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# Evaluation of the revision of the BSE monitoring regime in Croatia

European Food Safety Authority

## Abstract

On 22 January 2015, Croatia submitted to the European Commission (EC) a request to revise its bovine spongiform encephalopathy (BSE) monitoring programme. The EC requested the European Food Safety Authority (EFSA) to provide scientific and technical assistance on an assessment of the capacity of the proposed revised monitoring programme in Croatia to allow the detection of BSE, both classical and atypical strains, with a design prevalence of at least one case per 100,000 animals in the adult cattle population of the EU26 group (EU25 and Croatia). Under this revision Croatia would stop testing all healthy slaughtered cattle and would test all 'at risk' cattle of active surveillance above 36 months of age. The EC resolved that the EU26 should be considered as a unique epidemiological unit for this assessment. Data related to the EU26 were updated to run the Cattle Transmissible Spongiform Encephalopathies Monitoring Model (C-TSEMM), previously applied to similar assessments. This model allows the estimation of the design prevalence of the same surveillance regime applied by a group of countries. Using data up to 2014, the current EU25 surveillance regime would allow the detection of BSE in the EU25 with a design prevalence of at least 1 per 3,769,555 of the cattle adult population, lower (i.e. more sensitive) than the minimum requirement of 1 case per 100,000. The addition of Croatia to the EU25 epidemiological unit (EU26) assuming the current EU25 surveillance regime resulted in an ability in EU26 to detect BSE with a design prevalence of at least 1 per 3,789,838 of the adult cattle population. It is recommended: [1] to run the C-TSEMM model on an annual basis with updated data; [2] to monitor MS data in order to evaluate the surveillance coverage and [3] to identify any shortcomings affecting the overall sensitivity of the surveillance system.

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**Keywords:** BSE, Croatia, EU25, EU26, monitoring, prevalence, surveillance

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## Summary

The European Commission (EC) has requested the European Food Safety Authority (EFSA) to provide scientific and technical assistance on an assessment of the capacity of the proposed revised bovine spongiform encephalopathy (BSE) monitoring programme in Croatia to allow the detection of BSE, both classical and atypical strains, with a design prevalence of at least 1 case per 100,000 of the adult cattle population of the EU26, i.e. the epidemiological unit made of all European Union (EU) Member States (MS) except Bulgaria and Romania.

Regulation (EC) No 999/2001 allows the revision of individual surveillance programmes if there is a demonstrable improvement of the BSE situation based on epidemiological criteria. Following various past assessments, all MS except Croatia, Bulgaria and Romania (EU25) have been authorised to modify their BSE monitoring programmes.

On 22 January 2015, Croatia submitted to the EC a request to revise its BSE monitoring programme. Under this revision Croatia would stop testing all healthy slaughtered (HS) cattle and would test all 'at risk' cattle identified through active surveillance (i.e. emergency slaughter (ES) fallen stock (FS) and animals identified as disease suspect at *ante mortem* inspection (AM) above 36 months of age) plus all TSE clinically suspected cases (CS) obtained via passive surveillance.

The EC favourably assessed the Croatian implementation of the BSE monitoring system, the bovine identification and traceability system and the feed ban, resolving that the EU26 should be considered as one unique epidemiological unit for this evaluation, consistent with the approach adopted in previous assessments of BSE surveillance in the EU.

Data related to the EU25 and to Croatia have been updated to apply the Cattle Transmissible Spongiform Encephalopathy (TSE) Monitoring Model (C-TSEMM), an in-house model originally developed to evaluate the performance of different BSE monitoring regimes in cattle, and previously applied to similar assessments. The model, that considers as surveillance components CS, HS, FS and ES (including AM), is designed to estimate the sensitivity of surveillance systems in terms of the minimum design prevalence detected for a group of countries that apply the same surveillance regime. It is not possible to directly model the design prevalence in a scenario where the surveillance regime of a MS joining an epidemiological unit is different from that of the unit (EU25), such as the proposed BSE monitoring programme of Croatia.

Following the description of the requirement described in the ToR, the sensitivity of the surveillance system has been described as the design prevalence that surveillance scenarios for the populations of interest are able to detect. This estimated design prevalence is compared to the minimum requirement of 1 case per 100,000. If a result shows a denominator larger than 100,000, the detection level is referred to as a lower design prevalence than the one required, and indicates that the surveillance scenario has a higher sensitivity than the minimum required.

The results of the assessment showed that, using data up to 2014, the former EU25 BSE surveillance regime (HS older than 72 months, ES and FS older than 48 months, all CS) would allow the detection of BSE (both classical and atypical strains) with a design prevalence of at least 1 per 4,684,990 of the adult population (cattle older than 24 months), higher (i.e. less sensitive) than the 1 per 6,354,930 obtained when applying data up to 2011, but lower than the minimum required (1 per 100,000). This reduction in sensitivity is due to the cessation of the compulsory testing of HS animals since 2013.

The results of the assessment showed that, using data up to 2014, the current EU25 BSE surveillance regime (no HS testing, ES and FS older than 48 months, all CS) would allow the detection of BSE (both classical and atypical strains) with a design prevalence of at least 1 per 3,769,555 of the adult population, higher (i.e. less sensitive) than the 1 per 4,021,940 obtained when applying data up to 2011, but lower than the minimum required (1 per 100,000). This reduction in sensitivity is due to the lower absolute number of 'at risk' animals of active surveillance and TSE clinically suspected cases tested across the EU25 between 2012 and 2014.

After the addition of Croatia to the EU25 epidemiological unit (EU26) and assuming the current EU25 surveillance regime for all MS including Croatia, the design prevalence of the surveillance in the EU26 would be 1 per 3,789,838 adult population, lower than the minimum required (1 per 100,000).

If Croatia implemented the proposed surveillance regime (no HS testing, ES and FS older than 36 months, all CS) the sensitivity at the EU26 level would be slightly higher (i.e. lower design prevalence) than the one applying the current EU25 surveillance regime.

It is recommended that the C-TSEMM model is run on an annual basis, and with updated data, in order to monitor the ability of the current surveillance regime to detect BSE at both MS and EU26 levels. The outputs could be included in the EU TSE Annual Report. However, the adequacy and assumptions of the model should be revised considering the evolution of the epidemiological situation of BSE in the EU. It is also recommended to monitor the data at MS level in order to evaluate the coverage by testing group in the context of changing standing cattle populations, and to identify any shortcomings affecting the overall sensitivity of the surveillance system.

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## 1. Introduction

### 1.1. Background and Terms of Reference as provided by the requestor

According to Regulation (EC) No 999/2001<sup>1</sup> (TSE Regulation), each Member State (MS) shall carry out an annual monitoring programme for bovine spongiform encephalopathy (BSE), including a screening procedure using rapid tests approved for that purpose. Article 6 Chapter III of the TSE Regulation states that '*this programme shall cover, as a minimum, the following subpopulations:*

- (a) all bovine animals above 24 months of age sent for emergency slaughter or with observations at ante mortem inspections;*
- (b) all bovine animals above 30 months of age slaughtered normally for human consumption;*
- (c) 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).'*

However, a MS which can demonstrate, based on epidemiological criteria, the improvement of the BSE situation on its territory, may send an application to the Commission with a view to get authorization for the revision of its monitoring programme.

Since 2009, all MS except Croatia, Bulgaria and Romania (EU25) have progressively been authorised, based on their favourable epidemiological situation and following positive EFSA assessments (EFSA, 2012; EFSA BIOHAZ Panel, 2008, 2009, 2010, 2011) to review their BSE monitoring programmes.

