

LIKELY IMPACT ON THE RISK TO HUMAN HEALTH OF REDUCING THE LEVEL OF BSE TESTING OF HEALTHY CATTLE SLAUGHTERED FOR FOOD

ISSUE

1. The Food Standards Agency (FSA) has asked SEAC to consider and advise on the bovine spongiform encephalopathy (BSE) risk to the food supply from changes to the requirements for BSE testing of healthy cattle slaughtered for human consumption.

BACKGROUND

2. European Community TSE legislation requires all Member States (MS) to carry out an annual programme for monitoring BSE. The legislation also allows MS that meet certain conditions to revise their BSE monitoring programmes. Currently, 17 MS, including UK, have been authorised to do so. In relation to healthy cattle slaughtered for human consumption, in these MS all such cattle aged over 48 months must be BSE tested.
3. A fuller explanation of the development of the current legislation on BSE testing is at Annex 1.
4. In December 2010, EFSA adopted a scientific opinion¹ which provides an update on the risk for human and animal health related to the revision of the BSE monitoring system. This opinion concludes that, for the seventeen MS already authorised to revise their BSE monitoring programmes, updated data on BSE surveillance from 2001 to 2009 shows that the BSE epidemic has been declining and is converging to the sensitivity limit of a surveillance system that uses currently-approved rapid BSE tests. Based on an assumption of a declining Classical BSE trend, which EFSA considers the “more realistic” scenario, EFSA also concludes that, in the whole of the 17 MS concerned:
 - if the age threshold for BSE testing healthy cattle slaughtered for human consumption were raised to 72 months, less than one BSE case may be expected to be missed in 2011;
 - if BSE testing of such cattle were to cease altogether from 1st January 2013, less than one BSE case would be missed each calendar year from 2013 onwards.

¹ [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](#)

5. On the basis of the EFSA opinion, the Commission is now planning a further change to the relevant legislation. Draft amending legislation was agreed by MS last month that would allow 22 MS (including UK)² to:
 - raise the age threshold for BSE testing of healthy cattle slaughtered for human consumption from 48 months to 72 months from July 2011; and
 - test only a sample³ of over 72 months healthy cattle slaughtered for human consumption from January 2013.
6. For all other cattle for which BSE testing is required (i.e. cattle subject to emergency slaughter or showing clinical signs at *ante mortem* inspection and fallen stock), the amendment would require testing in these 22 MS to cover at least all cattle aged over 48 months (which is no change for the 17 MS including UK already authorised to revise their BSE monitoring programmes).
7. The UK would wish to implement the changes to BSE testing of healthy cattle slaughtered for human consumption which MS have now agreed, subject to agreement by Department of Health 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.

LIKELY IMPACT OF THE CHANGE IN THE UK

8. The VLA BSE control model can output the number of expected cases missed in Great Britain if monitoring is reduced and estimate the consequent impact on the amount of infectivity entering the food supply (in terms of bovine oral ID50 units). Annex 2 describes the analysis carried out by the VLA using the model to assess the impact of reducing BSE testing of healthy cattle slaughtered for human consumption. Results are presented in terms of the impact, compared with a baseline of continuing to test healthy slaughter and emergency slaughter cattle at over 48 months, of:
 - (1) raising the age threshold for testing healthy slaughter cattle only to 72 months; and
 - (2) stopping testing of healthy slaughter cattle altogether.
9. The VLA analysis indicates that:
 - if the threshold for testing healthy slaughter cattle were raised from 48 to 72 months, there would be -
 - no increase in the number of test positives missed in GB (from a mean of 0.05) over the two year period 2011 to 2012, and

² comprising the 17 MS already authorised to revise their BSE monitoring programmes plus 5 others in which EFSA concluded that the BSE epidemiological “should be considered to be at least equivalent to that in these 17”

³ sample size to be determined by the European Commission over the next 18 months

- no increase in infectivity consumed in 2011 and a slight increase in 2012.
 - if testing of healthy slaughter cattle were stopped completely,
 - a mean of 2 test positives would be missed over the same two year period, and
 - the amount of infectivity consumed would increase (compared with testing at 48 months) from 18 to 42 bovine oral ID₅₀ for 2011 and from 14 to 33 bovine oral ID₅₀ for 2012.
10. The healthy cattle slaughtered for human consumption that have tested positive for BSE in UK since November 2005, when testing of such cattle started, are listed in Annex 3.
11. Three cases of atypical BSE have been identified in UK to date. All three were H-type BSE cases in old animals, born before the feed ban became fully effective in August 1996, detected through testing of fallen stock⁴.

