

BSE Food Safety Assessment Report <u>Sweden</u>

August 2016

Strategic Science, International and Surveillance Section

Food Standards Australia New Zealand

Executive summary

Food Standards Australia New Zealand (FSANZ) is the regulatory authority responsible for conducting Bovine Spongiform Encephalopathy (BSE) food safety assessments of countries that seek to export beef or beef products to Australia under the Australian Government's policy on BSE food safety announced in 2009¹. FSANZ assesses information submitted by applicant countries and supplementary information collected from various sources, and draws an evidence based conclusion on the BSE food safety status of the applicant countries. Information provided by the applicant countries must address the requirements detailed in the *Australian Questionnaire to Assess BSE Risk²* (Australian Questionnaire). The Australian Questionnaire is based on the *Questionnaire for BSE Risk Status Recognition*³ published by the World Organisation for Animal Health (OIE). Importation of beef and beef products into Australia is only permitted from countries which have been assessed by FSANZ and are assigned a favourable BSE risk status of 'Category 1' or 'Category 2'. Countries seeking market access for fresh beef products are subject to an additional assessment of animal quarantine risks conducted by the Australian Government Department of Agriculture and Water Resources.

No classical BSE cases have been reported in Sweden. Sweden recorded one case of Htype atypical BSE in 2006. Sweden was assigned a 'Negligible' BSE risk status by the OIE and the European Union in 2008, and has maintained a "Negligible" BSE risk status.

FSANZ has carried out an assessment of legislative measures concerning the prevention and control of BSE in Sweden, and conducted an in-country assessment to verify the effectiveness of the BSE preventative measures implemented in Sweden. Five main control areas were examined in this BSE food safety assessment report:

- (1) *Import controls* to prevent the release of the BSE agent through imports of live bovine animals, beef and beef products, feedstuffs and related products containing protein of bovine animals.
- (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 cattle and cattle-derived products can be effectively identified and recalled if required.
- (5) **Surveillance programs** to ensure that BSE affected cattle are identified and prevented from entering the feed and food production and supply systems.

BSE specific import controls introduced by the Swedish Government since 1989 have successfully prevented the BSE agent from entering Sweden. In the last eight years live bovine animals traded into Sweden has been limited to Denmark, Finland and Germany. Both Denmark and Finland are countries recognised by the OIE with a "Negligible" BSE risk status. While Germany is recognised by the OIE with a 'Controlled' BSE status, the trade of live bovine animals from Germany was restricted to water buffalos only, and no BSE case has so far been reported among water buffalos in Germany. The inward trade of feedstuffs containing animal protein in the last eight years has been limited to EU Member States and Norway. The inward trade and import of beef and beef products for human consumption in the last eight years was limited to countries recognised by the OIE with either a 'Negligible' or a 'Controlled' BSE risk status. The EU Traces system has been effectively implemented by Sweden and this system registers and traces any live bovine animals and products containing animal protein that are imported into the country. Based on the above, it is considered that live cattle, beef and beef products, and feedstuffs imported/traded into

Sweden in the last eight years presented a negligible risk of introducing the BSE agent into Sweden.

Sweden has had an effective ruminant feed ban in place since 1991. From 2001, processed proteins derived from all animals have been prohibited from being fed to ruminants. Sweden's ruminant feed ban has been effectively implemented through the following measures:

- 1. Ruminant feed is produced on exclusive production lines that prevents possible contamination from feed produced for non-ruminant animals.
- 2. Sweden's slaughtering establishments are subject to comprehensive food safety oversight and are regularly audited by Swedish Government that prevent animals suspected of BSE infection from entering the human food or animal feed chains.
- 3. Animal protein other than milk and milk-based products and those exempt by Regulation (EC) No 999/2001, is banned from being fed to farming animals except fish meal which is only permitted as an ingredient of feed for farmed pig, poultry and fish of different species. Every fish meal consignment is registered under the EU Traces system and monitored by Swedish Board of Agriculture.
- 4. Monitoring and enforcement of the ruminant feed ban in Sweden under a risk-based feed monitoring and testing system has been effectively implemented.

The Swedish Government's robust requirements on cattle slaughterhouses and supervision of the processes of cattle slaughter ensure that potentially BSE infected cattle are prevented from entering the human food supply. This has been achieved through the following measures:

- A dedicated Swedish Government veterinary office staffed with qualified official veterinarians that oversees the operations at Swedish slaughtering establishments.
- Ante-mortem and post mortem inspections are conducted by Swedish Government official veterinarians at all slaughtering establishments.
- Downer animals and BSE suspect animals at slaughterhouses are destroyed with Government oversight.
- All specified risk material and Category 1 materials in Sweden are destroyed by incineration.
- The Swedish National Food Agency conducts risk-based inspections and reviews of quality assurance systems in all slaughtering establishments on a regular basis.

Recall of beef or beef products in the event of a food incident involving beef in Sweden is managed under the Rapid Alert System for Food and Feed of the European Union. All food businesses in Sweden including slaughtering establishments are required to keep product receiving and forwarding information to ensure traceability of beef and beef products. Traceability and recall simulations are conducted regularly by Swedish slaughtering establishments which provide the basis for effective beef recall and trace back in the case of a food incident involving beef. Information placed on the labels of beef and beef products produced and placed on the market for sale in Sweden enables the concerned product to be traced back to the individual cattle farm and/or individual animal.

BSE has been a notifiable disease in Sweden since 1989. Ongoing BSE awareness education programs were introduced in 1994 and are comprehensive, and have reached a

wide range of primary producers and food business operators involved in producing and supplying beef for human consumption.

BSE diagnostic methods applied by the Swedish National Veterinary Institute conform to the methodologies recommended by the OIE. Cattle subject to sampling for BSE diagnosis in Sweden is consistent with the requirements established by the European Union and the OIE.

Sweden's 80 district veterinary offices located throughout the country play a critical role in enabling effective BSE prevention and control in Sweden because of their proximity to farms and slaughtering establishments.

The combination of the registration of animal holdings, identification for individual cattle, the upkeep of a register at each animal holding by primary cattle producers, and the Swedish central cattle registry enables accurate, reliable and rapid tracing of animals if BSE was to occur in Sweden.

Sweden has appropriate contingency plans in place in the event of a feed or food emergency.

Sweden has an ongoing BSE surveillance program, and is currently conducting the OIE specified Type B surveillance. BSE surveillance points accumulated by Sweden in the period of 2001 – 2007 and 2008 - 2014 exceeded the target of OIE specified Type A BSE surveillance and Type B BSE surveillance respectively.

Sweden has comprehensive and well established controls to prevent the introduction into and amplification of the BSE agent within its cattle population that ensure beef and beef products produced in Sweden are safe for human consumption. This BSE food safety risk assessment concludes that imported beef and beef products originating from Sweden are safe for human consumption and recommends the Kingdom of Sweden be assigned **Category 1** status for country BSE food safety risk.

Acronyms

BSE	bovine spongiform encephalopathy
CABs	Swedish County Administrative Boards
CDB	Central database for bovine animals, also named Central Cattle Registry, administered by Swedish Board of Agriculture
EU	The European Union
FBO	Food Business Operator
FSANZ	Food Standards Australia New Zealand
НАССР	hazard analysis critical control point
ISO	International Organization for Standardization
MBM	meat and bone meal
MANCP	Multi-Annual National Control Plan
MUPs	local municipal authorities
NFA	Swedish National Food Agency (<i>Statens Livemedelsverket,</i> abbreviated as <i>SLV</i> in Swedish)
OIE	World Organisation for Animal Health (Office International des Epizooties)
PIMKO	Priorities within and between control areas (<i>Prioriteringar inom och mellan kontrollområden</i> in Swedish).
QA	Quality Assurance
RASFF	EU's Rapid Alert System for Food and Feed
SBA	Swedish Board of Agriculture (Statens Jordbruksverket, abbreviated as SJV in Swedish)
SVA	Swedish National Veterinary Institute (<i>Statens veterinärmedicinska anstalt,</i> abbreviated as <i>SVA</i> in Swedish)
SRM	specified risk material
TSE	transmissible spongiform encephalopathy

Glossary

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

BSE agent is the infectious misfolded protein material, also described as prion which causes BSE.

Processed animal protein refers to animal protein derived entirely from Category 3 material (see section 1.2 of this report for a description on Category 3 material), which have been treated in accordance with Section 1 of Chapter II of Annex X of Regulation (EC) No 142/2011⁴ so as to render them suitable for direct use as feed material or for any other use in feedingstuffs, including pet food, or for use in organic fertilisers or soil improvers. Processed animal protein does not include blood products, milk, milk-based products, milk-derived products, colostrum, colostrum products, centrifuge or separator sludge, gelatin, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, including eggshells, tricalcium phosphate and collagen.

Specified risk material (SRM) The Australian BSE food safety policy defines BSE risk materials as tonsils and distal ileum from bovine animals of any age; brains, eyes, spinal cord, skull and vertebral column of bovine animals over 30 months of age.

Table of Contents

EXECU	TIVE SUMMARY	11						
ACRON	IYMS	v						
GLOSS	ARY	.vi						
INTRO	DUCTION	8						
OVERV	IEW OF SWEDEN'S BSE REGULATORY SYSTEM	9						
BSE HIS	STORY	11						
POTEN	TIAL FOR RELEASE OF THE BSE AGENT THROUGH IMPORTED MATERIALS	12						
1	IMPORTATION OF MBM, GREAVES, STOCKFEED AND PET FOODS	12						
2	IMPORTATION OF LIVE BOVINE ANIMALS	15						
3	IMPORTATION OF BEEF AND BEEF PRODUCTS	16						
4	SUMMARY: POTENTIAL FOR RELEASE OF THE BSE AGENT THROUGH IMPORTED MATERIALS	17						
EXPOS	URE CONTROL	19						
5	PRE-SLAUGHTER CONTROLS: RUMINANT FEED BAN	20						
6	ANTE-MORTEM SLAUGHTER CONTROLS	27						
7	POST-SLAUGHTER CONTROLS: POST-MORTEM INSPECTION, SRM REMOVAL, AND RENDERING PROCEDURES	31						
8	SUMMARY: EXPOSURE CONTROL	33						
BSE FO	OD SAFETY CONTROLS	35						
9	BEEF PRODUCTION SYSTEMS	35						
10	TRACEABILITY SYSTEMS FOR BEEF AND BEEF PRODUCTS	36						
11	FOOD RECALL SYSTEMS	38						
12	SUMMARY: BSE FOOD SAFETY CONTROLS	39						
BSE CO	NTROL PROGRAMS AND TECHNICAL INFRASTRUCTURE	40						
13	BSE EDUCATION AND AWARENESS	40						
14	DISEASE NOTIFICATION AND DIAGNOSES	40						
15	CATTLE IDENTIFICATION AND TRACEABILITY	44						
16	SUMMARY: BSE CONTROL PROGRAMS AND TECHNICAL INFRASTRUCTURE	49						
BSE SU	RVEILLANCE	50						
17	Sweden's BSE surveillance program	50						
18	Sweden's BSE surveillance points data	50						
19	SUMMARY: BSE SURVEILLANCE	51						
CONCL	USIONS AND BSE RISK CATEGORISATION	53						
REFERE	NCES	55						
APPEN	DICES	60						
Арре	NDIX 1:	60						
ORG	ANISATIONAL STRUCTURES OF KEY SWEDISH NATIONAL AGENCIES INVOLVED IN THE ADMINISTRATION OF PREVENTION AND)						
CON	FROL OF BSE	60						
Appe	Appendix 2:							
Cour	NTRIES OF ORIGIN AND AMOUNTS OF BOVINE MEAT IMPORTED INTO SWEDEN BETWEEN 2007 AND 2014	63						
APPE	NDIX 3:	67						
Key I	35E LEGISLATIVE CONTROLS OF SWEDEN AND THE EUROPEAN UNION	67						

Introduction

Food Standards Australia New Zealand (FSANZ) is the Australian Government agency responsible for the development and maintenance of the *Australia New Zealand Food Standards Code*. FSANZ sets a number of joint food standards for both Australia and New Zealand, but is not responsible for setting food safety and primary production processing standards in New Zealand.

On behalf of the Australian Government, FSANZ is responsible for assessing food safety risk of bovine spongiform encephalopathy (BSE), and assigning BSE food safety risk status to countries that seek to export beef or beef products to Australia. FSANZ evaluates BSE food safety risk according to internationally accepted scientific practices for the prevention and control of BSE.

Under the Australian Government's BSE food safety policy introduced in October 2009¹, a country seeking to export beef or beef products to Australia must submit an application to FSANZ in accordance with the requirements set out in the *Australian Questionnaire to Assess BSE Risk²* (the Australian Questionnaire). The application should provide sufficient data and information to describe the country's BSE risk and risk management measures implemented to prevent and control the BSE risk. Data requirements described in the *Australian Questionnaire* are based on the *Questionnaire for BSE Risk Status Recognition*³ published by the World Organisation for Animal Health (OIE). The *Australian Questionnaire* and processing systems in the applicant country.

The food safety assessment across the beef supply chain for BSE risk conducted by FSANZ is comprised of: (a) a desk-based assessment that evaluates information provided by the applicant country; and (b) an in-country verification assessment that verifies the effectiveness of the key BSE prevention and control measures implemented in the applicant country. The desk-based assessment evaluates the applicant country's response to the *Australian Questionnaire*, any information provided as appendices to the applicant country's response to the *Australian Questionnaire*, and any relevant information that is publicly accessible. The latter is represented by data and information published by the applicant country, relevant statistics and audit reports published by the OIE, the European Commission, the United States of America and others, and articles in relevant scientific journals. The in-country verification inspection assesses the competent authority's oversight of BSE prevention and control measures implemented at beef and/or dairy cattle farms, in feed producing establishments, and at cattle slaughtering and rendering establishments in the applicant country.

The Kingdom of Sweden (Sweden) submitted an application to FSANZ for categorisation of Sweden's BSE food safety risk in May 2013. An in-country verification visit was undertaken in October 2015 by FSANZ risk assessment personnel in the major cattle and dairy production areas of Sweden.

This report was prepared based on a review of information provided in the Swedish submissions, the relevant European Union (EU) and Swedish legislation on BSE and transmissible spongiform encephalopathies (TSEs), Sweden's responses to the European Commission's program for monitoring TSEs and for the eradication of BSE and of scrapie, findings of the relevant audit reports prepared by the EU Food and Veterinary Office (FVO), and findings of the in-country verification visit mentioned above.

Overview of Sweden's BSE regulatory system

Prevention and surveillance of BSE in Sweden is managed at three levels, national, regional and local (Table 1).

At the national level, the Swedish National Food Agency (*Livemedelsverket* or *Statens Livemedelsverket*, NFA) controls food safety and ensures beef and beef products available for human consumption in Sweden are safe. NFA develops government policy and regulation on food safety, aligns Swedish national food safety control measures with those of the EU, and monitors the food supply for safety. The Swedish Board of Agriculture (*Jordbruksverket* or *Statens Jordbruksverket*, SBA) controls animal health and cattle identification, and develops policy and regulation to ensure feed available for use in Sweden is safe and monitors the safety of feed. The Swedish National Veterinary Institute (*Statens veterinärmedicinska anstalt*, SVA) hosts the national reference laboratory for TSEs and conducts TSE diagnosis and related risk assessments. Administratively, the NFA, SBA and SVA are national authorities/agencies under the Swedish Ministry of Enterprise and Innovation. The Swedish Ministry of Enterprise and Innovation directs the work of these agencies through providing annual 'letters of directions', appropriate ordinances and legislation. The performance of the NFA, SBA and SVA are reflected in their annual reports, which are submitted to the Swedish Government.

The organisational structures of the NFA, the SBA and the SVA are shown in Appendix 1.

At the regional level, the 21 County Administrative Boards (CABs) control the primary production of food and feed inclusive of the production of food animals to ensure food and feed safety. The CABs fall administratively under the Swedish Ministry of Finance.

At the local level, the 290 local municipal authorities (MUPs) control food establishments and small establishments producing food of animal origin in their respective municipalities to ensure the safety of food. The MUPs also fall administratively under the Swedish Ministry of Finance.

Authority	Responsibilities
National level	
NFA	Controls all slaughterhouses and almost all cutting plants to ensure a safe supply of food of animal origin through policy/regulation and inspection; controls separation and disposal of specified risk material; and hosts Swedish national reference laboratory for food
SBA	Controls animal health, feed safety including safe use of animal by- products, and animal welfare through policy/regulation and inspection; and administers Sweden's central cattle registry
SVA	Hosts the Swedish national reference laboratory for TSE; and conducts risk assessments on behalf of SBA
Regional level	
CABs	Controls primary production of food and feed including animal health and animal welfare at the regional level
Local level	
MUPs	Controls food establishments to ensure a safe food supply at the local level including small establishments where food of animal origin is produced

Table 1: Roles of various Swedish Government authorities in the prevention, control and surveillance of BSE in Sweden

Food recalls in Sweden are managed through the EU's Rapid Alert System for Feed and Food (RASFF). NFA is the RASFF contact point for food recalls and alerts. SBA is the RASFF contact point for feed recalls and alerts⁴.

