SCIENTIFIC OPINION

Scientific Opinion on a second update on the risk for human and animal health related to the revision of the BSE monitoring regime in some Member States[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2, 3]

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ABSTRACT

The Bovine Spongiform Encephalopathy (BSE) monitoring system implemented in the European Union (EU) has been reviewed in this opinion for twenty five Member States (MSs). For this revision, MSs were divided into three groups depending on the number of years during which they have implemented the EU monitoring regime, and/or on the similarities of their epidemiological situations. Key assumptions made include: (i) full past compliance (for at least 6 years) with EU regulatory requirements for the surveillance and control of cattle BSE, (ii) future continuity of the BSE controls, and (iii) perfect sensitivity of the rapid tests employed for BSE surveillance. Two methodologies were applied to these three groups of MSs using available EU BSE monitoring data. The first one looks at the age of detected cases in each calendar year, while the second looks at the number of cases in successive annual birth cohorts. For the first group of MSs, these methodologies were applied in order to estimate the number of Classical BSE cases that would be missed under three different scenarios: (i) an increase in the age for BSE testing in cattle; (ii) stopping testing in cattle born after a certain date, and (iii) stopping testing of healthy slaughter cattle after certain dates. In the second group of MSs, the epidemiological situation was at least equivalent to that of the first group, and thus the conclusion was that they can be considered together for any potential revision of the BSE monitoring system. For the third group of MSs, it was not possible to calculate detailed estimates as their particular epidemiological situation compromises the application of some of the methods used. Recommendations are made in order to overcome the limitations encountered, and to ensure fitness of the EU monitoring regime for the purposes for which it is currently used.

KEY WORDS

BSE, Atypical BSE, monitoring regime, European Union, revision

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SUMMARY

Following a request from the European Commission, the Panel on Biological Hazards (BIOHAZ) was asked to deliver a Scientific Opinion on a second update on the risk for human and animal health related to the revision of the BSE monitoring regime in some Member States (MSs).

The European Food Safety Authority (EFSA) published on 17 July 2008 an Opinion related to the revision of the BSE monitoring regime in some MSs[4], followed by another Opinion updating that one on 22 April 2009[5]. The first of the opinions analysed the data related to the BSE surveillance in the first 15 MSs to joint the European Union[6], while in the second one the analysis was extended to Cyprus and Slovenia (EU17).

For this Opinion, the BIOHAZ Panel was asked to analyse the data available for the EU17 group, but also to consider 8 further EU MSs[7] (EU8) that are now in a position to be eligible for a revision of their annual BSE monitoring programme, as they have implemented EU legislation on BSE for at least 6 years.

The same general considerations and methodology applied in the previous EFSA Opinions[8] were used in this document. Moreover, all these Opinions should be read together in order to have a description of the methodology used, and to fully appreciate the implications of setting different age limits for BSE monitoring in cattle. Two methods were used in this Opinion: (i) the first of them looks at the age of detected cases in each calendar year, (ii) while the other looks at the number of cases in successive annual birth cohorts. For the latter method, two scenarios are simulated: (i) the first scenario considers a constant incidence of BSE starting from the 2004 birth cohort (this can be understood as the “worst case” scenario); (ii) the second scenario considers a continue decay rate of the BSE epidemic in birth cohorts since 2004 in the EU17, based on the decline of the cohort incidence in previous cohorts (this can be understood as the “more realistic” scenario).

It has to be noted that it is assumed that all 25 EU MSs considered in this Opinion have implemented for at least six years a BSE surveillance system and control measures, as set out in the Regulation (EC) 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. If this assumption cannot be verified, the conclusions of this opinion will not apply to the respective MS. It is also assumed that all 25 EU MSs will continue to implement currently applied measures regulated through Regulation (EC) 999/2001. Furthermore, it is assumed that the rapid tests employed for BSE surveillance in the EU have a sensitivity of 100%**.**

The BIOHAZ Panel confirmed that the updated data on BSE surveillance from 2001 to 2009 shows for both the joint EU17 and each of the individual EU17 countries in which sufficient case data are available[9], that the BSE epidemic has been declining and is converging to the sensitivity limit of a surveillance system that uses currently approved rapid BSE tests.

4 EFSA (European Food Safety Authority), 2008a. Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States. The EFSA Journal, 762, 1-47

5 EFSA (European Food Safety Authority), 2009. Updated risk for human and animal health related to the revision of the BSE monitoring regime in some Member States. The EFSA Journal, 1059, 1-40.

6 Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom.

7 Poland, Czech Republic, Slovakia, Hungary, Latvia, Lithuania, Estonia, Malta.

8 EFSA Panel on Biological Hazards (BIOHAZ), 2008a. Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States. The EFSA Journal, 762, 1 – 47; EFSA Panel on Biological Hazards (BIOHAZ), 2008b. Further consideration of age-related parameters on the Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States. The EFSA Journal, 763, 1-8; EFSA Panel on Biological Hazards (BIOHAZ), 2009. Updated risk for human and animal health related to the revision of the BSE monitoring regime in some Member States. The EFSA Journal, 1059, 1-40.

9 A minimum number of 50 cases was considered necessary to obtain statistically reliable estimates. In countries with less than 50 cases statistical methods are not able to reliably estimate the trend but the number of cases remains very low.

For the EU17 group, different situations (changes in BSE monitoring) were assessed as proposed by the EC, employing the same methodology as in previous BIOHAZ Panel Opinions.

Three situations were assessed under a first scenario which includes the assumption of a constant prevalence of Classical BSE for birth cohorts since 2004 (which can be considered as the **"worst case" scenario**):

(i) In a first situation where the age limit for Classical BSE testing would be raised above 48 months in healthy slaughtered and at risk cattle, the results showed that in healthy slaughtered animals aged respectively up to 60, 72, 84 or 96 months, less than two, four, five or six cases per each of the respective age category can be expected to be missed annually. In at risk animals aged respectively 60, 72, 84 or 96 months, less than three, six, eight and ten cases per each of the respective age category can be expected to be missed annually;

(ii) Under the situation where BSE testing would be stopped for bovine animals born respectively after 31 December 2003, 2004, 2005 or 2006, the results showed that less than six Classical BSE cases per birth cohort can be expected to be missed in the healthy slaughtered cattle population, and less than twelve Classical BSE cases per birth cohort can be expected to be missed in the at risk cattle population;

(iii) Under the third situation where testing for healthy slaughtered animals would stop on 1 January 2011, 2012 or 2013, less than seven, six and six Classical BSE cases would be missed for each of the respective years. After this date and with the hypothesis that Classical BSE incidence will remain constant in the EU17, less than six Classical BSE cases would be missed for each calendar year.

The same three situations where assessed under a second scenario, this time under the assumption of a declining Classical BSE trend for birth cohorts since 2004 (which can be considered as the "**more realistic" scenario**):

(i) In a first situation where the age limit for BSE testing would be raised above 48 months in healthy slaughtered and at risk cattle, the results showed that in healthy slaughtered animals aged respectively 60, 72, 84 or 96 months, less than one, one, two or two cases per each of the respective age category, can be expected to be missed in 2011. After this date and with the hypothesis that Classical BSE continue to decline, a yearly decline in the number of cases should be observed. In at risk animals aged respectively 60, 72, 84 or 96 months, less than one, two, three and four cases per each of the respective age category can be expected to be missed in 2011. After this date and with the hypothesis that Classical BSE continue to decline, a yearly decline in the number of cases should be observed;

(ii) Under a second situation where BSE testing would be stopped for bovine animals born respectively after 31 December 2003, 2004, 2005 or 2006, less than two Classical BSE cases per birth cohort can be expected to be missed in EU17 healthy slaughtered cattle population and less than three Classical BSE cases per birth cohort can be expected to be missed in EU17 at risk cattle population;

(iii) Under a third situation where testing for healthy slaughtered animals would stop on 1 January 2011, 2012 or 2013 less than three, two and one Classical BSE cases would be missed for each of the respective years. After this date and with the hypothesis that BSE continue to decline, less than one Classical BSE case would be missed for each calendar year.

It is pointed out that these figures are estimated with the model employed in this opinion and previously related documents. The likelihood of detecting new cases in specific age groups is very low, but there remains a small probability of detecting one or more cases in some of these age groups.

Regarding the MSs in the EU8 group, it was concluded that the Classical BSE epidemiological situation is different between a group of 5 MSs (Estonia, Hungary, Latvia, Lithuania and Malta) and another group of 3 MSs where BSE has been detected (Czech Republic, Poland and Slovakia) since the full implementation of the EU surveillance system (1 May 2004). In the group of 5 MSs were no BSE cases have been detected since the full implementation of the EU surveillance system, the Classical BSE epidemiological situation should be considered to be at least equivalent to that of the EU17. Therefore, a similar testing regime could be applied to this group of 22 EU MSs. On the other hand, the trend of the Classical BSE epidemic in the group of 3 MSs shows two waves in the Classical BSE incidence per birth cohort and in the average age of the Classical BSE cases detected. This second wave pattern compromises the establishment of clear similarities between the trend of the Classical BSE epidemic in the EU17 and in this group of 3 MSs. For this group of 3 MSs it was concluded that at the moment it would not be informative to estimate the number of undetected Classical BSE cases, should the testing age be changed in this group.

The BIOHAZ Panel recommended to comprehensively reassess the sensitivity of the present or intended new EU surveillance system for detecting the prevalence of Atypical BSE, re-emergence of Classical BSE, or the emergence of a novel TSE in cattle. It was also recommended to gather results from further test years (e.g. 2010 and 2011) in the group of 3 MSs from active surveillance in animals aged 30 months and over (i.e. healthy slaughtered group), and 24 months and over (i.e. at risk group) in order to confirm a declining Classical BSE trend. Finally, if BSE testing of the healthy slaughtered cattle would be reduced or stopped, it is recommended to ensure that attention is paid to the possible entrance of at risk animals in the non tested population.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Extensive epidemiological data on BSE have been collected through EU BSE surveillance over the last 9 years. This monitoring has provided a reliable insight into the prevalence and evolution of BSE in the Member States and has demonstrated that the control measures in place have been effective since the prevalence of the disease is clearly declining. Since 2001 more than 86 million tests have been carried out in the European Union[10].

According to the TSE Regulation (Regulation (EC) N° 999/2001), a Member State which can demonstrate the improvement of its epidemiological situation may apply for a revision of its national BSE monitoring programme for both at risk (e.g. emergency slaughtered cattle, cattle with observations at ante mortem inspection and fallen stock) and healthy slaughtered cattle. The applying Member State shall demonstrate that there is a clearly declining or consistently low BSE prevalence on its territory, that it has implemented and enforced for at least 6 years a full BSE testing scheme and a total feed ban for farmed animals. The stringent eligibility criteria initially limited a possible revision of their BSE monitoring programmes to the "old" 15 Member States.

Up to now, 17 Member States have been authorised to do so by increasing the age limit for testing from 30 months to 48 months for healthy slaughtered bovine animals and from 24 months to 48 months for at risk bovine animals. This authorisation has been given following a favourable assessment of the application dossiers submitted by the concerned Member States and subsequent EFSA opinions[11] concluding that less than one BSE case would be missed annually in these countries if the age limit for BSE testing was increased to 48 months.

The 17 Member States are listed in the Annex to Decision 2009/719/EC, authorising certain Member States to revise their annual BSE monitoring programmes[12]. This list includes all the Member States which were members of the EU before 1 May 2004 (EU15), Slovenia and Cyprus.

Since then, the BSE epidemiological situation across the EU has continued to improve and some Member States who joined the EU after 1 May 2004 are now in a position to be eligible for a revision of their annual BSE monitoring programme.

In this context, it seems appropriate to reassess the situation in the 17 Member States which are already authorised to apply a revised programme and to assess the data available in the other Member States which have now implemented EU legislation on BSE for at least 6 years (EU8 Member States[13]).

10 Detailed epidemiological information on BSE monitoring can be found in TSE annual reports released by the Commission: (http://ec.europa.eu/food/food/biosafety/tse_bse/monitoring_annual_reports_en.htm)

11 EFSA (European Food Safety Authority), 2008. Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States. The EFSA Journal. 762, 1–47
Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission on the updated risk for human and animal health related to the revision of the BSE monitoring regime in some Member States. The EFSA Journal (2009) 1059, 1-40

12 OJ L 256, 29.9.2009, p. 35.

13 Poland, Czech Republic, Slovakia, Hungary, Latvia, Lithuania, Estonia, Malta.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA is requested to provide an update of its previous opinions on the risk for human and animal health related to the revision of the BSE monitoring regime in some Member States. More specifically, EFSA is requested:

- to reassess collectively the data of the 17 Member States which are already authorised to apply a revised BSE programme and to consider different scenarios raising the age limit above 48 months (with 12 months intervals) for BSE testing of healthy slaughtered and at risk cattle. EFSA is also asked to evaluate the options where the BSE testing would be stopped for bovine animals born respectively after 31 December 2003, 2004, 2005 or 2006 in these countries;

- as regards the EU8 Member States[14], to assess their data individually or grouped for countries with a similar epidemiological profile (e.g. countries with no BSE cases detected or very small bovine population). Different scenarios for raising the age limit above 30 months (with 12 months intervals) for BSE testing of healthy slaughtered cattle and above 24 months for at risk cattle should be assessed. EFSA is also asked to evaluate the option where BSE testing would be stopped for bovine animals born after 30 April 2006 in these countries. It has to be assumed that the Member States concerned by the assessment are in a position to comply with the legal criteria for having their BSE monitoring systems revised.

Further consideration of the Terms of Reference

After receiving the mandate and following discussions with the European Commission, EFSA was further requested to evaluate the risk for human and animal health related to completely stop testing healthy slaughtered animals but maintaining testing of the at risk animal group after a certain date. This date should start as from first of January 2011 and, where possible, providing results at twelve months intervals.

14 Poland, Czech Republic, Slovakia, Hungary, Latvia, Lithuania, Estonia, Malta.

ASSESSMENT

1. Introduction

This Scientific Opinion follows three previous ones delivered on a similar subject (EFSA, 2008a, 2008b and 2009). The same general considerations and methodology applied in the first Opinion of the series, the EFSA scientific Opinion on the "Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States" (EFSA, 2008a) are used in this assessment. Hence, this first opinion has to be read as part of the current one in order to both have a thorough description of the methodology used and to fully appreciate the implications of setting different age limits for BSE monitoring in cattle.

It has to be highlighted that in the current mandate from the European Commission (EC) it is also requested to evaluate options where BSE testing would be stopped for animals born after certain dates (see Terms of Reference). For this, the methodology applied is similar to the one used in the Scientific Opinion on "Further consideration of age-related parameters on the risk for human and animal health related to the revision of the BSE monitoring regime in some Member States" (EFSA, 2008b).

For the purposes of this Scientific Opinion, the following nomenclature has to be taken into account:

- By EU17 it is understood the group of EU Member States (MSs) composed by: Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Slovenia, Spain, Sweden and United Kingdom.

  These are the EU MSs that have been authorised to increase the age limit for testing from 30 months to 48 months for healthy slaughtered bovine animals and from 24 months to 48 months for at risk bovine animals. In particular, on 1st January 2009 fifteen EU MSs[15] were authorised to apply a revised BSE monitoring programme with an increased age limit for BSE testing (Commission Decision 2008/908/EC). Slovenia was authorised to apply such a programme on 29 September 2009 and effectively applies it effectively since 1 December 2009 (Decision 2009/719/EC). Cyprus was authorised to apply a revised programme on February 2010 via Decision 2010/66/EC. Nevertheless, testing age in some of these MSs varied after the new legislation entered into force as some of them implemented a younger age testing regime for some target groups (see Table 1 for details on BSE testing ages for bovine animals in the different EU MSs).