PREVIOUS SEAC CONSIDERATION

12. SEAC commented on the VLA BSE control model (Version 3.0) at its meeting of December 2006. SEAC generally accepted the methodology and data used and made suggestions for refinements to the model. It was noted that the model could be updated as new information becomes available. SEAC felt that, once further refined, the model would provide a very useful tool to analyse the effect of potential changes to BSE controls. The model has since been refined and updated accordingly and was published in a peer-reviewed journal⁵ in 2010. The latest version (Version 8.0) is based on BSE testing results up to 31 December 2010.
13. SEAC first considered the impact of changing the age thresholds for BSE testing at its meeting of April 2008 (before the change to the UK surveillance programme referred to in paragraph 4 of Annex 1 was made). The Committee was asked to assess the validity of an analysis carried out by the VLA 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 is at Annex 4.
14. 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.

⁴ [Stack et al \(2009\) Third atypical BSE case in Great Britain with an H-type molecular profile. *Veterinary Record* 2009;165:605-606](#)

⁵ Adkin, A., Nicholls, V., Arnold, M., Wells, G., and Matthews, D. (2010) Estimating the impact on the food chain of changing bovine spongiform encephalopathy (BSE) control measures: the BSE Control Model. *Prev. Vet. Med.* 93: 170-182

- 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.
15. Following that discussion, the VLA, in consultation with SEAC epidemiologists, produced a report that provided 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 were content with the information provided.
16. The VLA's report was subsequently discussed by the Committee at its meeting of October 2008. The minute of that discussion, with the Committee's advice to the FSA Board on the increased risks to human health from raising the age at which healthy slaughtered cattle are tested for BSE, is at Annex 5.

ADVICE SOUGHT FROM THE COMMITTEE

17. The Committee is asked to consider the output from the latest analysis carried out by the VLA to evaluate the effect of changes to the requirements for BSE testing of healthy slaughter cattle and to comment on the risk to consumers from exposure to BSE (including H- and L-type BSE) that would result if, from 2011,
- a) the age threshold for BSE testing healthy slaughter cattle were raised from 48 to 72 months; or
 - b) BSE testing of healthy slaughter cattle were to stop altogether.

DEVELOPMENT OF CURRENT BSE TESTING REQUIREMENT

1. 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 must include the testing of all cattle aged over 24 months subject to 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.
2. As part of the European Commission's TSE Roadmap, published in July 2005, 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 better targeting of surveillance. The TSE Regulation was subsequently amended to allow MS to apply to revise their BSE monitoring programmes.
3. Applicant MS must be able to demonstrate declining or low prevalence of BSE and that they have implemented the EU cattle identification, BSE testing and feed ban requirements for at least six years. The application must include the result of a comprehensive risk analysis showing that the revised BSE monitoring programme will ensure the protection of human and animal health.
4. The UK submitted an application to revise its surveillance programme in August 2008. This was accepted following scrutiny by a European Commission ad hoc working group of experts. Subsequently, following an opinion from EFSA⁶, the European Commission introduced legislation that, from 1 January 2009, allowed the 15 MS (including UK) then eligible to revise their BSE monitoring programmes to raise the age threshold for testing all three categories of cattle listed in paragraph 2 to 48 months. This change was made in the UK with effect from 1 January 2009. Two further MS were subsequently allowed similarly to revise their BSE monitoring programmes in the light of an updated opinion from EFSA⁷.
5. The TSE Roadmap 2, published in July 2010, outlines the Commission's strategy for continuing the review of measures started by the first Roadmap over the period 2010-2015 while assuring a high level of food safety. The strategic goal envisaged in Roadmap 2 for BSE surveillance is to continue to adapt the monitoring system with a better targeting of the surveillance activity, while keeping the capacity to monitor the evolution of the epidemiological situation and to assess the effectiveness of the protective measures in place.

⁶ [Risk for human and animal health related to the revision of the BSE monitoring regime in some Member States. The EFSA Journal \(2008\) 762, 1-47](#)

⁷ [Updated risk for human and animal health related to the revision of the BSE monitoring regime in some Member States. The EFSA Journal \(2009\) 1059, 1-40](#)

ANNEX 2

MODELLING BSE CONTROLS: A CHANGE IN THE AGE AT TESTING

Model background

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., 2010). 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 carcasses in abattoirs. The approach taken is a stochastic risk assessment based on individual infected animals, where uncertainty and variability are modelled separately. This minute documents the results from Version 8.0 of the BSE control model, which has been further developed with the inclusion of an additional forecasted year of 2012. These results are summarised in terms of the impact of two different control scenarios:

- (1) Continuation of baseline of testing at >48 months for healthy slaughter (HS) and emergency slaughter (ES)
- (2) Raising the age of testing to >72 months for HS only
- (3) No testing of HS

The following Table summarises the controls modelled.

