SEAC Spongiform Encephalopathy Advisory Committee

PROPOSALS TO REDUCE BSE TESTING OF CATTLE SLAUGHTERED FOR FOOD - IMPACT ON RISK TO HUMAN HEALTH

ISSUE

1. At SEAC 100, the Food Standards Agency (FSA) asked SEAC to consider and advise on a risk analysis, prepared by the Veterinary Laboratories Agency (VLA), that provided estimates of the impact on the bovine spongiform encephalopathy (BSE) risk to the food supply of proposed changes to the European Union (EU) requirements for BSE surveillance.

2. The committee asked for further information about the modelling. This information has been provided by the VLA and is in Annex 1.

3. In July 2008 the European Food Safety Authority (EFSA) produced two Scientific Opinions on the Risk for Human and Animal Health Related to the Revision of the BSE Monitoring regimes, Annex 2 and 3.

BACKGROUND

4. The EU TSE Regulation (Regulation (EC) No 999/2001) requires all Member States (MS) to carry out an annual programme for monitoring TSEs. In relation to cattle, the annual monitoring programme in all MS must include the testing of all cattle aged over 24 months sent for emergency slaughter or showing clinical signs at ante mortem inspection, all fallen stock aged over 24 months and all cattle aged over 30 months slaughtered normally for human consumption.

5. As part of the TSE Roadmap a strategic goal was set to reduce the numbers of tests of cattle whilst continuing to measure the effectiveness of the BSE controls in place by targeting surveillance. As a result in January 2007 an amendment was made to the TSE Regulation[1] which allowed MS to apply to revise their BSE monitoring programmes. The applicant MS must be able to

[1] made by Regulation (EC) No 1923/2006 of the European Council and of the Parliament

demonstrate an improvement in their epidemiological situation. They must also provide proof of their capability to determine the effectiveness of the measures in place and ensure the protection of human and animal health, based on a comprehensive risk analysis.

6. The UK would wish to operate a revised BSE monitoring programme subject to agreement by DH and the FSA Board that any additional risk to consumers that could result from reducing the current testing of cattle slaughtered for human consumption would be acceptably low. The FSA Board will consider the results from the VLA model on the impact on the BSE risk to the food supply in formulating its advice.

PREVIOUS SEAC CONSIDERATION

7. At SEAC 100 the Committee was asked to assess the validity of the analysis carried out by the VLA (Annex 4) in evaluating the effect on risk to consumers from exposure to BSE for a number of options for changes to BSE surveillance and to comment on the values produced. The minute of the SEAC discussion can be found in Annex 5.

8. In summary the Committee noted that:

- clarification should be provided on some of the outputs of the modelling identified during the discussion and on the fit of the model predictions to the observed BSE surveillance and case data.
- it is important to acknowledge the uncertainties around a number of key parameters in the model such as the infectivity in tissues and the number of infected cattle entering the food chain (as estimated by back calculation).
- it would be useful to consider if the relative contribution of changing the age of testing of the HS and ES/FS cattle simultaneously alters the assessment compared with considering them independently.
- it is important to keep the assumptions used in the model under review as they may be affected by changes made in the control regime.
- BSE testing of cattle provides important data on the incidence of the disease and confers some public health protection. Demonstrating a low level of disease provides reassurance about the effectiveness of controls.

FURTHER WORK BY VLA

9. Since SEAC 100 the VLA, in consultation with SEAC epidemiologists, has produced a report that provides a comparison of the results produced by the model with surveillance data and information about how key uncertainties (prevalence, infectivity and number of animals entering the food chain) are handled in the modelling. SEAC's epidemiologists are content with the information provided at Annex 1.

EFSA ASSESSMENTS

10. Since SEAC 100 EFSA have produced two Scientific Opinions (Annex 2 and 3) that assess the risk to human and animal health from a range of options for increasing the age limits for testing[2]. The results obtained from the EFSA modelling are broadly similar to those from the VLA model. For example the EFSA opinions show that:

    - If the age of BSE testing increases to 36, 48 or 60 months of age for healthy slaughtered animals, the modelling shows that less than one case for the first two age limits and less than two cases for the third age limit can be expected to be missed annually in the old 15 EU[3] MS.
    - If the age of BSE testing increases to 30, 36, 48 or 60 months of age for at risk animals, the modelling shows that less than one case for the first three age limits and less than three cases for the fourth age limit can be expected to be missed annually in the old 15 EU MS.