According to Decision 2007/363/EC of the European Commission⁵, BSE prevention and control in EU Member States falls under the multi-annual national control plan (MANCP) described by Regulation (EC) No 882/2004⁶. The development and implementation of a single integrated MANCP in Sweden is led by a Steering Committee comprised of Director Generals of the NFA, SBA and SVA with inputs from CABs, MUPs, the Swedish National Forensics Centre (*Statens kriminaltekniska laboratorium*, SKL) and the Swedish Surgeon General (Fig 1). The Swedish MANCP directs efforts to control the safety of foods available for sale in Sweden including those imported into Sweden, from primary production to consumption. It also encompasses feed safety, animal health and animal welfare. The Swedish MANCP covers Swedish contingency plans for animal or food-borne disease emergencies, feed and food contamination incidents, and other related human health risks.

Each year, the Swedish Government publishes a report on the MANCP which reports the results of the inspections and analyses conducted by Swedish Government under the MANCP umbrella. The first Swedish MANCP for the period 2007-2009 was submitted to the European Commission in March 2007. The latest Swedish MANCP for the period 2015-2018 is vailable at: <u>http://www.livsmedelsverket.se/produktion-handel--</u>

<u>kontroll/livsmedelskontroll/nationell-plan-for-kontrollen-i-livsmedelskedjan-nkp/</u> (accessed 7 Jan 2016). The Swedish MANCP is updated yearly.





BSE History

In December 2014 Sweden had a cattle population of approximately 1.434 million and approximately 18,200 cattle herds. The average size of the herds varied from 15 (beef herds) to 78 (dairy herds) cattle. The majority of cattle in Sweden are distributed in the southern regions (Fig 2A). Over the last eight years, the Swedish cattle population has remained stable (Fig 2B). The Swedish cattle industry is dominated by dairy production⁷. Approximately two thirds of the beef produced in Sweden is of dairy breeds⁸. Housing of cattle in Sweden is in-doors during winter, and grazing for the remaining months of the year (<u>http://www.nationsencyclopedia.com/Europe/Sweden-ANIMAL-HUSBANDRY.html</u>, accessed 18 Feb 2016).







Fig 2B: Cattle production in Sweden (2006 – 2014)

Source: SBA

Classical BSE is responsible for the large scale BSE epidemic believed to have started in the United Kingdom in the 1980s⁹, and is regarded as the infectious agent causing variant Creutzfeldt Jacob Disease (vCJD) in humans¹⁰. No classical BSE cases have been detected in Sweden.

Atypical BSE occurs spontaneously, infrequently and randomly in cattle of old age worldwide. In contrast to classical BSE, the detection of atypical BSE cases in a country or region does not adversely affect the BSE risk status of that country or region. Sweden recorded one case of H-type atypical BSE in a 12 year-old beef cow in March 2006¹¹.

Sweden and Finland were the first two countries in Europe to be recognised by the OIE¹² and the European Union¹³ with a 'negligible' BSE risk status in 2008.

Source: Statistics Sweden accessed 27 Apr 2015.

Potential for release of the BSE agent through imported materials

Meat and bone meal (MBM), greaves and stock feed of ruminant origin, beef and beef products can be contaminated with and live cattle can be infected by the infectious agent of BSE. The importation into Sweden of products containing proteins derived from ruminants, beef and beef products, and live cattle poses a potential BSE food safety risk to Sweden.

Section 1.1 of the *Australian Questionnaire* requests information on annual volumes of MBM that have been imported into Sweden during the last eight years. Section 1.2 of the *Australian Questionnaire* requests information of live cattle that have been imported into Sweden during the last seven years. Evidence of the country of origin of the cattle must be supplied, as well as the BSE risk status of the exporting countries. Section 1.3 of the *Australian Questionnaire* requests data concerning the origin and annual volumes of beef and beef products that have been imported into Sweden during the last eight years.

This chapter assesses the potential for release of the BSE agent through imported MBM, greaves, stock feed and pet food, live cattle, and commodities of cattle origin into Sweden. It identifies the relevant legislation, certification arrangements, and other control measures that prevent the introduction of the BSE agent into Sweden through imported goods.

1 Importation of MBM, greaves, stockfeed and pet foods

1.1 Overview

MBM of ruminant origin is the primary BSE infectivity source through which cattle have been exposed to BSE in the past. Importation of MBM and feeds containing MBM into Sweden poses a potential risk of introducing the BSE agent into Sweden. As an EU member state, inflow of goods from EU member states, and Norway and Switzerland into Sweden, is described as trade. Inflow of goods from third countries into Sweden is described as imports.

1.2 Legislation

Importation of MBM, greaves, feedstuffs, pet foods, organic fertilisers and soil improvers containing animal protein into Sweden is regulated under various EU and Swedish health rules on animal by-products not intended for human consumption. These health rules regulate the collection, transport, storage, handling, processing, use and disposal of animal by-products not intended for human consumption to prevent such products and their derivatives from imposing a risk to animal health and human safety in Sweden.

To facilitate the segregation and control, animal by-products not intended for human consumption in Sweden are classified into three categories (Category 1 material, Category 2 material, and Category 3 material) according to their relative level of potential risk to animal health and human safety. These categories are briefly described below.

- <u>Category 1 material</u> refers to specified risk material (SRM) for TSE and the entire bodies and all body parts of animals suspected of being infected with TSE according to Article 8 of Regulation (EC) No 1069/2009¹⁴.
- <u>Category 2 material</u> refers to animals that have died or been killed other than being slaughtered or killed for human consumption, and animal products from a country outside of the European Community that failed to comply with EC legislation for their import according to Article 9 of Regulation (EC) No 1069/2009.

• <u>Category 3 material</u> refers to carcasses and parts of animals slaughtered which are fit for human consumption in accordance with EC legislation, but are not intended for human consumption due to commercial reasons according to Article 10 of Regulation (EC) No 1069/2009.

For disposal and use, Regulation (EC) No 1069/2009 defines that:

- Category 1 material must be disposed of as waste through incineration or coincineration, and can be used as a fuel for combustion, or for the manufacture of certain products described under clause 33, 34 and 36 of Regulation (EC) No 999/2001¹⁵.
- Category 2 material must be disposed of as waste through incineration or coincineration, and can be used for the manufacturing of organic fertilisers or soil improvers, composted or transformed into biogas, used as a fuel for combustion, or for the manufacture of certain products described under clause 33, 34 and 36 of Regulation (EC) No 999/2001.
- Category 3 material can be disposed of through incineration or co-incineration, and can be used for the manufacturing of feed for farmed animals, pet food, organic fertilisers or soil improvers, composted or transformed into biogas, used as a fuel for combustion, or for the manufacture of certain products described under clause 33, 34 and 36 of Regulation (EC) No 999/2001.

A full description of the disposal and use of the three categories is found in Article 12, 13 and 14 of Regulation (EC) No 1069/2009.

In Sweden, Category 1 material is destroyed by incineration, Category 2 material is used for biogas production, and Category 3 material is used for production of pet food, or feed for fur animals, or organic fertilisers or soil improvers according to the following Swedish regulations:

- SJVFS 2011:21¹⁶ a Swedish regulation amending Swedish ordinance (SJVFS 2006:84) on animal by-products which can spread contagious diseases to animals, issued by SBA
- SFS 2006:805¹⁷ a Swedish Act on feed and animal by-products, issued by the Swedish Ministry of Agriculture
- SFS 2006:814¹⁸ a Swedish regulation on feed and animal offal, issued by the Swedish Ministry of Agriculture
- SFS No: 2006:1165¹⁹ a Swedish regulation on charges for the official control of feed and animal by-products, issued by the Swedish Ministry of Industry
- SJVFS 2007:21²⁰ a Swedish regulation and general advice on the control of feed and animal by-products, issued by SBA.

Due to its remoteness and prescribed by clause 23 of SJVFS 2011:21, fallen stock in the northwestern part of Sweden are allowed to be buried. The number of cattle in the northwestern part of Sweden represents approximately 2.3 % of the total bovine population in Sweden.

Regulation (EC) No 999/2001 prohibits the import of MBM, greaves, feedstuffs, pet foods, organic fertiliser and soil improvers containing animal protein from countries outside of EU unless the country of origin produces and markets such products at the same level of stringency as those implemented by EU Member States in the production and marketing of animal by-products and their derived products not intended for human consumption.

The above mentioned Resolutions are listed under Appendix 3 to this report.

1.3 Details of imports and trade of MBM, greaves, feedstuff and pet food

Between 2007 and 2014, Sweden received 105,612 tons of MBM, greaves, feedstuff and pet food which contained processed animal protein from five EU Member States and Norway (Table 2). Poultry was the principal animal species from which the processed animal protein was derived in the above imported products. A majority of the above traded products was used for pet food production.

<u> </u>									
Exporting country	2007	2008	2009	2010	2011	2012	20103	2014	Sum
Denmark	69	29	2,015	148	152	10,600	7,944	1,240	22,197
France	0	0	0	54	0	0	0	0	54
Germany	1,075	746	875	1,149	1,293	0	0	140	5,278
Netherlands	4,466	3,607	3,311	3,440	3,267	0	101	3,262	21,454
Norway	1,153	7,778	7,141	10,209	12,560	9,547	588	7,536	56,512
UK	0	0	0	0	0	46	23	49	118
Total									105,612

Table 2: Quantity (tons) and country of origin of products containing processed animal proteins imported/traded into Sweden between 2007 and 2014

Among the above traded products containing animal protein, only those containing processed animal protein (see Glossary for definition of processed animal protein) can be used as pet food or an ingredient of pet food. As a result, products containing processed animal protein traded into Sweden in the past eight years are considered to have posed a negligible risk of introducing the BSE agent.

Although data are not shown in this report, feed and feed ingredients of plant origin from countries outside the EU have been imported into Sweden in the last eight years, and have been used mainly for pet food production. Examples of such imports include soy products imported from Brazil, and hay products from the United States and Iceland. These products posed no BSE risk to Sweden.

1.4 Import control

Import controls preventing the BSE agent from being introduced into Sweden through imported products are managed through inspection and verification at Swedish border inspection posts and under the EU Traces system (http://ec.europa.eu/food/animals/traces/index en.htm, accessed 17 January 2016).

Import into Sweden of food, animal by-products, live animals, feed, and pet food are controlled at Swedish border inspection posts co-administered by NFA and SBA. NFA manages food imports, and SBA manages import of animal by-products, live animals, feed and semen. For each consignment, the inspection is carried out in three steps:

A document check which verifies the country of origin of the imported material, the EU approval of the establishment permitted to export specified commodities to EU Member States, the certification by the competent authority of the country of origin, and the relevant declaration regarding conformance to the TSE requirements prescribed by Regulation (EC) No. 1069/2009¹⁴, Regulation (EC) No 142/2011²¹, Regulation (EC) No 999/2001¹⁵, and other relevant EC and Swedish regulations on TSE.

- 2. An identification check that verifies the identity of the consignment with the reference number on the health certificate issued by the competent authority of the exporting country.
- 3. Physical checks that open the container and inspect the goods, including taking samples for analysis as appropriate.

In addition to the above control measures, establishments producing feed in Sweden that use imported materials containing processed animal protein are required to be approved by SBA. Hygiene in relation to the transportation of such imported materials and compliance with relevant Swedish hygiene requirements and hazard control measures in primary production involving the use of these materials is managed by the CABs. The latter involves inspections, audits and surveillance where samples of compound feed are collected at farm level, and samples of compound feed and imported raw material for feed production are collected at feed-mills. These samples are analysed for the likely presence of MBM by the SVA. The above activities are coordinated by SBA.

1.5 Rendering processes used in source country

Rendering parameters for animal by-products permitted for the manufacturing of pet food or feed for animals or organic fertilisers as defined by Regulation (EC) No $1069/2009^{14}$ are: processing, after reduction in particle size to not more than 50 mm, to a core temperature of more than 133 °C for at least 20 minutes without interruption at an absolute pressure of at least 3 bar.

2 Importation of live bovine animals

2.1 Overview

Importation of live bovines represents a potential BSE food safety risk if imported cattle were sourced from countries where adequate control programs to minimise the risk of BSE exposure have not been put in place.

2.2 Legislation

To prevent animals from entering EU territories carrying infectious diseases such as BSE that affect animal health and human safety, the European Council issued Directive 2004/68/EC²² which establishes the general animal health conditions for the import into an EU territory of live bovine animals, and prescribes the requirements to be fulfilled by a third country that is authorised by the EU to export live bovine animals into EU.

Commission Regulation (EU) No 206/2010²³ and the amending regulations prescribe a list of third countries, territories and regions permitted to export live bovine animals to EU and include the prescribed veterinary certification requirements for the importation.

The above mentioned Resolutions are listed under Appendix 3 to this report.

2.3 Details of imports and trade of live cattle

Between 2008 and 2014, Sweden received a total of 135 live bovine animals from Denmark, Finland and Germany (Table 3), largely for breeding purposes. No live bovine animals have been imported from countries outside of the EU territory during this period.

Both Denmark and Finland are recognised by the OIE as countries with a 'Negligible' BSE risk status. Germany is recognised by the OIE as a country with a 'Controlled' BSE risk status. Only water buffalos have been received from Germany, and no BSE case has been found in water buffalos in Germany. It is unlikely that live bovine animals that have entered Sweden in the last seven years have introduced the BSE agent into Sweden.

Exporting country	2008	2009	2010	2011	2012	2013	2014	Sum
Denmark	8	2	24	20 ^{note1}	32	7	23	116
Finland	0	1	0	0	0	0	0	1
Germany	0	0	0	0	13 ^{note 2}	0	5 ^{note 2}	18

 Table 3: Number and country of origin of live bovine animals imported/traded into Sweden

 between 2008 and 2014

Note 1: 12 of the 20 were bison Note 2: Water buffalos only

Total

2.4 Import control

Import controls to prevent the BSE agent from being introduced into Sweden through imported live bovine animals is managed through inspection and verification at Swedish board inspection posts and under the EU Traces system to ensure their compliance with Council Directive 2004/68/EC²², Commission Regulation (EU) No 206/2010²³ and the amending regulations, as well as the EU traceability requirements. SBA monitors the imports/trades and enters the relevant information of the consignments into the Traces system.

Live bovine animals imported/traded into Sweden are individually identified with ear tags from the country of origin and are also given Swedish ear tags according to the Swedish regulation on marking and registration of bovine animals (SJVFS 2012:33²⁴). Their movements are tracked and recorded on the EU Traces system and Sweden's bovine animal central database (CDB). CDB is also referred as the Swedish Central Cattle Registry.

3 Importation of beef and beef products

3.1 Overview

Importation of beef and beef products represents a potential BSE food safety risk if they are sourced from countries or regions where adequate control measures to minimise the risk of BSE exposure have not been put in place.

3.2 Legislation

Commission Regulation (EU) No 206/2010²³ and the amending regulations prescribe a list of third countries, territories or regions permitted to export fresh meat to an EU territory and the associated certification requirements. Countries exporting beef and beef products to Sweden must comply with European Council Directive 2002/99/EC²⁵ which prescribes the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.

Intra-Community trade of beef and beef products and import of beef and beef products from a third country must comply with the requirements prescribed under Regulation (EC) No 853/2004²⁶ and Regulation (EC) No 854/2004²⁷.

135

The above mentioned Resolutions are listed under Appendix 3 to this report.

3.3 Details of importation and trade of beef or beef products

Data from Statistics Sweden (accessed 18 Jan 2016) indicate that between 2007 and 2014 Sweden imported/received a total of 685,433 tonnes of beef and beef products from 38 countries. This includes 345,787 tonnes of fresh beef (fresh and chilled) (Table A2A of Appendix 2 to this report), 269,562 tonnes of frozen beef (Table A2B of Appendix 2 to this report), 4,653 tonnes of edible offal of bovine animals, swine, sheep, goats, horses, asses, mules or hinnies (Table A2C of Appendix 2 to this report), and 65,431 tonnes of processed (prepared or preserved) meat and offal of bovine animals (Table A2D of Appendix 2 to this report). Countries of origin of the beef and beef products were Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, New Zealand, Norway, Paraguay, Poland, Romania, Russia Federation, Serbia, Slovak Republic, Slovenia, Spain, United Kingdom, United States of America, and Uruguay.

These countries are recognized by the OIE with a 'Negligible' or 'Controlled' BSE risk status except for the Russian Federation and Serbia which do not have an OIE assigned BSE risk status. Importation from the Russian Federation was restricted to a small amount of edible offal of non-ruminant origin classified under the standard international trade classification code (SITC) of 0125. Importation from Serbia was restricted to a very small quantity of shelf-stable processed beef products. Both Russia and Serbia are countries permitted to export fresh meat of prescribed species into EU member states under Commission Regulation (EU) No 206/2010²³. It is noted that both the Russian Federation and Serbia have not reported a case of BSE.

It is considered that there is a very low likelihood that these imports have introduced the BSE agent into Sweden.

3.4 Import control

Import controls to prevent the BSE agent from being introduced into Sweden through imported meat of bovine animals is managed through inspection and verification at Swedish board inspection posts and under the EU Traces system. The NFA monitors the imports and enters the relevant information about the consignment into the Traces system.