Table 1: BSE control measures included in the BSE Control model (Version 8.0)

Year	Age of animal at death	Specified Risk Materials removal				Testing prior to food chain entry
		DRG & vertebral column (months)	Tonsil & distal ileum	& Head and spinal cord (months)	Head de-boning	
2005	<30 m of age	>30	All ages	>6	None	HS ≥ 30m; ES ≥ 24m; all CS

2006 & 2007	DOB> 31 July 1996	>24	All ages	>12	All ages	HS≥ 30m; ES≥ 24m; all CS
2008	DOB > 31 July 1996	>30	All ages	>12	All ages	HS≥ 30m; ES≥ 24m; all CS
2009	DOB > 31 July 1996	>30	All ages	>12	All ages	HS/ES≥ 48m; all CS
2010-2012 (baseline)	DOB > 31 July 1996	>30	All ages	>12	All ages	HS/ES≥ 48m; all CS
2010 - 2012 (HS >72m)	DOB > 31 July 1996	>30	All ages	>12	All ages	HS≥ 72m; ES≥ 48m; all CS
2010 - 2012 (no test of HS)	DOB > 31 July 1996	>30	All ages	>12	All ages	ES≥48m; all CS

HS=Healthy Slaughter; ES=Emergency Slaughter; CS=Clinical Suspect

The population of interest considered by the model is those animals eligible for the food chain and born after 31 July 1996. The assessment considers the number of animals testing positive by surveillance year from 2005 to 2012. Changes in the age at testing are only simulated for 2010 and forecasted years that is 2011 and 2012.

Baseline results

Both variability and uncertainty are considered in the model and are represented by 5th and 95th percentiles (within parentheses), which indicate the range within which 90% of the results lie. The greater the range between the percentiles means there is greater total uncertainty. Model 1 was run for 300,000 iterations using Latin Hypercube sampling. Model 2 was run for 40,000 iterations. It should be emphasised that not all variability and uncertainty has been estimated in the calculations, as not all can be quantified. Therefore the 5th and 95th percentiles describe the amount of *quantified* variability and uncertainty included in the model. The risk assessment has been developed such that only variability in the parameters can be modelled; however, these results are not presented here.

Infectivity per infected carcass entering the food chain

For the baseline, the amount of infectivity for an infected carcass that has by-passed control measures and enters the food chain estimated for those controls in place in 2005 has a mean of 6.1×10^{-5} bovine oral ID₅₀ (4.1×10^{-20} , 1.1×10^{-4}). The distribution

is highly left-skewed with very low values occurring frequently: the occurrence of very infrequent high values has resulted in the mean of the distribution lying between the 90th and 95th percentiles. The mean infectivity during 2006 increases to approximately 0.05 (3.6×10^{-20} , 4.3×10^{-2}) bovine oral ID₅₀ and then gradually decreases over the next five years to an estimated 0.03 bovine oral ID₅₀ (7.9×10^{-23} , 9.0×10^{-3}) per animal in 2012. The maximum levels of infectivity on a single carcass are estimated to be 0.5 bovine oral ID₅₀ in 2005, rising to 198 in 2006 and gradually declining to 100 by 2010. In 2012 relatively high maximum infectivity levels were seen likely to be due to outlier values that represent very rare, low probability events as shown in Table 2. However, when the 95th percentiles are considered the trend of decreasing infectivity after 2006 can be seen extending in 2012.

Table 2: Mean infectivity per infected carcass entering the food chain (bovine oral ID₅₀) along with minimum and maximum values and 5th and 95th percentiles (baseline results)

	2005	2006	2007	2008	2009	2010	2011	2012
Mean	6.1×10^{-5}	4.8×10^{-2}	4.0×10^{-2}	4.1×10^{-2}	3.8×10^{-2}	3.2×10^{-2}	3.3×10^{-2}	2.9×10^{-2}
Min	0	0	0	0	0	0	0	0
Max	0.5	198	117	165	126	100	105	164
5 th	4.1×10^{-20}	3.6×10^{-20}	6.7×10^{-21}	7.0×10^{-23}	7.5×10^{-23}	1.4×10^{-23}	2.5×10^{-24}	7.9×10^{-23}
95 th	1.1×10^{-4}	4.3×10^{-2}	3.3×10^{-2}	3.2×10^{-2}	2.2×10^{-2}	1.6×10^{-2}	1.5×10^{-2}	9.0×10^{-3}

Number of infected carcasses bypassing controls

The estimated average number of cattle that are infected and entering the food chain annually is provided in Table 3. During 2005 before OTM rule was replaced by testing, an estimated mean of 181 infected cattle were not identified by testing controls and were consumed over one year. In 2006, following the replacement of the OTM rule (with BSE testing), this increased to a mean estimate of approximately 344 infected animals. For the years 2007 to 2012, the mean number of infected animals is estimated to decrease steadily to 236 by 2012 (73, 507).