ADVICE SOUGHT FROM THE COMMITTEE

11. The FSA Board is meeting on the 15th October 2008 to consider the results from the model on the impact on the BSE risk to the food supply in formulating its advice on a UK application to increase the age of BSE testing. As part of this consideration the Board has asked for the view of SEAC on the validity of the analysis of risk provided by the model.

12. To provide the board with an agreed SEAC view on the modelling the following conclusion has been drafted. It is based on the

[2] In summary, EFSA is requested to provide an assessment of significant additional risks to public or animal health from:
(i) raising the test limit for "healthy slaughtered" from 30 to 36, 42, 48, 54 or 60 months. "Healthy Slaughtered" means healthy slaughtered for human consumption
(ii) raising the test limit for "risk animals" from 24 to 30, 36, 42, 48, 54 or 60 months. "Risk Cattle" includes fallen stock, emergency slaughtered, problem at ante-mortem

[3] Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, UK

Committee's consideration at SEAC 100 and the subsequent discussions between the VLA and SEAC epidemiologists, the further information provided by VLA and the findings of the EFSA assessments. Members are asked to provide comments on the draft conclusion by **12th October 2008**. A revised conclusion will be tabled for final agreement at SEAC 101.

Draft Conclusion

As the conclusion has yet to be agreed by the committee, it has been removed from this version of the paper.

SEAC Spongiform Encephalopathy Advisory Committee

Further Work by VLA

This information has been removed from this version of the paper as it is unpublished.

SEAC Spongiform Encephalopathy Advisory Committee

EFSA OPINION
Risk for Human and Animal Health related to the Revision of the BSE Monitoring Regime in some Member States.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902007644.htm

SEAC Spongiform Encephalopathy Advisory Committee

EFSA OPINION
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.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902007703.htm

SEAC Spongiform Encephalopathy Advisory Committee

VLA MODELLING AND ANALYSIS
(presented at SEAC 100)

ITEM 7 – PROPOSALS TO REDUCE BSE TESTING OF CATTLE SLAUGHTERED FOR FOOD - IMPACT ON RISK TO HUMAN HEALTH (SEAC 100/4)

Modelling EFSA proposed options for GB BSE surveillance

VLA modellers and risk analysts have developed models that can estimate the impact of different BSE surveillance options, and the impact of risk mitigating controls. The key models are the back calculation model developed by Arnold and Wilesmith (2003) and the risk assessment termed the "BSE-Control Model" (Adkin et al., 2007). Both models can output the number of expected cases missed given a change in surveillance controls. The BSE Control Model can also estimate the impact of variations in Specified Risk Material (SRM) removal and the total amount of infectivity entering the food chain, given that cases are missed.

The BSE Control Model uses the same input data as the back calculation model and some of its outputs, together with information on the processing of carcases in abattoirs. The approach taken is a stochastic assessment based on individual infected animals where uncertainty and variability are modelled separately.

Version 4 of the assessment (Adkin et al., 2007) was further developed in late 2007 so that both age at slaughter related control measures and date of birth measures could be investigated. In addition, the model can estimate the number of future test positives in 2008 and 2009 given assumptions regarding prevalence estimates and the slaughter/death population during those years. In this minute, the results from the BSE Control Model Version 5 (Adkin et al., in preparation) are provided for the following control options:

Stream	Control options											
	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**
HS*	**30**	**36**	**42**	**48**	**54**	**60**	**30**	**30**	**30**	**30**	**30**	**30**
ES/FS*	**24**	**24**	**24**	**24**	**24**	**24**	**30**	**36**	**42**	**48**	**54**	**60**

***HS=Healthy slaughter, ES=Emergency slaughter, FS=Fallen stock**

These options aim to mirror those put forward in the Commission's mandate to EFSA in which EFSA is invited to consider age options between 30 and 60 months (with 6 months intervals) for BSE testing of healthy slaughtered cattle and between 24 and 60 months (with 6 months intervals) for testing of at risk cattle. Option A is the currently implemented control measure in Great Britain. It is assumed that for each of these control measures, in terms of removal of SRM, vertebral column is removed at 30 months of age and brain and spinal cord are removed 12 months of age. This is in-line with SRM removal procedures expected to be implemented later this month.

The population of interest considered by the BSE Control Model Version 5 is those animals eligible for the food chain and born after 31 July 1996. The model considers the number of animals testing positive by surveillance year from 2005 to 2009. However, in this minute, only those results for 2008 and 2009 are considered. Two classifications of results can be obtained from Version 5 of the BSE control model. The first is regarding estimation of the expected number of test positive animals and the second is the total annual amount of infectivity entering the food chain. Both categories of results are described below.

