

BSE
Food Safety
Risk
Assessment
Report
Croatia

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Risk Assessment Biological Sciences Section

Food Standards Australia New Zealand

Executive summary

Food Standards Australia New Zealand (FSANZ) is the regulatory body responsible for conducting Bovine Spongiform Encephalopathy (BSE) food safety assessments of countries that seek to export beef or beef products to Australia. FSANZ analyses the information provided by applicant countries and assigns them a BSE risk status. The requirements detailed in the *Australian Questionnaire to Assess BSE Risk*¹ are consistent with those of the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code* (2016)². Croatia made a submission in 2010 to be assessed under the current BSE policy.

Croatia was previously assessed by the Australian BSE Country Categorisation Committee for Human Food Products (ABCCC) in 2003 for the purpose of country categorisation. The review was based on:

- a completed FSANZ country questionnaire and associated information
- Eurostat export statistics on exports of live cattle and of MBM and greaves from European Union (EU) member states during the period 1980 to 2000.

At the time of the ABCCC review, the ban on rendering Specified Risk Material (SRM) had been in place for five years, but only two years had elapsed since the introduction of the total ban on feeding meat and bone meal (MBM) to farm animals, the exclusion of fallen stock from rendering, and efficient BSE surveillance. It was concluded that at the time of the review, the risk of recycling and amplification of infectious material was very stable, but that it had been unstable in the recent past. Croatia was assigned to Category C, as a country assessed as having had considerable exposure to BSE risk materials, but having not reported any cases of BSE.

FSANZ has conducted an assessment of Croatian legislative measures concerning control and prevention of BSE, and an in-country assessment of the application and enforcement of these legislative measures. Croatia currently has robust controls to prevent the amplification of the BSE agent within the Croatian cattle population and contamination of the human food supply with the BSE agent. Control procedures were observed to be operating efficiently during the in-country assessment.

Importation of MBM or greaves is prohibited in Croatia, and effective border controls are in place. Repeated revisions of legislation has ensured that controls to prevent the importation of cattle incubating BSE, and food products of bovine origin that might contain the BSE agent, have been as rigorous as, or more rigorous than, OIE recommendations for more than a decade. The exception has been the importation of bone-in meat, which is not recommended by OIE, but because only bone-in meat inspected and certified as suitable for human consumption in an EU country has been permitted, this is not considered to be a significant source of risk. Croatia has been diligent in monitoring the BSE status of other countries and has kept up to date with evolving knowledge of BSE transmission.

Procedures are in place to protect against cross-contamination of feed between ruminant and non-ruminant species. Sampling is in place to ensure that fishmeal used in animal feed production does not contain mammalian proteins, although sampling has been mandatory only since 2006.

Food safety controls are established in Croatia to ensure effective protection of the human food supply from potential BSE contamination. Croatian regulations related to management of SRM such as central nervous tissue at slaughter are fully aligned with European Commission (EC) regulations and OIE recommendations. All beef and beef products are fully traceable back to the animal or animals from which it came, and all bovines in Croatia must

be identified and registered. All food business operators are required to have a procedure for the recall of products as part of Hazard Analysis and Critical Control Point (HACCP) requirements, and Croatia has a rapid alert system and procedures to deal with food safety emergencies.

BSE has been a notifiable disease in Croatia since 1996 and effective BSE education and awareness programs are in place. Farmers, veterinarians, and slaughterhouse personnel are educated to recognise the clinical signs associated with the disease through ongoing awareness and education exercises for BSE. There are incentives to facilitate reporting, and penalties for failure to report suspect clinical cases.

Diagnostic capability is good, and diagnostic tests compliant with Chapter 2.4.6 of the OIE *Manual of Standards for Diagnostic Tests and Vaccines for Terrestrial Animals* have been validated and are subject to appropriate, ongoing quality control, including collaborative inter-laboratory testing with national reference laboratories of other countries.

Croatia has a sophisticated, centralised animal identification system and database, which is fully aligned with EU regulations.

Surveillance points data provided with Croatia's submission in 2011 did not meet the requirements of Type A surveillance for the seven year period 2004-10, resulting in a recommendation of Category 2 status for Croatia. Since May 2014, Croatia has carried out Type B surveillance that complies with the guidelines in Articles 11.4.20 to 11.4.22 of the OIE's *Terrestrial Animal Health Code* for a negligible risk country. Croatia's surveillance points total for the seven year period 2010-16 was 69,853, exceeding the OIE Type A points target of 22,100 for an adult cattle population between 100,001 to 200,000. In-country assessment by FSANZ personnel confirmed that Croatian legislation relevant to BSE prevention and control is effectively enforced.

The risk of BSE entering and recycling within the bovine feed system or entering the human food supply in Croatia is negligible and Croatia now meets all the requirements of Category 1 status. This BSE food safety risk assessment therefore concludes that beef and beef products imported from Croatia are safe for human consumption and recommends **Category 1** status for Croatia.

Acronyms

ABCCC	Australian BSE Country Categorisation Committee
AV	Authorised Veterinarian
BIP	Border Inspection Post
BSE	Bovine Spongiform Encephalopathy
CAA	Croatian Agriculture Agency
CCP	Critical control point
CLC	Croatian Livestock Centre
CNS	Central nervous system
DAWR	Australian Government Department of Agriculture and Water Resources
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FSANZ	Food Standards Australia New Zealand
HACCP	Hazards Analysis and Critical Control Points
MA	Ministry of Agriculture (current competent authority)
MAFRD	Ministry of Agriculture, Fisheries and Rural Development (former name of the competent authority, prior to restructuring in 2012)
MBM	Meat-and-bone meal
OIE	Office International des Epizooties (World Organisation for Animal Health)
OV	Official Veterinarian
RASFF	Rapid Alert System for Food and Feed
SRM	Specified risk material
SVI	State Veterinary Inspector
TAIEX	Technical Assistance and Information Exchange
TSE	Transmissible spongiform encephalopathy
UK	United Kingdom of Great Britain and Northern Ireland
US	United States of America

VD

Veterinary Directorate

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Introduction

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

In general, data requirements in the Australian Questionnaire are consistent with those of *Chapter 11.4 – Bovine Spongiform Encephalopathy* of the *OIE Terrestrial Animal Health Code (2016)*². The Australian Questionnaire also seeks additional information on animal traceability and identification, and animal slaughtering and processing systems.

Croatia submitted an application to FSANZ for country categorisation of BSE food safety risk on 14 April 2011. Croatia submitted relevant documentation, according to the official OIE questionnaire, to the OIE on 23 March 2011. This report describes the BSE food safety risk assessment conducted by FSANZ, taking into consideration information provided in annual updates from 2014 to 2017, to determine the risk that the BSE agent is present in beef and beef products imported from Croatia.

Overview of Croatia's BSE regulatory system

Croatia became the 28th member country of the European Union (EU) on 1 July 2013. Regulations for BSE controls are mainly set by the European Commission (EC) to allow BSE controls to be harmonised across the EU and to support an agenda for BSE eradication. EC legislation is introduced as Directives or Regulations that must be adopted by member countries. Other rules for implementation are set either by the EC or by national regulatory bodies. Croatia has been subject to EC regulations on BSE since it became a member of the EU in 2013. The legislative arrangements outlined in this report were true at the time of the FSANZ in-country assessment and Croatia has now transitioned to EU Regulations.

BSE History

No cases of BSE have been confirmed in Croatia to date. A single case of suspected BSE in a dead heifer in Croatia was reported on 17 February 2006. Samples were sent to the reference laboratory at Weybridge in the United Kingdom³ (UK) and the results were negative⁴.

Croatia formally requested determination of its BSE status under Regulation (EC) No 999/2001. The Final Report on the Geographical BSE-Risk (GBR) of Croatia⁵ and the Scientific Steering Committee (SSC) opinion on the GBR of Croatia⁶ were adopted in June 2002. In light of the instability of BSE control in Croatia before 2001, the SSC concluded that 'it is likely but not confirmed that domestic cattle in Croatia are (clinically or pre-clinically) infected with the BSE-agent (GBR-III)'. However the SSC also concluded that as a result of control measures taken from 1 January 2001, the situation had changed from extremely unstable to very stable, and that 'it is regarded unlikely that further propagation of the disease occurs after beginning of 2001'.

The OIE General Assembly classified Croatia as having a controlled BSE risk in May 2012, a status that was maintained up until May 2014, at which time Croatia's BSE risk status was re-classified to negligible BSE risk at the 82nd OIE General Assembly.

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

Potential for release of the BSE agent through imported materials

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

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

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

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

1 Importation of MBM or greaves

1.1 Overview

Importation of animal protein sourced from ruminants poses a food safety risk as it is the primary route through which cattle are exposed to BSE infectivity. Importation of protein from animal sources is highly restricted in Croatia. No MBM, greaves or feedstuffs containing animal protein of mammalian origin have been imported into Croatia within the last eight years.

1.2 Legislation

The Ministry of Agriculture (MA), formerly the Ministry of Agriculture, Fisheries and Rural Development (MAFRD), administers and enforces legislation regarding the importation of animal protein, including MBM, into Croatia. This Ministry was formerly named the Ministry of Agriculture, Forestry and Water Management and before that, the Ministry of Agriculture and Forestry. The current internal structure of the MA is presented in **Appendix 1**.

Restrictions on the importation and use of MBM and greaves are specified in Orders and Ordinances published in the Official Gazette. Before 2000, these Orders were pursuant to the Animal Health Care and Veterinary Act. Since 2000, the Orders and Ordinances have

been pursuant to the *Veterinary Act* and amendments.

Prohibition of the importation of MBM and other high-risk tissues and products of animal origin from countries identified as having had cases of BSE was first gazetted on 7 March 2000 (Official Gazette 30/2000). The original prohibition underwent amendment by means of a series of Orders, which refined the list of banned imports and added, or occasionally deleted, countries from the list of countries considered to have BSE. MBM has been banned specifically in all Orders. Greaves for inclusion in products for animal consumption have been included in a general ban on 'other fodder containing proteins of animal origin' since December 2000, as well as in a general ban on 'bovine derived products' since 9 July 2001.

On 8 March 2007, the 03/2006 Order was replaced by a detailed Ordinance updating and consolidating all measures for the prevention, control and eradication of TSEs. This Ordinance was the first to refer specifically to greaves. The Ordinance was partly aligned with the European Community (EC) Regulation No. 999/2001 of the European Parliament and the Council, and was replaced by the current legislation, an Ordinance dated 10 July 2009, which is fully aligned with Regulation (EC) No. 999/2001 of the European Parliament and the Council.

A continuous ban on the inclusion of ruminant protein, other than that derived from milk or derivatives of milk, in ruminant feed has been maintained by Croatia by Orders or Ordinances since March 1997. This ban applies to both domestically produced feed and imported feed.

An exclusion that could apply to MBM was introduced in February 2001, in that the general ban on high risk tissues was stated to not apply to 'dog and cat food from countries with no occurrence of transmissible spongiform encephalopathies'. The legislation underwent minor revisions, but usually permitted importation of dog and cat food raw material derived from ruminants originated from countries with no occurrence of BSE, until June 2004 when Croatia adopted a system of categorising countries in terms of BSE risk. At that time, importation of dog and cat food became generally permissible unless the food contained bovine tissue from countries in Category 4 which at that time included Portugal and the UK. Portugal was subsequently removed from Category 4. In March 2007, when Croatia moved to align its legislation with that of Regulation (EC) No. 999/2001 of the European Parliament and the Council, it became permissible to import dog and cat food from countries with a high incidence of BSE (Category 5).

1.3 Details of MBM imports

Croatia has not imported MBM or any ruminant-derived feed ingredients from any country within the past 8 years. Importation of MBM is prohibited.

Border Inspection Posts (BIPs) must be notified about shipments of animal feeds or feed ingredients in advance of arrival. Feed shipments entering Croatia are sampled for prohibited proteins at the BIP, and notification of the shipment is sent to the relevant veterinary colleague at the destination of the shipment. The shipment cannot be used until the results of testing for prohibited proteins are received. Testing is conducted at the Laboratory for Microbiology of Feed, in the Veterinary Health Department of the Croatian Veterinary Institute. Microscopic examination is the routine method employed, although the laboratory also has capability in immunoassay and has occasionally used PCR on samples of unspecified origin.

In the past, Croatia has imported fishmeal for use in feed for pigs and poultry, but in recent years, domestic production of fishmeal has been sufficient for making these feeds, because the agricultural industry has been declining in size. All shipments of imported fishmeal must

be tested for mammalian proteins.

When inspecting a shipment of meat for use within Croatia, BIP personnel check the destination. Thus a shipment of any type of ruminant-derived protein could not be imported if the destination is a feed mill.

2 Importation of live cattle

2.1 Overview

Importation of live cattle represents a potential food safety risk if imported cattle are sourced from countries that do not have adequate control programs in place to minimise the risk of BSE exposure. Cattle have been imported into Croatia during the past seven years, but import requirements have been in place to prevent the introduction of cattle that could be preclinically infected with BSE.

2.2 Legislation

All import shipments of live cattle into Croatia are subject to the approval of the competent authority (MA). Until November 2009, for each shipment an Administrative Decision (Decision on Import) was issued, defining the animal health requirements to be met. These requirements, which included the BSE status of the country of origin, had to be confirmed in the veterinary certificate accompanying the shipment. The Administrative Decision template for calves and heifers for fattening required compliance of the country of origin with OIE recommendations. The templates for cattle for fattening, and for cattle for breeding, required the country of origin to be classified as having at least a controlled BSE risk. Since November 2009, animal health conditions for importing live cattle into Croatia have been specified in veterinary certificates, of which specimens have been provided to FSANZ.

Croatian legislation pertaining to the importation of live cattle has been repeatedly revised to reflect the BSE status of other countries. Importation of live cattle from specified countries in which BSE had occurred was banned in July 2001, with subsequent Orders adding more countries to the list, or occasionally removing countries from the list of banned countries. Current importation regulations, including those concerning inspection of imported cattle, are fully aligned with EU regulations.

In January 2004, an Order was gazetted that stated that the ban on importation of live cattle was 'not applicable to consignments from countries in Category I and II according to GBR (Geographical Risk of Bovine Spongiform Encephalopathy) assessment of SSC (Scientific Steering Committee) of the European Commission, except for Canada and USA'. The Order was also not applicable to consignments from countries for which the central competent authority of the exporting country confirmed to the Ministry of Agriculture and Forestry (the name of the competent authority at that time) that the imported animals had not been fed any mammalian-based proteins.

In June 2004, this Order was replaced by a system in which countries were identified as belonging in one of four categories in terms of BSE. Imports of live cattle became permissible provided conditions appropriate to the category were met. Countries with no history of BSE, and in which animals were not fed MBM or mammalian-derived proteins were classed in Category 1. Category 2 countries were those with a history of BSE cases, but in which the prohibition on feeding mammalian proteins to ruminants was efficiently enforced. Importation of cattle from Category 2 countries became permissible provided the cattle were permanently marked in a way that permitted tracing back to the dam and herd of origin, and provided the cattle were not the offspring of a dam that was suspected of having BSE. Category 3 included countries with a history of BSE cases, and in addition to the requirements for

Category 2, there was a requirement that the cattle were born, reared and kept in herds where no case of BSE had been confirmed in the previous 7 years, and cattle afterwards added to the herd came from a herd or farm with a similar status, or that the cattle were born after the date from which the prohibition of feeding cattle with protein of mammal origin was efficiently enforced. Portugal and the UK, historically both with a relatively high incidence of BSE, were in Category 4, and importation from these countries remained prohibited. Details of the countries assigned to each Category, and the import requirements for each Category, are presented in **Appendix 2**. The system was maintained until 2007 when Croatia adopted the classifications of the EC. The import requirements for countries in Categories 1 and 2 essentially match the import recommendations in the OIE *Terrestrial Animal Health Code* for countries with negligible risk and no history of BSE, with negligible risk but history of BSE cases or with controlled risk, respectively. The import requirements for cattle from countries in Category 3 are more rigorous than the import recommendations in the OIE *Terrestrial Animal Health Code* for countries with controlled risk.