Table 3: Number of infected animals in GB by-passing controls and entering the food chain in a random year

Year	Mean (5 th , 95 th percentiles)
2005	180 (104, 291)
2006	344 (193, 567)

2007	315 (170, 535)
2008	329 (176, 562)
2009	272 (127, 502)
2010	271 (114, 527)
2011	262 (106, 517)
2012	236 (73, 507)

Total annual amount of infectivity consumed

The amount of infectivity consumed in 2005 is different compared to that of subsequent years, with an estimated mean of 0.02 bovine oral ID₅₀ consumed (2.2×10^{-3} , 0.08). During 2006 a number of different controls were amended including discontinuation of the OTM rule from 7 November 2005, relaxation on rules relating to consumption of head meat and the lowering of the age of removal of vertebral column from 30 to 24 months. The risk assessment assumes that these conditions were in place for the entire year represented as 2006 and remained the same in 2007. These changes in control measures and yearly prevalence estimates resulted in an increase, as compared to 2005, in the amount of infectivity consumed rising to an estimated 33 (3, 107) bovine oral ID₅₀ in 2006 and 27 (2, 97) bovine oral ID₅₀ in 2007. Between 2006 and 2007 the slight reduction in infectivity may be due to the gradual decline in prevalence in the absence of changes in controls.

In 2008, the age at removal of vertebral column was raised from 24 to 30 months and an estimated 27 (3, 99) bovine oral ID₅₀ were consumed in the food chain. At the beginning of 2009 the age at testing of cattle was raised to 48 months for healthy slaughter, emergency slaughter and fallen stock. Under these conditions, an estimated mean of 22 (1, 89) bovine oral ID₅₀ were consumed in 2009. The amount of infectivity consumed decreased slightly to 18 (0.8, 79) bovine oral ID₅₀ in 2010. It is estimated that this decreasing trend will continue in 2011 and 2012 whereby the estimated amount of infectivity in the food chain is 18 (0.7, 79) bovine oral ID₅₀ in 2011 and 15 (0.3, 74) bovine oral ID₅₀ in 2012 given no further changes in testing or controls from those in place in 2009.

When viewing these results it needs to be emphasised that the units are in bovine oral ID₅₀ doses and not human oral doses. It is possible to estimate the expected number of human cases of variant CJD (clinical cases or infections) that may result from such exposure by an estimation of the cattle to human species barrier. Work has been

carried out to estimate this species barrier (for example, Ferguson and Donnelly, 2003), but there is a large amount of uncertainty associated with such estimates. Current estimates used in European risk assessments are based on historical exposure of the UK population (Comer and Huntly, 2004) and current levels of vCJD clinical cases in the UK indicate a species barrier of approximately 4000 (EFSA, 2006). Under the circumstances, for the purposes of this risk assessment, variation in exposure in terms of bovine oral ID₅₀ was considered sufficient to enable estimations of change in the risk of exposure to infectivity with changes in control measures.

Validation of the risk assessment

There are two sources of information not used in the model that can be used to investigate the validity of the model and its outputs: GB surveillance data of test positive animals (born after 31st July 1996) by age and stream, and results from other models assessing the amount of infectivity entering the food chain. When comparing the proportion of observed test positive animals, of an age eligible for the food chain, by the exit category in which they were detected, the risk assessment estimates are slightly increased when compared to the observed data for 2009 and 2010, as shown in Figure 1. For both years, there were no test positive clinical suspects; therefore the model overestimated the number of test positive animals for these years. Overall, however, the model is predicting that the fallen stock stream will yield the most positive animals compared to the other streams as observed in the actual data for 2009 and 2010. In 2010, the only test positive animals were in the fallen stock stream.

When considering the total number of cases per year, it can be seen that this version of the risk assessment is overestimating the total number of test positive animals in 2009 (a mean of 7 versus an observed 3 positive animals) but for 2010, the model estimates for the total number of test positive animals are in agreement with the observed data (a mean of 6.7 cases versus an observed 6 positive animals).

