BSE Food Safety Risk Assessment Report

The Netherlands

Last Update: October 2012

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[1], 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)[2] which are based on those of the Office International des Epizooties (OIE) *Terrestrial Animal Health Code (2011)* (TAHC).[3] 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, Fisheries and Forestry.

The Netherlands made a submission to FSANZ in May 2011 to be assessed for BSE food safety risk. The Netherlands has not been previously assessed by FSANZ for BSE risk status and currently does not hold market access for beef and beef products with Australia.

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

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

(2) ***Feed ban controls*** to prevent contamination of the animal feed supply with the BSE agent

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

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

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

Bovines and bovine-derived products that are imported into the Netherlands are mainly sourced from European Union (EU) countries that are subject to harmonised legislation for BSE across the EU. Most live cattle, that are imported for veal production, are slaughtered at less than one year old. These animals represent negligible BSE risk. Bovine-derived products for feed production are also predominantly sourced from EU countries but only low risk materials (non-SRM) are permitted for import and only for specific use such as pet food or fertiliser. Beef or beef products for human consumption is sourced from EU countries and countries which have been assessed as negligible or controlled BSE risk status by the OIE. Only minimal numbers of bovines and minimal amounts of bovine-derived products have been imported from third countries (non-EU) and these are regulated through EU-based processes for approval of specific establishments in eligible countries and rigorous certification processes covering quarantinable diseases and food safety measures.

Since 2001, there has been an EU-wide total feed ban in place which prohibits the feeding of animal protein apart from fishmeal to farmed animals. The Netherlands has prohibited the feeding of ruminant protein to ruminants since 1989 and procedures to prevent cross-contamination of feed between ruminant and non-ruminant species have been in place since 1999. Procedures to comply with feed ban controls are applied at slaughter and during processing to prevent the recycling of the BSE agent. Stringent practices are enforced around the use of stockfeed so that feeding of ruminant protein to ruminants is prevented. Ante-mortem inspection procedures to identify animals potentially affected by BSE and post-mortem procedures to ensure the removal and destruction of specified risk materials are well-established. These practices are important to prevent the BSE agent from entering the feed and human food production systems.

Traceability systems include both an electronic traceability system that allows tracking of all animals, animal-derived feed, and animal-derived food products placed on the market (TRACES) and a cattle identification system which records all movements of cattle within The Netherlands and between EU countries. The Dutch cattle identification system has been in place since 1990 and has evolved to the point where there are few inaccuracies are demonstrated (for example, animals that have left a holding with no destination recorded) and there is strong adherence to procedures to ensure all animals have correct identification. Cattle identification data is integrated into the TRACES system so that if a BSE case is confirmed, all cohort animals and feed sources for those animals can be identified and, if needed, removed from the market and appropriately dealt with under the BSE control program.

BSE has been a notifiable disease in The Netherlands since 1990 and since then 88 cases have been identified. On-going awareness and education programs have meant that farmers, veterinarians, and slaughterhouse personnel are well-informed and recognise BSE presentation in clinically affected animals,and understand actions which must be undertaken when a suspect clinical case is identified. Diagnostic capability is supported by a national reference laboratory which has played an internationally-recognised role in BSE diagnostics and research since the epidemic was first identified.

Improvements in diagnostic capability (the “BSE rapid test”) allowed the implementation of an active surveillance program for BSE in 2001. The Netherlands meets the requirements for “Type A” surveillance according to the guidelines set in Articles 11.5.20 to 11.5.22 of the TAHC. Type A surveillance is the highest level of surveillance recommended under the guidelines, allowing the detection of at least 1 case per 100,000, with a mandatory requirement to test older cattle which are at highest risk for BSE. The declining numbers of BSE-positive cattle identified through the active surveillance program in the past seven years are evidence that BSE control measures have been effectively implemented and enforced in The Netherlands.

BSE control measures were observed to be operating effectively during the in-country assessment conducted by FSANZ. 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 through both random and targeted programs and significant adverse findings with respect to official BSE controls have not been identified by the competent authority as a result.

In conclusion, The Netherlands has clearly demonstrated that it has put into practice comprehensive and effective controls throughout the production chain to prevent the introduction and amplification of the BSE agent within the Dutch cattle population and any contamination of the human food supply with the BSE agent. Control measures exist across all levels of production including practices at the slaughterhouse, disease surveillance, feed production, animal identification and traceability, and import regulations.The integration of all of these measures at various establishments was observed first hand at the in-country verification visit. Therefore, this assessment concludes that imported beef and beef products sourced from The Netherlands pose a negligible risk to human health. It is recommended, thererfore, that The Netherlands be given a **Category 1** for country BSE food safety risk status.

List of Acronyms

BSE	Bovine Spongiform Encephalopathy
CVI	Central Veterinary Institute
EC	European Commission
EFSA	European Food Safety Authority
EFTA	European Free Trade Agreement
EL&I	Ministerie van Economische Zaken, Landbouw en Innovatie (Ministry of Economic Affairs, Agriculture, and Innovation)
FVO	Food and Veterinary Office (of the EC)
FSANZ	Food Standards Australia New Zealand
HACCP	Hazard Analysis Critical Control Point
KDS	Animal Sector Quality Inspectorate
MBM	Meat and bone meal
NRL	National Reference Laboratory
NVWA	Nederlandse Voedsel –en Warenautoriteit (Dutch Food and Consumer Products Safety Authority)
OIE	Office International des Epizooties (World Organisation for Animal Health)
PAP	Processed animal proteins
PVE	The Product Boards for Livestock, Meat, and Eggs
RASFF	Rapid Alert System for Food and Feed
RIKILT	Rijks-KwaliteitsInstituut voor Land- en Tuinbouwproducten (Dutch Institute of Food Safety)
SRM	Specified risk material
TRACES	Trade Control and Expert System
TSE	Transmissible Spongiform Encephalopathy
WHO	World Health Organization

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 BSE risk.

BSE agent is the infectious misfolded 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. Testing laboratories generally use commercial test kits as approved by the competent authority.

Cohorts as defined under Section 4 of the Australian Questionnaire are all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed had 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.

PAP (processed animal proteins) as defined by EU legislation means meat-and-bone meal, meat meal, bone meal, blood meal, dried plasma and other blood products, hydrolysed proteins, hoof meal, horn meal, poultry offal meal, feather meal, dry greaves, fishmeal, dicalcium phosphate, gelatine and any other similar products including mixtures, feedingstuffs, feed additives and premixtures, containing these products.

Third countries for the purposes of this assessment are non-EU countries.

TRACES or Trade Control and Expert System is the electronic system that enables traceability of all animals and products of animal origin across the EU.

National Reference Laboratory (NRL) refers to laboratories that are appointed by the EU and have scientific and technical expertise relating to the designated area of animal or public health (e.g. detection of animal proteins in feeds or diagnosis of TSEs).

PCR is polymerase chain reaction used to identify DNA of bovine material in feed samples to monitor the effectiveness of the feed ban.

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 goat.

SRM are specified risk materials defined under the Australian BSE food safety policy[1] 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.

Working Instructions are detailed procedures and protocols set by the NVWA which are implemented at a production facility (slaughterhouse, feed company, and rendering plant) to ensure compliance with BSE control measures.

Table of Contents

Introduction

FSANZ is the regulatory body responsible for assessing the BSE food safety risk of, and assigning a status to, countries that seek to export beef or beef products to Australia. Under Australia's BSE food safety policy[1] individual countries submit applications to FSANZ that should include comprehensive data around 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*).*[2] In general, data requirements in the Australian Questionnaire are based on those of *Chapter 11.5 – Bovine Spongiform Encephalopathy* of the OIE *Terrestrial Animal Health Code (2011)* (TAHC).[3] The Australian Questionnaire also seeks information on animal traceability and identification, and animal slaughtering and processing systems.

FSANZ evaluates BSE food safety risk according to scientifically recognised and internationally accepted practices for the control and prevention of BSE. FSANZ assesses the information and data submitted by the applicant country through: (1) a desk assessment of documentation; and (2) an in-country verification component which aims to verify relevant controls around the introduction and spread of BSE. The verification visit provides a snapshot of the systems that are in place.

In addition to submitted documentation, legislation and standards underpinning BSE controls are also examined as part of the desk assessment. Publically available documentation issued by other statutory bodies, such as various EU agencies, or scientific literature may also be reviewed as supplementary material.

The Netherlands submitted an application to FSANZ for assessment of BSE food safety risk on 12 May 2011. The Netherlands submission was a compilation of its 2006 submission to the OIE and annexes demonstrating various aspects of their BSE control systems and history. The in-country verification visit was conducted in March 2012 and the findings of visits to various establishments across the production system as well as information on the competent authority oversight are integrated into this report.

The following report describes the findings of The Netherlands assessment and concludes with a country BSE risk category that indicates the BSE food safety risk that may be associated with beef and beef products manufactured in The Netherlands. The Netherlands does not currently have market access to Australia for beef or beef products.

Overview of BSE Regulatory System

The regulatory structure for BSE controls in The Netherlands is summarised in Figure 1. Legislation is mainly set by the European Commission (EC) which allows BSE controls to be harmonised across the EU and supports an agenda for BSE eradication. EC legislation is introduced as Directives or Regulations that must be adopted by member countries. Other rules for implementation are set either by the EC or by national regulatory bodies.

The Ministry of Economic Affairs, Agriculture, and Innovation (EL&I) sets policy to support the agriculture and food sectors and has responsibility for animal health and food safety policy and management. The Ministry of EL&I was formed in 2010 through a merger between

the Ministry of Economic Affairs and the Ministry of Agriculture, Nature and Food Quality. The Ministry of EL&I also directs the National Service for the Implementation of Regulations which is responsible for the Department for Animal Registration.

The Food and Consumer Product Safety Authority (NVWA) is the competent authority under the Ministry of EL&I and is responsible for monitoring plant health, animal health and welfare, and food safety across the production chain. The NVWA has powers for monitoring and enforcement of BSE requirements as set by the EC or national legislation. Prior to 2012, supervision in these areas was covered by three separate agencies: the General Inspection Service, the Plant Protection Service, and the Food and Consumer Product Safety Authority. The merger of the three agencies has simplified oversight of compliance with animal health and food safety legislation.

The NVWA is made up of six divisions of which the Veterinary and Imports Division is responsible for implementing programs for BSE controls including testing and certification of live animals and meat products, monitoring compliance with food safety regulations, monitoring and control of zoonotic risks, and import controls for animals and animal-derived products. The Division employs 437 staff of which 229 are official veterinarians. The division is organized into five units that implement and supervise these activities: (1) slaughterhouse controls, (2) livestock controls, (3) import controls, (4) development and evaluation, and (5) the Chief Veterinary Inspectorate. The Chief Veterinary Inspectorate oversees the NVWA Incident and Crisis Centre which handles suspected cases of notifiable diseases (e.g. rabies, avian influenza, tuberculosis, and BSE), and implementation of preventative measures, education and training of animal disease officers, and risk assessment for disease outbreaks occurring abroad.

Analytical testing is performed by three non-government institutes that operate under statutory arrangements with the Ministry of EL&I. The Rijks-KwaliteitsInstituut voor Land- en Tuinbouwproducten (RIKILT) Institute of Food Safety is a private research institute and acts as the national reference laboratory for detection of animal proteins in feed. The Central Veterinary Institute (CVI) is the national reference laboratory for OIE- listed animal diseases and is responsible for BSE testing and conducting research on transmissible spongiform encephalopathies (TSEs). The Animal Health Service is authorised by the Ministry of EL&I to conduct inspections for monitoring animal disease, diagnostic analyses, proficiency testing, and certification of farms and laboratories.

