45	415	0	24	0	197	681
2010	0	574	0	0	270	312	1,156
2011	0	510	0	68	270	0	848
2012	0	202	0	0	1,245	0	1,447
Total	159	2,093	0	104	1,785	1,500	5,641

Table 4 Imports of edible bovine offal in tonnes for human consumption by country of origin for the period 2005-2010

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

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

No imports of MBM have been received in the past ten years from countries other than Brazil, Argentina and Uruguay, all of which are categorised as having negligible BSE risk by the OIE. All imports are well regulated and exporting facilities are subject to a pre-export certification process from SAG and are subject to yearly inspections and audits to ensure continued compliance. Exported bovine material must be certified by the competent authority in the respective countries confirming that the manufacturing process complies with the requirements of Chilean regulations.

No cattle have been imported into Chile since 2003 and ten water buffalo were imported from Australia in 2006 for breeding purposes. While no specific ban restricts the importation of cattle, in practice no imports of live animals occur and the introduction of new genetic material occurs solely through the importation of semen and embryos.

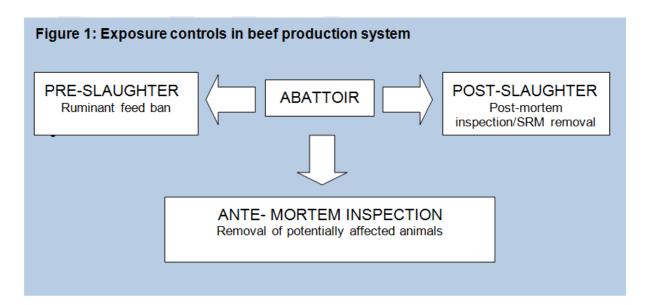
The majority of beef and edible bovine offal imports have originated from other South American countries that have BSE negligible risk status. Imports have also originated from Australia and the USA. All countries wishing to export beef and beef products to Chile are subject to a risk assessment in accordance with the standards stated in the OIE Terrestrial Animal Health Code.

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. Depending on the BSE status of a country (such as whether a case of BSE has occurred and/or risk factors for BSE exist), prevention is achieved through regulations in three key areas across the beef production system:

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

Scientific evidence (Heim and Mumford 2005; Mumford and Kihm 2006; Hörnlimann et al. 2006; Ducrot et al. 2008) published since the BSE epidemic in the UK has established that feed ban regulations and procedures to prevent cross-contamination of ingredients used for cattle feed are critical control measures for preventing the recycling and amplification of BSE. Measures to prevent non-ambulatory (downer) cattle from entering the animal feed and human food chain should also be adopted. For countries where BSE has occurred or risk factors exist, controls should also extend to exclusion of potentially infectious tissue (SRM) from animal feed including pet food and human food products. Controls throughout the beef production chain to prevent exposure to BSE are summarised in Figure 1.



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

5 Pre-slaughter controls: ruminant feed ban

5.1 Overview

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

5.2 Legislation

5.2.1 Ruminant feed ban

The feeding of ruminant protein to ruminants was banned in Chile in 2000 through *Resolution No. 3124/2000*. This ban was subsequently modified by *Resolution No. 614/2004* which prohibited the feeding of mammalian protein to ruminants.

5.2.2 Use of ruminant material for non-ruminant animal feed

No specific legislation restricts the feeding of ruminant material to non-ruminant animals.

5.2.3 Labelling of animal feed

The composition, labelling, marketing and trade of animal feed, including ingredients, supplements and finished products, are controlled by *Ministry of Agriculture (MINAGRI) Decree 307/1979* and its modifications provided in *MINAGRI Decree 79/2005*. Accordingly, animal feed, supplements or additives containing mammalian proteins must have stamped on the most visible side of the container the following: USE TO FEED RUMINANTS IS FORBIDDEN.

5.2.4 Controls on animal feed manufacturers

Animal feed manufacture in Chile is controlled to prevent contamination of ruminant feed with mammalian protein and systems are in place to manage production lines and to detect, trace and recall contaminated product. The requirements for the operation of a feed mill or feed ingredient manufacturer, including storage of raw and finished feed and disposal of waste to avoid feed contamination, are set out in *Resolution No. 5580/2005*. Specific requirements for the handling of ingredients of animal origin, including the separation of production lines for ruminant and non-ruminant animal feed and feed testing, are set out in *Resolution No. 2487/2009*. The scope and requirements of a feed mill or ingredient manufacturer's quality assurance program is set out in *Resolution No. 5025/*2009, including the requirement to have in place a traceability and recall protocol.

5.2.5 Import controls

Finished feed containing mammalian protein and feed ingredients of animal origin imported to manufacture finished product in Chile are subject to certification and import controls. *Resolution No. 3138/1999* establishes the authorisation requirements for manufacturers who export animal products to Chile. *Resolution No. 53/1999* establishes the health requirements for importing pet food and states that animals used for the manufacture of pet food must come from countries free from BSE and scrapie. *Resolution No. 1113/2002* amends *Resolution No. 53/1999* and defines the time, temperature and pressure requirements for the processing of MBM in imported pet food.

The manufacture of MBM in an exporting country must comply with Chilean regulations and have equivalent processing parameters. *Resolution No. 699/2001* defines the time,

temperature and pressure requirements for the processing of MBM.

5.3 **Production and use of bovine materials in animal feedstuffs**

Updated information about the feed production sector was obtained during the in-country verification visit. There are 45 factories in Chile producing feed and/or supplements for ruminants, of which 20 produce ruminant feed only. A further two feed manufacturers that currently use MBM to manufacture pet food also manufacture ruminant feed and other animal feed. In both of these facilities, raw materials, ingredients, finished product and production lines are housed separately to minimise the risk of cross contamination.

Ninety six factories produce medicated feed and/or supplements for pigs, poultry and fish, 30 factories produce non-medicated feed and/or supplements for pigs, poultry and fish and 21 factories manufacture pet food. During the in-country verification visit, it was explained that in practice, bovine materials are only used in the manufacture of pet food. Poultry, pig and horse feed do not contain MBM, therefore the risk of cross-contamination of ruminant feed at the farm level where more than one livestock species is produced is negligible.

5.4 Analysis of feed samples

An explanation of the feed testing program, including the sampling framework and laboratory analysis, was provided during the in-country verification visit. All feed mills producing ruminant feed are required to be audited at least once per year for compliance with regulations and this also informs the sampling framework. The number of samples collected and the frequency of sample collection are based on risk analysis and larger facilities may be sampled several times per year. Samples are collected by SAG officials and submitted to the official SAG Veterinary Diagnostic Laboratory Service (VDLS) for analysis by microscopy.

The Chemical Residue Laboratory within the VDLS is the only diagnostic facility that performs testing for the presence of mammalian proteins in animal feed. The Chemical Residue Laboratory has been ISO17025/2005 accredited since 2004 and participates in inter-laboratory proficiency testing every two years (coordinated by the Argentinean feed testing laboratory). Animal protein is detected by microscopic examination in accordance with the European Commission Regulation (EC) No 152/2009 (EU 2009a). The laboratory is subjected to internal audits one to two times per year, external audits annually by a Chilean auditing company and ISO17025 accreditation is assigned by the National Standards Institute every four years.

5.5 Evaluation of the ruminant feed ban

Feed mill operations are externally monitored through an official SAG audit program. Manufacturers of non-medicated animal feed, including feed for ruminants, are audited once per year and manufacturers of medicated animal feed are monitored every six months. Pet food manufacturers are audited annually. It was confirmed during the in-country verification visit that feed manufacturers producing both pet food and ruminant feed are audited several times per year for compliance with regulations. Audits cover all aspects of feed manufacture along the supply chain; including site and equipment inspection, receival and handling of raw ingredients, approved suppliers of raw materials, production line operations and structural separation of production lines if pet food and ruminant feed are both produced; and storage facilities, transport, sanitation, hygiene, staff training and product labelling.

In 2005 and 2006, dairy farms were targeted for inspection to ensure compliance with the ruminant feed ban. In this period, 303 dairy farms were inspected and all were found to be compliant. The continued compliance with the ruminant feed ban is monitored through the

PABCO² certification program whereby feed purchased off farm is subject to verification by an accredited veterinarian and audit by an official SAG veterinarian.

