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SCIENTIFIC OPINION

Scientific Opinion on the review on the risk for human and animal health related to the revision of the BSE monitoring regime in three EU Member States [1]

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The Bovine Spongiform Encephalopathy (BSE) monitoring system implemented in the European Union (EU) has been reviewed in this opinion for three EU Member States (MSs): Czech Republic, Poland and Slovakia. These three MSs have been already considered in a recent revision of the BSE monitoring regime in EU MSs done in 2010. However, in that revision the full assessment of these 3 MSs was not possible due to data limitations. In the current revision, updated data from the years 2004 to 2010 (i.e. one further year of BSE monitoring data compared to the former assessment) on BSE monitoring in cattle from these three MSs had been considered. Key assumptions made for this review 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 BSE controls, and (iii) perfect sensitivity of the rapid tests employed for BSE monitoring. Two methodologies were applied in order to assess the trend of the Classical BSE epidemic and to estimate its future trend, based on the number of cases per birth cohort that may be observed in the future. 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. The application of these methodologies, in particular the second one, provided an estimate of the number of BSE cases that would be missed in these three MSs as a group under a theoretical increase in the current age for BSE testing in the healthy slaughtered and at risk cattle testing groups. Recommendations were made in order to overcome limitations encountered during the analysis, 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, Czech Republic, Poland, Slovakia.

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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 review of the risk for human and animal health related to the revision of the BSE monitoring regime in Czech Republic, Poland and Slovakia. In particular, the BIOHAZ Panel was asked to reassess the BSE epidemiological situation of these three MSs, grouped and individually, and to updated if justified the conclusions and recommendations of the former Opinion.

The BIOHAZ Panel adopted on 9 December 2010 an Opinion[4] related to the revision of the BSE monitoring regime in a number of EU MSs[5]. Following this, the Commission provided EFSA with corrected and new (i.e. for the year 2010) BSE monitoring data for three of the MSs in that group, the Czech Republic, Poland and Slovakia, which are the MSs subjected to the current assessment. It has to be noted that it is not attempted in this Opinion to merge or assess the BSE monitoring regime of these three MSs together with the group of MSs assessed in the previous Opinion. In order to do so, validated data from 2010 for all the MSs should be considered, but it was not available at the time of the current assessment.

The same general considerations and methodology applied in previous related EFSA Opinions[6] 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 (called Method 1), (ii) while the other looks at the number of cases in successive annual birth cohorts (called Method 3). 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, 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 the three 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 three 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 concluded that the average age of detected BSE cases in EU3 from 2004 to 2010 is lower (between 5.8 and 11 excluding Atypical BSE cases) than the age of BSE cases detected in EU17 between 2001-2009 (between 9.1 and 12.4). However, in 2009 and 2010 an increase in the age of detected cases (excluding Atypical BSE cases) was observed in the three EU MSs compared to

[4] EFSA Panel on Biological Hazards (BIOHAZ), 2010; 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. EFSA Journal 2010;8(12):1946. [39 pp.] doi:10.2903/j.efsa.2010.1946. Available online: www.efsa.europa.eu/efsajournal.htm

[5] These were: Austria, Belgium, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and United Kingdom.

[6] 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.

2008. Furthermore, this delayed increase in the age of cases in the EU3 when comparing with the EU17 has to be considered in perspective with the very small number of cases and the full implementation of the EU BSE control measures in the EU3 at a later date (i.e. 2004) as compared to the EU17 (i.e. 2001).

The Panel also concluded that with the additional data of a further year of monitoring results (i.e. 2010), the model employed shows that the confidence in the predictions of the number of cases in the cohorts since 2000 for the EU3 has increased substantially. Due to this and based on the results of the analysis performed with Method 3, the decline of the Classical BSE epidemic is significant in the EU3.

Thus, based on the model[7] 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 (considered as the "**worst case**" scenario), and considering the situation where by the age limit for Classical BSE testing would be raised above 30 months in healthy slaughtered and above 24 months in at risk cattle, results show that: (a) in healthy slaughtered animals aged respectively up to 48, 60, 72, 84 or 96 months, less than one, one, two, two or two cases per each of the respective age limits can be expected to be missed annually in EU3 by an active surveillance system that uses currently approved rapid BSE tests; (b) in at risk animals aged respectively up to 30, 48, 60, 72 or 84 months, less than one, one, one, two or three cases per each of the respective age limits can be expected to be missed annually in EU3 by an active surveillance system that uses currently approved rapid BSE tests. Under a "**more realistic**" scenario, which assumes a declining Classical BSE trend, results show that (a) in healthy slaughtered animals aged respectively 48, 60, 72, 84 or 96 months, less than one, one, one, two or two cases per each of the respective age limits can be expected to be missed in 2012; (b) in at risk animals aged respectively 30, 48, 60, 72 or 84 months, less than one, one, one, two or two cases per each of the respective age limits can be expected to be missed in 2012. In this second scenario, after 2012 and with the hypothesis that Classical BSE would continue to decline, a yearly decline in the number of cases should be observed. 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. The Panel also highlighted that since validated data including those for 2010 have not been provided for the other EU MSs considered in the previous Scientific Opinion[8], the impact of the new data from the EU3 on a collective assessment of all EU Member States regarding the revision of the BSE monitoring regime can not be determined, in particular with regards to the estimated final number of undetected cases

The BIOHAZ Panel recommended that in order to monitor the trend of the Classical BSE epidemic and the trend in the age of the cases observed in these three MSs, the results of future testing years should be evaluated. The Panel also recommended that any future modification of the monitoring system should not compromise the capacity of the system to monitor these trends. Finally, key recommendations made in previous related Opinions do remain valid.

[7] A spreadsheet with the calculations done is published separately in the same web page of this Scientific Opinion.

[8] These were: Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Portugal, Slovenia, Spain, Sweden and United Kingdom.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

On 9 December 2010 EFSA adopted 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[9].

One of the conclusions of this Opinion is that "*the trend of the Classical BSE epidemic in the group of 3 Member States 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*[10] *and in this group of 3 Member States. 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 Member States.*"

Furthermore, for these 3 Member States (Czech Republic, Slovakia and Poland), the Opinion recommends "*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*".

Since the adoption of the Opinion, Czech Republic and Poland have informed the Commission that the numbers of BSE cases detected in their countries in 2007 and 2009 have to be corrected. Furthermore, BSE monitoring for the whole year 2010 are now available for those three Member States.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

Taking into account the corrected number of BSE cases in the two Member States and the full BSE surveillance data for 2010 for all the three Member States, EFSA is invited:

- To reassess the BSE epidemiological situation as regards Czech Republic, Slovakia and Poland grouped and individually,
- To update, if justified, the conclusions and recommendations of the Opinion adopted on 9 December 2010.

Clarifications of the Terms of Reference:

Following discussions with the Commission, it was further clarified that the scenarios to be assessed relate only to the raising of the age limit for BSE testing (when possible at 12 months intervals) above 30 months for healthy slaughtered cattle and above 24 months for at risk cattle.

[9] EFSA Journal 2010:8(12):1946 [74 pp.] doi:10.2903/j.efsa.2010.1946

[10] 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.

ASSESSMENT

1. Introduction

This Scientific Opinion follows the previous EFSA Opinion adopted by the BIOHAZ Panel on a similar subject on December 2010 (EFSA, 2010), where the BSE monitoring regime was assessed for a number of EU MSs (i.e. Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovenia, Slovakia, Spain, Sweden and United Kingdom) and three previously related ones (EFSA, 2008a, 2008b, 2009). The same general considerations and methodology applied in those are used in this assessment. In particular, the current Opinion has to be read together with the first one and the last one (EFSA, 2008a, 2010) in order to understand both the approach and methodology employed.

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

- By EU3 it is understood the group of EU MSs composed by: Czech Republic, Poland and Slovakia. These are the three 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 (EC, 2001)for at least 6 years. In the case of these 3 MSs that is since 1st May 2004 (EFSA, 2010). However, for practical reasons and in order to be consistent with the previous EFSA Opinion BSE data are considered for the analysis since 1st January 2004.

- 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.

- 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).

In this Opinion it is not attempted to merge or assess the BSE monitoring regime of the EU3 together with all the MSss assessed in the previous Opinion(EFSA, 2010). In order to do so, validated data from 2010 for all the MSs should be considered, but it was not available at the time of the current assessment.

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

Data sources as described below have been employed for the analysis presented in this Opinion. It has to be noted that these data were validated with contact points provided by the European Commission for the 3 MSs between 23rd March and 12th April 2011. It is assumed that the data validated by the MSs are the most up to date and correct one.

- Data are considered since 1st January 2004[11]. Data on BSE cases detected in the EU employed in the assessments presented herewith was received from the European Commission (EC) on 10 March 2011. Corrections to these dataset were received from all 3 MSs. The validated data employed in the assessment done in this Opinion are presented in Appendices A and B.

- 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 10 March 2011. Corrections to these dataset were received from all 3 MSs.

- Data on the adult bovine population (over 24 months of age) in the MSs considered in this Opinion were retrieved from EUROSTAT[12] on 23 March 2011. Corrections to cattle population datasets were received from Czech Republic and Slovakia.

Small differences will be found between data presented in this Opinion and that of related previous Opinion (EFSA, 2010). This is due to:

- Corrections made by the MSs on the details of the reported BSE cases done when validating data submitted to the European Commission.

- Updates in the EUROSTAT database used to retrieve number of cattle over 24 months of age in the EU3.

As per previous EFSA Opinions dealing with similar requests (EFSA, 2008a, 2008b, 2009, 2010), three are the 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 3 EU MSs considered for this mandate have implemented a BSE surveillance system and control measures as set out in the Regulation (EC) 999/2001 (as amended) 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 3 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 and 2010) were used to analyze the trend of the BSE infection in the EU3. 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 in several studies published in peer-reviewed scientific journals (Ducrot et al., 2008; Saegerman et al., 2005; Saegerman et al., 2006).

[11] When applicable, the number of BSE cases diagnosed before 1st May 2004 in the MSs of the EU3 group is addressed in relevant tables.

[12] EUROSTAT data available at: http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home – Database 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)

- **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. Detailed explanation on this method is presented in Appendix C.

  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 EU3. This can be considered a **"worst case"** scenario for EU3.

  - **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 EU3 for cohorts since 2004 based on the decline of the cohort incidence in previous cohorts calculated by log-linear regression.

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.

The evaluation of the epidemiological situation of the three MSs with Method 1, as presented in the following section, did not suggest that any of them has a different epidemiological situation that would affect the analysis. Therefore, the three MSs can be assessed as a unique group.

Nevertheless, there are three considerations that have to be taken into account when considering the grouping of these 3 MSs:

- The statistical power of the results employing Method 3 would be compromised if the MSs data would be analysed separately, in particular for Czech Republic and Slovakia;

- Poland has detected a number of Atypical BSE cases. These Atypical BSE cases do not affect the analysis under Method 3, since these calculations and forward predictions are mostly influenced by information from the more recent birth cohorts, while the atypical BSE cases found, are all very old and thus belong to much older birth cohorts. However, Atypical BSE cases affect the results done with Method 1. For this reason, the analysis done under Method 1 was undertaken with data both including and excluding Atypical BSE cases in order to reflect the impact of these;

- There might be differences between the three MSs in the demographic structure of the cattle populations. The impact of these differences has not been assessed due to time and data limitations.

Like for all modelling exercises, the validity of the results presented in this Scientific Opinion relies on the validity of the data provided to the BIOHAZ Panel.

3. Results of the assessment of the BSE monitoring regime in the EU3

3.1. Assessment of the Active BSE monitoring programme per testing group and age category during the period 2004 to 2010

For background information, current BSE testing age is carried out in the EU in line with ages as presented in Table 1.

Table 1: BSE testing ages for bovine animals during 2010 in the EU3.

	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		
Testing age	> 30	> 24	> 24	> 24	NAL[1]	NAL

[1]NAL=No age limit

Results are presented both including and excluding Atypical BSE cases. Out of the MSs of the EU3 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 7 years in the EU3. Table 2 shows the prevalence of BSE cases (per 10,000 animals) in the EU3 found through active surveillance. It has to be noted that no cases have been identified thought passive surveillance in the EU3.

Table 2: Prevalence (number of BSE cases per 10,000 animals tested) of BSE in the EU3 for active surveillance from 2004 to 2010. Please note that cases from eradication measures are not considered in either type of surveillance (3 cases in 2005).

	Year of testing						
	2004	2005	2006	2007	2008	2009	2010
Including Atypical BSE[1]	0.33	0.37	0.15	0.16	0.07	0.07	0.04
Excluding Atypical BSE	0.30	0.34	0.13	0.13	0.07	0.06	0.04

[1]The 9 Atypical BSE cases identified since 2004 were all reported in Poland

When comparing the prevalence in the EU3 for the period 2004 to 2010 with the prevalence in the EU17 for the period 2001 to 2006 (i.e. first six years of the implementation of the total feed ban), it can be noticed that the yearly prevalence in the EU3 is in the range of approximately 4 to 9 times lower than that of the EU17 as presented in the previous EFSA Opinion (EFSA, 2010).

In the EU 3 group, more than 5.6 million tests have been carried out in the framework of BSE Active Surveillance since 1st January 2004. Of these, 94 animals were found positive, including 9 Atypical BSE cases detected in Poland. These included 62 (6 Atypical BSE cases in Poland) out of 4,887,033

healthy slaughtered cattle tested (0.13 per ten thousand healthy slaughtered cattle tested), and 32 (3 Atypical BSE cases in Poland) out of 800,415 at risk cattle tested (0.4 per ten thousand at risk cattle tested). In the framework of BSE Passive Surveillance in EU3 during the period 2004 – 2010 a total of 160 bovine animals were tested and none was positive. Three positive animals have been diagnosed in the frame of testing under eradication measures.

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 2010 data per target group are reported in Table 3.

Table 3: Number of BSE cases (including Atypical BSE cases) detected through the BSE Active and Passive Surveillance in EU3 during the period 2004 – 2010 per target group.

Target Group	**N° of detected BSE cases per year**							
Active Surveillance	2004	2005	2006	2007	2008	2009	2010	**Total**
Healthy slaughtered	15	18	9	9	4	5	2	62
At risk animals								
Emergency slaughter	5	2	0	1	2	0	0	10
Fallen stock	5	7	4	3	0	1	1	21
Presenting Clinical signs at ante mortem inspection	0	1	0	0	0	0	0	1
Total Active Surveillance	25	28	13	13	6	6	3	94
Passive Surveillance								0
Suspects subject to lab	0	0	0	0	0	0	0	0
Eradication Measures	0	3	0	0	0	0	0	3
Grand Total	25	31	13	13	6	6	3	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 EU3 between 2004 and 2010 data per target group are reported in Table 4.

Table 4: Number of BSE cases (excluding Atypical BSE cases) detected through the BSE Active and Passive Surveillance in EU3 during the period 2004 – 2010 per target group.

Target Group	**N° of detected BSE cases per year**							
Active Surveillance	2004[1]	2005	2006	2007	2008	2009	2010	**Total**
Healthy slaughtered	14	17	7	8	4	4	2	56
At risk animals								
Emergency slaughter	4	2	0	1	2	0	0	9
Fallen stock	5	6	4	2	0	1	1	19
Presenting Clinical signs at ante mortem inspection	0	1	0	0	0	0	0	1
Total Active Surveillance	23	26	11	11	6	5	3	85
Passive Surveillance								
Suspects subject to lab	0	0	0	0	0	0	0	0
Eradication Measures	0	3	0	0	0	0	0	3
Grand Total	23	29	11	11	6	5	3	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 – 2010 per birth cohort and year of detection, including Atypical BSE cases, is reported in Table 5.

Table 5: 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 2004 – 2010 per birth cohort and year of detection.

	N° of detected BSE cases per year							
Birth Cohort	2004	2005	2006	2007	2008	2009	2010	**Total**
1992	2	1	-	-	-	-	-	3
1994	1	1	2	-	-	-	-	4
1995	3	1	1	3	-	1	1	10
1996	5	2	3	1	-	-	-	11
1997	2	2	1	-	-	-	-	5
1998	3	2	1	1	-	-	-	7
1999	2	5	2	3	2	2	-	16
2000	5	13	2	1	1	1	1	24
2001	2	3	1	2	1	-	-	9
2002	-	1	-	-	-	-	1	2
2003	-	-	-	1	1	1	-	3
2004	-	-	-	1		1	-	2
2005	-	-	-	-	1	-	-	1
Total	25	31	13	13	6	6	3	97

[1] In 2004, seven cases were diagnosed before 1st May.
- = No cases

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 – 2010 per birth cohort and year of detection, excluding Atypical BSE cases, is reported in Table 6.

Table 6: 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 2004 – 2010 per birth cohort and year of detection.

	N° of detected BSE cases per year							
Birth Cohort	2004[1]	2005	2006	2007	2008	2009	2010	**Total**
1992	1	-	-	-	-	-	-	1
1994	1	-	1	-	-	-	-	2
1995	2	1	1	1	-	-	1	6
1996	5	2	2	1	-	-	-	10
1997	2	2	1	-	-	-	-	5
1998	3	2	1	1	-	-	-	7
1999	2	5	2	3	2	2	-	16
2000	5	13	2	1	1	1	1	24
2001	2	3	1	2	1	-	-	9
2002	-	1	-	-	-	-	1	2
2003	-	-	-	1	1	1	-	3
2004	-	-	-	1	-	1	-	2
2005	-	-	-	-	1	-	-	1
Total	23	29	11	11	6	5	3	88

[1] In 2004, seven cases were diagnosed before 1st May.
- = No cases

The number of BSE cases in the individual MSs detected through the BSE Surveillance (Active and Passive) and the culling of animals in the framework of BSE eradication measures during the period 2004 to 2010, arranged by birth cohort and year of detection is provided in Appendix C.

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.
- In the EU3 over the period 2004 to 2010 the prevalence of BSE was lower than in the EU17 over the period 2001 to 2006 (i.e. first six years of the implementation of the total EU feed ban).
- The number of BSE cases has gone down from 31 in 2005 (peak) to 3 in 2010. The EU3 are all new EU MSs since 1 May 2004, since when the full EU total feed ban has been implemented in these MSs. In the EU3 a total of 17 cases have been born since 2001, and 3 cases are born after 30th April 2004.

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

This assessment is done employing Method 1 and Method 3, as described in section 2.

3.2.1. Calculations based on Method 1

The number of BSE cases, the BSE incidence per million cattle over 24 months of age and the average age of cases per year of detection in the EU3 MSs, considering both BSE Active and Passive Surveillance and the animals culled in the framework of BSE eradication measures, are shown in Table 7. As per the previous related EFSA Opinions, the calculation of the average ages presented in this Opinion was based on the average age calculated by the deduction of the year of birth from the year of testing in the BSE case based on data validated by the MSs. The results were rounded up to the next decimal value.

Table 7: Number of BSE cases, incidence per million cattle over 24 months and average age in years of cases during the period 2004 – 2010 per year of detection in the EU3 MSS (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							Total
		2004[1]	2005	2006	2007	2008	2009	2010	
Czech Republic	N° cases	7	8	3	2	0	2	0	22
	Incidence	9.9	11.7	4.4	3.0	0	3.0	0	
	Average age	5.9	5.0	6.3	10.0	NA	5.5	NA	
Poland	N° cases INC	11	20	10	9	5	4	2	61
	N° cases EXC	9	18	8	7	5	3	2	52
	Incidence INC	3.6	6.5	3.3	3.0	1.6	1.3	0.7	
	Average age INC	8.3	6.9	9.4	8.2	6.8	10.8	12.5	
	Average age EXC	7.8	6.3	9.0	7.1	6.8	9.7	12.5	
Slovakia	N° cases	7	3	0	2	1	0	1	14
	Incidence	24.2	10.5	0	7.2	3.7	0	3.9	
	Average age	5.3	5.0	NA	6.0	7.0	NA	8.0	
EU3	N° cases INC	25	31	13	13	6	6	3	97
	N° cases EXC	23	29	11	11	6	5	3	88
	Incidence INC	6.2	7.6	3.3	3.3	1.5	1.5	0.8	
	Average age INC	6.8	6.2	8.7	8.2	6.8	9.0	11.0	
	Average age EXC	6.4	5.8	8.3	7.5	6.8	8.0	11.0	

[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 was calculated employing the updated data and was compared to that previously submitted and presented in the former EFSA Opinion (EFSA, 2010). This considers both BSE Active and Passive Surveillance and the culling of animals in the framework of BSE eradication measures, as shown in Figure 1 (including Atypical BSE cases) and Figure 2 (excluding Atypical BSE cases).

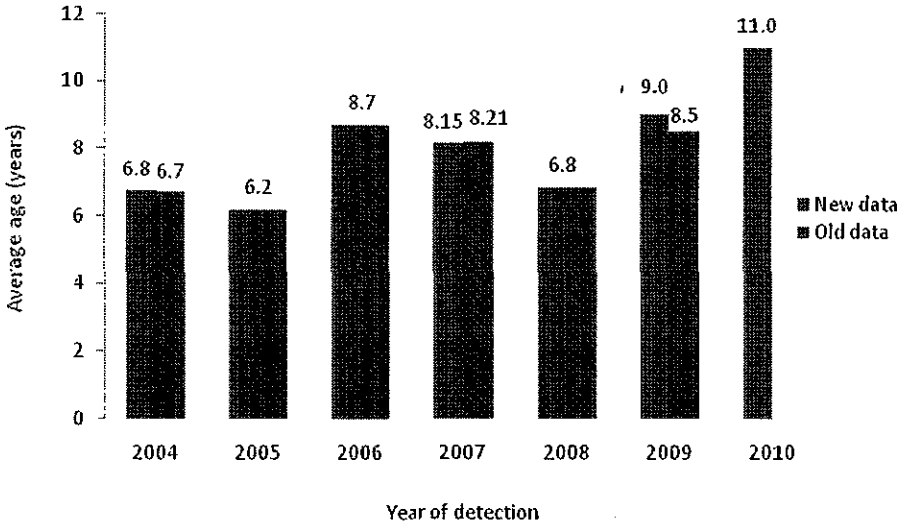

Figure 1: Comparison of the average age (in years) of BSE cases (including Atypical cases) presented in the previous EFSA Opinion (EFSA, 2010) and the results employing updated data. Results are presented per year of detection in the EU3 between 2004 and 2010, considering both BSE Active and Passive Surveillance and the culling of animals in the framework of BSE eradication measures.

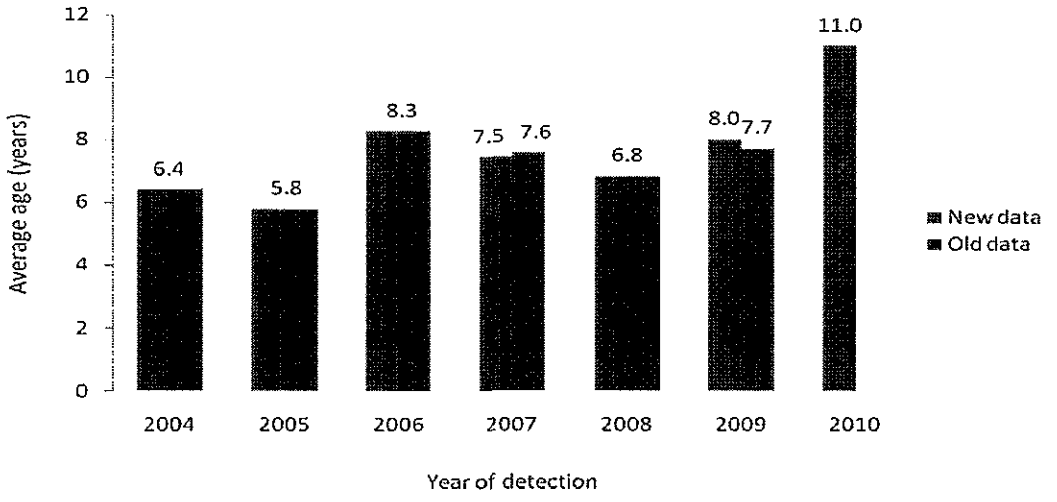

Figure 2: Comparison of the average age (in years) of BSE cases (excluding Atypical cases) presented in the previous EFSA Opinion (EFSA, 2010) and the results employing updated data. Results are presented per year of detection in the EU3 between 2004 and 2010, considering both BSE Active and Passive Surveillance and the culling of animals in the framework of BSE eradication measures.

The trend in the average age at the MS level, excluding reported Atypical BSE cases, is presented in Figure 3. It has to be noted that this Figure has to be read together with the number of cases as presented in Table 7.

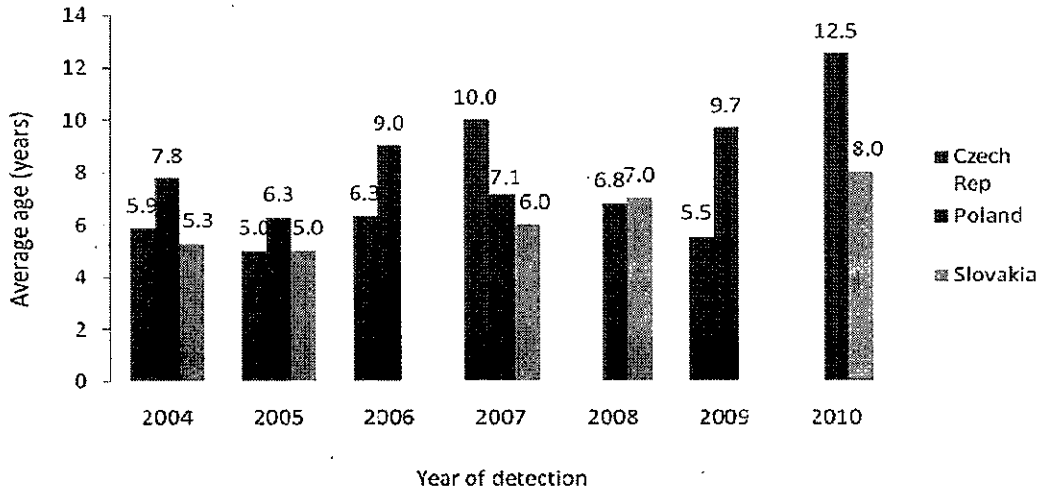

Figure 3: Average age of the BSE cases (excluding reported Atypical BSE cases) detected between 2004 and 2010 in the Czech Republic, Poland and Slovakia. Actual number of BSE cases can be found in Table 7.

The increase in the age of the BSE cases in the EU3 is delayed when compared with the trend observed in the group of 17 MSs evaluated in the former EFSA Opinion (EFSA, 2010). However, this has to be considered inform the perspective with the very small number of cases and with the full implementation of the EU BSE control measures in the EU3 at a later date (i.e. 2004) as compared to the EU17[13] (i.e. 2001).

3.2.1.1. Concluding remarks from calculations based on Method 1.

- The average age of detected BSE cases in EU3 as a group from 2004 to 2010 is lower (between 5.8 and 11 years, excluding Atypical BSE cases) than the age of BSE cases detected in EU17 from 2001 to 2009 (between 9.1 and 12.4 years, see EFSA 2010). However, in 2009 and 2010 an increase in the age of detected cases (excluding Atypical BSE cases) was observed in the EU3 compared to 2008.

- The delayed increase in the age of cases in the EU3 when comparing with the EU17 has to be considered form the perspective of the very small number of cases and the full implementation of the EU BSE control measures in the EU3 at a later date (i.e. 2004) as compared to the EU17 (i.e. 2001).

- Any future modification of the monitoring regime should not compromise the capacity of the system to monitor the trend in the age of the cases detected.

[13] As per the previous related Opinions, it is assumed that all the EU17 MSs have full implementation of the EU BSE control measures since 2001.

- In order to monitor the trend of the Classical BSE epidemic and the trend in the age of the cases observed in the EU3 MSs, the results of future testing years should be evaluated.

3.2.2. Calculations based on Method 3.

A detailed description of the methodology employed for Method 3 can be found in Appendix C.

In the former EFSA Opinion (EFSA, 2010), it was concluded that for Method 3:

> *"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".*

It was further 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".*

With the additional data of a further year of monitoring results (i.e. 2010), the significance of the predictions of the number of cases in the cohorts since 2000 for the EU3 has increased substantially. Due to this, it is now apparent that the decline of the epidemic is significant ($p<0.05$) despite the wave pattern that can also be observed. This can be seen in the results of the calculations under Method 3, Scenario 2. The 95% confidence interval of the estimated annual decline is consistently above zero, (eg > 0.174), so it can be concluded that the Classical BSE epidemic is declining in these three MSs, assuming constant level of BSE control measures since 2004. Results on the estimation of the expected number of BSE cases per birth cohort in the EU 3 are presented in Table 8, including upper 95% confidence interval.

Table 8: Estimation of the expected number of BSE cases per birth cohort in the EU3 based on the age at onset distribution based on calculations performed under Method 3, Scenario II. Further details on methodology presented in Appendix C.

Birth cohort	Total observed cases	Fraction of the distribution of expected cases already tested	Expected number of cases	Upper 95% CI
1995	8	0.11	73.89	NA
1996	11	0.22	52.28	NA
1997	5	0.40	12.74	NA
1998	7	0.66	10.99	NA
1999	16	0.87	18.99	NA
2000	24	0.95	26.18	29
2001	9	0.93	9.94	12
2002	2	0.89	2.32	5
2003	3	0.78	3.95	7
2004	2	0.60	3.47	9
2005	1	0.34	3.05	13

NA=No applicable. CI calculated for birth cohorts after 2000 only.

It has to be noted that since validated data, including those for 2010, have not been provided for the other EU MSs considered in the previous Scientific Opinion[14], the impact of the new data from the EU3 on a collective assessment of all EU Member States regarding the revision of the BSE monitoring regime can not be determined, in particular with regards to the estimated final number of undetected cases.

A spreadsheet with the calculations used when performing Method 3 is provided and published separately in the same web page as this Opinion.

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 2010.

The expected total number of detected BSE cases in the EU3 (based on upper 95% confidence limit for birth cohorts since 2004) by calendar year and age category in this scenario is provided in Table 9, which considers all the 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 EU3 (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.

	Age category (months)										
Year	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2012	0	0.08	0.19	1.50	2.53	2.09	1.29	0.54	0.20	0.38	8.81
2013	0	0.08	0.19	1.50	2.53	2.09	1.29	0.61	0.27	0.27	8.81
2014	0	0.04	0.19	1.50	2.53	2.09	1.29	0.61	0.30	0.36	8.81

The expected number of BSE cases detected in the EU3 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 10.

Table 10: Expected number of BSE cases detected in the healthy slaughter stream in the EU3 (based on upper 95% confidence limit for birth cohorts since 2004) by calendar year and age category (in months) in Scenario I.

	Age category (months)										
Year	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2012	0	0.03	0.04	0.52	0.69	0.41	0.25	0.08	0.02	0.04	2.08
2013	0	0.03	0.04	0.52	0.69	0.41	0.25	0.09	0.03	0.03	2.08
2014	0	0.01	0.04	0.52	0.69	0.41	0.25	0.09	0.03	0.04	2.08

Thus, based on Scenario I in healthy slaughtered animals aged respectively up to 48, 60, 72, 84 or 96 months, less than one, one, two, two or two cases per each of the respective age limits can be

[14] These are: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovenia, Slovakia, Spain, Sweden and United Kingdom.

expected to be detected annually in EU3 by an active surveillance system that uses currently approved rapid BSE tests.

The expected number of BSE cases in the EU3 detected in the at risk testing 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 11.

Table 11: Expected number of BSE cases detected in the at risk group in the EU3 (based on upper 95% confidence limit for birth cohorts since 2004) by calendar year and age category (in months) in Scenario I.

	Age category (months)										
Year	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2012	0	0.06	0.11	0.73	1.00	0.85	0.57	0.29	0.12	0.26	3.98
2013	0	0.06	0.11	0.73	1.00	0.85	0.57	0.32	0.15	0.18	3.98
2014	0	0.03	0.11	0.73	1.00	0.85	0.57	0.32	0.17	0.24	4.03

Thus, based on Scenario I in at risk animals aged respectively up to 30, 48, 60, 72 or 84 months, less than one, one, one, two or three cases per each of the respective age limits can be expected to be detected annually in EU3 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 EU3 (based on upper 95% confidence limit for constant trend of reduction by birth cohorts over the period 1995 to 2004) by calendar year and age category in this scenario is provided in Table 12, which considers all possible testing streams: healthy slaughter, at risk and eradication measures. Tables 13 and 14 present results for the healthy and at risk groups, respectively.

Table 12: Expected total number of BSE cases in the EU3 (based on the extrapolation of the upper 95% confidence limit for the trend over the period 1995 to 2004, 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.

	Age category (months)										
Year	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2012	0	0.04	0.10	0.92	1.83	1.74	1.22	0.54	0.20	0.38	6.96
2013	0	0.03	0.09	0.75	1.55	1.51	1.08	0.57	0.27	0.27	6.11
2014	0	0.03	0.08	0.67	1.27	1.27	0.93	0.50	0.29	0.36	5.39

The expected number of BSE cases detected in the EU3 healthy slaughter stream (based on upper 95% confidence limit for constant trend of reduction by birth cohorts over the period 1995 to 2004) by calendar year and age category in this scenario is provided in Table 13.

Table 13: Expected number of BSE cases detected in the EU3 in the healthy slaughter stream (based on the extrapolation of the upper 95% confidence limit for the trend over the period 1995 to 2004, from 2004 onwards) by calendar year and age category (in months) in Scenario II.