On 22 January 2015, Croatia submitted to the European Commission (EC) a request to revise its BSE monitoring programme, in order to stop testing healthy slaughter animals and to test all 'at risk' cattle above 36 months of age of active surveillance.<sup>2</sup> Following questions from the Commission, Croatia sent a revised application on 22 April 2015. The services of the EC assessed favourably the elements of the Croatian application related to the implementation of the BSE monitoring system, bovine identification and traceability system and implementation of the feed ban.

In accordance with Article 31 of (EC) Regulation 178/2002, EFSA is requested:

- to provide scientific and technical assistance on an assessment of the capacity of the proposed testing regime as in the above described revised BSE monitoring programme in Croatia to allow the detection of BSE (both classical and atypical strains) with a design prevalence of at least one case per 100,000 of the adult bovine animal population of the EU26 group (EU25 and Croatia).

### 1.2. Interpretation of the Terms of Reference

The present report includes the design prevalence of EU25 and EU26 taking into account the surveillance and ancillary data until the end of 2014.

Following clarifications with the EC:

- The EC favourably assessed the Croatian implementation of the BSE monitoring system, bovine identification and traceability system and implementation of the feed ban. The EU25 and Croatia should be considered as a unique epidemiological unit for this evaluation (EU26), consistent with the approach adopted in a previous assessment of BSE surveillance in the EU (EFSA, 2012).
- Providing results at EU25 level using updated data allows the comparison with those previously reported by EFSA (2012), which considered surveillance data until 2011. The present report is expected to provide, as an output of the previously used Cattle Transmissible Spongiform Encephalopathy (TSE) Monitoring Model (C-TSEMM), conclusions on the BSE design prevalence that the current EU BSE surveillance system would be able to detect, at both the EU25 and EU26 levels.

<sup>1</sup> Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. OJ L 147, 31.5.2001, p. 1–40.

<sup>2</sup> See Section 1.3 for definitions of the surveillance streams included in the 'at risk' group of active surveillance.

- The focus of the present report is not to describe the ability of the current and proposed surveillance programmes to detect BSE in Croatia alone.

### 1.3. The Croatian monitoring programme in the context of EU BSE surveillance

The main purpose of BSE surveillance in the EU is to monitor the trend of the BSE epidemic. According to Article 6, point 1 of Regulation (EC) No 999/2001 (TSE Regulation) '*each MS shall carry out an annual monitoring programme for TSE based on both active and passive surveillance*'. BSE active surveillance in the EU is based on the systematic testing of cattle of defined target groups over a certain age. For this purpose, rapid tests approved and listed under Annex X of the TSE Regulation rapid are used.

Since 4 February 2013, with the adoption of Commission Implementing Decision 2013/76/EU amending Decision 2009/719/EC,<sup>3</sup> a number of MS have been allowed to decide not to test one of the testing routes of active surveillance, the healthy cattle submitted to regular slaughtering for human consumption or slaughtered in the context of a disease eradication campaign other than BSE, without clinical signs of disease (HS), while they must continue to test all cattle over 48 months of age in the 'at risk' groups of active surveillance (EC, 2015):

- emergency slaughter (ES): cattle subject to 'special emergency slaughtering' as described in the EU legislation;
- fallen stock (FS): animals that have died or been killed on the farm or in transport, but not slaughtered for human consumption nor killed in the framework of an epidemic;
- *ante mortem* (AM): animals with clinical signs at *ante mortem* inspection i.e. cattle sent for normal slaughter but the slaughter of which was deferred because they were: (a) suspected of suffering from a disease which is communicable to humans and to animals or showing symptoms or being in a general condition indicating that such a disease may occur; (b) showing symptoms of a disease or of a disorder of their general condition which is likely to make their meat unfit for human consumption.

In Romania, Croatia and Bulgaria, the age limit for testing cattle is 30 months for all healthy slaughtered animals and 24 months for at risk animals of active surveillance (point 2 of Section I of Chapter A of Annex III of the TSE Regulation). MS may decide to apply stricter schemes. BSE passive surveillance consists of the bovine animals reported as TSE suspect (clinically suspected cases, CS), as defined in Article 3 of the TSE Regulation, and subject to the measures described in Articles 12 and 13.

Between 2008 and 2014 the BSE surveillance system in Croatia has been based on a combination of passive and active surveillance. It consists of the testing of all CS reported by farmers to the veterinary authority (passive surveillance) and the testing of the following bovine subpopulations of active surveillance:

- 1) 'at risk' cattle older than 24 months: FS, ES and AM;
- 2) HS older than 30 months.

Croatia is proposing a 'revised BSE monitoring programme', applied to all cattle born and reared in the Republic of Croatia, and to any cattle imported from the EU25 MS, that will be implemented in its entire territory, including the testing of all CS, and active surveillance of the following bovine subpopulations:

- 1) 'at risk' cattle older than 36 months;
- 2) no testing of HS.

<sup>3</sup> 2013/76/EU: Commission Implementing Decision of 4 February 2013 amending Decision 2009/719/EC authorising certain Member States to revise their annual BSE monitoring. OJ L 35, 6.2.2013, p. 6–7.

No changes are proposed for cattle originating from third countries or MS that do not implement the current BSE monitoring programme, in accordance with points 2 and 3 of Part I of Chapter A of Annex III to the TSE Regulation.

## **2. Data and Methodologies**

### **2.1. Data**

The data used in the evaluation performed for this report were determined by the requirements of the C-TSEMM - the modelling tool selected to conduct the analysis. The data sources and data used in the evaluation are described below.

#### **2.1.1. Data related to EU25 MS**

##### **Data on the standing cattle population**

The standing cattle population at MS level for the period 2001-2012 was collated by EFSA for previous mandates where the C-TSEMM was applied (EFSA, 2012, 2013a,b).

Data for the standing cattle population by MS for the age intervals 0–11 months and 12–23 months were obtained from Eurostat up to 2014.

EU25 data, up to 2012, for cattle older than 24 months (in 12-month intervals up to 155 months) were previously gathered by EFSA through a questionnaire. In the absence of available data for MS for 2013 and 2014, the populations recorded for 2012 were used.

##### **Data on the number of cattle tested and test results**

The numbers of cattle tested, and positive test outcomes by surveillance stream for each MS, for the period 2002-2014, were obtained from the EU TSE database hosted by the EC (data accessed by EFSA).

The previous version of C-TSEMM (Adkin et al., 2012) applied by EFSA (2012) used data reported by MS up to December 2012. Surveillance results up to 31 December 2014 were added to the dataset for all EU25 MS. In some cases, the age of the animals tested was no longer collected in the same intervals as previously. For example, some MS are now reporting data from cattle classified as above or below 72 months of age. In these cases, it was assumed that the proportion of animals tested in each of the age intervals was the same as the proportion tested in the previous two years where more detailed data were available.

##### **Data on the number of cattle dead or slaughtered and not tested**

Previously (EFSA, 2012, 2013a,b), data on the number of cattle dead/slaughtered and not subject to testing according to the legal requirements (i.e. below the age for testing) were elicited through an EFSA questionnaire sent individually to each MS, and were current up to July 2012. For the updated C-TSEMM, it was assumed that the populations of dead and slaughtered cattle which were not tested in each MS for the more recent years were stable. Therefore, the proportion of animals dead/slaughtered and not tested in each age interval was assumed to be the same as the proportion of animals dead/slaughtered in the previous two years, from which the data were available. These assumed proportions were only used to estimate the number of animals that may be tested in theoretical surveillance scenarios (Adkin et al., 2012), so this assumption does not affect the design prevalence estimated by the model for the tested scenarios.