The number of feed samples tested for the presence of mammalian protein from 2005-2012 are listed in Table 5. Two were detected in the reporting period and on both occasions appropriate corrective actions were taken to remove contaminated feed from the supply chain and prevent exposure of cattle to the contaminated batches. In 2012, the contaminated sample was tested by PCR to identify the species of animal protein detected. No ruminant protein was identified but trace amounts of poultry and pig DNA was detected.

Veer	Numberteeted	Number of infringements
Year	Number tested	(Positive for presence of animal protein)
2005	221	1
2006	171	0
2007	130	0
2008	124	0
2009	112	0
2010	93	0
2011	236	0
2012	236	1
Total	1323	2

Table 5 Results of feed testing

6 Ante-mortem slaughter controls

6.1 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 risk of infection with the BSE agent. Such animals should be targeted and prevented from entering the ruminant feed and human food chains.

6.2 Legislation

The Ministry of Health (MoH) has the responsibility for approving slaughterhouse facilities and has regulatory control over its operation. Slaughterhouses must comply with the *Food Sanitary Regulation* of the MoH (Supreme Decree No. 977/1996 with subsequent amendments) that sets out the hygiene and other food safety requirements for the supply of food for human consumption. *Technical Standard* 62/2002 of the MoH sets out the requirements for the veterinary inspection of animals for food and establishes the criteria for classifying animal products as fit-for-human-consumption. Through an agreement between the MoH and SAG, the sanitary inspection of animals and their meat is delegated to SAG.

Decree No. 94/2008 of the Ministry of Agriculture establishes the definition of a slaughterhouse, cold store and meat cutting plant, and the structure, operation and minimum equipment required to carry out its functioning.

6.3 Ante-mortem procedures

Official documentation, individual animal identification and age information are inspected and recorded upon arrival at the slaughterhouse. It is illegal for slaughterhouses to receive

² Planteles Animales Bajos Certificación Oficial (Certification of Herds under Official Control) refers to a voluntary quality control program for on-farm management. Refer to glossary for more detail.

animals without an FMA (animal movement) form (see section 15.3). At export certified facilities, if full traceability cannot be established (individual animal level traceability is a minimum requirement for the European market) then animals are processed for the domestic market. In the situations where full traceability cannot be established and cattle are diverted to the domestic beef supply, the mandatory use of FMA forms allow for traceability to the farm or herd level. Cattle are examined by the official veterinarian according to *Technical Standard 62/2002* for evidence of disease, including the skin, gait, behaviour, temperature, and breathing. Cattle must be rested for a minimum of six hours and must be processed in a timely manner to minimise stress; a longer rest period may be required if recommended by the official veterinarian. Results of ante-mortem inspection are recorded and any special precautions for slaughter or recommendations for post-mortem inspection are reported according to *Technical Standard 62/2002*.

6.4 Slaughtering methods

Export certified establishments use a penetrating captive bolt to stun cattle prior to slaughter. We were informed during the in-country verification visit that this was a newly introduced stunning procedure and that previously a non-penetrating captive bolt was used. The change was implemented to improve animal welfare and comply with EU regulations (Council regulation (EC) No 1099/2009) that came into effect on 1 January 2013 (EU 2009b).

6.5 Handling of BSE suspect cases

The procedures for handling BSE suspect cases are set out in *Technical Instructive BIOSEM/IT1: Procedure on how to slaughter and destroy bovines upon detection of bovine spongiform encephalopathy (BSE).* Suspect animals are isolated in specified pens and slaughtered after all other healthy cattle have been processed. Samples of brain stem tissue are collected and submitted to the VDLS for BSE testing. Risk material from suspect animals, which includes the head (except for tongue and masseter muscles), spinal cord, vertebral column and intestines (duodenum to rectum), are destroyed through incineration. Carcasses from BSE suspect animals are stored separately to prevent contamination of product intended for human consumption; the carcass can be released for human or animal consumption after a negative result is reported from the VDLS. During the in-country verification visit, we were informed that in practice, however, carcasses that fail ante-mortem inspection are generally rendered into MBM or chemically treated, transported in sealed containers and processed off-site. Animals that fail ante-mortem do not enter the human food supply chain.

In the event of a positive BSE test result, the carcass and all risk material must be destroyed by incineration and burial. Following processing of BSE suspect animals, work surfaces and equipment are decontaminated according to *BIOSEM/IT1*.

6.6 Compliance with regulations

In order to operate, slaughter house establishments must be registered and approved by SAG and meet a minimum set of requirements. Official SAG veterinarian's onsite have overall responsibility for ante-mortem and post-mortem inspection and certification of meat being fit-for-human-consumption. This official oversight is complemented by a quality assurance unit within the establishment to ensure compliance with regulations. During the incountry verification visit, we were informed that internal audits of systems occur every three months and SAG conduct a full audit annually. SAG also conducts inspections of operations every three months. The identification of a non-conformity by SAG does not alter the audit frequency but will result in follow-up inspections to ensure that corrective actions have been taken and are effective. The export facilities inspected during the in-country verification visit are certified for ISO 9001: Quality Management Systems by a private Chilean company.

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

7.1 Overview

Post-slaughtering controls are required to ensure that products from diseased animals and tissues potentially containing BSE infective material do not enter the animal feed or human food supply chains.

7.2 Legislation

7.2.1 Post-mortem inspection

Like ante-mortem slaughter controls (section 6.2), slaughterhouses must comply with the *Food Sanitary Regulation* and the post-mortem inspection requirements specified in *Technical Standard 62/2002*. Carcasses must be certified as fit for human consumption and suitable for rendering by an official SAG veterinary inspector.

7.2.2 Definition of specified risk material

Resolution No. 5992/2010 states that ruminant animals are free of SRM if they originate from countries designated by the OIE as a BSE negligible risk. By this definition, no SRM is present in the national bovine population of Chile or in the MBM imported from Brazil, Argentina and Uruguay. As such there are no restrictions on ruminant material that can be fed to non-ruminant animals and this will remain the case while Chile maintains 'negligible' risk status. This 2010 resolution replaced *Resolution No. 5338/2005* which defined SRM as brain, cerebellum, eyes, tonsils, spinal cord, spleen and distal ileum of animals aged over 30 months, as well as the distal ileum of bovine and ovine animals regardless of their age. Under the 2005 resolution, SRM was required to be incinerated or disposed of in an authorised sanitary landfill and was prohibited from being fed to any animal.

7.2.3 Rendering requirements

Resolution No. 5037/2005 establishes health measures to prevent BSE by defining the time, temperature and pressure requirements for the manufacture of MBM and defining the type of animals and animal products that can be used in the manufacture of MBM.

7.3 Post-mortem procedures

Post-mortem procedures are supervised and monitored by the official SAG veterinary inspector. Procedures monitored include:

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

An official SAG veterinarian has the responsibility of collecting brain stem tissue in a necropsy room if ante-mortem inspection indicates possible neurological disease consistent with a BSE case.

7.4 Rendering processes

One rendering plant was inspected during the in-country verification visit and this was linked to one of the slaughter houses visited. Raw materials are only received from the attached slaughter house and no dead animals can be received off-site or from farms. Raw material is ground to a maximum particle size of 50mm and cooked in a vapour saturated environment at a temperature exceeding 133°C for a minimum period of 20 minutes and an absolute pressure of three bars. The cookers are monitored electronically to ensure compliance with requirements. However, during the inspection we were informed that the measuring devices for pressure and temperature are calibrated on installation and not monitored on an on-going basis. It is recommended that SAG adopt a program of auditing the calibration of temperature and pressure measuring devices used in rendering facilities throughout Chile.

After cooking, the rendered material is centrifuged and ground into MBM flour and bagged in 50kg bags. No bulk product is trucked from the facility that was inspected during the incountry verification visit. All bags were appropriately and clearly marked on the bag itself and also on a paper tag stitched into the top of the bag that included the batch number and manufacture date.

7.5 Compliance with regulations

The audit program for compliance with regulations pertaining to post-mortem inspections and SRM removal are the same as for ante-mortem inspection (section 6.6). For rendering facilities, official SAG audits are conducted twice per year. Audits cover all aspects of rendering along the supply chain; including site and equipment inspection, receival and handling of raw ingredients, supplier list of raw materials, production line operations, storage facilities, product labelling, client list and dispatch records.