Regulations and enforcement of BSE control are also enacted through the Product Boards for Livestock, Meat, and Eggs (PVE). The PVE is a statutory trade organisation that is authorised by the government to implement programs ensuring compliance with food safety and animal health legislation and conduct activities that promote quality assurance. The PVE is funded through charges for services provided to the government and through levies imposed on slaughtering and export of livestock.

A summary of the EU and Dutch legislative framework for BSE controls is provided in Appendix 1.

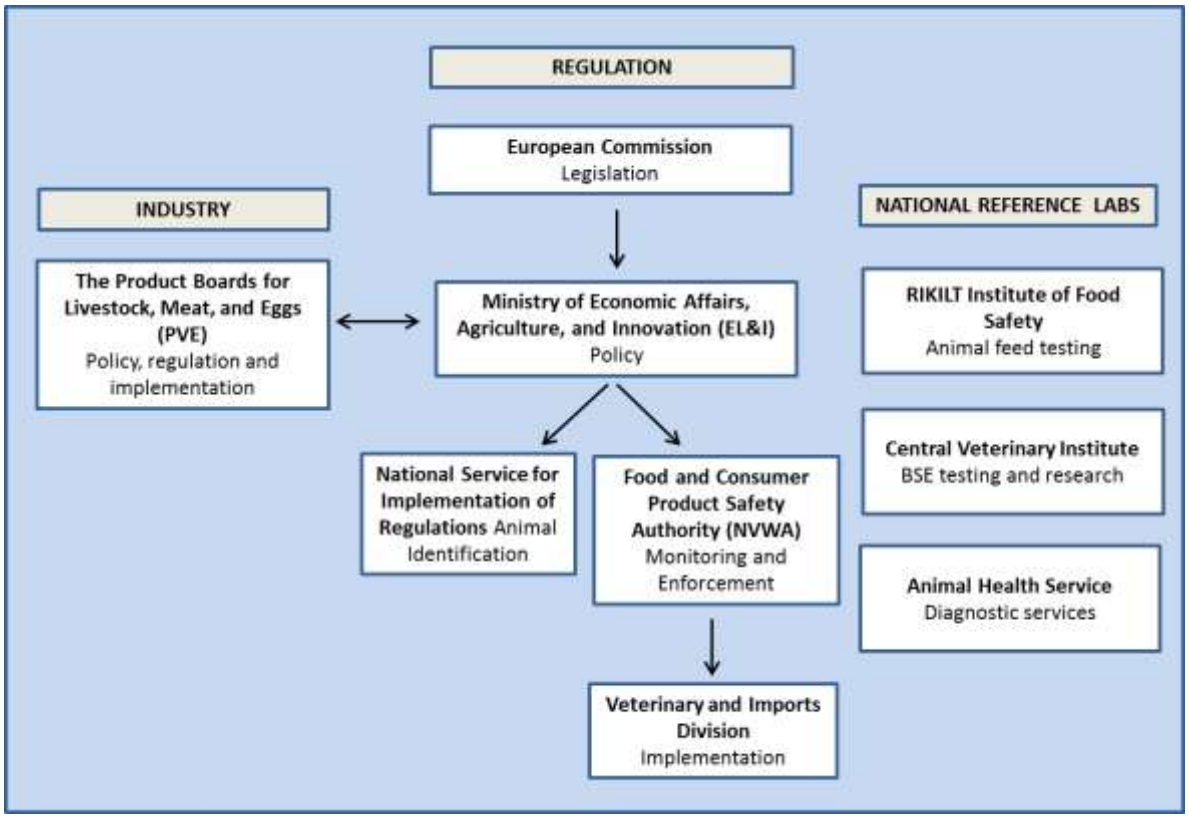

Figure 1: *Structure for BSE Controls in the Netherlands*

BSE History

BSE has been detected in 88 bovines in The Netherlands since 1997.[4] The number of cases peaked in 2002-2003 with 41 cattle diagnosed and the majority of these (28) born in 1996/97. The incidence of BSE has declined in line with other European countries in response to the implementation of BSE controls across Europe. Most BSE cases occurred in dairy herds (80 cases) which is consistent with the feeding regimes for dairy herds at that time providing a greater chance of exposure to contaminated feed. The fact that the last three BSE cases were detected in very old cows (greater than 11 years old) is evidence that BSE controls have been effective in preventing exposure to the infective agent, and therefore the development of new BSE cases.

The number of BSE cases detected in the Netherlands from 1997 to date, as reported in the BSE portal on the OIE website[4], is shown in Table 1. The Netherlands' submission contains details of the BSE cases reported in the Netherlands to 2010 including date and place of birth, date of death, BSE diagnosis, and the surveillance stream under which cases were detected. Details on cases identified from 2006 to present were confirmed through the OIE's World Animal Health Information Database (WAHID) portal.[5] The Netherlands qualifies for negligible BSE risk status with the OIE[a] as all BSE cases detected were born more than 11 years ago.

[a] Under Article 11.5.3 of the OIE TAHC, countries which have had BSE but every indigenous case has been born more than 11 years ago may be eligible for negligible risk status.

Submitted documentation and other reports published in the scientific literature, as summarised below, provided a comprehensive investigation and analysis of the 88 BSE cases occurring in The Netherlands to October 2011.

Table 1: Number of Reported BSE Cases in The Netherlands

Year	97	98	99	00	01	02	03	04	05	06	07	08	09	10	11	12
# BSE cattle	2	2	2	2	20	24	19	6	3	2	2	1	0	2	1	0

Investigations of BSE in The Netherlands. Several papers analysing BSE outbreaks in The Netherlands have been published in the scientific literature.[6-8] These studies reported that the most likely source of BSE infection in The Netherlands was through feeding of protein concentrates cross-contaminated with ruminant protein during the production process. Typically MBM has not been used for ruminant feed in The Netherlands. Regional feed producers with mixed production lines were identified as the most significant risk factor linked to BSE cases.[8]

Improvement in diagnostic testing methods and characterisation of BSE types has permitted more extensive testing of recent BSE cases (2007 to present) and retrospective testing of brain isolates of cases up to 2006.[9] These studies have shown that of the 88 BSE cases identified in The Netherlands, three were L-type (diagnosed in 2002, 2003, and 2010) and one was H-type (diagnosed in 2001). Epidemiological and biological studies suggest that H- and L-type BSE are sporadic forms of the disease and not generally associated with an animal consuming infected feed by consumption of contaminated feed.[10]

Geographical Distribution of BSE cases: A spatial analysis of 82 Dutch BSE cases (1997-2006) examined whether a clustering pattern could be identified and point to possible sources giving rise to the BSE outbreak.[6] The study concluded that these 82 cases were clustered into three regionally distinct birth cohorts. The source of the infection was associated with two MBM suppliers where the processing procedures enabled ruminant feed to be contaminated with pig and poultry feed containing ruminant protein.

***Identification and fate of risk animals for all BSE cases*:** The submission provided a detailed explanation of the culling strategies that were employed once BSE cases began to appear. Basically, from 1997 to 2003, all ruminants and cohorts on the affected farm were culled and destroyed. After 2003, this was modified to include only cohorts and offspring. The identification of cohorts was possible because of the compulsory identification system established in 1990 that enabled all animals to be identifiable and their movements traced. Over 7000 cohort cattle were destroyed under the culling strategy and none of these animals tested positive for BSE.

Effectiveness of implemented of BSE controls. In response to the spread of BSE from the United Kingdom to other European countries, overarching BSE regulations were introduced in the EU under Regulation (EC) No 999/2001. These regulations introduced strict requirements, enforceable across all EU countries, which covered:

- declaration of country BSE status
- provisions for control and eradication of TSEs such as removal of SRM
- legislation on imports and export of cattle and small ruminants
- requirements for national reference laboratories
- instructions for feed sampling and TSE testing.

In addition, The Netherlands implemented a number of regulations in advance of the comprehensive rules introduced under Regulation (EC) No 999/2001, as detailed in the relevant chapters of this report.

A comparison of the birth year of BSE cases and year that BSE controls were implemented demonstrates the effectiveness of controls on eradication of BSE in The Netherlands. Submitted data shows that the greatest exposure to BSE infectivity was likely to have occurred in 1996 and the requirement to remove and incinerate slaughterhouse SRM (introduced in 1997) was effective in eliminating a substantial amount of infective material from the cattle production system. Additional controls succeeded in further reduction of BSE infection rates, supporting scientific reports that effective removal of BSE infective material requires implementation of controls across the beef production chain.[11-14]

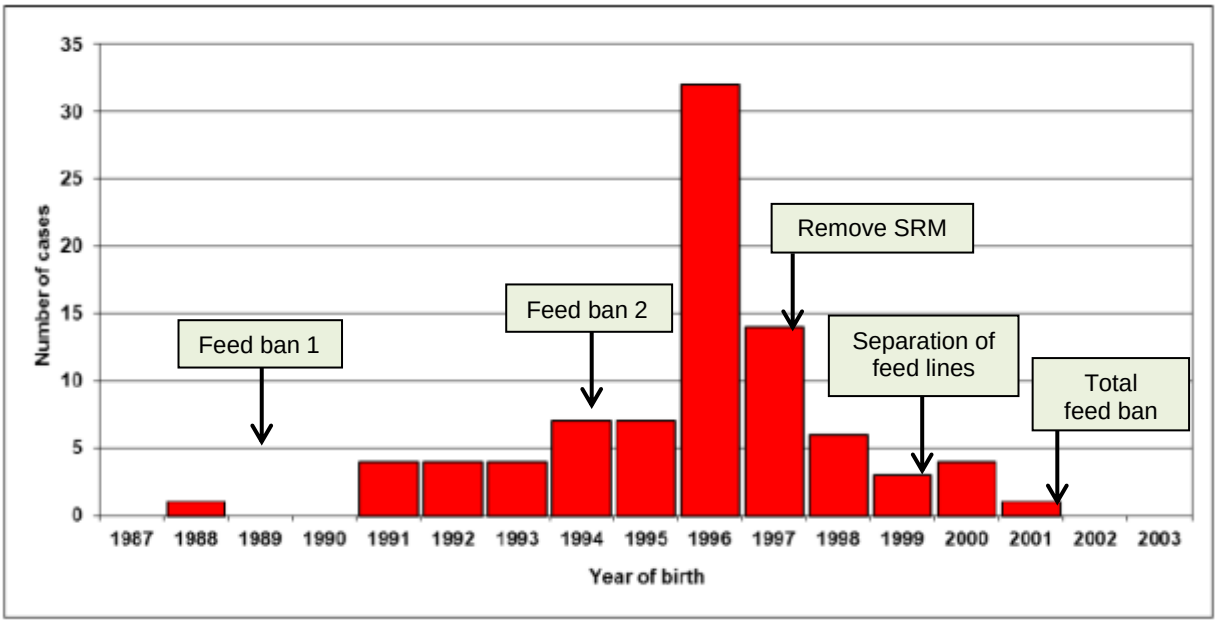

Figure 2: *Year of birth of 87 BSE cases in The Netherlands*[b]

Variant Creutzfeld-Jacob disease (vCJD) in The Netherlands

[b] Figure excludes 2011 BSE case and is reproduced from submitted documentation. Details of control measures are provided in relevant sections of this report.

vCJD is a TSE disease of humans resulting from exposure to food products or blood contaminated with the BSE agent. Three cases of vCJD have been diagnosed in The Netherlands.[15] None had significant exposure risks (e.g. history of residency in the United Kingdom or blood transfusion), suggesting that their exposure would have occurred in The Netherlands. All have died from the disease.