An *Ordinance on the compulsory identification and registration of bovine animals* (Official Gazette, 99/2007) prescribed the procedure for including all imported cattle, except those imported for immediate slaughter, into a national bovine database, the Central Register of Domestic Animals. Identification of individual animals is by ear-tag, and allows tracing of the destiny of each imported animal.

2.3 Details of live cattle imports

Information was provided on the number and fate of imported cattle from 2004, when the category system was introduced, to 2010. Imports of cattle have been for production, breeding or immediate slaughter. All imports required veterinary certification, and specimens of veterinary certificates were included in the submission.

Numbers of cattle imported into Croatia in the interval 2004 - 2010 inclusive are presented in **Table 1**.

Origin	Category under Croatian legislation	Number of Cattle Imported 2004 - 2010		
		Breeding Stock	For Production	For Immediate Slaughter
Austria	3	11 932	101	-
Bulgaria	3	-	2918	20
Canada	2	349	-	-
Czech Republic	3	1 437	48 033	530
France	3	684	-	-
Germany	3	25 375	867	20
Hungary	3	2 188	18 476	115 404
Italy	3	135	60	57
Lithuania	3	-	3 341	-
Netherlands	3	10 951	-	-
Norway	1	60	-	-
Poland	3	307	12 415	225 527
Romania	3	-	342 180	30 434
Slovakia	3	94	63 683	1 035
Slovenia	3	48	-	-
Sweden	2	968	-	38 520
Switzerland	3	129	-	-
United Kingdom	4	31	-	-
USA	2	3	-	-

Details of all imported cattle, except those slaughtered within 20 days of the veterinary check conducted at the time of crossing the border, are entered into the national bovine database, which allows tracing of all imported cattle as well as those born in Croatia. This system has been progressively aligned with the EU regulations since 2003 and is currently fully aligned with those regulations. Examples of information in the database were included in the submission. The bovine database contains all relevant information needed to retrieve information about the dam and cohort related to any animal suspected of having BSE. Information includes but is not limited to Identification (ID) Code, date of birth, sex, ID Code of the mother, ID Codes of calves, all movements of the animal, information about the keeper, all the bovine animals that have ever been kept on the farm, and all movements to and from a specified farm in a specified time interval. Date of slaughter or death is also recorded. The database can also be searched by county, village, farm or slaughterhouse.

Individual identification and registration of all bovine animals are compulsory in Croatia, and subject to on the spot inspections by the Veterinary Directorate (VD), which is an organisational unit within the MA. Inspections are required to cover at least 10% of holdings each year. Cattle are individually identified by an ear-tag in each ear. Cattle imported from EU Member States retain their original ear-tags while those from other countries are given new tags while retaining the ear-tags they had on arrival. For each animal, the Croatian Livestock Centre (CLC) issues a Movement Document which accompanies the animal every time it is moved, and is returned to the CLC upon the death or slaughter of the animal. The Movement Document accompanying an animal on its arrival from an EU Member State is surrendered to the approved veterinarian on the animal's arrival.

The BIPs in Croatia require at least 24 hours' notification of live animal shipments. They have access to the EU electronic Trade Control and Expert System (TRACES) although they will not be able to input data into it until Croatia joins the EU. Through TRACES, they receive notification of impending shipments of live animals from EU countries. The transport company and the importer in Croatia are also required to give the BIP 24 hours' notice, in addition to notification from TRACES.

Each animal on a truck must have its own papers including identification, date of birth and identification details of parents. All shipments of animals or animal-derived products must have a certificate of import, and the exporting company must verify all the information on the import certificate. A shipment of live animals is not allowed through the BIP unless a precise destination (i.e. the specific farm) is stated on the documentation. The BIP has online access to the register of farms. After verifying all details including origin and that the animal was born after the date of the MBM feeding ban, BIP veterinarians visually inspect the animals on the truck, verifying the ear-tags of at least 10%.

If the final destination of the animals is within Croatia, BIP veterinarians notify the local Official Veterinarian (OV) at the destination when the shipment passes through the BIP. OVs are full-time employees of the Veterinary Inspection Service of the MA, whereas AVs are veterinarians employed by the Veterinary Inspection Service under full- or part-time contract. Both are legally authorised by the Veterinary Inspection Service to conduct activities of the Service.

If a shipment of live animals is in transit through Croatia, notification of the shipment is sent to the BIP of departure.

Croatian legislation is also fully aligned with the EU directive on humane treatment of animals when being shipped. Compliance is very good, and since the legislation was introduced there have been no deaths in transit, but if an animal died in a truck it would be classified as Category 1 material and tested for BSE at the rendering facility regardless of age or other risk factors. An animal unfit to admit, that for animal welfare reasons could not be returned to

the originating country, would be quarantined. BIPs have the authority to stop a shipment that lacks adequate documentation. Both the MA and the country of origin are notified of any stopped shipment, and the shipment may be sent back.

The BIPs have Standard Operating Procedures (SOPs) in place for processes including inspection, sampling, quarantine, release, and rejection procedures. They receive regular updates from the MA, via the MA website, and this ensures that any updates are made rapidly.

3 Importation of beef and beef products

3.1 Overview

This Section focuses on the risk of releasing the BSE agent through the importation of beef-containing food products intended for human consumption.

3.2 Legislation

3.2.1 Regulatory Agencies

Until November 2009, importation of products of bovine origin was subject to approval by MAFRD. Under the Ordinance which established full alignment of Croatian regulations concerning importation of beef and beef products with EC regulations, MAFRD was identified as the competent authority for enforcement. Following organisational restructuring in 2012, the competent authority is the MA.

3.2.2 Legislation

Importation of high-risk tissues and bovine products from Belgium, Canada, Denmark, the Falkland Islands, France, Germany, the Republic of Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Oman, Portugal, Switzerland and the UK was prohibited in March 2000. This ban was later extended to cover high-risk tissues from any country and the list of tissues considered to be high-risk was extended. Prohibition of import of all bovine-derived products from Belgium, the Czech Republic, Denmark, France, Germany, Greece, the Republic of Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Portugal, Spain, Switzerland and the United Kingdom was gazetted in July 2001. This prohibition was refined over time with addition, and occasionally removal, of countries from the list of countries from which imports were banned. Restrictions were relaxed for some products such as gelatine, if thorough processing had occurred.

In June 2004 Croatia replaced the total ban on bovine products from countries in which BSE had occurred with legislation that assigned countries to categories with different clearance requirements. This system was refined by revisions to the legislation until March 2007 when an Ordinance was issued achieving partial alignment with the EC regulations, and adopting EC classifications for BSE risks of countries of product origin. In July 2009 this Ordinance was replaced with an Ordinance bringing Croatia into full alignment with Regulation (EC) No. 999/2001 of the European Parliament and the Council.

There is extensive documentation to show that legislation was periodically reviewed in light of evolving knowledge of the BSE status of countries and of evolving knowledge of transmission of BSE. This documentation is in the form of multiple, frequent revisions of the legislation related to imported animals and animal-derived products, as well as revisions in legislation related to husbandry and slaughter of Croatian-born cattle.

3.2.3 Clearance requirements

From the lifting of total bans on certain countries in June 2004 through to adoption of the EC classifications for BSE status of countries in March 2007, Croatia applied a categorisation system that assigned countries to one of four categories.

Category 1 included countries such as Australia and New Zealand in which BSE had never occurred. From June 2004, imports of meat products from Category 1 countries were permitted, subject to certain conditions. Meat and meat products from domestic ruminants could not include specified high-risk tissues, and had to be accompanied by a veterinary health certificate to confirm that animals had not been fed MBM or cattle feed containing tissues of mammals, and that the exporting country has a system enabling the monitoring of origin of fresh meat from cattle, sheep and goats and production plants in which meat was produced. Suet for use in the food industry had the same veterinary certification requirements as meat, and suet for industrial processing, and melted fat, required a veterinary health certificate to confirm that animals were not fed MBM or cattle feed containing tissues of mammals. These requirements are similar to the OIE recommendations for meat and meat products from countries with negligible BSE risk (Article 11.5.10) although a requirement for ante-mortem and post-mortem inspection was not specified by Croatia.

Category 2 included countries such as Canada, Sweden and USA. From June 2004, imported meat products from Category 2 countries had more rigorous veterinary certification requirements than those from Category 1 countries. For meat, the veterinary health certificate had to confirm that the exporting country has an efficiently enforced prohibition on feeding ruminants proteins from other ruminants and cattle feed containing mammal tissues. The legislation initially required that any cattle over 30 months old from which meat or meat products are obtained had been tested for BSE after slaughter, with a negative result, but this was later replaced by a requirement that the exporting country enforced obligatory testing of all cattle showing clinical signs of BSE. Veterinary certification was also required to confirm that the animals were not stunned or slaughtered by gas injection into the cranial cavity, or by penetration of the cranial cavity; that specified high-risk tissues, and mechanically separated meats were not present; and that the exporting country has a system enabling the monitoring of origin of fresh meat from cattle, sheep and goats and production plants in which meat was produced. Similar veterinary certification requirements were imposed for suet and melted fat. These requirements are similar to the recommendations of the OIE for meat and meat products from countries with controlled BSE risk (Article 11.5.11) although a requirement for ante and post-mortem inspection was not specified by Croatia.

Category 3 included the largest number of countries, including most EC countries and a number of eastern European countries. Meat products from Category 3 countries had to meet the same conditions as meat products from Category 2 countries, and in addition: Products could not contain mechanically separated meat from bones, spine or head of cattle; any cattle over 24 months old from which meat or meat products were obtained had been tested for BSE after slaughter, with a negative result; and meat or meat products from cattle not tested for BSE had to be from cattle less than six months old.

Category 4 included Portugal and the UK in June 2004, until Portugal was reclassified to Category 3 in January 2005. Importation of meat products from Category 4 countries remained prohibited.

3.3 Type of imported beef or beef products

3.3.1 Fresh or frozen beef

The countries of origin and total quantity of bovine meat imported into Croatia from 2004 to

2010 inclusive are presented in Table 2. The prohibitions on high-risk tissues apply to imported meat and include mechanically separated meat if it originates from a country with confirmed BSE occurrence. Bovine meat that is imported bone-in, such as a half- or quarter-carcass, must have a 'health mark' stamp to show that it has been inspected and found to be fit for human consumption in the country of origin. Packaged meat must have appropriate identification for trace-back, as required by EU regulations.

Table 2: Beef imports into Croatia 2004-10 inclusive

Origin	Category under Croatian legislation	Total (kg)	% of total	Years of import (inclusive)
Argentina	1	3 412 521	6.59	2005-10
Austria	3	4 135 087	7.99	2004-09
Australia	1	1 259 028	2.43	2004-09
Belgium	3	20 962	0.04	2010
Brazil	1	12 880 617	24.87	2004-10
Canada	2	81 806	0.16	2008
Denmark	3	3 301 807	6.38	2004, 2006, 2008–10
France	3	401 361	0.78	2006-10
Germany	3	1 374 493	2.65	2004-10
Hungary	3	175 137	0.34	2004, 2007
Italy	3	138 967	0.27	2004, 2005, 2009-10
Netherlands	3	14 215 092	27.45	2004–10
New Zealand	1	399 582	0.77	2004-05, 2010
Paraguay	1	245 919	0.47	2009-10
Poland	3	5 090 396	9.83	2004-10
Portugal	4	193 019	0.37	2006-07
Slovenia	3	88 645	0.17	2006-10
Spain	3	31 935	0.06	2005, 2007, 2009
Sweden	Not classified	137 820	0.27	2009
USA	2	161	0.00	2008-09
Uruguay	1	4 198 390	8.11	2004-09
Total:		51 782 745	100	

All meat shipments arriving at BIPs for importation into Croatia, or transit through Croatia, are weighed, although it is recognised that fresh meat is subject to some fluctuation in weight. For frozen meat, the documentation required at the BIP includes the number of packages, the weight, the day of freezing and the day of slaughter. BIP personnel check the destination of shipments of imported meat to ensure that it is an appropriate premise, for example that the destination for a shipment of frozen meat has freezer facilities. Sampling of imported meat by BIPs is determined by the annual monitoring plan drawn up by the VD.

3.3.2 Tallow

All tallow imported into Croatia in the years 2004-10 inclusive originated in Poland. Imports were made in 2006, 2007 and 2009. The total amount of tallow imported during those three years was 125,184 kg.

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

The documentation submitted by Croatia supports a conclusion that the risk of the BSE agent being released into the Croatian cattle population through imports of MBM, live cattle, or beef and beef products is very low.

Feeding of ruminant-derived proteins, other than milk or milk products, to ruminants has been banned in Croatia since 1997. Importation of MBM or greaves from countries with BSE

has been banned under Croatian legislation from 2000. Since 2007, Croatian legislation has been progressively aligned with EC regulations, and since July 2013, regulations for BSE controls are mainly set by the European Commission (EC) to allow BSE controls to be harmonised across the EU. Croatia has not imported MBM or any ruminant-derived feed ingredients from any country within the past 8 years, with the exception of food for domestic pets. Personnel at BIPs closely scrutinise shipments of pet food. Croatia does not currently have a fur-farming industry.

Importation of live cattle from countries in which BSE had occurred was prohibited from 2001, and since 2004 has been reviewed as the BSE status of countries has changed. Since 2004, Croatia has progressively relaxed its legislation to allow imports of live cattle from other countries. However, countries of origin have been categorised according to the incidence of BSE and/or the OIE categorisation regarding BSE risk category, and restrictions have been placed on imports from each category. The category system imposed by Croatia between 2007 and 2009 is presented in **Appendix 2**, and is generally similar to or more rigorous than OIE recommendations. Since 2009 Croatia has been fully aligned with EC regulations with regard to BSE risk of imported cattle.

Importation of beef and beef products from countries with BSE was prohibited in 2000, with revisions of legislation occurring subsequently. In 2004 a total ban on imports was replaced with a category system. Documentation appropriate to the categorisation of the country of origin, in the form of veterinary certification, is required with each shipment. The category system initially adopted was Croatia's own system, and was similar to, but not the same as, the OIE recommendations. Since 2009 Croatia has been fully aligned with EC regulations with regard to importation regulations pertaining to bovine meat, meat products, and live cattle.

Although large numbers of live imports, and high volumes of beef and beef products, have been imported into Croatia, import restrictions to minimise the risk of importing BSE-infected animals or products have been in place for more than seven years. From 2004 to 2007, the import restrictions on live cattle were as rigorous as, or more rigorous than, the OIE recommendations. During the same period, the import restrictions on beef and beef products closely resembled the OIE recommendations. OIE does not recommend the importation of bone-in meat, but Croatia accepts bone-in meat provided it has been appropriately inspected, and marked as fit for human consumption, in the EU country of origin.

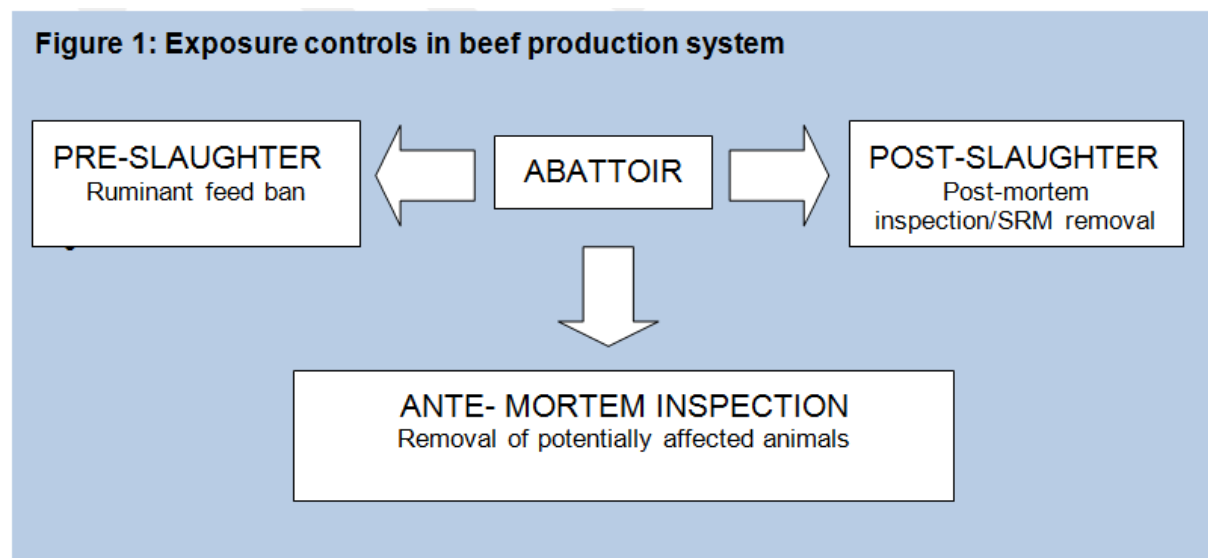
The frequent revision of legislation related to imports of cattle and products derived from cattle illustrates that Croatia has been diligent in monitoring the BSE status of other countries. The relaxation of absolute bans in favour of permitting imports with appropriate restrictions is evidence that Croatia has kept up to date with evolving knowledge of BSE transmission and risk, and reflects international standards.