8 Summary: exposure control

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

- A ruminant feed ban that has been in place since December 2000. The ban was strengthened in 2004 to prohibit the feeding of mammalian protein to ruminants.
- Separation of ruminant feed lines to minimise the risk of cross contamination in feed production factories.
- Monitoring of feed ban on farms operating under the PABCO certification program.
- Effective and comprehensive SAG oversight of ruminant feed manufacturers to ensure compliance with the ruminant feed ban. This is achieved through a systematic audit and feed testing program.

Regulated processes both at ante- and post-mortem inspections ensure that BSE suspect animals are not processed for the animal feed or human food supply and SAG has comprehensive oversight of establishments that manufacture MBM to ensure compliance with regulations and processing requirements. The introduction of the BSE agent and subsequent amplification and recycling within the bovine feed system or introduction to the human food supply in Chile is, therefore, unlikely.

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 Chile.

9 Beef production systems

9.1 Legislation

The Ministry of Health has the responsibility for approving slaughterhouse facilities and has regulatory control over its operation. Section 6.2 outlines the specific legislation that pertains to beef production systems. *Technical Standard 62/2002* sets out the (1) general operational and hygiene practices; (2) general inspection procedures; (3) criteria for classifying meat as fit for human consumption; and (4) stamping of animals as fit for human consumption. No cattle in Chile are classified as having SRM, as described in Section 7.2.

9.2 Hygiene practices for the minimisation of cross-contamination

Procedural Manual: Inspection in Slaughterhouse establishments (P-PP-IT-005) sets out the responsibilities of the official SAG veterinarian and technical officers and describes the activities, records and reporting required of slaughterhouse establishments. The procedural manual sets out that brain, cerebellum, eyes, tonsils, and spinal medulla of ruminants older than 30 months of age and the distal ileum of ruminants of all ages are separated from the production line. By definition, no SRMs are present in the Chilean bovine population; however SRMs previously defined and set out in the procedural manual are removed for commercial purposes. The tongue and masseter muscles are removed from the head for human consumption and the remainder of the head is separated from the production line. These carcass parts are routinely removed on the slaughter line and are either rendered to make MBM or are chemically treated and sent to a non-human food facility for further processing.

If suspect cases are identified during ante mortem inspection they are isolated from other cattle and slaughtered after all healthy animals. Stunning methods that inject compressed gas or air into the skull, or that sever the medulla are prohibited. Samples of brain tissue are collected after removal of the head and sent to the veterinary diagnostic laboratory for BSE testing. Carcass and by-products are identified and kept until laboratory results are obtained. Work surfaces are decontaminated with sodium hypochlorite or with sodium hydroxide according to *Technical Instructive BIOSEM/IT1: Procedure on how to slaughter and destroy bovines upon detection of bovine spongiform encephalopathy (BSE).*

10 Traceability systems for beef and beef products

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

10.1 Legislation

Traceability of beef through the entire supply chain is a shared responsibly of SAG and the MoH. SAG has regulatory oversight of traceability of cattle from farm to slaughterhouse and *Technical Standard 62/2002* of the MoH stipulates the requirement for identification of carcasses and beef products through the abattoir.

Beef export facilities must comply with specifications detailed in SAG *Resolution No. 1045/2013* and have in place an auditable traceability system as a pre-requisite for certification of the facilities Quality Assurance System. *Resolution No. 1045/2013* abolished *Resolution No. 4577/2012* which in turn abolished *Resolutions No. 3360/1999* and *No. 3685/1999*. The requirement to have a traceability system in place was specified in the current and abolished resolutions.

For the domestic beef market, traceability systems are required under the *Food Sanitary Regulation* of the MoH, Supreme *Decree No. 977/1996*, which was modified by *Decree No. 45/2006*. The modifications introduced by *Decree No. 45/2006* sets out that establishments that produce, prepare, preserve and package food must comply with Good Manufacturing Practices (GMP) in a systematic and auditable manner and must implement a HACCP plan along its entire production line, according to the *Official Chilean Standard NCh 2861/2011* of the National Standards Institute. A prerequisite requirement of HACCP certification is to have an auditable traceability system for raw materials and finished product. The prerequisite program, including traceability, must be audited independent of the HACCP plan. According to *Resolution No. 658/2006*, establishments producing meat and meat products are grouped in the category of foods considered the highest priority for implementation of a certified HACCP plan.

10.2 Details of the traceability systems

All fresh beef and beef products are traceable from retail to source animal or herd by means of a package label. Traceability to an individual animal is possible for animals with an official ear tag (described in section 15, below). For cattle without an official ear tag, traceability to herd and farm is possible. The label contains information such as product type and product code, box weight, number of boxes in a batch, batch number, and slaughter, production and expiry dates. The batch numbers of boxed product and the slaughter and production dates are recorded together with the animal identification numbers collected upon entry to the abattoir allowing full traceability through the supply chain.

For the domestic beef market, food businesses are required to have in place auditable systems that maintain procedures and records to allow the origin of food, raw materials or ingredients to be identified, adequate labelling and the businesses that have received product can be identified.

For export certified facilities, auditable systems, procedures and records must be implemented so that they can ensure the following:

- Allow the origin of the raw material to be identified.
- Confirm processed products received from other establishments comply with the demands of the destination country or market.
- Confirm the final product and its ingredients are adequately labelled to facilitate full traceability by means of documentation or other relevant information.
- Identify the final product.
- Identify the establishments that have received product.

- Can recuperate products when required.
- Place the information pertinent to traceability at the disposition of the competent authorities.

Export certified facilities are required to re-evaluate their traceability system at least once a year or if the product has been associated with a foodborne illness, information indicates a risk for human health, the product has been withdrawn due to safety problems or changes have been made to national legislation or the legislation of the destination country.

11 Recall systems

Traceability and recall systems are inextricably linked and as is the case for traceability of beef and beef products through the entire supply chain, product recall is a shared responsibly of SAG and the MoH.

11.1 Legislation

Beef export facilities must comply with specifications detailed in SAG *Resolution No. 1045/2013* and have in place an auditable recall protocol as a component of the traceability system.

For the domestic beef market, recall protocols are required to comply with the *Food Sanitary Regulation.* Food businesses must implement a HACCP plan along its entire production chain and a prerequisite requirement of HACCP certification, as defined by the Official Chilean Standard NCh 2861/2011 of the National Standards Institute, is to have an auditable recall protocol. The prerequisite program, including product recall, must be audited independent of the HACCP plan. Prior to the 2011 Standard, NCh 2861/2004 did not make specific reference to recall. However, an auditable recall protocol was considered together with traceability in the MoH guidance document on prerequisite programs, *Prerequisite Program: Fundamental Basis for Food Safety (Programa de Pre-requisitos: Base Fundamental para la Inocuidad Alimentaria 2004).*

11.2 Food recall process

Food industries are required under the prerequisite program to have a traceability and recall program administered by a quality assurance department. Records must be archived in case of the need to recall product which includes records of product dispatch, distribution centres, warehousing and retailers to identify the geographical range and volume of product distribution. Businesses are required to implement the recall protocol; however we were informed during the in-country assessment that the MoH manage large product recall operations when public health is threatened and coordinate activities with the SAG and other agencies where required. Food industries are required to undertake recall exercises yearly to test the integrity of the recall protocol and methodology.

In the case of exported product, the respective competent authorities in Chile and the receiving country are informed of the recalled product and details of product labels and volumes are provided.

12 Summary: BSE food safety controls

Food safety controls are a shared responsibility of the Ministry of Health and SAG and current practices have been in place since 2004. Compliance with regulations ensures good hygienic practices are employed throughout the beef production and supply chain and

auditable traceability and recall systems enable the recovery of potentially contaminated food products. Food industries, including slaughterhouses, are required to test the effectiveness and efficiency of food recalls through annual mock recalls and the recovery of contaminated beef and beef products could be achieved in a timely and effective manner in the event of an animal disease emergency such as BSE.

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

13 BSE Education and Awareness

The BSE education and awareness program was launched in Chile in 1996, the same year that BSE was officially declared a notifiable disease. The program has and continues to focus on the ability of key stakeholders in cattle production to recognise the clinical signs of disease, the processes for reporting suspected cases and the collection and submission of samples.