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

Sweden has appropriate measures legislated by the EU and the Swedish Government that effectively prevent the BSE agent from entering Sweden via imported products containing proteins of animal origin. The likelihood that the BSE agent has been released into Sweden through importation of live bovine animals or products of bovine origin is low which is supported by the following:

- 1) Import restrictions, border inspection measures, and TSE surveillance measures as legislated under various EC and Swedish regulations on TSE have been effectively implemented
- The inflow of products into Sweden containing processed animal protein for purposes other than for human food in the last eight years has been limited to EU Member States and Norway

- 3) The inflow of live bovine animals in the last seven years has been limited to Denmark, Finland and Germany. Both Denmark and Finland are countries recognised by the OIE with a "Negligible" BSE risk status. Germany is recognised by the OIE as a 'Controlled" BSE status and animals have been restricted to water buffalo; no BSE case has been reported among water buffalo in Germany
- 4) The importation and inward trade of beef and beef products for human consumption in the last eight years was limited to countries recognised by the OIE with either a 'Negligible' or a 'Controlled' BSE risk status except Serbia where a small amount of processed, shelf-stable processed beef products was imported. Serbia has not reported a BSE case
- 5) The EU Traces system registers and traces live bovine animals, beef and beef products and products containing processed animal protein imported/traded into Sweden.

Exposure control

The exposure of cattle to BSE infectivity and the amplification of BSE infectivity within the feed system are minimized 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 effective implementation of appropriate regulatory measures 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 human food production systems
- **Post-slaughter** controls which ensure that potentially infected tissues are removed and do not enter the animal feed and human food production systems.

Scientific evidence^{28, 29, 30, 31} published since the BSE epidemic in the United Kingdom has established that the ruminant feed ban is a critical control measure to prevent the recycling and amplification of the BSE agent in cattle herds. The ruminant feed ban is comprised of: (1) the prohibition of ruminant protein being fed to ruminants; and (2) the elimination of cross-contamination of animal feeds that may bring ruminant protein into cattle feed. Measures to prevent non-ambulatory (downer) cattle from entering the human food and animal feed supply chain form part of the overall control to protect food and feed from exposure to the BSE agent. For countries where BSE has occurred or risk factors for BSE exist, controls should be extended to exclude potentially infectious tissue, i.e. SRM, from contaminating human food products and animal feed.

Controls throughout the beef production chain to prevent the exposure of human food and animal feed to the BSE agent are summarised in Figure 3.





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

5 Pre-slaughter controls: ruminant feed ban

5.1 Overview

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

5.2 Legislation

5.2.1 Ruminant feed ban

In response to the BSE epidemic, the Swedish government prohibited the use of the following materials as ruminant feed or an ingredient of ruminant feed:

- Meat and bone meal of ruminant origin since 1991 (Swedish regulation LSFS 1990:51³²)
- Mammalian protein since 1995 (Swedish regulation SJVFS 1995:25³³) the ban on feeding ruminants mammalian derived proteins was introduced by the EU in July 1994 through Commission Decision 94/381/EC³⁴, and Sweden became a Member State of the EU in 1995
- Processed animal protein since 1 January 2001 (Council Decision 2000/766/EC³⁵ and Commission Decision 2001/9/EC³⁶, Regulation (EC) No 999/2001¹⁵, Regulation (EC) 1069/2009¹⁴ and Regulation (EC) 142/2011²¹, Swedish regulation SFS 2006:814¹⁸ and SFS 2011:419³⁷).

Fallen stock and diseased parts of a slaughtered animal were prohibited from being fed to animals other than fur or zoo animals from January 1986 by Swedish regulation LSFS 1985:35³⁸.

Article 7 of Regulation (EC) No 999/2001¹⁵ prohibits the feeding to ruminants of protein derived from animals. Annex IV of Regulation (EC) No 999/2001¹⁵ extends this prohibition to dicalcium phosphate and tricalcium phosphate of animal origin. The following products of animal origin are exempt from the ruminant feed ban:

- 1. milk, milk-based products, milk-derived products, colostrum and colostrum products
- 2. egg and egg products
- 3. collage and gelatine derived from non-ruminants
- 4. hydrolysed proteins derived from parts of non-ruminants or ruminant hides and skins.

Clause 8 of Annex I of Regulation (EC) No 852/2004³⁹ requires food business operators (FBOs) rearing animals or producing primary products of animal origin to keep records on the nature and origin of feed fed to the animals.

5.2.2 Use of ruminant material for non-ruminant animal feed

Since 1 January 2001, the total feed ban introduced by the EU (Council Decision 2000/766/EC³⁵ and Commission Decision 2001/9/EC³⁶, Regulation (EC) No 999/2001¹⁵, Regulation (EC) No 1069/2009¹⁴ and Regulation (EC) No 142/2011²¹) prohibited the inclusion of processed animal protein in feed for non-ruminant farmed animals except fur animals. Annex IV of Regulation (EC) No 999/2001¹⁵ extends this prohibition to:

1. collagen and gelatine of ruminant origin

- 2. blood products
- 3. hydrolysed protein of animal origin
- 4. dicalcium phosphate and tricalcium phosphate of animal origin other than that produced, sold and used in accordance with the conditions specified in Chapter III and Chapter IV of Annex IV of Regulation (EC) No 999/2001¹⁵.

The following products of animal origin are permitted to be included in feed for non-ruminant farmed animals:

- 1. hydrolysed proteins derived from non-ruminants or from ruminant hides and skins
- 2. fish meal
- blood products derived from non-ruminants produced, sold and used in accordance with the conditions specified in Chapter III and Chapter IV of Annex IV of Regulation (EC) No 999/2001¹⁵.

Milk and milk products are exempt from the above prohibition. Fish meal can be used as an ingredient in feed for pigs, poultry, and fish of different species in Sweden (Regulation (EC) No 142/2011²¹).

A SBA approval is required if ruminants are kept on a farm where pig or poultry feed containing processed fish meal is stored or used according to Section D, Annex IV of Regulation (EC) No 999/2001¹⁵. The SBA's approval is subject to a satisfactory outcome of an assessment that on-farm measures are implemented to prevent such feed being fed to ruminants.

Ruminant material classified as Category 3 material by Regulation (EC) No 1069/2009¹⁴ can be used as an ingredient for pet food and in feed for fur animals in Sweden.

5.2.3 Labelling of animal feed

In Sweden, pig or poultry or fish feed containing fish meal must be labelled with '*Detta foder kan innehalla animalisket protein! Fodret far inte anvandas for utfodring av idisslare*'. In English, it reads "*This feed may contain animal protein! The feed is not allowed to be fed to ruminants*". This label captures the essence of the labelling requirement specified under Section A of Chapter IV of Annex IV of Regulation (EC) No 999/2001¹⁵ where any packaging of feedingstuffs containing fishmeal must be clearly marked with the words 'contains fishmeal — shall not be fed to ruminants'.

5.2.4 Controls on the manufacture of animal feed

Regulation (EC) No 999/2001¹⁵ prescribes that feed for ruminants must be produced at establishments that do not process animal protein or produce or store feed containing fish meal. Under exceptional circumstances, Swedish establishments producing feed containing fish meal may be approved by SBA to produce feed for ruminants. However, the process lines in these establishments must be strictly separated to prevent contamination of ruminant feed by fish meal. A satisfactory outcome of an official audit conducted by SBA is a pre-requisite of the SBA approval.

Regulation (EC) No 183/2005⁴⁰ prescribes conditions and arrangements that ensure traceability of feed, conditions and arrangements for registration and approval of establishments producing, storing or supplying feed. Feed producers must establish and apply a safety management system based on the Hazard Analysis and Critical Control Points (HACCP) principles to ensure that feed is produced in accordance with good hygiene practice to prevent, eliminate or minimise the contamination by hazards that can potentially

compromise feed safety. Consistent with the requirements of Regulation (EC) No 183/2005⁴⁰, SBA issued a regulation and guideline on the production of animal feed in Sweden (SJVFS 2007:21²⁰), and maintains a list of approved and registered feed businesses operating in Sweden. The penalty for violation to the rules set up for the ruminant feed ban is limited to fines according to the Swedish Act on feed and animal by-products (SFS 2006:805¹⁷).

Commission regulation (EC) No 152/2009⁴¹ prescribes the sampling regime and methods of analysis for animal feed.

5.2.5 Import controls

Importation of MBM, greaves, and stockfeed, pet foods, organic fertiliser and soil improvers containing processed animal protein into Sweden is regulated by Regulation (EC) No 999/2001¹⁵, Regulation (EC) No 1069/2009¹⁴ and Regulation (EU) No 142/2011²¹, and Swedish regulation SFS 2006:814¹⁸, SFS No: 2006:1165¹⁹, and SJVFS 2007:21²⁰.

Regulation (EC) No 1069/2009¹⁴ and Commission regulation (EU) No 142/2011²¹ prohibit the import of MBM, greaves, and feedstuffs, pet foods, organic fertiliser and soil improvers containing processed animal protein from countries outside of the EU unless the country of origin produces and markets such products at the same level of stringency as those implemented by EU Member States.

The above mentioned Resolutions are listed under Appendix 3 to this report.

5.3 Production of ruminant feed

Production of feed in Sweden is guided by the guidelines issued by SBA (SJVFS 2007:21²⁰) which approves and registers feed production establishments upon satisfactory outcomes of audits, and monitors feed manufacturer's compliance with ruminant feed legislation and guidelines. Fish meal is the only permitted protein of non-plant origin that can be used as an ingredient in feed for pig, poultry and fish in Sweden.

In 2014, there were 25 feed mills producing ruminant feed in Sweden. Among them, three produced ruminant feed exclusively. The remaining 22 produced feed for multiple species of farmed animals. Ruminant feed was produced on dedicated production lines in all 22 feed mills.

The FSANZ in-country verification inspection to Sweden observed the operation of a large feed mill located in the southwest of Sweden. The feed mill produced feed for multiple species including ruminants. It had a dedicated production line for ruminant feed production (plant 1, pellet mill A, labelled green colour). Dosing, crushing and mixing of fish meal were carried out at plant 2 and on pellet mills B, D and E (labelled red colour) which were dedicated to the production of feed for piglets. The biosecurity controls implemented by the feed mill require that ruminant feeds produced at the establishment contain no MBM, meat meal, bone meal, blood meal, fish meal or poultry offal meal. This was achieved through controls on: (1) the formulation of the feed; (2) purchasing of the raw materials; and (3) producing ruminant feed on a dedicated production line. New ingredients and new suppliers of raw materials were subject to risk analyses conducted by the feed mill. The risk analysis includes an audit of the quality assurance system of the supplier and a certification of the HACCP system implemented by the supplier. This feed mill was approved and registered with SBA.

It was observed that fish meal used to produce feed for piglets at the feed mill was sourced from a Danish supplier which was audited and certified for good manufacturing practice in

fish meal production by the feed mill. Shipments of fish meal were monitored under the EU Traces system and relevant shipment documentation was certified by the competent authority of Denmark and forwarded to SBA for verification and recording into the Traces system.

To verify compliance with the ruminant feed ban, samples were taken from every batch of delivered raw ingredients at loading and from finished feeds throughout the production, storage and dispatch phases. Sample analysis was conducted by SVA. The dispatch of every batch of animal feed containing fish meal was accompanied with a comprehensive delivery document which contained the SBA approval number of the feed mill, and an instruction of '*Detta foder kan innehalla animalisket protein! Fodret far inte anvandas for utfodring av idisslare*'. In English, it reads '*This feed may contain animal protein! The feed is not allowed for feeding ruminants*'. The delivery documents issued by the feed mill contain a declaration by the feed mill that the analysis of the feed was in accordance with the ruminant feed ban regulations. Feed produced at the feed mill was transported by specialised delivery trucks in accordance with relevant requirements on feed transportation prescribed by Regulation (EC) 183/2005⁴⁰. Each shipment of feed was lodged with an on-truck computer system which would notify the SBA, the feed mill, the receiver and external stakeholders including RASFF in an event of a crisis, for example if the feed were contaminated with *Salmonella*.

The feed mill was certified for ISO9001 and ISO14001 accreditations. SBA conducted regular audits at this feed mill, and the latest SBA audit occurred on 27 August 2015 with official sampling. Risk-based self-audits were conducted once a year by the feed mill. Other inspections and audits included those conducted by MUPS on food related inspections of silos used for grain storage, external organisations for organic certification and ISO certification audits. Tracing back finished feed from the farm to production and to raw ingredients was managed by the feed mill's information management system. Practice feed recalls were conducted regularly.

5.4 Evaluation of the ruminant feed ban

Sweden has implemented a combination of control measures to ensure that the ruminant feed ban is effective. The combination of control measures is represented by the following components:

- A total feed ban that prevents the feeding of mammalian proteins to ruminants (see section 5.4.1)
- All ruminant materials not intended for human consumption are destroyed, preventing the recycling of the BSE agent (if present) within Sweden (see section 5.4.2);
- An audit, approval and registration system operated by SBA that establishes the official supervision of activities involved in the production and sale of animal feed (see section 5.4.3);
- A risk-based surveillance system operated by SBA that systematically inspects businesses producing or handling animal feed (see section 5.4.4); and
- An inspection framework operated by SBA and CABs that monitors the effectiveness of the ruminant feed ban at feed mills and animal farms (see section 5.4.5).

5.4.1 The Total feed ban

To protect ruminants from exposure to feed potentially contaminated with the BSE agent, the EU introduced a ban on the feeding of processed mammalian animal protein to cattle, sheep and goats in July 1994 (Commission Regulation 94/381/EC³⁴). The ban was expanded in January 2001 to prohibit processed proteins of all animal species from being fed to any

farmed animals (Council Decision 2000/766/EC³⁵ and Commission Decision 2001/9/EC³⁶, and Regulation (EC) No 999/2001¹⁵). This expanded ban is described as the total feed ban. It sets a zero-tolerance level for the BSE agent in feed because cattle could be infected by as little as 1 mg of infectious tissue in their feed (Wells et al., 2007⁴²). The total feed ban prevents the intentional or unintentional inclusion of ruminant protein in ruminant feed.

Clause 8 of Annex I of Regulation (EC) No 852/2004³⁹ requires FBOs rearing animals or producing primary products of animal origin to keep records on the nature and origin of feed fed to the animals.

As a Member State of the EU Sweden implemented the total feed ban from 2001. Fishmeal is exempt from the total feed ban, but can only be used in pig, poultry or fish feed.

5.4.2 All ruminant materials not intended for human consumption are destroyed

Described in Section 1.2 of this report, all ruminant materials not intended for human consumption either generated within Sweden or imported into Sweden, are destroyed by incineration or co-incineration, and can be used as a fuel for combustion.

5.4.3 Official supervision of activities involving production and sale of feed

Prescribed by Regulation (EC) No 183/2005⁴⁰, all feed businesses engaged in the production and/or sale of feed additives, premixes and compound feed containing feed additives in Sweden must be registered and/or approved by SBA. The SBA approval is subject to a satisfactory outcome of an on-site inspection/audit conducted by SBA. The approval and registration may be suspended or revoked if the establishment fails to fulfil the conditions applicable to its activity or has serious deficiencies.

5.4.4 Sampling and analysis of feed samples

The analysis of ruminant feed for the presence of processed animal protein plays a vital role in monitoring the effectiveness of the ruminant feed ban. SBA regulation SJVFS 2014:7⁴³ prescribes the frequency of official inspection for businesses engaged in the production, import, storage and sale, transportation of animal feed, and businesses engaged in the handling, storage, processing including destruction of animal by-products not intended for human consumption. Taking samples is a part of the official inspection. The frequency of official inspection is determined by:

- The risk category of the product involved (1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 where 1 represents the highest risk category, and 10 represents the lowest risk category)
- The rating of the experience of the business in handling animal feed and/or animal by-products (AAA, AA, A, B, C, D and E where AAA represents the highest and E represents the lowest rating of experience)
- A volume factor that reflects the volume of animal feed and/or animal by-products handled by the businesses (0.25, 0.50, 0.75, 1, 2 and 3).

The number of official annual inspections for a business handling animal feed or animal byproducts is determined by the product of the basic frequency of official inspection per year (Table 4) and the volume factor (Tables 5A and 5B).

Table 4: Basic frequency	of official inspection per year to a business involved in handling	g
animal feed or animal by-	product	-

Risk Category of the Product			Experience	Rating of th			
	AAA	AA	A	В	С	D	E
1	*	*	*	*	*	*	*
2	1/2	1	2	3	4	5	6
3	1/3	1/2	1	2	3	4	5
4	1⁄4	1/3	1/2	1	2	3	4
5	¹ / ₅	1⁄4	1/3	1/2	1	2	3
6	¹ / ₆	¹ / ₅	1⁄4	¹ / ₃	1/2	1	2
7	¹ / ₇	1/6	¹ / ₅	1⁄4	¹ / ₃	1/2	1
8	¹ /8	¹ / ₇	1/6	¹ / ₅	1⁄4	¹ / ₃	1/2
9	1/9	1/8	¹ / ₇	1/6	¹ / ₅	1⁄4	¹ / ₃
10	1/10	1/9	1/8	¹ / ₇	1/6	1/5	1⁄4

* Where the frequency of inspection is under specific consideration. For example businesses approved to manufacturing medicated animal feed are inspected at least once a year regardless of the volume factor.

For example, a business producing 60,000 tons of compound feed for food producing animals per annum is qualified with a volume factor of 2 (Table 5B) and a risk category of 7 (according to Table 1 of SJVFS 2014:7⁴³). In its first year of operation (corresponds to an experience rating at E), the frequency of inspection per year is 2, being 1 (basic frequency of inspection per year) x 2 (volume factor). It means that this business would receive two official inspections by SBA in its first year of operation and samples are taken for analysis as part of the official inspection.