- By EU8 it is understood the group of EU MSs composed by: Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland and Slovakia. These are the EU MSs for which the assessment of their individual or grouped situation is requested, and for which it has to be assumed that they have implemented the requirements of Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies for at least 6 years. Further in the Opinion, a differentiation is made between those EU MSs of the EU8 group where BSE has not been detected (called EU5, which includes Estonia, Hungary, Latvia, Lithuania and Malta) and where BSE has been detected (called EU3, which includes Czech Republic, Poland and Slovakia).

- By BSE, it is understood all types of TSEs known to naturally occur in cattle unless otherwise differentiated (i.e. Classical BSE (or C-BSE) and Atypical BSE (both types: L-BSE and H-BSE).

15 Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom.

Table 1: BSE testing ages for bovine animals during 2009 in the different 27 EU MSs. Source: European Commission.

EU MS	Target group					
	Active surveillance				Passive surveillance	BSE eradication measures
	Healthy slaughtered	At risk animals			BSE suspects	
		Emergency slaughter	Fallen stock	Clinical signs at *ante-mortem* inspection		
Austria	> 48	> 48	> 24	> 48	NAL[1]	NAL
Belgium	> 48	> 48	> 48	> 48	NAL	> 24
Bulgaria	> 30	> 24	> 24	> 24	NAL	NAL
Cyprus	> 30	> 24	> 24	> 24	NAL	NAL
Czech Republic	> 30	> 24	> 24	> 24	NAL	NAL
Denmark	> 48	> 48	> 48	> 48	NAL	> 24
Estonia	> 30	> 24	> 24	> 24	NAL	NAL
Finland	> 48	> 48	> 48	> 48	NAL	NAL
France	> 48	> 24	> 24	> 24	NAL	> 24
Germany	> 48	> 48	> 48	> 48	NAL	NAL
Greece	> 48	> 48	> 48	> 48	NAL	NAL
Hungary	> 30	> 24	> 24	> 24	NAL	NAL
Ireland	> 48	> 48	> 48	> 48	NAL	> 48
Italy	> 48	> 48	> 48	> 48	NAL	NAL
Latvia	> 30	> 24	> 24	> 24	NAL	NAL
Lithuania	> 30	> 24	> 24	> 24	NAL	NAL
Luxembourg	> 48	> 48	> 24	> 48	NAL	> 24
Malta	> 30	> 24	> 24	> 24	NAL	NAL
Netherlands	> 48	> 48	> 48	> 48	NAL	NAL
Poland	> 30	> 24	> 24	> 24	NAL	NAL
Portugal	> 48	> 36	> 36	> 36	NAL	> 24
Romania	> 30	> 24	> 24	> 24	NAL	NAL
Slovakia	> 30	> 24	> 24	> 24	NAL	NAL
Slovenia	> 48[2]	> 48[2]	> 48[2]	> 48[2]	NAL	NAL
Spain	> 48	> 36	> 36	> 36	NAL	NAL
Sweden	> 48	> 48	> 48	> 48	NAL	NAL
United Kingdom	> 48	> 48	> 48	> 48	NAL	NAL

[1]NAL=No age limit
[2]Since 1st December 2009

It has to be noted that the main general conclusions of the first Opinion on the subject (EFSA, 2008a) do remain valid in the context of the current one:

- The purpose of the TSE surveillance in cattle in the EU is mainly to monitor the BSE epidemic.
- Prevention of human exposure to BSE Agent mainly relies on SRM removal.
- Prevention of animal exposure to and propagation of TSE Agents mainly relies on the Feed Ban.

2. Data, assumptions and assessment methodology

The following data sources have been employed for the analysis presented in this Opinion:

- Data on BSE cases detected in the EU employed in the assessments presented herewith was received from the European Commission (EC) on 18 June 2010. For the MSs of the EU17 group, and in line with the analysis performed in previous Opinions, data are considered from 1st January 2001. For the MSs of the EU8 group, data are considered since 1st January 2004[16].

- Data on the number of rapid TSE tests performed in the EU in the frame of BSE monitoring have been received from the European Commission (EC) on 28 October 2010.

- Data on the adult bovine population (over 24 months of age) in the MSs considered in this Opinion were retrieved from EUROSTAT[17] on 31 August 2010.

Small differences were found between data presented in this Opinion and that of related previous Opinions (EFSA, 2008a and 2009). This is due to:

- New cases reported beyond the time span of the previous Opinions.

- Corrections made by the MSs on the reported BSE cases done when verifying results previously reported.

- Updates in the EUROSTAT database used to retrieve number of cattle over 24 months of age in the EU MSs.

Those differences are indicated for each MS in each table where data is presented (see Appendix A for individual MS data). However, these differences have a negligible impact on the assessment.

As per previous EFSA Opinions dealing with similar requests ((EFSA, 2008a, 2008b and 2009), three are key assumptions made for each EU MS considered in this Opinion in order to render the analysis and the conclusions valid:

- It is assumed that all 25 EU MSs considered for this mandate have implemented a BSE surveillance system and control measures as set out in the Regulation (EC) 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies for at least six years. If this assumption cannot be verified, the conclusions of this opinion will not apply to the respective MS.

- It is assumed that all 25 EU MSs considered for this mandate will continue to implement currently applied measures regulated through Regulation (EC) 999/2001 aimed at controlling and reducing BSE in the EU MSs.

- It is assumed that the rapid tests applied in the frame of the Regulation (EC) 999/2001 for BSE surveillance have a sensitivity of 100%**.**

For the purpose of this assessment, Methods 1 and 3 employed in previous related Scientific Opinions, as described under section 2.1. of the Opinion on the “Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States” (EFSA, 2008a) were used to analyse the trend of the BSE infection in the EU17 and the EU8. In brief:

- **Method 1** looks at the age of detected cases in each calendar year (Saegerman et al., 2005), where an increasing mean age of detection indicates a declining epidemic. The method has been applied

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16 When applicable, number of BSE cases diagnosed before 1st May 2004 in the MSs of the EU8 group are addressed in the relevant tables.

17 EUROSTAT data available at: http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home – Data tree: Statistics> Data Navigation Tree> Database by themes> Agriculture, forestry and fisheries> Food: From farm to fork statistics (food) > inputs to the food chain (food_in)> Livestock (1000 heads) (food_in_pagr2)

in several studies published in peer-reviewed scientific journals (Saegerman et al., 2005 and 2006; Ducrot et al., 2008).

- **Method 3** looks at the number of cases in successive annual birth cohorts. This method is able to provide an assessment of the future trend of the BSE infection (see Appendix B for further details).

  Two different scenarios are considered for the purpose of the calculations performed under method 3:

  - **Scenario I:** assumes a constant incidence of BSE starting from the 2004 birth cohort for the EU17 and for the EU8. In practice the yearly estimate of the number of BSE cases per age group is the same from 2008 onwards for EU 17. This can be considered a **"worst case"** scenario for EU17. In the EU8, such scenario can not be applied because the trend of the BSE epidemic, as discussed later on in this Opinion remains unsure.

  - **Scenario II:** can be considered **"more realistic"** as it is derived from the observed data and assumes a continue decay rate of the BSE epidemic in EU 17 for cohorts since 2004 based on the decline of the cohort incidence in previous cohorts calculated by log-linear regression. In the EU8, such scenario can not be applied because the trend of the BSE epidemic in these MSs, as discussed later on in this Opinion, remains unsure.

As per the previous Opinions a further method considered was the application of Age-Period-Cohort models (**Method 2**, as called in the previous Opinions). However and as per those previous Opinions, this method was not applied due to lack of data and the short time-frame.

In line with the terms of reference of the mandate received from the EC, the analysis performed following the methodologies described above are applied to the EU17 and to the EU8 separately. Results are presented and discussed in the sections that follow.

3. Assessment of the BSE monitoring regime in the EU1

3.1. Analysis of the BSE monitoring programme per category and age during the period 2001 to 2009 in EU17

Detailed epidemiological information on BSE monitoring can be found in the TSE annual reports released by the EC, available at:

http://ec.europa.eu/food/food/biosafety/tse_bse/monitoring_annual_reports_en.htm

Table 2: Extensive epidemiological data on BSE has been collected via the BSE Active and Passive Surveillance over the last 9 years in the EU17, and has demonstrated that the control measures in place against BSE have been efficient and that the prevalence of the disease is clearly declining or remained consistently at a low level (see Table 2). Prevalence (number of BSE cases per ten thousand of animals tested) of BSE in the EU17 for passive and active surveillance from 2001 to 2009.

	Year of testing								
	2001	2002	2003	2004	2005	2006	2007	2008	2009
Active Surveillance	1.22[1]	1.38	1.01	0.65	0.50	0.31	0.17	0.13	0.09
Passive Surveillance	0.303	0.250	0.116	0.057	0.026	0.016	0.009	0.005	0.003

[1]This result is different to that reported in the previous EFSA Opinion (EFSA, 2009) as in this table tests carried out by Cyprus and Slovenia in 2001 and 2002 are taken into account

From 2001 until the end of 2009 more than 80 million of tests have been carried out in the framework of BSE Active Surveillance in the EU17. Of these 5,181 animals were positive. These included 1,248 out of 69,620,780 million healthy slaughtered cattle tested (18 per million healthy cattle tested), and 3,933 out of 11,038,532 at risk cattle (356.2 per million), while testing schemes differed between MSs during this period of time. For example: Germany tested younger healthy stock than most MS. In the framework of BSE Passive Surveillance in EU17 during the period 2001 – 2009 a total 21,238 bovine animals were tested and 2,410 were positive.

In 2009 and based on the data made available by the Commission for this Opinion, no BSE cases have been reported in EU17 in the framework of BSE Surveillance in: Austria, Belgium, Cyprus, Finland, Greece, Luxemburg, The Netherlands, Slovenia and Sweden. Moreover, also in 2008 no cases have been reported in these same countries, except 1 case in The Netherlands.

With respect to the number of BSE cases detected through the BSE Active and Passive Surveillance in EU17 since 2001 the data per target group are reported in Table 3.

Table 3: Number of BSE cases detected through the BSE Active and Passive Surveillance and Eradication measures in EU17 during the period 2001 – 2009 per target group.

Target Group	**No of detected BSE cases per year**									
Active Surveillance	2001	2002	2003	2004	2005	2006	2007	2008	2009	**Total**
Healthy slaughtered	277	293	264	162	97	73	34	25	23	1248
At risk animals										
Emergency slaughter	323	508	317	169	123	31	7	6	3	1487
Fallen stock	400	610	407	309	218	163	96	78	31	2312
Presenting Clinical signs at ante mortem inspection	36	24	32	11	16	9	4	2	0	134
Total Active Surveillance	1036	1435	1020	651	454	276	141	111	57	5181
Passive Surveillance Suspects subject to lab	1121	674	304	173	75	37	16	8	2	2410
Eradication Measures	9	10	3	5	13	1	1	3	0	45
Grand Total	2166	2119	1327	829	542	314	158	122	59	7636

The total number of BSE cases detected through BSE Surveillance (both Active and Passive) and the culling of animals in the framework of BSE eradication measures in EU17 during the period 2001 – 2009 per birth cohort and year of detection is reported in Table 4.

Table 4: Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the culling of animals in the framework of BSE eradication measures in EU17 during the period 2001 – 2009 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	**Grand Total**
1980		1								1
1981	1									1
1983			1							1
1984	1	3				1				5
1985	1	2	2		1					6
1986	13	10	3	3	1					30
1987	21	30	9	6	6	1		1		74
1988	20	28	21	6		1		2		78
1989	25	37	21	17	5	5	1	1	1	113
1990	28	54	22	21	9	7	1	3	1	146
1991	66	78	47	27	22	8	1	1		250
1992	120	156	85	55	37	15	10	1	2	481
1993	330	245	179	94	56	27	17	9	6	963
1994	577	458	218	122	94	48	26	18	5	1566
1995	668	617	303	136	67	37	23	10	12	1873
1996	247	273	163	80	39	25	10	23	5	865
1997	43	91	153	86	35	23	6	14	4	455
1998	4	30	73	97	45	32	17	8	5	311
1999	1	6	25	51	60	37	16	9	5	210
2000			1	19	49	36	21	8	6	140
2001					8	8	2	4	1	23
2002					3	1	3	4	2	13
2003								4	3	7
2004									1	1
Grand Total	2166	2119	1326	820	537	312	154	120	59	7613[1]

[1]Please note the total number of BSE cases is lower than in Table 3 since the year of birth of 23 BSE cases is not known, which are not considered under this table.

The number of BSE cases detected through the BSE Surveillance (Active and Passive) and the culling of animals in the framework of BSE eradication measures during the period 2001 – 2009 per MS of the EU17 group, birth cohort and year of detection is provided in Appendix A.

When interpreting the significance of these data the following points should also be considered:

- The likely point in the incubation period at which PrP^{res} is detectable with the rapid BSE tests depends on the infective dose (Arnold *et al.*, 2007). While the range of doses of exposure of field cases of BSE is not known, an oral attack rate study has shown that the mean incubation period arising from doses in the range 0.1-1g fits with that estimated for field cases (Wells et al., 2007). For a 1g dose, it was found that PrP^{res} was detectable at 97% of the incubation period (Arnold *et al.*, 2007). This degree of under-detection has to be taken into account when estimating infection prevalence from surveillance data.

- A constant decline (on average about 35% per year) in the total number of cases (coming from both BSE Active and Passive Surveillance) has been recorded and is likely due to a reduction in exposure to the BSE agent in EU 17: from 2,166 cases in 2001 to 59 cases in 2009, and the number of cattle infected with BSE is likely to continue to decline.
- Out of this, 44 cases were related to animals born after the start of the total feed ban in 2001.
- The Geographical BSE Risk (SSC, 2002) as well as the stage of the BSE epidemic can vary considerably between MSs.

3.2. Assessment based on an increase of testing age at 12 months intervals.

3.2.1. Calculations based on Method 1

The number of BSE cases, the BSE incidence per million cattle over 24 months[18] of age and the average age of cases per year of detection in the EU17 MS, considering both BSE Active and Passive Surveillance and the animals culled in the framework of BSE eradication measures, are shown in Table 5.

Table 5: Number of BSE cases, incidence per million cattle over 24 months and average age in years of cases during the period 2001 – 2009 per year of detection in the EU17 MS (the data consider both BSE Active and Passive Surveillance and the culling of animals in the framework of BSE eradication measures).

