

FSA Workshop hosted by the Royal Society: Risk Assessment – Social Science Insights

Case study: The review of the OTM rule

1. SUMMARY

The Agency conducted a review to determine if it would be advisable to replace the OTM rule with the BSE testing program used in other EU countries. The risk assessment for the review was provided by the Spongiform Encephalopathy Advisory Committee (SEAC). The appropriate risk management was considered by a stakeholder group, taking account of the risk assessment and proportionality. At the conclusion of the review the FSA Board agreed that it would be appropriate to advise Ministers that a move to replace the OTM rule by BSE testing would be justified.

2. BACKGROUND

2.1 The Over Thirty Month (OTM) rule

This was introduced in the UK in 1996 after the probable link between BSE and vCJD was established. It followed advice from the independent expert Spongiform Encephalopathy Advisory Committee (SEAC) on the risk.

The OTM rule bans the sale of beef in the UK from cattle aged over 30 months at slaughter. Legislation was already in place banning the feeding of animal protein to ruminants which was considered as the most likely method by which the disease was being spread. Legislation banning those tissues understood to carry the heaviest infection load had been introduced in 1989. These other requirements have developed with time and are now incorporated into the EC TSE legislation that applies to all member states.

2.2 Previous review of the OTM Rule

The Food Standards Agency considered the Rule in its Review of BSE Controls, published in December 2000. This recommended that January 2002 was the earliest date on which a decision could be taken to announce the year of birth of animals after which animals could enter the food supply, subject to a continuing decline in the disease.

2.3 2002 Review of the OTM rule

The Terms of reference for the review are given in Annex 1.

3. COMMITTEES PARTICIPATING IN THE REVIEW

3.1 SEAC (The Spongiform Encephalopathy Advisory Committee)

This is the government advisory committee on TSEs, dealing with questions raised by Defra, DoH, FSA and the corresponding devolved departments. Its

role is risk assessment. The membership and Terms of reference applicable at the time of the review can be found in Annex 2. The committee is served by an independent secretariat and is subject to independent review at least every five years.

3.2 FSA/SEAC risk assessment group (RAG)

This was an expert group set up specifically for the OTM review. The group was chaired by Professor Peter Smith, then chair of SEAC, and membership was drawn from SEAC and other experts in the fields of risk assessment and BSE. The Terms of reference and membership can be found at Annex 3.

3.3 Core stakeholder group

This group was set up specifically for the OTM review by the FSA. Appropriate representatives of industry, the veterinary profession and consumer organisations were invited to become members. The Human BSE Foundation and officials from other government departments attended meetings as observers. The Terms of reference and membership can be found at Annex 4.

4. THE PROCESS

The stakeholder group decides the requirements of the quantitative risk assessment.

The risk assessment work is carried out with constant oversight from RAG.

RAG reports the risk assessment results to SEAC for their consideration.

The stakeholder group considers the risk assessment results along with costs and other issues of proportionality to provide a recommendation to the FSA Board on changes to the OTM rule.

The FSA Board considers the stakeholder report and provides advice to Ministers on changes to the OTM rule.

Information is provided to the general public via the website and open meetings at all stages of the process.

4.1 The stakeholder group decides the requirements of the quantitative risk assessment

The possible alternatives for changes to the OTM rule that could be modelled for the risk assessment were fairly limited. Essentially cattle could be restricted from entering the food supply by age or by date of birth. The former would place a continuing restriction on cattle, whereas the latter would mean that eventually all cattle could enter the food supply (subject to normal

restrictions). All possible ages and years of birth were modelled in comparison to retaining the OTM rule, and no decision on the most appropriate limits were made prior to seeing the results. Based on the observation that more BSE cases are found in 'casualty' animals it was also agreed that the modelling should consider the contribution to the risk from these animals.