Exposure control

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

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

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



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

5 Pre-slaughter controls: ruminant feed ban

5.1 Overview

Under the Australian BSE Questionnaire, countries must demonstrate that an effective ruminant feed ban has been effectively implemented. More specifically, evidence is required to support that ruminant-derived MBM has not been fed to cattle for the last 8 years.

5.2 Legislation

The inclusion of proteins originating from ruminants, other than those derived from milk, in the diet of ruminants has been prohibited in Croatia since 1997, under the *Order on the prohibition of use of proteins originating from ruminants (except for milk and milk products) in ruminants' diet*. This legislation was subsequently revised in 2001 to prohibit the use of protein of animal origin for feeding of all animal species from which meat is used for human consumption, under the *Order on the prohibition to use proteins of animal origin for feeding animals* (Official Gazette 08/01). This ban has undergone refinement through successive pieces of legislation in light of emerging knowledge about transmission of TSEs. Currently, the only animal-derived proteins permitted in feed for ruminants are milk or colostrum, eggs, gelatine from non-ruminants, hydrolysed protein from non-ruminants or skin of ruminants. In addition, food for non-ruminants may include fish meal, dicalcium phosphate, tricalcium phosphate and blood products from non-ruminants.

Regulations governing animal feed production, storage and transport are enforced by state veterinary inspectors (SVIs) of the Veterinary Inspection Service of the MA. Under the *Ordinance on feed hygiene* and the *Ordinance on conditions in animal feed business*, establishments found to be in breach of the regulations may have their registration or approval, as applicable, suspended or revoked.

Regulations specifying the requirements of animal feed production and storage have been in place in Croatia since 1998, and have been subject to improvement by successive Ordinances. The regulations have been designed to prevent cross-contamination in the production, storage and transport of animal feeds. All animal feed business establishments must be registered by the VD.

5.3 Use of bovine materials in animal feedstuffs

Croatia has not imported MBM or any ruminant-derived feed ingredients from any country within the past 8 years, and the inclusion in livestock feed of proteins originating from ruminants of any country has been prohibited since March 1997. The risk of cross-contamination of domestically produced animal feedstuffs with imported ruminant-derived MBM that may be contaminated with the BSE agent therefore appears to be negligible.

MBM or greaves of bovine origin have not been fed to cattle in Croatia in the past 8 years. MBM for export may be produced in rendering plants in Croatia, subject to conditions of heating, pressure and particle size produced that have been specified in legislation since the *Ordinance on the procedure for handling animal carcasses and waste of animal origin and their destruction* was gazetted in 2003. The conditions for pressure sterilisation specified in that Ordinance, including temperature of at least 133°C for not less than 20 minutes, at a water vapour pressure of not less than 3 bar, are the same as those recommended in the OIE *Terrestrial Animal Health Code*. The *Ordinance on the procedure for handling animal carcasses and waste of animal origin and their destruction* was superseded in 2006 by the *Ordinance laying down rules for the handling of animal by-products not intended for human*

consumption. The conditions for steam sterilisation of Category 1 materials, including all material from potentially TSE-infected animals, in that Ordinance match the recommendations in the OIE *Terrestrial Animal Health Code*.

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

Legislation governing the requirements for animal feed production and storage facilities in Croatia has been in place since 1998, when the *Ordinance laying down the conditions to be met by animal feed production and storage facilities* was gazetted, although that Ordinance did not specifically address measures to prevent cross-contamination. The 1998 Ordinance was superseded in 2005 by the *Ordinance laying down the conditions and arrangements for approving establishments and intermediaries operating in the animal feed sector*. Since the gazetting of that Ordinance, legal requirements for animal feed establishments and intermediaries have included the following requirements relevant to BSE control:

- All animal feed business establishments must be registered with, and approved by, the VD of MA
- Facilities must be constructed and operated in a way to minimise the risk of cross-contamination between feed production lines
- All establishments must employ, either as a full-time employee or on a contract basis, a tertiary-qualified person responsible for quality assurance.
- Establishments must operate under good manufacturing practices, employing a Hazards Analysis and Critical Control Points system (HACCP).
- All feedstock and products must be subject to monitoring for hygiene and quality by a competent and equipped laboratory service.
- Samples of each batch of feed, additive or pre-mix must be collected and retained.
- Establishments must operate good storage practices. Storage of products and feedstock must be designed to prevent the switch, contamination or cross-contamination with other feedstock.
- Unsafe waste products must be stored and disposed of in such a way as to prevent contamination

Thus, legislation has been in place since 2005 mandating the separation of production lines to prevent cross-contamination between ruminant and non-ruminant feed. Recordkeeping requirements under the *Ordinance laying down the conditions and arrangements for approving establishments and intermediaries operating in the animal feed sector* were comprehensive.

The 2005 Ordinance was superseded in 2006 by the *Ordinance on conditions in animal feed business*, which preserved all the above requirements but also contained additional mandatory protective measures, including controls on imported feed, and testing of fishmeal for mammalian proteins.

The *Ordinance on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, gazetted in 2007, complemented the *Ordinance on conditions in animal feed business*. Measures in this Ordinance included unannounced inspections of establishments by the MA, and testing of feed and food. The legislation also addressed quality aspects of inspections and analyses, such as characterisation of methods of analysis, and reference laboratories to be used.

Further refinement of legislation pertaining to manufacture, storage and transport of animal feed was gazetted in 2008 in the *Ordinance on feed hygiene*, which brought Croatia's legislation concerning animal feed production and storage facilities into full alignment with EC Regulations. This Ordinance also covered development and dissemination of guides to Good

Manufacturing Practice (GMP) and application of HACCP principles, and regard to relevant codes of practice of the *Codex Alimentarius*.

Legislation concerning the manufacture, storage and transport of feed is also contained in Ordinances specifically addressing the prevention and control of TSEs. The first version of the *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies* was gazetted in 2007. This Ordinance reiterated the ban on feeding animal-derived proteins to farm animals which had been in Croatian legislation since 1997. The Ordinance provided more specifics, including:

- That ruminant feed cannot be transported in the same vehicle as feed for non-ruminants and thorough cleaning and disinfection must occur between transport of ruminant feed and transport of non-ruminant feed.
- That animal feed, such as pet food, which contains ruminant blood or processed animal protein other than fish flour, may not be produced in premises that produce food for farm animals other than carnivores farmed for fur
- That storage, transport and packing of pet food and food for carnivores farmed for fur must be physically separate from storage, transport and packing of feed for other farm animals.

This Ordinance was superseded in 2009 by another Ordinance with the same title, to bring Croatian legislation into full alignment with EC regulations. Differences between the previous 2007 Ordinance and the 2009 Ordinance are minor.

5.5 Evaluation of the ruminant feed ban

Control of the feed ban was assessed by FSANZ personnel in the course of the in-country visit in March 2012.

Two feed mills, one of which produces feed for ruminants, were included in the visit. Both mills use fishmeal for pig and poultry rations. All batches of fishmeal are tested for prohibited mammalian proteins. All suppliers of raw materials, including those supplying fishmeal, must be registered with the Veterinary Inspection Service, all raw materials must be registered as being for livestock feed, and all raw materials must have appropriate documentation from the manufacturer or supplier. Fishmeal is held in 'quarantine' storage until results of analysis are received. Both feed mills retain raw material records for fishmeal for longer than the mandatory 5 years. Laboratory results must be retained for 10 years. Both feed mills are subject to regular visits by OVs. The SVI determines the frequency of visits and inspections. Inspection of premises includes, among other inspections, sampling, storage retention and analysis results of samples of ingredients and finished feed; records of non-conforming feed and/or product recalls; traceability of incoming ingredients and finished products; the use of animal proteins, including fish meal, in manufacturing; and records of purchasers of the finished products.

Most feed is sold in bags rather than as bulk feed, although both feed mills have dedicated vehicles that are registered for transport of bulk feed. The label for each product is sewn into the closing seam of the bag. Labels include warnings that the product contains fishmeal and must not be fed to ruminants. In addition, signs are placed on the walls above fishmeal-containing products in retail shops, to indicate that those products are not to be fed to ruminants. Labels on bags also specify the composition, manufacturer, date of production, expiry, and batch, and shipments of bags are also accompanied by a dispatch Order, so that both trace-forward and trace-back can be conducted if necessary.

Annual control plans for the monitoring of the ruminant feed ban and other surveillance measures related to TSEs, including food production and by-product industries, are

developed by the Veterinary Inspections Service of the MA. The *Annual Plan of Official Controls and Monitoring of Animal Feeding stuffs in 2010* were included in the submission as an example. The annual plan is risk assessment-based, with a risk assessment for each facility.

Shipments of animal feed or feed ingredients in transit across Croatia are weighed at the BIP of arrival and the BIP of departure, to ensure that there is no removal of any part of the shipment within Croatia.

All testing of raw materials and feeds is conducted in the Laboratory for Microbiology in Feed, Veterinary Public Health Department, Croatian Veterinary Institute. Microscopy is the compulsory method, although the laboratory also has immunoassay capability. The laboratory has provided the following data on tests conducted in the years 2001-2007 (Tables 3 and 4):

Year	Microscopic examination	Immunoenzyme test	PCR	Positive	Total
2001	182	0	0	0	182
2002	228	0	0	0	228
2003	539	11	6	0	556
2004	392	164	4	0	560
2005	360	139	9	0	508
2006	244	56	0	0	300
2007	227	31	0	0	258

Year	Fish meal	Fish feed	Compound feed	Other feed
2001	118	5	49	10
2002	131	0	73	24
2003	136	190	187	26
2004	75	343	103	39
2005	68	273	51	116
2006	49	31	64	156
2007	48	26	74	110

6 Ante-mortem slaughter controls

6.1 Overview

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

6.2 Legislation

BSE has been a notifiable disease in Croatia since 1996. The current *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies* is fully aligned with EC Regulations. The successive Ordinances have, from 1996, all included regulations for movement control, examination, slaughter, testing and disposal of animals suspected of having a TSE. The VD is required to inform the EC and other countries of cases of TSE.

All of the successive pieces of legislation since 1996 have empowered the MA to place strict movement controls on suspect animals and their cohort, to slaughter suspect animals and other animals at risk, undertake laboratory tests of tissues, and dispose of the carcasses.

BSE is also notifiable under the *Ordinance on the manner and procedure of reporting suspicion of an infectious animal disease and submitting reports on the appearance and cessation of an infectious animal disease and the contents of the prescribed forms*, which was gazetted in 2004. This legislation lists all the animal diseases and zoonoses that are notifiable in Croatia, and complements the *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies* by specifying the legal obligations of animal owners and veterinarians to report suspected cases of notifiable diseases. Veterinarians are required to report zoonotic diseases to health authorities as well as to the MA.

Veterinary inspection of bovine animals, to ensure that tissues are fit for human consumption, occurs before and after slaughter and is mandated under the *Veterinary Act* and the *Ordinance on official controls of products of animal origin*. Under the terms of the *Veterinary Act*, all bovine animals must be slaughtered in a slaughterhouse and must have ante-mortem and post-mortem veterinary inspections. The *Ordinance on official controls of products of animal origin* mandates veterinary inspections of slaughterhouses, game handling plants and cutting plants. The veterinary inspections include ante-mortem inspection, post-mortem inspection, handling of SRM and laboratory testing.

Under the *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies*, surveillance for TSEs must cover, at minimum: all bovine animals above 24 months of age sent for emergency slaughter or with suspicious clinical signs at ante-mortem inspections; all bovine animals above 30 months of age slaughtered normally for human consumption; and all bovine animals above 24 months of age not slaughtered for human consumption which have died or been killed on the farm, during transport or in an abattoir (fallen stock). These requirements, first gazetted in 2007, are more rigorous than the recommendations of the OIE *Terrestrial Animal Health Code*, which only requires testing of clinically normal cattle at routine slaughter if they are 36 months or older.

6.3 Ante-mortem procedures

The *Ordinance on official controls of products of animal origin* specifies the following requirements for ante-mortem examination of animals:

- The OV must carry out an ante-mortem inspection of all animals within 24 hours of arrival at the slaughterhouse and less than 24 hours before slaughter.
- The OV must assess whether animal welfare has been compromised, including verifying compliance with rules on animal welfare related to slaughter and to transport to the slaughterhouse.
- The OV must determine whether there is any condition which might adversely affect human or animal health, with particular attention to detection of zoonotic diseases and diseases listed by the OIE.
- In addition to routine ante-mortem inspections, the OV must inspect any animals that the food business operator or auxiliary has put aside.
- In the case of emergency slaughter, the OV at the slaughterhouse must examine the declaration accompanying the body of the animal.

- Results of all ante-mortem inspections are recorded and all documentation must be kept for at least three years after the date of slaughter.

FSANZ personnel visited two slaughterhouses in the course of the FSANZ in-country assessment of Croatia. Every animal arriving at a slaughterhouse must have appropriate documentation on arrival including a certificate of health, movement Order and identification. If animal identification cannot be verified, slaughter is prohibited, and proof of identity is required within two days. If no proof is forthcoming, the animal is terminated and becomes Category 1 material, and therefore must be rendered and incinerated. If an animal was dead on arrival, it would automatically become Category 1 material.

Ante-mortem inspection is conducted by AVs. Abnormal animals are separated out, the SVI is notified, and the case may be handed over to the SVI if the animal is deemed not fit for slaughter.

AVs, who are accredited by the Croatian Accreditation Agency, are present at ante-mortem inspection and post-mortem inspection on every slaughter day.

6.4 Slaughtering methods

Current legislation related to slaughter is found in the *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies*, which has been fully aligned with EC regulations since 2009. Pithing and gas injection into the cranial cavity are unacceptable for use on domestic ruminants the meat of which is intended for human or animal consumption. The unacceptability of pithing, laceration of central nervous tissue, and gas injection were also alluded to in the 2007 version of the Ordinance, although less clearly stated.

Stunning is performed by captive bolt, followed by exsanguination to ensure death. The hole left in the skull by the bolt is plugged to prevent leakage of brain material. Stunning and slaughter are under the control of OVs and are subject to audit by SVIs.

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

7.1 Overview

Croatia has procedures for post-mortem inspection, SRM removal and rendering procedures which have been fully aligned with those of the EC since 2009.

7.2 Legislation

Post-mortem inspection is mandated under the *Ordinance on official controls of products of animal origin*. According to this Ordinance, particular attention is to be paid to the detection of zoonotic diseases and diseases as listed by the OIE.

Measures taken to manage SRM are specified in the *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies*, which has been fully aligned with EC regulations since 2009, and also in the *Ordinance on animal by-products not intended for human consumption*.