Member State		Year of testing									Total
		2001	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	
Austria	N° cases	1	0	0	0	2	2	1	0	0	6
	Incidence	1.0	0.0	0.0	0.0	2.1	2.1	1.1	0.0	0.0	
	Average age	5	NA[1]	NA	NA	12	9.5	11	NA		
Belgium	N° cases	46	38	15	11	3	1	0	0	0	114
	Incidence	30.3	26.1	10.6	7.8	2.2	0.7	0.0	0.0	0.0	
	Average age	6	6.7	7.4	7.5	10	12	NA	NA		
Cyprus	N° cases	0	0	0	0	0	0	0	0	0	0
	Incidence	0	0	0	0	0	0	0	0	0	
	Average age	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Denmark	N° cases	6	3	2	1	1	0	0	0	1	14
	Incidence	6.7	3.5	2.4	1.3	1.3	0	0	0	1.3	
	Average age	5	5.3	6.5	14	9	NA	NA	NA	14	
Finland	N° cases	1	0	0	0	0	0	0	0	0	1
	Incidence	2.4	0	0	0	0	0	0	0	0	
	Average age	6	NA	NA	NA	NA	NA	NA	NA	NA	
France	N° cases	277	240	111	51	32	8	7	8	10	744
	Incidence	24.9	21.8	10.4	4.9	3.1	0.8	0.7	0.8	0.9	
	Average age	6.4	7.2	8.1	8.8	9.4	9.3	10.7	12.4	13.6	
Germany	N° cases	125	106	54	65	32	16	4	2	2	406
	Incidence	19.4	17	8.8	10.8	5.5	2.8	0.7	0.3	0.3	
	Average age	5.5	6.4	5.9	6.2	6.2	7	7.8	8	11	

18 Data on adult cattle population of the EU17 retrieved from EUROSTAT.

Member State		Year of testing									Total
		2001	2002	2003	2004	2005	2006	2007	2008	2009	
Greece	N° cases	1	0	0	0	0	0	0	0	0	1
	Incidence	3	0	0	0	0	0	0	0	0	
	Average age	5	NA	NA	NA	NA	NA	NA	NA	NA	
Ireland	N° cases	242	334	183	126	77	38	29	22	9	1060
	Incidence	79.5	111.1	61.2	41.4	25.1	12.6	9.8	7.5	3.0	
	Average age	6.6	7.8	8.7	9.8	10.1	11.1	11.5	11.5	11.1	
Italy	N° cases	50	36	31	8	8	7	2	1	2	145
	Incidence	15.5	11.9	10.4	2.8	2.7	2.5	0.7	0.4	0.7	
	Average age	5.7	6.5	7.8	7.3	8.1	8.3	12.5	13	12	
Luxemburg	N° cases	0	1	0	0	1	0	0	0	0	2
	Incidence	0	10.3	0	0	10.8	0	0	0*	0	
	Average age	NA[2]	6	NA	NA	4	NA	NA	NA	NA	
Netherlands	N° cases	20	24	18	6	3	2	2	1	0	76
	Incidence	11.2	13.5	10.1	3.5	1.8	1.2	1.2	0.6	0	
	Average age	6.3	6.2	6.7	8.3	4.7	8.5	7.5	8	NA	
Portugal	N° cases	110	86	133	92	53	32	13	21	6	546
	Incidence	142.2	110.6	170.1	113.2	64.4	39.2	15.7	25.3	7.3	
	Average age	6.7	7.3	7.7	8.5	9.7	10.9	11.4	12.6	13.3	
Slovenia	N° cases	1	1	1	2	1	1	1	0	0	8
	Incidence	4.7	4.6	4.8	9.9	5.1	5.1	4.9	0	0	
	Average age	5	7	4	5	5	6	7	NA	NA	
Spain	N° cases	83	127	167	137	103	77	34	25	18	771
	Incidence	24.1	35.8	46.6	38.2	29.7	24.1	10.1	7.7	5.5	
	Average age	6.3	6.5	6.8	6.8	6.7	7.5	9.0	10.2	12.4	
Sweden	N° cases	0	0	0	0	0	1	0	0	0	1
	Incidence	0	0	0	0	0	1.5	0	0	0	
	Average age	NA	NA	NA	NA	NA	12	NA	NA	NA	
United Kingdom	N° cases	1,203	1,123	612	330	226	129	65	42	11	3741
	Incidence	243.7	228.3	125.1	67.1	46.1	26.5	13.6	9	2.4	
	Average age	7.6	8.9	9.6	10.7	11.2	11.8	11.9	12.6	12.0	
EU17	N° cases	2,166	2,119	1,327	829	542	314	158	122	59	7636
	Incidence	54.2	53.9	34.2	21.7	14.3	8.4	4.2	3.3	1.6	
	Average age	7	8.1	8.6	9.1	9.5	10.1	10.9	11.8	12.4	

[1]NA=Non Applicable

The trend of the average age of BSE cases per year of detection in the EU17, considering both BSE Active and Passive Surveillance and the culling of animals in the framework of BSE eradication measures, is shown in Figure 1.

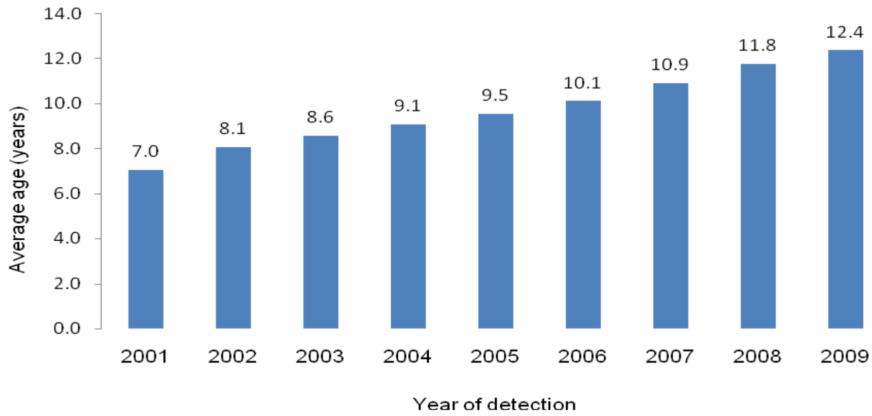

Figure 1: Average age (in years) of BSE cases per year of detection in the EU17, considering both BSE Active and Passive Surveillance and the culling of animals in the framework of BSE eradication measures.

3.2.1.1. Conclusion from calculations based on Method 1

- From the analysis of the average age per year we can conclude that in each country within the EU17 where a sufficient number[19] of cases have been found since 2001, there has been an increasing trend in the average age of the detected BSE cases per test year during the last 9 years and at present it is equal to or higher than 11 years in each of these countries.

- The shape of the age distribution of BSE cases depends on two aspects: the age distribution of the cattle population and the level of BSE transmission in the past (de Koeijer *et al.*, 2002).

- Assuming that the age distribution of cattle in the countries has not changed substantially, this indicates that the transmission of BSE has decreased as a consequence of the implementation of the control measures.

- Consequently, the updated data on BSE surveillance from 2001 to 2009 confirm for both the joint EU17 and each of the individual EU17 countries in which sufficient case data are available[13] that the BSE epidemic has been declining and is converging to the sensitivity limit of a surveillance system that uses currently approved rapid BSE tests.

[19] A minimum number of 50 cases were considered necessary to obtain statistically reliable estimates. In countries with less than 50 cases statistical methods are not able to reliably estimate the trend but the number of cases remains very low.

3.2.2. Calculations based on Method 3

As discussed in section 2, for the purpose of these calculations two different scenarios were used:

- **Scenario I**: assumes a constant incidence of BSE starting from the 2004 birth cohort (in practice the yearly estimate of the number of BSE cases per age group is the same from 2009 onwards). This could be considered as the "worst case" scenario.

- **Scenario II**: can be considered more realistic as it is derived from the observed data and assumes a continue decay rate of the BSE epidemic for cohorts since 2004 based on the cohort incidence decline in previous cohorts calculated by log-linear regression (over the period 1994 to 2003).

Due to the restricted data available for recent cohorts and to the methodologies applied the approach only partially took into account the expected additional effect of the enhanced control measures taken in 2001 in the EU (see Appendix B). Moreover, the scenarios are based on upper 95% confidence limit of the calculated expected number of cases. Consequently they can be considered as worst case scenarios.

A Excel worksheet with the calculations used when performing this method is provided as an Annex to this Opinion and published separately in the same web page[20].

3.2.2.1. Results from Scenario I

Since this scenario assumes constant incidence in birth cohort since 2004, these estimates will be the same for each year after 2009.

The expected total number of detected BSE cases in the EU17 (based on upper 95% confidence limit for birth cohorts since 2004) by calendar year and age category in this scenario is provided in Table 6, which considers all the possible testing streams: healthy slaughter, at risk and eradication measures. Tables 7 and 8 present results for the healthy and at risk groups, respectively.

Table 6: Expected total number of BSE cases in the EU17 (based on upper 95% confidence limit for birth cohorts since 2004) by calendar year and age category (in months) in Scenario I. This considers all the possible slaughter streams: healthy, at risk and eradication measures.

Year	**Age category (months)**										
	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2011	0.00	0.23	0.54	4.17	7.04	5.80	3.81	1.82	1.16	5.24	29.81
2012	0.00	0.12	0.54	4.17	7.04	5.80	3.59	1.78	0.91	1.53	25.48
2013	0.00	0.00	0.27	4.17	7.04	5.80	3.59	1.68	0.89	1.20	26.64

The expected number of BSE cases detected in the EU17 in the healthy slaughter stream (based on upper 95% confidence limit for birth cohorts since 2004) by calendar year and age category in this scenario is provided in Table 7.

20 The Excel worksheet with the calculations will be published following publication of this Scientific Opinion.

Table 7: Expected 1 number of BSE cases detected in the healthy slaughter stream in the EU17 (based on upper 95% confidence limit for birth cohorts since 2004) by calendar year and age category (in months) in Scenario I.

Year	Age category (months)										
	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2011	0.00	0.08	0.1	1.44	1.92	1.13	0.73	0.28	0.13	0.61	6.42
2012	0.00	0.04	0.1	1.44	1.92	1.13	0.69	0.27	0.1	0.18	5.87
2013	0.00	0.00	0.05	1.44	1.92	1.13	0.69	0.26	0.1	0.14	5.73

Thus, based on Scenario I in healthy slaughtered animals aged respectively up to 60, 72, 84 or 96 months, less than two, four, five or six cases per each of the respective age limit, can be expected to be detected annually in EU17 by an active surveillance system that uses currently approved rapid BSE tests.

The expected number of BSE cases in the EU17 detected in the at risk stream (based on upper 95% confidence limit for birth cohorts since 2004) by calendar year and age category in this scenario is provided in Table 8.

Table 8: Expected number of BSE cases detected in the at risk group in the EU17 (based on upper 95% confidence limit for birth cohorts since 2004) by calendar year and age category (in months) in Scenario I.

Year	Age category (months)										
	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2011	0.00	0.15	0.30	2.04	2.79	2.35	1.69	0.96	0.66	3.54	14.48
2012	0.00	0.08	0.30	2.04	2.79	2.35	1.59	0.95	0.52	1.04	11.66
2013	0.00	0.00	0.15	2.04	2.79	2.35	1.59	0.89	0.51	0.81	11.13

Thus, based on Scenario I in at risk animals aged respectively up to 60, 72, 84 or 96months, less than three, six, eight and ten cases per each of the respective age limit can be expected to be detected annually in EU17 by an active surveillance system that uses currently approved rapid BSE tests.

3.2.2.2. Results from Scenario II

The expected total number of detected BSE cases in the EU17 (based on upper 95% confidence limit for constant trend of reduction by birth cohorts over the period 1994 to 2003) by calendar year and age category in this scenario is provided in Table 9, which considers all possible testing streams: healthy slaughter, at risk and eradication measures. Tables 10 and 11 present results for the healthy and at risk groups, respectively.

Table 9: Expected total number of BSE cases in the EU17 (based on the extrapolation of the upper 95% confidence limit for the trend over the period 1994 to 2003, from 2004 onwards) by calendar year and age category (in months) in Scenario II. This considers all the possible slaughter streams: healthy, at risk and eradication measures.

Year	Age category (months)										
	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2011	0.00	0.03	0.11	1.25	3.38	4.64	3.81	1.82	1.16	5.24	21.44
2012	0.00	0.01	0.06	0.83	2.11	2.78	2.87	1.78	0.91	1.53	12.88
2013	0.00	0.00	0.02	0.50	1.41	1.74	1.72	1.34	0.89	1.20	8.82

The expected number of BSE cases detected in the EU17 healthy slaughter stream (based on upper 95% confidence limit for constant trend of reduction by birth cohorts over the period 1994 to 2003) by calendar year and age category in this scenario is provided in Table 10.

Table 10: Expected number of BSE cases detected in the EU17 in the healthy slaughter stream (based on the extrapolation of the upper 95% confidence limit for the trend over the period 1994 to 2003, from 2004 onwards) by calendar year and age category (in months) in Scenario II.

Year	Age category (months)										
	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2011	0.00	0.00	0.01	0.23	0.50	0.47	0.57	0.28	0.13	0.61	2.79
2012	0.00	0.00	0.01	0.14	0.31	0.29	0.29	0.21	0.10	0.18	1.53
2013	0.00	0.00	0.00	0.09	0.19	0.18	0.18	0.11	0.08	0.14	0.96

Thus, based on Scenario II in healthy slaughtered animals aged respectively 60, 72, 84 or 96 months, less than one, one, two or two cases per each of the respective age category, can be expected to be missed in 2011. After this date and with the hypothesis that Classical BSE continue to decline, a yearly decline in the number of cases should be observed.

The expected number of BSE cases detected in the EU17 in the at risk stream (based on upper 95% confidence limit for constant trend of reduction by birth cohorts over the period 1994 to 2003) by calendar year and age category in this scenario is provided in Table 11.

Table 11: Expected number of BSE cases detected in the EU17 in the at risk stream (based on the extrapolation of the upper 95% confidence limit for the trend over the period 1994 to 2003, from 2004 onwards) by calendar year and age category (in months) in Scenario II.

Year	Age category (months)										
	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2011	0.00	0.01	0.04	0.41	0.89	1.27	0.80	0.52	0.44	2.02	6.4
2012	0.00	0.00	0.01	0.24	0.56	0.75	0.48	0.43	0.35	0.59	3.41
2013	0.00	0.00	0.00	0.08	0.33	0.47	0.29	0.26	0.29	0.46	2.18

Thus, based on Scenario II in at risk animals aged respectively 60, 72, 84 or 96 months, less than one, two, three and four cases per each of the respective age category can be expected to be missed in 2011. After this date and with the hypothesis that Classical BSE continue to decline, a yearly decline in the number of cases should be observed.

3.2.2.3. Conclusion from calculations based on Method 3 for EU 17

- These conclusions apply in the context of the continuous decrease of the BSE epidemic in the EU17 and the continuation of the BSE control measures currently in place.
- According to Scenario I,
  - In healthy slaughtered animals aged respectively up to 60, 72, 84 or 96 months, less than two, four, five or six cases per each of the respective age category can be expected to be missed annually in EU17 by an active surveillance system using currently approved rapid BSE tests.
  - In at risk animals aged respectively 60, 72, 84 or 96 months, less than three, six, eight and ten cases per each of the respective age category can be expected to be missed annually in EU17 by an active surveillance system using currently approved rapid BSE tests.
- According to Scenario II:
  - In healthy slaughtered animals aged respectively 60, 72, 84 or 96 months, less than one, one, two or two cases per each of the respective age category, can be expected to be missed in 2011 in EU17 by an active surveillance system using currently approved rapid BSE tests. After this, a year decline in the number of cases should be observed should the current trend on BSE cases continue.
  - In at risk animals aged respectively 60, 72, 84 or 96 months, less than one, three, five and six cases per each of the respective age category can be expected to be missed in 2011 in EU17 by an active surveillance system using currently approved rapid BSE tests. After this, a year decline in the number of cases should be observed should the current trend on BSE cases continue.
- These figures are estimated with the model employed in this and previously related Scientific Opinions. The likelihood of detecting new cases in specific age groups is very low, but there remains a small probability of detecting one or more cases in some of these age groups.

3.3. Assessment based on a complete stop of testing based on certain dates of birth for EU17 from 1 January 2011

3.3.1. Calculations based on Method 3, Scenario I

This scenario assumes a constant BSE incidence since 2004. Thus, it could be considered as the "worst case" scenario.