The education and awareness materials for recognising disease signs and reporting suspect cases are targeted at farmers, stockbreeders and other cattle handlers. A leaflet providing details of the disease, its history, clinical signs and how to report a suspect case is available and distributed amongst stakeholders. In addition farmers, stockbreeders, agricultural technicians and agricultural students have received training in disease recognition and reporting through various media including video. Farms under official control (PABCO) are provided information on disease recognition and reporting suspect cases to official or accredited veterinarians.

Official SAG veterinarians based in regional offices and private veterinarians who are accredited by SAG conduct investigations in the field for a variety of diseases including BSE, and are required to have training in BSE clinical signs, sample collection and sample submission. For private veterinarians, SAG has produced a technical manual entitled, *Procedural Manual: Observation, Sample Collection and Reporting of Bovines Eligible for BSE Surveillance by Accredited Veterinarians.* Official SAG veterinarians are required to follow official SAG policy regarding disease investigation, sample collection and actions taken should a BSE case be confirmed; as such they are trained in the procedures for the identification and handling of BSE suspect cases. Official SAG veterinarians and staff working at abattoirs are also required to receive training in recognition of BSE clinical signs and SAG veterinarians at slaughterhouses have the responsibility of collecting samples for submission to the laboratory. The procedures followed are outlined in Section 14.3 below.

To test the effectiveness of the BSE education and awareness program, SAG has conducted several mock health emergency exercises since 1996.

A quality control and education feedback loop is in place at the official veterinary diagnostic laboratory, whereby the sample quality and formalin concentration of submitted samples are tested and if problems are encountered then the veterinarian submitting the sample is informed and advised to take corrective actions.

14 Disease notification and diagnoses

14.1 Overview

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

14.2 Legislation

BSE notification in Chile is based on three complementary pieces of legislation: *Statutory Decree RRA 16*, referred to as the *Animal Health Law*, sets out the mandatory requirement for all animal owners or keepers to report animals affected, or suspected of being affected by a notifiable contagious disease; *Law No. 18,755*, modified by *Law No. 19,283*, establishes the authority of SAG to enforce the *Animal Health Law*; and *Decree No. 249/1996* establishes BSE as a notifiable disease.

14.3 Identification and handling BSE suspects

As defined in Technical Instructive BIOSEM/MP1: *Procedures manual for BSE contingency*, clinically suspect BSE cases typically show neurological signs of disease manifested as insidious and progressive changes in behaviour, sensitivity and locomotion. Such changes are generally observed by the animal owner or keeper and reported to an official SAG veterinarian or a veterinarian accredited by SAG. The measures taken if such a case is identified are outlined in Box 1.

t a fa	arm:
•	Owner is required to inform a SAG veterinarian (or SAG accredited veterinarian). Veterinarian visits farm and carries out clinical examination and epidemiological assessment.
•	Suspect animal is restrained, sedated and euthanized according to Technical Instructive BIOSEM/IT1: Procedure on how to slaughter and destroy bovines upon detection of bovine spongiform encephalopathy (BSE).
•	Sample collected according to Technical Instructive BIOSEM/IT2: Collecting and forwarding samples for BSE
•	The carcass and all parts are destroyed by incineration according to Technical Instructive BIOSEM/IT1: <i>Procedure on how to slaughter and destroy bovines upon detection of bovine spongiform encephalopathy (BSE)</i> and Technical Instructive BIOSEM/MP1: <i>Procedures manual for BSE contingency.</i>
•	Quarantine and animal movement restrictions are applied to herd and establishment according to Technical Instructive BIOSEM/MP1: <i>Procedures manual for BSE contingency</i> .
٠	Animal movement restrictions are lifted if negative result received from laboratory
Atas	laughterhouse:
•	Suspect cases identified during ante-mortem inspection are isolated from other cattle and slaughtered after all healthy animals.
•	Samples of brain tissue are collected after removal of the head and sent to the veterinary diagnostic laboratory for BSE testing.
•	Carcass and by-products are identified and kept until laboratory results are obtained. Work surfaces are decontaminated with sodium hypochlorite or with sodium hydroxide.

Follow-up on confirmation of BSE case

- Quarantine and movement restrictions imposed on establishment.
 - Investigation conducted by SAG veterinarians on farm to identify:
 - Animals imported from the same source as the confirmed case
 - o Progeny born within the 2 years before or after the onset of clinical signs
 - Birth and feeding cohort animals and their location
 - Mother of a confirmed case
 - All other ruminants on premises
 - Possible disease origin
 - Feed and other materials that may be possible sources of contamination
- Progeny and cohort animals are euthanized and destroyed.

Since 2010, all clinically suspect BSE cases have been reported from farms, indicating that identification is occurring early in the supply chain and provides assurance that the BSE awareness program and disease notification are working effectively.

14.4 Diagnostic tests

The VDLS is the only diagnostic facility that performs testing for BSE and other TSEs and performs both immunohistochemistry and immunological rapid tests for the detection of BSE in cattle. Chapter 2.4.6 of the OIE *Manual of Standards for Diagnostic Tests and Vaccines for Terrestrial Animals* provides details of acceptable methods for detecting BSE in bovine animals. Sample collection and diagnostic procedures used in Chile are compliant with these OIE standards.

Two samples are collected from animals selected for BSE testing, one is fixed in formalin for histopathology and immunohistochemistry and the other is kept fresh for testing by a commercial rapid test. All clinically suspect samples are tested by both rapid test and immunohistochemistry. For other animal types prescribed under the BSE surveillance program (emergency slaughter, fallen animals and routine slaughter), samples are first screened by rapid test.

For immunohistochemistry, positive control slides, including strong and weak markers, are prepared each month. Control samples for both BSE and scrapie are received from Canada and the USA, which include brain stem and lymph node tissue samples. When field samples are received into the pathology laboratory, formalin concentration is tested and the quality of the sample is assessed. If formalin concentration or sample quality is not to required specifications the veterinarian who collected and prepared the sample is informed in order to improve the surveillance system.

Both rapid tests used in Chile, *Prionics-Check PrioSTRIP* and *IDEXX HerdChek BSE-Scrapie antigen* ELISA, have been approved by the European Commission for monitoring BSE in bovine animals (EU 2010). Under Chile's TSE surveillance program, the *PrioSTRIP* test has been used almost exclusively for BSE surveillance for the past two years and the *IDEXX antigen* ELISA has been used primarily for scrapie surveillance during the same time period. The *PrioSTRIP* rapid test has been used routinely since 2010 replacing a commercial western blot test (*Prionics-Check WESTERN*). The *IDEXX HerdChek BSE-Scrapie antigen* ELISA has been used routinely since 2005. Diagnostic capacity has been suitable for the entire surveillance period outlined in section 17 below. The timeline of diagnostic capacity is outlined in Appendix 4.

14.5 Laboratory assurances and auditing

The immunohistochemistry laboratory participates in regional proficiency testing, coordinated by the OIE regional reference laboratory in Argentina, and obtained a satisfactory rating from the regional reference laboratory most recently in December 2012. No inter-laboratory proficiency testing program is in place for the rapid tests. However, the manufacturer's instructions are followed and tests are repeated if manufacturer supplied control samples do not perform as intended.

Internal audits are conducted one to two times per year according to the procedure for conducting internal audits. The VDLS has obtained ISO17025 certification from the National Standards Institute of Chile for laboratory procedures for the detection of animal protein in livestock feed and for classical swine fever, avian influenza and foot and mouth disease viruses. The laboratory procedures for the detection of the BSE agent has not been ISO17025 certified, however good laboratory practices are implemented.

14.6 Penalties and reporting incentives

Failure of individuals and companies to notify authorities of a suspected BSE case can result in penalties as prescribed in the *Animal Health Law, No 18,755*. Financial incentives are not provided to livestock owners or companies who report suspect animals.

15 Cattle identification and traceability

15.1 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 effective and timely identification, tracing and removal of beef and beef products (suspected to be BSE-infected) from markets and the distribution chain.

15.2 Legislation

Resolution No. 3423/2008 establishes the Official Animal Traceability Program with amendments made by *Resolution No. 5895/*2012 and *No. 621/2013*. The Official Animal Traceability Program consists of:

- i. Register of Livestock Establishments (RUP)
- ii. Annual Livestock Statement
- iii. Official Animal Identification (Official Individual Identification Device (DIIO))
- iv. Animal Movements Register (Animal Movement Form (FMA))
- v. Animal Information System (SIPEC).