Volume Factor	Volume handled (ton/year)*					
	Animal by-produc	ts (raw materials)	Feed additives and premixes			
	Wet weight**	Dry weight				
0.25	<u><</u> 10,000	<u><</u> 20,000	<u><</u> 10,000			
0.50	10,001 – 20,000	20,001 - 40,000	10,001 – 20,000			
0.75	20,001 – 30,000	40,001 - 60,000	20,001 - 30,000			
1	30,001 - 40,000	60,001 - 80,000	30,001 - 40,000			
2	>40,000	>80,000	>40,000			

Table 5A: Volume factor for businesses handling feed material, feed additives, and premixes

Note: * Volume handled applies to import, or production, or sale; ** Refers to brewers grain, silage etc.

In Sweden, analysis of ruminant feeds for the likely presence of animal proteins is carried out by SVA. SVA employs a microscopic method for the screening animal protein in a feed sample in accordance with Commission Regulation (EC) 152/2009⁴¹. If animal proteins are found, a polymerase chain reaction (PCR) method is then applied to identify the species of the animal from which the protein is derived.

Table 5B: Volume factor for businesses handling compound feed

Volume Factor	Volume handled (ton/year)*					
	For food producing animals	For pet or fur animal				
0.25	<u>≤</u> 1,000	<u><</u> 50				
0.50	1,001 – 5,000	51 – 100				
0.75	5,001 – 10,000	101 – 500				
1	10,001 – 50,000	501 – 1,000				
2	50,001 - 100,000	1,001 – 10,000				
3	>100,000	>10,000				

Note: * volume handled applies to import, or production, or sale.

5.4.5 Surveillance of feed mills and animal farms by competent authorities

Table 6A provides a summary of official inspections carried out by SBA at feed mills between 2009 and 2014. Column 4 of the table lists the number of feed mills officially inspected by SBA per annum. Samples were taken from almost all the officially inspected feed mills. Visual inspections conducted at the feed mills may or may not involve taking samples of feed.

Year	Type of	No of	No of plants	Total number of	No of plants	No of plants	No of plants in (C)
	plant	plants	in (A)	visual inspections	in (B) with	in (B) with	with positive test
		-	inspected	in (B)	infractions	sampling	outcomes ^{Note 1}
		(A)	(B)			(C)	
2009	Ruminants only	0	0	0	0	0	0
	Multi species	49	39	103	0	39	0
2010	Ruminants only	0	0	0	0	0	0
	Multi species	49	37	92	0	37	0
2011	Ruminants only	0	0	0	0	0	0
	Multi species	49	22	55	0	21	0
2011	All	49	22	55	0	21	0
2012 ^{Note 2}							
2013 ^{Note 3}	Ruminants only	2	2	5	0	2	0
	Multi species	18	13	31	0	12	0
2014 ^{Note 3}	Ruminants only	3	0	0	N/A	N/A	N/A
	Multi	22	14	45	0	12	0

Table 6A: Findings of official inspections for Swedish feed mills between 2009 and 2014

Note 1: Positive test in this table refers to detection of protein from land animals in a feed or a feed ingredient at a feed mill Note 2: Data not provided due to transition to a new format of reporting to the OIE

Note 3: Data refers to those plants that produced ruminant feed

Table 6B presents a summary of the number of feeds and feed ingredients sampled and analysed between 2008 and 2014. Minor infractions were found between 2008 and 2011. One sample took in 2008 (see note 1 under Table 6B) found traces of materials from land animals in an ingredient imported from Poland. It was notified to the RASFF system.

	Feed materials		Compound feed for ruminants		Compound feed for non-		
Year	No of samples taken	No of infractions	No of samples taken	No of infractions	No of samples taken	No of infractions	
2008	175	1 ^{Note 1}	225	0	356	2 ^{Note 4}	
2009	83	6 ^{Note 2}	192	0	324	2 ^{Note 4}	
2010	66	0	130	0	298	2 ^{Note 3}	
2011	35	0	196	0	124	3 ^{Note 4}	
2012	78	0	112	0	120	0	
2013	50	0	47	0	41	0	
2014	35	0	33	0	42	0	

Table 6B: Samples of feed material analysed between 2008 and 2014

Note 1: Traces of material from land animals were found in sugar beet feed material originated from Poland, and RASFF was notified.

Note 2: Traces of fish meal found in three different feed ingredients (corn, corn meal and rape seed expeller)

Note 3: Fish meal found in feed for laying hens for the reason that fish meal was not an ingredient.

Note 4: Fish meal found in pig feed for the reason that fish meal was not an ingredient

In addition to inspections conducted by SBA, CABs conduct official inspections of feed mills and animal farms as part of their function of controlling primary production of food and feed. The official inspections conducted by CABs involve sample collection. Analysis of the collected samples is conducted by either SVA or local laboratories. These inspections and surveillance activities conducted by SBA and CABs monitor the compliance with the ruminant feed ban.

6 Ante-mortem slaughter controls

Ante-mortem inspection removes potentially diseased animals from entry into the slaughtering lines that produce meat for human consumption.

In Sweden, the NFA is responsible for the official control of all slaughterhouses and cutting plants except some of the cutting plants in Stockholm and Gothenburg where the MUPs are responsible for the official controls⁴. The official controls involve inspection, approval, registration and audit. Every registered slaughtering establishment in Sweden has a permanent NFA veterinary office that is staffed by official NFA veterinarians.





According to Year Book 2014 published by SBA, Sweden produces approximately 133,000 tons of beef each year. Less than 5% of the beef produced in Sweden is exported. The major export destinations are Denmark, Finland and Germany (Fig 4).

6.1 Overview

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

6.2 Legislation

The operation of slaughterhouses and cutting plants in Sweden is governed by requirements prescribed under Regulation (EC) No 852/2004³⁹, 853/2004²⁶ and 854/2004²⁷, and Swedish Food Act SFS 2006:804⁴⁴ as described below.

Regulation (EC) No 854/2004²⁷ establishes the guidelines for inspection, approval and withdraw of the approvals, registration, and audit of establishments that produce products of animal origin to ensure the hygiene and safety of meat and meat products. It prescribes antemortem inspection procedures and FBO's obligations in producing meat for human consumption. The Regulation requires Sweden's competent authority to maintain up-to-date lists of approved establishments, with their respective approval numbers and other relevant information, and make them available to other EU Member States and the public. Chapter V of Section II of Regulation (EC) No 854/2004²⁷ prescribes that meat derived from cattle that have not undergone ante-mortem inspection be declared unfit for human consumption.

The Swedish Food Act (SFS 2006:804⁴⁴) charges NFA with the responsibility to authorise the operation of slaughterhouses including the approval and registration.

SECTION III of Annex II of Regulation (EC) No 853/2004²⁶ prescribes specific requirements on food chain information in receiving animals for FBOs operating slaughterhouses. The FBOs must request, receive, check and act upon the following food chain information in respect of cattle sent or intended to be sent to the slaughterhouse:

- The FBO must not accept cattle onto the slaughterhouse premises unless they have requested and been provided with relevant food safety information contained in the records kept at the origin of the cattle
- The FBO must be provided with the above information no less than 24 hours before the arrival of cattle at the slaughterhouse
- The relevant food safety information referred in the above includes:
 - ✓ The animal health status of the origin of cattle
 - ✓ The health status of the cattle to be received
 - Veterinary medicinal products or other treatments administered to the cattle within a relevant period together with their dates of administration and withdrawal periods
 - ✓ The occurrence of diseases that may affect the safety of beef
 - ✓ The results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the cattle or other samples taken to diagnose diseases that may affect the safety of beef
 - Relevant reports about previous ante- and post-mortem inspections of cattle from the origin of the animals
 - ✓ Production data, when this might indicate the presence of a disease
 - ✓ The name and address of the private veterinarian provide veterinarian services to the establishment the cattle originated from
- Upon deciding to accept cattle onto the slaughterhouse premises after evaluating the relevant food chain information, the FBO must make it available to the official veterinarian without delay. The FBO must notify the official veterinarian of any information that gives rise to health concerns before ante-mortem inspection of the cattle concerned

Section II of Annex II of Regulation (EC) No 853/2004²⁶ prescribes that each animal or, where appropriate, each lot of animals accepted onto the slaughterhouse premises:

- Must be properly identified
- Must be accompanied by the relevant information from the place of origin
- Does not come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health, except when the competent authority so permits
- Is clean

- Is healthy
- Is in a satisfactory state as regards welfare on arrival at the slaughterhouse.

Annex I of Regulation (EC) No 854/2004²⁷ prescribes that:

- The official veterinarian is to carry out an ante-mortem inspection of all cattle before slaughter
- The inspection must take place within 24 hours of arrival at the slaughterhouse and less than 24 hours before slaughter
- Ante-mortem inspection must determine whether there is any condition which might adversely affect human or animal health and particular attention must be paid to the zoonotic diseases and diseases listed by the OIE.

Regulation (EC) No 852/2004³⁹ establishes general requirements of food hygiene for food business operators.

Chapter 3 of the SBA regulation SJVFS 2012:27⁴⁵ prescribes that cattle that have been injured during transportation or upon arrival at the abattoir shall be put to death immediately after arrival at the abattoir. This applies also to cattle displaying signs of illness, and to weak or non-weaned animals.

6.3 Ante-mortem procedures

In Sweden transportation of cattle is restricted to a maximum of eight hours. The movement of cattle including receiving of cattle by slaughterhouses and outgoing cattle from cattle farms is notified to the SBA within seven days of the movement. Cattle arriving at the slaughterhouses without ear tags are destroyed and their remains disposed of by incineration unless the cattle owners provide sufficient information about the cattle and can identify the ear tag within 24 hours.

The NFA official veterinarians stationed at slaughtering establishments conduct ante-mortem inspections in accordance with Regulation (EC) No 854/2004²⁷ and guided by SBA regulation SJVFS 2012:27⁴⁵. The FBOs ensure that fallen cattle are collected and their bodies are disposed of as Category 1 material.

The above processes were observed to be operating effectively by FSANZ risk assessors during the verification visit in which two Swedish slaughterhouses were inspected.

Cattle identification numbers (ID) are linked to slaughter numbers used by slaughterhouses in Sweden. Slaughterhouses use cattle ID to verify the age of the cattle. The identities of the cattle slaughtered are cross-checked with information stored in the CDB database.

Regulation (EC) No 1760/2000⁴⁶ prescribes that whenever an animal is moved, it shall be accompanied by its passport which is issued by the competent authority of the Member State within 14 days of the notification of the birth of the animal. It is noted that cattle passports aren't used in Sweden because the national database for cattle identification, i.e. the CDB system administered by SBA, has been approved for this purpose by the European Commission Decision 1999/693/EC⁴⁷.

The two slaughtering establishments inspected by FSANZ risk assessors had good compliance with above ante-mortem procedures, including the records kept for ante-mortem inspections conducted.

6.4 Slaughtering methods

In accordance with Regulation (EC) No 1099/2009⁴⁸ and SBA regulation SJVFS 2012:27⁴⁵, cattle are stunned by captive bolt stunners in Sweden. A bullet gun can be used under specific conditions. It was observed in two slaughtering establishments inspected that stunning was carried out with a pneumatic bolt stunning gun.

After splitting the carcass, one of the ear tags is placed into a plastic bag and pinned to the right half of the carcass to assist identification and tracing of the carcass.

Only cheek meat and the tongue are harvested from the head. The remaining head is disposed of as Category 1 material. The spinal cord is removed and also disposed of as Category 1 material. Vertebral column is removed during cutting and deboning, and disposed of as Category 1 material.

The slaughtering process is supervised by NFA officials.

The FSANZ in-country verification inspection found good compliance with the above slaughtering controls in the two Swedish slaughtering establishments visited. The inspection team noted a high level of supervision by NFA veterinarians on the quality control system at the two establishments throughout the slaughtering process.

6.5 Handling of BSE suspect cases

BSE has been a notifiable disease in Sweden since 1989 under the Swedish Act of Epizootic Diseases (SFS 1999:657⁴⁹).

Article 11 of Regulation (EC) No 999/2001¹⁵ prescribes that EU Member States shall ensure that any animal suspected of being infected by TSE is notified immediately to the competent authorities. EU Member States shall regularly inform each other and the Commission of the cases of TSE notified. It prescribes that any animal suspected of being infected by TSE shall be either placed under an official movement restriction until the results of a clinical and epidemiological examination carried out by the competent authority are known, or killed for laboratory examination under official control. The notification applies to all animal owners, veterinarians, and anyone who is responsible for the animal.

In accordance with SJVFS 2010:9⁵⁰ and its amendment (SJVFS 2013:3⁵¹), the following animals are sampled for BSE test at slaughterhouses in Sweden:

- All cattle suspected of BSE
- Fallen and emergency slaughtered cattle of Swedish origin >48 months of age
- Fallen and emergency slaughtered cattle of non-Swedish origin >24 months of age
- All healthy slaughtered cattle over 30 months of age of non-Swedish origin.

At slaughterhouses, cattle with clinical signs suggestive of BSE infection are identified by NFA official veterinarians through ante-mortem inspections Downer animals and BSE suspect animals are destroyed by FBOs. The bodies of the dead animals are collected by businesses specialised in the destruction and disposal of dead animals. Brain stem samples are taken either by the slaughterhouses or by the business disposing the body of the dead animal and sent to SVA for BSE testing. For imported cattle over 30 months of age of non-Swedish origin that are slaughtered, brain samples are always sampled and sent to SVA for BSE testing.

Brain stem samples from slaughterhouses are accompanied with an ear tag taken from the source animal and a completed referral form for TSE examination (form code SVA23806-1) prescribed by SVA. The form describes the reason behind the sampling (due to ante-mortem inspection, or destruction/autopsy, or increased sampling of healthy slaughtered animal or emergency slaughter), date of the slaughter, date of sample taken, slaughter number and cattle identification number. Such samples are usually transported to the BSE diagnosis laboratory by the Swedish postal service. Sample test results are usually returned within two days if the result is negative. SVA notifies the slaughterhouses or dead animal body disposal businesses the result of the diagnosis via a formal report which quotes the cattle ID and slaughter number.

The FSANZ in-country verification inspection found good compliance with the system for the detection and processing of BSE suspect cases and sampling of animals for BSE test at the two slaughtering establishments visited.

6.6 Compliance with regulations

Compliance with ante-mortem regulations by Swedish slaughtering establishments is facilitates by: (1) all Swedish slaughterhouses being approved, registered and supervised by NFA; (2) NFA official veterinarians monitoring slaughterhouse operations, conducting antemortem inspections, and certifying meat produced being suitable for human consumption; and (3) the removal and disposal of SRM being supervised and monitored by NFA veterinary personnel. The NFA veterinary teams stationed at slaughtering establishments conduct regular audits of the quality assurance (QA) systems at the establishments, including specific BSE prevention procedures and requirements.

In addition to the daily supervision and conduct of anti-mortem inspections, the NFA conducts risk-based inspections and reviews the operation of slaughterhouses to verify compliance with BSE prevention and control regulations. Under the five-year prioritization plan of 2012 to 2016 (abbreviated as PIMKO for *Prioriteringar Inom och Mellan Kontroll Områden* (in English PIMKO stands for *priorities within and between control areas*) established by NFA, handling of animal by-products and BSE controls are specifically targeted for annual inspection and review.

The NFA's oversight is complemented by the quality assurance (QA) systems of the slaughtering establishments to ensure compliance with food safety and food hygiene regulations. It was observed that QA systems of the two slaughtering establishments cover good manufacturing practices, HACCP system, and the sanitation standard operating procedures. In general, the QA systems are audited once a year by the slaughtering establishments and in response to changes made at operational level. The QA systems at the two slaughtering establishments visited by FSANZ risk assessors were appropriately certified.

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

7.1 Overview

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

7.2 Legislation

7.2.1 Post-mortem inspection

Article 5 of Regulation (EC) No 854/2004²⁷ prescribes that the official veterinarians shall carry out post-mortem inspections at slaughterhouses. This is be assisted by the official auxiliaries.

Chapter V of Section II of Annex I of Regulation (EC) No 854/2004²⁷ prescribes that meat derived from cattle that has not undergone post-mortem inspection be declared unfit for human consumption.

Chapter 2 of Section I of Annex I of Regulation (EC) No 854/2004²⁷, prescribes that postmortem inspection of carcasses and accompanying offal must be undertaken without delay after slaughter. All external surfaces are to be viewed and particular attention is to be paid to the detection of zoonotic diseases and diseases listed by the OIE. Additional examinations are to take place, such as palpation and incision of parts of the carcass and offal and laboratory tests (whenever considered necessary) to reach a definitive diagnosis or to detect the animal disease if present.

As part of the post-mortem inspection, the official veterinarian is to check the removal, separation and marking of specified risk material. The official veterinarian is to ensure that the FBO takes all necessary measures to avoid contaminating meat with specified risk material during slaughter (including stunning) and removal of specified risk material.

Specific instructions to the post-mortem inspection of bovine animals are prescribed under Chapter II of Annex I of Regulation (EC) No 854/2004²⁷.

7.2.2 Definition of specified risk material

Defined by Annex V of Regulation (EC) No 999/2001¹⁵, specified risk material of bovine animals whose origin is in an EU Member State or third country (or a region) with a 'Controlled' or 'Undetermined' BSE risk is: (i) the skull, excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months; (ii) the 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 wings of the sacrum, but including the dorsal root ganglia, of animals aged over 30 months; and (iii) the tonsils, the last four meters of the small intestine, the caecum and the mesentery of animals of all ages. The above applies also to EU Member States with a 'Negligible' BSE risk status.