The expected number of BSE cases detected in the healthy slaughter group in the EU17 (based on upper 95% confidence limit for birth cohorts since 2003) by birth cohort and age category in Scenario I is provided in Table 12.

Table 12: Expected number of BSE cases in the healthy slaughter group in the EU 17 detected (by birth cohort and age category (in months) in Scenario I. Expected number of bovines that would be missed per age category from 2011 onwards are in the grey area of the table, as the ones in the white area would have already been tested in previous years. The total sum missed column represents the numbers missed per birth cohort. (All numbers based on upper 95% confidence limit for birth cohorts from 2004 to 2011).

Birth cohort	Age category (months)										
	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total sum missed**
2004	0.00	0.08	0.10	1.44	1.92	[1.13]	0.69	0.26	0.09	0.13	1.73
2005	0.00	0.08	0.10	1.44	[1.92]	1.13	0.69	0.26	0.09	0.13	3.26
2006	0.00	0.08	0.10	[1.44]	1.92	1.13	0.69	0.26	0.09	0.13	4.93
2007	0.00	0.08	[0.10]	1.44	1.92	1.13	0.69	0.26	0.09	0.13	5.71
2008	0.00	[0.08]	0.10	1.44	1.92	1.13	0.69	0.26	0.09	0.13	5.79
2009	0.00	0.08	0.10	1.44	1.92	1.13	0.69	0.26	0.09	0.13	5.83

In table 12 and based on Scenario I, the expected number of healthy slaughtered bovines that would be missed from 1 January 2011 onwards for animals in the birth cohorts 2004 to 2009 are in the grey-shaded area of the table. The expected number of positives in the white area would have already been slaughtered in previous years. The 'total sum missed' column represents the numbers missed per birth cohort. In this scenario, the number of expected BSE cases per birth cohort remains constant for each birth cohort. For the first of the age categories, only 50% of the value between square brackets should be counted, because it could be considered that (on average) half of the animals at that age would have been slaughtered in the previous year. In this scenario, the number of expected BSE cases per birth cohort remains constant for each birth cohort.

The following could be concluded for the healthy slaughter group when analysed under Scenario I:

- It has to be noted that the currently approved BSE monitoring regime in the EU17 would miss BSE cases in animals aged below 48 months of age (since the age limit for BSE testing in both healthy and at risk bovines is 48 months of age).

- If testing of healthy slaughtered cattle would stop from 1 January 2011 for cattle born after 31 December 2003, overall less than 28 BSE cases would be missed, while less than one case would be missed with the current monitoring system. However, one has to account that these calculations account only for cases that would occur in the birth cohorts up to 2009. For birth cohorts after 2009, the number missed per birth cohort will be the same as in the 2009 birth cohort as the incidence remains constant. In 2011 alone, less than three BSE positive cases would be missed in the healthy slaughtered stream if cattle born after 31 December 2003 are not tested.

- If testing would be stopped in healthy slaughtered cattle born after 31 December 2003, 2004 or 2005, the expected value estimated from modelling shows that less than six BSE cases per birth cohort can be expected to be missed in EU17.

The expected number of BSE cases detected in the at risk group in the EU17 (based on upper 95% confidence limit for constant trend of reduction by birth cohorts since 2000) by calendar year and age category in Scenario I is provided in Table 13.

Table 13: Expected number of BSE cases in the at risk group in the EU 17 detected by birth cohort and age category (in months) in Scenario I. Expected number of bovines that would be missed per age category from 2011 onwards are in the grey area of the table, as the ones in the white area would have already been tested in previous years. The total sum missed column represents the numbers missed per birth cohort. (All numbers based on upper 95% confidence limit for birth cohorts from 2004 to 2011).

Birth cohort	Age category (months)										Total sum missed
	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	
2004	0.00	0.15	0.30	2.04	2.79	[2.35]	1.59	0.89	0.48	0.75	4.89
2005	0.00	0.15	0.30	2.04	[2.79]	2.35	1.59	0.89	0.48	0.75	7.46
2006	0.00	0.15	0.30	[2.04]	2.79	2.35	1.59	0.89	0.48	0.75	9.87
2007	0.00	0.15	[0.30]	2.04	2.79	2.35	1.59	0.89	0.48	0.75	11.04
2008	0.00	[0.15]	0.30	2.04	2.79	2.35	1.59	0.89	0.48	0.75	11.27
2009	0.00	0.15	0.30	2.04	2.79	2.35	1.59	0.89	0.48	0.75	11.35

In Table 13 and based on Scenario I, the expected number of at risk cattle that would be missed from 1 January 2011 onwards for animals in the birth cohorts 2004 to 2009 are in the grey-shaded area of the table. The expected number of positives in the white area would have already been slaughtered in previous years. For the first of the age categories, only 50% of the value between square brackets should be counted because it could be considered that (on average) half of the animals at that age would have been slaughtered in the previous year. The ‘total sum missed’ column represents the numbers missed per birth cohort. In this scenario, the number of expected BSE cases per birth cohort remains constant for each birth cohort.

The following could be concluded for the at risk group when analysed under Scenario I:

- It has to be noted that the currently approved BSE monitoring regime in the EU17 would miss BSE cases in animals aged below 48 months of age (since the age limit for BSE testing in both healthy and at risk bovines is 48 months of age).

- If testing of at risk cattle would stop from 1 January 2011, overall less than 56 BSE cases would be missed, while less than two cases would be missed with the current monitoring system. However, one has to account that these calculations account only for cases that would occur in the birth cohorts from up to 2009. For birth cohorts after 2009, the number missed per birth cohort will be the same as in the 2009 birth cohort as the incidence remains constant. In 2011 alone, less than four BSE positive cases would be missed in the at risk stream if cattle born after 31 December 2003 are not tested.

- If BSE testing would be stopped in at risk cattle born after 31 December 2003, 2004 or 2005, the expected value estimated from modelling shows that less than 12 BSE cases per birth cohort can be expected to be missed in EU17.

The manner to employ tables 12 and 13 for making further estimates on the number of BSE cases missed based on Scenario I for a possible stop testing starting at different dates and/or for different dates of birth should be as follows, illustrated with these two further examples:

- If testing of healthy slaughtered cattle born after 31 December 2003 would stop from 1 January 2012, then one should move the grey-shaded area to the next age category and perform the calculations in the same manner as per 2011.

- If testing of healthy slaughtered cattle would stop for cattle born after 31 December 2004, would stop from 1 January 2011, then the birth cohort line of 2004 should not be taken into account in the calculation.

Table 14 compiles the number of BSE cases that would be missed based on Scenario I by birth cohort (2004 to 2008) should BSE testing stop for healthy slaughtered or at risk cattle both for 2011 and 2012.

Table 14: Estimated number of detectable BSE cases per birth cohort (2004-2008) that would be missed based on Scenario I if BSE testing of the healthy slaughtered stream or the at risk stream would be stopped by 1 January 2011 or 1 January 2012. Based on upper 95% confidence for birth cohorts limit since 2004.

	Birth cohort					
Date of Stop testing	2004	2005	2006	2007	2008	**Total**
From 1st January 2011						
Healthy slaughter	1.73	3.25	4.93	5.70	5.79	21.42
Risk animals	4.89	7.46	9.87	11.04	10.52	43.79
From 1st January 2012						
Healthy slaughter	0.82	1.73	3.25	4.93	5.70	16.45
Risk animals	2.92	4.89	7.46	9.87	11.04	36.19

3.3.2. Calculations based on Method 3, Scenario II

This scenario considers that the incidence follows a linear decline as per the trend observer in the EU17. Thus, it could be considered as the "more realistic" scenario.

The expected number of BSE cases detected in the healthy slaughter group for the EU17 (based on upper 95% confidence limit for constant trend of reduction by birth cohorts since 2000) by calendar year and age category in Scenario II is provided in Table 15.

Table 15: Expected number of BSE cases in the healthy slaughter group for the EU 17 detected by testing year and age category (in months) in Scenario II. Expected number of bovines that would be missed per age category from 2011 onwards are in the grey area of the table, as the ones in the white area would have already been tested in previous years. The total sum missed column represents the numbers missed per birth cohort. (All numbers based on the extrapolation of the upper 95% confidence limit for the trend over the period 1994 to 2003, from 2004 onwards).

Birth cohort	Age category (months)										
	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total sum missed**
2004	0	0.04	0.05	0.75	1.00	[0.59]	0.36	0.13	0.05	0.07	0.90
2005	0	0.02	0.03	0.46	[0.61]	0.36	0.22	0.08	0.03	0.04	1.58
2006	0	0.02	0.02	[0.29]	0.38	0.23	0.14	0.05	0.02	0.03	0.99
2007	0	0.01	[0.01]	0.17	0.23	0.14	0.08	0.03	0.01	0.02	0.68
2008	0	[0.01]	0.01	0.12	0.15	0.09	0.06	0.02	0.01	0.01	0.46
2009	0	0.00	0.00	0.06	0.08	0.05	0.03	0.01	0.00	0.01	0.23

In table 15 and based on Scenario II, the expected number of healthy slaughtered bovines that would be missed from 1 January 2011 onwards for animals in the birth cohorts 2004 to 2009 are in the grey-shaded area of the table. The expected number of positives in the white area would have already been slaughtered in previous years. The 'total sum missed' column represents the numbers missed per birth cohort. In this scenario, the number of expected BSE cases per birth cohort remains constant for each birth cohort. For the first of the age categories, only 50% of the value between square brackets should be counted, because it could be considered that (on average) half of the animals at that age would have been slaughtered in the previous year. In this scenario, the number of expected BSE cases per birth cohort will decay progressively.

The following could be concluded for the healthy slaughter group when analysed under Scenario II:

- It has to be noted that the currently approved BSE monitoring regime in the EU17 would miss BSE cases in animals aged below 48 months of age (since the age limit for BSE testing in both healthy and at risk bovines is 48 months of age).

- If testing of healthy slaughtered cattle would stop from 1 January 2011 for cattle born after 31 December 2003, overall less than five BSE cases would be missed, while less than one case would be missed with the current monitoring system. However, one has to account that these calculations account only for cases that would occur in the birth cohorts up to 2009. For birth cohorts after 2009, the number missed per birth cohort will decay. In 2011 alone, less than one BSE positive case would be missed in the healthy slaughtered stream if cattle born after 31 December 2003 are not tested.

- If testing would be stopped in healthy slaughtered cattle born after 31 December 2003, 2004 or 2005, the expected value estimated from modelling shows that less than two BSE cases per birth cohort can be expected to be missed in EU17.

The expected number of BSE cases detected in the at risk group (based on upper 95% confidence limit for constant trend of reduction by birth cohorts since 2000) by calendar year and age category in Scenario II is provided in Table 15.

Table 16: Expected number of BSE cases in the at risk group for the EU 17 detected by testing year and age category (in months) in Scenario II. Expected number of bovines that would be missed per age category from 2011 onwards are in the grey area of the table, as the ones in the white area would have already been tested in previous years. The total sum missed column represents the numbers missed per birth cohort. (All numbers based on the extrapolation of the upper 95% confidence limit for the trend over the period 1994 to 2003, from 2004 onwards).

Birth cohort	Age category (months)										
	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total sum missed**
2004	0	0.10	0.20	1.39	1.89	[1.60]	0.61	0.33	0.22	0.29	2.24
2005	0	0.06	0.12	0.82	[1.11]	0.94	0.36	0.19	0.13	0.17	2.35
2006	0	0.04	0.07	[0.49]	0.67	0.56	0.21	0.12	0.08	0.10	1.99
2007	0	0.02	[0.05]	0.33	0.45	0.38	0.14	0.08	0.05	0.07	1.51
2008	0	[0.01]	0.02	0.16	0.22	0.19	0.07	0.04	0.03	0.03	0.77
2009	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0

In table 16 and based on Scenario II, the expected number of at risk bovines that would be missed from 1 January 2011 for animals in the birth cohorts 2004 to 2009 are in the grey-shaded area of the table. The expected number of positives in the white area would have already been slaughtered in previous years. For the first of the age categories, only 50% of the value between square brackets should be because it could be considered that (on average) half of the animals at that age would have been slaughtered in the previous year. The 'total sum missed' column represents the numbers missed per birth cohort. In this scenario, the number of expected BSE cases per birth cohort will decay progressively.

The following could be concluded for the at risk group when analysed under Scenario II:

- It has to be noted that the currently approved BSE monitoring regime in the EU17 would miss BSE cases in animals aged below 48 months of age (since the age limit for BSE testing in both healthy and at risk bovines is 48 months of age).

- If testing of at risk cattle would stop from 1 January 2011, overall less than nine BSE cases would be missed, while less than one case would be missed with the current monitoring system. However, one has to account that these calculations account only for cases that would occur in the birth cohorts from up to 2009. For birth cohorts after 2009, the number missed per birth cohort will decay. In 2011 alone, less than four BSE positive cases would be missed in the at risk stream if cattle born after 31 December 2003 are not tested.

- If BSE testing would be stopped in at risk cattle born after 31 December 2003, 2004 or 2005, the expected value estimated from modelling shows that less than three BSE cases per birth cohort can be expected to be missed in EU17.

The manner to employ tables 15 and 16 for making further estimates on the number of BSE cases missed based on Scenario II for a possible stop testing starting at different dates and/or for different dates of birth should be as follows, illustrated with these two further examples:

- If testing of healthy slaughtered cattle born after 31 December 2003 would stop from 1 January 2012, then one should move the grey-shaded area to the next age category and perform the calculations in the same manner as per 2011.

- If testing of healthy slaughtered cattle would stop for cattle born after 31 December 2004, would stop from 1 January 2011, then the birth cohort line of 2004 should not be taken into account in the calculation.

Table 17 compiles the number of BSE cases that would be missed based on Scenario II by birth cohort (2004 to 2008) should BSE testing stop for healthy slaughtered or at risk cattle both for 2011 and 2012.

Table 17: Estimated number of detectable BSE cases per birth cohort (2004-2008) that would be missed based on Scenario II if BSE testing of the healthy slaughtered stream or the at risk stream would be stopped by the 1 January 2011 or 1 January 2012. Based on upper 95% confidence for birth cohorts limit since 2004.

	Birth cohort					
Date of Stop testing	2004	2005	2006	2007	2008	**Total**
From 1st January 2011						
Healthy slaughter	0.90	1.04	0.99	0.68	0.46	4.07
Risk animals	3.70	3.31	2.16	1.48	0.75	11.40
From 1st January 2012						
Healthy slaughter	0.43	0.55	0.65	0.59	0.46	2.68
Risk animals	1.95	2.18	1.88	1.44	0.74	8.19

3.3.3. Assessment based on stop testing healthy slaughtered cattle after certain date

It was further requested by the European Commission to evaluate the situation whereby testing of healthy slaughtered cattle would stop after certain date but maintaining testing of the at risk animal group. This date should start as from first of January 2011 and, where possible, providing results at twelve months intervals.

The answer to this question can be estimated based on results for method 3 presented in tables 7 (for scenario I) and 10 (for scenario II).

Based on scenario I, if testing for healthy slaughtered animals would stop on 1 January 2011, 2012 or 2013 less than 7, 6 and 6 BSE cases would be missed for each of the respective years (See table7). After this date and with the hypothesis that BSE incidence will remain constant in the EU17, less than 6 BSE cases would be missed for each calendar year.

Based on scenario II, if testing for healthy slaughtered animals would stop on 1 January 2011, 2012 or 2013 less than 3, 2 and 1 BSE cases would be missed for each of the respective years (See table10). After this date and with the hypothesis that BSE continue to decline, less than one BSE case would be missed for each calendar year.