Resolution No. 3423/2008 and the subsequent amendments made by *Resolution No. 5895/2012* and *No. 621/2013* defines the traceability program and sets out that the registration of livestock establishments and the use of animal movement forms are mandatory and failure to comply with the program is subject to penalties. The resolutions also stipulate that companies supplying DIIO's must supply DIIO's that can be fitted with a

radiofrequency device.

The traceability program was first created in 2004 by *Resolution No. 3321/2004* and modified by *Resolution No. 2862/2006*. This resolution was repealed with the introduction of *Resolution No. 3423/2008*.

15.3 Current identification systems for cattle

The Animal Traceability and Computer-based Systems Unit within the Livestock Protection Division of SAG is responsible for identification and traceability of cattle and buffalo. The regulatory framework as it applies to various stakeholders in the supply chain is described in the table below.

	PABCO A	PABCO B	Animal importing facilities	Facilities engaged in Disease control & eradication programs	Andes pasture (origin & destination facilities)	Facilities bordering on neighbouring countries	Animal Fairs	Slaughterhouses & On- farm abattoirs	Supplier facilities	Milk Suppliers to dairy & cheese farms & milk collection centres
Establishment Registration	✓	~	~	~	✓	~	~	~	~	\checkmark
Annual Stock Statement	\checkmark	~	\checkmark	\checkmark	\checkmark	\checkmark	×	×	~	\checkmark
Issue FMA form	✓	~	~	~	✓	~	~	×	~	\checkmark
Mandatory Use of DIIO	\checkmark	×	\checkmark	\checkmark	\checkmark	\checkmark	×	×	×	×

15.3.1 Register of Livestock Establishments

It is mandatory for all establishments that house live cattle and buffalo for reproduction, breeding, production, marketing and trade, slaughtering, exhibition, sports activities and or rehabilitation on a permanent or temporary basis to be registered with SAG. The SAG issues a unique identifying number to each livestock establishment, referred to as *Rol Único Pecuario* (RUP), that identifies the region, province, municipality and sequential community number. An example of the number format is listed below:

Region		Provinc	e	Community		Sequential No.			
0	0	0	0	0	0	0	0	0	0

15.3.2 Annual Livestock Statement

For every establishment that has an RUP number, an annual statement (*Formulario de declaracion de existencia de animals*) of all the animals held, by species and class, is submitted to SAG. This data is recorded in the *Official Animal Information System*.

15.3.3 Official Animal Identification (Official Individual Identification Device (DIIO))

Animal identification is a process by which animals are officially identified by means of an Official Individual Identification Device (DIIO) which is an authorised ear tag or

radiofrequency device (RFD). These tags and RFDs can only be issued by a SAG accredited business and are fitted to cattle by an official SAG veterinarian or SAG accredited veterinarian. It is mandatory for cattle farms that operate under the official SAG certification program (PABCO, Program for Certification of Herds under Official Control) to register births within six months or before they are moved off the property. In practice, calves are tagged at 2-3 weeks of age. An official SAG or accredited veterinarian affixes the tags and a form (*Formalario de Identificacion Individual Oficial de Bovinos*) is submitted to the regional SAG office and data is entered into the *Animal Information System*. In the event of a death, the SAG regional office is notified and the ear tags are removed and the number cannot be reused.

The distribution of DIIO's by private companies is controlled by the SAG through a form based system (*Formulario de Distribucion y Control de Despositivos de Identificacion Individual*), recording the details of the supplier and receiver, the number of DIIO's distributed and the number range on the tags. The same form is used by suppliers and receivers for notifying SAG of lost, mislaid or damaged DIIO's.

According to official data provided during the in-country verification visit, an estimated 73% of live cattle were fitted with a DIIO up to the reporting period of September 2012.

15.3.4 Animal Movements Register (Animal Movement Form (FMA))

This register keeps track of all movements of individually identified animals or batches of animals (if not individually identified) from one livestock establishment with an RUP to another. Tracking is achieved through the use of an official animal movement form (*Formulario de movimiento animal (FMA)*) that livestock establishments obtain from SAG regional offices. Data requirements on the form include name, date, RUP number, and establishment origin, details of the Transport Company, establishment destination, and species of animal and animal identification number.

The animal movement form is critical to the traceability system and it is illegal for cattle to be moved between establishments without this form and even if animals are not fitted with a DIIO, then the establishment number is recorded with any identifying marks such as brands. Each form has four copies: one copy is retained by the seller, one by the buyer, one copy is sent to the SAG regional office of animal origin and the final copy to the SAG regional office of animal destination. End receivers of cattle and buffalo, such as slaughterhouses, are not required to complete an animal movement form but cannot receive animals unless individual animals or a consignment of animals is accompanied by an animal movement form.

All movements are recorded in the *Official Animal Information System* and at present are predominantly received through paper forms and manually entered by SAG regional office staff. The paper submission system means that delays of 1-2 weeks can be experienced from the time of movement to the time data is entered into the information system. In combination with the individual animal identification, the animal movement forms allow rapid and full traceability to farm of origin and identification of feed and birth cohorts. For animals that are currently not identified with an official ear tag, traceability to herd level and farm of last point of sale is rapid using the unique RUP number; however traceability to farm of origin and identification of farm records.

15.3.5 Animal Information System (SIPEC)

This is the nation-wide information system used by SAG. All data for the animal traceability program are entered and managed by SIPEC. The data, treated as confidential, are obtained from paper forms or the system's electronic features. Farms and businesses can register

with SIPEC to enter data into the system, but at the time of the visit, this phase of the program was in its infancy and much of the program is still paper based.

15.4 Evaluation and inspection

Cattle farms that operate under the official SAG certification program (PABCO) are audited by official or accredited veterinarians two times per year, covering all aspects of the business including registration of births and deaths, feed inputs, use of veterinary products and data management. Other livestock establishments such as slaughterhouses are subject to audit by SAG officials covering all aspects of the business including animal receival.

16 Summary: BSE control programs and technical infrastructure

BSE has been listed as a notifiable disease in Chile since 1996. Official, accredited and private veterinarians, farmers and other cattle handlers have been educated to recognise the clinical signs associated with the disease through ongoing training and awareness programs. A key requirement for certification of farms under official control (PABCO) is the reporting of all sick, injured and dead animals to SAG and having all veterinary and feed inputs audited by SAG. The capacity to accurately diagnose diseased animals is underpinned by a national laboratory that participates in an international proficiency testing program, uses validated diagnostic methods that are approved by the OIE and provides feedback on sample quality to collecting veterinarians.

This assessment considers Chile's cattle traceability system to be satisfactory. A centralised data management system is used to manage data on establishments handling cattle, animal registration, animal identification, animal movements and deaths. Chile is currently moving towards a system of identifying cattle by an individual radiofrequency device; however most cattle are identified by a unique numbered ear tag and movement and animal identification records are primarily submitted on paper forms. For animals with an official individual identification device (ear tag or radiofrequency tag), the animal information system is able to identify all movements and establishments for the life of the animal. This ultimately ensures that effective trace-back can be achieved when required.

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*. The degree and quality of surveillance for BSE within the cattle population of a country, combined with other systems for BSE control, helps to determine the BSE risk status of the country. This chapter provides details of Chile's surveillance activities and historical data.

17 Chile's BSE surveillance program

The current surveillance program commenced in 2005 and was modified in 2007. The categories of animals tested are based on Chapter 11.5 of the OIE's Terrestrial Animal Health Code. Surveillance for BSE is undertaken in the following cattle sub-populations:

- Clinically suspect cattle over 30 months of age
- Emergency slaughter cattle over 30 months of age, including cattle condemned at ante mortem inspection
- Fallen stock over 30 months of age
- Healthy cattle over 36 months of age sampled during routine slaughter.

The *Animal Health Law* sets out the mandatory requirement for all animal owners or keepers to report animals affected, or suspected of being affected by a notifiable contagious disease; and Decree 249/1996 establishes BSE as a notifiable disease (see Appendix 2). The surveillance program is implemented in accordance with the following manuals and technical instructions:

- Procedural manual No 1: Procedure for Investigating Reports of Animal Health Events,
- Technical Instruction No 2: Technical Instruction for Bovine Spongiform Encephalopathy Surveillance,
- Technical Instruction BIOSEM/IT2: Sample Collection and Shipment for Laboratory Diagnosis of Bovine Spongiform Encephalopathy.