7.2.3 Rendering requirements

Specified risk material is not rendered in Sweden and is destroyed by incineration or coincineration, and can be used as a fuel for combustion.

7.3 Post-mortem procedures

During the in-country verification inspection visit, the following post-mortem procedures were observed as being supervised and monitored by NFA official veterinary inspectors:

- Cattle stunning and bleeding
- Carcass identification
- Verification of cattle ID
- Hoof and hide removal
- Removal of head
- Evisceration
- Inspection of organs and tissues on the slaughtering platform

- Disposal of inedible parts of carcass
- Carcass splitting
- Monitoring temperature reduction of carcasses
- Removal and disposal of spinal cord
- Removal and disposal of head including brains
- Recording post-mortem inspection data
- Certification of carcasses being fit-for-human-consumption.

The spinal cord is removed after the carcass is split and disposed of as SRM. Other SRM material such as the brain and eyes are removed in the offal processing room through disposal of the entire head after the harvest of cheek meat and tongue.

Post-mortem inspection conducted by NFA official veterinary personnel includes the inspection and palpation of carcasses, examination of viscera, mammary gland and intestines, and heart, and incision of the liver for the presence of parasites.

7.4 Rendering processes

Rendering parameters for Category 3 material which could be used as an ingredient in pet food or feed for fur animals or organic fertilizer as prescribed by Regulation (EC) No 1069/2009¹⁴ and Regulation (EC) 142:2011²¹ are processing, after reduction in particle size to not more than 50 mm, to a core temperature of more than 133 °C for at least 20 minutes without interruption at an absolute pressure of at least 3 bar. This conforms to international guidelines.

There was no rendering plant that processed the remains of ruminants operating in Sweden in 2015 when FSANZ conducted the verification visit.

7.5 Compliance with regulations

As described in section 7.3 of this report, post-mortem inspections are conducted by NFA officials. The removal and disposal of SRM is verified daily and inspected by NFA official veterinary personnel. Swedish slaughtering establishments conduct regular audits to verify their compliance with food safety regulations. NFA conducts regular inspection of slaughtering establishments to verify business compliance with relevant food safety requirements.

8 Summary: exposure control

The risk of introducing to and amplifying the BSE agent in cattle herds within Sweden is effectively prevented through:

- An effective ruminant feed ban that has been in existence since 1991; this ban was expanded in 2001 where all processed animal proteins were prohibited from being fed to ruminants
- Ruminant feed is produced in Sweden on exclusive production lines
- Fish meal is the only animal based ingredient permitted to be used in feed for farmed pig, poultry and fish, and all fish meals imported into Sweden are registered on the EU Traces system and are monitored by SBA
- Monitoring and enforcement of the ruminant feed ban in Sweden is managed under a risk-based feed surveillance system designed and conducted by SBA.

The Swedish Government's robust requirements around and supervision of the processes for all slaughtering establishments ensure that potentially BSE infected animals are prevented from entering the human food chain. The effectiveness of this is achieved through the following measures:

- A dedicated NFA office permanently staffed with qualified Government veterinarians that oversees the operations of all slaughtering establishments
- Ante-mortem and post-mortem inspections are conducted systematically by NFA officials at all slaughtering establishments
- Downer animals and BSE suspect animals at slaughterhouses are destroyed and the bodies of the dead animals are collected by businesses specialised in the destruction and disposal of dead animals
- SRM and Category 1 and Category 2 material are destroyed by incineration or coincineration, and can be used as a fuel for combustion
- The NFA conducts ongoing supervision and risk-based regular inspection and review of the QA systems of all Swedish slaughtering establishments.

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 the existence of effective and timely systems to accurately identify, trace and recall meat and meat products in the event of a food safety incident associated with BSE. The following Chapter addresses these requirements in Sweden.

9 Beef production systems

9.1 Legislation

Regulation (EC) No 852/2004³⁹, 853/2004²⁶, 854/2004²⁷, No 178/2002⁵² and Regulation (EU) 931/2011⁵³ prescribe regulatory requirements for FBOs on the construction of the establishments; workforce; production, packing, labelling and transportation of meat and meat products; hygiene practice and HACCP, removal of specific risk materials, recall and traceability of products in the production, processing and distribution of meat or meat products for human consumption.

Regulation (EC) No 854/2004²⁷ prescribes that the operation of slaughterhouses must be supervised by qualified official veterinarians. FBOs must offer all assistance needed to ensure that official controls carried out by the competent authority can be performed effectively. These include particularly:

- Giving access to all buildings, premises, installations or other infrastructures
- Making available any documentation and records required under the present regulation or considered necessary by the competent authority for judging the situation.

The Swedish Food Act (SFS2006:804⁴⁴) charges NFA at the national level (protection of human health and safety), CABs at the county level (primary production) and MUPS at the municipal level (environment and health protection) with the authority to exercise official controls on all Swedish establishments producing, processing and distributing meat or meat products for human consumption.

An individual who violates regulatory rules concerning the handling of specified risk materials, the manufacture or use of animal products or the transfer of animals, either intentionally or unintentionally in Sweden, will be subject to a fine or imprisonment (not exceeding one year) according to Swedish Act on Zoonotic Diseases (SFS 1999:657⁴⁹). In case of illegal transportation of animals or animal products, such property shall be declared forfeited, unless it is manifestly unreasonable.

Regulation (EC) No 852/2004³⁹, 853/2004²⁶, 854/2004²⁷ state that meat and meat products produced as human food must be fit for human consumption.

9.2 Hygiene practices for the minimisation of cross-contamination

In Sweden, the whole head after the harvest of the cheek meat and tongue and the spinal cord of slaughtered cattle are disposed of as Category 1 material regardless of the age of the animal at the time of slaughter. In the two slaughterhouses inspected by FSANZ risk assessors, spinal cords were removed with either a suction system or a blunt knife and

deposited in a SRM bin labelled with '*Kategori 1 EJ Avsett SOM Livsmedel*'. In English, it reads '*Category 1 not for human consumption*'. SRM bins and transport pipes were clearly identified with a red colour. Category 1 materials were taken away by businesses specialised in the transportation, destruction and disposed of animal by-products not intended for human consumption. Both slaughterhouses paid for the removal and disposal of animal by-products according to the weight disposed.

In a cutting plant inspected by FSANZ risk assessors, it was observed that the duration of a carcass from the entry into and exit from the cutting line was controlled at approximately 30 minutes. At the entry of the cutting room, a barcode was generated to instruct the cutting process. Carcasses were processed after being cooled to 16.9°C. The cutting room operated at 12°C. The cutting line was sanitised daily.

Each operator had a screen monitor in front of him/her to guide the process. Large pieces of cuts had labels attached to them which enabled the product to be traced to individual cattle slaughtered. Trimmings were able to be traced to the batch of cattle slaughtered.

Trimmings were deposited into stainless steel bins (with a plastic bag), and were immediately chilled with dry ice and wheeled to cold storage.

The NFA conducts regular inspections of meat processing establishments in accordance with a NFA standard operating procedure. Records provided by NFA showed that in 2012/2013 among 446 inspections conducted at approximately 180 slaughtering establishments, approximately 2% of the inspections found deviations from the regulatory requirements. The deviations included: (1) animal wastes not adequately covered with a lid to prevent access by birds; (2) a lack of adequate commercial documentation in the transportation of animal by-products; (3) deviations in categorising animal wastes; (4) transfer of Category 3 materials to a business who was not a recipient of animal by-products; and (5) inadequacies in staining animal by-products. The deviations were followed up either by appropriate corrective actions or legal processes.

10 Traceability systems for beef and beef products

In Sweden, NFA regulates the traceability requirements for beef and beef products in the case of a disease event.

10.1 Legislation

ANNEX II of Regulation (EC) No 853/2004²⁶ prescribes that beef and beef products available for sale in Sweden must carry an identification mark before they leave the food business establishment. The identification mark should carry: (1) the approval number of the food business where beef or beef product is manufactured, or processed or packed; (2) the country or region of the origin of the beef or beef product; and (3) a symbol of the European Community.

Article 18 of Regulation (EC) No 178/2002⁵² prescribes that FBOs in Sweden must have a system and a procedure in place to identify FBOs from whom they have received and to whom they have delivered beef or beef products. These must be made available to the competent authorities when required.

Required by Article 3 of Regulation (EU) 931/2011⁵³, FBOs in Sweden must ensure that the following information concerning consignments of beef or beef product is made available to the FBOs to whom beef or beef product is supplied and, upon request, to the competent authority:

- a) An accurate description of the product
- b) The volume or quantity of the product
- c) The name and address of the FBO from which the product has been dispatched
- d) The name and address of the consignor (owner) if different from the FBO from which the product has been dispatched
- e) The name and address of the FBO to whom the product is dispatched
- f) The name and address of the consignee (owner), if different from the FBO to whom the product is dispatched
- g) A reference identifying the lot, batch or consignment, as appropriate
- h) The date of dispatch.

The above information must be updated on a daily basis and kept for an appropriate period, commensurate with the nature and size of the food business.

Regulation (EC) No 178/2002⁵² established an EU-wide rapid alert system (RASFF) for the notification of a direct or indirect risk to human health as a result of food. In the case of a public health risk arising from food, the rapid alert system is activated to either suspend the placement on the market or the use of the food in question, or lay down special conditions for the food in question, or implement any other appropriate interim measures. The EU Commission manages the rapid alert system, and NFA is the contact point in Sweden for the system in case of a food incident or emergency.

10.2 Details of the traceability systems

In Sweden, traceability of beef and beef products is managed by a combination of the identification mark attached to the beef or beef product, the product information generated through receiving and forwarding the product that is maintained by the FBOs, and the CDB database administered by SBA. Information required in the tracing of beef and beef products can be generated from:

- The identification mark placed on the beef or beef product that shows the FBO from which the beef or beef product originates through the approval number and the country of origin of the product
- The product information generated through receiving and forwarding the product that is maintained by the FBOs and enables the concerned beef or beef product to be traced to the food business establishment where the animal is slaughtered
- The slaughterhouse concerned is able to trace the beef to the farm of origin based on the slaughter record and information stored in the CDB database.

In case of a recall, large pieces of beef cuts can be traced back to the individual animal from which the beef is derived according to information contained in the labels attached to the beef cuts. Trimmings can be traced to the batch of cattle slaughtered.

The FSANZ risk assessors were shown the beef traceability system in a Swedish cutting plant inspected in October 2015. The M3 Graphical Lot Tracker (as a part of its QA system) used by the cutting plant had three components (customer list, stock products, and stock components). It assists the cutting plant to trace back concerned beef or beef products in case of a recall. On average, this plant conducted two recalls per year. Most of the recalls concerned ready to eat products for allergen or *Listeria monocytogenes* contamination. As part of the QA system, practice recalls were conducted regularly at this plant.

11 Food recall systems

In Sweden, NFA is responsible for recall of beef or beef products. MUPS are responsible for food recall at the municipal level in conjunction with the concerned FBOs. When a recall occurs at the municipal level, the relevant CAB is informed. When a food recall goes to the national scale, NFA steps in and plays a leading and coordination role. Food recalls in Sweden often also involve health authorities.

11.1 Legislation

Food withdraw from market or recall in Sweden is a part of the follow up actions under the rapid alert system (RASFF) established by Regulation (EC) No 178/2002⁵² for the notification of a direct or indirect risk to human health arising from food.

11.2 Food recall process

Food recall in Sweden is managed under the RSAFF system. A food recall in Sweden involves part or all of the following steps (Fig 5):

- Food inspectors have inspected a product on the market or at the border. A FBO has tested the product. They may have taken samples and have received the results from a laboratory. A consumer has reported an issue with a food product to the authority.
- It is found that the food product is non-compliant and needs to be reported through the national system.
- The authority (MUPS or NFA) decides if the issue falls under the scope of the RASFF and reports it to NFA.
- The NFA verifies and completes the RASFF notification where necessary and forwards it to the European Commission. It uses a RASFF notification form to provide details of the findings and measures (where a withdrawal or recall of the concerned food may be involved) taken and adds relevant documents such as bills of lading, lists of food businesses having received the products and analytical reports.



Fig. 5: Food recall process under the RSAFF system in Sweden

The above food recall process is applicable to all food produced, imported, processed, transported, stored and sold in Sweden.

12 Summary: BSE food safety controls

In Sweden, recall of beef or beef products is managed under the RASFF system. NFA is responsible for BSE food safety controls including recall of concerned products at the national level and MUPS are responsible for recall of beef or beef products at the municipal level in case of a food incident.

All food businesses in Sweden including slaughtering establishments are required to keep product records to ensure the traceability of beef and beef products.

Traceability and recall simulations are conducted regularly at Swedish slaughtering establishments which provide the basis for effective beef recall and trace back in case of a food incident involving beef.

Information placed on the labels of beef and beef products produced and placed for sale in Sweden enables the concerned product to be traced back to the cattle farm of origin and/or individual cattle.

BSE Control Programs and Technical Infrastructure

The following Chapter addresses the requirements stated by the *Australian Questionnaire* of having appropriate control programs that support a capability to adequately identify, notify, and diagnose cattle that display signs meeting the case definition of BSE, and examines the Swedish systems on BSE notification, investigation of clinical suspects, diagnostic methods for BSE, and BSE awareness programs.

This Chapter also assesses Sweden's cattle identification and traceability system which underpins the investigation of any BSE case should it occur.

13 BSE Education and Awareness

One of the key criteria in determining a country's BSE risk status established by Regulation (EC) 999/2001¹⁵ is an on-going awareness program for veterinarians, animal farmers, and workers involved in the transportation, marketing and slaughter of bovine animals, to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations.

Sweden's BSE education and awareness program started formally in 1994 when BSE and TSEs were included in the Swedish Epizootic Handbook. Between 1994 and 2013, more than 26,445 Swedish people across the country had participated in BSE awareness education activities ranging from lectures, conferences, symposiums, seminars, workshops and training courses. Attendees to the training and awareness programs have included Government and private veterinarians, related professionals such as laboratory technicians, primary producers (animal farmers and feed producers), slaughterhouse operators, veterinary students, staff of competent authorities involved in managing animal health and welfare. The content of the education and awareness program covers BSE background, compliance with the ruminant feed ban, BSE surveillance, sampling and notification.

BSE awareness educational materials have been incorporated into university degree courses in the field of human health, animal health and food and feed production. BSE awareness educational materials produced as booklets and brochures have been widely distributed. A handbook on Epizootic Diseases has been sent out regularly to all veterinarians by Swedish Government. Booklets about BSE have been sent by post to all farmers with cattle and sheep. Information about BSE has been included in the cross compliance scheme which is updated yearly. BSE awareness information has been made available and updated regularly on a number of Swedish websites for example, <u>www.jordbruksverket.se</u>, <u>http://www.epiwebb.se</u>, and <u>http://www.sva.se</u>. The SVA's mobile app of animal diseases A-

<u>http://www.epiwebb.se</u>, and <u>http://www.sva.se</u>. The SVA's mobile app of animal diseases A-Z also includes BSE.

14 Disease notification and diagnoses

14.1 Overview

This Section examines the procedures of notification and diagnoses of animals that are tested under the TSE surveillance and monitoring program in Sweden.

14.2 Legislation

<u>Compulsory notification</u>: BSE was made notifiable in Sweden in 1989 under the Swedish Act of Epizootic Diseases (SFS 1999:657⁴⁹). BSE was made notifiable by Commission Decision

90/134/EEC⁵⁴. Article 11 of Regulation (EC) 999/2001¹⁵ prescribes that EU Member States shall ensure that any animal suspected of being infected by a TSE is notified immediately to the competent authorities.

The Swedish Act on Epizootic Diseases (SFS 1999:657⁴⁹) prescribes that any person who, in their profession come into contact with animals or animal products and who have reason to suspect that a case of epizootic disease has occurred, shall promptly notify SBA and CAB. This notification requirement also applies to any person responsible for a laboratory where such a disease has been found or where there is reason to suspect cases of this disease. Once becoming aware of a BSE suspect, CABs immediately notify SVA, the district veterinarian and the municipal councils.

<u>Penalties</u>: An individual who fails to fulfil his or her obligation to notify an infectious disease, such as BSE, either intentionally or unintentionally in Sweden, will be subject to a fine or imprisonment (not exceeding one year) according to Swedish Act on Zoonotic Diseases (SFS 1999:657⁴⁹).

<u>Compensation</u>: According to the Swedish Act on Epizootic Disease (SFS 1999:657⁴⁹), the Swedish Government shall compensate anyone who, as a result of regulations or decisions that have been issued under Swedish Act on Epizootic Diseases (SFS 1999:657⁴⁹) or because of decisions issued under the EU regulations complemented by Swedish Act on Epizootic Diseases (SFS 1999:657⁴⁹) for:

- Loss due to livestock killed
- Costs due to decontamination procedures
- Production loss
- Other loss of earnings.

Individuals who have participated in the prevention or control of an infectious disease, such as BSE are entitled to compensation from the Swedish Government for work loss, loss of time, travel and subsistence, and the establishment or equipment provided in the participation of prevention or control, and for loss of income or benefits.

In the case of a suspected case of BSE, the Swedish Government pays for all veterinary fees, laboratory examinations and the cost associated for disposing of the dead animal.