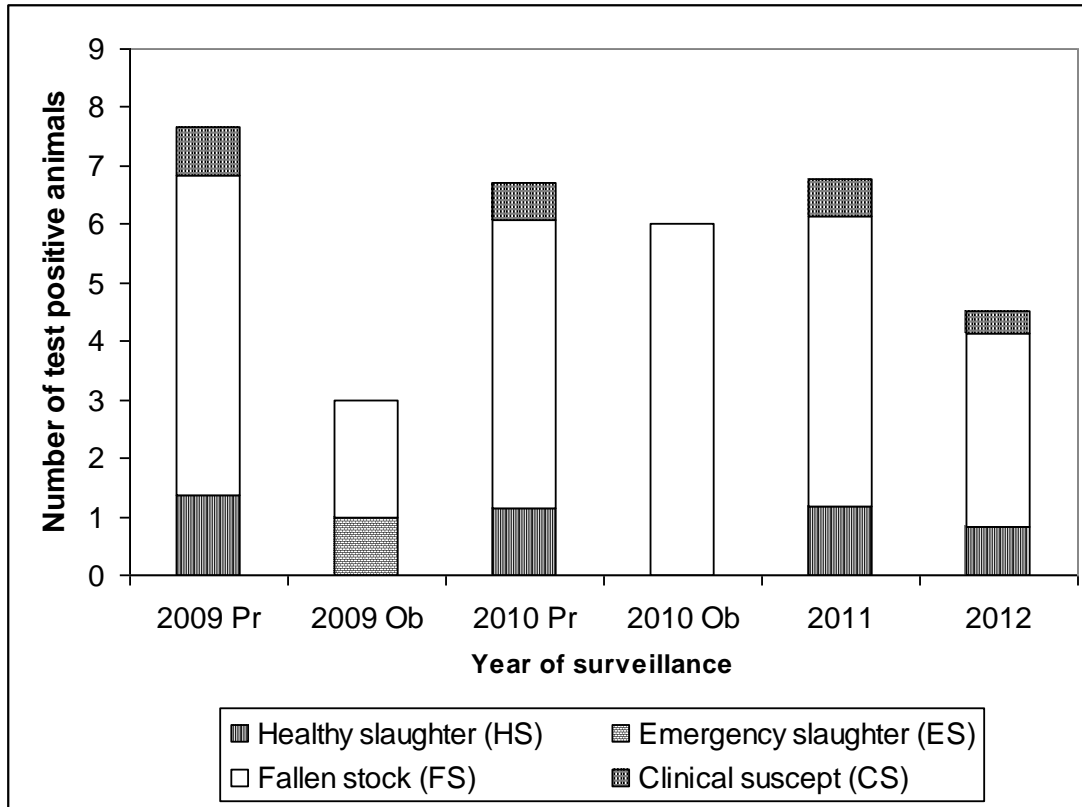


Figure 1: Number of test positive animals by year of surveillance observed from 2009 to 2010 and predicted by the BSE Control Model (Ob=Observed data; Pr=Predicted by the model)

The mean amount of infectivity consumed annually in GB can be compared to other estimates available in the literature. For example, Comer estimated that the exposure in 2001 was 0.25 bovine oral ID₅₀ for the UK population, and was predicted to fall to a little over 0.1 bovine oral ID₅₀ by 2004 given the continuation of the control measures in place (Comer, 2009; Comer and Huntly, 2004). The BSE control model estimates similar orders of magnitude at this time, with a mean value of 0.02 bovine oral ID₅₀ in 2005.

Scenario results

Infectivity per infected carcass entering the food chain

As detailed in the model background two scenarios were tested: increasing the age at testing to 72 months of HS and no testing of HS. Table 4 provides the mean amount of infectivity per infected carcass that enters the food chain for the baseline simulation and for the two scenarios. The estimated mean amount of infectivity for baseline controls in 2011 and 2012 is 3.3×10^{-2} and 2.9×10^{-2} bovine oral ID₅₀, respectively. A slight increase in the mean amount of infectivity is estimated if testing of HS is increased to 72 months and a larger increase in the mean amount of infectivity is observed for all years if no testing of HS is conducted.

Table 4: Mean (5th, 95th percentiles) infectivity per infected carcass entering the food chain (bovine oral ID₅₀) for each of the different testing scenarios

	2010	2011	2012
	3.2×10^{-2}	3.3×10^{-2}	2.9×10^{-2}
Baseline	(1.4×10^{-23} , 1.6×10^{-2})	(2.53×10^{-24} , 1.5×10^{-2})	(7.9×10^{-23} , 9.0×10^{-3})
HS >72 months	4.4×10^{-2} (1.3×10^{-23} , 1.7×10^{-2})	3.4×10^{-2} (2.3×10^{-24} , 1.6×10^{-2})	3.3×10^{-2} (7.9×10^{-23} , 9.8×10^{-3})
No testing of HS	8.7×10^{-2} (1.9×10^{-23} , 2.9×10^{-2})	8.4×10^{-2} (2.5×10^{-24} , 3.0×10^{-2})	7.4×10^{-2} (1.2×10^{-22} , 1.6×10^{-2})

Number of infected carcasses bypassing controls

In the baseline model (testing at 48 months), it is estimated that in 2011 and 2012 a mean of 262 and 236 infected animals, respectively, will bypass controls and enter the food chain annually. This increases by one animal to 263 animals in 2011 and remains at 236 animals in 2012 if HS animals are tested from 72 months. If HS are not tested, the mean number of animal increases slightly compared the baseline to a mean of 264 animals in 2011 and 238 animals in 2012.