It is recommended that if BSE testing of the healthy slaughtered cattle would be reduced or stopped, it has to be ensured that attention is paid to the possible entrance of at risk animals in the non tested population.

4. Assessment of the BSE monitoring regime in the EU8

4.1. Analysis of the Active BSE monitoring programme per category and age during the period 2004 to 2009 in EU8

Results are presented both including and excluding Atypical BSE Cases. Out of the MSs of the EU8 group, Poland reported that since 2004 a total of 9 Atypical BSE cases have been diagnosed.

Epidemiological data on BSE has been collected via the BSE Active and Passive Surveillance over the last 6 years in the EU8. It has to be noted that out of the eight MSs of interest, only three - referred to as EU3 - have reported positive BSE cases: Czech Republic, Poland and Slovakia. Thus, in five of the MSs of the EU8 group – referred to as EU5: Estonia, Hungary, Latvia, Lithuania and Malta) - BSE cases have not been identified through the EU BSE monitoring regime. In the EU3, where cases have been identified, there is no clear continuous decline on the yearly prevalence (see Table 18).

Table 18: Prevalence (number of BSE cases per ten thousand of animals tested) of BSE in the EU3 for active surveillance from 2004 to 2009. No cases have been identified through passive surveillance in the EU3.

	Year of testing					
	2004	2005	2006	2007	2008	2009
Active Surveillance						
Including Atypical BSE	0.13	0.33	0.34	0.15	0.17	0.07
Excluding Atypical BSE	0.13	0.30	0.32	0.13	0.15	0.07

When comparing the prevalence in the EU3 for the period 2004 to 2009 with the prevalence in the EU17 for the period 2001 to 2006 (i.e. 6 first years of the total feed ban), it can be noticed that the yearly prevalence in the EU3 is in the range of 10 to 4 times lower than that of the EU17.

In the EU5 group, where BSE has not been identified, more than 1.48 million tests have been carried out in the framework of BSE surveillance between 2004 and 2009. Of these tests, about 1.3 million were tests done in healthy slaughtered cattle, while approximately 181,000 at risk cattle were tested.

In the EU 3 group, more than 4.8 million of tests have been carried out in the framework of BSE Active Surveillance since 2004. Of these 94 animals were positive, including 9 Atypical cases detected in Poland. These included 61 (6 Atypical BSE cases in Poland) out of 4,145,823 healthy slaughtered cattle tested (14.71 per million healthy cattle tested), and 33 (3 Atypical BSE cases in Poland) out of 714,603 at risk cattle tested (46.17 per million). In the framework of BSE Passive Surveillance in EU3 during the period 2004 – 2009 a total of 157 bovine animals were tested and none was positive.

In 2009, no BSE cases have been reported in EU8 in the framework of BSE Surveillance in: Estonia, Hungary, Latvia, Lithuania, Malta and Slovakia. Moreover, also in 2008 no cases were reported in these same countries except 1 case in Slovakia.

With respect to the number of BSE cases, including Atypical BSE cases, detected through the BSE Active and Passive Surveillance in EU3 between 2004 and 2009 data per target group are reported in Table 19.

Table 19: Number of BSE cases (including Atypical BSE cases) detected through the BSE Active and Passive Surveillance in EU3 during the period 2004 – 2009 per target group.

Target Group	**N° of detected BSE cases per year**						
Active Surveillance	2004[1]	2005	2006	2007	2008	2009	**Total**
Healthy slaughtered	15	18	9	9	4	6	61
At risk animals							
Emergency slaughter	5	2	0	1	2	0	10
Fallen stock	5	7	4	4		2	22
Presenting Clinical signs at ante mortem inspection	0	1	0	0	0	0	1
Total Active Surveillance	25	28	13	14	6	8	94
Passive Surveillance							0
Suspects subject to lab	0	0	0	0	0	0	0
Eradication Measures	0	3	0	0	0	0	3
Grand Total	25	31	13	14	6	8	97

[1] In 2004, seven cases were diagnosed before 1st May.

With respect to the number of BSE cases, excluding Atypical BSE cases, detected through the BSE Active and Passive Surveillance in EU8 between 2004 and 2009 data per target group are reported in Table 20.

Table 20: Number of BSE cases (excluding Atypical BSE cases) detected through the BSE Active and Passive Surveillance in EU8 during the period 2004 – 2009 per target group.

Target Group	**N° of detected BSE cases per year**						
Active Surveillance	2004[1]	2005	2006	2007	2008	2009	**Total**
Healthy slaughtered	14	17	7	8	4	5	55
At risk animals							
Emergency slaughter	4	2	0	1	2	0	9
Fallen stock	5	6	4	3	0	2	20
Presenting Clinical signs at ante mortem inspection	0	1	0	0	0	0	1
Total Active Surveillance	23	26	11	12	6	7	85
Passive Surveillance							0
Suspects subject to lab	0	0	0	0	0	0	0
Eradication Measures	0	3	0	0	0	0	3
Grand Total	23	29	11	12	6	7	88

[1] In 2004, seven cases were diagnosed before 1st May.

The total number of BSE cases detected through the BSE Surveillance (both Active and Passive) and the culling of animals in the framework of BSE eradication measures in EU3 during the period 2004 – 2009 per birth cohort and year of detection, including Atypical BSE cases, is reported in Table 21.

Table 21: Number of BSE cases (including Atypical BSE cases) detected through the BSE Surveillance (Active and Passive) and the culling of animals in the framework of BSE eradication measures in EU3 during the period 2003 – 2009 per birth cohort and year of detection.

	N° of detected BSE cases per year						
Birth Cohort	2004[1]	2005	2006	2007	2008	2009	**Total**
1992	2	1					3
1994	1	1	2				4
1995	2	1	1	3		1	8
1996	6	2	3	1			12
1997	2	2	1				5
1998	3	2	1	2			8
1999	2	5	2	3	2	2	16
2000	5	13	2	1	1	2	24
2001	2	3	1	2	1		9
2002		1					1
2003				1	1	1	3
2004				1		2	3
2005					1		1
Grand Total	25	31	13	14	6	8	97

[1] In 2004, seven cases were diagnosed before 1st May.

The total number of BSE cases detected through the BSE Surveillance (both Active and Passive) and the culling of animals in the framework of BSE eradication measures in EU3 during the period 2004 – 2009 per birth cohort and year of detection, excluding Atypical BSE cases, is reported in Table 22.

Table 22: Number of BSE cases (excluding Atypical BSE cases) detected through the BSE Surveillance (Active and Passive) and the culling of animals in the framework of BSE eradication measures in EU3 during the period 2003 – 2009 per birth cohort and year of detection.

	N° of detected BSE cases per year						
Birth Cohort	2004[1]	2005	2006	2007	2008	2009	**Total**
1992	1						1
1994	1		1				2
1995	1	1	1	1			4
1996	6	2	2	1			11
1997	2	2	1				5
1998	3	2	1	2			8
1999	2	5	2	3	2	2	16
2000	5	13	2	1	1	2	24
2001	2	3	1	2	1		9
2002		1					1
2003				1	1	1	3
2004				1		2	3
2005					1		1
Grand Total	23	29	11	12	6	7	88

[1] In 2004, seven cases were diagnosed before 1st May.

The number of BSE cases detected through the BSE Surveillance (Active and Passive) and the culling of animals in the framework of BSE eradication measures during the period 2004 – 2009 per MS of the EU8 group, birth cohort and year of detection is provided in Appendix A.

When interpreting the significance of these data the following points should also be considered:

- BSE has not been detected in 5 of the EU8 MSs (the EU5 group): Estonia, Hungary, Latvia, Lithuania and Malta. Three MSs (the EU3 group), these being Czech Republic, Poland and Slovakia, account for all the BSE cases detected in the EU8 group.

- The likely point in the incubation period at which PrP^{res} is detectable with the rapid BSE tests depends on the infective dose (Arnold et al., 2007). While the range of doses of exposure of field cases of BSE is not known, an oral attack rate study has shown that the mean incubation period arising from doses in the range 0.1-1g fits with that estimated for field cases (Wells et al., 2007). For a 1g dose, it was found that PrP^{res} was detectable at 97% of the incubation period (Arnold et al., 2007). This degree of under-detection has to be taken into account when estimating infection prevalence from surveillance data.
- In the EU3 over the period 2004 to 2009 the prevalence of BSE was lower than in the EU17 over the period 2001 to 2009. However, there is not yet a clear declining trend in the BSE epidemic in the EU3, as there is in the EU17.
- The number of cases has gone down from 31 in 2005 (pick) to 8 in 2009. The EU8 are all new EU MSs since 1 May 2004, since when the EU total feed ban has been implemented in these MSs. In the EU3 a total of 44 case have been born since 2001, and 4 cases are born after 30th April 2004.
- The Geographical BSE Risk (SSC, 2002) as well as the stage of the BSE epidemic can vary considerably between MSs.

4.2. Assessment based on an increase of testing age at 12 months intervals.

4.2.1. Calculations based on Method 1

The number of BSE cases, the BSE incidence per million cattle over 24 months of age[21] and the average age of cases per year of detection in the EU8 MSs, considering both BSE Active and Passive Surveillance and the animals culled in the framework of BSE eradication measures, are shown in Table 23.

[21] Data on adult cattle population of the EU8 retrieved from EUROSTAT.

Table 23: Number of BSE cases, incidence per million cattle over 24 months and average age in years of cases during the period 2003 – 2009 per year of detection in the EU8 MS (the data consider both BSE Active and Passive Surveillance and the culling of animals in the framework of BSE eradication measures). Results including and excluding Atypical BSE cases.

Member State		Year of testing						Total
		2004	2005	2006	2007	2008	2009	
Czech Republic	N° cases	7	8	3	3	0	3	24
	Incidence	10.7	12.5	4.6	4.7	0	4.6	
	Average age	5.9	5	6.3	9.7	NA	5.3	
Estonia	N° cases	0	0	0	0	0	0	0
	Incidence	0	0	0	0	0	0	
	Average age	NA[2]	NA	NA	NA	NA	NA	
Hungary	N° cases	0	0	0	0	0	0	0
	Incidence	0	0	0	0	0	0	
	Average age	NA	NA	NA	NA	NA	NA	
Latvia	N° cases	0	0	0	0	0	0	0
	Incidence	0	0	0	0	0	0	
	Average age	NA	NA	NA	NA	NA	NA	
Lithuania	N° cases	0	0	0	0	0	0	0
	Incidence	0	0	0	0	0	0	
	Average age	NA	NA	NA	NA	NA	NA	
Malta	N° cases	0	0	0	0	0	0	0
	Incidence	0	0	0	0	0	0	
	Average age	NA	NA	NA	NA	NA	NA	
Poland	N° cases INC[1]	11	20	10	9	5	5	60
	N° cases EXC[2]	9	18	8	7	5	4	51
	Incidence INC	3.6	6.5	3.3	3	1.6	1.7	
	Average age INC	8.3	6.9	9.4	8.2	6.8	10.4	
	Average age EXC	7.8	6.3	9	7.1	6.8	9.5	
Slovakia	N° cases	7	3	0	2	1	0	13
	Incidence	25.9	11.1	0	7.9	4	0	
	Average age	5.1	5	NA	6	7	NA	
EU8	N° cases INC[3]	25	31	13	14	6	8	97
	N° cases EXC[4]	23	29	11	12	6	7	88
	Incidence INC	4.8	6	2.6	2.8	1.2	1.6	
	Average age INC	6.7	6.2	8.7	8.2	6.8	8.5	
	Average age EXC	6.4	5.8	8.3	7.6	6.8	7.7	

[1] In 2004, seven cases were diagnosed before 1st May.
[2] NA=Non applicable.
[3] INC=Including Atypical cases
[4] EXC=Excluding Atypical cases

The trend of the average age of BSE cases per year of detection in the EU3, considering both BSE Active and Passive Surveillance and the culling of animals in the framework of BSE eradication measures, is shown in Figure 2.

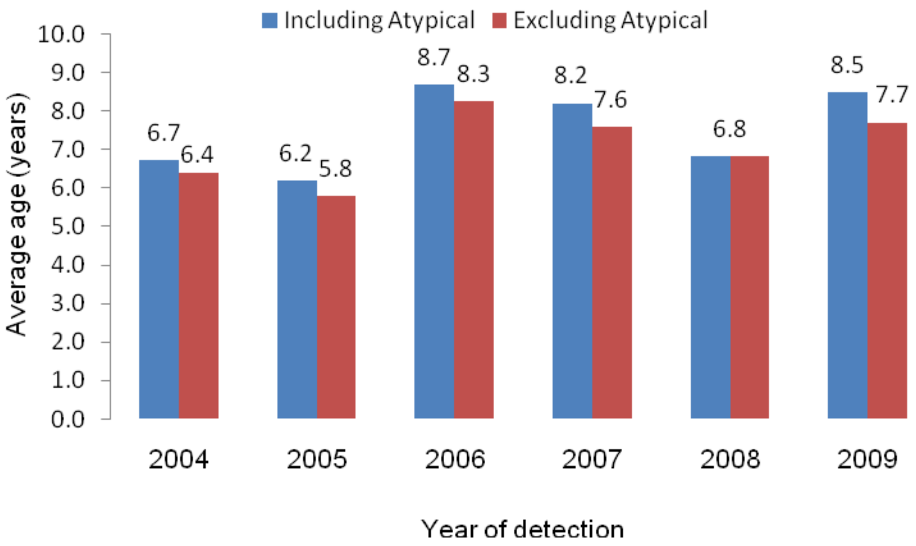

Figure 2: Average age (in years) of BSE cases (including Atypical cases) per year of detection in the EU3 between 2004 and 2009, considering both BSE Active and Passive Surveillance and the culling of animals in the framework of BSE eradication measures.

4.2.1.1. Conclusion from calculations based on Method 1for EU8

- In the EU5 there were no BSE cases detected since the full implementation of the EU surveillance system (1 May 2004). The BSE epidemiological situation in the EU5 should be considered at least equivalent to that of the EU17. Therefore, a similar testing regime could be applied to this group of 22 EU MSs.

- The average age of detected BSE cases in EU3 since 2004 is lower (between 5.8 and 8.3 excluding Atypical BSE cases) than the age of BSE cases detected in EU17 (between 9.1 and 12.4). Furthermore, the average age of the detected BSE cases per test year has not consistently increased over the last 6 years, as it has occurred in the EU17. These impede establishing similarities between the trend of the Classical BSE epidemic in the EU17 and in the EU3.

- The shape of the age distribution of BSE cases depends on two aspects: the age distribution of the cattle population and the level of BSE transmission in the past, at the time that the animals were born (de Koeijer *et al.*, 2002).

4.2.2. Calculations based on Method 3

The trend of the BSE epidemic in the EU3 group shows two waves in the BSE incidence per birth cohort (see Table 22) and thus such a pattern will also appear in the average age of the BSE cases detected (see Figure 2). Due to this wave pattern, a linear regression does not prove a significant constant declining trend of the BSE epidemic in this group of 3 MSs.

This pattern did not appear in the analysis of the EU 17 (at least not very strongly), which allowed for the very simple linear extrapolation of scenarios I and II as they were applied in Method 3 to evaluate the trend of the BSE epidemic in EU17. The second wave pattern (i.e. a temporary increase in the BSE incidence during an overall long term decline) has already been reported in literature in the past (SSC, 1999; Budka et al., 2008; Ducrot et al., 2010). This second wave pattern compromises the establishment of clear similarities between the trend of the Classical BSE epidemic in the EU17 and in the EU3. It specifically complicates the determination of two key factors needed for the application of Method 3 in the EU3 group:

- For Scenario I and II, a good reference year from which to extrapolate the future estimates,
- For Scenario II, choice of reference years for the estimation of the annual rate of decline.