4.2 The risk assessment work is carried out with constant oversight from RAG

The risk assessment modelling was commissioned by the FSA from Professor Ferguson's group at Imperial College. In brief, the objective was to use data on cattle testing and demography to estimate the number and age of infected animals and hence the amount of infectivity that had entered the food chain in the past and is predicted to go into the food chain in the future. In a final calculation estimates of the number of additional vCJD cases that could result from the various options for changing the OTM rule were prepared. Separate models were prepared for GB and NI because the pattern of the BSE epidemic differed. Most beef imports are also subject to the OTM rule, therefore a further assessment was prepared for RoI as the major exporter to the UK. In addition staff in the epidemiology group at the Veterinary Laboratories Agency also modelled the GB risk to highlight any discrepancies with the results from the Imperial model.

These were quantitative risk assessments of which the components were: the available data, assumptions where data is lacking or uncertain and the mathematical modelling. The RAG was responsible for advising on the assumptions and peer reviewing the modelling. They met a total of 8 times between May 2002 and April 2004.

4.3 RAG reports the risk assessment results to SEAC for their consideration

As the government's advisory committee on the risk from TSEs SEAC's role in this process was essentially one of peer reviewing the quantitative risk assessments and advising on their robustness. This required consideration of all elements of the modelling by the experts on SEAC. The committee produced a statement of their views on the modelling, the assumptions to be used and the uncertainties following the final meeting on this subject (July 2004), attached at Annex 5. This was included in the paper for the FSA Board open meeting that followed. Further peer review of this work was provided through the standard journal publication process.

4.4 The stakeholder group considers the risk assessment results along with costs and other issues of proportionality to provide a recommendation to the FSA Board on changes to the OTM rule

The FSA set up the core stakeholder group (CSG) to advise it on whether or not the OTM rule could be varied without unacceptable risk to consumers and, if so, to make recommendations on the measures that should replace it. They were asked to take into account all the relevant factors including, the risk assessment, costs and benefits and enforceability and practicality. TSE

legislation was introduced by the EC in 2001 that applies to all member states. This allows meat from OTM animals to go for human consumption providing that it has tested negative for BSE and has had the high risk tissues removed. The group had to consider whether these requirements would now provide adequate public health protection from BSE in UK and imported beef.

This group met a total of 9 times between July 2002 and March 2003. Based on the results of the risk assessment, expressed in terms of vCJD cases, they considered a number of possible date of birth limits, including no limit, in comparison to retaining the OTM rule. They concluded that in terms of risk there was little difference between all the options and that any increase in risk would be exceedingly small. The cost of applying the OTM rule has been some £300-400 million p.a.. This declines as the proportion of OTM cattle allowed into the food chain following BSE testing increases. Whilst recognising the suffering caused to patients and their families from the inevitably fatal outcome from vCJD, clearly expressed by the human BSE foundation, the CSG recognised that the value of preventing a fatality that would result from retaining the OTM rule was far in excess of the top end of the range that has been used for assessing Government policies. This discussion was informed by an independent report prepared by DNV consulting and a review prepared by the FSA economics division.

CSG then recommended that 'on the basis that the additional public health benefit provided by the OTM rule relative to the other options is small but the additional costs of maintaining it continue to be large, a move to one of the options for replacing the rule by testing would be justified'. A variety of technical issues were considered in the discussion on practicality and enforceability which led the group to recommend that 'demonstrable arrangements for reliable and timely BSE testing and traceability of all parts of the tested animals retained at the abattoir should be put in place before any move to replace the OTM rule by testing of OTM animals is made'.

A report of the CSG discussions and recommendations was prepared and issued for 12 weeks' public consultation. The report and a summary of the responses received during the public consultation were included in the paper considered by the FSA Board in July 2003.

4.5 The FSA Board considers the stakeholder report and provides advice to Ministers on changes to the OTM rule

Papers are presented by the executive for consideration by the FSA Board. The Board met in public on 10/07/03 to consider the CSG report and discuss the replacement of the OTM rule with testing. Minutes of all Board meetings are published on the FSA website. Following this meeting the FSA advised Ministers that the OTM rule could be replaced by BSE testing.

Subsequent to this, the results of a survey of human tissues were announced which indicated that the future number of vCJD cases might be higher than the figure used in the risk assessment. These results were considered by

RAG and SEAC and the final step of the risk assessment, which converts the BSE risk into a vCJD risk, was amended to take account of these results. The resulting changes to the risk assessment were put to the FSA Board on 06/07/04. At this public meeting the Board agreed it would still be appropriate to advise Ministers that a move to replace the OTM rule by BSE testing would be justified. They also agreed that, given the importance of the effective implementation of BSE testing, Ministers should not change the OTM rule until an independent group has advised that all the necessary arrangements for testing have been put in place.