The list of tissues identified as SRM in Croatian legislation has evolved with growing scientific knowledge. The 1997 *Order on the prohibition of using tissues, organs and mechanically separated meat of ruminants as risky raw material, which could contain the causative agent of the bovine spongiform encephalopathy (BSE) in production of meat products* identified as 'risky' brain, spinal cord, eyes, thymus, spleen, intestines, visible

lymphatic tissue, visible nervous tissue, and mechanically separated meat if the spinal cord was not removed prior to separation. The 2007 version of the *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies* identified SRM as the skull including the brain, eyes, tonsils and spinal cord of bovines aged over 12 months, and the intestinal tract from of bovines of all ages. In addition, for meat from countries with a high incidence of BSE (Category 5), the Ordinance specified the additional SRM of trigeminal ganglia, thymus and spleen of bovines over 6 months, and the vertebral column including dorsal root ganglia of bovine animals over 30 months. The 2007 *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies* was superseded in 2009 by another Ordinance with the same title. Under this Ordinance, bovine SRM for a country with a controlled or undetermined BSE risk are defined as follows:

- The skull excluding the mandible and including the brain and eyes and the spinal cord of animals aged over 12 months
- The vertebral column excluding 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
- The tonsils, intestines from duodenum to rectum, and mesentery of animals of all ages.

The addition of the skull and spinal column to the list of SRM brought Croatian legislation into full alignment with OIE recommendations.

Both the 2007 and the 2009 versions of the Ordinance specified that SRM must be removed at premises approved by the MA, and the Croatian authorities advised FSANZ inspectors that this approval has only been granted to slaughterhouses. SRM must be stained with a dye and marked immediately on removal, and completely destroyed by incineration or other method prescribed in the *Ordinance on by-products of animal origin not intended for human consumption*.

Registration with the MA of establishments conducting business operations with food of animal origin is mandated under the *Veterinary Act*, the *Food Act*, and the *Ordinance on official controls of products of animal origin* (2007), which requires that all premises for slaughter of cattle are compliant with Ordinances on the hygiene of foodstuffs, on specific hygiene rules for food of animal origin, and on health rules concerning animal by-products not intended for human consumption. Official controls on cattle slaughter premises include audits of good hygiene practices and HACCP-based procedures. The *Ordinance on official controls of products of animal origin* (2007) also mandates that the OV must check the removal, separation and, where appropriate, marking of SRM, and must ensure that the food business operator takes all necessary measures to avoid contaminating meat with SRM during stunning, slaughter and removal of SRM.

7.3 Post-mortem procedures

FSANZ personnel visited two slaughterhouses in the course of the in-country assessment of Croatia, and observed slaughter procedures, SRM removal and inspection procedures. Stunning, SRM removal and post-mortem procedures are controlled by SOPs and appropriate training of staff.

Each animal has a unique lot number that follows the carcass throughout the slaughter process and onto the final product. At the larger slaughterhouse, this was tracked using electronic chips, but at the smaller slaughterhouse, which slaughters cattle only once a week, it was achieved using paper tags. The head and internal organs are assigned the same number. Cattle over 30 months are slaughtered separately to younger cattle, and the

carcasses are stored separately until results of BSE testing are received from the national laboratory. Results are received within 15 hours, while half-carcasses are undergoing the post-slaughter chilling process. Brainstem samples are submitted from all cattle over 30 months, and veterinarians select which of the younger cattle are tested as part of the national BSE surveillance program. In addition to the carcass, the head and internal organs are held until results for each animal are received.

SRM include head and eyes of all cattle over 12 months, tonsils and spinal cord from cattle of all ages, and vertebral column from cattle over 30 months. Bones, blood and sieved floor washings are also treated as Category 1 material and sent for rendering, as are any condemned carcasses. All documentation of SRM shipments is retained for verification.

The SVI conducts phase inspections at least once every month. OV's and AV's are present every day, and AV is always present at ante-mortem and post-mortem inspections. Post-mortem inspections are conducted on the head, viscera, thoracic organs and carcass.

It is the responsibility of food production companies to have a traceability system. The lot number that allows traceability is printed on each package of fresh meat, with the exception of mince meat or processed meat because these contain meat from several animals. However these are marked with the date of production and records are kept of which animals were used for that purpose on that day. Lot numbers are included on all shipping documents and invoices. Both slaughterhouses regularly conduct simulated recalls. The larger slaughterhouse reported traceability within 30 minutes for fresh meat and approximately one hour for processed products, while the smaller slaughterhouse can complete traceability within two hours. All records are retained for three to five years, depending on the precise nature of the record, with the exception of some BSE-related records which are retained for seven years.

7.4 Handling of suspect diseased cattle

Under the *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies*, any animal suspected of being infected by a transmissible spongiform encephalopathy (TSE) is killed and its brain and any other tissues specified by the MA sent to the national reference laboratory, or the EC reference laboratory, to be tested for TSE. All parts of the body of the suspect animal may be either retained under official control until a negative diagnosis has been made, or disposed of in accordance with the *Ordinance on animal by-products not intended for human consumption*.

Under the *Ordinance laying down rules for handling of animal by-products not intended for human consumption* (2006) and the *Ordinance on animal by-products not intended for human consumption* (2009) that superseded it, all body parts, including the hide or skin, of an animal suspected of being infected with a TSE, and of animals killed in the context of TSE eradication measures, are classified as Category 1 material. Category 1 material may be incinerated at an approved incineration plant, or processed at an approved processing plant using one of five processing methods specified in the Ordinance. All of these methods involve reduction in particle size followed by specified combinations of time, temperature and pressure. The resulting material is finally disposed of as waste by incineration at an approved incineration plant. The Ordinance allows for these methods to be replaced by other means approved by the EC, in the event of developments in scientific knowledge. The Ordinance includes regulations for the transport and storage of Category 1 material, and for its physical separation from other material at processing plants that also process material of other Categories.

7.5 Rendering processes

Rendering processes in Croatia are specified in the *Ordinance on animal by-products not intended for human consumption*, which has been fully aligned with EC regulations since July 2009. Rendered material from animals suspected of having a TSE must be incinerated after processing. Rendered material from animals not suspected of having a TSE may be incinerated, but alternative uses of the rendered by-products are permitted. Rendered fats may be further processed into fat derivatives for technical uses such as in organic fertilizers or soil improvers, and proteinaceous material may be used for similar purposes or transformed in an approved biogas plant or composting plant. Manure, digestive tract content separated from the digestive tract, milk and colostrum may be applied to land or processed in an approved biogas plant or composting plant if the VD does not consider them to present a risk of spreading any serious transmissible disease.

7.6 Compliance with legislation

Slaughterhouses must be approved by the VD of MA under the *Ordinance on official controls of products of animal origin*, and are subject to audits by the VD. These audits include verification of compliance with the *Ordinance on the hygiene of foodstuffs*, the *Ordinance laying down specific hygiene rules for food of animal origin*, and the *Ordinance laying down health rules concerning animal by-products not intended for human consumption*.

There are nine establishments in Croatia that are approved to process animal by-products, of which only four process material originating from ruminants. Of the latter, only one is approved for processing Category 1 material. This facility shares an address with a facility that processes Category 3 material, but although the two facilities are owned by the same company, they are separate production systems in separate buildings. Of the other three establishments that process material from ruminants, one establishment processes Category 3 material and the other two establishments deal in melting fat. The raw material for these two establishments may include bovine lard, which is purchased from approved slaughterhouses. MBM and greaves produced in these establishments is not used in Croatia. At the time of the in-country inspection by FSANZ, Croatia was exporting MBM to Vietnam, but this export trade will cease when Croatia joins the EU. The only product of ruminant origin that may be used for feed in Croatia is rendered fat processed from Category 3 material.

The submission included documentation of audit findings in rendering plants and feed mills in 2008, 2009 and 2010. No evidence has been found that cattle are fed MBM or greaves of bovine origin.

During the course of the in-country assessment of Croatia's BSE control, FSANZ personnel visited the only rendering facility that handles Category 1 material from cattle. The rendering facility implements ISO 9001. This was instituted at the same time as a HACCP system. The Critical Control Points (CCPs) are receipt, separation and rendering. The facility is inspected at least once a month by regional Veterinary Inspectors.

A clear audit trail is maintained throughout the process of collecting SRM from slaughterhouses and fallen stock from farms, so that all shipments can be traced at any time during the collection and rendering procedure. The company has its own fleet of transport trucks dedicated to collection of Category 1 material. Category 1 material is chopped or separated to a particle size not exceeding 50 mm, followed by rendering for at least 20 minutes at temperature and pressure conditions of not less than 133°C and 3 bar, respectively, as specified in EU regulations.

When an animal dies on a farm, the farmer notifies the AV, who collects the brainstem sample and records the death in the bovine database. The animal is transported to the rendering facility by a registered carrier. An authorised staff member removes ear-tags and

enters the receipt and rendering of the carcass into the national database. Ear-tags are returned to the Croatian Agriculture Agency, which manages the bovine database. Some sampling of carcasses for BSE occurs at the rendering facility. All cows over 24 months are tested and then immediately rendered.

8 Summary: exposure control

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

- A ruminant feed ban that has been in place since 1997 and is subject to enforcement including sampling of feed for prohibited material. Testing of these samples has been conducted since 2001.
- Procedures in place to ensure that animals suspected of being infected with a TSE cannot be used for consumption by any species.
- Procedures in place within feed mills and rendering facilities, on imported material and at storage facilities, during transport and on farms, to prevent cross-contamination of ruminant and non-ruminant material.
- Audit and sampling procedures to ensure that animal feedstuffs do not contain ruminant-derived protein.

Croatian regulations related to management of SRM such as central nervous tissue at slaughter are fully aligned with EC regulations and OIE recommendations. Quality systems are in place to ensure appropriate slaughtering and processing techniques are employed to minimise cross-contamination of carcasses. The risk of BSE entering and recycling within the bovine feed system or entering the human food supply in Croatia is currently low. However, testing of ruminant feed for prohibited proteins was not mandatory prior to 2006. Thus, although exposure control is currently robust, it has been in place for a relatively short time.

BSE food safety controls

The Australian Questionnaire requires countries to have in place effective controls during the slaughtering process so that food for human consumption is prevented from becoming contaminated with materials that may be BSE-infected. It also requires a country to demonstrate effective and timely systems for the accurate identification, traceability and recall of meat and meat products in the event of a food safety issue. The following Chapter addresses these requirements within Croatia.

9 Beef production systems

9.1 Hygiene practices for the minimisation of cross-contamination

Measures to prevent SRM, such as central nervous system (CNS) tissue, contaminating the food supply are mandated in the *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies*, which has been fully aligned with EC regulations since 2009. Examples of such measures include, but are not limited to, prohibition of stunning techniques which may lacerate CNS tissue, specified method of harvesting bovine tongue so that tonsil tissue is not included, and sealing of the frontal shot hole and *foramen magnum* before harvesting meat from a bovine head. A sampling plan, using an appropriate laboratory test to detect the presence of CNS tissue, is required in Order to verify that measures to reduce contamination are properly implemented.

10 Traceability systems for beef and beef products

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

10.1 Legislation

Traceability of food and food-producing animals through all stages of production, processing and distribution is a requirement under the *Food Act*. EU regulations are transposed into Croatian legislation under four Ordinances, all originally published in Official Gazette 99/07, which constitute the 'EU hygiene package'. The Ordinances are as follows: The *Ordinance on the hygiene rules for food of animal origin* is fully aligned with EC Regulation 853/2004, the *Ordinance on the hygiene of foodstuffs* is fully aligned with EC 852/2004, the *Ordinance on official controls of products of animal origin* is fully aligned with EC 854/2004, and the *Ordinance on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules* is fully aligned with EC 882/2004. Updated versions of the *Ordinance on the hygiene rules for food of animal origin* were published in the Official Gazettes 28/10 and 45/11. Other relevant pieces of legislation include the *Ordinance on labelling, advertising and presenting of foodstuffs* (Official Gazette 63/11, 79/11) and the *Ordinance on the labelling of beef* (Official Gazette 52/10).

Traceability of bovine meat and meat products, specifically, is mandated under the *Ordinance on the labelling of beef*. Beef must be labelled to ensure a link between the identification of the carcass, half-carcass, quarter or piece of meat and the individual animal or group of animals from which it was derived. Labelling must occur during or immediately after packing. The label must include:

- A batch number that allows trace-back to countries of birth, fattening and slaughter of the live animal(s) of origin.
- The approval number of the slaughterhouse
- The approval number of the cutting facility
- The country of birth
- All countries of fattening
- Age in months, if the animal was not more than 12 months old at slaughter, or a 'V' for veal if the animal was less than 8 months old, and 'Z' for beef from animals aged between 8 and 12 months inclusive.

When constituting or mincing a batch of meat from multiple bovines, operators are required to ensure that all the animals belong to the same group in terms of countries of birth, fattening and slaughter, and that all were slaughtered at the same slaughterhouse. If a cut of meat originates from only one animal, the batch number may be the animal's ear-tag number.

The *Ordinance on implementing measures for certain products subject to food law*, which is fully aligned with EC regulations, mandates the food chain information that must be communicated between the operator who raised or kept the animals, and the slaughterhouse to which they are sent. The effectiveness of the communication process must be verified by the OV at the slaughterhouse.

A procedure for recall of products from the market is a mandatory part of HACCP documentation for approved food business operators, and is subject to official audits and controls performed by OVs and SVIs.

11 Recall systems

11.1 Legislation

Every single bovine animal can be identified and traced back to its origin because of the mandatory requirements of the *Ordinance on the compulsory identification and registration of bovine animals* (2007). If information is required for trace-back, the operator, who raised or kept the animals, has a responsibility to provide this to the slaughterhouse. This requirement is mandated by the *Ordinance on implementing measures for certain products subject to food law* (2008). Traceability of beef and beef products is mandated by the *Ordinance on the labelling of beef* (2010).

A rapid alert system, and plans to deal with emergencies and crisis management, are requirements under Chapter IV of the *Food Act* (2007), and also under the *Ordinance on the rapid alert system for food and feed* (OG 134/09).

An *Ordinance on traceability requirements for food of animal origin* was in the process of publication at the time of FSANZ's in-country inspection in March 2012.

11.2 Food recall process

Food recall capability is mandated under the *Food Act*. Requirements pertaining to food business operators are covered in Articles 21 and 22 of the *Food Act* and the requirements pertaining to the Competent Authority are covered in Article 10. Article 10 includes the obligation to inform the public of food-related risk. Rapid response is mandated by Article 47 of the *Food Act*. Additional relevant legislation is the *Ordinance on the Rapid Alert System for Food and Feed* (Official Gazette 134/2009)

A procedure for recall of products from the market is required as part of the HACCP requirements of all approved food business operators, and is subject to official audit and controls by OVAs and SVAs.

Croatia has a Rapid Alert System for Food and Feed (CRO RASFF), which is connected to the EU RASFF through the national contact point, which is the Food Safety and Phytosanitary Policy Directorate.

Information on recalls is published on the Croatian Government website. In addition, food operators are required to publish information on food recalls in a publicly accessible manner, and are subject to fines if they fail to do so. An emphasis is placed on keeping consumers fully informed.

Croatia has developed a Food and Feed Crisis Management Plan.

12 Summary: BSE food safety controls

Food safety controls are established in Croatia to allow effective protection of the human food supply from potential BSE contamination. Measures to prevent SRM contaminating the food supply are in place and have been fully aligned with EC regulations since 2009. All beef and beef products are fully traceable back to the animal or animals from which it came, and all bovine animals in Croatia must be identified and registered. All food business operators are required to have a procedure for recall of products in place as part of HACCP requirements, and Croatia has a rapid alert system and procedures to deal with emergencies in food safety.

BSE Control Programs and Technical Infrastructure

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

13 BSE Education and Awareness

Since 2000, Croatia has regularly held one-day courses entitled 'Prevention, diagnostics and control of bovine spongiform encephalopathy' and 'BSE-diagnostics and sampling of brain tissue'. The course includes theoretical and practical classes covering clinical features of BSE, brain sampling for BSE laboratory diagnostics, BSE diagnostics and legislation concerning BSE. Completion of this training is a requirement for veterinarians taking samples of brain tissue in slaughterhouses.

In 2010, workshops on the procedure of reporting suspected or confirmed cases of certain contagious animal diseases, as specified in the *Ordinance on the notification of animal diseases*, were carried out. The diseases specified in that Ordinance include BSE.

Information provided as part of the submission, and during the in-country assessment, showed that Croatia conducts regular training courses and workshops for AVs, OVAs and SVIs on the implementation of BSE control, and that SVIs attend training provided by the EC-Technical Assistance and Information Exchange (EC-TAIX).