Potential for release of the BSE agent through imported materials

Release of the BSE agent into a country's cattle population can occur through the importation of specific commodities infected with the BSE agent and their subsequent exposure to susceptible animals. Commodities that could potentially introduce BSE, if contaminated, include MBM or animal feed containing MBM, live cattle, and fresh meat or food products of bovine origin particularly if SRMs are not removed or cross contamination has occurred during processing or SRM removal.

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

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

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

General rules for trade within and into the European Union in regards to BSE

In general, all products imported into EU countries must satisfy the same safety standards as products produced within the EU. Generally, the term "introduction" refers to commodities (live animals and animal products) imported into the EU market from third countries (i.e. non-EU) and "trade" refers to movement of commodities between EU member countries.

There are several levels of regulations that restrict the trade or introduction of live cattle or products derived from cattle.

Firstly, non-EU countries must undergo an approval process which includes a competent authority assessment.[16] The main purpose of this assessment is to evaluate whether the animal and public health situation (for example, the prevalence of certain animal diseases) the official services, legislation, control systems and production standards meet EU requirements. Approved countries are listed in EU legislation (Regulation (EC) No 206/2010) and products can be introduced subject to specified certification requirements.

Secondly, restrictions are also based on the BSE risk status of the exporting country and this applies to any bovine products placed on the EU market whether introduced from a third country or traded between EU countries. Criteria for the determination of country BSE risk status were defined in 2001 under Regulation (EC) No 999/2001. Amendments adopted in 2007 (Regulation (EC) No 722/2007) mean that BSE status of countries is determined by a risk analysis in accordance with OIE recommendations for BSE controls (i.e. country has been assessed and categorised by the OIE as *negligible* or *controlled* BSE risk status). Countries currently recognised under the EC regulation with *negligible* or *controlled* status are listed in Table 2. Countries with *undetermined* BSE status may also export bovine animals or bovine products to EU countries if prescribed conditions required under this risk status are met.

Consignments of live cattle, or products derived from cattle, that move across EU borders from third countries are subject to certification and inspection at specified border control posts. The conditions under which such commodities can be traded depend on the BSE risk category of the exporting country. Specific BSE-related conditions for each commodity (MBM, live cattle, or beef and beef products) are detailed in the relevant sections of this report.

Lastly, requirements under specific country legislation may also be applied. Mostly these are rules or instructions to ensure compliance with EU-legislation, or laws that were introduced before the general EC rules for TSE control were enacted in 2001.

Table 2: List of Countries and BSE Risk Status[1]

	EC Member Countries		EFTA Countries	Third Countries
Negligible Status	Finland Sweden		Iceland Norway	Argentina Australia New Zealand Paraguay Singapore Uruguay
Controlled Status	Belgium *Bulgaria* Czech Republic Denmark Germany Estonia Ireland Greece Spain France Italy Cyprus Latvia	Lithuania Luxembourg Hungary Malta Netherlands Austria Poland Portugal Romania Slovenia Slovakia United Kingdom	Switzerland Liechtenstein	Brazil Canada Chile Taiwan Mexico United States

[1] *Source: Decision 2008/829/EC*

1 Importation of MBM

1.1 Overview

Processed animal protein (PAP) is the term used in the EU to describe all meat meals (including MBM), greaves, processed products derived from animals, and any other similar products including mixtures, feedingstuffs, feed additives and premixtures containing these

products intended for feeding to animals (not human food). Importation of ruminant-derived PAP poses a food safety risk as it is the primary route through which cattle are exposed to BSE infectivity. The Netherlands permits trade of certain PAP-containing low risk materials from other countries for specific uses. The definition of these materials and restrictions on the processing and use of imported and domestically produced bovine by-products (including MBM) are discussed in detail in Section 5.

1.2 Legislation

Imports of products derived from animals are permitted from countries listed in Decision 2008/829/EC (as amended, see Table 2).

Regulations for import controls on animal derived material into the EU are set under Regulation (EC) No 1069/2009 which consolidated a number of previous regulations covering the handling and use of animal by-products. Regulation (EC) No 1069/2009, in combination with Regulation (EC) No 999/2001, defines animal by-products, sets criteria for categorisation of materials according to risk, and sets requirements for their processing and use. These areas are explained in detail in Section 5.

1.3 Details of MBM imports

1.3.1 Countries of origin

The Netherlands has provided data on imports of MBM and greaves from 2003 to 2010. Countries which have exported MBM and greaves to the Netherlands are either EU member countries with OIE recognised BSE status (*negligible* or *controlled*) or third countries which have not had indigenous BSE cases (Australia, New Zealand, United States, and Norway). The main source countries for MBM and products containing MBM, based on the volumes provided for this time period, are Norway, Germany, Italy, the United Kingdom, France, Poland, and Belgium.

1.3.2 Types of materials, species composition and uses

Category 3, according to EC regulations is low risk animal material which may contain non-SRM bovine materials or animal by-products from other farmed species (see Section 5). These are permitted to be traded or imported from approved third countries subject to the rules around handling these materials including separation of transport and processing lines (Section 5) and traceability (Section 10). The only permitted uses for Category 3 materials are for fertiliser, technical applications, or processing into pet food.

Category 1 and 2 materials which contain the tissues of highest risk for BSE must be destroyed by incineration. These materials are not permitted for import from third countries or for trade between EU countries except under specific circumstances (e.g. transported for destruction in another EU country).

1.3.3 Certification and clearance

Certification requirements for all animal-derived products are harmonised in the EU and are set out in Regulation (EC) No 1069/2009. Chapter II of this regulation sets out specific requirements in relation to importation of PAP. Imported animal protein is permitted to enter The Netherlands through the six EU-approved Border Inspection Points (BIP). All

consignments must be accompanied by a health certificate which provides information such as country of origin details, description of the commodity, and an animal health attestation signed by the official veterinarian of the exporting country. Commercial documentation includes a description of the material (quantity, category of animal by-products from which the material was derived, species, ear-tag number), as well as details of origin and destination. Before clearance at the BIP, documentation is checked by an NVWA official veterinarian and sampled to test compliance for microbiological contamination.

The paper-based system for certification has been replaced by the electronic system TRACES (Trade Control and Expert System) which is described in Section 10.

Import controls of all EU countries are audited by the European Commission Food and Veterinary Office (FVO) with the most recent audit for The Netherlands completed in 2009.[17] According to the report of this audit, no major issues were identified in relation to imports of MBM or processed animal protein products.

1.3.4 Rendering process used in source country

Imported mammalian protein must be processed to the minimum rendering specifications assigned by the OIE to remove BSE infectivity (heating to a core temperature of more than 133°C for at least 20 minutes at a pressure of at least 3 bars produced by saturated steam, with a particle size of not more than 50 mm). This control measure has been in place in The Netherlands since 1997 and is declared on the health certificate that must be signed by the official veterinary authority of the exporting country.

2 Importation of live cattle

2.1 Overview

Importation of live cattle represents a potential food safety risk if imported cattle are sourced from countries which do not have adequate control programs to minimise the risk of BSE exposure. The Netherlands has imported live cattle primarily from EU-member countries during the last seven years. These animals are mostly calves imported at 14 days old to be slaughtered at 6 months for the veal industry.

2.2 Legislation

As with importation of PAP products, legislation for the importation of cattle within the EU or from third countries is harmonised across the EU. Controls for trade of live cattle are covered in part under Regulation (EC) No 999/2001 as amended in Regulation (EC) No 722/2007 which sets out criteria for the categorisation of countries according to BSE risk status. Under this regulation,

> **Negligible risk status means:** Animals must be (1) born and continuously raised in country of negligible status; (2) permanently identifiable to enable traceability back to dam and herd of origin; and (3) if indigenous BSE present, then the animals must be born after the date from which a ruminant feed ban was in place or after the date of birth of the last indigenous case of BSE.
>
> **Controlled risk status means:** Animals must be (1) born and continuously raised in country of controlled status; (2) permanently identifiable to enable traceability back to

dam and herd of origin; and (3) animals must be born after the date from which a ruminant feed ban was in place or after the date of birth of the last indigenous case of BSE.

Undetermined risk status means: Animals must be: (1) permanently identifiable to enable traceability back to dam and herd of origin; and (2) born at least 2 years after a ruminant feed ban was in place or 2 years after the date of the last indigenous BSE case if born after the date of the feed ban.

Negligible or controlled risk status will not ensure that the imported animals are not BSE infected, but indicates the minimal likelihood that animals sourced from these countries will introduce the BSE agent into the food chain. The conditions under these risk categories are in line with the international standards set in Chapter 11.5 of the OIE TAHC (2011).

Certification requirements for the introduction of live animals or fresh meat from third countries (i.e. non-EU) are set in Regulation (EC) No 206/2010. The regulation provides a list of third countries which are permitted to import live cattle into the EU. Only specified countries (none have had cases of BSE) and certain classes of cattle are permitted for entry into an EU country under this regulation but only if they satisfy veterinary certification requirements set out in Annex 1 of Regulation (EC) No 206/2010. Certification requirements include health certificates, passports containing full animal history, and animal identification. These conditions are checked as part of inspection processes at a BIP.

2.3 Details of live cattle imports

With exception of one animal imported from the United States in 2005, imports of live cattle into The Netherlands over the past 7 years have been sourced solely from EU countries and all with either negligible or controlled BSE risk status according to the OIE.

Since 2002, over 90% of all bovines imported into the Netherlands (850,000 in 2010) have been calves brought for veal production. The main source countries for veal calves are Germany, Poland, and Belgium. These animals are slaughtered at 26 weeks to one year old and, with other control systems in place, these animals represent a negligible risk of releasing the BSE agent into the Dutch cattle system. Nevertheless, the ability to segregate animals born, raised and slaughtered in the Netherlands from imported cattle (as required under the Australian policy for BSE) was confirmed with Dutch officials and industry representatives during the in-country verification visit.

Smaller numbers of bovines (about 25,000 per year) are imported for slaughter at older than one year or for breeding. The major source countries for these two classes of cattle are Belgium/Luxembourg and Germany.

According to the 2010 Country Profile report issued by the EC Directorate-General for Health and Consumers[18], cattle imported from Member States are tested for BSE if they are over 30 months of age. Since 2001 when active BSE surveillance commenced in The Netherlands, only one animal, imported for slaughter, in 2005 was diagnosed and tested positive for BSE. The animal was culled and destroyed immediately after importation into The Netherlands.

Under certification requirements, cattle traded within the EU must be tagged with identification that indicates country of origin and enables them to be traced to the dam and herd of origin.

3 Importation of beef and beef products

3.1 Overview

This section focuses on the risk of releasing the BSE agent through the importation of beef-containing food products which are intended for human consumption. As with imports of PAP and live cattle, importation of beef and beef products are regulated through EC legislation covering both intra-community trade and importation from third countries. Imports are not permitted from countries which do not have adequate BSE controls and regulations in place. Very small amounts of beef products have been imported from countries which are not assessed for BSE risk but only from specific EU-approved and audited establishments. The likelihood that BSE could be released through importation of a beef food product is minimised by requiring removal of SRM at slaughter, regardless of the BSE risk status of the source country.