##### **Data on BSE case types**

All MS that have had cases of BSE are currently participating in a retrospective classification exercise of BSE cases dating back to 2003 in which cases are being re-tested and classified into the following case types: Classical BSE, Atypical H-type BSE, or Atypical L-type BSE. Completed case type data from a number of MS (the Czech Republic, Germany, Spain, France, Luxemburg, Slovenia and the United Kingdom) were provided by the EC to EFSA, and included in the model.

### 2.1.2. Data related to Croatia

#### Data provided in the application for revision of annual BSE-monitoring, provided by Croatia to the EC:

Data provided in the Croatian application include:

- number of cattle tested Croatia, by surveillance stream (HS, FS, ES, AM) and year for the period 2008-2014;
- total size of the Croatian cattle population by year for the period (2012–2014).

Additional data obtained by EFSA from the Croatian competent authority, following a request for additional information, include:

- distribution of the cattle population by age and year for the period 2012–2014;
- total number of cattle born by year for the period 2012–2014;
- number of cattle slaughtered or found dead by year for the period 2001–2014;
- number of cattle tested for BSE, by age, year and surveillance stream, with test results for the period 2002–2014;
- number of cattle tested for BSE not required by the legislation (below the age of testing) by year for the period 2002–2014.

More details of the surveillance programme and surveillance data in Croatia are included in Appendix A.

## 2.2. Methodology

The C-TSEMM (Adkin et al., 2012) was originally developed to evaluate the performance of different BSE monitoring regimes in cattle. Previous assessments of the performance of the BSE monitoring regime in cattle in the EU were carried out using the C-TSEMM. For details of the model and its assumptions, see Adkin et al. (2012). The C-TSEMM requires that, for modelling scenarios applicable to a group of countries, it must be possible to merge them together as a unique epidemiological unit, as was considered the case with the EU25, and as such to estimate the design prevalence that the surveillance regime can detect when applied to the entire cattle population of the unit. In order to merge a group of countries together as a unique epidemiological unit, the C-TSEMM requires that all members of the epidemiological unit apply the same surveillance regime. It is not possible to directly model the design prevalence in a scenario where the surveillance regime of a MS joining the epidemiological unit is different from that of the unit (EU25), such as the proposed BSE monitoring programme of Croatia.

The C-TSEMM uses individual MS BSE case data and the number of animals tested between 2001 and 2014. Following the assumptions described in section 2.1.2 in Adkin et al. (2012), there are four surveillance components included in the model: CS, HS, FS and ES (including AM).

The C-TSEMM requires annual historical information on the standing population, slaughter/death of animals in each surveillance stream, those animals which have been tested, and test results by case type (Classical BSE, Atypical H-type BSE, or Atypical L-type BSE or unknown). These data are required for each MS, so when individual country estimates were not available, an EU average was used.

The data imported into the C-TSEMM only include the BSE test data according to the EU legislation in terms of surveillance stream and age thresholds for testing. Any additional data from MS that tested beyond the EU requirements have been disregarded in the calculations. For example, in 2014 France continued testing healthy cattle slaughtered for human consumption older than 72 months of age. For those MS whose testing program exceeds the legal requirement, the model will under-estimate the design prevalence that their surveillance system is able to detect.

The model provides different outputs for the evaluation of alternative surveillance scenarios at either individual MS level or aggregated level (EU25 and EU26). One of them is the underlying prevalence of BSE in the population (1 per X) that the surveillance scenario would be able to detect (design prevalence) which is presented in this report.

The data for the EU26 were updated with the required information for Croatia to produce an updated consolidated input data Excel file. The visual basic for applications (VBA) code and R model code were amended and final results from model runs are reported in Section 3.

For MS with no BSE cases detected after 2001, an alternative estimate of prevalence is required by the C-TSEMM. For MS in that category, prevalence has been assumed to be the average prevalence of groups of MS with BSE cases. Two groups have been used previously by the C-TSEMM: EU-17 and the EU-8 (for more details, see Adkin et al. (2012)). In the case of Croatia, a MS with no detected BSE cases, an alternative estimate of prevalence was required for the model, and the merged prevalence for the EU25 was used as an appropriate proxy.

### 3. Results of the assessment

The outputs of the C-TSEMM model applying a combination of surveillance scenarios to the two epidemiological units, namely EU25 and EU26, using data up to 2011 and up to 2014 are presented in Table 1 and described below. There are four surveillance components included in the model: CS, HS, FS and ES (including AM).

**Table 1:** Summary of the design prevalence at EU25 and EU26 levels by surveillance regime up to 2011 and 2014, respectively

Epidemiological unit	Surveillance regime	Surveillance data	
		2011	2014
<b>EU25</b>	<b>HS &gt; 72 m, ES/FS &gt; 48 m, all CS (former EU25 regime)</b>	1 per 6,354,930	1 per 4,684,990
<b>EU25</b>	<b>no HS testing, ES/FS &gt; 48 m, all CS (current EU25 regime)</b>	1 per 4,021,940	1 per 3,769,555
<b>EU26</b>	<b>no HS testing, ES/FS &gt; 48 m, all CS (current EU25 regime)</b>	N.A.	1 per 3,789,838

CS: clinical suspects; ES: emergency slaughter; FS: fallen stock; HS: healthy slaughtered; m: minute.

In a previous evaluation based on data up to 2011 (EFSA, 2012), it was estimated that the former EU25 BSE surveillance regime (HS older than 72 months, ES and FS older than 48 months, all CS) allowed the detection of BSE (both classical and atypical strains) with a design prevalence of at least 1 per 6,354,930 of the adult population<sup>4</sup> (cattle older than 24 months).

Using data up to 2014, it is estimated that the former EU25 BSE surveillance regime (HS older than 72 months, ES and FS older than 48 months, all CS) would allow the detection of BSE (both classical and atypical strains) with a design prevalence of at least 1 per 4,684,990 of the adult population<sup>4</sup> (cattle older than 24 months), lower than the minimum required (1 per 100,000). This reduction in sensitivity is due to the cessation of the compulsory testing of HS animals (from 3,757,280 HS tested in 2012 to 1,384,879 HS tested in 2014).

Using data up to 2011, the current EU25 BSE surveillance regime (no HS testing, ES and FS older than 48 months, all CS) would have allowed the detection of BSE (both classical and atypical strains) with a design prevalence of at least 1 per 4,021,940 adult population.<sup>4</sup>

For comparison and using data up to 2014, it is estimated that the current EU25 BSE surveillance regime (no HS testing, ES and FS older than 48 months, all CS) would allow the detection of BSE (both classical and atypical strains) with a design prevalence of at least 1 per 3,769,555 of the adult population<sup>4</sup>, lower than the minimum required (1 per 100,000). This reduction in sensitivity is due to the lower absolute number of at risk animals and CS tested across the EU25 between 2012 and 2014 (ES from 65,811 to 61,000; FS from 942,499 to 828,875, and CS from 580 to 566).

After the addition of Croatia to the EU25 epidemiological unit (EU26) and assuming the current EU25 surveillance regime for all MS including Croatia, the design prevalence of the EU26 would improve to 1 per 3,789,838 of the adult population<sup>4</sup> compared to the estimate of the EU25 without Croatia and

<sup>4</sup> 95% confidence level.

lower than the minimum required (1 per 100,000). Country-specific design prevalence estimates are displayed in Appendix B.