14 Disease notification and diagnoses

14.1 Overview

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

14.2 Legislation

BSE has been a notifiable disease in Croatia since 1996 under successive Ordinances specifically addressing BSE or TSEs, of which the current version, *Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies* is fully aligned with EC Regulations. The successive Ordinances have all included regulations for movement control, examination, slaughter, testing and disposal of animals suspected of having a TSE.

BSE is also notifiable under the *Ordinance on the manner and procedure of reporting suspicion of an infectious animal disease and submitting reports on the appearance and cessation of an infectious animal disease and the contents of the prescribed forms*, which was gazetted in 2004.

14.3 Identification and handling BSE suspects

Training in BSE is provided to AVs, OVAs, SVIs and slaughterhouse personnel who handle SRM on the recognition of BSE clinical signs, as described in Section 13. Training of staff handling SRM is compulsory under the *Ordinance on the prevention, control and eradication*

of certain transmissible spongiform encephalopathies.

The MA works to continuously raise the BSE awareness of farmers and other people involved in breeding and production of cattle by means of workshops and courses, as well as through an annual veterinary check on each farm. During the annual veterinary check, the veterinarian is obliged to inform the keeper, both orally and in writing, of their obligation to report suspected disease as well as their obligation to maintain the ban on feeding mammalian-derived proteins. BSE awareness of farmers and others involved in breeding and production of cattle is also maintained in the course of frequent interactions with AVs.

The MA has prepared a *National Contingency Plan for Bovine Spongiform Encephalopathy (BSE)*. A copy of the July 2010 version of this document was included with the submission. In the event of a case of suspected BSE occurring on a farm, the animal may be killed or sent for emergency slaughter by a veterinarian employed by the Veterinary Inspection Service. On-farm killing must be performed by a veterinarian or a professionally qualified veterinary technician under the supervision of a veterinarian. Appropriate brainstem sampling technique is specified in an illustrated leaflet, *Bovine Animal Sampling for Bovine Spongiform Encephalopathy (BSE) Testing*, which also covers personal protective equipment, equipment needed, sample submission, disinfection and the offices that must be notified of the suspect BSE case by the veterinarian. If it is not possible to perform sampling in the specified manner, the head of the carcass is sent to the laboratory.

All testing of tissue samples is performed at one central laboratory in Zagreb, the Laboratory for Ruminant Pathology and Transmissible Spongiform Encephalopathy of the Croatian Veterinary Institute. Initially, histopathology was used as the diagnostic method. TSE testing by rapid immunological tests commenced in May 2001, in anticipation of EU legislation which came into force in June 2001 requiring all member states to have BSE monitoring in place. Rapid tests had only recently become available at that time.

14.4 Diagnostic tests

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

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

Diagnostic procedures and methods used in Croatia are compliant with Chapter 2.4.6 of the *OIE Manual of Standards for Diagnostic Tests and Vaccines for Terrestrial Animals*. For samples from animals that are not clinical suspects, the laboratory uses the Prionics®-Check PrioSTRIP as the routine diagnostic method, and Idexx HerdCheck as the confirmatory test. Prionics®-Check WESTERN was formerly used as the standard confirmatory test, but EFSA does not accept this method. However Prionics®-Check WESTERN, which is accepted by OIE, remains the method of choice for autolysed or putrefied samples which are occasionally submitted from fallen stock. Quality of samples from slaughterhouses, in contrast, is excellent.

When the brainstem sample is from a clinical suspect, then tests include histopathology,

electron microscopy or immunohistochemistry. If results of routine screening of an animal that was not a suspect were to be suspicious, then the remaining brainstem would be examined by histopathology, electron microscopy or immunohistochemistry

The Government pays half the cost of testing cattle of 30 months or older. For cattle of younger ages the owner of the stock pays the full cost of testing. The Government began sponsoring the collection of fallen stock in 2006, and this has been associated with a substantial increase in the number of samples submitted from fallen stock.

To the end of 2011, a total of 273 102 bovine samples had been tested for BSE at the laboratory. Total number of tests conducted on bovine samples, from 2001 to 2011 inclusive, are presented in **Table 5**.

Table 5: Bovine samples tested for BSE in Croatia, 2001 - 11 inclusive											
Slaughter type	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
≥ 30 months	9176	14986	11670	13417	14914	22622	19323	17403	24927	35869	33253
< 30 months	8	25	7	5	3	10	0	0	0	0	0
Clinical suspect	222	410	724	866	477	696	402	809	863	855	739
Emergency slaughter	309	501	603	509	698	731	240	496	778	555	632
Euthanised	0	0	0	0	0	5	0	0	7	26	14
Fallen stock	13	50	131	304	632	3366	5046	6219	7703	10121	8736
Total	9728	15972	13135	15101	16724	27425	25011	24927	34278	47427	43374

For the first few years of laboratory operation, a low priority was placed on testing fallen stock because they could not enter the human food chain. However a greater emphasis has been placed on fallen stock in recent years, with a steady increase in the number tested.

14.5 Laboratory assurances and auditing

The laboratory has been using the Prionics®-Check WESTERN test since 2001. The use of the Prionics®-Check PrioSTRIP as a routine diagnostic method was adopted in 2007. Both tests were subject to comprehensive validation and are accredited under a quality system. Training of CVI experts in the use of these diagnostic tests has been in place since 2001.

The Laboratory for Ruminant Pathology and Transmissible Spongiform Encephalopathy is subject to internal auditing twice a year, and participates regularly in interlaboratory testing with national reference laboratories of other countries. The most recent testing at the time of submission was conducted in September 2009 with the Neurocenter Laboratory in Bern, Switzerland, which is the TSE reference laboratory of the OIE.

14.6 Penalties and reporting incentives

Penalties and compensation are both covered by the *Veterinary Act*.

Failure of an animal holder to notify a veterinarian of signs of suspected infectious disease, or failure of a veterinarian to notify the competent veterinary authority, may result in a fine of 30 000.00 to 50 000.00 HRK (about AUD\$5500 to 9500).

Animal owners are entitled to compensation, at market value on the day of implementation, for animals killed for diagnostic or preventative purposes.

15 Cattle identification and traceability

15.1 Overview

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

15.2 Legislation

Since 2007, the system for the identification and registration of bovine animals in Croatia has been fully aligned with Regulation (EC) No 1760/2000, and Commission Regulations (EC) No 494/98, (EC) No 1082/2003, (EC) No 911/2004, and (EC) No 644/2005. The relevant pieces of legislation are the *Veterinary Act* (Official Gazette 41/07), the *Ordinance on the compulsory identification and registration of bovine animals* (Official Gazette 99/07), and the *Ordinance on the implementation of the system for the compulsory identification and registration of bovine animals* (Official Gazette 99/2007).

15.3 Current identification systems for cattle

All cattle bred in Croatia must be tagged with an ear-tag (**Figure 1**) applied to both ears, with both tags bearing a unique identification number that makes it possible to identify the animal and trace it back to the holding on which it was born. Tags must be applied within 20 days of birth, and before it leaves the holding of birth. If an ear-tag is lost, it must be replaced with another ear-tag containing the same information as the origin, and also a mark in Roman numerals to indicate the version of the tag. Each animal has a Movement Document which must accompany the animal whenever it is moved. On the death or slaughter of the animal, the Movement Document is returned to the CLC. All keepers of cattle are required to keep a register of bovine animals at the holding, and report all movements to and from the holding, and all births and deaths of animals on the holding, within 3 to 7 days of each event. The register of bovines at the holding must include information for not less than the previous three years, and must be available at all times to the VD on request. The VD is required by the *Ordinance on the compulsory identification and registration of bovine animals* to make unannounced inspections of at least 10% holdings in Croatia each year, to ensure compliance with the identification requirements.

All information on bovine births, deaths and movements is held on a central database. The current software application for the bovine database was adopted in May 2011.

The animal keeper is ultimately responsible for ensuring that records of identification, registration and movement notification are correct. Under Article 36 of the *Veterinary Act*, OVs are empowered to impose administrative sanctions which may include restriction on the movement of animals, and destruction of animals without compensation, or court penalties. The VD contracts Authorised Veterinary Organisations (AVOs) for the conduct of specific activities related to identification and registration. Only AVOs can conduct movement registrations.

All farms must be registered in the Farms Register, under Article 38 of the *Veterinary Act*. A farm is defined as any establishment, construction or, in the case of an open-air farm, any

place within the territory of the Republic of Croatia in which animals are, temporarily or permanently, held, kept or handled. Each farm has a unique identifying number termed a JIBG, and every keeper on a farm has a unique code known as the IKG. The CAA maintains the Farms Register as part of an online database that also includes the register of individual cattle. The database is updated in real time.

For any individual bovine animal, the database allows prompt retrieval of information including date of birth, sex, breed, colour, ID code of the dam, ID number of progeny, all the movements of the animal, the farm on which it is presently located, all other bovines currently on the same property, all the bovines that have ever been kept on the same farm, and all movements of cattle from and to the farm in a specified interval. The database can be used for epidemiological surveillance in that it allows the user to retrieve all the data about animals subject to testing (by county, village, farm or slaughterhouse) and to compare it with laboratory data on animals tested.

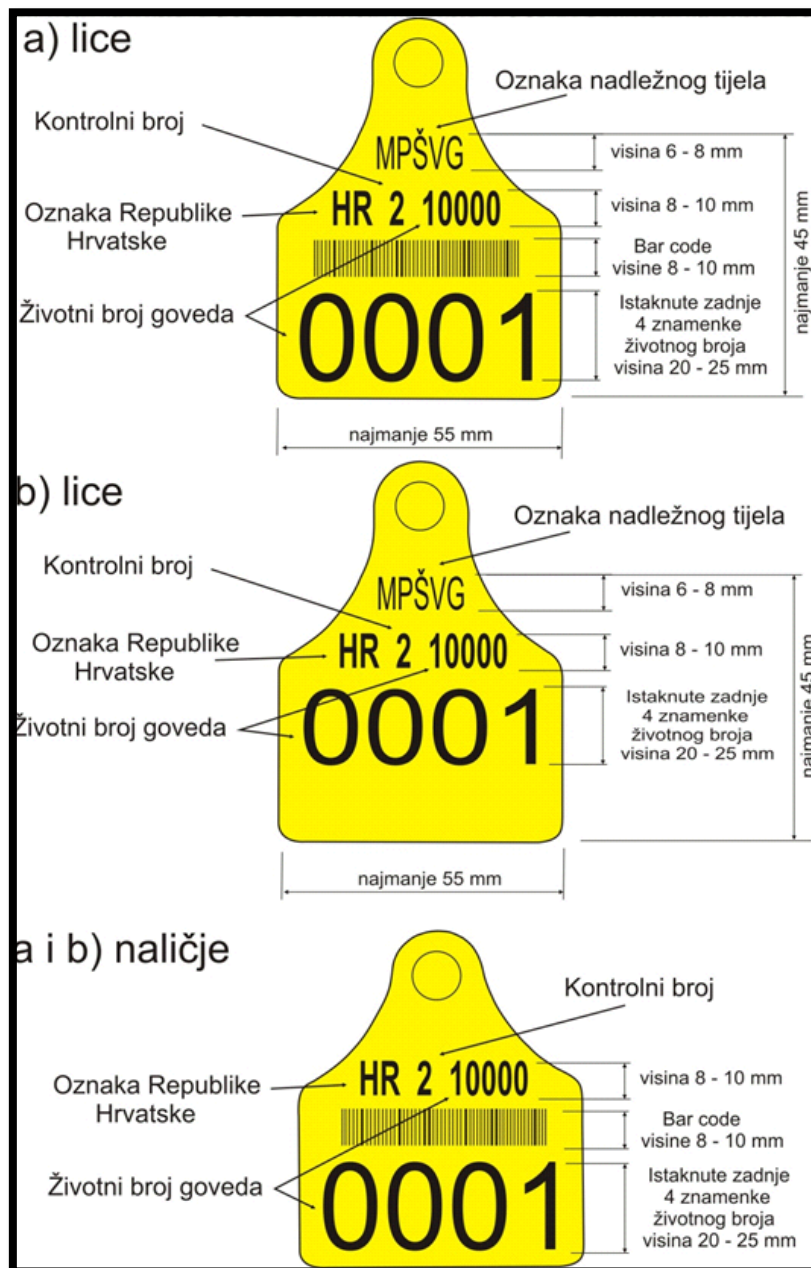


Figure 2: Layout of ear-tags for permanent individual identification of cattle in Croatia.

Replacement ear-tags are available if an animal loses an ear-tag. The keeper has 28 days to report a missing ear-tag and order a new one. In the rare event of an animal losing both ear-tags, the keeper has 3 days to provide the AV with proof that it is the correct animal. Keepers are motivated to ensure that animals are tagged because an animal with no ear-tags cannot be issued movement documentation by an AV, and transport operators will not accept them on trucks.

When an animal is sold, the AV issues the movement document and health certificate, and updates both the national electronic register and the written register of livestock that is maintained on the farm.

Loss of both ear-tags while in transit to a slaughterhouse is a very rare event. If the identity of an animal arriving at a slaughterhouse cannot be verified, proof of identity is required within 2 days, or the animal will be terminated and rendered as Category 1 material, regardless of age. Authorised personnel at slaughterhouses enter data into the database of intention to slaughter, and of the slaughter itself. All ear-tags are ultimately sent back to the national database from slaughterhouses or the rendering facility.

Maintenance of the database is ensured through annual veterinary checks of farms and their written registers by AVs, inspections by SVIs and OVVs, and movement documentation. Inspections by SVIs are on the basis of an annual plan developed by the Veterinary Inspection Directorate branch of the MA. The annual plan calls for inspection of at least 5% of holdings, although 10% of holdings were inspected in 2010 and in 2011. The decision of which holdings to inspect is made at the regional level and takes into account the type of holding, the age of animals on the holding, and the history of noncompliance. Discrepancies discovered during farm inspections must be reported to the local office of the Veterinary Inspection Service.

The CAA submits data on cattle movement monthly to the VD, which analyses the data for unfinished movements and dispatches them to the appropriate branch of the inspection service. On the basis of inspections, the VD directs the CAA on corrections to the database.

15.4 Imported cattle

Under the *Ordinance on the compulsory identification and registration of bovine animals*, bovines imported into Croatia must be given ear-tags like those of Croatian-born cattle within 20 days of import, unless the animal comes from an EU Member State, in which case it retains its original ear-tags. Cattle slaughtered within 20 days of import do not need to be given Croatian ear-tags, but must pass the veterinary checks associated with border control. The Movement Documents of cattle entering Croatia from EU Member States must be submitted to the CLC, which returns the document to the issuing state. Movement Documents must be issued to imported cattle within 14 days of import.

16 Summary: BSE control programs and technical infrastructure

BSE control programs and technical infrastructure are appropriate, and include controls at three levels: Large producers have control systems under HACCP, and there are also state monitoring and risk-based inspection activities.

BSE has been a notifiable disease in Croatia since 1996. BSE education and awareness programs are in place. Farmers, veterinarians, and slaughterhouse personnel are educated to recognise the clinical signs associated with the disease through ongoing awareness and education exercises for BSE. There are incentives to facilitate reporting, and penalties for failure to report suspect cases.

There is one diagnostic laboratory, the Laboratory for Ruminant Pathology and Transmissible Spongiform Encephalopathy, which uses diagnostic tests compliant with the OIE Standards. The tests have been validated and are accredited under a recognised quality system. The Laboratory for Ruminant Pathology and Transmissible Spongiform Encephalopathy regularly participates in interlaboratory testing with national reference laboratories of other countries.

Croatia has a centralised animal identification system and database, and identification of cattle born in or imported into Croatia is mandatory. The system for the identification and registration of bovine animals has been fully aligned with EU regulations.

BSE Surveillance

Section 3 of the Australian Questionnaire requires countries to provide evidence of the number of BSE-related samples collected for each cattle subpopulation, with data stratified by year and age group. Such data are then used to derive BSE surveillance point calculations using the recommendations of Chapter 11.4 of OIE's *Terrestrial Animal Health Code*.² The degree and quality of surveillance for BSE within the cattle population of a country, combined with other systems for BSE control, helps to determine the BSE risk status of the country.