Other important features of Chile's BSE surveillance program include:

- Official SAG veterinarians and private veterinarians who are accredited by SAG to collect and submit samples for BSE surveillance receive training in clinical observation, sample collection and reporting in accordance with SAG regulations.
- Dairy cattle exposed to Canadian MBM from 1998 to 2000 prior to the implementation
 of the ruminant feed ban were quarantined on farm from 2005 and were officially
 identified and tagged with specific individual animal identification tags. These animals
 could only be slaughtered in specified slaughterhouses and the carcasses were held
 until laboratory testing results were completed. Of the 313 cattle subjected to these
 quarantine arrangements, no animals tested positive for BSE and no animals
 exposed to Canadian MBM were alive at the time of the FSANZ in-country verification
 visit.

- Animal age is determined by official records and dental chronometry.
- The collection of samples is representative of the cattle populations and the number of cattle slaughtered in each region. The majority of samples are received from Los Lagos (X), Los Rios (XIV), Bio Bio (VIII), Araucania (IX), Santiago Metrapolitan (RM) and O'Higgins (VI), these regions also account for the majority of cattle numbers and economic activity from cattle production. Table A1.1 and Figure A1.2 in Appendix 1 contain the most recent cattle population statistics and economic activity data.

18 Chile's BSE surveillance points data

The BSE surveillance program in Chile complies with the guidelines set out in Chapter 11.5 of the OIE's Terrestrial Animal Health Code. As a BSE negligible risk country, Chile is required to practice 'Type B' surveillance which allows detection of one BSE case in 50,000 adult cattle (at 95% confidence interval). The adult cattle population in Chile is greater than 1,000,000 head and for this population size the OIE recommended target for 'Type B' surveillance is 150,000 points, collected over seven consecutive years.

Chile's surveillance points total for the seven year period from 2006 to 2012 was 536,087 (Table18.1), enough to satisfy the requirements of Type B surveillance. Detailed surveillance points data for the years 2005-2011 are presented in Table 18.2, and show that appropriate attention is paid to testing older cattle which are at greatest risk of subclinical or clinical BSE.

In 2012, the unconfirmed differential diagnosis of the BSE clinical suspect cases were reported as encephalitis (4%), meningitis (8%), hypomagnesemia (8%), listeriosis (8%) and intoxication (17%); in 55% of cases the differential diagnosis could not be determined.

Year	Clinical suspect	Emergency	Fallen stock	Routine slaughter	Total points				
2006	328	5,631	2,210	731	186,779.1				
2007	152	6,499	2,522	442	90,001.3				
2008	202	5,220	1,519	288	112,187.2				
2009	54	1,496	805	6	31,472.7				
2010	68	896	787	0	36,119.4				
2011	99	1,164	1,104	3	57,998.3				
2012	40	230	303	36	21,529.2				
Total	943	21,136	9,250	1,506	536,087.2				

Table 18.1 BSE surveillance data summarised by the number of samples collected for each surveillance sub-population and total points accumulated for the period 2006-2012.

Age	Clinically	Clinically suspect Emergency		cy slaughter Fallen stock		Routine slaughter		
class	Samples	Points	Samples	Points	Samples	Points	Samples	Points
01400	Campies	Tomts	Campies	2005	Campics	Tomts	Campies	Tonits
>1,1/2,1/10	4	0	5	2	5	1	2	0.02
≥1y<2yrs	4 27	0 7020	210		5 113	22.6	158	
≥2y<4yrs				84 4005 0				15.8
≥4y<7yrs	95	71250	666	1065.6	304	273.6	795	159
≥7y<9yrs	56	12320	343	240.1	152	60.8	313	31.3
≥9yrs	18	810	29	3	39	3.9	61	0
Total	200	91400	1253	1394.7	613	361.9	1329	206.12
2006								
≥1y<2yrs	3	0	8	3.2	11	2.2	0	0
≥2y<4yrs	36	9360	520	208	397	79.4	41	4.1
≥4y<7yrs	210	157500	3126	5001.6	1261	1134.9	474	94.8
≥7y<9yrs	49	10780	1381	966.7	353	141.2	150	15
≥9yrs	30	1350	596	119.2	188	18.8	66	0
Total	328	178990	5631	6298.7	2210	1376.5	731	113.9
				2007				
≥1y<2yrs	0	0	25	10	2	0.4	0	0
≥2y<4yrs	24	6500	649	259.6	403	80.6	35	3.5
≥4y<7yrs	90	67500	3635	5817.6	1388	1249.2	130	26
≥7y<9yrs	27	6380	1651	1157.8	478	191.6	161	16.1
≥9yrs	11	675	539	108.8	251	25.1	116	0
Total	152	81055	6499	7353.8	2522	1546.9	442	45.6
Total	102	01000	0100	2008	2022	1010.0	112	10.0
≥1y<2yrs	5	0	18	7.2	2	0.4	0	0
≥1y<2yrs ≥2y<4yrs	29	7540	440	176	231	46.2	21	2.1
≥4y<7yrs	118	88500	2556	4089.6	906	40. <u>2</u> 815.4	144	29
≥4y<7yrs ≥7y<9yrs	42	9240	1069	4089.0 1126.3	297	118.8	85	29 8.5
	8	9240 360	597	1120.3	83	8.3	38	0
≥9yrs Totol	202	105640	5220		1519		288	
Total	202	105640	5220	5518.5 2009	1519	989.1	200	39.6
21,420,000	4	0	2			0		0
≥1y<2yrs	1	0		0.8	0	0	0	0
≥2y<4yrs	9	2340	131	52.4	134	26.8	2	0
≥4y<7yrs	34	24750	779	1246.4	465	418.5	3	0
≥7y<9yrs	10	2200	503	352.1	163	65.2	1	0
≥9yrs	0	0	81	16.2	43	4.3	0	0
Total	54	29290	1496	1667.9	805	514.8	6	0
	1.	_	1.	2010	T -		1 -	-
≥1y<2yrs	1	0	1	0.4	1	0.2	0	0
≥2y<4yrs	15	3900	55	22	111	22.2	0	0
≥4y<7yrs	37	27750	468	748.8	476	428.4	0	0
≥7y<9yrs	13	2860	306	214.2	167	66.8	0	0
≥9yrs	2	90	66	13.2	32	3.2	0	0
Total	68	34600	896	998.6	787	520.8	0	0
2011								
≥1y<2yrs	0	0	1	0.4	1	0.2	0	0
≥2y<4yrs	14	3640	128	51.2	160	32	0	0
≥4y<7yrs	64	51750	558	892.8	580	522	2	0
≥7y<9yrs	20	5060	416	291.2	250	100	1	0
≥9yrs	1	45	61	12.2	113	11.3	0	0
Total	99	56085	1164	1247.8	1104	665.5	3	0
		00000		0	1.101	000.0		5

Table 18.2 BSE surveillance data for the period 2005-2011 summarised by the number ofsamples and points accumulated for each surveillance sub-population stratified by age class.

19 Summary: BSE surveillance

Chile has an ongoing BSE surveillance program and is required to carry out 'Type B' surveillance in compliance with the guidelines set out in Chapter 11.5 of the OIE Terrestrial Animal Health Code. Current surveillance practices have been in place since 2005. Chile's surveillance program achieved 536,087 points for the 7 year period from 2006-2012, which exceeded the target of 150,000 points specified by the OIE for a country, zone or region with an adult cattle population greater than 1,000,000 head. The points total also exceeded the target of 300,000 points required for 'Type A' surveillance.

Conclusions and BSE risk categorisation

Overall, Chile has demonstrated that there are well-established and effective systems in place across the beef production sector to prevent the introduction and amplification of BSE within the cattle population and to prevent contamination of the human food supply with the BSE agent.

Control measures to prevent the introduction, recycling and amplification of the BSE agent in Chile are well established. This is largely a consequence of Chile having negligible external exposure to the BSE agent through imported bovine material and strict internal controls to prevent potential amplification in the Chilean cattle population. Chile only imports MBM from South American countries with BSE 'negligible' risk status. Strict processing requirements that are sufficient to inactivate the BSE agent should it be present in rendered material must be met both domestically and in exporting countries. Chile does not currently import live cattle or buffalo and only ten water buffalo from Australia have been imported into Chile in the past ten years. The majority of beef and beef products imported for human consumption are currently sourced from South American countries with BSE 'negligible' risk status, followed by Australia and the United States of America (USA).