In March 2005 the FSA issued a 12 week public consultation on proposals for implementing a managed transition from the Over Thirty Months rule to BSE testing.

4.6 Information provided to the general public via the website and open meetings at all stages of the process

RAG meetings, the OTM items at SEAC meetings and the stakeholder group meetings were closed sessions since they always included pre-publication data. However there were numerous occasions when there was an opportunity for public input to the review.

The review was launched at an open public meeting in July 2002. Some 120 people at the public meeting saw presentations by SEAC Chair Professor Peter Smith, NFU Scotland President Jim Walker, British Meat Federation Director Peter Scott, and Dr John Godfrey, a member of the consumer organisation Foodaware. Questions and contributions were then taken from the floor, with Sir John Krebs chairing a panel including the above speakers and Kevin Hawkins, Safeway's Director of Communications and Dick Sibley, Senior Vice-President of the British Cattle Veterinary Association. The views expressed at this meeting were reported to the CSG. In March 2003 the public were again consulted at an open meeting on the view reached by the stakeholder group, prior to the production of their final report. Further open meetings were held in July 2005 in London, Cardiff, Edinburgh and Belfast to provide an opportunity for stakeholders and the public to discuss the proposed OTM Rule change process, including the outcome of the BSE testing trials.

The public FSA Board meetings referred to above, and other meetings at which the Board received an update on progress all included opportunities for public questions from the floor or via the web/E-mail.

Throughout the review the FSA (and other government departments) have placed information in the public domain in the form of press releases and supporting information. Entering 'OTM review' as a search item on the FSA website will produce almost 400 hits, demonstrating the level of information available to the public on this issue, in keeping with the FSA policy on being open. Further communication has, of course, taken place in response to individual enquiries from members of the public and the media.

OTM Rule Review

Terms of reference

Agreed by an intra-government project board

To review:-

- the Over Thirty Months rule, as applied to beef of UK origin, taking into account
 - a scientific risk assessment of options to amend the rule
 - the practicality and enforceability of any variation in the rule
 - the views of stakeholders
- the effect of any variation in the rule on the risk to UK consumers from OTM beef of non-UK origin
- and to make recommendations

The Spongiform Encephalopathy Advisory Committee (SEAC)

Terms of reference during 2004

To:

Advise on Transmissible Spongiform Encephalopathies (TSEs) at the request of:

Department of Environment, Food and Rural Affairs (Defra)

Department of Health (DH)

Food Standards Agency (FSA)

Scottish Executive

Welsh Assembly Government

Northern Ireland Executive

Provide independent scientific advice on food safety, public and animal health issues relating to TSEs taking account of the remits of other bodies with related responsibilities.

Provide scientifically based assessment of risk from TSEs to public and animal health and food safety taking appropriate account of scientific uncertainty and assumptions in formulating advice. The committee will convey the nature and extent of such uncertainties with the advice.

Advise on important general principles or new scientific discoveries in TSEs to assist in the identification of new or emerging TSE risks for public or animal health and food.

Advise on the scientific basis and risks associated with the introduction of new control measures or the reduction, phasing out or withdrawal of current control measures which are in place to protect public health or animal health from TSEs.

Identify where research is desirable to reduce the scientific uncertainty and inform the assessment of public and animal health and food safety risks relating to TSEs.

Terms of reference during 2002 and 2003

To provide scientifically based advice to the
Department for Environment, Food and Rural Affairs (Defra),
the Department of Health (DH),
Devolved Administrations,
and the Food Standards Agency (FSA)
on matters relating to spongiform encephalopathies, taking account of the
remits of other bodies with related responsibilities.

Membership of the Committee during the period of the review

Professor Peter G. Smith, Chairman.

Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine.

Professor Adriano Aguzzi (until Nov. 2003)

Head of the Institute of Neuropathology, University of Zurich, Director of the Swiss Reference Centre for Prion Diseases and Associate Dean for Research Zurich Medical School, Switzerland.