The estimation of the number of cases per birth cohort in the EU3 based on the already cases detected in cohorts since 2000 and the age at onset distribution (see Appendix B) shows that, although the EU3 displays a decline in the number of BSE cases found each test year (see Tables 20 and 21 above), an analysis of the incidence per birth cohort leads to a diffuse picture (see Table 24 below).

Table 24: Prediction of number of cases per birth cohort in the EU3 based on the age at onset distribution. Calculations performed under Method 3 (see Appendix B).

Birth cohort	Total observed cases	Expected number of cases	Upper 95% confidence interval
1996	12	56	91
1997	5	13	26
1998	8	13	23
1999	16	19	26
2000	24	27	33
2001	9	10	13
2002	1	1	4
2003	3	5	9
2004	3	9	22
2005	1	9	43

The analysis presented in Table 24 shows a clear decline in BSE cases until the 2002 birth cohort as compared to the previous cohorts, followed by an increase (second wave) in the next birth cohorts. In the birth cohorts after 2002, even the expected incidence is higher than the upper confidence limit for the 2002 birth cohort, proving a (temporary) increase in incidence). Thus, despite declining incidence per test year, in a linear extrapolation based on full birth cohort evaluation, this decline is not yet significant (using a 95% confidence interval). Partly due to this wave pattern, a linear regression does not prove a significant constant declining trend of the BSE epidemic in this group of 3 MSs. The lack of significance is also due to both the relatively low number of cases and mostly a result of the small fraction of the more recent birth cohorts that has been tested. Results from further test years (e.g. 2010 and 2011) should provide sufficient data for estimating significant results. Once further data would be available, the use of a third scenario which takes into account the wave dynamics, could then be considered for future analysis as linear extrapolation over a relatively short data collection period is not realistic in an epidemic with a temporal wave pattern (Hogasen et al., 2007 and Ducrot et al., 2008).

In conclusion and for the MSs of the EU3 group, at the moment, it would not be informative to estimate the number of undetected BSE cases should the testing age be changed. Therefore, it is recommended to gather results from further test years (e.g. 2010 and 2011) from active surveillance in animals aged 30 months and over (i.e. healthy slaughtered group) and 24 months and over (i.e. at risk group) in order to confirm a declining Classical BSE trend in the MSs of the EU3 group.

5. Atypical BSE

A detailed description of Atypical BSE with regard to its distinct types known as H- and L- (or BASE) type BSE has been presented in a previous related EFSA Scientific Opinion (EFSA, 2008a).

Atypical BSE cases seem to be associated to two distinct major prion strains which are mainly characterised by biochemically distinct PrP^{Sc} profiles, named high-type (H-type or H-BSE) and low-type (L-type or L-BSE). The electrophoretic migration of the unglycosylated PrP^{Sc} is higher (H-BSE) or lower (L-BSE) than Classical BSE (C-BSE) (Buschmann et al., 2006). An additional distinctive signature of H-type and L-type PrP^{Sc} is the smaller proportion of the diglycosylated PrP^{Sc} compared to the C-type PrP^{Sc}, more obvious in L-BSE (Biacabe et al., 2004; Casalone et al., 2004). Transmission experiments in different mouse models, including transgenic mice expressing bovine PrP^{C}, showed that H-BSE and L-BSE exhibited strain-specific features clearly distinct between each other and that also differed from C-BSE (Buschmann et al., 2006; Beringue et al., 2006; Capobianco et al., 2007; Beringue et al., 2007 and 2008).

5.1. Atypical BSE detection in cattle

Since its first report, Atypical BSE cases were described in a number of European and non European countries. According to the data available in scientific literature or obtained through the EU active surveillance system, cases have been reported in several European countries (Jacobs et al., 2007; Stack et al., 2009), Japan (Yamakawa et al., 2003; Masujin et al., 2008), USA (Richt et al., 2007) and Canada (Dudas et al., 2010). Atypical BSE cases found in different EU MSs since 2001 are presented in Table 26.

Table 25: Atypical BSE cases detected in the EU MSs since 2001.

Member State	Year of testing									Grand Total
	2001	2002	2003	2004	2005	2006	2007	2008	2009	
Austria							1			1
Denmark				1						1
France	1	3	4	1	1	2	2	5	4	23
Germany		1		1						2
Ireland		1								1
Italy		1	1				1		1	4
Netherlands	1	1	1							3
Poland		1*		2	2	2	2		1	10
Sweden						1				1
United Kingdom					1		1		1	3
Grand Total	2	8	6	5	4	5	7	5	7	49

*This case is not accounted for in the calculations of the EU8 group as was detected before 2004.

Atypical BSE cases were detected almost exclusively in animals over 8 years of age. All these natural cases were identified by active surveillance testing. However, there is currently no data available on the performance of the validated rapid assays used for cattle TSE testing, for detection of Atypical BSE cases, both in terms of their analytical sensitivity and earliness of the detection of infected animals.

To date, the available demographic and biological evidences suggest that Atypical BSE (H and L type) might represent spontaneous forms of bovine spongiform encephalopathies (Brown et al., 2006; Biacabe et al., 2008).

5.2. Atypical BSE Type L (L-BSE)

Atypical L-BSE has been reported to be transmissible to different animal models. In particular, intra-cerebral (IC) inoculation of the L-BSE Agent in cattle provokes a TSE which is both clinically and pathologically distinct from C-BSE (Lombardi et al., 2006). To date, there are no available results concerning the oral transmission of L-BSE in cattle.

Bioassay in transgenic (Tg) mice over-expressing the bovine PrP^C seems to indicate that infectivity might disseminate in some peripheral tissues in animals IC challenged with L-BSE (Suardi et al., 2009). However, studies on the tissue distribution of L-BSE prion in the organism of cattle are still in progress, and thus the pathogenesis of L-BSE (including tissue infectivity load) remains largely unknown.

In classical BSE cases, pathogenesis studies have established that abnormal PrP deposition in the brainstem first occurs at the obex level, where substantial amount of this disease specific Protein accumulate during the late incubation phase (Simmons et al.; 2010, Arnold et al.; 2007, Wells et al.; 2003). As a consequence, targeting obex for Classical BSE rapid testing is considered as the most sensitive approach for detecting cases within the framework of the active surveillance system.

In Atypical BSE (Both L and H type), the dynamics of the PrP deposition in the different brain areas is poorly documented, and the suitability of the obex as the target tissue for testing that would allow an early and sensitive detection of these conditions remain largely unknown. On one hand all the Atypical BSE cases detected so far were identified through the active surveillance system, indicating that obex testing with currently validated tests allow the detection of at least a part of the Atypical cases. However on other hand the distribution of PrP in L-BSE, as observed from a very limited number of samples, clearly indicate that brainstem deposition of abnormal PrP in the context of L-BSE is poor by comparison to other areas (Casalone et al., 2004). This last finding strongly support the contention that active surveillance system as currently applied could have a more limited sensitivity to detect Atypical BSE cases than C-BSE cases in field cattle population.

Proof of principle of the L-BSE ability to propagate in sheep was brought by the IC propagation of a L-BSE isolate into ARQ/ARQ and in Tg mice expressing the ovine PrP^C variants. The propagation of L-BSE in sheep seemed to result in a TSE with a different profile to that of C-BSE (Nonno et al., 2008). Unexpectedly L-BSE isolates transmitted to either Tg mice expressing ovine PrP^C (Beringue et al., 2007) or inbred wild-type mouse lines (Capobianco et al., 2007) resulted in a disease with similar phenotypic features than those of the C-BSE Agent. However, the inoculation of tissues collected in mice over-expressing ovine PrP^C inoculated with C-BSE and L-BSE in bovine PrP^C transgenic mice, resulted into two different phenotypes specific of each agent indicating that the tg338 passaged agents, although producing a similar signature in the brain, were actually different (Beringue et al, Neuroprion 2010).

Results from several studies that focus on the potential human risk from Atypical L-BSE are available. Kong and colleagues (2008) investigated the infectivity and phenotype of L-BSE or BASE by IC inoculating Tg mice expressing the human PrP^C (M129M) with brain homogenates from two L-BSE affected cattle. Sixty percent of the inoculated Tg mice became infected after 20-22 months incubation, a transmission rate higher than those reported for C-BSE. A quarter of L-BSE infected Tg mice, but none of the Tg mice infected with sporadic CJD (sCJD), showed presence of PrP^{res} in the spleen, indicating that the L-BSE Agent may be lymphotropic. The pathological prion protein isoforms in L-BSE infected humanized Tg mouse brains were different from those of the original cattle L-BSE or sCJD. Minimal brain spongiosis and long incubation time were observed in the L-BSE infected Tg mice. A similar study was performed in another Tg mice expressing the human PrP^C (M129M- Tg650) (Beringue et al., 2008). In contrast with C-BSE prions, L-BSE prions appeared to propagate in these mice with no obvious transmission barrier. Another study evaluated the transmission of L-BSE to a non-human primate (Comoy et al., 2008). Brain homogenates from cattle with C-BSE and L-BSE were IC inoculated into cynomolgus monkeys (*Macacca fascicularis*). The single monkey infected with L-BSE had a shorter survival, and a different clinical evolution, histopathology, and prion protein (PrP^{res}) pattern than what was observed for either C-BSE or vCJD-inoculated animals. These results were interpreted to suggest a possibly higher degree of pathogenicity of L-BSE than C-BSE in primates.

Taken together, these experimental studies may demonstrate that L-BSE or BASE is easily transmissible to both humanised mice and primates, and may be more virulent to humans than C-BSE.

More recently transmission of L-BSE into bank voles resulted in a TSE which phenotype (incubation period, PrP^{Sc} biochemical properties and vacuolar lesion profiles) were identical to the one observed after transmission of a VV2 s-CJD case in this rodent model (Nonno et al., 2009).

Finally, it has to be mentioned that there is no data available about the impact of the TSE inactivation process currently applied to processed animal proteins (134°C, 2 Bar pressure, 20min) on the infectivity of the L-BSE Agent.

5.3. Atypical BSE Type H (H-BSE)

There is currently no data available on the pathogenesis and the tissue infectivity distribution of H-BSE in ruminants.

H-BSE has been transmitted into a number of laboratory animal models. In most of the reported cases the transmission features obtained were distinct from those observed after inoculation with C-BSE (Beringue et al., 2006). However, in a recently presented work, Espinosa and colleagues (2010) described the transmission of four French and one Polish H-BSE isolates into transgenic mice expressing bovine PrP^C (Tg110 mice) by IC challenge. Following these transmissions, two H-BSE isolates resulted into the propagation in some mice (respectively 3 and 2 out of 12) of a TSE displaying a C-BSE phenotype. Second passage of prions into TgBov mice confirmed that the TSE agent was C-BSE.

These results, if confirmed, would imply that C-BSE might emerge spontaneously from a H-BSE type isolate (in the absence of any interspecies passage), which could indicate that H-BSE might be a source of the C-BSE agent.

Finally and equally to L-BSE, there is no data about the impact of the TSE inactivation process currently applied to processed animal proteins on the infectivity of the H-BSE Agent.

5.4. Conclusions on Atypical BSE

The following can be concluded regarding Atypical BSE:

- The origin and pathogenesis of atypical forms of BSE in its natural host are unknown.
- The performances of the current TSE monitoring system, both in terms of their analytical sensitivity and earliness of the detection of animals infected with Atypical BSE are unknown. However, present knowledge on the distribution of the TSE Agent in the brain makes it unlikely that Atypical BSE would be reliably detected using posterior brain stem as tissue target.
- The efficacy of the TSE inactivation process currently applied to processed animal proteins on Atypical BSE has not been assessed.

- Some preliminary data seem to indicate that the Classical BSE Agent might emerge from atypical H-type BSE. At moment, these data need to be considered with caution.

- All available data indicate that Atypical BSE Type-L has a higher ability than Classical BSE to propagate in host expressing the human PrP^C.

From a human and animal health point of view, minimising exposure of consumers and food animals to the Atypical BSE Agents (e.g. via food and feed) will help in preventing possible transmission and propagation of these TSE Agents.

6. The impact of the TSE testing policy on TSE monitoring in cattle

As presented in a previously related EFSA Opinion currently EU BSE surveillance aims at detecting (EFSA, 2008a):

- any changes in the trend of the BSE epidemiology, like a decrease or an increase in the number of BSE cases per period in a given region, or in a specific cattle subpopulation (young animals, old animals);
- a hypothetical new emerging TSE in cattle, such as was done for Atypical BSE.

The objective of the current Opinion is to assess the human and animal health consequences of a modification of the TSE monitoring system in cattle, including options in which TSE testing would be stopped in healthy slaughtered and /or at risk animals born after certain dates. Such scenarios would directly impact on the capacity of the EU TSE monitoring system to fulfil these objectives.

Furthermore, the possible future relaxation of certain TSE control measures in cattle, and the lack of knowledge related to Atypical BSE strongly plead for the continuation of an adapted TSE monitoring system in cattle.

The previously related Opinion (EFSA, 2008a) considered the ability of a monitoring system to detect new trends in the epidemiology of BSE, such as a decrease or an increase in the number of BSE cases in a given period and in a given region, or in a specific cattle subpopulation (e.g. young animals, old animals), or an hypothetical new emerging TSE in cattle, such as observed with Atypical BSE.

The conclusions of that previous Opinion remain entirely valid, in particular it can be noted that:

- passive surveillance on its own cannot be considered as an adequate approach for TSE surveillance;

- targeted testing of the at risk population could represent an efficient tool for identifying a possible re-emergence of BSE and/or of a new TSE epidemics if it should occur in cattle.

If a new TSE monitoring system in cattle might be designed, it may consider together the following:

- the scientific data and uncertainties related to TSE in cattle, and

- the need for ensuring a high level of protection towards TSE risks.

6.1. Concluding remarks on the ability of a monitoring system to detect new trends in the epidemiology of BSE

As per the previous Opinion (EFSA, 2008a), the following conclusions remain valid:

- *"BSE Passive Surveillance has been demonstrated to be a very insensitive detection system.*
- *In contrast active surveillance has been demonstrated to be a more appropriate method for BSE monitoring.*
- *Targeting at risk population and certain age groups would enable early changes in the trend of BSE epidemic to be detected.*
- *An age limit of 48 months of age in at risk animals would allow for the detection of the majority of the cases if Classical BSE re-emerges.*
- *If a new TSE epidemic emerges in cattle, an optimised active surveillance system for its detection should integrate current knowledge on cattle TSEs and likely hypotheses for early and efficient detection. Testing young animals may allow for an earlier detection of this epidemic.*
- *An age limit of 24 month in at risk animals would result in: (i) an increased sensitivity of surveillance in case of BSE re-emergence, (ii) an optimised system for early and efficient detection of emerging new TSEs in cattle."*

It is recommended to comprehensively reassess the sensitivity of the present or intended new EU surveillance system for detecting the prevalence of Atypical BSE, re-emergence of Classical BSE or the emergence of a novel TSE in cattle.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

General conclusions

- The purpose of the BSE surveillance in cattle in the EU is mainly to monitor the BSE epidemic.
- Prevention of human exposure to BSE Agent mainly relies on SRM removal.
- Prevention of animal exposure to and propagation of TSE Agents mainly relies on the Feed Ban.
- The updated data on BSE surveillance from 2001 to 2009 confirm for both the joint EU17 and each of the individual EU17 countries in which sufficient case data are available[22], that the BSE epidemic has been declining and is converging to the sensitivity limit of a surveillance system that uses currently approved rapid BSE tests.
- The updated data on BSE surveillance from 2004 to 2009 for the EU8 shows that two subgroups can be made regarding the epidemiological situation of the individual MSs. In one subgroup, composed by Estonia, Hungary, Latvia, Lithuania and Malta no positive BSE cases have been identified. In the other group, composed by Czech Republic, Poland and Slovakia where BSE cases have been identified, the trend of the BSE epidemic shows two waves in the BSE incidence per birth cohort with a minimum in the birth cohort of 2002. Partly due to this wave pattern, a linear regression does not prove a significant constant declining trend of the BSE epidemic in this group of 3 MSs.
- From a human and animal health point of view, minimising exposure of consumers and food animals to the Atypical BSE Agents (e.g. via food and feed) will help in preventing possible transmission and propagation of these TSE Agents.