A ruminant feed ban prohibiting the feeding of ruminant protein to ruminants was legislated in Chile in December 2000 and this prohibition was extended to ban the feeding of mammalian protein to ruminants in 2004. Audit, inspection and sampling procedures are in place to ensure that contamination of ruminant feedstuffs with prohibited mammalian proteins is prevented during production, storage and transport.

Official veterinary oversight of slaughter processes, defined instructions and quality assurance systems for both ante- and post-mortem activities ensure that BSE suspect animals are not processed for animal feed or human consumption. Since Chile is currently recognised as a BSE 'negligible' risk country, no SRM is currently defined. In practice, brain, cerebellum, eyes, tonsils, and spinal medulla and the distal ileum of cattle are separated from the production line. Effective enforcement of these measures was evident from inspections conducted as part of the in-country verification visit.

Systems for animal identification and traceability and recall of beef products are wellestablished in Chile. Procedures to register livestock establishments, register cattle births and deaths, individually identify animals and monitor movements are effective and support the management of BSE controls in Chile. The animal information system enables the competent authority to reliably and quickly trace animals to farm-of-origin if required. Beef and beef products intended for human consumption are traceable through the food supply chain and food businesses are required to have an effective recall protocol in place for the recovery of product if required.

The official Veterinary Diagnostic Laboratory Service uses diagnostic tests compliant with the OIE Standards. Participation in a regional proficiency testing program and quality control of sample collection and submission ensures that laboratory testing and reporting are maintained at a high standard. Active surveillance for BSE in Chile is in line with OIE recommendations and targets and samples representative numbers of cattle sub-populations at highest risk of BSE. Chile meets the surveillance points target for both Type A and Type B surveillance. Chile has a comprehensive BSE contingency plan to trace, identify and cull cohort animals of BSE cases should BSE be detected.

The competent authority responsible for BSE controls in Chile, SAG, demonstrated a high degree of oversight of all BSE related controls during the in-country visit. Good communication between the central office in Santiago and regional SAG offices was evident;

as was the strong working relationship between official SAG veterinarians and stakeholders along the beef supply chain.

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

References

Ducrot C, Arnold M, de KA, Heim D, Calavas D (2008) Review on the epidemiology and dynamics of BSE epidemics. Vet Res 39(4):15

EU (2009a) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed. <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:054:0001:0130:EN:PDF</u>. Accessed 26 June 2013a

EU (2009b) Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:303:0001:0030:EN:PDF. Accessed 1 July 2013b

EU (2010) Commission Regulation (EU) No 956/2010 of 22 October 2010 amending Annex X to regulation (EC) No 999/2001 of the European parliment and of the Council as regards the list of rapid tests.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:279:0010:0012:EN:PDF. Accessed 24 April 2013

FSANZ (2010a) Bovine Spongiform Encephalopathy (BSE): Requirements for the Importation of Beef and Beef Products for Human Consumption – Effective 1 March 2010. Food Standards Australia New Zealand.

http://www.foodstandards.gov.au/industry/bse/bseimports/Pages/default.aspx. Accessed 4 July 2013a

FSANZ (2010b) Australian Questionnaire to Assess BSE Risk. Food Standards Australia New Zealand.

http://www.foodstandards.gov.au/industry/bse/bsequestionnaire/Pages/default.aspx. Accessed 4 July 2013b

FSCJ (2011) Risk assessment report on beef and beef offal imported to Japan from Chile (Prions/Self-tasking).

http://www.fsc.go.jp/english/evaluationreports/prions/risk_assessment_report_chile.pdf. Accessed 24 September 2012

Heim D, Mumford E (2005) The future of BSE from the global perspective. Meat Science 70(3):555–562

Hörnlimann B, Bachman J, Bradley R (2006) Portrait of Bovine Spongiform Encephalopathy in cattle and other ungulates. In: Hörnlimann B, Riesner D, and Kretzschmar H. (eds) Prions in Humans and Animals. de Gruyter, Berlin, p. 233–249

Mumford EL, Kihm U (2006) Integrated risk reduction along the food chain. Annals New York Academy of Sciences 1081:147–152

OIE (2012) OIE Terrestrial Animal Health Code - Chapter 11.5. - Bovine spongiform encephalopathy.

http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.11.5.htm. Accessed 4 July 2013

OIE (2013) Bovine Spongiform Encephalopathy Status of Members. http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/list-of-bse-riskstatus/. Accessed 8 July 2013

Appendices

Appendix 1: Overview of the cattle population and beef production in Chile

The cattle population in Chile at the last census in 2007 was 3.7 million head. The majority of breeding cows in Chile are for dairy production and the dairy industry, therefore, has a strong influence on beef production. Dairy cattle are generally managed extensively with the provision of minimal concentrated feed. Approximately 15% of dairy producers account for 80% of total milk production, and four firm's process about 75% of milk collected in Chile. The Los Lagos Region (Region X) is the largest dairy producing region in Chile with 23% of total cattle population in 2012, over 60% of Chile's dairy herds and nearly 5,000 dairy producers. Holstein is the predominant breed. Other major dairy producing regions are Regions IX (La Araucanía) and XIV (Los Rios). Dairy herds in the northern and central regions, close to the Santiago market, are typically housed and fed a diet of maize based concentrates supplemented with lucerne roughage. Beef cattle are mostly a by-product of the dairy industry, and consist mainly of pure-breed Holstein male calves and steers and Holstein cross-breeds. There are, however, pure beef enterprises with tropical and continental beef breeds and crossbreds, found mostly on improved or irrigated pastures in the regions with semiarid or Mediterranean-like climates. Breeds of cattle traditionally used for beef production include the Clavel Aleman. Other breeds that are found in southern Chile include Red and Black Angus, Hereford, Limousin, Charolais.

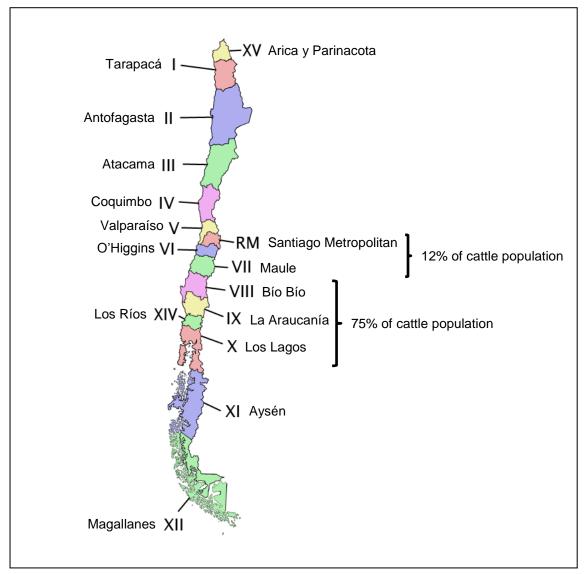


Figure A1: Map of Regions of Chile

Region Number	Region name	Cattle population [#]
XV	Arica y Parinacota	2,268
I	Tarapacá	123
II	Antofagasta	282
III	Atacama	7,148
IV	Coquimbo	41,288
V	Valparaíso	103,089
RM	Santiago Metropolitan	102,039
VI	O'Higgins	83,350
VII	Maule	258,228
VIII	Bío Bío	449,401
IX	La Araucanía	668,140
Х	Los Lagos	1,047,194
XI	Aysén	193,802
XII	Magallanes	141,759
XIV	Los Ríos	621,598
Total		3,719,709