Results

Number of animals tested and test positive

Given the above options and assumptions regarding the slaughter/death population born after 31 July 1996 (Adkin et al., in prep), the expected number of animals tested is provided in Table 1.

Table 1: Comparison of Options by the estimated number of animals tested by year

Options	Number of animals tested							
	Healthy slaughter		Emergency slaughter		Fallen stock		Total (all streams)	
	2008	2009	2008	2009	2008	2009	2008	2009
A	556,758	556,788	5,336	5,968	188,425	192,330	750,519	755,086
B	494,122	494,152	5,336	5,968	188,425	192,330	687,883	692,450
C	450,187	450,217	5,336	5,968	188,425	192,330	643,948	648,515
D	413,957	413,987	5,336	5,968	188,425	192,330	607,718	612,285
E	375,374	375,404	5,336	5,968	188,425	192,330	569,135	573,702
F	338,302	338,332	5,336	5,968	188,425	192,330	532,063	536,630
G	556,758	556,788	4,660	5,292	175,549	179,454	739,967	741,534
H	556,758	556,788	4,198	4,831	162,317	166,222	723,273	727,841
I	556,758	556,788	3,902	4,532	149,253	153,158	709,913	714,478
J	556,758	556,788	3,621	4,248	136,999	140,904	697,378	701,940
K	556,758	556,788	3,355	3,977	125,238	129,143	685,351	689,908
L	556,758	556,788	3,104	3,720	113,923	117,828	673,785	678,336

The estimated number of test positive animals missed during 2008 and 2009 combined for each option as compared to a 100% testing is outlined in Table 2. Table 3 displays the percentage of test positive animals missed per option during 2008 and 2009 combined. The results in both tables are based on a conservative assumption that the prevalence of BSE in Great Britain will remain constant for cattle born from July 2001 (estimates show a declining prevalence for cattle born from July 1996 to July 2001 – see Annex 4). Both variability and uncertainty are considered in the model and this is represented by 5th and 95th percentiles within parentheses, which indicate the range within which 90% of the results lie.

Table 2: Comparison of Options by the estimated number of test positive animals missed during 2008 and 2009 assuming flat prevalence of BSE from July 2001

Control option	Number of test positive animals missed (mean, min, max)		
	Healthy slaughter	Emergency slaughter	Fallen stock
A	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
B	$2.3x10^{-3}$ ($2.1x10^{-4}$, $1.0x10^{-2}$)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
C	$4.7x10^{-3}$ ($4.3x10^{-4}$, $2.0x10^{-2}$)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
D	$1.1x10^{-2}$ ($9.3x10^{-4}$, $5.0x10^{-2}$)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
E	$4.5x10^{-2}$ ($3.1x10^{-3}$, $2.0x10^{-1}$)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
F	$6.7x10^{-2}$ ($4.7x10^{-3}$, $3.0x10^{-1}$)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
G	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 ($2.1x10^{-4}$, $1.0x10^{-2}$)
H	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 ($2.1x10^{-4}$, $1.0x10^{-2}$)
I	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	$1.5x10^{-2}$ ($1.8x10^{-3}$, $1.3x10^{-1}$)
J	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	$4.2x10^{-2}$ ($5.0x10^{-3}$, $3.6x10^{-1}$)
K	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	$9.2x10^{-2}$ ($1.1x10^{-2}$, $7.9x10^{-1}$)
L	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	$1.7x10^{-1}$ ($2.1x10^{-2}$, 1.5)

Table 3: Comparison of Options by the average percentage test positive animals missed during 2008 and 2009 assuming flat prevalence of BSE from July 2001

Control option	Percentage of missed test positive animals by stream (mean)		
	Healthy slaughter	Emergency slaughter	Fallen stock
A (current)	0.0%	0.0%	0.0%
B	0.19%	0.0%	0.0%
C	0.38%	0.0%	0.0%
D	0.94%	0.0%	0.0%
E	3.75%	0.0%	0.0%
F	5.63%	0.0%	0.0%
G	0.0%	0.0%	0.03%
H	0.0%	0.0%	0.03%
I	0.0%	0.0%	0.35%
J	0.0%	0.0%	0.98%
K	0.0%	0.0%	2.17%
L	0.0%	0.0%	4.13%

It can be seen from Tables 2 and 3 that the number and percentage of test positive animals missed in the Emergency Slaughter stream is always zero. For the Healthy Slaughter stream, the number of test positive animals missed during 2008 and 2009 combined is low and below one for all strategies; for the current strategy it is estimated that no test positive animals are missed. Similarly, for the Fallen Stock stream, the number of test positive animals missed during 2008 and 2009 is low and below one for all strategies considered.