3.2 Legislation

3.2.1 Legislation

Animal products intended for human consumption are highly regulated through EU legislation, summarised in Appendix 1. These include setting and defining:

- General animal health rules in relation to introducing products of animal origin for human consumption.
- Requirements for ante- and post-mortem inspection for traded or imported products.
- Hygiene rules for food of animal origin including definitions of different types of meat products.
- Conditions for trade between Member States for products of animal origin intended for human consumption.
- Third countries that are eligible to bring in fresh meat into the EU within specific veterinary certification requirements as detailed in this regulation

Under Regulation (EC) No 722/2007, products traded between Member States or sourced from a third country must meet requirements for ante- and post-mortem inspection and ensure that SRMs are removed. Countries must certify that these requirements are met. Specific production facilities must be EU-approved to be eligible to export products to the EU and are inspected by the FVO to ensure that certification requirements are complied with.

Additional certification requirements are detailed in Regulation (EC) No 206/2010 which covers specific rules on imports of products from third countries.

3.2.2 Conditions for imports

As listed in Regulation (EC) No 722/2007, imports are restricted based on the BSE risk status of the source country (Table 2). Countries categorised under conditions set out in this Regulation must meet requirements for feed ban controls and surveillance (in accordance

with OIE recommendations). In addition requirements covering importation of fresh meat, minced meat and meat preparations, meat products, rendered animal fats, greaves and gelatine (as defined in Regulation (EC) No 853/2004) are listed. Trade in beef products is subject to presentation of an animal health certificate at border inspection which at minimum means that the products do not contain SRM or mechanically separated meat and the source animal has passed ante- and post-mortem inspection. Under Annex VI of Regulation (EC) No 722/2007, specific BSE-linked certification conditions include:

> **Negligible status means**: Products (1) are derived from animals that were born, continuously-reared, and slaughtered in a negligible risk country, and (2) were born after the date in which the ruminant feed ban was in place (for countries with indigenous BSE cases).
>
> **Controlled status means:** Products (1) do not contain nervous or lymphatic tissues exposed during the deboning process, and (2) have not been slaughtered after stunning by means of gas injected into the cranial cavity (or related methods).Carcasses and half carcasses may be imported with the vertebral column if all SRM has been removed (i.e. spinal column and dorsal root ganglia), and carcasses are labelled and recorded as specified under regulation.
>
> **Undetermined status means:** Products (1) do not contain nervous or lymphatic tissues exposed during the deboning process, (2) have not been fed MBM or greaves derived from ruminants, (3) have not been slaughtered after stunning by means of gas injected into the cranial cavity (or related methods). Carcasses and half carcasses may be imported with the vertebral column if all SRM has been removed (i.e. spinal column and dorsal root ganglia), and carcasses are labelled and recorded as specified under regulation.

3.3 Amounts of imported beef or beef products

From 2004-2010, The Netherlands imported both fresh beef and retorted beef products from both EU and non-EU countries. Over this period, approximately two million metric tons of fresh beef were imported with almost 90% of this amount sourced within the EU. For EU countries, Belgium/Luxembourg, Ireland, Poland, and the United Kingdom were the largest exporters (1.32 million metric tons) whereas for non-EU countries, Argentina, Brazil, and Uruguay were the largest exporters (0.25 million metric tons).

For retorted beef products, approximately 0.19 million metric tons were imported for the period 2004-2010 from both EU and non-EU countries. For EU countries, products were mainly sourced from Belgium/Luxembourg and Germany whereas for non-EU countries the main exporters were Argentina and Brazil.

Very small amounts of fresh beef (2955 metric tons) and retorted beef (34 metric tons) have been sourced from countries which have not been assessed for BSE risk by the OIE (China, Botswana and Namibia). Under certification requirements, meat can be imported only from EU-approved establishments and under conditions specified above in Section 3.2.2. (i.e. SRM removal and ante- and post-mortem inspection).

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

The assessment of import controls indicates that the risk of the BSE agent being released into the cattle population in The Netherlands through imports of MBM, live cattle, or beef and beef products is very low.

Trade in products containing animal protein is highly regulated in the EU and only Category 3 material containing only low risk animal protein is imported. The Netherlands has imported these materials only for the purposes of pet food, fertiliser or technical use and only from countries with negligible or controlled BSE risk status. In-country verification confirmed that imported animal protein to be used in pet food is transported, processed and stored separately from processed animal protein destined to be fed to farmed animals (only fishmeal is permitted). The only ingredients imported for ruminant feed are of plant origin and only from designated and accredited suppliers. These stringent controls are the main mechanism that prevents the release of prion-contaminated materials into The Netherlands.

Live cattle have been imported from countries with negligible or controlled BSE risk status. The majority of imported cattle are imported and slaughtered at less than 12 months old and represent minimal risk of exposure of the Dutch beef industry to the BSE agent. In-country verification confirmed that most imported veal cattle are introduced through companies that employ vertically-integrated systems that also promote a high degree of control across production.

Beef and beef products are mainly sourced from EU countries where production and processing is tightly regulated for BSE control. Under import regulations for third countries, fresh meat may be sourced from non-EU countries but can be considered to represent minimal risk due to the small amounts imported into The Netherlands and the conditions to which countries must certify to bring in these products.

Underpinning controls on imports is the European TRACES system which is the electronic system that enables government authorities and businesses to track and trace products of animal origin (food and feed ingredients sourced from animals) and live animals that are traded on the EU market (see Section 10).

Exposure control

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.

Reviews on the effect of BSE control measures on the epidemiology of the disease emphasize 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.[11-14] 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 applied across the beef production chain to prevent exposure to BSE are summarised in Figure 3.

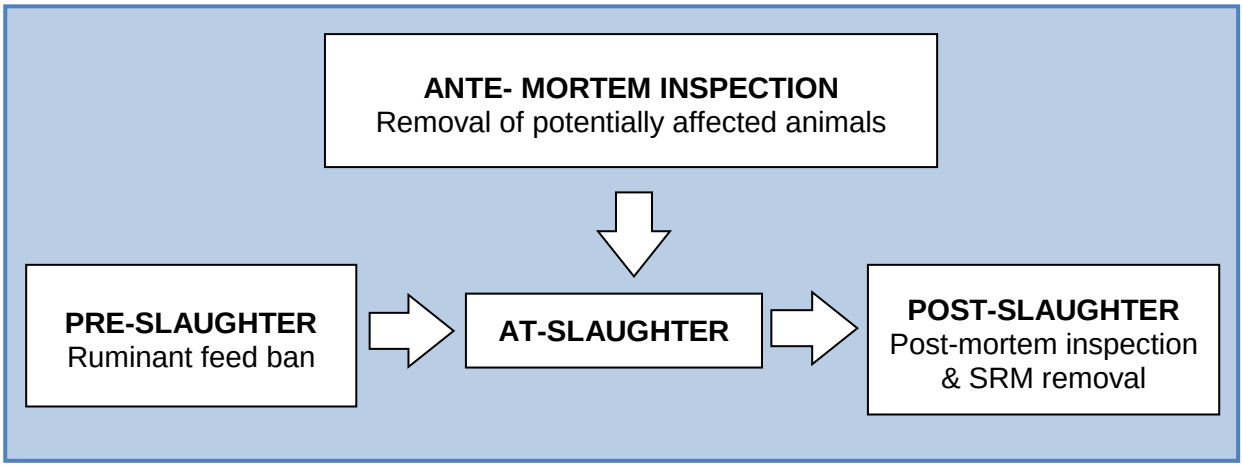

Figure 3: *Exposure controls in beef production system*

Regulation (EC) No 999/2001 introduced mandatory controls for BSE across the whole of the animal feed and food production chain within the EU in order to eradicate the disease. For some measures, such as feed ban controls introduced in 1989, The Netherlands government introduced controls well before EU-wide regulations were implemented.

This chapter describes the control measures used by The Netherlands to prevent the contamination and recycling of the BSE agent in cattle feed and contamination of food for human consumption.

5 Pre-slaughter controls: feed ban

5.1 Overview

The Australian Questionnaire requires that countries demonstrate that ruminant-derived MBM has not been fed to cattle for the last 8 years and that an effective ruminant feed ban has been effectively implemented.

5.2 Legislation

5.2.1 Feed ban

The Dutch government prohibited the use of ruminant MBM for use in ruminant feed in 1989 (ruminant to ruminant feed ban) and prohibited imports of MBM from the United Kingdom, Ireland, and Switzerland in 1990. Subsequent legislation was implemented in 1994 to comply with Decision 1994/381/EC which banned the use of mammalian protein for feeding to ruminants (mammalian to ruminant feed ban). A total ban prohibiting the use of PAP for use in feed for any farmed animals produced for food (total feed ban) has been in place since 2001 under Decision 2000/766/EC.

Since the total feed ban was implemented, several amendments to EU feed ban regulations have been introduced to allow use of some animal protein to be fed to farmed animals under very restricted conditions. The intention of these amendments is to allow the use of certain animal proteins (e.g. fishmeal) which are considered safe from BSE as determined by scientific risk assessments conducted by the European Food Safety Authority (EFSA). The amendments are summarised in Appendix 1.

5.2.1 Use of animal-derived by-products

BSE-related restrictions on the use of animal protein are implemented based on the categorisation of the material under Regulation (EC) No 1069/2009, as summarised below.

Category 1: Carcasses of animals suspected or confirmed of TSE infection and their cohorts; specified risk material (see Section 7 of this report)

Category 2: Products of animal origin imported from a third country which fail to comply with EC veterinary legislation; carcasses of animals that died other than being slaughtered for human consumption

Category 3: Carcasses, parts of animals, and products of animal origin which were intended and considered safe for human consumption but not destined for humans for commercial reasons; hides, skins, horns, and feet of animals not suspected of TSEs (i.e., low risk materials).

The basic requirements for the processing or destruction of animal by-products have been in place since 2001 under Regulation (EC) No 999/2001. Category 1 and 2 materials cannot be used for feeding to any farmed animal and are destroyed by rendering then incineration (or used for biofuel). Category 3 material is the only animal by-product (i.e. not suitable for human consumption) which may be processed but only for pet food, fertiliser, or technical uses. Category 3 materials must be rendered according to OIE recommended conditions before use.

5.2.3 Prevention of cross-contamination

Prior to the EC regulations for BSE controls introduced in 2001, The Netherlands introduced several requirements to minimise or eliminate cross-contamination of feedstuffs with bovine material. Regulations were first imposed in 1993 which prohibited the use of production machinery after it had been used to produce feed containing MBM and banned MBM from the United Kingdom, Ireland, and Switzerland in any ruminant feed production facility. Regulations were strengthened in 1999 when complete physical separation of ruminant and non-ruminant feed production was introduced and, in line with a zero-tolerance policy on contamination of feedstuffs, inspection of feed production establishments was also introduced to ensure compliance.

5.3 Production and use of animal feedstuffs

There are 80 animal feed producers in The Netherlands of which 46 are registered and approved with the NVWA to manufacture feed containing fishmeal. These are the only establishments permitted to produce feed containing animal protein and only for use in pig and poultry feed. Most feed mills in The Netherlands are members of a quality assurance scheme (*TRUSTFEED*) so that all raw materials are sourced from a registered supplier that has been assessed for feed safety controls.