## 4. Conclusions

- The sensitivity of the surveillance system has been reported in terms of the design prevalence that surveillance scenarios for the populations of interest are able to detect, following the requirement described in the ToR. The estimated design prevalence is compared to the minimum requirement of 1 case per 100,000 (1/100,000). If a result shows a denominator larger than 100,000, the detection level is referred to as a lower design prevalence than the one required, and so indicates a higher sensitivity of the surveillance scenario. Conversely, a reduction of the sensitivity of a surveillance scenario means it has the ability to detect a higher design prevalence than that of the scenario used for comparison.
- The results obtained with 2014 data indicate that, at EU25 level:
  - a) the current EU25 surveillance regime (no HS testing, ES and FS older than 48 months, all CS) has a sensitivity higher than that needed to detect the minimum required (1 per 100,000);
  - b) the ability of the current EU25 surveillance regime to detect cases of BSE in the adult cattle population has been reduced compared to the one estimated with 2011 data.
- A key assumption of the analysis conducted using the C-TSEMM was that the merged prevalence for the EU25 could be used as an appropriate proxy for the true BSE prevalence in Croatia. For instance in 2014 there were 9 BSE cases (4 in HS, 1 in ES and 4 in FS) in the EU25 group. This assumption results in an overestimate of prevalence for MS with no recorded cases as they are merged with MS where cases have been confirmed. Therefore the actual ability of the surveillance system to detect BSE in those MS is likely to be lower than the one estimated by the model. This limitation does not apply to the estimation at EU25 and EU26 levels, but only at MS level.
- Methodological constraints prevent the C-TSEMM from producing the exact estimation of the ability of the surveillance system to detect BSE given the specified design prevalence as required by the ToR (i.e. different surveillance regimes in the EU25 and Croatia). Therefore the modelled scenario considered that the current EU25 surveillance regime was applied to Croatia as well.
- The results obtained with 2014 data indicate that, at EU26 level:
  - a) the current EU26 surveillance regime (no HS testing, ES and FS older than 48 months, all CS) would be able to detect a design prevalence lower than the one required (1 per 100,000);
  - b) the transition of the current Croatian surveillance regime to the one implemented at the EU25 level would have a minimum impact on the level of detection at the EU26 level.
- If Croatia implemented the proposed surveillance regime (no HS testing, ES and FS older than 36 months, all CS), the sensitivity at the EU26 level would be slightly higher (i.e. lower design prevalence) than the one applying the current EU25 surveillance regime.

## 5. Recommendations

- To run the C-TSEMM model on an annual basis with updated data in order to monitor the ability of the current surveillance regime to detect BSE at both MS and EU26 levels. The outputs could be included in the EU TSE Annual Report. However, the adequacy and assumptions of the model should be revised to take into consideration the evolution of the epidemiological situation of BSE in the EU.
- To monitor the data at MS level in order to evaluate the surveillance coverage by testing group and the overall surveillance system sensitivity in the context of changing standing cattle populations.
- To identify any shortcomings affecting the overall sensitivity of the surveillance system based on the outcome of the previous recommendation.

## Documentation provided to EFSA

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## Glossary

<i>Ante mortem</i>	Bovine animals sent for normal slaughter but the slaughter of which was deferred because they were: (a) suspected of suffering from a disease which is communicable to humans and to animals or showing symptoms or being in a general condition indicating that such a disease may occur; (b) showing symptoms of a disease or of a disorder of their general condition which is likely to make their meat unfit for human consumption.
Cohort	A group of bovine animals which includes both: (i) animals born in the same herd as the affected bovine animal, and within 12 months preceding or following the date of birth of the affected bovine animal; and (ii) animals which at any time during the first year of their lives were reared together with the affected bovine animal during the first year of its life (point 2(b) Annex I Regulation (EC) No 999/2001).
Clinical suspects	Clinical suspects. Bovine animals reported as TSE suspects (clinically suspected cases), as defined in Article 3 of the TSE Regulation, and subject to the measures described in Articles 12 and 13. Clinically suspected animals are normally obtained via passive surveillance.
Design prevalence	The underlying prevalence of BSE in the population of interest that the surveillance system should be able to detect, expressed in the form 1 per X individuals the population. According to Point 1 Chapter D Annex II of the TSE Regulation, <i>'the design prevalence is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease'</i> .
Epidemiological unit	A group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common environment (e.g. animals in a pen), or because of common management practices (OIE, 2014).
Emergency slaughter	Bovine animals subject to 'special emergency slaughtering' as described in the EU legislation.
EU8	Estonia, Hungary, Latvia, Lithuania, Malta, Czech Republic, Poland and Slovakia.
EU17	Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Slovenia, Spain, Sweden and United Kingdom.
EU25	All MS from 1 July 2013 except Bulgaria, Croatia and Romania.
EU26	All MS from 1 July 2013 except Bulgaria and Romania.
Fallen Stock	Bovine animals that have died or been killed on the farm or in transport, but not slaughtered for human consumption nor killed in the framework of an epidemic.
Healthy Slaughter	Healthy bovine animals submitted to regular slaughtering for human consumption or slaughtered in the context of a disease eradication campaign other than BSE, without clinical signs of disease.

## Abbreviations

AM	<i>Ante mortem</i>
BIOHAZ	Biological Hazards
BSE	Bovine spongiform encephalopathy
CS	Clinical suspects
C-TSEMM	Cattle TSE Monitoring Model
EC	European Commission
EFSA	European Food Safety Authority
ES	Emergency slaughter
EU	European Union
FS	Fallen stock
HS	Healthy slaughtered
MS	Member State of the European Union
TSE	Transmissible spongiform encephalopathy
VBA	Visual basic for applications

## Appendix A – Input data from Croatia for the C-TSEMM

The paragraphs in italics below are transcribed verbatim from the application for Revision of Annual BSE monitoring programme, submitted by Croatia.

*The Republic of Croatia currently implements an annual BSE-monitoring programme according to Article 6 Chapter III of Regulation (EC) No 999/2001, as follows:*

### ***Bovine animals older than 24 months:***

- *FS (bovine animals which have died or have been killed on the farm or in transport, but not slaughtered for human consumption nor killed in the framework of an epidemic);*
- *ES (bovine animals subject to "special emergency slaughtering" as described in Community legislation);*
- *CS (animals with clinical signs at ante mortem examination)<sup>5</sup>.*

### ***Bovine animals older than 30 months:***

- *HS (bovine animals subject to normal slaughter for human consumption);*
- *and animals without clinical signs of disease slaughtered in the context of a disease eradication campaign other than BSE.*

*The Republic of Croatia is proposing to the European Commission the following revised (modified) Annual BSE-Monitoring Programme:*

### ***Identification of the subpopulations, age limits and sample sizes***

*No testing of any healthy slaughter bovines.*

*Testing of all at risk bovines (FS, ES and animals with clinical signs at AM) aged over 36 months.*

*The proposed revised BSE-Monitoring Programme shall apply to all the bovine animals born and reared in Republic of Croatia, and to all the bovine animals born and reared in the other Member Countries having in place and implementing in their respective territories an identically revised BSE-Monitoring Programme.*

*All the bovine animals originating from third countries or Member Countries that do not implement the (common) revised BSE-Monitoring Programme shall within the territory of the Republic of Croatia be subjected to the current BSE-monitoring scheme in accordance with points 2 and 3 of Part I of Chapter A of Annex III to the Regulation (EC) No 999/2001.*

### ***Geographical area where programme will be implanted***

*The proposed revised BSE-Monitoring Programme will be implemented in the entire territory of the Republic of Croatia (21 counties).*

On the basis of the information received from the Croatian competent authority<sup>6</sup> the bovine standing population by age category and year is reported in Table 1. The total numbers of cattle tested by surveillance stream are shown in Tables 2–6. The total or estimated (when not available by age category) number of cattle for each surveillance stream is shown in Tables 6-10. The data displayed in Tables 2–10 have been aggregated following the requirement of the C-TSEMM model and are displayed in the way they have been imported into the model.