Professor Roy Anderson (until Nov. 2003)

Head of the Department of Infectious Disease and Epidemiology, Imperial College School of Medicine, University of London.

Mr John Bassett (from Feb. 2004)

Risk assessor, specialising in microbiology, at the Unilever Safety and Environmental Assurance Centre.

Professor Christopher Bostock (until Apr. 2004)

Consultant on TSE Research.

Dr David Brown (from Feb. 2004)

Lecturer in the Department of Biology and Biochemistry at the University of Bath.

Mr Colin Browne (from Feb. 2004)

Partner in the Maitland Consultancy, which provides advice to corporate organisations on external communications.

Professor Graham Bulfield

Vice-Principal and Head of the College of Science and Engineering at the University of Edinburgh.

Professor Robin Carrell (until Apr. 2004)

Professor of Haematology at the University of Cambridge

Dr Jacky Chambers (from Feb. 2004)

Director of Public Health, Heart of Birmingham Teaching Primary Care Trust and Birmingham City Council.

Dr Deirdre Cunningham (until Nov. 2003)

Public Health and Medical Director of the Southeast London Strategic Health Authority.

Professor Nigel Hooper (from Feb. 2004)

Professor of Biochemistry at the School of Biochemistry and Microbiology, University of Leeds.

Professor James Ironside

Deputy Chair.

Professor of Clinical Neuropathology in the University of Edinburgh and Director of the National CJD Surveillance Unit, Edinburgh.

Mr Peter Jinman

Private Veterinary Surgeon and member of the Royal College of Veterinary Surgeons.

Professor Harriet Kimbell (until Nov. 2003)

Associate Professor at the Guildford College of Law.

Dr Corinne Lasmezas (from June 2003)

Head of the prion research group at the Service de Neurovirologie (SNV), France.

Professor Jean Manson (from Feb. 2004)

Head of TSE division and Neuropathogenesis Unit at the Institute for Animal Health.

Professor Colin Masters (until Nov. 2003)

Professor and Head of the Department of Pathology, University of Melbourne, Australia

Professor Ian McConnell

Professor of Veterinary Science at the University of Cambridge and Director of Research at the University of Cambridge Veterinary School.

Ms Diane McCrea (from Feb. 2004)

Independent consultant on food and consumer affairs.

Professor Graham Medley (from Feb. 2004)

Head of the Ecology and Epidemiology Research Group in the Department of Biological Sciences at the University of Warwick.

Dr Peter Rudge (from Feb. 2004)

Consultant neurologist at the National Hospital for Neurology and Neurosurgery and is physician attached to the CJD cerebral biopsy committee.

Dr Jiri Safar (until Nov. 2003)

Adjunct Associate Professor in the Department of Neurology at the University of California, San Francisco, USA.

Professor Margaret Stanley (from Apr. 2004)

Professor in Epithelial Biology in the Department of Pathology, University of Cambridge.

FSA/SEAC Risk Assessment Group

Terms of reference

Agreed by the group at its first meeting

To assist SEAC in advising the Food Standards Agency on the

- predicted course of the BSE epidemic in UK cattle from 2002 taking into account the results of testing;
 - extent of BSE in cattle over thirty months of age now and in the future;
 - level of BSE infectivity entering the food chain now and in the future continuing with the current controls;
 - levels of BSE infectivity which might enter the food chain now and in the future in moving to the controls prescribed in the EU legislation including testing;
- taking into account the impact of the animal feed controls, cattle identification, TSE tests and other measures since March 1996.

Membership

Professor Peter G. Smith

Chairman.

Chairman of SEAC. Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine.

Professor Roy Anderson

SEAC member. Head of the Department of Infectious Disease and Epidemiology, Imperial College School of Medicine, University of London.

Ray Bradley

Former SEAC member. Veterinarian. BSE consultant.

Professor Simon Cousens

Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine.

Professor Bryan Grenfell

Department of Zoology, University of Cambridge.

Dr. Dagmar Heim

Veterinarian. Swiss Federal Veterinary Office.

Peter Jinman

SEAC member. Private Veterinary Surgeon and member of the Royal College of Veterinary Surgeons.

Professor Sir John Krebs

FSA Chairman

Professor Graham Medley

Head of the Ecology and Epidemiology Research Group in the Department of Biological Sciences at the University of Warwick.

Dr. Phil Minor

National Institute for Biological Standards and Control

Dr. Gérard Pascal

Chairman of the EU Scientific Steering Committee

Professor Mark Woolhouse

Centre for Tropical Veterinary Medicine. University of Edinburgh.

Plus expert advisers from
Imperial College
Veterinary Laboratories Agency
DNV Consulting
Defra

Core Stakeholder Group

Terms of reference

Agreed by the group at the first meeting

To advise the Food Standards Agency on whether, or not, the over thirty months rule may be varied without unacceptable risk to consumers. If so, to make recommendations on appropriate measures that could replace the rule, taking into account:

- a scientific assessment of the BSE risk from the current arrangements, i.e. retaining the OTM rule, including from both imported and domestic products;
- a scientific assessment of the BSE risk from the various options for replacing the OTM rule, including from both imported and domestic products;
- practicality and enforceability;
- costs and benefits;
- the requirements of EU legislation; and
- the views of stakeholders.

Membership

Professor Sir John Krebs
Chairman
FSA Chairman

Siôn Aron
Farmers Union of Wales

Mike Attenborough,
Meat and Livestock Commission

Dr. Jon Bell (from Jan. 2002)
FSA Chief Executive

Anne Campbell
Scottish Food Advisory Committee

Neil Cutler
National Farmers Union

Alistair Donaldson
Scottish Association of Meat Wholesalers

Dr. John Godfrey
Foodaware and FSA Consumer Committee

Phil Gore

Suffolk Coastal DC

Jill Nute

OVS, Royal College of Veterinary Surgeons

Brian Oliphant

NI consumer representative

Geoffrey Podger (until Dec. 2002)

FSA Chief Executive

Dr. Debby Reynolds

FSA Veterinary Director

Professor Peter Smith

Chair of the FSA/SEAC Risk Assessment Group. SEAC Chairman.

SEAC statement 2nd July 2004

Updated approach to assessing the future number of vCJD cases arising from relaxation of the OTM scheme

1. The OTM rule risk assessment work carried out in 2003 suggested that allowing BSE test-negative cattle born after 1st August 1996 into the human food chain over a five year period (2004-2009) might increase the number of cases of vCJD attributable to BSE exposure by about 0.03 cases over the next 60 years (upper limit 1.9 cases). This estimate was based on an assumed "worst case" scenario that past exposure to the BSE agent in food could potentially give rise to 5000 vCJD cases (over the next 60 years). The number of 5000 was an illustrative figure that represented a pessimistic upper limit, taking into account predictions of epidemic size based on annual numbers of vCJD deaths to date. It was not derived from a statistically-based confidence interval.

2. SEAC considered findings reported recently from a retrospective survey of prion protein accumulation in appendix and tonsil tissue to assess if this "worst-case" scenario continues to be appropriate. The committee discussed whether a total epidemic size of 5000 remained pessimistic in the context of new data on the prevalence of infection based on a retrospective study of appendix/tonsil tissue. Opinion was divided among SEAC members. Some considered that the figure of 5000 remained an appropriate pessimistic upper limit, others favoured basing the upper limit on the results of the, then unpublished, appendix/tonsil survey.

The updated analysis

3. The FSA commissioned a group at Imperial College to update the OTM risk assessment, taking account of the new data and improving the statistical rigour of the analysis.

4. The 2003 analysis considered combined "worst case" scenarios with respect to (i) the amount of infected material that might enter the human food chain (following a change in the OTM rule), as a proportion of all such material entering the food chain since the BSE epidemic started, and (ii) the possible total size of the vCJD epidemic. The new analysis took simultaneous account of uncertainty in both these scenarios. These uncertainties were considered jointly in a statistical analysis to provide estimates (and associated confidence intervals) of vCJD cases arising from exposure in the 2004-2009 periods that would be attributable to a change in the OTM rule. Because of the difference of view within SEAC with respect to the relative weights to be given to different methods of projecting the total size of the vCJD epidemic, separate analyses were conducted basing this projection (i) on the retrospective appendix and tonsil survey data alone, or (ii) on the annual numbers of vCJD deaths observed since 1996, alone.

5. The new analysis extends the work of the 2003 analysis and considers in an integrated and probabilistic manner uncertainties in the BSE modelling and in the vCJD predictions.

Update to BSE analysis

6. Two conservative assumptions were made in calculating the proportion of infectious material that would enter the food chain between 2004 and 2009 consequent on a change to the OTM rule. These assumptions were also used in the 2003 OTM risk assessment.

i. The assumption of a constant BSE infection rate for future cattle cohorts.

7. It is clear that the August 1996 feed ban did not completely eliminate BSE infection as some cattle born after that date have been diagnosed with BSE. The latest date for which modelling of the BSE epidemic can provide an estimate of the level of infection is 1999. Two plausible assumptions are (i) that the infection level in the 1999 birth cohort will not diminish in later cohorts and will continue at the same level to 2009, or (ii) that the infection level declines in cohorts born after January 2001 (the date of the EU-wide feed ban). The updated analysis, like the 2003 analysis, used the more conservative of these two assumptions and assumed the infection risk will not diminish.

ii. The assumption of low BSE test sensitivity.

8. Studies coordinated by the EU have shown that the current BSE tests have very high sensitivity among cattle showing clinical signs of BSE infection. However, due to the variation in the incubation period for BSE, it is not possible to determine how sensitive current BSE tests are prior to clinical onset. The updated analysis was based on the conservative assumption that the test will only pick up infected animals in approximately the last 3 months prior to clinical disease (as was also assumed in the 2003 analysis).

9. A number of assumptions regarding **differential mortality** were used in the modelling. These assumptions allow for the possibility that BSE-infected animals, but without recognised signs of BSE, will die or be slaughtered at an earlier age than BSE uninfected animals. This assumption has been included in previous modelling and found to improve the fit of the model, particularly with respect to explaining the relatively high level of BSE test positivity among OTMS casualty animals. The new analysis examined several periods for differential mortality ranging from 3 months before onset to one year before onset.

10. Using the assumptions given above, estimates were derived of the number of infected cattle, at different stages of their incubation periods, that would be consumed over a five-year period (2004-2009) associated with changing the OTM rule. By integrating these data with estimates of residual infectivity in different tissues at different stages of the incubation period, estimates were obtained of the likely extent of human exposure (measured in bovine infectious units). These estimates were compared with estimated historic

exposure so that future exposure over a five year period, from 2004 – 2009, could be expressed as a percentage of past exposure (before 2004). Options were considered in which only healthy animals or healthy and casualty animals were allowed to enter the food chain.

Predicting the total size of the vCJD epidemic

11. The recently published data from the retrospective appendix and tonsil survey suggest that the prevalence of infections may be higher than predictions based on the clinical case data alone. In view of the variance in the views of SEAC members about the interpretation of these data, the new analysis based predictions of future vCJD infections (arising from OTM rule change) on the most conservative scenario. This scenario was based on estimates of prevalence of infection with the vCJD agent derived from the appendix/tonsil survey data and the assumption that all three positive samples, reported in the study, represent infections with the vCJD agent that would progress to clinical disease.

12. The tonsil/appendix survey related predominantly to individuals aged 10-30 years old and it is necessary to make assumptions to extrapolate findings to other age groups. It could be assumed that the occurrence of vCJD cases in different age groups reflects the relative infection rates in different age groups. Alternatively it might be assumed that all individuals had similar susceptibility/exposure irrespective of their age and that the findings in the 10-30 year old group could be applied directly to other age groups. Both of these possibilities were included in the modelling.

13. A further assumption was made that despite the finding, to date, that all cases of vCJD have been homogenous for methionine at codon 129 of the PRPN gene; all genotypes were equally susceptible to vCJD.

14. The new analysis also considered variation in the appendix/tonsil test sensitivity, that is, the proportion of all infected individuals who would test positive. The test may not detect all infected individuals and it would be appropriate to assume a sensitivity of less than 100%. However, there are few data to guide the choice of a sensitivity level.

Outcome of SEAC discussion

15. Four additional experts with expertise in risk modelling and epidemiology attended the meeting to advise SEAC and provide a peer review of the modelling methodology. The additional experts are listed in Annex 1.

16. SEAC and attending experts welcomed the new analysis by the group from Imperial College and agreed that the approach was more appropriate than that used previously. They endorsed the methodology of integrating the BSE modelling and the vCJD data to estimate the number of vCJD infections arising from changes to the OTM rule and associated uncertainties. They agreed that the analysis provided a more defensible approach than the 2003 analysis as it took simultaneous account of uncertainties at different stages of

the modelling. They agreed that estimation of confidence limits improved the statistical rigour of the risk assessment.

17. SEAC acknowledged that the estimates of the number of vCJD infections attributable to the OTM change are dependent on the various assumptions made in the analysis. However, even with the conservative assumptions recommended for the updated analysis, a change to the OTM rule would contribute a very small number of future infections relative to the number of infections attributable to past exposure.

18. SEAC were asked to advise on which assumptions would be most appropriate to account for the range of scientific uncertainties. It was agreed that the following assumptions were appropriate in generating estimates to be presented to the FSA board to consider the risk management options for changing the OTM rule.

BSE modelling

19. In terms of the BSE model, SEAC and attending experts agreed that two of the key assumptions used in the analysis were still appropriately conservative (constant infection risk after 1999 and low sensitivity of BSE tests beyond 3 months from BSE onset).

20. SEAC agreed that it was conservative, but prudent, to use a worst-case scenario to account for the possibility that differential mortality in BSE infected animals could occur within the last 12 months of the incubation period, rather than a shorter period. SEAC recognised that this was likely to be pessimistic but in view of the paucity of the data on this issue, SEAC agreed it was an appropriate precautionary stance.

vCJD epidemic size

21. SEAC agreed that the new developments have increased the scientific uncertainty around predictions of the evolution of the vCJD epidemic. They agreed that a pessimistic approach would be to base predictions of the vCJD epidemic on the prevalence data alone (from the appendix/tonsil survey) rather than on the clinical case data.

22. SEAC agreed that in view of the lack of data and the significant uncertainty it was appropriate to assume that the testing used in the appendix/tonsil survey would identify only 50% of individuals infected with the vCJD agent. SEAC recommended that the analysis should be revised for the FSA board to assume this level of sensitivity.

23. SEAC agreed that it would be overly cautious to dismiss the clinical case data in informing the assumption on age dependent susceptibility/exposure. Therefore they agreed that in estimating prevalence levels of infection it was appropriate that the estimates should be adjusted, taking into account the age distribution of cases of vCJD. Furthermore, all genotypes should be assumed to have similar susceptibility.

Recommendations on presentation to the FSA Board

24. SEAC noted that estimates were presented as two options, either that healthy animals only or a combination of healthy and casualty animals were allowed into the foodchain. SEAC noted that although the number of casualty animals entering the food chain was relatively small, casualty animals contributed disproportionately to the level of risk if the OTM rule were changed. While this is unsurprising as the majority of BSE positives have been found in casualty animals, SEAC agreed that the inclusion of casualty animals increases the risks associated with changing the OTM rule and suggested that the FSA Board note this when considering the risk management options.

25. SEAC noted that the risk assessment was limited by the paucity of data and significant scientific uncertainties remained. Despite the use of “pessimistic scenarios” throughout the analysis, the lack of data meant that some components of the risk assessment were based on expert judgement rather than being fully informed by all the required data. It is important that Government is made aware of this.

26. SEAC recommended that when the risk assessment data are presented to the FSA board, it was important that they should also be provided with the corresponding estimate of the total size of the epidemic so that the numbers of additional cases attributed to changing the OTM rule can be seen as a proportion of all cases of vCJD.

ANNEX 1

Dr Mark Arnold, VLA Centre for Epidemiology & Risk Analysis
Mr Philip Comer, Environmental Services, Det Norske Veritas Ltd
Professor Simon Cousens, London School of Hygiene and Tropical Medicine
Professor Christl Donnelly, Imperial College, London
Dr Azra Ghani, Imperial College, London
Professor John Wilesmith, Defra AHWDG