No imported or domestic MBM or prohibited animal protein has been used for feeding to cattle for well over 8 years. Animal by-products are mainly used for pet food production in The Netherlands. Potential cross-contamination of ruminant feed with feed intended for other species (which may contain fishmeal as the only permitted animal protein) is further reduced by the predominance of specialised dairy farms in The Netherlands. Over 80% of cattle farms do not hold multiple species.

5.4 Analysis of feed samples

Raw materials and finished feed products are sampled at feed mills to test for animal protein contamination and other safety or quality measures. Samples are analysed on-site or by private laboratories using the microscopic method to detect bone fragments (Regulation (EC) No 152/2009) which would be a constituent of prohibited materials such as MBM. The method utilises markers to characterise the bone fragments according to the size and density of lacuna and thereby allows differentiation of mammalian (and bird) fragments from fish fragments (which is permitted in some animal feeds). The method allows detection of mammalian protein (not species specific) to a level of 0.1% or less which is acceptable under EC requirements. The Netherlands has also used Polymerase Chain Reaction methods to identify the species of animal protein in positive samples and confirm levels of contamination.

RIKILT Institute of Food Safety is the EU-appointed national reference laboratory for animal feed testing in The Netherlands. RIKILT carries out analyses of samples taken for official monitoring conducted by the NVWA and provides scientific and technical support to feed testing laboratories (as required under Directive 882/2004/EC). In this capacity, RIKILT conducts or supervises annual proficiency testing involving Dutch and EU laboratories.

5.5 Evaluation of the ruminant feed ban

The effectiveness of the feed ban is evaluated via annual monitoring of animal feed through NVWA programs and through targeted audits conducted by the FVO.

5.5.1 Dutch monitoring programs

The NVWA conducts official monitoring in compliance with Annex IV of the TSE regulation (Regulation (EC) 999/2001). Monitoring is conducted according to a national plan set by the NVWA which directs the type of feed to be sampled, establishments to be sampled (producers, processors, farms, storage facilities and border entry points), and number of samples to be taken. The plan is developed annually and is designed on a risk-based approach. Audits of feed mill establishments are also conducted and these are rotated with priority given to those never inspected and high risk establishments, such as those that handle animal protein (fish meal), under-going more frequent audits.

Results of official monitoring activities demonstrate that sufficient sampling methods are used to determine whether contamination of animal feed with ruminant protein is occurring. Samples are taken from feed establishments every three months by the NVWA and tested at approved laboratories. Under this monitoring, the amount of non-compliant feed in which mammalian material has been detected has been stable or in decline since 1999. If mammalian protein is detected, it is usually trace amounts of bone spicules in feedstuffs containing tuber and root crops, probably originating from rodents or related animals. It has been accepted that this represents negligible risk for BSE transmission in countries with negligible or controlled BSE risk status (Regulation (EC) No 163/2009). In all cases of infringements where mammalian protein was detected, only very small quantities of bone particles were found and no further actions were required.

In addition, monitoring of feed materials has been conducted through the Product Board for Animal Feed which is a statutory agency that operates in partnership with the animal feed industry. The Product Board conducts testing to determine feed composition, digestive properties, and levels of contaminants. Ruminant protein contamination is monitored through a risk-based approach and testing conducted according to EU-approved methods. Since 2010, this scheme is managed by GMP+ International which certifies companies against prescribed standards for feed safety and quality assurance to comply with EU legislation.

Two animal feed manufacturers were reviewed during the in-country visit. Both companies are certified with GMP+ and indicated that their in-house sampling and testing programs for protein or bone fragments was above that required under certification requirements or EU legislation. Samples of each raw material consignment and batches of finished products are retained for at least seven years and analysed by the manufacturer as needed (for example, in response to a recall incident or a customer request).

5.5.2 FVO audits

Regulation (EC) No 882/2004 provides authority to the EU for evaluation of feed ban compliance. The FVO conducts compliance audits based on a risk-based program which is developed annually. The scope of these audits generally covers all stages of the feed production chain, including pre-mixture manufacturers, feed mills, farms, recycling plants converting food products into feed, and entry points (i.e. designated border points where feed

imports are permitted for entry). The most recent audit for The Netherlands was completed in April 2011 and there were no significant issues relating to feed ban controls noted in the audit report.[19]

6 Ante-mortem slaughter controls

6.1 Overview

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

6.2 Legislation

Regulation (EC) No 854/2004 sets requirements to prevent the spread of BSE and ensure traceability of all materials. The Regulation requires slaughtering establishments to have procedures based on Hazard Analysis Critical Control Point (HACCP) principles which are approved and verified by the country Competent Authority (the NVWA). The slaughtering practices of pithing or high-pressure gas injection into the brain are prohibited under Decision 2000/418/EC.

6.3 Ante-mortem procedures

Ante-mortem activities are conducted by official NVWA veterinarians and practitioners, supervised by the NVWA. Post-mortem activities are conducted by official assistants (OA) and supervised by the official veterinarian but employed by the Animal Sector Quality Inspectorate (KDS), an independent organisation contracted by the NVWA. The official veterinarian conducts ante-mortem inspection and is responsible for oversight of all ante- and post-mortem procedures. The number of authorised veterinarians on-site varies depending on the size of the slaughterhouse (i.e., high or low throughput).

Slaughterhouses operate under “Working Instructions” that are developed by the NVWA and these provide procedures to be carried out to ensure that EU regulations for hygiene and food safety are maintained. The official or authorised veterinarian at slaughterhouses must conduct certain checks upon receipt of animals including supplier information and registration, animal welfare and health status, and identification.

Animals must have two ear tags and be registered in the national database to be considered fully identifiable. Animals that do not originate in The Netherlands are accompanied by a bovine passport. Animals that do not meet these criteria upon arrival at the slaughterhouse must be reported to the NVWA official veterinarian who will conduct an investigation and make a determination on action to be taken. If full identification cannot be verified, then the animal is removed from the production chain and processed as Category 1 material.

BSE control measures at ante-mortem inspection also include checks in relation to the age of the cow. Healthy animals aged over 72 months or over 30 months if from new EU Member States (Bulgaria and Romania) are sampled for BSE testing in The Netherlands using the rapid test (See Section 15.3). To facilitate sampling and tracking of carcasses, these animals are generally grouped together on the production chain.

6.4 Handling of BSE suspect cattle

BSE symptoms must be confirmed by the on-site official NVWA veterinarian and suspect animals are removed from the production chain for separate killing and tested for BSE. Fallen stock is removed for destruction at a rendering plant.

Carcasses and by-products from animals: (1) without identification and registration; (2) that are fallen stock and animals showing symptoms of BSE or neurological disease; or (3) that are deemed BSE positive according to the BSE rapid test, are designated as Category 1 materials (see Section 5.2.1) and are killed and removed from the establishment to be destroyed by rendering and incineration. Burial of animals or animal materials is prohibited.

Genuine BSE suspect cattle, as determined by the official veterinarian based on age and symptoms, are removed from the slaughtering premises alive and transported to the CVI for full examination and testing. However, this occurrence would be extremely rare since animals showing BSE symptoms generally would be detected at the farm and not permitted for transport to a slaughter facility.

6.5 Auditing and compliance

The official NVWA veterinarian conducts regular random checks to verify that procedures as specified in “Working Instructions” are implemented and followed. The official veterinarian also reviews information recorded during the ante-mortem inspection to identify inconsistencies and, in particular, to verify that the number of notified cattle is in agreement with the lists of submitted notified animals and total slaughtered animals. The NVWA conducts large official audits of all slaughterhouses at least once per year but may conduct more frequent, unannounced system inspections as needed.

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

7.1 Overview

Post-slaughtering controls are required to ensure that tissues potentially containing BSE infectivity do not enter the animal feed chain. SRM is defined through a categorisation system which permits high risk animal by-products (ABP) to be removed from the production chain and destroyed. SRM is classified as a Category 1 material (see Section 5.2.1) and is processed by rendering and then incineration.

7.2 Legislation

General requirements for post-slaughter controls are covered under the Regulation (EC) No 999/2001 which defines SRM and sets requirements for its destruction. The regulation has been amended several times. More specific procedures related to handling products not intended for human consumption were introduced under Regulation (EC) No 1774/2002 which contained provisions for the classification of risk materials and methods for their isolation and destruction. This legislation was repealed by Regulation (EC) No 1069/ 2009 which expanded controls in areas such as traceability of animal by-products and provided more stringent and harmonised controls, particularly for non-compliance, across Member States.

7.3 Definition of SRM

SRM are tissues that are most likely to contain BSE infectivity from an affected bovine animal. Under the Australian BSE food safety policy[1], SRM are defined 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.

SRM is defined for EU member countries through risk assessments conducted by EFSA and the definition has been modified since the term was first introduced in 1995. The present definition as in Article 3 of the TSE regulation (Regulation (EC) No 999/2001) is shown in Table 3. This definition is in accordance with Australian requirements.

Table 3: Definition of Bovine SRM

From bovines, all ages	• Tonsils • Intestines (from duodenum to the rectum) • Mesentery
From bovines, > 12 months	• Skull (excl. Mandible) • Brain • Eyes • Spinal cord
From bovines, > 30 months	• Vertebral column (excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and the wings of the sacrum) • Dorsal root ganglia

The above definition for SRM is consistent with assignment of BSE infectivity in bovine tissues set by the World Health Organization[20] ,with OIE recommendations on bovine tissues which should not be traded (TAHC[3], Article 11.5.14), and with the definition of SRM set in the Australian BSE food safety policy[1]

The Netherlands has had requirements to remove and destroy SRM since 1997. Up until 2001 when SRM rules were harmonised under EC legislation, SRM was defined as the skull including the brain, eyes, and tonsils of bovines, sheep and goats; the spinal cords of bovines, sheep and goats over 12 months of age; the spleens of sheep and goats of all ages; and fallen ruminants older that one year. Since 2001, these tissues are assigned as Category 1 material and must be destroyed by incineration.

7.4 Post-mortem procedures

Post-mortem procedures are carried out by KDS inspectors under contract by the NVWA to conduct post-mortem tasks including those in relation to BSE controls. As with ante-mortem controls, the NVWA develop “Working Instructions” that give post-mortem procedures specifically in relation to BSE controls. Key points contained in these instructions and confirmed during the in-country visit are summarised below:

- Sampling of the brainstem is handled by KDS that records identification information and removes the obex portion of the brainstem for the BSE rapid test. The results of the rapid test are generally known on slaughter day. If this is not achieved, the

carcass and by-products for that animal are not permitted to leave the premises until a BSE result is known.

- SRM is removed by slaughterhouse employees, stained with dye, and placed in receptacles labelled for Category 1 material. KDS officers inspect at designated control points along the production chain and where SRM have not been completely removed, the carcass will not receive a required health mark and is not released for further processing.
- If a positive BSE test result is obtained, the carcass and by-products are processed as Category 1 material. It is not a requirement that slaughter by-products are traceable to the individual animal, but if by-products have not been isolated for a positive carcass, then the entire batch becomes SRM and is designated Category 1. The head of the positive carcass is sent to the CVI for further investigation.

Post-mortem activities are supervised by the official veterinarians who also conduct periodic and random checks on specific tasks during processing. Only the official veterinarian can decide to condemn a carcass of it does not pass post-mortem inspection.