Table 5: Number of infected animals in GB by-passing controls and entering the food chain in a random year

Year	Mean number of infected animals in GB entering the food chain in a random year (5 th , 95 th percentiles)		
	48 months	HS>72 months	No testing of HS
2011	262 (106, 517)	263 (107, 518)	264 (107, 521)
2012	236 (73, 507)	236 (73, 508)	238 (74, 512)

Total annual amount of infectivity consumed annually

Under the baseline control scenarios it is estimated that a mean of 18 (0.7, 82) and 14 (0.3, 74) bovine oral ID₅₀ will be consumed in 2011 and 2012 respectively. It is estimated that there will be a slight increase in the amount of bovine oral ID₅₀ consumed in 2012 if testing of HS is increased to 72 months compared to baseline controls. It is estimated that if no testing of HS animals is undertaken, the amount of infectivity consumed will increase to 42 (1, 146) bovine oral ID₅₀ for 2011 and to 33 (0.5, 123) bovine oral ID₅₀ for 2012. The results for each scenario are given in Table 6.

Table 6: Total annual amount of infectivity entering the food chain

Year	Annual amount of infectivity (Bovine oral ID ₅₀) entering the food chain in a random year (5 th , 95 th percentiles)		
	48 months	HS>72 months	No testing of HS
2011	18 (0.7, 82)	18 (0.7, 78)	42 (1, 146)
2012	14 (0.3, 74)	16 (0.3, 80)	33 (0.5, 123)

Number of animals missed

Using Model 1 of the BSE control model Version 8.0, the number of cases missed if animals are tested at 48 months, testing of HS is increased to 72 months and if HS are not tested can be estimated compared to testing of all animals. Using 300,000 iterations of the model, the mean and 5th and 95th percentiles for the number of cases missed in the healthy stock and emergency slaughter stream over a two-year rolling period of 2011 to 2012 is estimated (Table 7). If the testing of HS is raised to 72 months, it is estimated that there is no increase in the number of test positive cases missed compared to the current regime. An estimated mean of two test positive case is missed over the two year period if HS animals are not tested.

Table 7: Number of cases missed for the two-year rolling period (2011 to 2012) for each testing scenario compared to testing all animals in the Healthy Stock and Emergency Slaughter stream

Stream	Testing regime		
	48 months	HS>72 months	No testing of HS
HS/ES	0.05	0.05	2.07
	(0.02, 0.11)	(0.02, 0.10)	(0.78, 4.35)

Conclusions

Overall the results provide evidence of the low amount of BSE infectivity being consumed in the human food chain due to the control strategies in place with, on average, 0.02 bovine oral ID₅₀ consumed in 2005 rising to 33 bovine oral ID₅₀ consumed during 2006, reducing to 18 bovine oral ID₅₀ in 2010 across GB. We are 90% certain that the true value for 2010 is between 0.84 and 79 bovine oral ID₅₀. The model predicts that under baseline controls the amount of infectivity consumed in 2011 and 2012 will be 18 and 15 bovine oral ID₅₀ respectively.

Two scenarios were considered in which the age of testing for HS was raised to 72 months and with no testing of HS. When the age at testing is raised to 72m, the model estimates a slight increase in the mean amount of infectivity consumed during 2012. If no testing of HS took place, the mean amount of infectivity consumed would increase to 42 and 33 bovine oral ID₅₀ in 2011 and 2012 respectively.

The most recent estimates of the size of the species barrier between cattle and humans (4000, EFSA, 2006) suggest that the probability of new cases of vCJD arising from this exposure is extremely low.

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BSE test positive results in healthy cattle slaughtered for human consumption in UK since November 2005

By the end of December 2010, around 2.5 million cattle slaughtered for human consumption (2.04 million in Great Britain and 0.44 million in Northern Ireland) had been tested for BSE in the period since November 2005, when BSE testing of cattle slaughtered for human consumption was introduced in the UK. Of these, 12 (10 in GB, 2 in NI) have tested positive for BSE (see below). All were subsequently confirmed as BSE cases.