14.3 Identification and handling BSE suspects

Annex VII of Regulation (EC) No 999/2001¹⁵ prescribes that following confirmation of the presence of a case of TSE in cattle the following cohorts and feedstuffs must be identified:

- All other ruminants on the holding of the animal in which the disease was confirmed
- Where the disease was confirmed in a female animal, its progeny born within a period of two years prior to, or after, the clinical onset of the disease
- All animals of the cohort of the animal in which the disease was confirmed
- The possible origin of the disease
- Other animals on the holding of the animal in which the disease was confirmed or on other holdings which may have become infected by the BSE agent or been exposed to the same feed or contamination source
- The movement of potentially contaminated feedingstuffs, of other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question.

The Swedish Act on Zoonotic Diseases (SFS 1999:657⁴⁹) prescribes that:

- Any person, who has reason to suspect that BSE has affected animals in his care, shall immediately notify the district veterinarian or other veterinarian. Pending a decision by a veterinarian, the person having animals in his or her care, must do what is reasonably required to prevent or minimise contamination.
- If a veterinarian has reason to suspect that a case of BSE has occurred, he or she shall immediately investigate to determine the nature of the disease, and otherwise do what is necessary to prevent cross-contamination. Those who have animals in their care are required to endure necessary intrusion and subject themselves to any necessary measures, and provide assistance necessary for the investigation. If it is necessary for the investigation, an animal suspected of being infected may be killed without the owner's consent.
- If a veterinarian has reason to believe that a case of BSE has occurred, the veterinarian shall, to the extent necessary counteract the spread of infection, impose a ban on entering the area where the disease has occurred or where the infection would otherwise be likely to occur. Such a decision must be submitted without delay to SBA. SBA shall promptly determine whether the decision shall remain in force. If there are substantial grounds for believing that a case of BSE has occurred, SBA shall, to the extent necessary counteract the spread of infection, impose the ban on entering the areas including areas where contamination are likely to occur.
- If a case of BSE has occurred, the establishment will be placed under official control. Prohibition or restriction will be imposed on the movement of animals or goods, handling of animals or goods, and access to the establishment concerned. SBA may:
 - Order the killing of the animals suspected of being infected or likely to spread the infection, and the killing of other animals
 - Order the disposal of dead animals, animal products, other products, waste and other material that could spread infection
 - Order decontamination processes to take place
 - Order the examination of animals and animal products for disease control purposes
 - Order a change to husbandry practices
 - Limit the movement of animals, transportation or other handling of animals, animal products, other products, waste and other material.
- The herd of the origin of the infection will be put under restrictions and investigated for possible sources of contamination; cohort animals are traced and culled. If the case is found at a slaughterhouse all parts of the body will be destroyed as well as the carcass before and two carcasses after the infected animal. The case will be reported to the EU.

In Sweden, SBA is the competent authority for issuing legislation, tracing the spread of the animal disease and dealing with herds with suspected or confirmed TSE. SBA shares responsibility for TSE monitoring with NFA and SVA, and informs other bodies of suspected and confirmed cases of TSE. TSE sampling information is compiled by SBA. Veterinarians attached to SBA's 80 district veterinary offices throughout the country as official veterinarians perform work on suspected or confirmed cases of TSE. NFA is responsible for official TSE

controls in slaughterhouses, including the retention of meat and animal by-products in anticipation of TSE analysis results.

In practice, the animal owner contacts the head veterinarian who assesses the suspected animal and subsequently contacts SVA and SBA. SBA directs the veterinarian to destroy the animal, take samples and implement movement restrictions. SVA conducts an autopsy at the SVA laboratory. In the event of a positive identification, SBA conducts an epidemiological investigation, identifies possible sources of infection and cohort animals. Animal owners are compensated for any animals destroyed.

No classical BSE cases have been detected in Sweden. Sweden detected one case of Htype atypical BSE in a 12 year-old beef cow in March 2006 and the case was reported to the OIE on 8 March 2006.

14.4 Diagnostic tests

The Swedish National Institute of Animal Health (SVA) hosts the Swedish National TSE Reference Laboratory, and conducts TSE preliminary and confirmatory diagnosis under the country's BSE control program. SVA conducts also post-mortem examination of animals suspected of BSE received from farms and animal disposal and destruction businesses.

SVA uses a number of rapid test kits for preliminary BSE diagnosis including BioRad (TSE short assay protocol and TeSeE Western Blot), Enfer and IDEXX products. Histopathology and immunohistopathology have been employed in the earlier years as the gold standard for BSE confirmatory diagnosis. In recent years, Western Blot technique has been used for confirmatory diagnosis.

Between 2006 and 2013, samples from fallen stock and emergency slaughter > 24 months of age, and BSE suspects were analysed by SVA. BSE preliminary diagnosis for a majority of healthy slaughtered animals was conducted by three private laboratories in Sweden using the three different rapid test kits (IDEXX HerdChek BSE antigen test kits, Enfer TSE test and Bio-Rad TeSeE rapid test) as all healthy cattle over 24 months of age slaughtered in Sweden were subject to BSE testing during that period. This age limit was lifted to 72 months in 2012. Samples of suspect positives or inconclusive diagnosis identified by the private laboratories were sent to SVA for confirmatory diagnosis. Approximately 20,000 samples are tested for TSE each year under the current TSE surveillance program⁵⁵.

At SVA, with each brain stem sample received, a 205-300 mg portion is taken for preliminary diagnosis. The remaining sample is stored under refrigeration until the result of the preliminary diagnosis becomes available. If the result is negative, the remaining sample is disposed of as Category 1 material. If the preliminary diagnosis is positive, the remaining sample is progressed to the confirmatory diagnosis stage.

SVA maintains Swedish BSE testing data. Details of the analysis of sampled animals are sent from SVA to SBA. Monthly sampling summaries are reported to the EU.

As described in the feed ban section, surveillance on ruminant feed for animal proteins is also carried out by the SVA using a microscopic method. If animal proteins are found in ruminant feed samples, a PCR method is then applied to identify the species of the animal from which the protein is derived.

SVA notifies suspected TSE cases, and confirms positive TSE cases in Sweden.

14.5 Laboratory assurances and auditing

SVA has implemented a Laboratory Information Management System (LIMS) that registers BSE samples received and retains the Swedish BSE surveillance data. The LIMS is connected to the CDB database administered by SBA, and verifies the identification of cattle from which the brain tissues are received from slaughterhouses or other sources.

As the national TSE reference laboratory, SVA coordinates diagnostic standards and methods, provides training, and organises proficiency testing of Swedish BSE diagnostic laboratories on a yearly basis.

SVA is a member of the European Reference Laboratories which:

- Provides expertise in the diagnosis and epidemiology of TSE
- Provides obligatory yearly proficiency testing in all diagnostic methods used in all the EU Member States reference laboratories
- Coordinates the application of methods employed by the EU for TSE diagnosis and surveillance in Sweden
- Conducts regular quality assurance assessments of rapid TSE test kits
- Characterises TSE isolates using the most relevant methods
- Collects and stores data and information of TSE diagnostic methods and results, and stores and supplies tissues and reference material to the United Kingdom Animal and Plant Health Agency's biological archive.

The SVA's BSE diagnostic laboratories are certified by the Det Norske Veritas and Germanischer Lloyd (DNV GL) for compliance with ISO/IEC 17025 standard, Good Laboratory Practice, and Environmental competency. DNV GL is an international certification body and classification society with expertise in technical assessment and risk management.

15 Cattle identification and traceability

15.1 Overview

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

Cattle identification and traceability in Sweden is described in the following sections.

15.2 Legislation

Regulation (EC) No 1760/2000⁴⁶ and the prior Regulation (EC) No 820/97⁵⁶ established an EU-wide system for the identification and registration of bovine animals. Commission Regulation (EC) No 911/2004⁵⁷ describes the details in relation to the implementation of requirements prescribed by Regulation (EC) No 1760/2000⁴⁶.

Swedish regulation SJVFS 2007:12⁵⁸ adopted the measures prescribed under Regulation (EC) No 1760/2000⁴⁶ and prescribes detailed instructions on the implementation of identification and registration of bovine animals in Sweden.

15.3 Current identification systems for cattle

Sweden follows the rules laid down by Regulation (EC) No 1760/2000⁴⁶ and the implementing Commission Regulation (EC) No 911/2004⁵⁷. The corresponding Swedish regulation is SJVFS 2007:12⁵⁸. The Swedish cattle identification and traceability system is comprised of the following four components:

1. Individual animal identification

All calves born in Sweden must be tagged within 20 days from birth, and must have one tag on each ear. The tags are yellow (Fig 6) and must be ordered from SBA. In addition to the ear tag, the owner of the cattle may choose to voluntarily identify the cattle with an electronic identification system, for example through radio-frequency identification (RFID).

Figure 6 shows examples of ear tags where SJV stands for SBA. The two positions at the front of the code on the ear tag are occupied by the letter of SE which stands for Sweden. This is followed by a 6 digit code representing the holding number (see Registration of holdings described below) which describes where the animal is kept or was born. The following four unique digits identify the individual animal. A small digit situated at either the top or the bottom of the right side of the 10 digits is a control digit that allows SBA to match the individual animal's identification with the physical location (holding number) where the animal is held.





When ear tags are lost, replacement ear tags are ordered through the "BEST" (in Swedish it means "to order") option which is a component of the CDB database. The replacement tag contains the same information as the original ear tag.

For intra-community traded cattle, that is cattle sourced from an EU Member State, the animal keeps its original ear tags from the country of origin, and also carries a set of Swedish ear tags that are red.

2. Registration of holdings

The holding number describes the physical location where the business operates. According to SJVFS 2007:12⁵⁸, registration of the holding contains the name, address, and phone number of the person or the corporation that keeps cattle, pigs, sheep or goats on the establishment; and the address of the production site, type of animals kept, and the type of business engaged.

In Sweden, each building where animals are kept for the winter period is considered a single holding although buildings grouped together are also considered a single holding. In the case of multiple grazing areas the characteristics of the land determines whether one or several holding numbers are needed.

3. Keeping a register at each holding

The above EU and Swedish regulations require each animal holding to maintain an animal register. The register must record at least the following information for each animal kept at the holding:

- The animal's identification code
- Date of birth
- Sex
- Breed or colour of the coat
- Date of death where applicable
- In the case of animals departing from the holding, the name and address of the keeper or the holding number to whom the animal is being transferred to, and the date of departure
- In the case of animals arriving on the holding, the name and address of the keeper or the holding number from whom the animal is received, and the date of arrival.

Changes in the herd under a holding must be recorded within 48 hours. The register must be kept for at least three years by the owner of the holding. Inspection of the register is a component of audits conducted by SBA and CABs. As a result, the animal register often contains the name and signature of the representative SBA or CABs officer who inspected the register and the dates on which such inspections were carried out.

For cattle intended for intra-community trade, passports are issued. The relevant regulations require that the passport must contain the following information:

- The identification code of the animal
- Date of birth
- Sex
- Breed or colour of the coat
- Identification code of the mother
- Identification number of the holding where the animal was born
- Identification numbers of all holdings the animal has been kept and dates of each change of holding
- Name and address of the keeper
- Signature of the keeper(s)
- Name of issuing authority (i.e. SBA)
- Date of the issue of the passport.

As described in section 6.3 of this report, cattle passports aren't used in Sweden because the CDB system administered by SBA has been approved by the European Commission for this purpose.

4. Central cattle registry (CDB)

CDB is the Swedish central database for bovine animals that has been in operation since 1 January 1998. The CDB database is based on an Oracle database management system, and is administrated by SBA. Information captured by CDB includes: (1) number of cattle at a holding; (2) cattle identification; (3) the control digit; (4) animal movement from or to a holding, and date of movement; and (5) date of birth of the animal. Information on any specific animals captured by the CDB database includes the animal's date of birth, holding number, date of movement, mother's birth date, and cattle identification.

According to SBA, access to the CDB database by Swedish cattle farmers is largely through the Internet (~70%). Where animal farmers do not have Internet access, information can be posted to SBA via mail using prescribed SBA forms. In the latter situation, SBA would input the data into the CDB.

The CDB system can be used for disease investigation when required. Relevant statistics can be obtained from the CDB database at any particular time including:

- Number of live cattle
- Number of births
- Number of buying reports
- Number of selling reports
- Number of animals slaughtered
- Number of "temporarily out" (adjusted) animals
- Number of animals dying of natural causes or destroyed.

Compliance with the above requirements is verified by the CABs and SBA in their inspections of cattle farms. Penalties can be imposed on cattle keepers who have incurred repeated late notifications to SBA, or other serious infractions, and to cattle transporters who transport untagged cattle. Penalties vary from movement restrictions of the concerned cattle to destruction of the cattle if the animal can't be identified, and a reduction to the aid that the cattle farmer may receive.

Slaughterhouses

Both slaughterhouses visited by the FSANZ in-country verification team used the SBA's CDB. Through the CDB, the operators at the ante-mortem inspection verify the animal's identity and age, and at the slaughtering line the individual animal identification number is entered into the database to verify the animal's identity. Information generated by slaughterhouses comes to SBA through the weekly slaughter reports and is then transferred to the CDB by CDB administrators at SBA.

Rendering plants

Rendering plants are no longer operating in Sweden. Information provided by SBA indicates that a rendering plant processing Category 3 material stopped operation in 2012, and two rendering plants processing Category 1 material stopped operation in 2006 and 2007 respectively.

Farms

The FSANZ risk assessors observed that all cattle on the two cattle farms that were visited carried yellow flag-shaped ear-tags on both ears. It was confirmed during the inspection that ear-tags were attached to calves by or before day 20 after birth. As part of the cattle identification and traceability requirement, the SBA's CDB database must be notified within seven days of an ear tag attachment. The seven day limit also applies to the sale and movement of cattle in and out of the holdings. Notification to the CDB database of cattle transported to an agricultural show was an example of the latter.

In the event that ear tags are lost, the farm would notify SBA and obtain replacement tags. Verification processes are built into the system whereby if an incorrect animal ID is entered, the request is rejected. The reissued ear tag has the same ID number. Issues with regard to cattle identification commonly encountered at the two cattle farms were mainly due to errors in the entry of holding registration numbers (outgoing and incoming).

SBA communicates with primary cattle producers via SMS, Internet, and letter. Reminder notifications are always sent to the primary producers a day before the due date of the registration. SBA statistics indicate that more than 90% of the cattle are registered on time.

15.4 Contingency plans

Article 13 of the Regulation (EC) No 882/2004⁶ requires EU Member States have contingency plans for feed and food in place, and are prepared to operate such plans in an event that feed or food is found to pose a serious health risk to animals or humans. The contingency plan shall specify:

- The administrative authorities to be engaged
- Their powers and responsibilities
- Channels and procedures for sharing information between the relevant parties.

The contingency plan is revised when there are changes in the organisation of the competent authority and through learnings gained from simulation exercises.

A contingency plan in response to crises involving epizootic diseases, feed and incidents related to animal health has been in operation since April 2010 in Sweden⁴. Exercises and 'real incidents' took place in 2010 and 2011. SBA works with other authorities at national, regional and local level in the case of an incident.

NFA, SVA, and the CABs have relevant contingency plans prepared in cooperation with SBA.

15.5 Evaluation and inspection

All cattle farms in Sweden are regularly inspected and audited by SBA and CABs. The inspections and audits cover all aspects of the farming operation including registration of births and deaths of cattle, feed inputs, animal ID. A cattle register is required to be maintained by all cattle farms.

During the FSANZ in-country inspection visit to Sweden, the compliance with animal individual identification requirements at two cattle farms, and the verification of cattle identification with the CDB database administered by SBA at two slaughtering establishments were verified to be in compliance with regulatory requirements.

The combination of control measures (the individual animal identification, registration of animal holdings, keeping a register at each animal holding, and the central cattle registry), implemented under Swedish regulation 2017:12⁵⁸ enables adequate cattle identification and traceability in Sweden.

16 Summary: BSE control programs and technical infrastructure

BSE has been a notifiable disease in Sweden since 1989. The compulsory nature of the notification together with good awareness of the need to report animals with signs of infectious diseases ensure animals suspected of BSE are reported to the Swedish authorities in a timely manner.

Veterinarians, animal farmers, cattle handlers and relevant professionals involved in animal production and animal health care in Sweden have been well educated to recognise the clinical signs associated with BSE through comprehensive and ongoing training and awareness programs.

BSE diagnostic methods applied by SVA conform to the OIE recommended methodologies.

Cattle subject to sampling for BSE diagnosis in Sweden is consistent with EU requirements and the latest international best practice.

The cattle identification and traceability system implemented by Sweden is comprehensive. The combination of the identification for individual cattle, registration of animal holdings, the upkeep of a register at each animal holding, and the central cattle registry enables accurate, reliable and rapid tracing of animals in case of a BSE event.

Sweden has appropriate contingency plans in place in case of a feed or food emergency.

BSE Surveillance

Section 3 of the *Australian Questionnaire* requires countries to provide evidence of the number of BSE surveillance samples collected for each cattle subpopulation, with data stratified by year and age group. Such data are then used to derive BSE surveillance point calculated based on the OIE recommendations⁵⁹. The degree and quality of surveillance for BSE within the cattle population of a country, combined with other systems for BSE control, help to determine the BSE risk status of the country. This chapter provides details of BSE surveillance activities in Sweden and historical data.

17 Sweden's BSE surveillance program

Until 2001, Sweden conducted passive surveillance for BSE where only clinical suspect animals were tested for BSE. Active surveillance for BSE started in January 2001, and BSE tests were applied to: all fallen stock and all emergency slaughtered cattle > 24 months of age, all BSE suspects, and 10,000 randomly-selected healthy cattle slaughtered over the age of >30 months each year. The latter was expanded to all healthy cattle slaughtered over the age of >30 months in June 2006 because of the identification of a case of H-type atypical BSE in a 12 year old cow.