7.5 Processing of animal by-products

All plants that handle slaughter waste and by-products including renderers, incinerators, composting, traders, storage and biodiesel fuel generators, must be registered and approved by the NVWA. Category 1 and 2 materials are transported using dedicated containers to the registered rendering plant which is located separately from the slaughtering facility. This is the only rendering plant in the Netherlands and it handles destruction of all Category 1 and 2 materials (by incineration) produced in the Netherlands. Delivery and processing of Category 3 materials is physically separate from that of Category 1 and 2 materials which are usually processed together. Rendering conditions (133 °C, 3 bars, >20 minutes, particle size<50 mm) are in line with OIE recommendations and have been required under Dutch law since 1997.

Under EC regulations, transport of Category 1 and 2 materials between EU countries is prohibited unless by special permit issued by the receiving country. The Netherlands does not process Category 1 or 2 materials from other countries.

All animal-derived materials (Category 3) used in further processing are traceable through the Trade Control and Expert System (TRACES) which is detailed in Section 10.

7.6 Evaluation of compliance with legislation

7.6.1 Dutch audit programs

Official controls (ante- and post-mortem inspection, SRM removal) in slaughter establishments are assessed by the NVWA through at least one annual audit as well as systems inspections conducted as required. The results of these assessments are used by the NVWA to determine frequency of additional audits or inspections. In serious cases (which are not common) the NVWA has the authority to suspend the license of the slaughtering establishment.

7.6.2 EU audit programs

EU missions to evaluate official controls are comprehensive and usually involve inspections at multiple sites. The general audit of official controls was last conducted by the FVO in 2007[21]. This was a comprehensive audit of systems in place across the food production chain and included assessment of the operations of the competent authorities. The general conclusion of the audit was that The Netherlands was in compliance with EU official controls.

Compliance with control measures applicable to handling animal by-products (ABP) was last reviewed by an FVO mission conducted in 2010.[22] The audit covered all aspects of handling bovine waste products: collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use and disposal for ABP and derived products. There were no significant issues with regard to processing of Category 1 or 2 materials.

Meat food safety systems were last reviewed by an FVO mission in 2006.[23] No specific issues linked to BSE controls were identified. Overall, the report indicates that there are systems in place to ensure post mortem controls in relation to BSE are effective.

8 Summary: Exposure control

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

- A *total* feed ban in place since 2001 which was preceded by a prohibition on the use of ruminant or mammalian MBM for feeding to ruminants since 1989.
- Regulated processes both at ante- and post-mortem inspection.
- Removal and destruction of SRM in place since 1997.
- Complete separation of ruminant feed lines to minimise risk of cross contamination in feed production in place since 1999.
- Compliance monitoring and sampling procedures conducted through NVWA control programs as well as through EU auditing programs.

Regulated processes both at ante- and post-mortem inspection levels ensure that any diseased and BSE-suspect animals are not processed for the animal or human food supply. Quality systems in place ensure that appropriate slaughtering and processing techniques are employed to minimise cross-contamination of carcasses. Critical controls (e.g. ante-/post-mortem inspection, removal/destruction of SRM) were clearly demonstrated at all slaughtering establishments viewed during the in-country verification inspection. Based on the early enforcement of BSE control measures, the risk of BSE entering and recycling within the bovine feed system or entering the human food supply in The Netherlands is negligible.

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 in The Netherlands.

9 Meat processing

9.1 Legislation

Annex I of Regulation (EC) No 854/2004 sets out food safety requirements for meat which include provisions for (1) responsibilities of the Official Veterinarian in: ante- and post mortem inspection, (2) inspection procedures, (3) removal, separation, and marking of SRM, (4) marking of animals and carcasses with official health mark, (5) documentation of inspection results and decisions, (6) communication of inspection results to operators across the production chain, and (7) qualifications and training of slaughterhouse staff (including official veterinarians).

Additional requirements prohibit the inclusion of ruminant bones in the production of mechanically separated meat (Regulation (EC) No 999/2001) and BSE testing to prevent contaminated meat from entering the human food chain must be conducted according to EC requirements for surveillance (detailed in Section 18).

More generally, Regulation (EC) No 852/2004 Article 5 Part 1 requires that HACCP plans must be properly documented and implemented and Regulation (EC) No 853/2004 sets out more general hygiene requirements for foods of animal origin.

Factories which process meat for human consumption must be registered and approved by the NVWA.

9.2 Procedures to prevent BSE contamination of food

Methods which spread CNS material into tissue destined for human consumption are banned. Specifically, EU legislation prohibits pithing[c] and stunning by use of gas injection into the cranial cavity in bovine animals.

As described in Section 7, carcasses are inspected for removal of SRM by an official veterinarian or KDS inspectors. SRM must be disposed of in such a way that cannot be diverted for food use. Only carcasses which pass inspection for SRM removal receive a health mark which permits them to be further processed.

Head meat (tongues, cheek meat) of animals over 12 months may be harvested, usually at a separate cutting facility. Heads can only be dispatched if eyes are present and undamaged and the frontal shot hole and the *foramen magnum* is sealed by an impermeable, durable stopper. The head is inspected by KDS inspectors before it can be dispatched and if it does

[c] Pithing is the laceration of the CNS by means of an elongated rod-shaped instrument introduced into the cranial cavity after stunning.

not meet specified requirements it is classified as Category 1 material and destroyed. Once useable head meat is removed, the remainder of the head is destroyed as Category 1 material.

All slaughtering procedures and processing are subject to inspection by KDS inspectors and monitoring by NVWA veterinarians.

9.3 Quality assurance systems in The Netherlands

Quality assurance systems or standard-setting schemes such as British Retail Consortium Global Standards (BRC), International Food Standard (IFS), or Safe Quality Food (SQF) are in operation at most slaughtering and meat processing establishments, as verified on the in-country visit. Certification by one of these schemes includes approval of production procedures with government authorities, purchase of raw materials from controlled and certified sources, auditing by government authorities or approved third parties, sampling of raw materials and finished products, chemical, microbiological and animal species analyses, and meeting country-specific requirements.

Some sectors of meat production incorporate quality assurance systems that are integrated across the production chain so that farms and feed producers are also included. Integrated Chain Control IKB is the Dutch national quality system which has been adopted by 90% of the veal production sector. The IKB scheme covers controls across animal welfare, food safety, animal health, and is linked to EC hygiene requirements for food and feed.

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 systems for beef are required under Regulation (EC) No 1760/2000. This legislation mandates that any beef product destined for human consumption must be traceable across the entire production chain including a complete history of the animal from which the product was sourced. The system allows efficient monitoring on the status of imports (and exports) as well as exchange of information on animal health, inspections, and identification and health emergencies.

10.2 Details of the traceability systems

TRACES[24] is a trans-European web-based system that allows exchange of electronic certification and other importation documents between the competent authorities responsible for animal health controls. The system covers imports and exports of animals, animal products (semen, ova, embryos, hatching eggs, and ABP including MBM and material containing MBM, and products of animal origin (fresh meat, meat products, meat

preparations, and milk). The system has been in place since 2004 and usage is mandatory for EU Member States. The system distinguishes trade within the EU, imports from third countries into the EU, and exports to a third country from the EU.

All fresh meat and meat products are traceable from retail to source animal by means of a unique number which is shown as a bar code on the packaging and can be entered into TRACES. The bar code contains production information such as source animal, parent animals, food that was eaten by the animal, and the farm where the animal resided. The bar code number is retained with all carcasses and parts of carcasses during processing. It is possible to electronically trace back and trace forward any meat exported from or sold in The Netherlands within 5 minutes.

11 Recall systems for beef and beef products

EU Member States conduct recalls of animal feed and food products using the Rapid Alert System for Food and Feed (RASFF) which has been in operation since 1979 (electronic since 2002). A full description of the web-based system can be found on the web. (http://ec.europa.eu/food/food/rapidalert/index_en.htm; accessed March 2012)

11.1 Legislation

Regulation (EC) No 178/2002 sets down the legal provisions and requirements for systems to adequately ensure the withdrawal and recall of food or feed products in the event of a food safety emergency.

11.2 Food recall process

RASFF provides a system for reporting food safety issues within the EU. Notifications are sent to the EC and Member States where there may be serious or indirect risks to human health from food or feed. Notifications are issued in several forms and result from border rejections on imports, feed or food testing, consumer complaints, food company notices, or bans on certain foods or ingredients. An “Alert” is the most serious type of notification and is issued when the food or feed presenting the risk is on the market and when immediate action is required.

In practice, the country Competent Authority is responsible for notifying RASFF when a food or feed risk is identified. RASFF in turn circulates notification to EU member countries and third countries that are importing the food or feed and have subscribed to receive notifications for the commodity of concern. There is also a website and a weekly newsletter that can be screened to identify food issues occurring in the EU.

The NVWA is the Competent Authority that provides information to RASFF and monitors and acts on notices forwarded by RASFF. The NVWA is responsible for ensuring that businesses have provisions and procedures in place that enable efficient removal of feed or food from the market if recalled.

In the most serious situations, RASFF would also be informed when an animal is confirmed a positive for BSE. In this situation the NVWA coordinates the response to manage the disposition of meat from feed or birth cohorts that may have entered the food chain.

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

The Chief Veterinary Inspector Department within the NVWA is responsible for coordinating the investigation and response to BSE events. The department is comprised of three units which includes a senior veterinary advisor, a crisis coordinator and the NVWA Incident and Crisis Center (VIC).The VIC performs a number of tasks including handling suspected cases and small outbreaks of notifiable diseases (including food or feed recalls if required), setting preventative measures, training of animal disease officers, conducting risk assessments in connection with disease outbreaks occurring abroad, and developing operational manuals.

The VIC utilises an action plan which sets out the steps that are implemented in the event of a BSE suspect case being identified (Appendix 2). The effectiveness of the action plan is demonstrated by BSE cases discovered in the Netherlands in 2010 and 2011 where characterisation of the disease (classical BSE), identification of cohort animals, and decisions to apply no further control measures were determined within 10 days of the date notifying the suspected outbreak.[5]

13 Summary: BSE food safety controls

Integrated food safety controls are well-established in the Netherlands to allow effective protection of the human food supply from potential BSE contamination. The Netherlands employs stringent food safety controls that meet international standards to prevent BSE contamination of beef for human consumption. This conclusion is based on legislation that ensures good hygienic practices are employed throughout the beef production chain, traceability systems to enable recall of food products, and contingency measures that would be enacted 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. Under Regulation (EC) No 999/2001 for the prevention, control, and eradication of TSE, EU Member States must have programs in place ensuring adequate training for relevant staff and sufficient measures to handle BSE cases should they occur. In general, as detailed in the next sections, The Netherlands introduced many of these programs well ahead of the implementation of the EU regulation.

14 BSE Education and Awareness

Education programs for TSEs have been in place since the 1990s. A formal training program administered by the NVWA is compulsory for official veterinarians and slaughterhouse personnel. Teaching materials provided in the submission demonstrate that programs cover appropriate BSE control areas including TSE regulatory systems, Dutch and EU legislation, incident management; and BSE symptoms, pathology and diagnosis. Official veterinarians and official assistants must pass a final exam on this material as terms of their employment by NVWA and KDS. Additional but not compulsory awareness programs have also been directed at farmers, feed producers, and the food industry.

Regular updated information on TSEs is generally published in *Tijdschrift Voor Diergeneeskunde* which is the official Dutch veterinary journal and is openly accessible to members of the veterinary professional organisation Koninklijke Nederlandse Maatschappij voor Diergheneeskunde (the Royal Dutch Veterinary Association).