Great Britain

	Date of birth	Date of death	Age at death (months)
1.	18/02/1997	28/07/2006	113
2.	10/09/1999	01/09/2006	83
3.	12/08/2002	06/09/2006	48
4.	27/07/2000	27/04/2007	81
5.	05/04/1999	28/06/2007	98
6.	21/09/1998	04/09/2007	107
7.	30/09/1997	04/02/2008	124
8.	11/01/2003	03/07/2008	65
9.	24/11/1999	08/07/2008	103
10.	26/09/1996	13/11/2008	145

Northern Ireland

	Date of birth	Date of death	Age at death (months)
1.	unknown	16/01/2007	unknown
2.	08/05/1997	4/11/2009	149

EXTRACT FROM MINUTES OF SEAC 100 (APRIL 2008)**ITEM 7 – PROPOSALS TO REDUCE BSE TESTING OF CATTLE SLAUGHTERED FOR FOOD - IMPACT ON RISK TO HUMAN HEALTH (SEAC 100/4)**

48 Mr David Carruthers (Food Standards Agency (FSA)) explained that the present requirements for BSE testing of cattle for human consumption were introduced in the UK in November 2005, replacing the over thirty months rule (OTM). Recent changes to the legislation, as proposed in the European Commission's TSE Roadmap, allow Member States to apply to raise the age at which animals are tested provided certain conditions are met. The Commission asked EFSA to consider a range of options for change. Any change to current testing requirements for animals tested for human consumption in the UK would need to be agreed by the FSA board. The FSA and Defra asked VLA to assess the impact on human health of the EFSA options using the VLA BSE control risk model. The outputs from the model will be used to inform the FSA Board of the potential changes in risk to human health from altering the testing regime. SEAC is asked to consider the validity of the inputs and outputs from the model in assessing the possible impact to human health of changes to the BSE testing requirements and also to consider the extent to which BSE testing in OTM cattle was effective in reducing the risk.

49 Dr Rowena Kosmider (VLA) presented an overview of the VLA model. The model incorporates estimates of the annual number and age of infected cattle that potentially by-pass controls, the infectivity from brain, spinal cord, tonsil, dorsal root ganglia and peripheral nervous system in animals by months before onset of clinical disease and the amount of infectious tissue entering the food chain per infected carcass. The model had been peer-reviewed by experts at Massey University and was considered at SEAC 95 (December 2006). The model has since been updated to include new estimates for prevalence of BSE infection derived using the back calculation method⁹, and to take into account changes to the slaughter population and in BSE surveillance and controls.

⁹ Arnold & Wilesmith (2003) Modelling studies on BSE occurrence to assist in the review of the over 30 months rule in Great Britain. *Proc. Royal Soc.* 270, 2141-2145.

¹⁰ Comer & Huntly (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. *J. Vet. Res.* 7, 523-543.

50 Dr Kosmider explained that 12 options for the minimum age for BSE testing were considered by raising the age of testing healthy slaughter (HS) cattle from between 30 up to 60 months or of emergency slaughter (ES) and fallen stock (FS) cattle from between 24 up to 60 months. Results from the model showed that compared with 100% testing strategy no additional test positive ES cattle would be missed for the ES control options considered. The options for changing the age of testing for both HS and FS cattle resulted in less than one test positive animal missed for all options

when compared with 100% testing strategy. For the current strategy of testing over 30 months HS and 24 month FS/ES cattle the estimated number of test positive animals expected in the 2008/2009 cattle population was a mean of 1.19 for HS, 0.08 for ES and 8.23 for FS cattle. The total annual infectivity entering the food chain for the current testing strategy was calculated to be a mean of 96.45 Bovine ID50s in 2008 decreasing to 34.29 Bovine ID50s in 2009.