Answer to ToRs regarding the MSs in the EU17 MSs group

Under the assumption that all MSs in the EU17 have implemented a BSE surveillance system and control measures as set out in the Regulation (EC) 999/2001 (as amended) for at least six years and that the sensitivity of the rapid tests used for BSE surveillance in cattle in the EU is 100%, it can be concluded for Classical BSE that:

- Based on the model developed and employed for estimating future Classical BSE cases and on the assumption of a constant prevalence of Classical BSE in birth cohorts since 2004 (**Scenario I**, which can be considered as the “**worst case**” scenario):
  - Situation where the age limit for Classical BSE testing would be raised above 48 months in healthy slaughtered and at risk cattle:

22 A minimum number of 50 cases was considered necessary to obtain statistically reliable estimates. In countries with less than 50 cases statistical methods are not able to reliably estimate the trend but the number of cases remains very low.

    - In healthy slaughtered animals aged respectively up to 60, 72, 84 or 96 months, less than two, four, five or six cases per each of the respective age category can be expected to be missed annually.
    - In at risk animals aged respectively 60, 72, 84 or 96 months, less than three, six, eight and ten cases per each of the respective age category can be expected to be missed annually.
  - Situation where BSE testing would be stopped for bovine animals born respectively after 31 December 2003, 2004, 2005 or 2006:
    - Less than six Classical BSE cases per birth cohort can be expected to be missed in EU17 healthy slaughtered cattle population.
    - Less than twelve Classical BSE cases per birth cohort can be expected to be missed in EU17 at risk cattle population.
  - Situation where testing of healthy slaughtered animals would be completely stopped but maintaining testing of the at risk animal group after a certain date:
    - If testing for healthy slaughtered animals would stop on 1 January 2011, 2012 or 2013 less than seven, six and six Classical BSE cases would be missed for each of the respective years. After this date and with the hypothesis that Classical BSE incidence will remain constant in the EU17, less than six Classical BSE cases would be missed for each calendar year.

- Based on the model developed and employed for estimating future BSE cases and on the assumption of a declining Classical BSE trend (**Scenario II**, which can be considered as the "**more realistic**" scenario):
  - Situation where the age limit for BSE testing would be raised above 48 months in healthy slaughtered and at risk cattle:
    - In healthy slaughtered animals aged respectively 60, 72, 84 or 96 months, less than one, one, two or two cases per each of the respective age category, can be expected to be missed in 2011. After this date and with the hypothesis that Classical BSE continue to decline, a yearly decline in the number of cases should be observed.
    - In at risk animals aged respectively 60, 72, 84 or 96 months, less than one, two, three and four cases per each of the respective age category can be expected to be missed in 2011. After this date and with the hypothesis that Classical BSE continue to decline, a yearly decline in the number of cases should be observed.
  - Situation where BSE testing would be stopped for bovine animals born respectively after 31 December 2003, 2004, 2005 or 2006:
    - Less than two Classical BSE cases per birth cohort can be expected to be missed in the healthy slaughtered cattle population.
    - Less than three Classical BSE cases per birth cohort can be expected to be missed in the at risk cattle population.
  - Situation where testing of healthy slaughtered animals would be completely stopped but maintaining testing of the at risk animal group after a certain date:

- If testing for healthy slaughtered animals would stop on 1 January 2011, 2012 or 2013 less than three, two and one Classical BSE cases would be missed for each of the respective years. After this date and with the hypothesis that BSE continue to decline, less than one Classical BSE case would be missed for each calendar year.

- These figures are estimated with the model employed in this and previously related Scientific Opinions. The likelihood of detecting new cases in specific age groups is very low, but there remains a small probability of detecting one or more cases in some of these age groups.

Answer to ToRs regarding the MSs in the EU8 MSs group

Under the assumption that all MSs in the EU8 have implemented a BSE surveillance system and control measures as set out in the Regulation (EC) 999/2001 (as amended) for at least six years, that they will continue to implement these control measures in the future and that the sensitivity of the rapid tests used for TSE surveillance in cattle in the EU is 100%, it can be concluded for Classical BSE that:

- The Classical BSE epidemiological situation is different between a group of 5 MSs where BSE has not been detected (Estonia, Hungary, Latvia, Lithuania and Malta) and another of 3 MSs where BSE has been detected (Czech Republic, Poland and Slovakia).

- In the group of 5 MSs were no BSE cases detected since the full implementation of the EU surveillance system (1 May 2004) the Classical BSE epidemiological situation should be considered at least equivalent to that of the EU17. Therefore, a similar testing regime could be applied to this group of 22 EU MSs.

- The trend of the Classical BSE epidemic in the group of 3 MSs shows two waves in the Classical BSE incidence per birth cohort and in the average age of the Classical BSE cases detected. This second wave pattern compromises the establishment of clear similarities between the trend of the Classical BSE epidemic in the EU17 and in this group of 3 MSs. At the moment, it would not be informative to estimate the number of undetected Classical BSE cases should the testing age be changed in this group of 3 MSs.

RECOMMENDATIONS

The following is recommended:

- To comprehensively reassess the sensitivity of the present or intended new EU surveillance system for detecting the prevalence of Atypical BSE, re-emergence of Classical BSE or the emergence of a novel TSE in cattle.

- If BSE testing of the healthy slaughtered cattle would be reduced or stopped, it has to be ensured that attention is paid to the possible entrance of at risk animals in the non tested population.

- In the MSs of the EU3 group to gather results from further test years (e.g. 2010 and 2011) from active surveillance in animals aged 30 months and over (i.e. healthy slaughtered group) and 24 months and over (i.e. at risk group) in order to confirm a declining Classical BSE trend.

- The recommendations made in the previous EFSA Opinion of 2008 on the revision of the BSE monitoring regime in some EU MSs remain valid.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission reference SANCO.E.2/MP/khk/D(2010)520216 on a request for a scientific opinion on the risk for human and animal health related to the revision of the BSE monitoring regime in some MSs, received on the 7 of June 2010

2. Data on BSE cases detected in the EU employed in the assessments presented herewith was received from the European Commission on the 18 June 2010.

3. Data on the number of rapid TSE tests performed in the EU in the frame of BSE monitoring have been received from the European Commission on 28 October 2010.

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APPENDICES

A. NUMBER OF BSE CASES DETECTED THROUGH THE BSE SURVEILLANCE (ACTIVE AND PASSIVE) AND THE ANIMALS CULLED IN THE FRAMEWORK OF BSE ERADICATION MEASURES SINCE 2001 (EU17) OR 2004 (EU8) PER MEMBER STATE, BIRTH COHORT AND YEAR OF DETECTION.

Data provided by the European Commission on 18 June 2010.

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Austria

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Austria since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	-	-	-	0
1992	-	-	-	-	1	-	-	-	-	1
1993	-	-	-	-	-	1	-	-	-	1
1994	-	-	-	-	1	-	-	-	-	1
1995	-	-	-	-	-	-	-	-	-	0
1996	1	-	-	-	-	-	1	-	-	2
1997	-	-	-	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	-	-	-	0
2000	-	-	-	-	-	1	-	-	-	1
2001	-	-	-	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	1	0	0	0	2	2	1	0	0	6

Belgium

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measure in Belgium since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	-	-	-	0
1991	1	-	1	-	1	-	-	-	-	3
1992	1	3	-	-	-	-	-	-	-	4
1993	1	1	-	-	-	-	-	-	-	2
1994	7	5	2	1	-	1	-	-	-	16
1995	18	8	2	-	-	-	-	-	-	28
1996	18	13	6	4	-	-	-	-	-	41
1997	-	8	3	4	2	-	-	-	-	17
1998	-	-	1	2	-	-	-	-	-	3
1999	-	-	-	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	46	38	15	11	3	1	0	0	0	114

Cyprus

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measure in Cyprus since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	-	-	-	0
1995	-	-	-	-	-	-	-	-	-	0
1996	-	-	-	-	-	-	-	-	-	0
1997	-	-	-	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	0	0	0	0	0	0	0	0	0	0

Czech Republic

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measure in Czech Republic since 2004 per birth cohort and year of detection.

	N° of detected BSE cases per year						
Birth cohort	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	0
1995	-	-	-	-	-	-	0
1996	1	-	-	1	-	-	2
1997	2	-	-	-	-	-	2
1998	1	-	-	2	-	-	3
1999	1	1	1	-	-	-	3
2000	2	6	2	-	-	-	10
2001	-	1	-	-	-	-	1
2002	-	-	-	-	-	-	0
2003	-	-	-	-	-	1	1
2004	-	-	-	-	-	-	0
2005	-	-	-	-	-	2	2
Total	7	8	3	3	0	3	24

Denmark

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measure in Denmark since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	1	-	-	-	-	-	1
1991	-	-	-	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	-	-	-	0
1993	1	-	-	-	-	-	-	-	-	1
1994	-	-	-	-	-	-	-	-	-	0
1995	-	-	-	-	-	-	-	-	1	1
1996	3	2	1	-	1	-	-	-	-	7
1997	1	-	1	-	-	-	-	-	-	2
1998	1	1	-	-	-	-	-	-	-	2
1999	-	-	-	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	6	3	2	1	1	0	0	0	1	14

Estonia

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Estonia since 2004 per birth cohort and year of detection.

	N° of detected BSE cases per year						
Birth cohort	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	0
1995	-	-	-	-	-	-	0
1996	-	-	-	-	-	-	0
1997	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	0
Total	0	0	0	0	0	0	0

Finland

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Finland since 2001 per birth cohort and year of detection.

Birth cohort	N° of detected BSE cases per year									Total
	2001	2002	2003	2004	2005	2006	2007	2008	2009	
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	-	-	-	0
1995	1	-	-	-	-	-	-	-	-	1
1996	-	-	-	-	-	-	-	-	-	0
1997	-	-	-	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	1	0	0	0	0	0	0	0	0	1

France

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in France since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	1	-	-	-	-	-	1
1987	-	-	1	-	-	-	-	-	-	1
1988	-	1	-	-	-	-	-	-	-	1
1989	-	-	1	-	-	-	-	-	-	1
1990	-	1	1	-	1	-	-	1	-	4
1991	-	3	2	-	-	-	-	-	-	5
1992	1	5	2	2	2	-	-	-	1	13
1993	30	17	7	4	3	1	-	2	2	66
1994	87	56	23	12	6	2	-	-	-	186
1995	134	103	41	10	7	-	3	-	2	300
1996	21	40	13	10	2	-	1	2	2	91
1997	4	10	16	4	3	2	1	1	1	42
1998	-	4	4	6	-	-	2	-	1	17
1999	-	-	-	2	5	2	-	-	1	10
2000	-	-	-	-	3	-	-	2	-	5
2001	-	-	-	-	-	1	-	-	-	1
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	277	240	111	51	32	8	7	8	10	744

Germany

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Germany since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	1	-	-	-	-	-	-	-	1
1988	-	-	-	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	-	-	-	0
1990	1	1	-	-	-	-	-	-	-	2
1991	1	-	-	1	-	-	-	-	-	2
1992	1	1	-	-	-	-	-	-	-	2
1993	-	3	-	-	-	-	-	-	-	3
1994	8	5	-	2	-	-	-	-	-	15
1995	40	32	8	2	1	1	-	-	-	84
1996	67	44	12	8	3	-	-	-	1	135
1997	5	11	13	14	1	-	-	-	-	44
1998	2	8	8	10	5	1	-	-	-	34
1999	-	-	13	18	11	9	3	-	-	54
2000	-	-	-	10	9	5	1	2	1	28
2001	-	-	-	-	2	-	-	-	-	2
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	125	106	54	65	32	16	4	2	2	406

Greece

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Greece since 2001 per birth cohort and year of detection.

Birth cohort	N° of detected BSE cases per year									Total
	2001	2002	2003	2004	2005	2006	2007	2008	2009	
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	-	-	-	0
1995	-	-	-	-	-	-	-	-	-	0
1996	1	-	-	-	-	-	-	-	-	1
1997	-	-	-	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	1	0	0	0	0	0	0	0	0	1

Hungary

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Hungary since 2004 per birth cohort and year of detection.

	N° of detected BSE cases per year						
Birth cohort	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	0
1995	-	-	-	-	-	-	0
1996	-	-	-	-	-	-	0
1997	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	0
Total	0	0	0	0	0	0	0

Ireland

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Ireland since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	2	2	-	1	-	-	-	-	-	5
1987	-	2	-	-	-	-	-	-	-	2
1988	1	4	-	-	-	-	-	-	-	5
1989	2	1	4	3	-	1	-	-	-	11
1990	1	10	3	3	-	-	-	-	-	17
1991	6	10	6	3	1	2	1	-	-	29
1992	8	14	7	12	2	2	-	-	-	45
1993	21	40	25	16	11	1	2	-	-	116
1994	52	51	31	18	25	6	8	6	1	198
1995	110	133	74	43	20	11	7	2	4	404
1996	39	60	30	18	10	11	6	8	-	182
1997	-	5	3	3	-	2	-	2	-	15
1998	-	-	-	4	-	1	1	-	-	6
1999	-	2	-	2	3	-	-	1	-	8
2000	-	-	-	-	3	-	3	-	1	7
2001	-	-	-	-	2	1	-	1	1	5
2002	-	-	-	-	-	-	1	-	1	2
2003	-	-	-	-	-	-	-	2	-	2
2004	-	-	-	-	-	-	-	-	1	1
2005	-	-	-	-	-	-	-	-	-	0
Total	242	334	183	126	77	38	29	22	9	1060

Italy

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Italy since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	1	-	-	-	-	-	-	-	-	1
1988	-	-	2	-	-	-	-	-	-	2
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	-	-	-	0
1991	-	1	-	-	-	-	-	-	-	1
1992	-	-	1	-	1	1	1	-	-	4
1993	2	-	3	-	-	-	-	-	-	5
1994	8	5	1	-	-	-	-	-	-	14
1995	12	10	4	-	-	-	-	-	-	26
1996	20	14	10	4	3	1	-	-	1	53
1997	7	4	9	3	1	1	1	1	-	27
1998	-	2	1	-	-	-	-	-	1	4
1999	-	-	-	1	2	2	-	-	-	5
2000	-	-	-	-	1	1	-	-	-	2
2001	-	-	-	-	-	1	-	-	-	1
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	50	36	31	8	8	7	2	1[1]	2	145

[1] One BSE case diagnosed in 2008 that did not appear in previous EFSA Opinions.

Latvia

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Latvia since 2004 per birth cohort and year of detection.

	N° of detected BSE cases per year						
Birth cohort	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	0
1995	-	-	-	-	-	-	0
1996	-	-	-	-	-	-	0
1997	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	0
Total	0	0	0	0	0	0	0

Lithuania

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Lithuania since 2004 per birth cohort and year of detection.