The reporting of clinical BSE suspects is one indicator of the improvement in BSE awareness since programs were initiated. In 1990, under-reporting of clinical suspects was an issue (zero clinical suspects reported) but by 1997, when the first Dutch BSE case occurred, numbers of clinical suspects had increased significantly (35 clinical suspects reported). The successful progression of knowledge and awareness around TSEs across the meat production chain was also evident from interviews conducted as part of FSANZ's in-country verification visit. Legislated controls and diagnostic methods are well-accepted and monitoring activities and compliance has become common practice.

15 Disease notification and diagnoses

15.1 Legislation

Notification of suspect BSE cases has been compulsory for farmers and veterinarians under passive surveillance programs since 1990. This legislation was enacted to comply with EU regulations under Directive 1992/450/EC which added BSE to the list of notifiable diseases and ordered that notification of outbreaks would be required until July 1992. The legislation went through a series of amendments to the current regulations prescribed under Regulation (EC) No 999/2001 on the generalised rules for the prevention, control and eradication of TSEs. Articles 12 and 13 of this regulation set out measures to be carried out in response to identification of BSE suspect animals.

15.2 Identification and handling BSE suspects

Any animal displaying behavioural or clinical signs, as described in Article 11.5.21 of the OIE TAHC[3], during ante-mortem inspection are defined as a "BSE suspect". Brain tissue from these animals is tested for BSE as part of the BSE surveillance program as discussed in Section 18 of this report.

Veterinarians or farmers notify NVWA if an animal is displaying BSE symptoms. After notification, an NVWA animal disease expert visits the holding together with the local veterinarian and their assessment is used to decide if the animal is a genuine BSE suspect. If BSE is suspected, the animal is transported alive to the CVI for a full diagnostic investigation. Animal movements on or off the holding are restricted until confirmatory testing and/or investigations are completed.

BSE suspects are also identified through rapid tests on samples from slaughtered animals as part of the BSE active surveillance program. If a positive result is obtained, the slaughterhouse is closed until the NVWA has determined that all parts of the suspect animal have been identified and removed for destruction and the head sent to the CVI for confirmatory testing. Carcasses of other animals (or parts thereof) that may have come into contact with the suspect animal are also removed for incineration. If the carcass or parts of the suspect animal cannot be identified, then all meat, carcasses and animal parts in the whole establishment are classified as Category 1 material and destroyed by incineration. The carcass and slaughter waste of sampled animals may be transferred to processing facilities but processing can only be started once the result of the rapid test is known, usually the next day.

If testing of clinical suspects or sampled animals confirms the presence of BSE, then trace-back procedures are carried out by the NVWA through the Incident and Crisis Center to identify birth or feed cohorts (see Section 12). Animals culled as part of the trace-back are destroyed by incineration.

15.3 Diagnostic methodology

The Central Veterinary Institute (CVI), formerly the CIDC-Lelystad, is the National Reference Laboratory responsible for TSE testing in The Netherlands. The Institute also conducts internationally recognised research in animal diseases and statutory work for the Dutch government for disease diagnosis.

Samples of brain stem tissue from animals targeted for surveillance testing are obtained under supervision of a NVWA official veterinarian at slaughterhouse establishments. Samples are sent to privately run laboratories for analysis using EU-accepted BSE rapid test: currently these are the Prionics (Westernblot) 2000, CEA (Biorad) 2000, IDEXX (Elisa) 2005, or the Roche (ELISA) 2005 tests. The CVI approves and monitors all laboratories authorised to conduct BSE rapid tests.

The CVI conducts all confirmatory testing for clinical suspects or positives identified through rapid tests. Histopathology and immunohistochemistry are used but if the sample is not suitable for these methods, then a western blot is conducted. All methods are in line with OIE recommendations under Chapter 2.4.6 of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2011.*[25]

These sampling and testing procedures have been in place in The Netherlands since the end of 2000.

15.4 Laboratory assurances and auditing

The CVI conducts random inspection visits to all laboratories conducting the BSE rapid test. Inspections cover (1) weekly inspections of rapid test results, (2) ring tests in which comparison of inter-laboratory results is conducted four times per year, (3) examination of positive and negative controls in all assays, and (4) retesting of samples at the CVI laboratories.

The BSE rapid test has been validated by the EU Institute for Reference Materials and Measurements (IRMM) since its introduction in 2001. External assessment of the CVI is conducted by the EU Community reference laboratory (the VLA, Weybridge, UK) or by the IRMM for proficiency and accuracy in rapid tests, histology, immunoassays. Interviews conducted at the CVI during the in-country verification visit confirmed that satisfactory results have been obtained in all external assessments.

15.5 Penalties and reporting incentives

No extra incentive payments are made to farmers or veterinarians for reporting suspected cases of BSE. However, full market value of BSE suspects, BSE-positive animals, and culled animals has been paid to farmers since 1997.

16 Cattle identification and traceability

16.1 Overview

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

A comprehensive cattle identification system has been in place in all EU Member States since 2000.

16.2 Legislation

The chronology of Dutch cattle identification and registration programs, as implemented under EU legislation, is summarised in Appendix 1 (under “Cattle Identification and Traceability”). It is illegal to possess, move, purchase, or sell a bovine animal that is not correctly identified and registered.

16.3 Cattle identification systems

The Department for Animal Registration is responsible for administering the animal identification system (I&R). The Department exists within the National Service for Implementation of Regulations under the Ministry of EL&I.

The main responsibilities of the I&R department are to register holdings for livestock and the issuing of holding numbers (a “UBN”) and to coordinate the issuance of ear tags through contact with farmers and manufacturers of ear tags. The department also handles any failures in the daily reporting, corrections of register entries, and handling queries through the department’s helpdesk. Inspection and compliance with the scheme is handled by the NVWA.

The current system enables traceability of all domestic and imported cattle. Data are communicated to a central electronic register by internet, telephone, or directly through computerised management systems employed at holdings. Data are organised through the UBN and includes holder information, ear tags held by holder, animal information (birth date, sex, mother, and hair colour), arrivals, departures, date of slaughter or death, and import/export information. The system is funded through a basic subscription paid by farmers (€ 33.50 p.a.) and through charges on notifications for births, arrivals, and imports. Yearly entries into the national database are between 12 and 15 million.

16.3.1 Ear tags

Ear tags are allocated by Department for Animal Registration. The conventional format for ear tags in all Member States is a two letter country code followed by up to 12 numeric digits. Cattle are tagged with a double ear tag at birth. The ear tags are generally plastic and contain an individual number which is linked to date and place of birth and other information related to the individual animal (breed, sex, identification code of the mother, identification number of the holding where the animal was born). Ear tags are destroyed at slaughter and cannot be recycled. Ear tag numbers for individual animals are retained with all consignments of meat destined for human consumption to enable full traceability.

16.3.2 Procedures at Holdings

Larger holdings (farms, slaughterhouses) have computerised management systems so that entries for movements or births are automatically transferred daily to the national database. Movements, births and deaths must be transferred to the database within 3-7 days. Lost tags occur occasionally and must be replaced within five days. Loss of both tags is rare but if it occurs, owners have 30 days to conduct an investigation to ascertain identification or the animal must be condemned as Category 1 material.

16.3.3 Passports

A passport is a paper document which must accompany individual animals if moved between Member States. Information on the passport includes the ear tag number, animal details (sex, breed, birth date and genetic dam), complete movement records, and a full animal health history.

16.4 Evaluation and inspection

The NVWA conduct audits of holdings (i.e. farms) to verify that correct identification procedures are in place. Generally 5% of farms are selected each year, either randomly or according to compliance history or risk. Farms that regularly show inconsistencies in animals held compared to database records will undergo further checks with a risk of sanctions if there is not improvement. There are very small numbers of cattle (785 out of 14 million entries to the system in a year) which have left a holding with no destination recorded. Records provided during the in-country verification visit demonstrated that these numbers represent a significant improvement to the system compared to when the I&R system was first implemented.

17 Summary: BSE control programs and technical infrastructure

BSE has been listed as a notifiable disease in The Netherlands since 1990 and government-implemented control programs introduced since that time demonstrates their commitment to prevent the spread of the disease. Government-run education programs, also in place since 1990, have helped raise awareness of the disease amongst farmers, veterinarians, and other cattle handlers, as reflected by the high numbers of clinical suspects reported. High levels of knowledge of the disease were also evident in discussions held at all establishments reviewed during the in-country verification visit. Diagnostic methodology is underpinned by a national reference laboratory that is internationally recognised for expertise in characterising TSEs. Cattle identification systems were first introduced in 1990 and operate effectively with mandatory registration of holdings, identification of individual cattle, a centralised electronic database, and controls to promote compliance, and a demonstrated capability to track and trace animals from birth to slaughter.

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. BSE surveillance points are then calculated annually using the recommendations of Chapter 11.5 of OIE's TAHC[3]. 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 and effectiveness of BSE control measures.

18 BSE surveillance program

Surveillance protocols mandated under Regulation (EC) No 999/2001 requires monitoring of the following populations:

- Testing of all risk animals over 24 months of age (fallen stock, emergency slaughter, and animals with clinical signs at ante-mortem inspection);
- Testing of all healthy slaughtered bovine animals above 30 months of age.

This strategy has been modified twice based on the continuing improvement of the BSE epidemiological situation in a number of European countries including The Netherlands. Firstly, the age limit for testing healthy animals and risk animals was raised to 48 months in January 2009, and then, in January 2011, the age limit for testing healthy animals was raised to 72 months (testing of risk animals remains at 48 months). Both revisions of the surveillance program were authorised by the EC (Decisions 2009/719/EC and 2011/358/EC) and after a favourable risk assessment by EFSA.

Accurate determination of animal age is confirmed by the mandatory animal identification scheme which requires individual ear tag numbers linked to full animal history, as described in Section 16.

From 1990 until 2001, when active surveillance was first implemented, tests for BSE on cattle were only undertaken through passive surveillance based on compulsory notification of suspect cases. Very few positive cases were reported until 1996/97 when awareness campaigns resulted in many more reports of suspect cases. The first case of BSE in The Netherlands was confirmed in 1997. In recent years, reporting of clinical suspects has dropped, reflecting the decreased prevalence of the disease.

Total numbers of cattle sampled and positive results from 1990 to present were provided. As expected, there was a significant increase in the number of BSE positive cases across all population groups in 2001 when active surveillance was introduced (similar results were observed in a number of EU member states when Regulation (EC) No 999/2001 came into force). The peak of BSE positive cases in The Netherlands occurred in 2002 and numbers have declined consistently over recent years.

Under the active surveillance scheme, all subpopulations (healthy slaughter, emergency slaughter, fallen stock) have been sampled at all slaughter facilities and across all age groups since 2001. Testing of clinical suspects is mandatory for all age groups. Representative numbers of animals are sampled from slaughterhouses (nine cattle

slaughterhouses each slaughtering more than 10,000 animals per year[26]) and rendering plants (two until 2002 and only one since 2003).

19 BSE surveillance points data

The OIE-recommended BSE surveillance strategy is a points-based system which sets target values to measure the risk of BSE present in the adult cattle population existing in a country (Articles 11.5.20 -11.5.22 of the TAHC). “Type A” surveillance will allow detection of one BSE case in 100,000 adult cattle and “Type B” surveillance will allow detection of one BSE case in 50,000 adult cattle (at 95% confidence interval). Since the adult cattle population in The Netherlands is greater than 1 million animals, the target for Type A surveillance is 300,000 points, and for Type B, 150,000 points, collected over seven consecutive years. The surveillance program in The Netherlands permits 80,000 to 100,000 points to be obtained in each year. From the submitted data, the total points for the seven year period from 2004 to 2010 were at least 440,280 which exceeds the 300,000 target required for Type A surveillance.