Croatia was recognised by the OIE as having negligible BSE risk status in May 2014 and as such is required to meet the minimum requirements of Type B surveillance². Type B surveillance allows the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, zone or compartment of concern, at a confidence level of 95%². The BSE surveillance programme in Croatia complies with the guidelines in Articles 11.4.20 to 11.4.22 of the OIE's *Terrestrial Animal Health Code*. This Chapter provides further details of Croatia's surveillance activities and historical data.

17 Croatia's BSE surveillance program

Testing for BSE of all cattle over 30 months of age at slaughter was mandated in 2001 in the *Order on obligatory testing of cattle for the presence of the causative agent of the bovine spongiform encephalopathy (BSE)* (Official Gazette 45/2001). Carcasses in slaughterhouses for which a negative result is received are marked with a seal to state that they are BSE-negative. The Order also mandated the retention of the meat and organs from slaughtered cattle of over 30 months of age until test results are received, and maintenance of records of the origin, age, ear-tag number, date of slaughter, test results and further handling of the meat from all cattle over 30 months of age.

Prior to mid-2016, BSE surveillance was stipulated in the *Order on measures to protect animals from infectious and parasitic diseases and the financing thereof*, a version of which was issued each year. Under the 2011 and 2012 versions of this Order, sampling for was performed on the following animals:

- All bovine animals over 24 months of age sent for emergency slaughter or with signs suggestive of central nervous system disease at ante-mortem inspection
- All bovine animals over 30 months of age intended for slaughter for human consumption; or slaughtered bovine animals within an eradication program without showing clinical symptoms
- All bovine animals over 24 months of age not slaughtered for human consumption, which have died or been killed on farm, during transport or at an abattoir (fallen stock).

These requirements for BSE surveillance were in place from 2005 to 2016 before being amended in June 2016 following Croatia's application to the European Commission to revise its BSE annual monitoring program. European Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals in Member States and European Commission Decision 2009/719/EC authorises Member States listed in the Annex thereto to revise their Bovine Spongiform Encephalopathy (BSE) annual monitoring program. In January 2015, Croatia submitted an application to the European Commission to revise its BSE annual monitoring program and the European Food Safety Authority (EFSA) published a scientific report on the evaluation of the revision of the BSE monitoring regime in Croatia in February 2016. In May 2016 the Annex to Decision 2009/719/EC was amended to include Croatia.

The Commission Implementing Decision (EU) 2016/851 authorised Croatia to revise its BSE annual monitoring program under the same conditions as granted to the other 25 member states listed in the Annex to Decision 2009/719/EC.

The current testing scheme is based on testing of the following subpopulations:

- All bovine animals above 48 months of age sent for emergency slaughter or with clinical signs at ante mortem, fallen stock, and animals culled under a BSE eradication program.
- All bovine animals clinically suspected for BSE, with no age limit.
- All healthy slaughtered bovine animals over 30 months of age originating from Bulgaria, Romania or other countries.

The number of tests by county or region were presented in Croatia's original 2011 submission to FSANZ. For the years 2008, 2009 and 2010 samples were collected from all regions of Croatia and are therefore representative of the cattle population of Croatia.

18 Croatia BSE surveillance points data

At the time of FSANZ's initial assessment of Croatia's Food Safety Risk Status for BSE in 2011, Croatia carried out Type A surveillance. At that time, for a cattle population in the range 200,000 to 400,000, the cumulative points target for a country, region or zone under Type A surveillance needed to be at least 60,000 over a period of seven consecutive years. Croatia's total points for the period 2004-10 inclusive was a sum of 48,944, less than that target, although annual points data showed progressive improvement.

In May 2014, Croatia's BSE risk status was classified as negligible by the OIE and since that time the country has been required to carry out Type B surveillance. Data summarising BSE sampling in Croatia from 2010-16, inclusive, were included in the 2017 Annual Update and are presented in **Tables 6 and 7**. The total number of samples collected and tested in the period 2010-16, inclusive, was 250,166. Croatia's adult cattle population (24 months and older) for the 2015-2016 reporting period was 182,443 head. According to the OIE's *Terrestrial Animal Health Code*, for a cattle population in the range 100,001 to 200,000, the cumulative points target for a country, region or zone under Type A surveillance is 22,100 over a period of seven consecutive years. Croatia's total points total for the period 2010-16, inclusive, was 69,853 (**Table 7**), which exceeds requirements for Type A surveillance.

Table 6: BSE Surveillance Points Data 2010-16

2010								
Age	Routine slaughter	Points	Fallen stock	points	Casualty slaughter	points	Clinical suspect	points
≥2, <4	8604	860.4	2206	441.2	469	187.6	4	1040
≥4, <7	14574	2914.8	6494	5844.6	560	896	1	750
≥7, <9	5903	590.3	456	182.4	153	107.1	0	0
≥9	6349	0	317	31.7	116	23.2	1	45
Totals	35430	4365.5	9473	6499.9	1298	1213.9	6	1835
2011								
≥2, <4	10898	1089.8	3516	703.2	689	275.6	3	780
≥4, <7	10208	2041.6	4391	3951.9	385	616	3	2250
≥7, <9	5679	567.9	480	192	162	113.4	1	220
≥9	6451	0	345	34.5	133	26.6	0	0
Totals	33236	3699.3	8732	4881.6	1369	1031.6	7	3250
2012								
≥2, <4*	16110	1611	4194	838.8	1011	404.4	1	260
≥4, <7	11545	2309	2290	2061	706	1129.6	1	750
≥7, <9	99	9.9	522	208.8	18	12.6	0	0
≥9	146	0	446	44.6	13	2.6	0	0
Totals	27900	3929.9	7452	3153.2	1748	1549.2	2	1010
2013								
≥2, <4*	4947	494.7	1545	309	220	88	2	520
≥4, <7	10772	2154.4	1877	1689.3	351	561.6	2	1500
≥7, <9	5669	566.9	654	261.6	157	109.9	3	660
≥9	6380	0	620	62	161	32.2	0	0
Totals	27768	3216	4696	2321.9	889	791.7	7	2680
2014								
≥2, <4*	5728	572.8	1860	372	388	155.2	2	520
≥4, <7	10810	2162	2181	1962.9	426	681.6	2	1500
≥7, <9	4784	478.4	821	328.4	194	135.8	0	0
≥9	7086	0	796	79.6	233	46.6	1	45
Totals	28408	3213.2	5658	2742.9	1241	1019.2	5	2065
2015								
≥2, <4*	4569	456.9	2077	415.4	133	53.2	1	260
≥4, <7	8101	1620.2	2685	2416.5	162	259.2	4	3000
≥7, <9	3756	375.6	961	384.4	36	25.2	2	440
≥9	6282	0	1083	108.3	55	11	0	0
Totals	22708	2452.7	6806	3324.6	386	348.6	7	3700
2016								
≥2, <4*	3540	354	1522	304.4	132	52.8	0	0
≥4, <7	6437	1287.4	2624	2361.6	175	280	0	0
≥7, <9	3165	316.5	1075	430	81	56.7	0	0
≥9	5087	0	1049	104.9	47	9.4	0	0
Totals	18229	1957.9	6270	3200.9	435	398.9	0	0

Table 7: Cumulative points data by year for 2010 – 16, inclusive

Year	Routine slaughter	Fallen stock	Casualty slaughter	Clinical suspect	Total points for year
2010	4365.5	6499.9	1213.9	1835	13914.3
2011	3699.3	4881.6	1031.6	3250	12862.5
2012	3929.9	3153.2	1549.2	1010	9642.3
2013	3216.0	2321.9	791.7	2680	9009.6
2014	3213.2	2742.9	1019.2	2065	9040.3
2015	2452.7	3324.6	348.6	3700	9825.9
2016	1957.9	3200.9	398.9	0	5557.7
Totals	20876.6	22924.1	5954.2	14540	69852.6

19 Summary: BSE surveillance

Since May 2014, Croatia has carried out Type B surveillance in compliance with the guidelines in Articles 11.4.20 to 11.4.22 of the OIE's *Terrestrial Animal Health Code*. Current surveillance practices have been in place since June 2016, preceded by stringent surveillance requirements from 2005 to 2016. Croatia's surveillance points total for the seven year period 2010-16, inclusive, was 69,853, exceeding the Type A points target of 22,100 as set out in the OIE's *Terrestrial Animal Health Code*.

Conclusions and BSE risk categorisation

Croatia currently has robust controls to prevent the introduction and amplification of the BSE agent within the Croatian cattle population and contamination of the human food supply with the BSE agent. In-country assessment by FSANZ personnel confirmed that Croatian legislation relevant to BSE prevention and control is effectively enforced.

Importation of MBM or greaves is prohibited, and border controls are in place. Updates to legislation have ensured that controls to prevent the importation of cattle incubating BSE, and food products of bovine origin that might contain the BSE agent, have been at least as rigorous as OIE recommendations for more than a decade. The exception has been the importation of bone-in meat, which is not recommended by the OIE, but because only bone-in meat inspected and certified as suitable for human consumption in an EU country has been permitted, this is not considered to be a significant source of risk. Croatia has been diligent in monitoring the BSE status of other countries and has kept up to date with evolving knowledge of BSE transmission.

Procedures are in place to protect against cross-contamination of feed between ruminant and non-ruminant species. Sampling is in place to ensure that fishmeal used in animal feed production does not contain mammalian proteins, although sampling has been mandatory only since 2006.

Food safety controls are established in Croatia to allow effective protection of the human food supply from potential BSE contamination. Croatian regulations related to management of SRM such as central nervous tissue at slaughter are fully aligned with EC regulations and OIE recommendations. All beef and beef products are fully traceable back to the animal or animals from which they originated, and all bovines in Croatia must be identified and registered. All food business operators are required to have a procedure for recall of products in place as part of HACCP requirements, and Croatia has a rapid alert system and procedures to deal with emergencies in food safety.

BSE has been a notifiable disease in Croatia since 1996. Effective BSE education and awareness programs are in place. Farmers, veterinarians and slaughterhouse personnel are educated to recognise the clinical signs associated with the disease through ongoing awareness and education exercises for BSE. There are incentives to facilitate reporting, and penalties for failure to report suspect cases. Diagnostic capability is sound, and diagnostic tests compliant with Chapter 2.4.5 of the OIE *Manual of Standards for Diagnostic Tests and Vaccines for Terrestrial Animals* (2017) have been validated and are subject to appropriate, ongoing quality control including inter-laboratory testing with national reference laboratories of other countries. Croatia has a sophisticated, centralised animal identification system and database, which is fully aligned with EU regulations.

Surveillance points data provided in Croatia's submission in 2011 did not meet the requirements of Type A surveillance for the seven year period 2004-10, resulting in a recommendation of Category 2 status for Croatia. Since May 2014, Croatia has carried out Type B surveillance that complies with the guidelines in Articles 11.4.20 to 11.4.22 of the OIE's *Terrestrial Animal Health Code* for a negligible risk country. Croatia's surveillance points total for the seven year period 2010-16 was 69,853, exceeding the OIE Type A points target of 22,100 for an adult cattle population between 100,001 to 200,000. In-country assessment by FSANZ personnel confirmed that Croatian legislation relevant to BSE prevention and control is effectively enforced.

The risk of BSE entering and recycling within the bovine feed system or entering the human food supply in Croatia is negligible and Croatia now meets all the requirements of Category 1

status. This BSE food safety risk assessment therefore concludes that beef and beef products imported from Croatia are safe for human consumption and recommends **Category 1** status for Croatia.

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http://ec.europa.eu/food/fs/sc/ssc/out272b_en.pdf

Appendix 1: Structure of the Competent Authority in Croatia

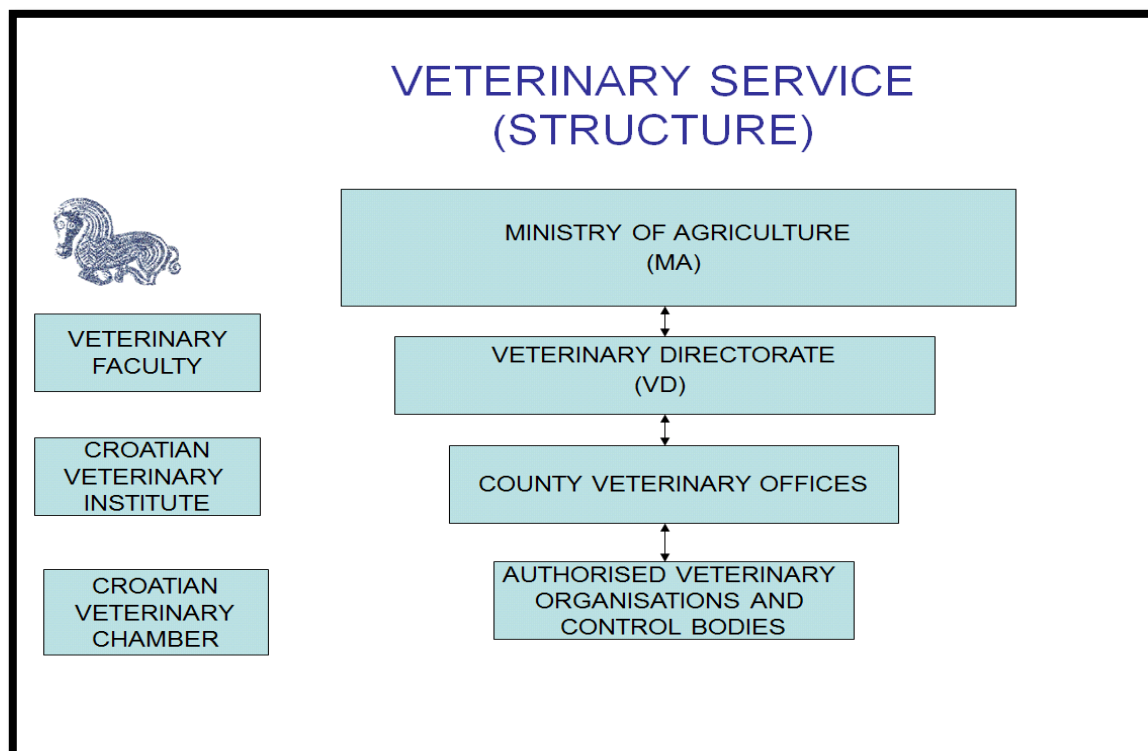
(Source of illustrations and information in this Section: Ministry of Agriculture Veterinary Directorate).

The competent veterinary authority (CVA) in the Republic of Croatia is the Veterinary Directorate (VD), which is an internal organisational unit of the Ministry of Agriculture (MA). The chief veterinary officer (CVO) is the director of the VD.

The organisation, activities and responsibilities of the veterinary service are regulated by the Veterinary Act (Official Gazette 41/07). More specifically, the Act regulates the area of animal health protection, implementation of veterinary public health measures, improvement of animal reproduction, and veterinary protection of the environment, official controls and inspectional supervision in the veterinary field.