Table A1.1 Cattle population by region

[#] Source: 2007 census

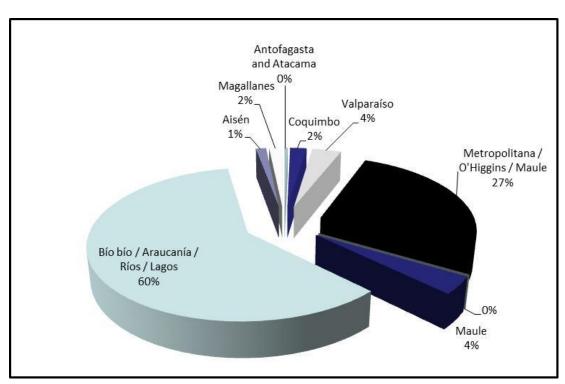


Figure A1.2: Regional distribution of economic benefit from cattle production (January-October 2011). Cattle production and trade of products is concentrated in the south central regions of Chile. Four south-central regions, Los Rios, Los Lagos, Bio Bio and Araucania accounted for 60% of economic benefit from cattle production and three central regions, Santiago Metrapolitan, O'Higgins and Maule, accounted for a further 27%. The remaining 13% of economic benefit was spread across five regions. (Source: ODEPA agricultural statistics; www.odepa.gob.cl)

Appendix 2: Key legislation for BSE control

Legislation	Year applied	Control measures		
General provisions and	overarching	regulations		
Statutory Decree RRA 16 (Animal Health Law)	1963 +	Establishes standards regarding animal health		
Law No. 18,755	1989	Establishes SAG and its powers and authorises SAG to enforce the <i>Animal Health Law</i>		
Law No. 19,283	1994	Amendment to Law No. 18,755		
Importation of MBM				
Resolution No. 53	1999	Health requirements on animals used in manufacture of MBM and pet food exported to Chile		
Resolution No. 1113	2002	Amends Re. No 53/1999 to define processing requirements for manufacture of MBM exported to Chile		
Resolution No. 5277	2004	Restricts bovines and bovine product imports to countries with BSE controls and have been approved by SAG		
Resolution 5037	2005	Establishes the processing requirements for the manufacture of MBM: vapour saturated environment; particle size (maximum 50mm); temperature (minimum 133°C); pressure (3 bar); time (minimum 20 min)		
Importation of cattle				
Resolution No. 5277	2004	Restricts bovines and bovine product imports to countries with BSE controls and have been approved by SAGk		
Importation of beef and	beef produc	cts		
Resolution No. 5277	2004	Restricts bovines and bovine product imports to countries with BSE controls and have been approved by SAG		
Pre-slaughter controls: f	eed ban			
Resolution No. 3124	2000	Ban on feeding ruminant protein to ruminants		
Resolution No. 614	2004	Ban extended to prohibit feeding mammalian protein to ruminants		
MINAGRI Decree 79	2005	Labelling of animal feed containing bovine products or MBM		
Resolution No. 5580	2005	Defines the structural and operational requirements for feed mills		
Resolution No. 2487	2009	Specific requirements for handling raw ingredients of animal origin to avoid cross-contamination		
Resolution No. 5025	2009	Details the scope of a feed mill or ingredient manufacturer's quality assurance system		
Resolution No. 3138	1999	Authorisation requirements on manufacturers of MBM and pet food that export to Chile		
Resolution No. 53	1999	Health requirements on animals used in manufacture of MBM and pet food exported to Chile		
Resolution No. 1113	2002	Amends Re. No 53/1999 to define processing requirements for manufacture of MBM exported to Chile		
Resolution No. 699	2001	Defines processing requirements of MBM and must be equivalent to Chilean standards		
Pre-slaughter controls:	ante morten			
Supreme Decree No. 977	1996 +	Establishes standards regarding food safety, implemented in slaughterhouses by SAG with authority from the Ministry of Health		
Food Sanitation Law				
(Ministry of Health)				
Technical Standard 62 (Ministry of Health)	2002	Minimum standards for the inspection, slaughter and identification of animals and meat for human consumption, implemented by SAG with agreement by Ministry of Health		
Post-slaughter controls: post mortem inspection, SRM removal and rendering				
Supreme Decree No. 977	1996 +	Food Sanitation Law		
Technical Standard 62	2002	Minimum standards for the inspection, slaughter and identification of animals and meat for human consumption		
Resolution 5037	2005	Establishes the processing requirements for the manufacture of		

		MBM: vapour saturated environment; particle size (maximum 50mm); temperature (minimum 133°C); pressure (3 bar); time (minimum 20 min)	
Resolution No. 5025	2009	Details the scope of a feed mill or ingredient manufacturer's quality assurance system	
Resolution No. 5992	2010	Defines specified risk material (SRM) and states that ruminant animals are free of SRM if they originate from countries designated by the OIE as a BSE negligible risk	
BSE specific regulations			
Decree No. 249	e No. 249 1996 Establishes BSE as a notifiable disease		
Cattle identification and	traceability		
Resolution No. 3423	2008	Establishes the animal traceability system	
Resolution No. 5895	2012	Amends No. 3423/2008 defining the animal traceability system	
Resolution No. 621	2013	Amends No. 3423/2008 defining the animal traceability system and establishes mandatory registration of livestock establishments (RUPs) and use of animal movement forms (FMA).	

+ = subsequent amendments made to original decree or resolution.

Appendix 3: Structure of the Agriculture and Livestock Service (SAG) and key responsibilities for BSE control

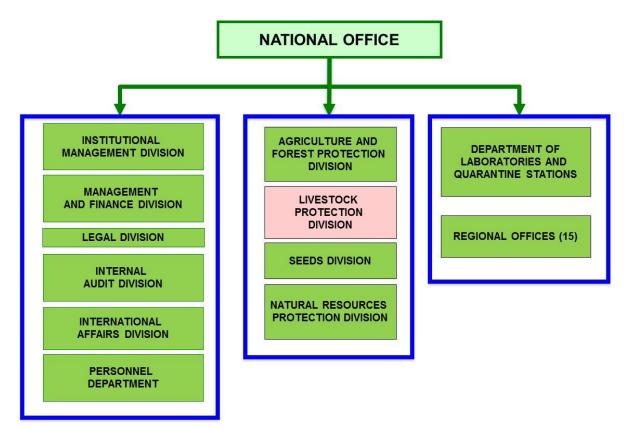


Figure A3.1: Structure and organisation of the Agriculture and Livestock Service (SAG)

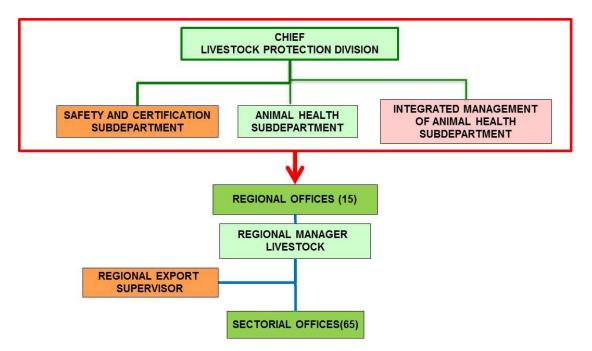


Figure A3.2: Structure of the Livestock Protection Division

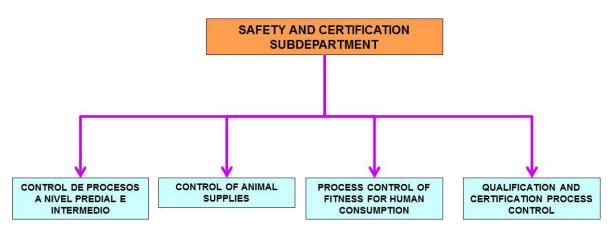


Figure A3.3: Structure of the Safety and Certification Sub-department

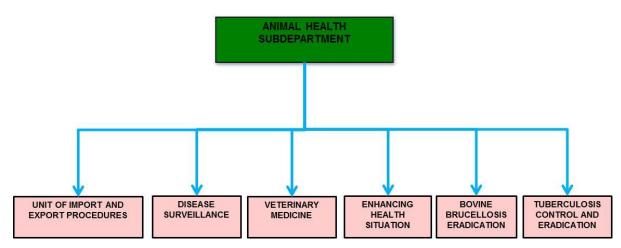


Figure A3.4: Structure of the Animal Health Sub-department

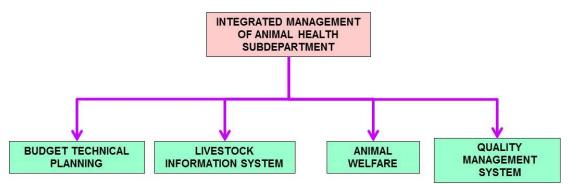


Figure A3.5: Structure of the Integrated Management of Animal Health Sub-department

Appendix 4: Timeline of diagnostic capacity at the official Veterinary Diagnostic Laboratory Service