The results in Table 3 are illustrated graphically in Figure 1; as Emergency slaughter is always 0.0%, these are not included in the Figure.

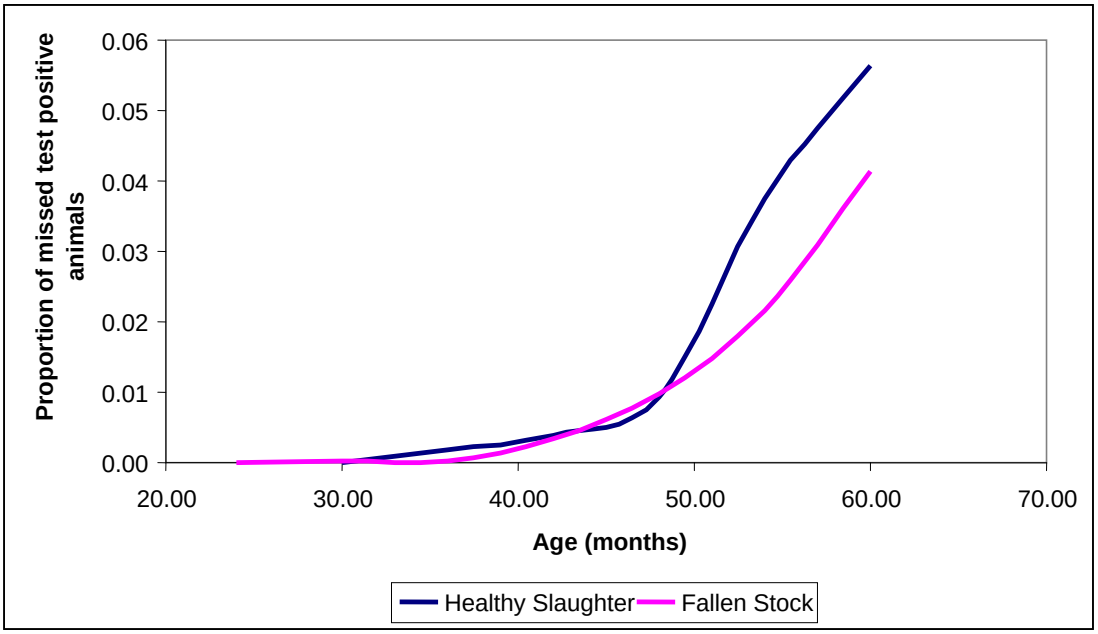

Figure 1: Illustration of the mean proportion of missed test positive animals within the healthy slaughter and fallen stock streams for 2008 and 2009

The number of test positive animals expected to be detected with the current strategy (Strategy A) and the other Options are outlined in Table 4.

Table 4: Comparison of total number of test positives expected to be detected during 2008 and 2009 by Option assuming flat prevalence of BSE from July 2001

Stream	**Control option**	**Number of test positive animals expected by stream (mean, min and max)**
Healthy slaughter	30 months (A)	1.19 (0.08, 5.27)
	36 months (B)	1.18 (0.08, 5.26)
	42 months (C)	1.18 (0.08, 5.25)
	48 months (D)	1.18 (0.08, 5.22)
	54 months (E)	1.14 (0.08, 5.07)
	60 months (F)	1.12 (0.08, 4.97)
Emergency slaughter	24 months (A)	0.08 (0.006, 0.37)
	30 -60 months (G-L)	0.0002 (0.0002, 0.01)
Fallen stock	24 months (A)	8.23 (0.57, 36.43)
	30 months (G)	8.23 (0.57, 36.42)
	36 months (H)	8.23 (0.57, 36.42)
	42 months (I)	8.20 (0.56, 36.30)
	48 months (J)	8.15 (0.56, 36.07)
	54 months (K)	8.05 (0.56, 36.64)
	60 months (L)	7.89 (0.55, 34.93)

Annual total infectivity

To estimate the annual total infectivity, Model 1 of the BSE Control Model Version 5 has been run which provides an estimate the annual number of animals infected and the mean amount of infectivity per infected animal. The latter is described in Bovine Oral ID_{50} doses. These results are inputted into an Annual Extension model (Model 2) to provide an estimate of the total amount of infectivity entering the food chain per year. The units for this are also Bovine Oral ID50 doses and not human oral doses.

Given the assumptions, data and modelling approaches outlined within Adkin et al., (2007), the number of animals by-passing controls annually, and the distribution of infectivity of those animals per year, the total amount of infectivity consumed by humans annually are shown in Table 5. These results are for the current control strategy (i.e. Strategy A). It should be noted that only animals destined for the food chain are included in Table 5 (e.g. Fallen Stock animals are not included).

Table 5: Total infectivity consumed by humans per year (Bovine oral ID_{50} per year)

Year	Total infectivity consumed per year (Bovine oral ID_{50} per year)
2008	96.95 (1.10, 257.35)
2009	34.29 ($1.8x10^{-3}$, 96.5)

It can be seen that from Tables 1 to 3 the number of missed test positive animals per Option is very low and less than 1 for 2008 and 2009. As such, there is minimal impact on the total annual amount of infectivity entering the food chain as the testing decreases for the Options outlined above. Given this, it was considered more useful to provide an estimate of the total amount of infectivity consumed by humans per year if 1, 2, up to 10 test positive animals were not detected and entered the food chain. In this circumstance, it is assumed that the SRM is removed as per current procedures. The results from this analysis are outlined in Table 6.

Table 6: Total amount of infectivity consumed (BO ID_{50}) per year if 1, 2, up to 10 test positive animals were missed

Number of animals missed	Total infectivity consumed per year	
	2008	2009
1	98.4 (2.3, 258.1)	34.6 ($2.2x10^{-3}$, 96.9)
2	99.2 (2.8, 259.4)	34.8 ($2.3x10^{3}$, 97.1)
3	99.9 (3.6, 260.2)	35.2 ($2.6x10^{-3}$, 97.3)
4	100.8 (4.5, 261.4)	35.5 ($3.1x10^{-3}$, 97.6)
5	101.6 (5.5, 262.5)	35.8 ($3.6x10^{-3}$, 98.0)
6	102.4 (6.1, 263.8)	36.1 ($4.8x10^{-3}$, 98.3)
7	103.2 (6.5, 264.4)	36.4 (0.1, 98.9)
8	104.1 (7.3, 265.9)	36.7 (0.4, 99.5)
9	104.9 (8.0, 266.9)	37.0 (0.7, 99.7)
10	105.8 (8.7, 267.3)	37.3 (0.9, 100.2)

It can be seen from Table 6 that the increased amount of total infectivity entering the food chain if 10 test positive animals were missed is 8.8 (7.6, 9.9) and 3.03 (0.97, 3.7) for 2008 and 2009 respectively. This latter amount is in contrast to the 11 million Bovine Oral ID50 doses which Comer & Huntly (2004) estimated entered the food chain in 1993.

Overall conclusions

The number of test positive animals missed for each of the proposed EFSA strategies is extremely low for both 2008 and 2009. Indeed, less than one test positive animal is missed for both healthy slaughter and fallen stock streams. It is for this reason that there is minimal impact on the total amount of annual infectivity entering the food chain if the age of testing is increased in line with the proposed strategies.

Rowena Kosmider
Centre for Epidemiology and Risk Analysis
Veterinary Laboratories Agency
8 April 2008

References:

Adkin, A., Nicholls, V., Arnold, M., Wells, G., and Matthews, D. (2007) BSE Control Model. Centre for Epidemiology and Risk Analysis. Veterinary Laboratories Agency. Version 4.0 dated 30th March 2007.

Adkin, A., Nicholls, V., Arnold, M., Wells, G., and Matthews, D. (in preparation) BSE Control Model. Centre for Epidemiology and Risk Analysis. Veterinary Laboratories Agency. Version 5.0 due for completion 31st March 2008.

Arnold, M., and Wilesmith, J. W. (2003) Modelling studies on BSE occurrence to assist in the review of the over 30 months rule in Great Britain. Proceedings of the Royal Society 270: 2141-2145.

Comer, P. and Huntly, P. (2004). Exposure of the human population to BSE infectivity over the course of the BSE epidemic in Great Britain and the impact of changes to the Over Thirty Month Rule. Journal of Veterinary Research 7 (5): 523-543.

SEAC Spongiform Encephalopathy Advisory Committee

Draft minute of the SEAC 100 Discussion

See paper SEAC 101/1