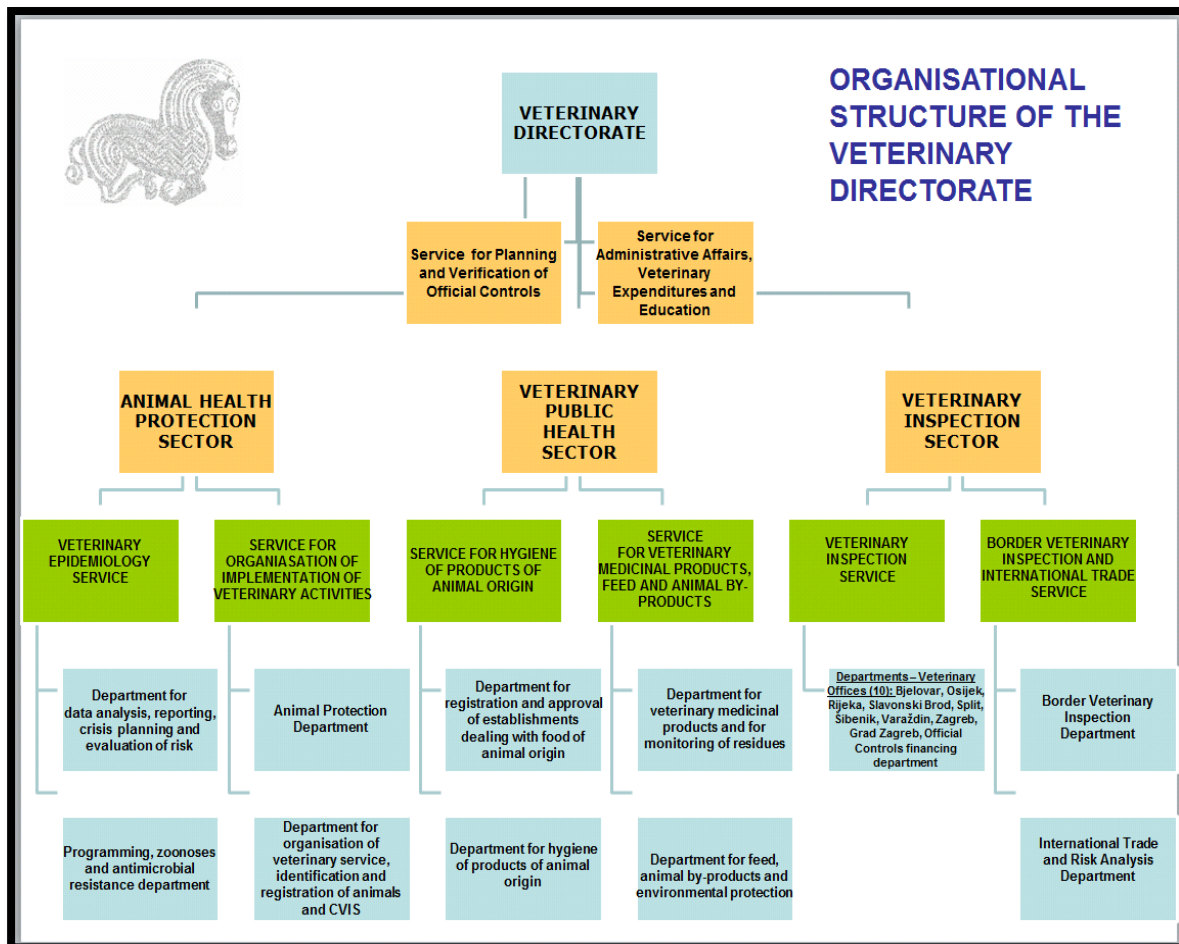
The VD is responsible for carrying out official controls including those related to feed safety and hygiene, and those related to animal health and welfare. The VD is also responsible for veterinary checks and controls on imported and transit consignments of animals and products of animal origin. The legal basis for official controls carried out by the VD includes the following:

- *Veterinary Act* (Official Gazette 41/07, 155/11)
- *Food Act* (Official Gazette 46/07, 155/11)
- *Animal Protection Act* (Official Gazette 135/06)
- *Act of Veterinary Medicinal Products* (Official Gazette 84/08)
- *Act of General Administrative Process* (Official Gazette 47/09)

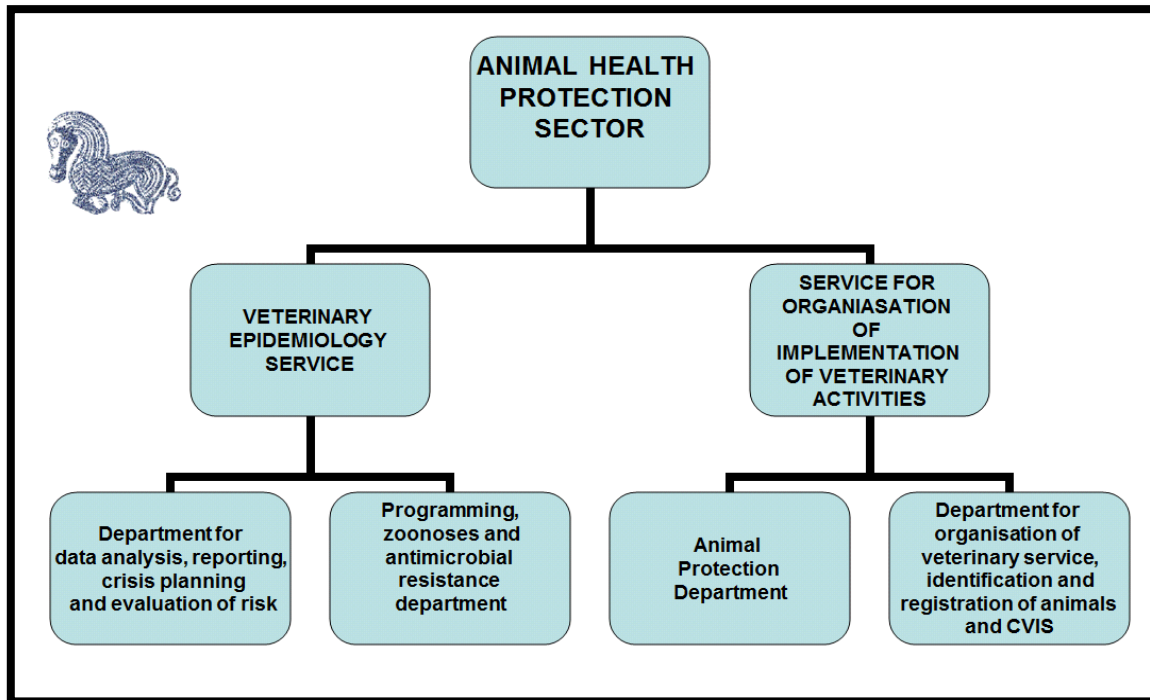


According to the Regulation on the internal organisation of MA, the following organisational units have been established within VD:

1. Sector for Animal Health Protection
2. Sector for Veterinary Public Health
3. Department for International Co-operation and EU Accession
4. Department for the Central Veterinary Information System.

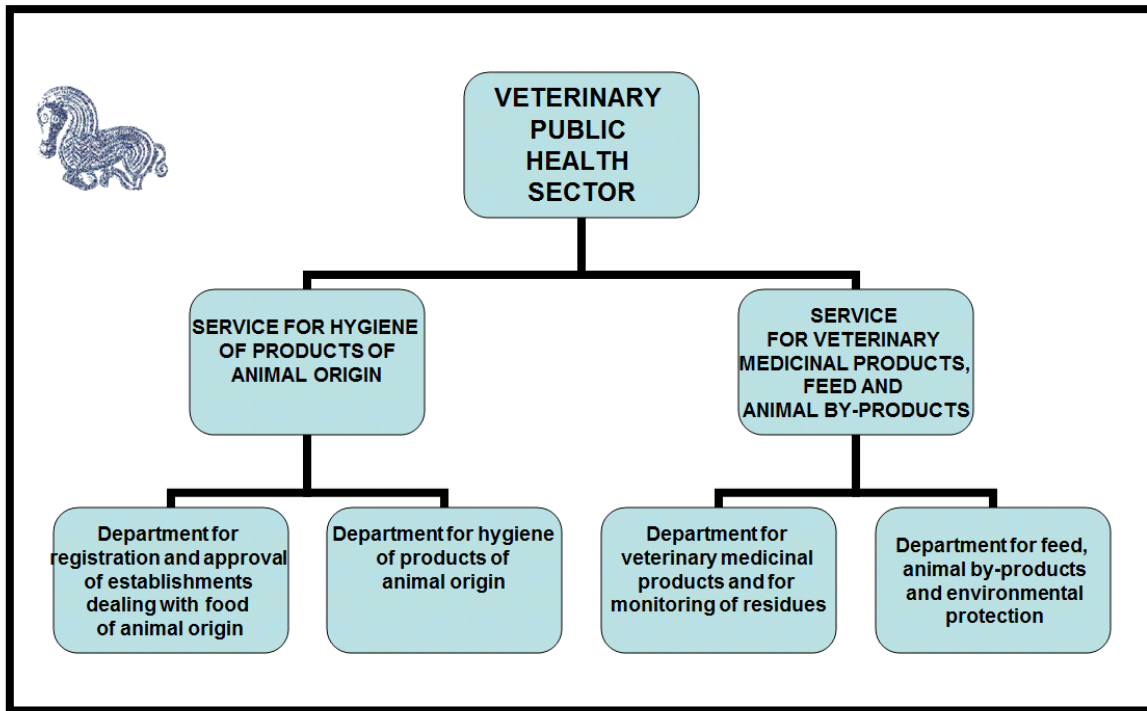


The responsibility of the **Animal Health Protection Sector (AHP)** of the Veterinary Directorate (VD) is to ensure the production of healthy animals, safe animal products and the protection of humans from zoonoses.

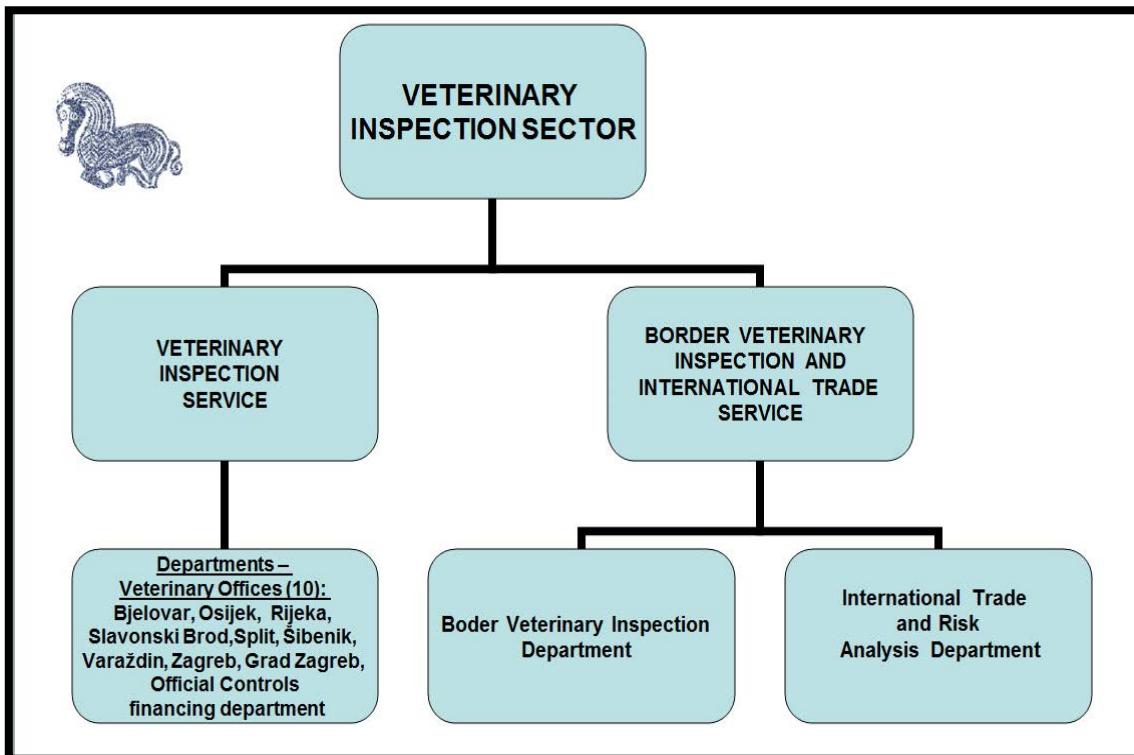


The responsibilities of the **Veterinary Public Health Sector** (VPH) of the VD include:

- drafting regulations on veterinary-sanitary conditions to be met by slaughterhouses, establishments for processing, preparation and storing of animal by-products, storing of animal feed, and animal feed factories; preconditions for aforementioned facilities; keeping the registry of authorised establishments
- stipulating the treatment of carcasses, animal by-products, and animal products for utilisation as well as their harmless removal
- preparing a programme for monitoring residues and other contaminants harmful for human health in products of animal origin designated for food and feed
- carrying out activities related to the control of production, trade and use of veterinary medicinal products and animal feed
- carrying out other legally prescribed activities related to safety and hygiene of products of animal origin, animal feed and veterinary public health.



The responsibilities of the **Veterinary Inspection Sector** of the VD are to carry out official controls in the veterinary field, which includes any type of control.



The **Veterinary Inspection Service** has a total of 65 branch offices employing 107 official veterinarians (OVs) and 87 state veterinary inspectors (SVIs), and also includes a Department for the Financing of Official Controls which employs 5 people. The organisational structure of the Veterinary Inspection Service is as follows:

1. Department of the Veterinary Office of the **City of Zagreb**
2. Department – Veterinary Office **Bjelovar** (11 branch offices)
3. Department – Veterinary Office **Osijek** (9 branch offices)
4. Department – Veterinary Office **Rijeka** (7 branch offices)
5. Department – Veterinary Office **Split** (6 branch offices)
6. Department – Veterinary Office **Varaždin** (7 branch offices)
7. Department – Veterinary Office **Zagreb** (16 branch offices)
8. Department – Veterinary Office **Šibenik** (5 branch offices)
9. Department – Veterinary Office **Slavonski Brod** (4 branch offices)

SVIs and OVs have legal powers to carry out official controls and to take measures, including enforcement measures and sanctions, on the basis of relevant Acts. Regulation 882/04/EU has been incorporated into Croatian law under the *Ordinance on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules* (OG 99/07), and Regulation 854/04/EU has been incorporated into Croatian law under the *Ordinance on official controls of products of animal origin* (OG 99/07, 28/10).

Official controls are carried out on the basis of documented procedures, to ensure that controls are carried out uniformly and are of consistent high quality. Checklists are employed whenever possible, to provide at least the minimum requirements referred to in regulatory criteria, to help maintain the focus and objectivity of the assessment, and to ensure transparency of the assessment process. All checklists, records, decisions, motions to indict and reports prepared by SVIs and OVs during official controls must be available for scrutiny by their superiors. The general public also has access to information on control activities, via the Ministry of Agriculture website.

There is risk-based prioritisation of official controls, so that frequency of official controls is proportionate to the risk.

Legally authorised persons include employees of the Authorised Veterinary Organisations (AVOs) and control bodies, and also Authorised Veterinarians (AVs) who work full- or part-time under contract to the Veterinary Inspection Service. All control bodies to which specific tasks related to official control are delegated are accredited in accordance with the Croatian standard on general criteria for the operation of various types of bodies performing inspection HRN EN ISO/IEC 17 020.

The Veterinary Directorate has delegated specific tasks of official control of food of animal origin to 30 accredited veterinary organizations as control bodies by contracts (163 AVs).

A total of 138 AVOs with 894 AVs have been involved in implementation of veterinary activities in accordance with Article 95, paragraph 3 of the Veterinary Act. Regional distribution of AVOs and AVs is presented in the following table:

Epizootiological regions	Authorised veterinary organisations	Authorised veterinarians
Dubrovnik-Neretva County	2	3
Splitsko-Dalmatia County	11	40
Šibensko-Knin County	4	17
Lika-Senj County	7	13
Zadar County	6	20
Primorje-Gorski Kotar County	6	25
Istra County	8	33
Sisak-Moslavina County	8	48
Karlovac County	8	32
The City of Zagreb	3	52
Zagreb County	10	104
Varaždin County	5	57
Međimurje County	2	35
Koprivnica-Križevci County	4	96
Virovitica-Podravina County	5	25
Slavonski Brod-Posavina County	11	34
Požega-Slavonia County	3	24
Osijek-Baranja County	10	67
Vukovar-Srijem County	7	54
Krapina-Zagorje County	7	29
Bjelovar-Bilogora County	11	80
Total	138	894



The **Department for Border Veterinary Inspection** of the Veterinary Inspection Service employs 50 people and operates 17 Border Veterinary Posts.

The **Department for International Trade and Risk Analysis** of the Veterinary Inspection Service employs 7 people.