<sup>5</sup> This surveillance stream is referred to in the report as *ante mortem* (AM).

<sup>6</sup> Information received from the Animal Health Protection Sector, Veterinary and Food Safety Directorate. Ministry of Agriculture of Croatia on 15 August 2015.

**Table 2:** Standing cattle population in Croatia 2012-2014

Age category (months)	Year		
	2012	2013	2014
< 24	262,584	245,074	229,862
24–29	22,069	23,096	22,154
30–35	21,049	20,311	20,488
36–47	41,571	36,365	36,809
48–59	34,135	34,956	31,640
60–71	24,191	27,844	29,081
72–83	20,356	19,188	22,658
84–95	16,417	15,661	15,414
96–107	14,082	12,404	12,177
108–119	11,123	10,491	9,547
120–131	8,314	8,267	7,994
132–143	5,016	6,092	6,280
144–155	3,338	3,736	4,636
> 155	7,426	7,549	8,582
<b>Total</b>	491,671	471,034	457,322

**Table 3:** Total number of tested cattle by age categories in Croatia between 2002 and 2014

Age category (months)	Year												
	2002*	2003*	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
<b>0–23</b>	33	27	10	8	13	2	32	33	776	29	70	150	139
<b>24–29</b>	53	53	65	19	79	146	337	742	1,109	1,629	2,209	747	833
<b>30–35</b>	231	358	317	374	650	539	431	2,550	3,514	4,387	5,859	2,317	2,552
<b>36–47</b>	907	1,075	1,404	2,128	3,378	2,904	3,253	5,178	7,158	9,090	13,251	4,750	4,078
<b>48–59</b>	2,279	2,043	2,338	2,996	5,034	4,544	4,630	6,500	8,746	6,096	6,657	5,513	4,514
<b>60–71</b>	2,337	2,088	2,390	3,053	5,039	4,496	4,526	6,303	8,533	5,951	7,395	4,512	4,723
<b>72–83</b>	1,032	914	1,058	1,365	2,348	2,165	2,213	3,129	4,221	2,941	490	3,839	3,532
<b>84–95</b>	2,291	1,674	1,894	1,641	2,664	2,477	2,338	2,555	3,426	3,322	368	3,389	3,000
<b>96–107</b>	2,118	1,543	1,742	1,499	2,383	2,157	2,020	2,254	3,098	3,000	272	3,063	2,570
<b>108–119</b>	1,343	968	1,125	1,056	1,704	1,645	1,532	1,460	1,967	1,992	187	2,424	2,252
<b>120–131</b>	1,103	787	910	851	1,356	1,282	1,176	1,172	1,602	1,622	129	1,950	1,781
<b>132–143</b>	772	553	641	598	953	899	828	821	1,118	1,132	80	1,208	1,414
<b>144–155</b>	486	347	401	376	601	572	525	519	708	717	71	744	901
<b>156–167</b>	861	606	695	646	1,009	920	821	882	1,233	1,247	69	1,353	1,431
<b>168–179</b>	94	66	77	76	136	149	141	116	151	153	29	181	203
<b>180–191</b>	21	15	18	20	43	57	57	35	41	42	17	57	68
<b>192–203</b>	1	1	2	4	13	21	23	10	8	8	9	16	21
<b>&gt; 204</b>	9	10	15	14	28	36	42	19	16	16	13	30	35
<b>&gt; 155</b>	986	699	806	760	1,228	1,183	1,085	1,062	1,450	1,467	138	1,637	1,758

\* For 2002 and 2003 the proportion of animals in ES and FS streams = average proportion by age in separate streams in 2004 and 2005.

**Table 4:** Total number of tested cattle by age categories in the healthy slaughtered risk group in Croatia between 2002 and 2014

(Age category (months))	Year													
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	
<b>0–23</b>	16	7	5	3	10	2	16	9	13	9	14	80	79	
<b>24–29</b>	32	10	41	12	18	121	209	113	154	186	82	173	205	
<b>30–35</b>	207	287	268	344	544	403	265	2,270	3,083	3,737	5,491	1,765	1,968	
<b>36–47</b>	809	863	1,086	1,878	2,807	2,250	2,281	4,237	5,754	6,975	10,537	3,578	3,100	
<b>48–59</b>	2,107	1,790	2,100	2,654	4,002	3,400	3,066	4,011	5,849	4,097	5,305	4,249	3,494	
<b>60–71</b>	2,171	1,844	2,164	2,734	4,122	3,502	3,159	4,132	6,024	4,220	6,173	3,604	3,664	
<b>72–83</b>	973	827	970	1,226	1,848	1,570	1,416	1,852	2,701	1,892	67	3,100	2,859	
<b>84–95</b>	2,183	1,535	1,712	1,464	2,231	1,905	1,671	2,006	3,064	2,948	45	2,758	2,420	
<b>96–107</b>	2,023	1,423	1,587	1,356	2,067	1,765	1,548	1,859	2,839	2,731	54	2,601	2,185	
<b>108–119</b>	1,274	876	990	921	1,414	1,250	1,071	1,260	1,813	1,831	39	2,058	1,917	
<b>120–131</b>	1,059	727	823	765	1,175	1,038	889	1,046	1,506	1,521	25	1,728	1,582	
<b>132–143</b>	736	506	572	532	817	722	619	728	1,048	1,058	22	1,065	1,232	
<b>144–155</b>	467	321	363	338	518	458	392	461	664	671	23	647	801	
<b>156–167</b>	839	576	652	606	931	823	705	829	1,194	1,206	32.5	1,272.1	1,338.0	
<b>168–179</b>	92	64	72	67	103	91	78	91	132	133	3.6	140.2	147.5	
<b>180–191</b>	20	14	16	14	22	20	17	20	29	29	0.8	30.4	32.0	
<b>192–203</b>	1	1	1	1	1	1	1	1	1	1	0.0	1.5	1.6	
<b>&gt; 204</b>	1	1	1	1	2	1	1	1	2	2	0.1	2.1	2.2	
<b>&gt; 155</b>	954	655	741	690	1,059	936	801	943	1,357	1,371	37.0	1,446.3	1,521	
<b>24–47</b>									6,620	8,990	10,898	26,899	*	
<b>48–83</b>	5,251	4,460	5,234	6,614	9,972	8,473	7,641	9,995	14,574	10,208	32,515			
<b>84–108</b>	4,206	2,958	3,299	2,820	4,298	3,670	3,219	3,865	5,903	5,679	10,063			
<b>&gt; 108</b>	4,490	3,085	3,489	3,246	4,983	4,404	3,772	4,438	6,389	6,452	14,144			

\* Assumed population proportions stable during the period 2012–2014. Actual data for years 2002–2011.