20 Summary: BSE surveillance

For a country such as The Netherlands which has had BSE cases, active surveillance monitors the progress and efficacy of control measures introduced to prevent the spread of BSE infection and, eventually, the eradication of the disease. In this context, BSE surveillance data accumulated by the Netherlands since 2001 demonstrates that Dutch BSE controls (feed ban, destruction of risk materials, and import restrictions) have effectively mitigated BSE risk.

Conclusions and BSE risk categorisation

Control measures to prevent the recycling and amplification of the BSE agent in The Netherlands are rigorous and well-established. This largely has been due to imposed legislated controls in response to the BSE epidemic in Europe. Most control measures are based in EU-wide legislation, introduced in 2001, but some control measures (e.g. feed ban controls) were introduced earlier through nationally coordinated programs and regulations.

The Netherlands imports significant numbers of cattle as well as meat and meat products predominantly from other EU countries or from countries which have been assessed as negligible or controlled risk for BSE. Ruminant-derived protein is not imported or traded on the EU market because of the restrictions on the use of animal by-products and the requirement that high risk material must be incinerated.

Eradication and prevention of BSE has been the over-arching aim across the EU since 2001. Control measures are based on the general principle that materials with the potential to contain prions are prevented from entering the feed or food chain. As a result, stringent measures for SRM removal, ante- and post-mortem inspection at slaughterhouses, and processing and use of ruminant by-products are in place. Effective enforcement of these measures was clearly evident from inspections conducted as part of the in-country verification visit.

The Netherlands has experienced 88 cases of BSE over the past 15 years and, in line with the rest of Europe, numbers of BSE-affected cattle have now dropped to very low numbers: only single cases have been detected annually in recent years out of a population of 3.5 million cattle (all ages). All diagnosed BSE cases (except one born in February 2001) have been cattle born before the ban on feeding animal protein to farmed animals was imposed across Europe in 2001. Furthermore, all BSE cases in The Netherlands were born more than 11 years ago, making The Netherlands eligible for *negligible* BSE risk status under OIE guidelines. Risk management strategies to investigate and respond to BSE cases have been developed and are actively employed to handle cases as they occur. Cases are detected through passive surveillance to identify clinical suspects as well as an active surveillance program that samples representative numbers of cattle sub-populations. Underpinning these strategies are systems that ensure the full traceability of animals through a comprehensive cattle identification program and of animal products through the EU-wide TRACES program. As a result, in all BSE cases, cohort animals from infected farms have been traced, identified and culled.

A significant portion of Dutch beef production and their export market is veal meat which is sourced from animals slaughtered at one year of age or less. These animals are not likely to act as an effective route for BSE transmission. Therefore, veal products imported into Australia would represent a negligible BSE risk.

This assessment concludes that imported beef and beef products sourced from The Netherlands pose a negligible risk to human health. It is recommended, therefore, that The Netherlands be given a **Category 1** for country BSE food safety risk status.

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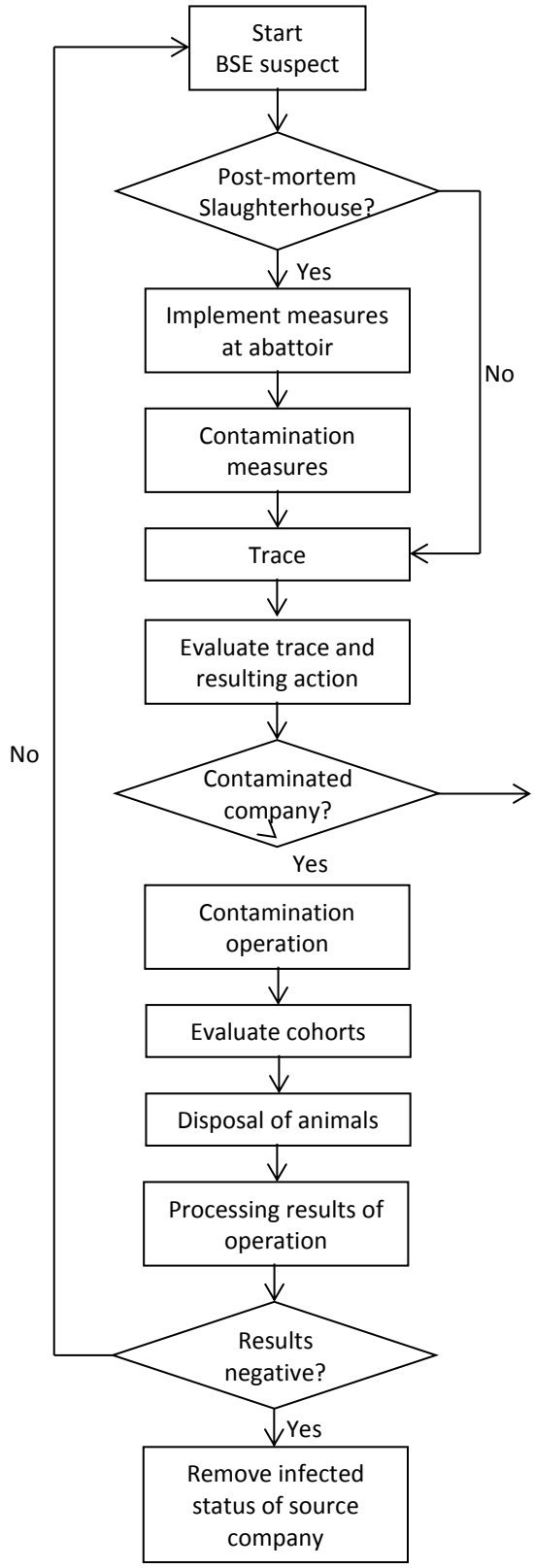
Appendix 1: Key Legislation for BSE Controls

LEGISLATION	CONTROL MEASURES
General	
Regulation (EC) 999/2001	Rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies including: • Definition of SRM • Categorisation of animal by-products (not for human consumption) • Controls for imports of live animals • Adequate training to handle BSE cases • Surveillance • Regulations on intra-community trade for products of animal origin • Restrictions on use of ruminant-derived material
Regulation (EC) No 722/2007	Definition and criteria for the BSE status of Member States (amendment to 999/2001)
Decision 2008/829/EC	Gives list of current BSE status of EU and Third countries
Importation of MBM	
Regulation (EC) No 1069/2009	Import controls on animal by-products
Regulation (EC) No 1774/2002	Certification requirements for animal protein
Importation of Live Cattle	
Regulation (EC) 206/2010	Certification requirements for introduction of live animals or fresh meat from third countries
Importation of Beef and Beef Products	
Directive 2002/99/EC	General animal health rules in relation to introducing products of animal origin for human consumption
Regulation (EC) 722/2007	Requirements for ante- and post-mortem inspection for traded or imported products
Regulation 853/2004	Hygiene rules for food of animal origin including definitions of different types of meat products
Regulation 854/2004	Conditions for trade between Member States for products of animal origin intended for human consumption
Regulation 206/2010	Lists third countries that are eligible to bring in fresh meat into the EU within specific veterinary certification requirements as detailed in this regulation
Pre-slaughter Controls: Feed Ban	
Dutch legislation 1989	Prohibition on the use of ruminant MBM in ruminant feed
Dutch legislation 1990	Prohibition on imports of MBM from the United Kingdom, Ireland, and Switzerland
Dutch legislation 1993	Prohibition on the use of production machinery after it had been used to produce feed containing more than 6% MBM
Dutch legislation 1999	Complete physical separation of ruminant and non-ruminant production lines
Decision 1994/381/EC	Ban on the use of mammalian protein for feeding to ruminants

Decision 2000/766/EC	Total ban on the processed animal protein for use in feed for any farmed animals
Regulation (EC) No 956/2008	Permits the use of fish protein to be used as milk replacers in calf feeds
Regulation (EC) No 163/2009	Allows use of materials of plant origin which contains insignificant amounts of bone spicules due to environmental contamination, but only where a favourable risk assessment has been conducted
Regulation (EC) No103/2009	Prohibits the use of milk and milk products derived from small ruminants for feeding to ruminants
Regulation (EC) No 1069/2009	Categorisation of animal risk material
Regulation (EC) No 152/2009	Sampling methods and preparations for testing feed for animal protein contamination
Directive 882/2004/EC	Official controls for food and feed and requirements for national authorities to carry out official controls
Regulation (EC) No 163/2009	Amendment to Regulation 999/2001 allowing insignificant amounts of bone spicules if there has been a favourable risk assessment
Ante-mortem Slaughter Controls	
Regulation (EC) 854/2004	Slaughtering establishments must procedures based on HACCP principles and approved and authorised by the national authority
Decision 418/2000/EC	Prohibition on the use of pithing or high-pressure gas injection into the brain during slaughter
Post-slaughter Controls: Post-mortem inspection, SRM removal, rendering procedures	
Regulation (EC) No 1774/2002	Rules for collection, transport, storage, handling, processing and use or disposal of animal by-products
Regulation (EC) No 1069/2009	Rules for collection, transport, storage, handling, processing and use or disposal of animal by-products (replacing1774/2002)
BSE Food Safety Controls	
Regulation (EC) No 854/2004	Food safety requirements for meat including inspection procedures and SRM removal
Regulation (EC) No 852/2004	Requirements for use of HACCP and documentation
Regulation (EC) No 852/2004	General hygiene requirements for foods of animal origin
BSE Control programs and Technical Infrastructure	
Dutch legislation 1990	BSE is listed as a notifiable disease
Directive 1992/450/EC	EU requirement for BSE as notifiable disease (amended under Regulation 999/2001)
Cattle Identification and Traceability	
Regulation (EC) No 1760/2000	Requirements for traceability systems for food
Regulation (EC) No 178/2002	Requirements for recall systems to ensure food withdrawal and recall from the market
Dutch legislation 1990	Computerised cattle identification scheme first established which recorded all cattle movements within Dutch herds.
Directive 1992/10/EC	Transfer of all Dutch data into EU system

Regulation (EC) No 820/1997	System established for identification and registration of bovine animals and labelling of beef and beef products by 1 January 2000 (in operation by 1999)
Regulation (EC) No 1760/2000	Specific rules to strengthen 1997 legislation including requirements for a computerised system and traceability for animals and products from third countries.
Regulation (EC) No 911/2004	Specifies requirements for ear tags, passports, and registers for data.

Appendix 2: Schematic of Action Plan in the Event of a Suspected BSE case



Description

BSE suspect animal identified through clinical inspection or post-mortem research. VWA Incident Crisis Centre (VIC) is informed.

VWA veterinarian exercises necessary measures – SRM removal, head of suspect animal sent to NRL.

If NRL determines positive rapid test, company declared “suspect” and government departments are notified.

Conduct tracing to identify cohort animals.

Tracing report prepared by VIC on BSE confirmation testing. Based on results, company declared “infected” and animals removed for destruction.

No – end of process.

Animals are retained at infected company. The NVWA issues written control measures for all live cattle to owner and all involved parties.

Cohort animals are evaluated by NVWA certified expert and value is determined.

Condemned animals transported to designated slaughterhouse.

Cohort animals tested for BSE. Identification and registration systems updated.

If all cohorts test negative, infected status of company is removed.