In June 2011, the VD established a **Service for Planning and Supervising the Implementation of Official Controls**. The roles of this service are as follows:-

- Preparation of the Annual official control plan of the Veterinary Inspection Service
- Participation in implementation of risk assessment in establishments dealing with food, feed and products of animal origin, in Order to determine the appropriate frequency of official controls in those establishments.
- Verification of the performance of official controls on the basis of the supervision of the SVIs and OVs
- Performance of official controls in Veterinary Inspection jurisdiction
- Participation in the organising and performing of education in the veterinary field
- Participation in the drafting of legislation drawn up by the Competent Authority

The Annual official control plan contains general information on the minimum frequency of official controls conducted by SVIs and OVs. It is created for all food, feed and animal by-product establishments. Results of the risk assessment processes for all these establishments are maintained in a VETI database.

Appendix 2: Details of Historical Legislation Related to BSE Control

Importation of Live Cattle

Prior to 2004, the Republic of Croatia banned imports of live cattle from all countries in which BSE had occurred, by means of numerous gazetted Orders. From 1997 through to 2001, eleven Orders were gazetted banning imports of cattle, bovine products and fodder of animal origin from specific countries named in the title of each Order. From 2001 through to 2004, banned countries of origin were listed in twenty-three successive Orders with titles including:

- *Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia (13 gazetted versions)*
- *Order on the prohibition of import into the Republic of Croatia of live animals, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia (7 gazetted versions)*

In January 2004 an Order was gazetted that stated that the ban on importation of live cattle was 'not applicable to consignments from countries in Category I and II according to GBR (Geographical Risk of Bovine Spongiform Encephalopathy) assessment of SSC (Scientific Steering Committee) of the EC, except for Canada and USA'. The Order was also not applicable to consignments from countries for which the central competent authority of the exporting country confirmed to the Ministry of Agriculture and Forestry (the name of the MA at that time) that the imported animals had not been fed any mammalian-based proteins.

In June 2004, the bans were replaced by a category system under the *Order on the prohibition of import into the Republic of Croatia with the purpose of preventing the transmissible spongiform encephalopathies from entering into the country.*

This Order classified countries into Categories 1, 2, 3 and 4, as follows:

Category 1:

Argentina, Australia, Botswana, Brazil, Chile, Iceland, Costa Rica, Namibia, Nicaragua, Norway, New Caledonia, New Zealand, Panama, Paraguay, El Salvador, Singapore, Swaziland, Uruguay, Vanuatu.

Category 2:

India, Canada, Kenya, Colombia, Costa Rica, Mauritius, Nigeria, Pakistan, USA, Sweden

Category 3:

Albania, Andorra, Austria, Belgium, Belarus, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Italy, Israel, Japan, Latvia, Lithuania, Luxembourg, Hungary, Macedonia, Malta, the Netherlands, Germany, Poland, Republic of Ireland, Romania, San Marino, Slovakia, Slovenia, Switzerland, Spain, Turkey

Category 4:

Portugal, United Kingdom of Great Britain and Northern Ireland

Veterinary health certificates accompanying imported live cattle were required to certify the following conditions for each category:

Category 1:

-That animals were not fed MBM or cattle feed containing tissues of mammals.

Category 2:

- That feeding ruminants with proteins obtained from mammals was prohibited in the country of origin and that the prohibition was efficiently enforced
- That the animals destined for export to the Republic of Croatia were permanently marked in accordance with the identification system which enables monitoring the origin back to mother of the cattle and the herd of origin, and that the animals were not offspring of a cow that was suspected of being infected with BSE

Category 3:

- That feeding ruminants with proteins obtained from mammals was prohibited in the country of origin and that the prohibition was efficiently enforced
- That the animals destined for export to the Republic of Croatia were permanently marked in accordance with the identification system which enables monitoring the origin back to mother of the cattle and the herd of origin, and that the animals were not offspring of a cow that was suspected of being infected with BSE
- That the cattle were born, reared and kept in herds where no case of BSE had been confirmed in the previous 7 years, and cattle afterwards added to the herd came from herd or farm with a similar status, or that the cattle were born after the date from which the prohibition of feeding cattle with protein of mammal origin was efficiently enforced

Category 4:

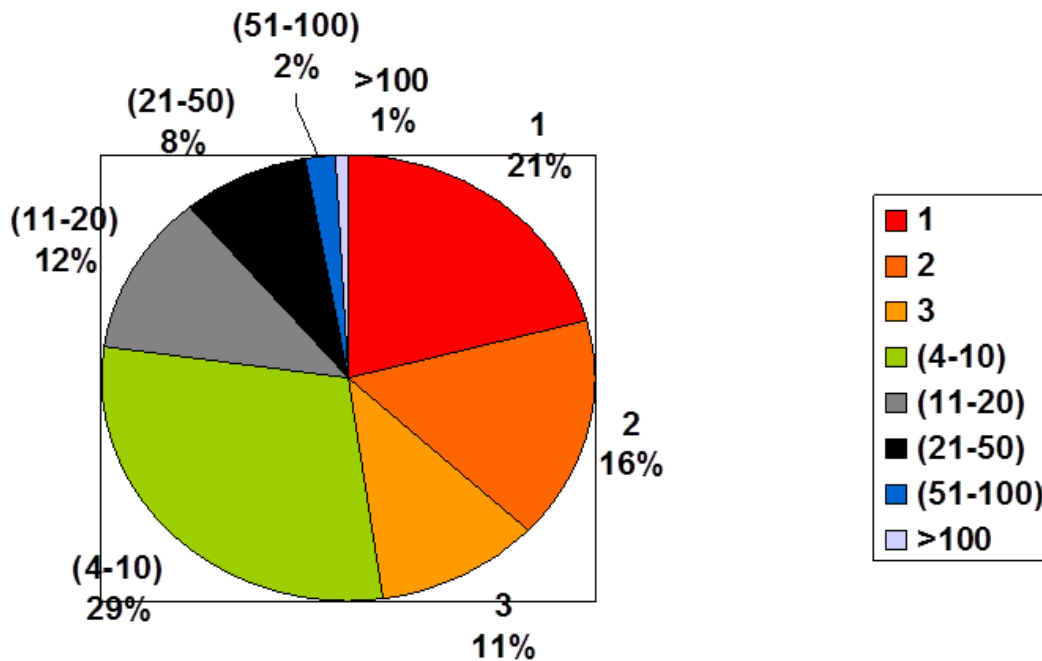
Importation of live cattle from Category 4 countries was prohibited.

The veterinary health certification requirements for Category 1 countries correspond to the recommendations in the OIE *Terrestrial Animal Health Code* for importation of cattle from a country with no history of BSE and negligible BSE risk. The veterinary health certification requirements for Category 2 countries correspond to the recommendations in the OIE *Terrestrial Animal Health Code* for importation of cattle from a country with negligible BSE risk but in which there has been an indigenous case, or from a country with controlled BSE risk. The veterinary health certification requirements for Category 3 countries are more rigorous than the recommendations in the OIE *Terrestrial Animal Health Code* for importation of cattle from a country with controlled BSE risk.

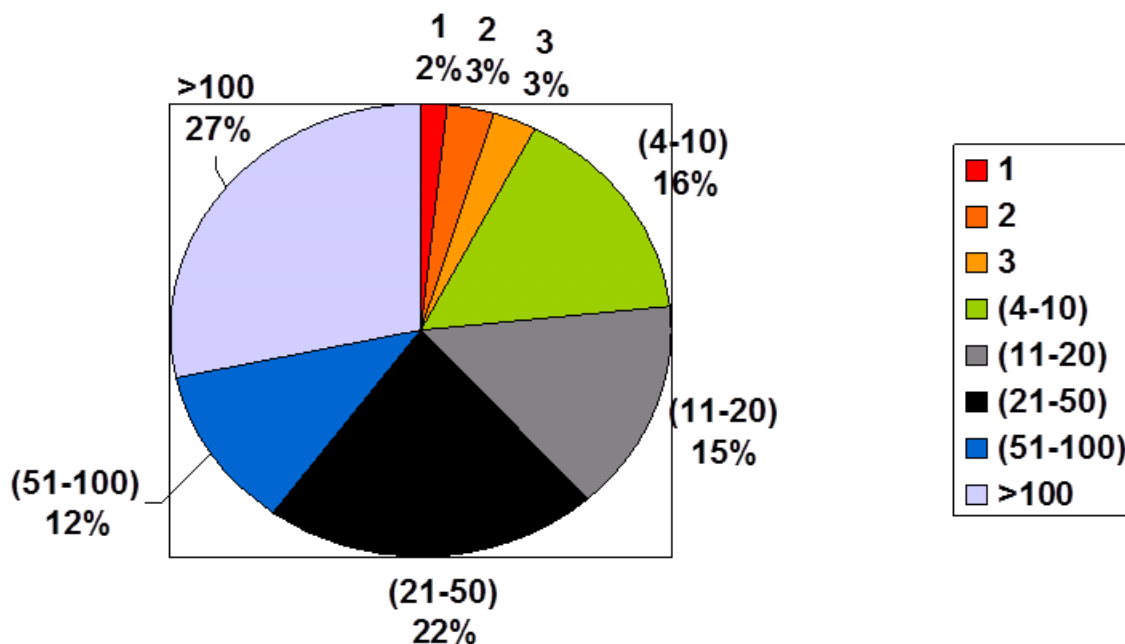
Appendix 3: Cattle and Holdings in Croatia

Croatia has approximately 40,000 registered cattle holdings, and approximately 500,000 cattle. Of these, approximately 235,000 are over the age of 24 months, and about 190,000 are dairy cows. Simmentals are the most popular breed because they are dual-purpose. Almost half of all cattle farms have 3 cows or fewer, but these smallholdings represent only 8% of all cattle in Croatia, as the following diagrams illustrate:

Herd Structure by Holding:



Herd Structure by Cattle:



Appendix 4: Chronological List of Croatian Legislation Relevant to BSE Control, 1996-2011

Title	Official Gazette	Date of Issue
Ordinance on the measures for detection, suppression and eradication of bovine spongiform encephalopathy	44/1996	05.06.1996
Order on the prohibition of use of proteins originating from ruminants (except for milk and milk products) in ruminants' diet	28/1997	12.03.1997
Order on the prohibition of importing cattle, products, raw material and waste material from cattle, originating from the Republic of Ireland into the Republic of Croatia	69/1997	04.07.1997
Order on the prohibition of importing cattle, products, raw material and waste material from cattle, originating from the United Kingdom into the Republic of Croatia	69/1997	04.07.1997
Veterinary Act	70/1997	07.07.1997
Order on the prohibition of using tissues, organs and mechanically separated meat of ruminants as risky raw material, which could contain the causative agent of the bovine spongiform encephalopathy (BSE), in the production of meat products	129/1997	02.12.1997
Ordinance laying down the conditions to be met by animal feed production and storage facilities	159/1998	14.12.1998
Order on the prohibition of import into the Republic of Croatia of high risk tissues and fodder of animal origin from countries with the occurrence of bovine spongiform encephalopathy	30/2000	07.03.2000
Order on the prohibition of import into the Republic of Croatia and transit over the territory of Croatia of cattle, bovine products and fodder of animal origin, originating from Switzerland	120/2000	01.12.2000
Order on the prohibition of import into the Republic of Croatia and transit over the territory of Croatia of cattle, bovine products and fodder of animal origin, originating from the Republic of Portugal	120/2000	01.12.2000
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, originating from the kingdom of Spain	120/2000	01.12.2000
Order on the prohibition of import into the Republic of Croatia and transit over the territory of Croatia of cattle, bovine products and fodder of animal origin, originating from the Republic of France	120/2000	01.12.2000
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, originating from the Federal Republic of Germany	120/2000	01.12.2000
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, originating from the Kingdom of the Netherlands	120/2000	01.12.2000
Order on the prohibition of import into the Republic of Croatia of high risk tissues, fodder of animal origin and ready-made cattle feed with fodder of animal origin	127/2000	20.12.2000

Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, originating from the Kingdom of Belgium	03/2001	12.01.2001
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, originating from the Republic of Italy	05/2001	22.01.2001
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, originating from the Kingdom of Denmark	07/2001	27.01.2001
Order on the prohibition to use proteins of animal origin for feeding animals	08/2001	31.01.2001
Order on the prohibition of import into the Republic of Croatia of high risk tissues, fodder of animal origin and ready-made cattle feed with fodder of animal origin	11/2001	09.02.2001
Order on obligatory testing of cattle for the presence of the causative agent of the bovine spongiform encephalopathy (BSE)	45/2001	18.05.2001
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	55/2001	15.06.2001
Order on the prohibition of import into the Republic of Croatia of high risk tissues, fodder of animal origin and ready-made cattle feed with fodder of animal origin	55/2001	15.06.2001
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	66/2001	20.07.2001
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	77/2001	07.09.2001
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	87/2001	10.10.2001
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	93/2001	26.10.2001
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	106/2001	30.11.2001
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	01/2002	03.01.2002
Order on the prohibition of import into the Republic of Croatia of	53/2002	10.05.2002

cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia		
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	70/2002	14.06.2002
Ordinance on the procedure for handling animal carcasses and waste of animal origin and their destruction	24/2003	18.02.2003
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	80/2003	16.05.2003
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	89/2003	30.05.2003
Order on the prohibition of import into the Republic of Croatia of live animals and products of animal origin with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	89/2003	30.05.2003
Order on the prohibition of import into the Republic of Croatia of live animals and products of animal origin with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	96/2003	10.06.2003
Order on the prohibition of import into the Republic of Croatia of live animals and products of animal origin with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	100/2003	17.06.2003
Order on the prohibition of import into the Republic of Croatia of live animals and products of animal origin with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	111/2003	15.07.2003
Order on the prohibition of import into the Republic of Croatia of live animals and products of animal origin with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	121/2003	29.07.2003
Order on the prohibition of import into the Republic of Croatia of live animals and products of animal origin with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	141/2003	08.09.2003
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	204/2003	30.12.2003
Order on the prohibition of import into the Republic of Croatia of live animals and products of animal origin with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	07/2004	19.01.2004

Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	27/2004	03.03.2004
Order on the prohibition of import into the Republic of Croatia of cattle, bovine products and fodder of animal origin, with the purpose of preventing the transmissible spongiform encephalopathies from entering into the Republic of Croatia	48/2004	29.03.2004
Order on the prohibition of import into the Republic of Croatia with the purpose of preventing the transmissible spongiform encephalopathies from entering into the country	79/2004	14.06.2004
Ordinance on the manner and procedure of reporting suspicion of an infectious animal disease and submitting reports on the appearance and cessation of an infectious animal disease and the contents of the prescribed forms	179/2004	17.12.2004
Order on the prohibition of import into the Republic of Croatia with the purpose of preventing the transmissible spongiform encephalopathies from entering into the country	15/2005	31.01.2005
Ordinance laying down the conditions and arrangements for approving establishments and intermediaries operating in the animal feed sector	96/2005	04.08.2005
Order on the prohibition of import into the Republic of Croatia with the purpose of preventing the transmissible spongiform encephalopathies from entering into the country	03/2006	09.01.2006
Ordinance laying down rules for the handling of animal by-products not intended for human consumption	56/2006	22.05.2006
Ordinance on conditions in animal feed business	84/2006	24.07.2006
Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies	39/2007	16.04.2007
Veterinary Act	41/2007	21.04.2007
Food Act	46/2007	07.05.2007
Ordinance on official controls of products of animal origin	99/2007	01.10.2007
Ordinance on official controls performed to ensure the verification of compliance with food and feed law, animal health and animal welfare rules	99/2007	01.10.2007
Ordinance on the obligatory identification and registration of bovine animals	99/2007	01.10.2007
Ordinance on the implementation of the system for the compulsory identification and registration of bovine animals	99/2007	01.10.2007
Ordinance on feed hygiene	41/2008	09.04.2008
Ordinance on registration and authorization on establishments where animal feed business operators operate	72/2008	23.06.2008
Ordinance on animal health requirements applicable to trade in bovine animals and swine	154/2008	29.12.2008
Ordinance on implementing measures for certain products subject	154/2008	29.12.2008

to food law

Ordinance on the notification of animal diseases	31/2009	11.03.2009
Ordinance on the BSE status of states or regions thereof	64/2009	03.06.2009
Ordinance on the prevention, control and eradication of certain transmissible spongiform encephalopathies	85/2009	17.07.2009
Ordinance on animal by-products not intended for human consumption	87/2009	21.07.2009
Ordinance on the labelling of beef	52/2010	28.04.2010