**Table 5:** Total number of tested cattle by age categories in the emergency slaughter risk group (including *ante mortem*) in Croatia between 2002 and 2014

Age category (months)	Year												
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
<b>0–23</b>	9	13	0	3	1	0	2	3	112	2	2	0	0
<b>24–29</b>	19	38	12	5	13	7	18	105	130	192	356	38	27
<b>30–35</b>	22	65	34	22	22	16	30	35	43	64	5	64	71
<b>36–47</b>	91	175	244	167	191	86	193	238	295	434	650	193	112
<b>48–59</b>	164	234	194	221	283	121	241	344	243	167	344	161	135
<b>60–71</b>	160	228	189	216	277	118	235	335	237	163	356	147	122
<b>72–83</b>	54	78	64	73	94	40	80	114	80	55	6	101	106
<b>84–95</b>	105	130	157	111	130	52	124	135	81	86	10	125	54
<b>96–107</b>	93	115	139	98	114	45	110	119	72	76	8	97	62
<b>108–119</b>	66	86	118	89	104	54	94	60	40	46	3	80	51
<b>120–131</b>	43	56	76	58	67	35	61	39	26	30	1	47	39
<b>132–143</b>	34	45	61	46	54	28	49	31	21	24	4	41	24
<b>144–155</b>	19	24	33	25	29	15	26	17	11	13	3	20	15
<b>156–167</b>	22	28	39	29	34	18	31	20	13	15	1	26	17
<b>168–179</b>	1	1	2	1	2	1	1	1	1	1	0	1	1
<b>180–191</b>	0	1	1	1	1	0	1	0	0	0	0	0	0
<b>192–203</b>	0	0	0	0	0	0	0	0	0	0	0.0	0.2	0.2
<b>&gt; 204</b>	7	9	12	9	11	6	10	6	4	5	0.5	8.2	5.3
<b>&gt; 155</b>	30	40	54	41	48	25	43	28	18	21	2.0	35.9	23.4
<b>24–47</b>								378	469	689	1,516	*	
<b>48–83</b>	379	540	447	511	654	279	556	793	560	385	1,477		
<b>84–108</b>	198	245	296	209	244	97	234	254	153	162	356		
<b>&gt; 108</b>	193	251	342	258	302	157	272	175	116	133	389		

\* Assumed population proportions stable during the period 2012–2014. Actual data for years 2002–2011.

**Table 6:** Total number of tested cattle by age categories in the fallen stock risk group in Croatia between 2002 and 2014

Age category (months)	Year													
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	
<b>0–23</b>	8	7	5	2	2	0	14	21	651	18	54	70	60	
<b>24–29</b>	2	5	12	2	47	18	110	523	824	1250	1770	536	600	
<b>30–35</b>	2	6	15	8	84	120	136	245	386	586	361	489	513	
<b>36–47</b>	7	37	74	83	380	568	779	703	1,108	1,680	2,063	978	866	
<b>48–59</b>	8	19	44	121	749	1,023	1,323	2,145	2,654	1,831	1,008	1,102	885	
<b>60–71</b>	6	16	37	103	641	876	1,132	1,836	2,272	1,567	865	761	937	
<b>72–83</b>	4	10	24	65	406	555	717	1,163	1,439	993	417	638	568	
<b>84–95</b>	3	8	25	67	303	520	543	414	281	288	313	506	526	
<b>96–107</b>	2	6	16	44	202	347	362	276	187	192	209	366	323	
<b>108–119</b>	3	6	17	46	186	341	368	141	113	115	145	286	284	
<b>120–131</b>	2	3	11	28	114	209	226	86	69	71	103	175	161	
<b>132–143</b>	1	2	8	20	81	149	161	62	50	50	54	102	157	
<b>144–155</b>	1	2	5	13	54	99	107	41	33	33	45	77	84	
<b>156–167</b>	1	1	4	11	43	79	86	33	26	27	35	55	76	
<b>168–179</b>	0	1	3	8	31	57	62	24	19	19	25	40	55	
<b>180–191</b>	0	1	2	5	20	37	40	15	12	12	16	26	35	
<b>192–203</b>	0	0	1	3	11	20	22	8	7	7	9	14	19	
<b>&gt; 204</b>	0	0	1	4	16	29	31	12	10	10	13	20	27	
<b>&gt; 155</b>	2	4	11	30	122	223	241	92	74	75	99.0	155	213	
<b>24–47</b>								1,472	2,318	3,516	8,176			
<b>48–83</b>	18	45	105	289	1,795	2,453	3,172	5,144	6,365	4,391	7,182			
<b>84–108</b>	5	14	41	111	505	867	905	690	468	480	2,242			
<b>&gt; 108</b>	8	17	52	137	557	1,020	1,103	421	339	345	2,140			

**Table 7:** Total and estimated (when not available by age category and expressed in decimal number) tested number of cattle by age categories in the clinical suspects risk group in Croatia between 2002 and 2014

Age category (months)	Year													
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	
0–23	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24–29	0	0	0	0	1	0	0	0	1.3	1	1	0	0	0
30–35	0	0	0	0	0	0	0	0	1.3	1	2	0	0	0
36–47	0	0	0	0	0	0	0	0	1.3	1	1	0	0	0
48–59	0	0	0	0	0	0	0	0	0.3	1	0	0	0	0
60–71	0	0	0	0	0	0	0	0	0.3	1	1	0	0	0
72–83	0	0	0	0	0	0	0	0	0.3	1	0	0	0	0
84–95	0	0	0	0	0	0	0	0	0	0.5	0	0	0	0
96–107	0	0	0	0	0	0	0	0	0	0.5	1	0	0	0
108–119	0	0	0	0	0	0	0	0	0.1	0	0	0	0	0
120–131	0	0	0	0	0	0	0	0	0.1	0	0	0	0	0
132–143	0	0	0	0	0	0	0	0	0.1	0	0	0	0	0
144–155	0	0	0	0	0	0	0	0	0.1	0	0	0	0	0
156–167	0	0	0	0	0	0	0	0	0.1	0	0	0	0	0
168–179	0	0	0	0	0	0	0	0	0.1	0	0	0	0	0
180–191	0	0	0	0	0	0	0	0	0.1	0	0	0	0	0
192–203	0	0	0	0	0	0	0	0	0.1	0	0	0	0	0
> 204	0	0	0	0	0	0	0	0	0.1	0	0	0	0	0
> 155*	0	0	0	0	0	0	0	0	0.6	0	0	0	0	0

\* Assumed that animals tested > 155 is equally likely by annual interval.

**Table 8:** Total number of cattle by age categories in Croatia between 2002 and 2014

Age category (months)	Year												
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
<b>0–23</b>	83,662	83,662	27,496	139,828	201,090	224,988	234,551	220,076	219,378	227,768	205,932	195,489	180,560
<b>24–29</b>	1,951	1,951	1,075	2,826	6,305	4,882	5,373	6,219	9,357	7,547	5,921	9,048	8,976
<b>30–35</b>	1,009	1,009	618	1,399	2,438	2,148	2,344	2,576	3,375	3,466	3,624	4,642	4,985
<b>36–47</b>	1,682	1,682	1,124	2,240	4,327	3,817	3,970	4,565	5,965	5,218	7,036	8,820	7,385
<b>48–59</b>	1,712	1,712	1,253	2,170	3,745	4,171	4,024	5,204	6,327	5,563	6,357	10,183	8,159
<b>60–71</b>	1,676	1,676	1,240	2,112	3,150	3,209	4,015	5,129	6,686	5,408	5,654	8,367	8,542
<b>72–83</b>	1,608	1,608	1,254	1,961	2,871	2,504	2,748	4,832	6,137	5,251	5,441	7,243	6,526
<b>84–95</b>	1,497	1,497	1,042	1,951	2,345	2,019	1,918	3,452	5,498	4,385	4,947	6,337	5,471
<b>96–107</b>	1,232	1,232	971	1,493	2,279	1,815	1,585	2,286	3,824	4,112	4,090	5,835	4,863
<b>108–119</b>	1,185	1,185	913	1,457	1,820	1,717	1,352	1,937	2,526	2,693	3,269	4,562	4,265
<b>120–131</b>	919	919	620	1,217	1,680	1,223	1,153	1,448	2,026	1,834	2,197	3,733	3,411
<b>132–143</b>	627	627	428	826	1,493	1,167	884	1,217	1,519	1,378	1,460	2,307	2,679
<b>144–155</b>	438	438	310	565	850	865	717	876	1,295	1,096	988	1,395	1,735
<b>156–167</b>	7,001	7,001	3,538	10,464	10,937	4,767	3,072	1,525	2,112	2,106	1,947	2,421	2,562
<b>168–179</b>	846	846	422	1,270	1,300	597	386	226	306	290	230	244	262
<b>180–191</b>	222	222	108	335	330	167	110	80	105	93	75	84	92
<b>192–203</b>	40	40	18	62	53	37	25	27	35	27	24	30	33
<b>&gt; 204</b>	63	63	30	97	81	62	53	52	64	41	170	365	389