	N° of detected BSE cases per year						
Birth cohort	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	0
1995	-	-	-	-	-	-	0
1996	-	-	-	-	-	-	0
1997	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	0
Total	0	0	0	0	0	0	0

Luxemburg

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Luxemburg since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	-	-	-	0
1995	-	-	-	-	-	-	-	-	-	0
1996	-	1	-	-	-	-	-	-	-	1
1997	-	-	-	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	-	-	-	0
2001	-	-	-	-	1	-	-	-	-	1
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	0	1	0	0	0	1	0	0	0	2

Malta

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in the Malta since 2004 per birth cohort and year of detection.

	N° of detected BSE cases per year						
Birth cohort	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	0
1995	-	-	-	-	-	-	0
1996	-	-	-	-	-	-	0
1997	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	0
Total	0	0	0	0	0	0	0

Netherlands

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in the Netherlands since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	-	-	-	0
1988	1	-	-	-	-	-	-	-	-	1
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	-	-	-	0
1991	-	-	1	1	-	-	-	-	-	2
1992	1	1	-	-	-	-	-	-	-	2
1993	2	1	-	-	-	-	-	-	-	3
1994	2	2	-	-	-	-	-	-	-	4
1995	4	3	-	-	-	-	-	-	-	7
1996	9	10	10	3	-	-	-	-	-	32
1997	1	4	5	1	-	1	-	-	-	12
1998	-	3	1	1	-	1	-	-	-	6
1999	-	-	1	-	-	-	1	-	-	2
2000	-	-	-	-	2	-	1	1	-	4
2001	-	-	-	-	1	-	-	-	-	1
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	20	24	18	6	3	2	2	1	0	76

Poland

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in the Poland since 2004 per birth cohort and year of detection. Cases presented in *italics* were diagnosed as Atypical BSE.

Birth cohort	N° of detected BSE cases per year						
	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	0
1992	1+*1*	*1*	-	-	-	-	1+*2*
1993	-	-	-	-	-	-	0
1994	1	*1*	1+*1*	-	-	-	2+*2*
1995	*1*	1	1	1+*2*	-	*1*	3+*4*
1996	4	2	2+*1*	-	-	-	8+*1*
1997	-	2	1	-	-	-	3
1998	2	2	1	-	-	-	5
1999	-	4	1	3	2	2	12
2000	1	4	-	1	1	2	9
2001	-	2	1	-	-	-	3
2002	-	1	-	-	-	-	1
2003				1	1	-	2
2004				1	-	-	1
2005	-	-	-	-	1	-	1
Total	9+*2*	18+*2*	8+*2*	7+*2*	5	4+*1*	51+*9*

Portugal

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Portugal since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	1	-	-	-	-	-	-	-	1
1985	-	-	-	-	1	-	-	-	-	1
1986	-	-	-	-	-	-	-	-	-	0
1987	-	1	1	-	-	-	-	-	-	2
1988	-	-	-	-	-	1	-	-	-	1
1989	2	-	1	-	-	-	-	-	-	3
1990	1	-	1	3	2	3	-	-	-	10
1991	-	1	-	1	-	1	-	-	-	3
1992	3	1	4	3	2	-	1	-	-	14
1993	22	11	24	14	8	3	3	3	-	88
1994	38	22	19	13	7	7	2	5	1	114
1995	17	19	12	8	6	1	1	2	3	69
1996	22	19	23	9	7	2	1	3	1	87
1997	5	8	28	23	10	4	2	5	-	85
1998	-	1	18	13	7	8	-	1	-	48
1999	-	2	1	3	2	2	2	1	1	13
2000	-	-	-	1	-	-	-	-	-	1
2001	-	-	-	-	-	-	1	-	-	1
2002	-	-	-	-	1	-	-	-	-	1
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	110	86	132	91	53	32	13	16	6	543

Slovakia

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Slovakia since 2004 per birth cohort and year of detection.

	N° of detected BSE cases per year						
Birth cohort	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	0
1995	1	-	-	-	-	-	1
1996	1	-	-	-	-	-	1
1997	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	0
1999	1	-	-	-	-	-	1
2000	2	3	-	-	-	-	5
2001	2	-	-	2	1	-	5
2002	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	0
Total	7	3	0	2	1	0	13

Slovenia

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Slovenia since 2001 per birth cohort and year of detection.

	N° of detected BSE cases per year									
Birth cohort	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	-	-	-	0
1994	-	-	-	-	-	-	-	-	-	0
1995	1	-	-	-	-	-	-	-	-	1
1996	-	1	-	-	-	-	-	-	-	1
1997	-	-	-	-	-	-	-	-	-	0
1998	-	-	-	1	-	-	-	-	-	1
1999	-	-	1	-	-	-	-	-	-	1
2000	-	-	-	1	1	1	1	-	-	4
2001	-	-	-	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
Total	1	1	1	2	1	1	1	0	0	8

Spain

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Spain since 2001 per birth cohort and year of detection.

Birth cohort	N° of detected BSE cases per year									Total
	2001	2002	2003	2004	2005	2006	2007	2008	2009	
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	1	-	-	-	-	-	-	-	-	1
1987	1	-	1	-	-	-	-	-	-	2
1988	1	1	1	-	-	-	-	-	-	3
1989	1	2	1	-	-	-	1	-	-	5
1990	1	-	1	1	-	-	-	-	1	4
1991	-	-	-	-	-	-	-	1	1	2
1992	1	1	2	1	-	-	1	1	-	7
1993	10	12	6	5	1	1	1	-	2	38
1994	13	9	9	4	3	1	-	1	1	41
1995	22	33	24	9	2	1	3	1	1	96
1996	20	33	34	14	7	4	1	2	-	115
1997	11	28	57	30	14	10	1	3	2	156
1998	-	7	26	49	24	18	7	5	3	139
1999	1	1	4	19	25	17	7	4	3	81
2000	-	-	1	5	26	24	12	3	4	75
2001	-	-	-	-	-	1	-	3	-	4
2002	-	-	-	-	1	-	-	1	-	2
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	83	127	167	137	103	77	34[1]	25[1]	18	771

[1] One BSE case diagnosed in 2007 that did not appear in previous EFSA Opinions plus another extra case in 2008.

Sweden

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in Sweden since 2001 per birth cohort and year of detection.

Birth cohort	N° of detected BSE cases per year									Total
	2001	2002	2003	2004	2005	2006	2007	2008	2009	
1980	-	-	-	-	-	-	-	-	-	0
1981	-	-	-	-	-	-	-	-	-	0
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	-	-	-	-	-	-	-	0
1984	-	-	-	-	-	-	-	-	-	0
1985	-	-	-	-	-	-	-	-	-	0
1986	-	-	-	-	-	-	-	-	-	0
1987	-	-	-	-	-	-	-	-	-	0
1988	-	-	-	-	-	-	-	-	-	0
1989	-	-	-	-	-	-	-	-	-	0
1990	-	-	-	-	-	-	-	-	-	0
1991	-	-	-	-	-	-	-	-	-	0
1992	-	-	-	-	-	-	-	-	-	0
1993	-	-	-	-	-	-	-	-	-	0
1994	-	-	-	-	-	1	-	-	-	1
1995	-	-	-	-	-	-	-	-	-	0
1996	-	-	-	-	-	-	-	-	-	0
1997	-	-	-	-	-	-	-	-	-	0
1998	-	-	-	-	-	-	-	-	-	0
1999	-	-	-	-	-	-	-	-	-	0
2000	-	-	-	-	-	-	-	-	-	0
2001	-	-	-	-	-	-	-	-	-	0
2002	-	-	-	-	-	-	-	-	-	0
2003	-	-	-	-	-	-	-	-	-	0
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	0	0	0	0	0	1	0	0	0	1

United Kingdom

Number of BSE cases detected through the BSE Surveillance (Active and Passive) and the animals culled in the framework of BSE eradication measures in United Kingdom since 2001 per birth cohort and year of detection.

Birth cohort	N° of detected BSE cases per year									Total
	2001	2002	2003	2004	2005	2006	2007	2008	2009	
1980	-	1	-	-	-	-	-	-	-	1
1981	1	-	-	-	-	-	-	-	-	1
1982	-	-	-	-	-	-	-	-	-	0
1983	-	-	1	-	-	-	-	-	-	1
1984	1	2	-	-	-	1	-	-	-	4
1985	1	2	2	-	-	-	-	-	-	5
1986	10	8	3	1	1	-	-	-	-	23
1987	19	26	6	6	6	1	-	1	-	65
1988	17	22	18	6	-	-	-	2	-	65
1989	20	34	14	14	5	4	-	1	-	92
1990	24	42	16	13	6	4	1	1	-	107
1991	58	63	37	21	20	5	-	1	-	205
1992	104	130	69	37	29	12	7	-	1	389
1993	241	160	114	55	33	20	11	4	2	640
1994	362	303	133	72	52	30	16	6	2	976
1995	310	275	138	64	31	23	9	4	1	855
1996	25	37	24	10	6	7	-	8	-	117
1997	9	13	18	4	4	3	1	3	1	56
1998	1	4	14	11	9	3	7	2	-	51
1999	-	1	5	6	12	5	3	3	-	35
2000	-	-	-	2	4	4	3	-	-	13
2001	-	-	-	-	2	4	1	-	-	7
2002	-	-	-	-	1	1	2	3	1	8
2003	-	-	-	-	-	-	-	2	3	5
2004	-	-	-	-	-	-	-	-	-	0
2005	-	-	-	-	-	-	-	-	-	0
Total	1,203	1,123	612	322	221	127	61	41	11	3,721

B. METHODOLOGY USED WHEN PERFORMING THE CALCULATIONS WITH METHOD 3

Introduction

The BSE risk in various risk categories, age-groups and birth cohorts using a general method as described by de Koeijer (2007) was calculated and from that further calculation steps were performed to derive a risk assessment on the requested issues. A summary of the calculation steps is given here, and can be traced back in the Excel worksheet that is provided as an Annex to this Opinion and published in the same web page[23].

The case data for all EU17 are pooled together for the period of active surveillance (2001 through 2008). They are ordered by birth cohort and age (into year groups). All cases where the year of birth or age is unknown and all cases older than 155 months are also excluded because their exact age is often unclear from the statistics and their numbers are extremely low. In a later stage a correction was applied for the cases that are ignored in the modelling by adding a small fraction to the cohort estimates.

By organising the data in birth cohorts it is clear that a selection of ages have been fully tested, whereas other ages were not tested at all. A normalised age at onset distribution of BSE in a cohort (up to 155 months) is used to calculate the fraction of cases that is expected to be found in the part of the cohort that has been tested in the period 2001 through 2008. From that the expected number of cases in the full cohort was estimated, subsequently the maximum number of cases using 95% confidence in a binomial sample was calculated (using an add-on excel function downloadable from http://statpages.org/confint.html) (Clopper and Pearson, 1934) and lastly a finite population correction for large samples was applied (Burstein, 1975). Since annually the number of animals tested is of the order of 10 million animals, relatively small variations in this number make no significant difference to the width of the confidence interval, so the 10 million is applied for the number tested throughout the analysis.

Finally the available data was evaluated to determine the proportion of the cases by age group that are found in the healthy slaughter or at risk categories. This proportion is then applied to evaluate the effect of changing surveillance in the various risk categories.

Two scenarios were applied to calculate the future risk of BSE. All scenarios that are included here are based on worst case assumptions. Various other scenarios have been assessed for sensitivity analysis, but details on those scenarios are not included in the spreadsheet or in the Opinion.

Scenario I: Calculates the upper confidence limit of the incidence in the 2004 birth cohort and assumes all subsequent birth cohorts to have that same incidence. Since the incidence is decreasing significantly in each birth cohort since 1995 this is a worst case assumption.

Scenario II: Estimates the decay rate of the epidemic from the cohort case incidences of the last ten well evaluated birth cohorts (1994-2003) by log-linear regression. The incidence in the 2004 cohort and onwards is projected forward using the upper 95% confidence interval of the 2003 cohort incidence and the upper confidence limit of the decay rate.

23 The file including the spreadsheet with the calculations will be published following publication of this Scientific Opinion.

Underlying assumptions and calculation rules

1) BSE infections occur mostly at a very young age.
2) The derived distribution for the age-at-onset is valid for the whole EU17, and will remain valid after 2008.
3) Uncertainty in the distribution of the age-at-onset is negligible
4) Local and regional variation in the age distribution of cattle population is not correlated with the local/regional BSE incidence.
5) The age distribution of cattle is sufficiently constant over the assessed period
6) All detectable BSE cases in the EU17 between 1 January 2001 and 31 December 2008 have been identified and are included in the applied dataset.
7) Animals from birth cohort of year x and age y will appear in the test years x+y and x+y+1. This depends on whether the test is performed before or after the birthday of the animal in a given year. It is assumed this is to be distributed in equal amounts.

Age at onset distribution

Using the age-at-infection and incubation period distributions from Arnold and Wilesmith (Arnold and Wilesmith, 2004) an age at onset distribution can be derived, which is based on reported case data from Great Britain (GB). A preliminary analysis showed that the age-at-onset distribution derived from the GB epidemic data had a lower mean age-at-onset than the observed data from the EU17, so an age-at-onset distribution from the available EU17 case data was derived. To do so, case data for the birth cohorts of 1994-1999 were used. Only the age categories which were fully tested by the end of 2007 were included. The relative risk of onset for each age category was calculated relative to the 7-year old age-group. Per age group, the average relative risks were determined and subsequently the newly derived age-at-onset distribution was normalized. Thus each of the included birth cohorts had equal weight in the final age-at-onset distribution.

The resulting distribution of the age at onset is given in lines 38 to 40 of each of the Excel worksheets.

Sensitivity analyses

Since the age-at-onset distribution could vary between countries due to, for example, differences in the age distribution of the cattle population, a sensitivity analysis was conducted to compare the applied age-at-onset distribution with the GB age-at-onset distribution (Arnold and Wilesmith, 2004). This is considered to be an extreme distribution, which has a much younger age at onset than found anywhere else, probably as a result of the high exposure during the nineteen eighties. It was found that using the GB age-at-onset distribution leads to 56% increase in the expected case numbers in the younger age categories (<48 months). Obviously it then leads to lower predicted case numbers in the older age categories (6 years and older). The EU17 distribution which was derived from the active surveillance data was considered to be the most suitable one to analyse the EU BSE situation since it reflected the age-at-onset of recent EU cases. Calculating the epidemic decay rate from the number of cases in successive birth cohorts (Scenario II) makes little difference in terms of the number of predicted cases in each birth cohort that each age at onset distribution produces for the next 5 birth cohorts. The Scenario II works with the birth cohort data.

It is assumed that prevalence in subsequent birth cohorts can display a wave over time which is a direct effect of a wave in past exposure. This wave blurs the effect of the extended control measures in 2001, since there are only three cohorts available with sufficient cohort data and the wavelength is a full generation long. Thus a time period of at least a full generation is needed in evaluating the growth rate of the epidemic. The applied log-linear regression overcomes the effect of the wave but necessarily uses so many past birth cohorts that the effect of the extra measures in 2001 averages away in the longer period of less pronounced decline.

It was also checked whether using only the healthy slaughter data in the analysis would lead to the same results as an analysis on the complete data, with the subsequent evaluation of the fraction which would appear in healthy slaughter. As can be expected, the calculations are not very sensitive to this assumption.

References from Appendix B

Arnold ME and Wilesmith JW 2004. Estimation of the age-dependent risk of infection to BSE of dairy cattle in Great Britain. Prev Vet Med 66. 1-4, 35-47.

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