

Appendix 4 – A Summary of Opinions from the Spongiform Encephalopathy Advisory Committee (SEAC)

1. SPECIFIED RISK MATERIAL

Strategic goal: to ensure and maintain the current level of consumer protection by continuing to assure the safe removal of SRM but modify list / age based on new and evolving scientific opinion.

SEAC CONSIDERATIONS

a) Vertebral column

In view of the fact that EFSA would be conducting a risk assessment on harmonising rules on the SRM age limit for vertebral column, the FSA commissioned DNV Consulting to assess risk from under thirty-month beef on the bone¹ and the change in risk to the UK population that would result if the age limit for vertebral column as SRM was reduced from 30 to 12 months of age. In April 2005 (SEAC 87)² SEAC was asked by the FSA to comment on the scientific validity of the approaches used by DNV and to comment on the findings.

The risk assessment was built on previous assessments undertaken for the FSA, as part of the review of the over thirty months rule (OTM)³. It included up-to-date data on BSE infectivity, butchery practices, and possible number of infected animals slaughtered for food⁴.

What did the risk assessment say?

It concluded that if the vertebral column of animals were to be classified as SRM from 12 months of age the median UK BSE exposure would reduce from 0.07 to 0.05 bovine oral ID₅₀ units per year. The proportion of Dorsal Root Ganglia consumed would reduce from 2.2 to 1.65%. In a hypothetical worse case scenario, if one fully infected animal entered the food supply, exposure would be 3 bovine oral ID₅₀/year, reducing to 2.4 bovine oral ID₅₀/year if vertebral column was SRM.

It was not possible to estimate the likely maximum infective dose to individuals who choose to consume beef on the bone because of lack of data on this population subgroup.

What did SEAC say?

SEAC concluded that it was content with the approach used and assumptions made in the risk assessment. It noted that:

¹ DNV Consulting (2005). Assessment of Risk from Under Thirty Month Beef-on-the Bone: Report for the Food Standards Agency. <http://www.seac.gov.uk/pdf/utmbobreport-rev220405.pdf>

² SEAC 87 minutes <http://www.seac.gov.uk/minutes/final87.pdf>

³ Comer PJ and Huntly PJ (2004) *Journal of Risk Research* 7, 523-43

⁴ SEAC paper 87/2 <http://www.seac.gov.uk/pdf/87-2.pdf>

- the assessment included a pessimistic assumption about the levels of infectivity entering the food chain from residual DRG associated with vertebral column
- some uncertainties remained with regard to the extent of the species barrier between cattle and humans.
- the risks were calculated for the UK population in general and not specifically considered the UK beef on the bone consuming population. However, although exposure would be higher in this group than assumed in the assessment, the risk to this population group is still likely to be very small.
- the change in classification of vertebral column as SRM from 30 months to 12 months would make a very small to negligible difference in risk, even to the small number of people who consume beef on the bone.

A summary of the SEAC discussion was issued after the meeting⁵.

b) Ox tongue and associated tonsil tissue

In September 2002 (SEAC 75) the committee received an update from the VLA of a long-term study of the pathogenesis of BSE in cattle. Cattle were orally dosed with 100g BSE infected bovine brain material and culled at various time points after infection and infectivity in tissues detected by cattle bioassay. Previously reported results from the cattle bioassay study had confirmed infectivity in the distal ileum, caudal medulla and spinal cord.

What did the study show?

One of the five cattle administered with a pooled sample of palatine tonsil taken from animals infected with BSE had shown clinical evidence of onset of BSE at 45 months post-administration. The four remaining animals were alive without evidence of clinical onset of BSE. The committee considered the finding as significant and was unlikely to be an artefactual result.

What did SEAC say?

The committee advised that the significance of the tonsil infectivity finding would be strengthened if any of the other four animals in the experimental group developed BSE.

Bovine tonsils are specified risk material (SRM) and thus, prevented from entering the food chain from six months of age in the UK but tongue is not classified as SRM. In view of this, the committee recommended that a risk assessment should be carried out to establish the level of exposure to BSE infectivity that the population might be exposed to, based on the results for cattle bioassay of tonsil.

A SEAC Statement was issued after the meeting⁶.

⁵ <http://www.seac.gov.uk/pdf/arm-210405.pdf>

⁶ <http://www.seac.gov.uk/statements/tonsil211002.pdf>

In June 2003 (SEAC 78)⁷ SEAC revisited the issue of the infectivity of ox tongue and associated tonsil.

What did the study say?

The remaining four animals in the cattle bioassay had no clinical signs of BSE at 58 months post-inoculation. The committee also considered a risk assessment prepared by DNV Consulting on behalf of the FSA, on the risk of BSE infectivity entering the food supply from ox tongue potentially contaminated with tonsil tissue. Included in the risk assessment were results from a study by the VLA that had looked at the amount of residual tonsil tissue on ox tongue and shown that a significant amount of tonsil tissue was present on around half of the ox tongues examined⁸.

What did SEAC say?

The committee noted the uncertainty in some of the assumptions made in the risk assessment, particularly with respect to the level of infectivity in tonsil tissue. However, the committee agreed that the potential risk of infectivity from consumption of ox tongue was likely to be very small.

A SEAC statement was issued after the meeting⁹.

c) SRM in small ruminants

SEAC has not considered, in detail, information relevant to changes in SRM controls for small ruminants.

In March 2005 (SEAC 86)¹⁰, in the light of the finding of possible BSE in a UK goat, FSA asked SEAC if there was further advice FSA should impart to consumers and what further information could be collected that might inform the possible food safety risks.

What information was available?

Dr Hope (VLA) informed the committee that a search of VLA archives for samples from TSE goat cases had identified 10 cases of TSE infection between 1984 and 1990. Nine out of the ten cases were indistinguishable from scrapie by IHC. However, in one case, a goat killed in 1984, the IHC results did not rule out BSE and would be further investigated. SEAC agreed that on the basis of the data presented, the TSE case in the Scottish goat was very likely to be BSE.

SEAC members asked Dr Hope if abnormal PrP had been found in the lymphoid tissue of the goat as this would provide additional information about the infectivity of goat tissues. Dr Hope indicated that all the available viscera had been tested by IHC and none had given a positive on IHC testing, although this negative result was not conclusive because of ante-mortem damage to the tissues¹¹.

⁷ Minutes of SEAC 78 <http://www.seac.gov.uk/minutes/draft78.pdf>

⁸ SEAC paper 78/2 DNV risk assessment http://www.seac.gov.uk/papers/seac78_2.pdf

⁹ Annex VI, 2003 Annual report) <http://www.seac.gov.uk/publicats/annualreport2003.pdf>

¹⁰ <http://www.seac.gov.uk/minutes/final86.pdf>

¹¹ Notes added post-meeting by VLA

The committee concluded that there was no evidence of BSE in current goat herds, but that this could not be excluded until further surveillance results are assessed. The risk from consumption of goat meat and meat products was therefore likely to be very low, particularly in the light of SRM controls. The committee concluded that on the basis of current evidence it was reasonable for the FSA to continue to not advise against the consumption of goat meat or dairy products. However, SEAC recommended a watching brief should be kept and further information should be considered as it accrues.

d) Production of dicalcium phosphate for poultry feed

In July 2000 (SEAC 62) SEAC considered whether bovine bones could be used to produce dicalcium phosphate for poultry feed.

Information considered.

SEAC considered an SSC opinion and various responses from members of UK industry involved in dicalcium phosphate production.¹²

What did SEAC say?

SEAC agreed that imported bovine bones and bones from UK cattle under thirty months of age with SRM removed could be used to produce dicalcium phosphate for poultry feed. However, because of concerns about intra-species recycling, this practice could only be allowed if it could be assured that the material would not be included in feed for any other livestock. If this could not be guaranteed then it should not be used.

2. FEED BAN

Strategic goal: a relaxation of certain measures of the current total feed ban when certain conditions are met.

i) Environmental contamination (bones of wild animals in beet pulp)

The Roadmap says that introduction of a tolerance on the presence of bone fragments in sugar beet pulp and other feedingstuffs due to environmental contamination would be considered only when a robust risk assessment has demonstrated the absence of cross contamination or the fraudulent incorporation of MBM. It is not clear exactly what this means. SEAC has not considered this issue (bones of wild animals) specifically. However it has

1. The IHC test allows provisional characterisation of BSE-like infections in small ruminants and can be applied to CNS and lymphoreticular tissues. However, the only tissues available from animals with experimental BSE tissues for use as test controls were generated by intracerebral challenge. It should be noted that sheep (and presumably goats) infected intracerebrally with TSE agents do not show a wide visceral distribution of infection specific PrP.

2. The UK goat with a BSE-like infection had a limited range of samples of viscera available for IHC. Unfortunately, both the spleen and the lymph nodes showed ante-mortem damage and in neither of the available samples of lymphoid tissue could secondary follicles of germinal centres be clearly recognized. Although IHC was carried out on these tissues, due to the poor quality of the samples, the possible presence, distribution and nature of potential peripheral disease specific PrP could not be determined.

¹² Hard copies available from SEAC Secretariat.

considered the infectivity of bone and bone marrow in cattle infected with BSE; depending upon what the Commission has in mind, this could be relevant to the issue of environmental contamination.

What did studies show?

Infectivity in bone marrow had been reviewed by SEAC in 1998 when the committee considered the results from a mouse bioassay study of the infectivity of sternal bone marrow from cattle orally exposed to BSE¹³. A single positive result from this mouse bioassay, at 38 months post inoculation, suggested that the level of infectivity was low. However, on the advice of SEAC, infectivity of bovine bone marrow had been examined in a more sensitive cattle bioassay.

In November 2003¹⁴, the committee noted that no clinical signs of BSE in any of the animals in the bioassay had been reported up to 55 months post inoculation¹⁵.

What did SEAC say?

The committee agreed the results from the cattle bioassay indicated that the level of infectivity was at most very low and considered that the single positive finding from the mouse bioassay might be an experimental artefact, but it could not be discounted. The committee agreed that a more detailed study would be needed before a more accurate quantification and analysis of bone marrow infectivity could be made and recommended re-examination of brain tissues from the original mouse bioassay experiment with the new and more sensitive diagnostic techniques.

ii) Fishmeal

SEAC has not considered data relevant to the issue of whether there should be introduction of a tolerance level for fishmeal (cross contamination) in ruminant feed.

iii) Amending feed ban provisions for non-ruminant proteins

SEAC has not considered data relevant to the issue of whether there should be introduction of a tolerance level for MBM in feed.

iv) Tallow

SEAC has not considered any quantitative risk assessment relevant to consideration of new provisions on tallow, in particular for use in milk replacers. However SEAC has considered the BSE infectivity of tallow and this could be relevant to consideration of provisions on tallow.

What did the study show?

In June 2004 (SEAC 83)¹⁶, SEAC was updated on the findings of an experimental study by the VLA on the effect of the rendering process on TSE

¹³ Wells GA, Hawkins SA, Green RB, Spencer YI, Dexter I, Dawson M. 1999. Limited detection of sternal bone marrow infectivity in the clinical phase of experimental Bovine Spongiform Encephalopathy (BSE). *Vet Rec.* Mar 13: **144** (11): 292-4

¹⁴ Minutes of SEAC 80 <http://www.seac.gov.uk/minutes/final80.pdf>

¹⁵ SEAC Paper 80/2 http://www.seac.gov.uk/papers/seac80_2.pdf

infectivity, and the distribution of abnormal PrP. In the study, infectivity levels in samples from all stages of the rendering process had been measured by mouse bioassay. The study had been conducted because it had been suggested that the solvent extraction of tallow from the greaves had previously protected the cattle food chain by either inactivating the BSE agent during the solvent and/or steam treatment, or by partitioning the agent into the tallow and thus removing it from the MBM.

The study showed the partitioning of some infectivity into tallow as demonstrated by bioassay of tallow fractions recovered from the greaves by centrifugation and flash heating. Infectivity was also detected in bulk tallow in 1/15 mice at 10^{-2} dilution of inoculum. However, the bioassay data remained incomplete, as some animals were still alive, particularly in the low-level infectivity assays.

It was noted that although in Britain tallow was no longer used in animal feed, it might be used as an ingredient in milk replacement rations for calves in other European countries. SEAC was informed that this tallow was melted fat from discrete adipose tissue, a different product from bulk tallow.

What did SEAC say?

The committee was asked to comment on the findings of the study in the context of their historical relevance to the start of the BSE epidemic. The committee concluded that the data from the current study were interesting findings which did not support the hypothesis that cessation of solvent extraction of greaves may have led to increased available infectivity in MBM and the start of the BSE epidemic. The committee indicated that issues relating to tallow and infectivity could be considered again when EFSA published its conclusions.

3. MONITORING PROGRAMMES

Strategic goal: to reduce the numbers of tests of bovine animals and at the same time continue to measure the effectiveness of the measures in place with a better targeting of the surveillance activity.

i) Bovine animals

SEAC has not considered information relating to a move from the current testing regime to maintenance surveillance.

ii) Small ruminants

SEAC has not considered information relevant to amending the current testing regime.

iii) Cervids (e.g. deer)

In November 2004 (SEAC 85)¹⁷ FSA asked SEAC to advise on the potential public and animal health risks of chronic wasting disease (CWD). While CWD

¹⁶ SEAC 83 was held in closed session.

¹⁷ Minutes of SEAC 85 <http://www.seac.gov.uk/minutes/final85.pdf>

had not been found in UK deer to date, FSA wished to consider what action could be taken to reduce the possible risks to consumers of venison should positive findings be made in future.

Most of the information on CWD is derived from research on North American deer and there are few data on UK species or human health aspects.

What information did SEAC consider?

SEAC considered a large amount of information presented in SEAC paper 85/2 and its Annexes.¹⁸

What did SEAC say?

SEAC noted that EFSA had issued an opinion on TSE surveillance in deer and members endorsed the EFSA opinion. In relation to the issues raised in the TSE Roadmap SEAC noted that:

- there is no evidence of transmission of CWD to humans from consumption of venison but data are extremely limited and it would be very difficult to detect a low level of infection. Additionally, although there are few data, there is some evidence to suggest the presence of a species barrier to transmission to humans. Studies of transgenic mice expressing human forms of PrP may give more information about a possible species barrier
- although a theoretical possibility exists, there is no evidence to suggest that BSE is present in UK deer. However, it is important to closely monitor the findings of an on-going study to look at the potential susceptibility of red deer to BSE.

A SEAC Position Statement on CWD in UK deer was issued after the meeting.¹⁹

4. THE CATEGORISATION OF COUNTRIES ACCORDING TO THEIR BSE RISK

Strategic goal: simplification of the categorisation criteria and conclusion of the categorisation of countries before 1 July 2007.

SEAC has not considered information relevant to the categorisation criteria for countries.

5. REVIEW OF CULLING POLICY WITH REGARD TO TSEs IN SMALL RUMINANTS

Strategic goal: review and relaxation of the eradication measures for small ruminants taking into account the new diagnostic tools available but ensuring the current level of consumer protection.

¹⁸ SEAC paper 85/2 and Annexes <http://www.seac.gov.uk/agenda/agen301104.htm>

¹⁹ <http://www.seac.gov.uk/statements/state180105.htm>.

SEAC has not considered information relevant to amendments to culling policy for small ruminants.

6. COHORT CULLING IN BOVINE ANIMALS

Strategic goal: to stop the immediate culling of the cohort.

In February 2003 (SEAC 77)²⁰ SEAC considered information, provided in Paper 77/4 and its Annexes²¹, in relation to cohort culling of cattle because new legislation was about to come into effect. Previously in the UK all offspring born after 1996 from BSE cases were culled. This policy had been put in place to protect the public from potentially BSE-infected beef getting into the food chain and to secure the agreement of other EU member states to the resumption of UK beef exports. However, in order to comply with the European TSE Regulations the cull requirements were about to be changed to implement a cull of offspring born two years prior to development of BSE or offspring born anytime after the development of BSE in the dam. Offspring born outside those two years and aged under 30 months would be able to go into the food chain.

What did SEAC say?

The Committee considered that there was no scientific evidence to suggest that moving to the EU rule would increase the risk of human exposure to BSE-infected animals.

7. UK RESTRICTIONS

Strategic goal: to discuss the lifting of the additional restrictions on exports of beef and beef products from the UK if the preset conditions are complied with.

On a number of occasions SEAC has considered information relevant to amending the OTM Rule and given its views. Most recently, in April 2004 (SEAC 82)²², the FSA asked the committee to comment on the conclusions reached by the FSA/SEAC Risk Assessment Group (RAG). RAG had been convened to provide scientific advice to the FSA on the levels of risk to the consumer from changes to the Over Thirty Month Rule (OTMR). Earlier in April, RAG had considered the impact of replacement of the OTMR with BSE testing of cattle over 30 months of age, taking into account new scientific data on a case of vCJD thought to be acquired by blood transfusion and the results of a retrospective survey of human tonsil and appendix tissue. SEAC members expressed a spectrum of views as to how the survey data and vCJD case data should be incorporated into the risk assessment. Both SEAC and RAG agreed that the new data did not fundamentally change the underlying assumptions in the risk assessment and that replacing the OTMR with testing cattle would result in only a very small increase in the estimated potential overall size of the vCJD epidemic.

²⁰ Minutes of SEAC 77 <http://www.seac.gov.uk/minutes/final77.pdf>

²¹ http://www.seac.gov.uk/papers/seac77_4.pdf

²² <http://www.seac.gov.uk/minutes/final82.pdf>

A statement summarising the RAG and SEAC consideration is given at Annex 9 of the 2004 SEAC Annual Report²³.

From the UK point of view, the next step towards amending the OTM Rule is that the FSA Board will consider, at its open meeting on 15 August, what advice the Agency will give to Ministers on a BSE testing system (trialled earlier this year) as part of a managed transition towards replacing the OTM Rule.

²³ <http://www.seac.gov.uk/publicats/annualreport2004.pdf>