**Table 9:** Total number of cattle by age categories in the healthy slaughtered risk group in Croatia between 2002 and 2014

Age category (months)	Year												
	2002*	2003*	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
<b>0–23</b>	80,179	80,179	25,654	134,703	192,136	213,304	219,782	201,084	196,740	205,770	182,519	169,292	158,303
<b>24–29</b>	1,611	1,611	857	2,364	5,475	3,986	4,122	4,754	7,408	6,005	4,848	7,653	7,591
<b>30–35</b>	798	798	492	1,103	1,918	1,453	1,423	1,557	2,201	2,420	2,166	2,107	2,318
<b>36–47</b>	1,365	1,365	880	1,849	3,382	2,666	2,477	3,001	4,080	3,774	3,949	3,789	3,196
<b>48–59</b>	1,435	1,435	1,049	1,820	3,020	3,028	2,679	3,607	4,570	4,131	3,721	4,415	3,606
<b>60–71</b>	1,379	1,379	976	1,781	2,639	2,491	2,763	3,714	4,906	4,212	3,385	3,727	3,765
<b>72–83</b>	1,349	1,349	1,013	1,685	2,471	2,015	1,969	3,549	4,658	4,167	3,372	3,216	2,943
<b>84–95</b>	1,304	1,304	922	1,685	2,027	1,658	1,468	2,706	4,396	3,625	3,147	2,855	2,467
<b>96–107</b>	1,112	1,112	891	1,332	1,991	1,509	1,225	1,823	3,155	3,456	2,623	2,687	2,236
<b>108–119</b>	1,060	1,060	827	1,293	1,626	1,450	1,072	1,620	2,141	2,317	2,158	2,112	1,965
<b>120–131</b>	825	825	567	1,082	1,501	1,060	919	1,215	1,724	1,617	1,408	1,755	1,604
<b>132–143</b>	565	565	388	741	1,356	1,032	729	1,013	1,305	1,217	978	1,093	1,251
<b>144–155</b>	395	395	286	504	790	746	606	726	1,111	958	651	653	817
<b>156–167</b>	6,853	6,853	3,469.8	10,236.1	10,756.8	4,612.3	2,931.5	1,381.8	1,936.7	2,000.9	1,428.4	1,287.6	1,352.7
<b>168–179</b>	756	756	382.5	1,128.5	1,185.9	508.5	323.2	152.3	213.5	220.6	157.5	142.0	149.1
<b>180–191</b>	164	164	82.9	244.6	257.0	110.2	70.0	33.0	46.3	47.8	34.1	30.8	32.3
<b>192–203</b>	8	8	4.1	12.2	12.8	5.5	3.5	1.7	2.3	2.4	1.7	1.5	1.6
<b>&gt; 204</b>	11	11	5.7	16.7	17.5	7.5	4.8	2.3	3.2	3.3	2.3	2.1	2.2
<b>&gt; 155</b>	7,792	7,792	3,945	11,638	12,230	5,244	3,333	1,571	2,202	2,275	1,624	1,464	1,538

\*2002 and 2003 assumed to be the same as the 2004–2005 average.

**Table 10:** Total and estimated (when not available by age category and expressed in decimal numbers) number of cattle by age categories in the emergency slaughter risk group (*ante mortem*) in Croatia between 2002 and 2014

Age category (months)	Year												
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
<b>0–23</b>	239	239	179	298	569	982	1,588	1,989	2,005	518	4,005	10,291	9,394
<b>24–29</b>	55	55	64	45	93	75	104	166	186	65	181	552	661
<b>30–35</b>	46	46	46	46	64	54	90	91	115	56	686	1,896	2,086
<b>36–47</b>	67	67	89	44	99	92	142	158	175	93	1,599	3,828	3,265
<b>48–59</b>	57	57	59	54	97	97	129	169	194	78	1,475	4,448	3,656
<b>60–71</b>	79	79	87	70	70	78	147	167	210	55	1,238	3,758	3,822
<b>72–83</b>	60	60	79	41	66	52	102	134	191	50	1,225	3,261	3,002
<b>84–95</b>	40	40	37	43	42	48	53	89	113	32	1,134	2,908	2,495
<b>96–107</b>	27	27	27	27	44	45	55	66	88	29	983	2,742	2,277
<b>108–119</b>	29	29	20	38	25	38	54	55	58	22	785	2,134	2,020
<b>120–131</b>	25	25	15	34	36	21	55	33	50	10	563	1,769	1,638
<b>132–143</b>	21	21	15	26	20	21	45	44	38	12	373	1,099	1,266
<b>144–155</b>	14	14	7	21	8	20	31	23	29	8	252	655	830
<b>156–167</b>	24	24	14	34	24	34	57	44	51	9	448	1,062	1,128
<b>168–179</b>	1	1	1	2	1	2	3	2	2	0	22	51	54
<b>180–191</b>	0	0	0	1	0	1	1	1	1	0	9	20	22
<b>192–203</b>	0	0	0.1	0.3	0.2	0.3	0.5	0.4	0.5	0.1	4.2	9.9	10.5
<b>&gt; 204</b>	8	8	4.6	10.7	7.5	10.9	18.2	14.1	16.2	2.7	142.3	337.1	357.8
<b>&gt; 155</b>	34	34	20	47	3	48	80	62	71	12	625	1,481	1,572

**Table 11:** Total number of cattle by age categories in the fallen stock risk group in Croatia between 2002 and 2014

Age category (months)	Year												
	2002*	2003*	2004*	2005*	2006*	2007*	2008	2009	2010	2011	2012	2013	2014
<b>0–23</b>	3,245	3,245	1,663	4,827	8,385	10,702	13,181	17,003	20,633	21,480	19,408	15,906	12,863
<b>24–29</b>	286	286	154	417	736	821	1,147	1,299	1,762	1,476	891	843	724
<b>30–35</b>	165	165	80	250	456	641	831	928	1,058	989	770	639	581
<b>36–47</b>	251	251	155	347	846	1,059	1,351	1,406	1,709	1,350	1,487	1,203	924
<b>48–59</b>	221	221	145	296	628	1,046	1,216	1,428	1,563	1,353	1,161	1,320	897
<b>60–71</b>	219	219	177	261	441	640	1,105	1,248	1,570	1,140	1,030	882	955
<b>72–83</b>	199	199	162	235	334	437	677	1,149	1,288	1,033	844	766	581
<b>84–95</b>	153	153	83	223	276	313	397	657	989	727	666	574	509
<b>96–107</b>	94	94	53	134	244	261	305	397	581	626	483	406	350
<b>108–119</b>	96	96	66	126	169	229	226	262	327	354	326	316	280
<b>120–131</b>	70	70	38	101	143	142	179	200	252	207	226	209	169
<b>132–143</b>	42	42	25	59	117	114	110	160	176	149	109	115	162
<b>144–155</b>	29	29	17	40	52	99	80	127	155	130	85	87	88
<b>156–167</b>	124	124	54	194	157	121	84	99	124	96	70	71	82
<b>168–179</b>	90	90	39	140	113	87	60	71	90	69	51	51	59
<b>180–191</b>	58	58	25	90	73	56	39	46	58	45	33	33	38
<b>192–203</b>	32	32	14	50	40	31	21	25	32	25	18	18	21
<b>&gt; 204</b>	45	45	20	70	56	43	30	36	45	35	25	26	29
<b>&gt; 155</b>	348	348	152	544	439	338	234	277	348	270	197	199	229

\*2002–2007 < 23 months estimated from the 2008–2011 average.