- 51 Dr Kosmider explained that, for illustrative purposes, the impact of missing one to ten BSE positive animals was modelled. The results showed that there would be a small incremental increase in infectivity up to an additional 8.8 Bovine ID50s in 2008 and 3.03 Bovine ID50s in 2009. These figures are very small compared with an estimate that around 11 million Bovine ID50s entered the food chain in 1993/10.
- 52 A member noted that there are a number of important uncertainties that need to be acknowledged when interpreting these data. Firstly, there is uncertainty in the accuracy of the back calculation model to estimate the prevalence of BSE infected animals that entered the food chain. Secondly, there are uncertainties about the level of infectivity in tissues during the BSE incubation period. It is important to know how well the predictions for the numbers of infected cattle generated by the model fit the surveillance and BSE case data to assess the validity of the model. Previously it had proved difficult to obtain a good fit. Mr Burke responded that there had been difficulties in obtaining accurate dates of birth for cattle born before July 1996 which may have led to these problems. Dr Kosmider stated that for validation purposes, outputs of the model were routinely compared against surveillance data. Information about the fit of predictions from the model to the observed data would be provided to the committee following the meeting.
- 53 A member sought clarification regarding the data presented in tables five and six in Annex 2 of SEAC paper 100/4. In table five, the amount of infectivity entering the food chain in 2008 and 2009 was less than 257.35 Bovine Oral ID50 (with 95% certainty). However, it was not clear how the number of infected animals entering the food supply was reflected in the figures. In table six, the increase in infectivity with increasing number of infected animals entering the food supply did not appear to be completely linear as may have been expected. Dr Kosmider agreed to respond to these points following the meeting.
- 54 A member asked why the modelling had not specifically considered the option preferred by the EU of testing at 42 months and 36 months for HS and ES/FS cattle, respectively. Dr Kosmider noted that this option could be modelled relatively quickly. Members noted that in terms of the absolute numbers of infected cattle, fewer test positive animals are missed by increasing the age of testing of HS cattle than increasing the age of testing of ES/FS cattle.
55. Members suggested that the model could be used to look at the change in risk from altering a number of different controls as this was important to consider as had been discussed earlier.

56. The Chair summarised the discussion noting 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.
- 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.

EXTRACT FROM MINUTES OF SEAC 101 (OCTOBER 2008)**ITEM 5 – PROPOSALS TO REDUCE TESTING OF CATTLE SLAUGHTERED FOR FOOD – IMPACT ON RISK TO HUMAN HEALTH (SEAC 101/2)**

12. The Chair introduced the item, stating that at SEAC 100, the Food Standards Agency (FSA) had asked SEAC to consider a risk assessment by the Veterinary Laboratories Agency (VLA) of the human health risk from increasing the minimum age at which cattle are tested for BSE. At that meeting, members raised a number of questions that had been addressed in correspondence since SEAC 100. A draft conclusion on the issue had been circulated to SEAC for comment and agreement. The finalised conclusion would be presented by the Chair to FSA Board immediately following SEAC 101.
13. Members were satisfied that the questions raised at SEAC 100 had been addressed. Members concluded that the risk assessment was suitable and gave a reasonable estimate of the risk to human health from increasing the age of BSE testing of cattle for human consumption. This risk was very low as long as the prevalence of BSE remains low. Therefore, it is important that surveillance continues to remain capable of detecting changes in the prevalence and incidence of BSE, the possible emergence of a further BSE epidemic and, possibly, the emergence of a new TSE in cattle.
14. Professor Sheila Bird (MRC – Biostatistics Unit) noted that the age at which cattle are tested could influence how early a new epidemic of BSE or of another TSE in cattle might be detected.
15. Members noted that the results from a simpler analysis of the effect of increasing the age of BSE testing produced by the European Food Safety Authority (EFSA) were not inconsistent with the results produced by the VLA analysis.
16. SEAC agreed the following conclusion which was to be provided to the FSA Board:

SEAC considered the results from a mathematical model that had been used to estimate the number of infected cattle that may be undetected as a result of raising the minimum age at which healthy slaughtered and fallen stock cattle must be tested for BSE. The model itself, produced by VLA, was previously reviewed by SEAC¹.

¹ Reviewed at SEAC 95, December 2006.

The increased risks to human health estimated by the model from raising the age at which healthy slaughtered cattle are tested for BSE (up to 60 months, the highest age modelled) are very small. The model estimates that much less than one BSE case would be missed annually in the GB herd by increasing the age of testing to 60 months for the healthy slaughter surveillance stream. Although uncertainties are inherent in such modelling, the validation of the model that has been conducted provides

assurances about the reliability of the results. Similar results from a different analysis by EFSA^{2,3} provide additional confidence in the findings. The EFSA analysis estimates that less than two BSE cases would be missed annually in the whole of the EU15⁴ by increasing the age of testing to 60 months for the healthy slaughter surveillance stream.

These risk assessments hold provided the incidence of BSE in cattle remains low. Therefore, regulations should not be modified unless effective surveillance remains in place. Surveillance is the only means of monitoring changes in the incidence and prevalence of BSE, the effectiveness of control measures in preventing an epidemic and the possible emergence of new prion diseases. As control measures to prevent cattle and human infection are modified, continued active and passive surveillance become increasingly important to ensure that the remaining controls are effective in minimising the risk to human and animal health.

² Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States. Scientific Opinion of the Panel on Biological Hazards. The EFSA Journal (2008) 762, 1-47.

³ 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. Opinion of the Panel on Biological Hazards. The EFSA Journal (2008) 763, 1-8.

⁴ Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom