

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 States¹

Scientific Opinion of the Panel on Biological Hazards

(Question No EFSA-Q-2008-266)

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PANEL MEMBERS

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SUMMARY

Following a request from the Kingdom of Belgium, the Panel on Biological Hazards was asked to deliver a 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.

The BIOHAZ Panel was asked to extend the assessment provided in the context of the EFSA's Scientific Opinion on the "Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States" to healthy slaughtered cattle up to 84 months of age and to healthy slaughtered cattle born after 31/12/2003.

The same analyses described under section 2.1 of the latter opinion were considered valid for this assessment. This assessment should be read together with the above mentioned Opinion in order to fully appreciate the implications of setting different age limits for BSE monitoring in cattle.

The BIOHAZ Panel concluded that in case the age of BSE testing increases to 72 or 84 months of age for healthy slaughtered animals respectively less than four and six cases can be expected to be missed annually in the old 15 European Member States (EU15)². Moreover, in case BSE testing would be stopped in healthy slaughtered cattle born after 31/12/2003, less than 6 BSE cases per birth cohort can be expected to be missed in EU15.

¹ For citation purposes: Scientific Opinion of the Panel on Biological Hazards on a request from Belgium 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. *The EFSA Journal* (2008) 763, 1-8

² Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom.

For further extrapolation of these calculations into the future, specific assumptions on the efficacy of the control measures since 2008 are required.

The Panel noticed that BSE Passive Surveillance has been demonstrated to be a very insensitive detection system as documented in the EFSA's Scientific Opinion on the "Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States".

The Panel further concluded that since no atypical BSE cases were detected in animals younger than 8 years old in EU15, it is unlikely, at the current state of knowledge, that the increase in age for rapid testing up 84 months of age would impair the detection of atypical BSE by currently validated BSE rapid tests.

Key words: BSE, Revision monitoring regime, human health, animal health

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BACKGROUND AS PROVIDED BY THE KINGDOM OF BELGIUM

The Scientific Committee of the Belgian Food Safety Agency (AFSCA) recently received a request for an opinion on relaxation of the active surveillance programme for BSE in cattle, in the form of the raising of the age limit for BSE testing, as proposed by the European Commission.

One of the questions in this request for an opinion relates to evaluation of the risks to animal health, and in particular to epidemiological surveillance for BSE, presented by each of the Commission's proposed options:

For routinely slaughtered cattle:

- Option 1: test all cattle over 42 months old;
- Option 2: test all cattle born before 1 January 2002 and 50% of cattle born after 1 January 2002 that are over 42 months old;
- Option 3: test all cattle born before 1 January 2004 and halt the testing of animals born after that date.

For at risk cattle (animals at carcass rendering plants and culled animals):

- Whichever option is chosen: test all cattle over 36 months old. A second question to the Scientific Committee concerns evaluation of the public health risks of these options.

The Commission at the same time requested the EFSA to evaluate the risks, to both public and animal health, of raising the age limit for BSE testing in successive age steps of six months between the ages of 30 months (2½ years) and 60 months (5 years) for routinely slaughtered cattle and between the ages of 24 months (2 years) and 60 months for at risk cattle groups.

In the opinion [...], the AFSCA Scientific Committee suggests waiting for this opinion from the EFSA, mainly because its risk evaluation will be based on a harmonised approach for all Member States.

It also proposes in its opinion that the EFSA risk analysis be extended to age brackets above 60 months for routinely slaughtered cattle, for the following reasons:

- First, consideration should at least be given to testing age brackets up to 84 months (7 years); this is the age mentioned by the French Food Safety Agency (AFSSA) in its opinions No 2006-SA-0329 of 17 July 2007 (www.afsca.fr/Documents/ESST2006sa0329.pdf) and No 2005-SA-0291 of 22 November 2005 (www.afssa.fr/Documents/ESST2005sa0291bAn2.pdf).
- Second, in order to include the age ranges covered by Options 2 and 3, under which old cattle are deemed to have reached the ultimate age limit.

TERMS OF REFERENCE AS PROVIDED BY THE KINGDOM OF BELGIUM

To help obtain a risk evaluation for these high age brackets, I should be most grateful if you would ask the EFSA working group in charge of this analysis to extend its evaluation to age brackets above 84 months and as far as possible to include the ages covered by Option 3 (very high ages, at the ultimate age limit).

Clarifications on the Terms of Reference

After receipt of the request it was clarified the latter had to be treated as a separate mandate and the assessment would have covered the old 15 Members States (EU15)³ and would have been limited to healthy slaughtered cattle up to 84 months of age and to healthy slaughtered cattle born after 31/12/2003.

ACKNOWLEDGEMENTS

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³ Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom.

ASSESSMENT

1. Introduction

This Opinion should be read together with the EFSA's Scientific Opinion on the "Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States" (EFSA, 2008) in order to fully appreciate the implications of setting different age limits for BSE monitoring in cattle.

2. Scientific assessment

The data on BSE surveillance used in this analysis were received from the European Commission on 29th April 2008.

The same analyses described under section 2.1 of the EFSA's Scientific Opinion on the "Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States" (EFSA, 2008) are valid for this assessment.

The results given in this assessment were calculated using Method 3 of section 2.1 of the above mentioned EFSA's Opinion.

For the purpose of this calculation two different scenarios were used:

- **Scenario I:** assumes a constant incidence of BSE starting from the 2003 birth cohort (in practice the yearly estimate of the number of BSE cases per age group is the same from 2008 onwards);
- **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 2003 based on the cohort incidence decline in previous cohorts calculated by log-linear regression.

Due to the restricted data available for recent cohorts and to the methodologies applied the approach did not take into account the expected additional effect of the enhanced control measures taken in 2001 in the EU (see Appendix B of the above mentioned Opinion). Moreover they are based on upper 95% confidence limit of the calculated expected number of cases. Consequently they can be considered as worst case scenarios.

For further extrapolation of these calculations into the future, specific assumptions on the efficacy of the control measures since 2008 are required.

The methodology used is described under Appendix B to the EFSA's Scientific Opinion on the "Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States" (EFSA, 2008) and can be traced back in the spreadsheet that can be downloaded from the web page on which the above mentioned Opinion is published.

The expected number of BSE cases detected in the healthy slaughter stream (based on upper 95% confidence limit for birth cohorts since 2003) by calendar year and age category in Scenario I is provided in Tab.1.

Table 1. **Expected number of BSE cases detected in the healthy slaughter stream (based on upper 95% confidence limit for birth cohorts since 2003) by calendar year and age category (in months) in Scenario I.**

Year	Age category (months)		Total	Total considering younger age categories*
	60 – 71	72 – 83		
2008	2.30	1.71	4.01	5.63
2009	1.92	1.35	3.27	4.89
2010	1.92	1.13	3.04	4.66
Total	6.13	4.19	10.32	15.18

* as provided in the EFSA’s Scientific Opinion on the “Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States” (EFSA, 2008)

In this scenario the number of expected BSE cases per age category will remain the same from the year 2010 onwards.

The expected number of BSE cases detected in the healthy slaughter stream (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 Tab.2.

Table 2. **Expected number of BSE cases detected in the healthy slaughter stream (based on upper 95% confidence limit for constant trend of reduction by birth cohorts since 2000) by calendar year and age category (in months) in Scenario II.**

Year	Age category (months)		Total	Total considering younger age categories*
	60 – 71	72 – 83		
2008	2.26	1.71	3.97	5.25
2009	1.57	1.33	2.90	3.80
2010	1.11	0.92	2.04	2.69
Total	4.94	3.97	8.91	11.74

* as provided in the EFSA’s Scientific Opinion on the “Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States” (EFSA, 2008)

In this scenario the number of expected yearly BSE cases per age category will decay progressively from 2008 onwards.

The expected number of BSE cases detected in the healthy slaughter stream (based on upper 95% confidence limit for birth cohorts since 2003) by birth cohort and age category in Scenario I is provided in Tab.3.

Table 3. **Expected number of BSE cases detected in the healthy slaughter stream (based on upper 95% confidence limit for birth cohorts since 2003) by birth cohort and age category (in months) in Scenario I.**

Birth cohort	Age category (months)						Total
	<36	36 – 47	48 – 59	60 – 71	72 – 83	>83	
2004	0.08	0.10	1.44	1.92	1.13	1.17	5.83
2005	0.08	0.10	1.44	1.92	1.13	1.17	5.83
2006	0.08	0.10	1.44	1.92	1.13	1.17	5.83
2007	0.08	0.10	1.44	1.92	1.13	1.17	5.83
2008	0.08	0.10	1.44	1.92	1.13	1.17	5.83
Total	0.39	0.50	7.21	9.58	5.64	5.85	29.15

In this scenario the number of expected BSE cases per birth cohort remains constant for each birth cohort.

The expected number of BSE cases detected in the healthy slaughter stream (based on upper 95% confidence limit for constant trend of reduction by birth cohorts since 2000) by birth cohort and age category in Scenario II is provided in Tab.4.

Table 4. **Expected number of BSE cases detected in the healthy slaughter stream (based on upper 95% confidence limit for constant trend of reduction by birth cohorts since 2000) by birth cohort and age category (in months) in Scenario II.**

Birth cohort	Age category (months)						Total
	<36	36 – 47	48 – 59	60 – 71	72 – 83	>83	
2004	0.05	0.07	0.98	1.30	0.77	0.79	3.97
2005	0.04	0.05	0.69	0.92	0.54	0.56	2.80
2006	0.03	0.04	0.52	0.69	0.41	0.42	2.10
2007	0.02	0.03	0.40	0.54	0.32	0.33	1.63
2008	0.02	0.02	0.29	0.38	0.23	0.23	1.17
Total	0.15	0.20	2.89	3.83	2.25	2.34	11.66

In this scenario the number of expected BSE cases per birth cohort will decay progressively.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- If the age of BSE testing increases to 72 or 84 months of age for healthy slaughtered animals, the modelling shows that respectively less than four and six cases can be expected to be missed annually in EU15.
- If, in the framework of BSE surveillance, BSE testing would be stopped in healthy slaughtered cattle born after 31/12/2003, the expected value estimated from modelling shows that less than 6 BSE cases per birth cohort can be expected to be missed in EU15.
- For further extrapolation of the calculations provided with this methodology into the future, specific assumptions on the efficacy of the control measures since 2008 are required.
- BSE Passive Surveillance has been demonstrated to be a very insensitive detection system as documented in the EFSA's Scientific Opinion on the "Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States".
- Since no atypical BSE cases were detected in animals younger than 8 years old in EU15, it is unlikely, at the current state of knowledge, that the increase in age for rapid testing up 84 months would impair the detection of atypical BSE by currently validated BSE rapid tests.

DOCUMENTATION PROVIDED TO EFSA

Letter (ref. n. E2-550-704 (a)) from the Kingdom of Belgium with a request to extend the assessment performed in the framework of the EFSA's mandate on the Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States (EFSA-Q-2008-007).

REFERENCES

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