In response to Commission Decision 2008/908/EC⁶⁰, the age of healthy cattle surveyed for BSE in Sweden was lifted to > 48 months, and subsequently lifted to > 72 months. The testing of healthy slaughtered cattle >72 months of age continued until March 2013.

Currently Sweden conducts OIE specified Type B surveillance, and the following categories of cattle are routinely tested for BSE:

- All cattle suspected of BSE
- Fallen and emergency slaughtered cattle of Swedish origin >48 months of age
- Fallen and emergency slaughtered cattle of non-Swedish origin >24 months of age
- All healthy slaughtered cattle at and over 30 months of age of non-Swedish origin.

18 Sweden's BSE surveillance points data

In 2006, the adult cattle population in Sweden was 765,000. The target satisfying OIE specified BSE Type A surveillance is 166,900 according to Chapter 11.4 of the 2014 version of the OIE *Terrestrial Animal Health Code*. The Swedish BSE surveillance points of 276,531 (Table 7A) accumulated over the period of 2001 to 2007 exceeded the above Type A BSE surveillance target set by the OIE by 66%.

In June 2015, the adult cattle population in Sweden was approximately 628,000. The target satisfying OIE specified BSE Type B surveillance is 71,500 according to Chapter 11.4 of the 2014 version of the OIE *Terrestrial Animal Health Code*. The total number of BSE surveillance points of 144,465 (Table 7A) accumulated over the period of 2008 to 2014 under the Swedish BSE surveillance program doubled the Type B surveillance target set by the OIE.

Surveillance data (not shown in this report) of clinically suspected cases for BSE identified under the Swedish BSE surveillance program indicate that approximately 93% of the clinical suspects were identified on farm. This reflects a high level of awareness of BSE among

Swedish cattle farmers. The clinical suspects ranged from 12 months to 120 months, and 80% of the clinical suspects were found between the age of 20 months and 66 months.

Year	Number of animals tested	Total BSE surveillance points
2001	28,103	40,520
2002	37,497	41,880
2003	34,580	39,455
2004	36,111	42,375
2005	35,277	35,576
2006	102,781	42,429
2007	188,914	34,296
Total	463,263	276,531
2008	180,540	33,557
2009	136,027	27,693
2010	118,537	27,239
2011	96,803	23,491
2012	59,104	14,432
2013	30,777	9,308
2014	9,493	8,745
Total	631,281	144,465

Table 7A: BSE surveillance points collected under the Swedish BSE surveillance program between 2001 and 2014

Data provided in Table 7B indicate that BSE surveillance for healthy cattle slaughtered in Sweden has declined significantly over the period of 2007 and 2014. This trend is a reflection of the EU decision of moving away from testing healthy cattle for BSE.

Year	Routine slaughter	Fallen stock	Casualty slaughter	Clinical suspect	Total
2007	23,854	8,568	294	1,580	34,296
2008	22,098	10,784	155	520	33,557
2009	18,909	8,044	220	520	27,693
2010	17,590	8,130	20	1,500	27,240
2011	12,954	7,537	0	3,000	23,491
2012	5,422	7,464	0	1,545	14,431
2013	2,236	6,854	174	45	9,309
2014	0	6,111	354	2,280	8,745

Table 7B: A breakdown of the BSE surveillance points for the period of 2007-2014

19 Summary: BSE surveillance

Sweden has an ongoing BSE surveillance program, and is currently conducting the OIE's specified Type B surveillance. Between 2001 and 2007, Sweden conducted OIE specified Type A BSE surveillance. A total of 276,531 BSE surveillance points were accumulated.

Between 2008 and 2014, Sweden accumulated a total of 144,465 BSE surveillance points. BSE surveillance points accumulated by Sweden in the period of 2001 – 2007 and 2008 - 2014 exceeded the OIE specified target for Type A BSE surveillance and target for Type B BSE surveillance respectively. BSE surveillance of healthy cattle slaughtered while contributing the highest proportion of the surveillance points prior to 2012 in Sweden has ceased since March 2013.

Conclusions and BSE risk categorisation

BSE specific import controls introduced by the Swedish Government since 1989 have successfully prevented the BSE agent from entering Sweden. In the last eight years live bovine animals traded into Sweden has been limited to Denmark, Finland and Germany. Both Denmark and Finland are countries recognised by the OIE with a "Negligible" BSE risk status. While Germany is recognised by the OIE with a 'Controlled' BSE status, the import of live bovine animals from Germany was restricted to water buffalos only, and no BSE case has so far been reported among water buffalos in Germany. The inward trade of feedstuffs containing animal protein in the last eight years has been limited to EU Member States and Norway. The inward trade and import of beef and beef products for human consumption in the last eight years was limited to countries recognised by the OIE with either a 'Negligible' or a 'Controlled' BSE risk status. The EU Traces system has been effectively implemented by Sweden and this system registers and traces any live bovine animals and products containing animal protein that are imported into the country. Based on the above, it is considered that live cattle, beef and beef products, and feedstuffs imported into Sweden in the last eight years presented a negligible risk of introducing the BSE agent into Sweden.

Sweden has had an effective ruminant feed ban in place since 1991. From 2001, processed proteins derived from all animals have been prohibited from being fed to ruminants. Sweden's ruminant feed ban has been effectively implemented through the following measures:

- 1. Ruminant feed is produced in Sweden on exclusive production lines that prevents possible contamination from feed produced for non-ruminant animals.
- 2. Sweden's slaughtering establishments are subject to comprehensive food safety oversight and are regularly audited by Swedish Government that prevent animals suspected of BSE infection from entering the human food or animal feed chains.
- 3. Animal protein other than milk and milk-based products and those exempt by Regulation (EC) No 999/2001 is banned from being fed to farming animals in Sweden except fish meal which is only permitted as an ingredient of feed for farmed pig, poultry and fish of different species. Every fish meal consignment entering Sweden is registered under the EU Traces system and monitored by the Swedish Board of Agriculture.
- 4. Monitoring and enforcement of the ruminant feed ban in Sweden under a risk-based feed monitoring and testing system has been effectively implemented.

The Swedish Government's robust requirements on cattle slaughterhouses and supervision of the slaughtering processes ensure that potentially BSE infected cattle are prevented from entering the human food supply. This has been achieved through the following measures:

- A dedicated Swedish Government veterinary office staffed with qualified official veterinarians that oversees the operations of all Swedish slaughtering establishments.
- Ante-mortem and post mortem inspections are conducted by Swedish Government official veterinary personnel at all Swedish slaughtering establishments.
- Downer animals and BSE suspect animals at slaughterhouses are destroyed with Government oversight.
- All specified risk material and Category 1 materials in Sweden are destroyed by incineration or co-incineration or used as fuel for combustion.

Recall of beef or beef products in the event of a food incident involving beef in Sweden is managed under the Rapid Alert System for Food and Feed of the European Union. All food businesses in Sweden including slaughtering establishments are required to keep product receiving and forwarding information to ensure traceability of beef and beef products. Traceability and recall simulations are conducted regularly by Swedish slaughtering establishments which provide the basis for effective beef recall and trace back in the case of a food incident involving beef. Information placed on the labels of beef and beef products produced and placed on the market for sale in Sweden enables the concerned product to be traced back to the individual cattle farm and/or individual animal.

BSE has been a notifiable disease in Sweden since 1989. Ongoing BSE awareness education programs were introduced in 1994 and are comprehensive, and have reached a wide range of primary producers and food business operators involved in producing and supplying beef for human consumption.

BSE diagnostic methods applied by the Swedish National Veterinary Institute conform to the methodologies recommended by the OIE. Cattle subject to sampling for BSE diagnosis in Sweden is consistent with the requirements established by the European Union and the OIE.

Sweden's 80 district veterinary offices located throughout the country play a critical role in enabling effective BSE prevention and control in Sweden because of their proximity to farms and slaughtering establishments.

The combination of the registration of animal holdings, identification for individual cattle, the upkeep of a register at each animal holding by primary cattle producers, and the Swedish central cattle register enables accurate, reliable and rapid tracing of animals if BSE was to occur in Sweden.

Sweden has appropriate contingency plans in place in the event of a feed or food emergency.

Sweden has an ongoing BSE surveillance program, and is currently conducting the OIE specified Type B surveillance. The BSE surveillance points accumulated by Sweden in the period of 2001 – 2007 and 2008 - 2014 exceeded the target of OIE specified Type A BSE surveillance and Type B BSE surveillance respectively.

Sweden has comprehensive and well established controls to prevent the introduction into and amplification of the BSE agent within its cattle population that ensure beef and beef products produced in Sweden are safe for human consumption. This BSE food safety risk assessment concludes that imported beef and beef products originating from Sweden are safe for human consumption and recommends the Kingdom of Sweden be assigned **Category 1** status for country BSE food safety risk.

References

- Australian Government (2009) Bovine Spongiform Encephalopathy (BSE): Requirements for the Importation of Beef and Beef Products for Human Consumption – Effective 1 March 2010. Food Standards Australia New Zealand. (Available at <u>http://www.foodstandards.gov.au/industry/bse/bseimports/Pages/default.aspx</u>. Accessed 15 April 2016)
- FSANZ (2010) Australian Questionnaire to Assess BSE Risk. Food Standards Australia New Zealand. (Available at http://www.foodstandards.gov.au/industry/bse/bsequestionnaire/Pages/default.aspx. Accessed 15 April 2016)
- 3. OIE (2009) Questionnaire for Bovine Spongiform Encephalopathy (BSE) Risk Recognition October 2009
- 4. EU Food and Veterinary Office (2015) Country Profile Organisation of Official Control, DG (SANCO)/2013-6835, Final Valid as of March 2015
- Commission Decision 2007/363/EC a guidelines of the European Commission to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council
- Regulation (EC) No 882/2004 a regulation of the European Parliament and of the Council laying down the official controls performed to ensure the verification of compliance with EU feed and food laws, animal health and animal welfare rules in EU member states
- Nyman S (2009) Can Swedish beef production become profitable by learning from Canadian beef production? http://exepsilon.slu.se:8080/archive/00003277/01/Studentarbete_290.pdf, accessed 11 February 2015
- 8. Hassle A (2007) Beef cattle on semi-natural grasslands production of meat and nature conservation, http://pub.epsilon.slu.se/1348/, accessed 27 April 2015
- Wells GA, Scott AC, Johnson CT, Gunning RF, Hancock RD, Jeffrey M, Dawson M, Bradley R (1987) A novel progressive spongiform encephalopathy in cattle. Veterinary Record 121(18): 419-420
- Brown P, Will RG, Bradley R, Asher DM, Detwiler L (2001) Bovine spongiform encephalopathy and variant Creutzfeldt - Jakob disease: background, evolution, and current concerns. Emerging Infectious Diseases 7(1): 6-16
- Gavier-Widén D, Nöremark M, Langeveld JPM, Stack M, Biacabe A-G, Vulin J, Chaplin M, Richt JA, Jacobs J, Acin C, Monleón E, Renström L, Klingeborn B, Baron TGM (2008) Bovine spongiform encephalopathy in Sweden: an H-type variant. J. Vet. Diagn. Invest. 20: 2-10
- 12. OIE (2008) Final report of the 76th General Session of the OIE World Assembly
- 13. Commission Decision 2008/829/EC a decision of the European Commission amending

the annex to decision 2007/453/EC establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk

- 14. Regulation (EC) No 1069/2009 a regulation of the European Parliament and the European Council that laid down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
- 15. Regulation 999/2001 a regulation of the European Parliament and the European Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
- 16. SJVFS 2011:21 a Swedish regulation amending Swedish ordinance SJVFS 2006:84 on animal by-products which can spread contagious diseases to animals, issued by SBA
- 17. SFS 2006:805 a Swedish Act on feed and animal by-products, issued by the Swedish Ministry of Agriculture
- 18. SFS 2006:814 a Swedish regulation on feed and animal offal, issued by the Swedish Ministry of Agriculture
- 19. SFS No: 2006:1165 a Swedish regulation on charges for the official control of feed and animal by-products, issued by the Swedish Ministry of Industry
- 20. SJVFS 2007:21 a Swedish regulation and general advice on the control of feed and animal by-products, issued by SBA
- 21. Commossion Regulation 142/2011 a regulation of the European Commission implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive
- 22. Council Directive 2004/68/EC a directive of the European Council laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC
- 23. Commission Regulation (EU) No 206/2010 a regulation of the European Commission laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements
- 24. SJVFS 2012:33 a regulation of the Swedish Board of Agriculture amending the Swedish Board of Agriculture's regulation (SJVFS 2007:12) on the labelling and registration of cattle
- 25. Council Directive 2002/99/EC a directive of the European Council laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption
- 26. Regulation (EC) 853/2004 a regulation of the European Parliament and the European Council laying down specific hygiene rules for on the hygiene of foodstuffs
- 27. Regulation (EC) 854/2004 a regulation of the European Parliament and the European

Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

- 28. Heim D, Mumford E (2005) The future of BSE from the global perspective. Meat Science 70(3):555–562
- 29. Mumford EL, Kihm U (2006) Integrated risk reduction along the food chain. Annals New York Academy of Sciences 1081:147–152
- Hörnlimann B, Bachman J, Bradley R (2006) Portrait of Bovine Spongiform Encephalopathy in cattle and other ungulates. In: Hörnlimann B, Riesner D, and Kretzschmar H. (eds) Prions in Humans and Animals. de Gruyter, Berlin, p. 233–249
- 31. Ducrot C, Arnold M, de KA, Heim D, Calavas D (2008) Review on the epidemiology and dynamics of BSE epidemics. Vet Res 39(4):15
- 32. LSFS 1990:51 a Swedish National Board of Agriculture's regulation on the amendment of the National Board of Agriculture's regulation (LSFS 1987:42) concerning feeding-stuffs for food-producing animals and horses
- 33. SJVFS 1995:25 a Swedish Board of Agriculture's regulations amending the Swedish Board of Agriculture's regulations (SJVFS 1993:177) on feeding stuffs
- 34. Commission Regulation 94/381/EC a regulation of the European Commission that banned mammalian derived protein from being fed to ruminants
- 35. Council Decision 2000/766/EC a decision of the European Council concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein
- 36. Commission Decision 2001/9/EC a decision of the European Commission concerning control measures required for the implementation of Council Decision 2000/766/EC concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein
- 37. SFS 2011:419 a Swedish Ministry of Agriculture's regulation amending the Order (2006: 814) on feed and animal by-products
- 38. LSFS 1985:35 a Swedish Agriculture Supplier's Board's regulation on animal feed
- 39. Regulation (EC) 852/2004 a regulation of the European Parliament and the European Council on the hygiene of foodstuffs
- 40. Regulation (EC) No 183/2005 a regulation of the European Parliament and European Council laid down requirements for feed hygiene
- 41. Commission Regulation (EC) No 152/2009 a regulation of the European commission laying down the methods of sampling and analysis for the official control of feed
- 42. Wells GAH, Konold T, Arnold ME, Austin AR, Hawkins SAC, Stack M, Simmons MM, Lee YH, Gavier-Widen D, and other authors (2007) Bovine spongiform encephalopathy: the effect of oral exposure dose on attack rate and incubation period in cattle. J. Gen. Virol. 88, 1363–1373
- 43. SJVFS 2014:7 a regulation of the Swedish Board of Agriculture amending the Swedish Board of Agriculture's company and general advice (SJVFS 2007:21) on public control of

feed and animal by-products

- 44. SFS 2006:804 the Swedish Food Act
- 45. SJVFS 2012:27 a SBA regulation and general advice on the slaughter and other killing of animals which entered into force on 1 January 2013 when the SBA regulations (SJVFS 2007:77) on the slaughter and other killing of animals ceased to apply
- 46. Regulation (EC) No 1760/2000 a regulation issued by the European Parliament and the European Council establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
- 47. Commission Decision 1999/693/EC a decision of the EU Commission recognising the fully operational character of the Swedish database for bovine animals
- 48. Regulation (EC) No 1099/2009 a regulation of the EU Council on the protection of animals at the time of killing
- 49. SFS 1999:657 Swedish Act on Epizootic Diseases
- 50. SJVFS 2010:9 a Swedish Board of Agriculture's regulation regarding obligatory supervision in respect of incidences of TSE diseases in cattle, sheep and goats
- 51. SJVFS 2013:3 a Swedish regulation regarding amendments to the Swedish Board of Agriculture's regulations (SJVFS 2010:9) regarding obligatory supervision in respect of incidences of TSE diseases in cattle, sheep and goats
- 52. Regulation (EC) 178/2002 a regulation of the European Parliament and the European Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- 53. Regulation (EC) 931/2011 a regulation of the European Parliament and the European Council on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin
- 54. Commission Decision 90/134/EEC a decision of the Commission of the European Community amending for the second time Council Directive 82/894/EEC on the notification of animal diseases within the Community and temporarily amending the frequency of notification for bovine spongiform encephalopathy
- 55. SANCO/10586/2014 The programme for the monitoring of transmissible spongiform encephalopathies (TSE) and for the eradication of bovine spongiform encephalopathy (BSE) and of scrapie Sweden
- 56. Council Regulation (EC) No 820/97 a regulation of the European Council establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products
- 57. Commission Regulation (EC) No 911/2004 a regulation of the European Commission implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards ear tags, passports and holding registers
- 58. SJVFS 2007:12 a Swedish regulation issued by SBA on the marking and registration of bovine animals