	Age category (months)										
Year	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2012	0	0.01	0.02	0.32	0.50	0.34	0.23	0.08	0.02	0.05	1.57
2013	0	0.01	0.02	0.26	0.42	0.29	0.21	0.09	0.03	0.04	1.36
2014	0	0.01	0.01	0.23	0.34	0.25	0.18	0.08	0.03	0.05	1.18

Thus, based on Scenario II in healthy slaughtered animals aged respectively up to 48, 60, 72, 84 or 96 months, less than one, one, one, two or two cases per each of the respective age limits can be expected to be detected in 2012. 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 EU3 in the at risk stream (based on upper 95% confidence limit for constant trend of reduction by birth cohorts over the period 1995 to 2004) by calendar year and age category in this scenario is provided in Table 14.

Table 14: Expected number of BSE cases detected in the EU3 in the at risk stream (based on the extrapolation of the upper 95% confidence limit for the trend over the period 1995 to 2004, from 2004 onwards) by calendar year and age category (in months) in Scenario II.

	Age category (months)										
Year	24-29	30-35	36-47	48-59	60-71	72-83	84-95	96-107	108-119	120 and older	**Total**
2012	0	0.02	0.05	0.45	0.72	0.71	0.54	0.29	0.12	0.24	3.14
2013	0	0.02	0.05	0.37	0.61	0.61	0.48	0.30	0.15	0.17	2.76
2014	0	0.02	0.04	0.33	0.50	0.52	0.41	0.27	0.16	0.22	2.47

Thus, based on Scenario II in at risk animals aged respectively up to 30, 48, 60, 72 or 84 months, less than one, one, one, two or two cases per each of the respective age limits can be expected to be detected in 2012. 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. Concluding remarks from calculations based on Method 3

- These conclusions apply in the context of the continuous decrease of the BSE epidemic in the EU3 and the continuation of the BSE control measures currently in place.
- With the additional data of a further year of surveillance results (i.e. 2010), the significance of the predictions of the number of cases in the cohorts since 2000 for the EU3 has increased substantially. Due to this, it is now apparent that there is a constant decline of the epidemic, as calculated under Method 3, Scenario 2.
- According to Scenario I:
    - In healthy slaughtered animals aged respectively up to 48, 60, 72, 84 or 96 months, less than one, one, two, two or two cases per each of the respective age limits can be expected to be detected annually in EU3 by an active surveillance system that uses currently approved rapid BSE tests.

- In at risk animals aged respectively up to 30, 48, 60, 72 or 84 months, less than one, one, one, two or three cases per each of the respective age limits can be expected to be detected annually in EU3 by an active surveillance system that uses currently approved rapid BSE tests.

According to Scenario II:

- In healthy slaughtered animals aged respectively up to 48, 60, 72, 84 or 96 months, less than one, one, one, two or two cases per each of the respective age limits can be expected to be detected in 2012. 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 up to 30, 48, 60, 72 or 84 months, less than one, one, one, two or two cases per each of the respective age limits can be expected to be detected in 2012. After this date and with the hypothesis that Classical BSE continue to decline, a yearly decline in the number of cases should be observed.

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.

It has to be noted that since validated data, including those for 2010, have not been provided for the other EU MSs considered in the previous Scientific Opinion[15], the impact of the new data from the EU3 on a collective assessment of all EU Member States regarding the revision of the BSE monitoring regime can not be determined, in particular with regards to the estimated final number of undetected cases.

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.

Finally, in order to confirm both the trend of the Classical BSE epidemic and the trend in the age of the cases observed in the EU3 MSs the results of future testing years should be evaluated. Any future modification of the monitoring system should not compromise the capacity of the system to monitor these trends.

4. Considerations on Atypical BSE

Considerations on Atypical BSE have been reviewed in the previous EFSA Opinion (EFSA, 2010).

Systematic testing of cattle over 30 months of age for abnormal PrP^C has allowed the identification of two new and distinct types of cattle TSE, termed H- and L- (or BASE) type BSE (or H-BSE and L-BSE), in a number of European countries (Casalone et al., 2004; Ducrot et al., 2008; Jacobs et al., 2007; Stack et al., 2009; Terry et al., 2007). Similar cases were also detected outside Europe (Japan and USA) (Clawson et al., 2008; Hagiwara et al., 2007).

In France a retrospective study of all the TSE-positive cattle identified through the compulsory EU surveillance programme between 2001-2007 was performed (Biacabe et al., 2008).

[15] These were: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovenia, Slovakia, Spain, Sweden and United Kingdom.

This study indicated that:

- All H-BSE and L-BSE cases detected by rapid tests were observed in animals over 8 years old in either the fallen stock surveillance stream or the abattoir (healthy slaughter) stream.
- No H-BSE and L-BSE were observed in the passive epidemio-surveillance network although, during retrospective interviews, the farmers and veterinarians for 6 of these animals reported clinical signs consistent with TSE in 3 fallen stock.
- Incidence of H and L type TSE is respectively 1.9 and 1.7 cases per million of over 8 years old tested animals.

Interestingly the number of Atypical BSE cases detected in countries that have already identified them seems to be comparable from year to year. However, since the performances of the currently available rapid test applied for initial TSE screening into cattle population towards Atypical BSE is still unknown (EFSA, 2010), no reliable estimate of the prevalence of Atypical BSE cases in the EU can be currently provided.

The origin of Atypical TSE cases in cattle is currently unknown. All EU Atypical BSE cases identified so far were born before the extended or real feed ban that came into law in January 2001 (Ducrot et al., 2008). Hence, as with the Classical type of BSE (C-BSE), exposure of these animals to feed contaminated with low titres of TSE cannot be excluded. However other origin for this TSE forms cannot be discarded. In particular, the unusually old age of all H- and L-type BSE identified cases and their apparent low prevalence in the population, could suggest that these Atypical BSE forms are arising spontaneously.

The uncertainties on the origin, contagiousness, and zoonotic potential of atypical BSE cases were highlighted recently in a joint EFSA-ECDC (European Centre for Disease Control and Prevention) Scientific Opinion (EFSA, 2011). Further monitoring of TSEs in cattle to investigate trends in the prevalence or age at detection of Atypical BSE cases is needed to help assess their risk to humans, and this especially applies to the situation in Poland with its relatively high number of Atypical BSE cases (see Appendix B and Table 7) and its ageing cattle population (see Table 2 in Appendix A).

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.

It should be considered 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 average age of detected BSE cases in EU3 from 2004 to 2010 is lower (between 5.8 and 11 years, excluding Atypical BSE cases) than the age of BSE cases detected in EU17 between 2001-2009 (between 9.1 and 12.4 years). However, in 2009 and 2010 an increase in the age of detected cases (excluding Atypical BSE cases) was observed in the EU3 compared to 2008.
- The delayed increase in the age of cases in the EU3 when comparing with the EU17 has to be considered from the perspective of the very small number of cases and the full implementation of the EU BSE control measures in the EU3 at a later date (i.e. 2004) as compared to the EU17 (i.e. 2001).
- From a human and animal health point of view, minimising exposure of consumers and food producing animals to the Atypical BSE Agents (e.g. via food and feed) will help in preventing possible transmission and propagation of these TSE Agents.

Answers to the Terms of Reference

With the additional data of a further year of monitoring results (i.e. 2010), the model employed shows that the confidence in the predictions of the number of cases in the cohorts since 2000 for the EU3 has increased substantially. Due to this and based on the results of the analysis performed with Method 3, the decline of the Classical BSE epidemic is significant in the EU3.

Under the assumption that all MSs in the EU3 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), and considering the situation where by the age limit for Classical BSE testing would be raised above 30 months in healthy slaughtered and above 24 months in at risk cattle:
  - In healthy slaughtered animals aged respectively up to 48, 60, 72, 84 or 96 months, less than one, one, two, two or two cases per each of the respective age limits can be expected to be missed annually in EU3 by an active surveillance system that uses currently approved rapid BSE tests.
  - In at risk animals aged respectively up to 30, 48, 60, 72 or 84 months, less than one, one, one, two or three cases per each of the respective age limits can be expected to be missed annually in EU3 by an active surveillance system that uses currently approved rapid BSE tests.

- Based on the model developed and employed for estimating future Classical BSE cases and on the assumption of a declining Classical BSE trend (**Scenario II**, which can be considered as the "**more realistic**" scenario), and considering the situation where by the age limit for BSE testing would be raised above 30 months in healthy slaughtered and above 24 months in at risk cattle:
    - In healthy slaughtered animals aged respectively up to 48, 60, 72, 84 or 96 months, less than one, one, one, two or two cases per each of the respective age limits can be expected to be missed in 2012. 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 up to 30, 48, 60, 72 or 84 months, less than one, one, one, two or two cases per each of the respective age limits can be expected to be missed in 2012. After this date and with the hypothesis that Classical BSE continue to decline, a yearly decline in the number of cases should be observed.

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.

Since validated data, including those for 2010, have not been provided for the other EU Member States considered in the previous Scientific Opinion[16], the impact of the new data from the EU3 on a collective assessment of all EU Member States regarding the revision of the BSE monitoring regime can not be determined, in particular with regards to the estimated final number of undetected cases.

RECOMMENDATIONS

The following is recommended:

- In order to monitor the trend of the Classical BSE epidemic and the trend in the age of the cases observed in the EU3 MSs, the results of future testing years should be evaluated. Any future modification of the monitoring system should not compromise the capacity of the system to monitor these trends.
- 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.
- The recommendations made in the previous EFSA Opinion of 2008[17] on the revision of the BSE monitoring regime in some EU MSs remain valid.

[16] These were: Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Portugal, Slovenia, Spain, Sweden and United Kingdom.

[17] 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.

DOCUMENTATION PROVIDED TO EFSA

1. Letter Ref. Ares(2011)176412-17/02/2011 from the European Commission received on 17 February 2011 requesting the reassessment of the BSE epidemiological situation as regards Czech Republic, Slovakia and Poland in view of updated BSE data. The BSE case data from these three MSs was attached to the letter.

2. Data on BSE cases from Czech Republic, Slovakia and Poland received via e-mail from the European Commission on 10 March 2011.

3. Data validated by the Czech Republic on BSE cases, number of tests performed and over 24 months cattle population for the period 2004 to 2010 received on 24 March 2011.

4. Data validated by Slovakia on BSE cases, number of tests performed and over 24 months cattle population for the period 2004 to 2010 received on 29 March 2011.

5. Data validated by Poland on BSE cases, number of tests performed and over 24 months cattle population for the period 2004 to 2010 received on 31 March and 12 April 2011.

REFERENCES

Arnold ME, Ryan JB, Konold T, Simmons MM, Spencer YI, Wear A, Chaplin M, Stack M, Czub S, Mueller R, Webb PR, Davis A, Spiropoulos J, Holdaway J, Hawkins SA, Austin AR and Wells GA, 2007. Estimating the temporal relationship between PrPSc detection and incubation period in experimental bovine spongiform encephalopathy of cattle. J Gen Virol, 88, 3198-3208.

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, 35-47.

Biacabe AG, Morignat E, Vulin J, Calavas D and Baron TG, 2008. Atypical bovine spongiform encephalopathies, France, 2001-2007. Emerg Infect Dis, 14, 298-300.

Burstein H, 1975. Finite Population Correction for Binomial Confidence Limits. J Am Stat Ass, 70, 67 - 69.

Casalone C, Zanusso G, Acutis P, Ferrari S, Capucci L, Tagliavini F, Monaco S and Caramelli M, 2004. Identification of a second bovine amyloidotic spongiform encephalopathy: molecular similarities with sporadic Creutzfeldt-Jakob disease. Proc Natl Acad Sci U S A, 101, 3065-3070.

Clawson ML, Richt JA, Baron T, Biacabe AG, Czub S, Heaton MP, Smith TP and Laegreid WW, 2008. Association of a bovine prion gene haplotype with atypical BSE. PLoS ONE, 3, e1830.

Clopper CJ and Pearson ES, 1934. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika, 26, 404 - 413.

de Koeijer AA, 2007. Analyzing BSE transmission to quantify regional risk. Risk Anal, 27, 1095-1103.

Ducrot C, Arnold M, de Koeijer A, Heim D and Calavas D, 2008. Review on the epidemiology and dynamics of BSE epidemics. Vet Res, 39, 15.

Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies., 999/2001, 1 - 40

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.

EFSA (European Food Safety Authority), 2008b. Further considerations 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 (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.

EFSA (European Food Safety Authority), 2010. 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. EFSA Journal, 8(12), 40.

EFSA (European Food Safety Authority), 2011. Joint Scientific Opinion on any possible epidemiological or molecular association between TSEs in animals and humans. EFSA Journal, 9(1), 111.

Hagiwara K, Yamakawa Y, Sato Y, Nakamura Y, Tobiume M, Shinagawa M and Sata T, 2007. Accumulation of mono-glycosylated form-rich, plaque-forming PrPSc in the second atypical bovine spongiform encephalopathy case in Japan. Jpn J Infect Dis, 60, 305-308.

Jacobs JG, Langeveld JP, Biacabe AG, Acutis PL, Polak MP, Gavier-Widen D, Buschmann A, Caramelli M, Casalone C, Mazza M, Groschup M, Erkens JH, Davidse A, van Zijderveld FG and

Baron T, 2007. Molecular discrimination of atypical bovine spongiform encephalopathy strains from a geographical region spanning a wide area in Europe. J Clin Microbiol, 45, 1821-1829.

Saegerman C, Speybroeck N, Vanopdenbosch E, Wilesmith J, Vereecken K and Berkvens D, 2005. Evolution de l'âge moyen lors de la détection des bovins atteints d'encéphalopathie spongiforme bovine (ESB):un indicateur utile de l'évolution de la courbe épizootique d'un pays. Epidémiol. et santé anim., 47, 123 - 139.

Saegerman C, Speybroeck N, Vanopdenbosch E, Wilesmith JW and Berkvens D, 2006. Trends in age at detection in cases of bovine spongiform encephalopathy in Belgium: an indicator of the epidemic curve. Vet Rec, 159, 583-587.

Stack MJ, Focosi-Snyman R, Cawthraw S, Davis L, Chaplin MJ and Burke PJ, 2009. Third atypical BSE case in Great Britain with an H-type molecular profile. Vet Rec, 165, 605-606.

Terry LA, Jenkins R, Thorne L, Everest SJ, Chaplin MJ, Davis LA and Stack MJ, 2007. First case of H-type bovine spongiform encephalopathy identified in Great Britain. Vet Rec, 160, 873-874.

Wells GA, Konold T, Arnold ME, Austin AR, Hawkins SA, Stack M, Simmons MM, Lee YH, Gavier-Widen D, Dawson M and Wilesmith JW, 2007. Bovine spongiform encephalopathy: the effect of oral exposure dose on attack rate and incubation period in cattle. J Gen Virol, 88, 1363-1373.

APPENDICES

A. DATA EMPLOYED IN THE ANALYSIS

Table 1: BSE case data validated by the Member States employed for the different analysis presented in this Opinion.

ID number	Sampling period year	Sampling period month	Country Name	Country Name Origin	Target group	Animal birth month	Animal birth year	Age group	Submission Date
1	2004	11	POLAND	Polska	Emergency slaughter	1	1994	120-131	12/31/2005
2	2004	11	POLAND	Polska	Healthy slaughtered animals	1	1996	96-107	12/31/2005
3	2004	1	POLAND	Polska	Healthy slaughtered animals	7	1992	132-143	12/31/2005
4	2004	1	POLAND	Polska	Fallen stock	4	1998	60-71	12/31/2005
5	2004	3	POLAND.	Polska	Healthy slaughtered animals	7	1996	84-95	12/31/2005
6	2004	3	POLAND	Polska	Healthy slaughtered animals	7	1998	60-71	12/31/2005
7	2004	4	POLAND	Polska	Healthy slaughtered animals	7	1996	84-95	12/31/2005
8	2004	5	POLAND	Polska	Healthy slaughtered animals	7	1995	96-107	12/31/2005
9	2004	6	POLAND	Polska	Healthy slaughtered animals	7	1996	84-95	12/31/2005
10	2004	8	POLAND	Polska	Emergency slaughter	7	1992	144-155	12/31/2005
11	2004	8	POLAND	Polska	Healthy slaughtered animals	7	2000	48-59	12/31/2005
12	2005	1	POLAND	Polska	Healthy slaughtered animals	1	1999	72-83	12/31/2005
13	2005	1	POLAND	Polska	Healthy slaughtered animals	7	1998	72-83	12/31/2005
14	2005	2	POLAND	Polska	Healthy slaughtered animals	6	2002	30-35	12/31/2005
15	2005	3	POLAND	Polska	Healthy slaughtered animals	1	1997	96-107	12/31/2005
16	2005	3	POLAND	Polska	Healthy slaughtered animals	1	1995	120-131	12/31/2005
17	2005	3	POLAND	Polska	Healthy slaughtered animals	7	2000	48-59	12/31/2005
18	2005	3	POLAND	Polska	Healthy slaughtered animals	1	1996	108-119	12/31/2005
19	2005	3	POLAND	Polska	Healthy slaughtered animals	1	1994	132-143	12/31/2005
20	2005	3	POLAND	Polska	Clinical signs at AM	6	2000	48-59	12/31/2005
21	2005	3	POLAND	Polska	Healthy slaughtered animals	3	1996	108-119	12/31/2005
22	2005	3	POLAND	Polska	Fallen stock	1	1992	> 155	12/31/2005
23	2005	4	POLAND	Polska	Eradication Measures	6	2000	48-59	12/31/2005
24	2005	5	POLAND	Polska	Healthy slaughtered animals	1	1997	96-107	12/31/2005
25	2005	6	POLAND	Polska	Healthy slaughtered animals	6	2001	48-59	12/31/2005
26	2005	6	POLAND	Polska	Healthy slaughtered animals	1	1998	84-95	12/31/2005
27	2005	8	POLAND	Polska	Healthy slaughtered animals	2	2000	60-71	12/31/2005
28	2005	11	POLAND	Polska	Healthy slaughtered animals	1	2001	48-59	12/31/2005

ID number	Sampling period year	Sampling period month	Country Name	Country Name Origin	Target group	Animal birth month	Animal birth year	Age group	Submission Date
29	2005	11	POLAND	Polska	Healthy slaughtered animals	8	1999	72-83	12/31/2005
30	2005	12	POLAND	Polska	Healthy slaughtered animals	1	1999	72-83	12/31/2005
31	2005	12	POLAND	Polska	Fallen stock	5	1999	72-83	12/31/2005
32	2006	1	POLAND	Polska	Healthy slaughtered animals	1	2001	60-71	9/29/2006
33	2006	2	POLAND	Polska	Fallen stock	1	1994	144-155	9/29/2006
34	2006	2	POLAND	Polska	Healthy slaughtered animals	1	1994	144-155	9/29/2006
35	2006	3	POLAND	Polska	Healthy slaughtered animals	2	1997	108-119	9/29/2006
36	2006	3	POLAND	Polska	Healthy slaughtered animals	1	1996	120-131	9/29/2006
37	2006	4	POLAND	Polska	Healthy slaughtered animals	1	1998	96-107	9/29/2006
38	2006	4	POLAND	Polska	Fallen stock	1	1996	120-131	9/29/2006
39	2006	5	POLAND	Polska	Healthy slaughtered animals	1	1995	132-143	9/29/2006
40	2006	6	POLAND	Polska	Healthy slaughtered animals	12	1999	72-83	9/29/2006
41	2006	8	POLAND	Polska	Fallen stock	1	1996	120-131	9/29/2006
42	2007	4	POLAND	Polska	Fallen stock	1	2000	84-95	7/16/2007
43	2007	4	POLAND	Polska	Healthy slaughtered animals	12	2004	24-29	7/16/2007
44	2007	5	POLAND	Polska	Healthy slaughtered animals	5	2003	48-59	7/16/2007
45	2007	6	POLAND	Polska	Healthy slaughtered animals	1	1999	96-107	7/16/2007
46	2007	6	POLAND	Polska	Healthy slaughtered animals	1	1999	96-107	7/16/2007
47	2007	6	POLAND	Polska	Healthy slaughtered animals	1	1999	96-107	7/16/2007
48	2007	7	POLAND	Polska	Healthy slaughtered animals	1	1995	144-155	01/09/2008
49	2007	8	POLAND	Polska	Healthy slaughtered animals	2	1995	144-155	01/09/2008
50	2007	12	POLAND	Polska	Fallen stock	1	1995	144-155	3/28/2008
51	2008	2	POLAND	Polska	Healthy slaughtered animals	1	1999	108-119	05/07/2008
52	2008	4	POLAND	Polska	Emergency slaughter	1	1999	108-119	7/22/2008
53	2008	6	POLAND	Polska	Emergency slaughter	2	2000	96-107	7/22/2008
54	2008	9	POLAND	Polska	Healthy slaughtered animals	3	2005	36-47	10/17/2008
55	2008	12	POLAND	Polska	Healthy slaughtered animals	6	2003	60-71	03/12/2009
56	2009	3	POLAND	Polska	Healthy slaughtered animals	1	1999	120-131	4/16/2009
57	2009	4	POLAND	Polska	Healthy slaughtered animals	1	1995	> 155	4/19/2010
58	2009	2	POLAND	Polska	Healthy slaughtered animals	9	1999	108-119	4/16/2009
59	2009	2	POLAND	Polska	Fallen stock	2	2000	108-119	4/16/2009
60	2010	5	POLAND	Polska	Healthy slaughtered animals	1	2000	120-131	7/30/2010
61	2010	12	POLAND	Polska	Healthy slaughtered animals	1	1995	> 155	1/28/2011
62	2004	2	SLOVAKIA	Slovensko	Healthy slaughtered animals	9	1995	96-107	12/31/2005
63	2004	3	SLOVAKIA	Slovensko	Fallen stock	10	1999	48-59	12/31/2005
64	2004	4	SLOVAKIA	Slovensko	Fallen stock	11	1995	96-107	12/31/2005
65	2004	8	SLOVAKIA	Slovensko	Healthy slaughtered animals	2	2000	48-59	12/31/2005

ID number	Sampling period year	Sampling period month	Country Name	Country Name Origin	Target group	Animal birth month	Animal birth year	Age group	Submission Date
66	2004	8	SLOVAKIA	Slovensko	Healthy slaughtered animals	2	2001	36-47	12/31/2005
67	2004	8	SLOVAKIA	Slovensko	Healthy slaughtered animals	1	2001	36-47	12/31/2005
68	2004	10	SLOVAKIA	Slovensko	Healthy slaughtered animals	2	2000	48-59	12/31/2005
69	2005	4	SLOVAKIA	Slovensko	Healthy slaughtered animals	5	2000	48-59	12/31/2005
70	2005	4	SLOVAKIA	Slovensko	Eradication Measures	5	2000	48-59	12/31/2005
71	2005	11	SLOVAKIA	Slovensko	Fallen stock	7	2000	60-71	12/31/2005
72	2007	11	SLOVAKIA	Slovensko	Healthy slaughtered animals	3	2001	72-83	12/27/2007
73	2007	9	SLOVAKIA	Slovensko	Healthy slaughtered animals	3	2001	72-83	9/17/2009
74	2008	7	SLOVAKIA	Slovensko	Healthy slaughtered animals	10	2001	72-83	08/08/2008
75	2010	5	SLOVAKIA	Slovensko	Fallen stock	11	2002	84-95	08/06/2010
76	2004	1	CZECH REPUBLIC	Ceská Republika	Fallen stock	12	1998	60-71	12/31/2005
77	2004	4	CZECH REPUBLIC	Ceská Republika	Healthy slaughtered animals	11	1997	72-83	12/31/2005
78	2004	5	CZECH REPUBLIC	Ceská Republika	Fallen stock	5	2000	48-59	12/31/2005
79	2004	6	CZECH REPUBLIC	Ceská Republika	Emergency slaughter	1	2000	48-59	12/31/2005
80	2004	7	CZECH REPUBLIC	Ceská Republika	Emergency slaughter	8	1999	48-59	12/31/2005
81	2004	8	CZECH REPUBLIC	Ceská Republika	Healthy slaughtered animals	5	1996	96-107	12/31/2005
82	2004	10	CZECH REPUBLIC	Ceská Republika	Emergency slaughter	11	1997	72-83	12/31/2005
83	2005	1	CZECH REPUBLIC	Ceská Republika	Healthy slaughtered animals	2	2000	60-71	12/31/2005
84	2005	2	CZECH REPUBLIC	Ceská Republika	Fallen stock	9	2000	48-59	12/31/2005
85	2005	4	CZECH REPUBLIC	Ceská Republika	Emergency slaughter	4	2000	60-71	12/31/2005
86	2005	10	CZECH REPUBLIC	Ceská Republika	Fallen stock	6	2000	60-71	12/31/2005
87	2005	10	CZECH REPUBLIC	Ceská Republika	Fallen stock	12	2000	48-59	12/31/2005
88	2005	11	CZECH REPUBLIC	Ceská Republika	Eradication Measures	1	2001	48-59	12/31/2005
89	2005	6	CZECH REPUBLIC	Ceská Republika	Emergency slaughter	10	2000	48-59	12/31/2005
90	2005	6	CZECH REPUBLIC	Ceská Republika	Fallen stock	5	1999	72-83	12/31/2005
91	2006	1	CZECH REPUBLIC	Ceská Republika	Healthy slaughtered animals	4	1999	72-83	6/21/2006
92	2006	11	CZECH REPUBLIC	Ceská Republika	Fallen stock	11	2000	72-83	12/12/2006
93	2006	12	CZECH REPUBLIC	Ceská Republika	Healthy slaughtered animals	3	2000	72-83	2/26/2007
94	2007	9	CZECH REPUBLIC	Ceská Republika	Emergency slaughter	7	1996	132-143	10/05/2007
95	2007	12	CZECH REPUBLIC	Ceská Republika	Fallen stock	1	1998	108-119	01/08/2008
96	2009	3	CZECH REPUBLIC	Ceská Republika	Healthy slaughtered animals	9	2003	60-71	04/07/2009
97	2009	5	CZECH REPUBLIC	Ceská Republika	Healthy slaughtered animals	5	2004	60-71	08/12/2009

Table 2: Number of tests per testing group performed validated by the Member States.

		Year							
Testing group	**Member State**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**Total tests**
Health slaughtered	Czech Republic	130,226	109,186	108,810	98,191	116,184	126,525	121,000	810,122
	Poland	447,332	472,428	551,950	546,302	556,583	587,339	590,171	3,752,105
	Slovakia	63,894	55,334	51,353	46,851	41,144	36,519	29,711	324,806
Eradication measures	Czech Republic	1,135	1,142	271	164	26	94	0	2,832
	Poland	65	212	1	42	7	5	2	334
	Slovakia	172	145	0	78	1	0	27	423
Risk animals	Czech republic	69,512	60,529	65,389	62,065	41,059	29,860	25,455	353,869
	Poland	33,708	43,295	56,007	57,414	54,967	50,721	47,063	343,175
	Slovakia	19,385	13,743	14,958	14,959	14,055	13,193	13,078	103,371
Suspects subject to laboratory confirmation	Czech republic	0	0	0	0	0	0	0	0
	Poland	11	41	34	52	9	8	4	159
	Slovakia	1	0	0	0	0	0	0	1

Table 3: Number of cattle BSE tests per age category and testing group performed in Czech Republic in 2010.

Age group (months)	Clinical signs at ante mortem	Emergency slaughter	Fallen stock	Healthy slaughtered animals	Total tests
< 24	0	0	31	1	32
24-29	5	318	2,850	0	3,173
30-35	5	147	2,076	13,367	15,595
36-47	4	312	3,953	22,692	26,961
48-59	3	290	3,740	22,224	26,257
60-71	2	272	3,163	18,489	21,926
72-83	1	221	2,217	14,101	16,540
84-95	0	129	1,631	10,409	12,169
96-107	0	77	1,172	7,038	8,287
108-119	1	49	825	4,650	5,525
120-131	0	38	650	3,010	3,698
132-143	0	25	434	2,017	2,476
144-155	0	10	255	1,244	1,509
> 155	0	21	528	1,758	2,307
Total tests	**21**	**1,909**	**23,525**	**121,000**	**146,455**

Table 4: Number of cattle BSE tests per age category and testing group performed in Poland in 2010.

Age groups (months)	Clinical signs at ante mortem	Emergency slaughter	Fallen stock	Clinical suspects and BSE eradication	Healthy slaughtered animals	Total tests
< 24	0	0	42	4	1	47
24 - 29	1	102	5,849	0	90	6,042
30 - 35	0	20	3,361	0	66,262	69,643
36 - 47	0	29	6,297	1	70,442	76,769
48 - 59	0	29	6,303	0	68,668	75,000
60 - 71	0	23	5,800	1	68,226	74,050
72 - 83	0	21	4,698	0	57,200	61,919
84 - 95	0	19	3,781	0	49,833	53,633
96 - 107	0	10	2,924	0	45,882	48,816
108 - 119	0	15	1,993	0	32,960	34,968
120 - 131	0	6	1,499	0	26,944	28,449
132 - 143	0	11	1,313	0	27,491	28,815
144 - 155	0	5	1,042	0	25,758	26,805
> 155	0	20	1,850	0	50,414	52,284
Total tests	**1**	**310**	**46,752**	**6**[1]	**590,171**	**637,240**

[1]Of which 4 where clinical suspects

Table 5: Number of cattle BSE tests per age category and testing group performed in Slovakia in 2010.

Age groups (months)	Clinical signs at ante mortem	Emergency slaughter	Fallen stock	BSE eradication	Healthy slaughtered animals	Total tests
<24	0	1	2	1	0	4
24-29	0	54	1,143	0	6	1,204
30-35	0	114	1,073	0	3,562	4,749
36-47	0	178	2,244	0	5,702	8,124
48-59	0	159	2,115	0	5,279	7,553
60-71	0	104	1,767	0	4,367	6,238
72-83	0	92	1,205	0	3,161	4,459
84-95	1	68	889	20	2,451	3,429
96-107	0	40	600	6	1,764	2,410
108-119	0	47	368	0	1,231	1,646
120-131	0	27	262	0	836	1,125
132-143	0	19	188	0	547	754
144-155	0	9	141	0	364	514
>155	0	28	140	0	441	609
Total:	**1**	**940**	**12,137**	**27**	**29,711**	**42,816**

B. NUMBER OF BSE CASES DETECTED THROUGH THE BSE SURVEILLANCE (ACTIVE AND PASSIVE) AND THE ANIMALS CULLED IN THE FRAMEWORK OF BSE ERADICATION MEASURES BETWEEN 2004 AMD 2010 PER MEMBER STATE, BIRTH COHORT AND YEAR OF DETECTION.

Data provided by the European Commission on 10 March 2011, and validated by the Member States on 24 March (Czech Republic), 29 March (Slovakia) and 31 March (Poland).

TABLE OF CONTENTS

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	2010	**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	-	-	1	-	-	-	**2**
1999	1	1	1	-	-	-	-	**3**
2000	2	6	2	-	-	-	-	**10**
2001	-	1	-	-	-	-	-	**1**
2002	-	-	-	-	-	-	-	**0**
2003	-	-	-	-	-	1	-	**1**
2004	-	-	-	-	-	1	-	**1**
Total	**7**	**8**	**3**	**2**	**0**	**2**	**0**	**22**

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.

	N° of detected BSE cases per year							
Birth cohort	2004	2005	2006	2007	2008	2009	2010	**Total**
1980	-	-	-	-	-	-	-	
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*	1	**4+*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	1	1	**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**	**3+*1***	**2**	**52+*9***

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	2010	**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	**2**	-	-	-	-	-	-	**2**
1996	-	-	-	-	-	-	-	**0**
1997	-	-	-	-	-	-	-	**0**
1998	-	-	-	-	-	-	-	**0**
1999	**1**	-	-	-	-	-	-	**1**
2000	**2**	**3**	-	-	-	-	-	**5**
2001	**2**	-	-	**2**	**1**	-	-	**5**
2002	-	-	-	-	-	-	**1**	**1**
Total	**7**	**3**	**0**	**2**	**1**	**0**	**1**	**14**

C. METHODOLOGY EMPLOYED WHEN PERFORMING 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 (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 published in the same web page as this Scientific Opinion.

The case data for all EU3 are pooled together for the period of active surveillance (2004 through 2010). They are ordered by birth cohort and age (into year groups). All cases older than 155 months are 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 2004 through 2010. 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 (1995-2004) by log-linear regression. The incidence in the 2005 cohort and onwards is projected forward using the upper 95% confidence interval of the 2004 cohort incidence and the upper confidence limit of the decay rate.

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 EU3, and will remain valid after 2010.
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 EU3 between 1 January 2004 and 31 December 2010 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

A specific upgrade to EU3 has not been made compared to the methodology employed in the former EFSA Opinion, because there are insufficient case data from these three Member States to do so.

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 group of 17 EU MSs[18] (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

[18] 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.

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.

A spreadsheet with the calculations used when performing Method 3 is provided as an Annex to this Opinion and published separately in the same web page.

References Appendix C

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.

Burstein H, 1975. Finite Population Correction for Binomial Confidence Limits. J Am Stat Ass 70. 349, 67 - 69.

Clopper CJ and Pearson ES 1934. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika 26. 4, 404 - 413.

de Koeijer AA, 2007. Analyzing BSE transmission to quantify regional risk. Risk Anal 27. 5, 1095-103.