## Appendix B – Country-specific design prevalence

Table 12 shows the estimation of the ability of the current EU25 surveillance regime (no HS testing, ES and FS older than 48 months, all CS) at MS level and the standing cattle population in 2014 of each MS imported into the model (for all MS except Croatia, the standing cattle population was assumed to be stable from 2012). Note that the estimation of Croatia alone corresponds to the implementation of the EU25 surveillance regime. The estimation of the design prevalence in Croatia alone applying the current and the proposed BSE surveillance regime have been added as footnote to the table for comparison.

**Table 12:** Estimated yearly achievable design prevalence in the EU26, the EU25, each EU25 single MS and Croatia applying the current EU25 surveillance regime at a confidence level of 95% (considering Classical BSE, L-type Atypical BSE and H-type Atypical BSE). Estimates provided by C-TSEMM on the basis of 2014 data.

Member State	Estimated yearly design prevalence achieved in standing population	Total standing cattle population
<b>Malta (MT)</b>	1 per 134	5,355
<b>Latvia (LV)</b>	1 per 3,629	167,151
<b>Cyprus (CY)</b>	1 per 3,979	20,819
<b>Lithuania (LT)</b>	1 per 3,996	310,163
<b>Estonia (EE)</b>	1 per 7,604	106,660
<b>Slovakia (SK)</b>	1 per 7,816	175,290
<b>Slovenia (SI)</b>	1 per 8,344	163,552
<b>Greece (EL)</b>	1 per 9,776	138,191
<b>Luxembourg (LU)</b>	1 per 9,990	69,152
<b>Hungary (HU)</b>	1 per 10,362	293,804
<b>Croatia (HR*)</b>	1 per 15,045	144,631
<b>Czech Republic (CZ)</b>	1 per 17,301	643,855
<b>Portugal (PT)</b>	1 per 33,833	572,966
<b>Sweden (SE)</b>	1 per 48,587	513,994
<b>Italy (IT)</b>	1 per 51,767	1,524,144
<b>Finland (FI)</b>	1 per 52,169	317,354
<b>Poland (PL)</b>	1 per 53,582	2,094,696
<b>Austria (AT)</b>	1 per 58,157	812,040
<b>Denmark (DK)</b>	1 per 151,455	733,541
<b>Spain (ES)</b>	1 per 151,475	2,640,720
<b>Belgium (BE)</b>	1 per 154,018	947,361
<b>Netherlands (NL)</b>	1 per 210,976	1,484,804
<b>United Kingdom (UK)</b>	1 per 296,090	3,178,605
<b>Ireland (IE)</b>	1 per 327,911	2,202,000
<b>Germany (DE)</b>	1 per 457,701	2,668,388
<b>France (FR)</b>	1 per 1,200,442	7,324,896
<b>EU25</b>	1 per 3,769,555	29,110,501
<b>EU25 and HR</b>	1 per 3,789,838	29,255,132

\*The estimations of the design prevalence in Croatia alone applying the current and the proposed BSE surveillance regime are as follows: 1 per 24,439 and 1 per 15,840, respectively.

According to the results shown in Table 12, 18 MS do not achieve the minimum requirement with the current level of surveillance. In previous assessments, the number of HS animals required to be tested was presented. However, taking into account the current surveillance regime, that estimation is no longer relevant.

As an alternative hypothetical scenario, Table 13 shows the estimated the number of FS animals required to be tested, given no testing of HS and with the current testing of ES and CS, to achieve a design prevalence of 1 per 100,000 with a 95% confidence level; the actual number of FS tested, and the estimated standing cattle population for MS with less than 200,000 cattle population in 2014. In

the absence of HS testing, the number of FS to test presented in Table 13 is reliant on the estimated proportion of predicted BSE cases allocated to the FS stream as compared to the ES and CS streams, based on historical data for that MS or using a proxy in the absence of data for that MS.

The results show that MS with small cattle populations would have to test in the FS stream a large proportion of their entire adult cattle population to achieve the target. This is unfeasible given the fact that only a small proportion of cattle die on farm and are eligible for testing under this stream (average proportion of the standing population tested as FS in the EU in 2013: 2.3%).

**Table 13:** Estimated number of FS animals that would need to be tested, given no testing of healthy slaughtered and all other streams maintained (emergency slaughter and clinical suspects), to achieve a design prevalence of 1 per 100,000 with a 95% confidence level, actual number of fallen stock tested in 2014 and total standing cattle population in 2014 in Member States with less than 200,000 cattle population in 2014

Member State	Number of FS to be tested (% of total standing population)	Actual number FS tested (> 48 m)	Total standing cattle population
<b>Slovakia (SK)</b>	93,897 (53.6%)	7,335	175,290
<b>Latvia (LV)</b>	63,357 (37.9%)	2,236	167,151
<b>Slovenia (SI)</b>	61,151 (37.4%)	5,024	163,552
<b>Greece (EL)</b>	23,241 (16.8%)	2,239	138,191
<b>Croatia (HR)</b>	26,665 (18.4%)	4,137	144,631
<b>Estonia (EE)</b>	54,016 (50.6%)	4,104	106,660
<b>Luxembourg (LU)</b>	20,802 (30%)	2,048	69,152
<b>Cyprus (CY)</b>	20,546 (98.7%)	816	20,819
<b>Malta (MT)</b>	40,466 (755%)	48	5,355

Results in Table 12 and 13 must be interpreted carefully. Firstly, in line with the eradication of BSE across the EU, there has been a steady decline in the occurrence of cases in the different surveillance streams per birth cohort: this information is used by C-TSEMM to assign a proportion of prevalence by MS between CS and FS (CS/FS), and separately between ES (including AM) and HS (ES/HS). This method is no longer a good estimate of the relative prevalence between exit streams, as it is susceptible to assigning 100% of cases to one exit stream based on the occurrence of a single case.

Secondly, there are a number of MS with few or no BSE cases since 2002 and therefore a proxy is used to estimate MS prevalence, which results in the likely 'overestimation' of the actual MS prevalence. As such, results for those MS relate to the average results for the EU25, which may not be an accurate reflection of the situation in the individual MS. In addition, as above explained, C-TSEMM has been further modified, due to a lack of cases by surveillance stream, to estimate the relative proportion of cases that would be allocated to CS/FS and separately to ES/HS. An exponential curve is now fitted to MS historical stream case data to predict the current splits between those groups of streams. In the absence of further information, where the MS case data do not produce a valid fit, the EU25 exponential curve is used. The combination of these two key assumptions increases the immeasurable uncertainty associated with some MS results.