- 59. Chapter 11.4 of the OIE Terrestrial Animal Health Code (version 8) published in 2014
- 60. Commission Decision 2008/908/EC a decision of the European Commission authorising certain Member States to revise their annual BSE monitoring programme

Appendices

Appendix 1:

Organisational Structures of Key Swedish National Agencies Involved in the Administration of Prevention and Control of BSE

Fig A1A: Organisational Structure of Statens Livemedelsverket (the Swedish National Food Agency)



Fig A1B: Organisational Structure of Statens Jordbruksverket (the Swedish National Board of Agriculture)



Fig A1C: Organisational Structure of Statens veterinärmedicinska anstalt (the Swedish National Veterinary Institute)

S Reg No. SVA25934 Version: 2 Organisation Structure of the Swedish National Veterinary Institute Director General Advisory Board Management Office of Quality (KVT) Office of Communication (KOM) Office of Customer relations (KUR) EURL/NRL Department Department Department Department Department Department of Animal Health of of of of of Chemistry Pathology Disease Control Microbiology Business and Wildlife Diseases (POV) and Epidemiology (ESS) and Antimicrobial Environment (MIK) Support Strategies (DOA) and Feed Hygiene (KMF) (VES) Main process: Diagnostics and analysis Main process: Research and development Main process: Knowledge communication Main process: Disease monitoring and contingency planning

Issued by: Gun-Britt Rydén

Approved: Jens Mattsson GDK – General Directors Office Valid from: 2016-02-15 1(1)

Countries of origin and amounts of bovine meat imported into Sweden between 2007 and 2014

Export country	2007	2008	2009	2010	2011	2012	2013	2014	Sum
Argentina	133	135	172	32	23	0	0	2	497
Australia	81	0	0	1	0	0	0	24	106
Austria	0	0	41	0	2	62	0	2	107
Belgium	128	496	273	177	210	201	261	293	2,039
Brazil	4,286	587	851	1,231	1,229	1,345	1,812	1,674	13,015
Bulgaria	0	0	2	0	0	3	0	0	5
Chile	0	4	6	6	6	6	2	3	33
Cyprus	0	0	0	0	0	0	0	17	17
Denmark	2,370	3,657	3,456	3,227	3,194	4,186	3,823	3,609	27,522
Estonia	0	0	30	159	34	125	148	115	611
Finland	875	447	696	802	976	398	238	271	4,703
France	4	19	9	4	19	6	32	9	102
Germany	5,058	5,751	4,447	4,488	5,480	7,477	7,094	5,726	45,521
Greece	0	0	0	0	3	25	35	5	68
Hungary	351	278	104	61	27	0	0	0	821
Ireland	19,532	20,494	16,089	14,883	17,690	15,677	14,986	14,638	133,989
Italy	37	43	22	6	68	190	208	482	1,056
Latvia	848	105	220	58	137	19	69	138	1,594
Lithuania	1,749	2,187	1,518	1,645	1,661	1,150	1,273	897	12,080
Luxembourg	0	0	0	18	11	2	0	0	31
Malta	0	0	0	0	21	0	0	0	21
Netherlands	3,674	4,300	4,926	7,468	9,603	13,052	15,798	15,105	73,926
New Zealand	0	0	0	4	5	3	2	1	15
Norway	0	0	0	0	2	1	0	1	4
Poland	106	1,040	1,777	1,925	1,308	1,532	1,800	2,597	12,085
Romania	0	0	20	0	0	741	678	516	1,955
Slovak Republic	0	0	0	0	0	1	2	1	4
Slovenia	0	0	1	3	5	4	1	0	14
Spain	2	32	447	695	727	956	1,254	1,132	5,245
United Kingdom	377	209	222	227	327	509	1,354	1,051	4,276
United States	22	0	0	15	0	0	0	0	37
Uruguay	259	674	809	495	524	584	537	406	4,288
Total									345,787

Table A2A: Volume of bovine meat (fresh or chilled) (tonnes)

Export Country	2007	2008	2009	2010	2011	2012	2013	2014	Sum
Argentina	21	73	69	54	22	4	1	0	244
Austria	1,109	959	753	741	851	1,446	1,369	1,659	8,887
Belgium	696	779	662	1,099	1,110	520	305	455	5,626
Brazil	2,112	726	88	191	269	276	250	540	4,452
Bulgaria	0	0	40	24	70	115	22	0	271
Chile	0	0	0	0	4	7	0	8	19
Czech Republic	0	0	0	0	0	1	0	0	1
Denmark	3,505	2,869	2,327	1,596	1,273	1,278	1,239	695	14,782
Estonia	0	31	10	25	66	83	49	30	294
Finland	263	162	731	756	1,290	819	893	803	5,717
France	28	37	20	25	1	4	166	212	493
Germany	8,246	9,032	8,493	8,152	5,865	6,832	9,230	11,330	67,180
Greece	1	0	0	0	4	7	0	0	12
Hungary	356	62	69	55	171	144	0	0	857
Ireland	7,704	9,946	8,041	8,037	8,981	7,540	7,208	9,060	66,517
Italy	137	182	229	117	75	52	130	207	1,129
Latvia	17	1	0	333	21	0	0	0	372
Lithuania	108	94	74	106	56	27	75	26	566
Netherlands	2,498	3,948	3,605	4,793	6,937	6,552	4,398	3,145	35,876
New Zealand	46	22	180	52	47	33	53	123	556
Norway	0	26	0	27	0	16	21	26	116
Paraguay	0	0	10	0	0	0	0	0	10
Poland	1,051	3,056	3,942	6,685	6,689	8,149	8,111	7,436	45,119
Romania	0	38	0	0	0	0	0	0	38
Slovak Republic	0	0	0	0	0	1	0	0	1
Spain	0	0	0	14	50	45	58	22	189
United Kingdom	1,248	85	130	98	457	345	276	82	2,721
Uruguay	260	492	1,375	1,162	1,115	1,213	989	911	7,517
Total									269,562

Table A2B: Volume of bovine meat (frozen) (tonnes)

Export country	2007	2008	2009	2010	2011	2012	2013	2014	Sum
Belgium	0	0	0	0	0	1	0	0	1
Denmark	537	116	76	33	59	128	140	431	1,520
Finland	73	30	5	199	233	0	18	27	585
Germany	28	43	27	30	63	89	18	4	302
Greece	0	0	0	0	0	0	2	2	4
Iceland	0	0	75	0	0	0	0	0	75
Ireland	10	5	13	10	27	48	59	32	204
Italy	26	18	0	0	0	0	0	0	44
Lithuania	0	1	6	0	0	0	0	0	7
Netherlands	115	112	80	110	124	133	153	154	981
New Zealand	0	0	0	0	0	8	6	3	17
Norway	212	115	115	1	0	15	4	10	472
Poland	0	0	0	0	6	7	4	292	309
Russia	0	24	50	0	0	0	0	0	74
Spain	0	0	0	0	0	0	44	13	57
United Kingdom	0	0	0	0	0	1	0	0	1
Total									4,653

Table A2C: Volume of offal derived from bovine animals, swine, sheep, goats, horses, asses, mules or hinnies (tonnes)

Export country	2007	2008	2009	2010	2011	2012	2013	2014	Sum
Argentina	0	0	14	2	6	0	0	0	22
Austria	0	12	27	95	85	137	350	513	1,219
Belgium	543	840	699	614	673	953	565	259	5,146
Brazil	1,917	2,023	1,786	1,492	974	740	1,280	869	11,081
Bulgaria	0	0	0	0	7	0	0	0	7
Croatia	113	130	115	132	104	126	67	40	827
Czech Republic	0	0	1	0	0	0	0	1	2
Denmark	3,164	2,547	2,240	3,213	2,643	2,320	1,969	1,862	19,958
Estonia	0	0	2	0	0	0	0	0	2
Finland	94	82	91	70	73	38	41	6	495
France	25	72	81	66	106	103	72	41	566
Germany	1,090	2,351	2,836	1,673	1,531	1,852	1,906	1,699	14,938
Ireland	1,173	1,211	821	1,014	859	806	1,047	1,105	8,036
Italy	146	46	96	76	91	106	97	105	763
Netherlands	42	119	113	200	289	184	113	55	1,115
Norway	1	2	1	29	14	38	8	20	113
Poland	2	12	6	193	284	180	138	0	815
Serbia	0	0	1	9	3	1	2	1	17
Slovenia	0	0	3	0	0	0	1	0	4
Spain	30	11	11	13	10	28	10	0	113
United Kingdom	10	31	2	29	8	12	17	11	120
United States	18	0	0	0	54	0	0	0	72
Total									65,431

Table A2D: Volume of processed bovine meat or offal imported (tonnes)

Appendix 3:

Key BSE Legislative Controls of Sweden and the European Union

Code of legislation	Title of the legislation
General	
Regulation (EC) No 999/2001	A regulation of the European Parliament and the European Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Regulation (EC) No 1069/2009	A regulation of the European Parliament and the European Council that laid down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Commission Regulation (EU) No 142/2011	A regulation of the European Commission implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive
Importation of MBM, live cattle	e, beef and beef products
Regulation (EC) No 999/2001	A regulation of the European Parliament and the European Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Regulation (EC) No 853/2004	A regulation of the European Parliament and the European Council laying down specific hygiene rules for on the hygiene of foodstuffs
Regulation (EC) No 854/2004	A regulation of the European Parliament and the European Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Regulation (EC) No 1069/2009	A regulation of the European Parliament and the European Council that laid down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Commission Regulation (EU) No 206/2010	A regulation of the European Commission laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements
Commission Regulation (EU) No 142/2011	A regulation of the European Commission implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive
Directive 2002/99/EC	A directive of the European Council laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption
Directive 2004/68/EC	A directive of the European Council laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC
SJVFS 2011:21	A Swedish regulation amending Swedish ordinance SJVFS 2006:84 on animal by-products which can spread contagious diseases to animals; issued by SBA
SFS 2006:805	A Swedish Act on feed and animal by-products, issued by the Swedish Ministry of Agriculture
SFS 2006:1165	A Swedish regulation on charges for the official control of feed and animal by- products, issued by the Swedish Ministry of Industry
SJVFS 2006:814	A Swedish regulation on feed and animal offal, issued by the Swedish Ministry of Agriculture
SJVFS 2007:21	A Swedish regulation and general advice on the control of feed and animal by- products, issued by SBA
SJVFS 2012:33	A regulation of the Swedish Board of Agriculture amending the Swedish Board of Agriculture's regulation (SJVFS 2007:12) on the labelling and registration of cattle
Pre-slaughter Controls: Feed	Ban
Regulation (EC) No 999/2001	A regulation of the European Parliament and the European Council laying down

	rules for the prevention, control and eradication of certain transmissible
Population (EC) No 852/2004	spongiform encephalopathies
	hygiene of foodstuffs
Regulation (EC) No 183/2005	A regulation of the European Parliament and European Council laid down requirements for feed hygiene
Commission Regulation (EC) No 152/2009	A regulation of the European Commission laying down the methods of sampling and analysis for the official control of feed
Regulation (EC) No 1069/2009	A regulation of the European Parliament and the European Council that laid down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Commission Regulation (EU) No 142/2011	A regulation of the European Commission implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive
Commission Decision 94/381/EC	A decision of the European Commission that banned mammalian derived protein from being fed to ruminants
Council Decision 2000/766/EC	A decision of the European Council concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein
Commission Decision 2001/9/EC	A decision of the European Commission concerning control measures required for the implementation of Council Decision 2000/766/EC concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein
SFS 2006:805	A Swedish Act on feed and animal by-products, issued by the Swedish Ministry of Agriculture
SFS 2006:814	A Swedish regulation on feed and animal offal, issued by the Swedish Ministry
SFS 2006:1165	A Swedish regulation on charges for the official control of feed and animal by- products, issued by the Swedish Ministry of Industry
SFS 2011:419	A Swedish Ministry of Agriculture's regulation amending the Order (2006: 814) on feed and animal by-products
LSFS 1985:35	A Swedish Agriculture Supplier's Board's regulation on animal feed
LSFS 1990:51	A Swedish National Board of Agriculture's regulation on the amendment of the National Board of Agriculture's regulation (LSFS 1987:42) concerning feeding-stuffs for food-producing animals and horses
SJVFS 1995:25	A Swedish Board of Agriculture's regulations amending the Swedish Board of Agriculture's regulations (SJVFS 1993:177) on feeding stuffs
SJVFS 2011:21	A Swedish regulation amending Swedish ordinance SJVFS 2006:84 on animal by-products which can spread contagious diseases to animals, issued by SBA
SJVFS 2007:21	A Swedish regulation and general advice on the control of feed and animal by- products, issued by SBA
SJVFS 2014:7	A regulation of the Swedish Board of Agriculture amending the Swedish Board of Agriculture's company and general advice (SJVFS 2007:21) on public control of feed and animal by-products
Ante-mortem Slaughter Contro	pls
Regulation (EC) No 1760/2000	A regulation issued by the European Parliament and the European Council establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Regulation (EC) No 999/2001	A regulation of the European Parliament and the European Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Regulation (EC) No 852/2004	A regulation of the European Parliament and the European Council on the hygiene of foodstuffs
Regulation (EC) No 853/2004	A regulation of the European Parliament and the European Council laying down specific hygiene rules for on the hygiene of foodstuffs
Regulation (EC) No 854/2004	A regulation of the European Parliament and the European Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
SFS 1999/657	Swedish Act on Epizootic Diseases
SFS 2006:804	Swedish Food Act
SJVFS 2012:27	A SBA regulation and general advice on the slaughter and other killing of

	animals which entered into force on 1 January 2013 when the SBA regulations (SJVFS 2007:77) on the slaughter and other killing of animals ceased to apply
Slaughter methods	
Regulation (EC) No 1099/2009	A regulation of the EU Council on the protection of animals at the time of killing
SJVFS 2012:27	A SBA regulation and general advice on the slaughter and other killing of animals which entered into force on 1 January 2013 when the SBA regulations (SJVFS 2007:77) on the slaughter and other killing of animals ceased to apply
Post-slaughter Controls: Post-	-mortem inspection, SRM removal, rendering procedures
Regulation (EC) No 999/2001	A regulation of the European Parliament and the European Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Regulation (EC) No 854/2004	A regulation of the European Parliament and the European Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Regulation (EC) No 1069/2009	A regulation of the European Parliament and the European Council that laid down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Commission Regulation (EU) No 142/2011	A regulation of the European Commission implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive
SFS 1999/657	Swedish Act on Epizootic Diseases
BSE Food Safety Controls	
Regulation (EC) No 178/2002	A regulation of the European Parliament and the European Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Regulation (EC) No 852/2004	A regulation of the European Parliament and the European Council on the hygiene of foodstuffs
Regulation (EC) No 853/2004	A regulation of the European Parliament and the European Council laying down specific hygiene rules for on the hygiene of foodstuffs
Regulation (EC) No 854/2004	A regulation of the European Parliament and the European Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Regulation (EC) No 931/2011	A regulation of the European Parliament and the European Council on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin
SFS 2006:804	Swedish Food Act
SJVFS 2010:9	A Swedish Board of Agriculture's regulation regarding obligatory supervision in respect of incidences of TSE diseases in cattle, sheep and goats
SJVFS 2013:3	A Swedish regulation regarding amendments to the Swedish Board of Agriculture's regulations (SJVFS 2010:9) regarding obligatory supervision in respect of incidences of TSE diseases in cattle, sheep and goats
BSE Control programs and Te	chnical Infrastructure
Regulation (EC) No 999/2001	A regulation of the European Parliament and the European Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Commission Decision 90/134/EEC	A decision of the Commission of the European Community amending for the second time Council Directive 82/894/EEC on the notification of animal diseases within the Community and temporarily amending the frequency of notification for bovine spongiform encephalopathy
Commission Decision 2007/353/EC	Guidelines of the European Commission to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council
Commission Decision 2008/829/EC	A decision of the European Commission amending the annex to decision 2007/453/EC establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk
Commission Decision 2008/908/EC	A decision of the European Commission authorizing certain Member States to revise their annual BSE monitoring programme
SFS 1999:657 SJVFS 2010:9	Swedish Act on Epizootic Diseases A Swedish Board of Agriculture's regulation regarding obligatory supervision in respect of incidences of TSE diseases in cattle, sheep and goats
SJVFS 2013:3	A Swedish regulation regarding amendments to the Swedish Board of

	Agriculture's regulations (SJVFS 2010:9) regarding obligatory supervision in respect of incidences of TSE diseases in cattle, sheep and goats
Cattle Identification, Traceabil	ity and BSE surveillance
Regulation (EC) No 820/97	A regulation of the European Council establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products
Regulation (EC) No 1760/2000	A regulation issued by the European Parliament and the European Council establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Regulation (EC) No 999/2001	A regulation of the European Parliament and the European Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Commission Regulation (EC) No 911/2004	A regulation of the European Commission implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards ear tags, passports and holding registers
Regulation (EC) No 882/2004	A regulation of the European Parliament and of the Council laying down the official controls performed to ensure the verification of compliance with EU feed and food laws, animal health and animal welfare rules in EU member states
Commission Decision 1999/693/EC	A decision of the EU Commission recognising the fully operational character of the Swedish database for bovine animals
SJVFS 2007:12	A Swedish regulation issued by SBA on the marking and registration of bovine animals