



FOOD STANDARDS AGENCY REVIEW OF THE OVER THIRTY MONTH RULE

PRELIMINARY RESULTS FROM AN ANALYSIS OF IMPORTS FROM THE REPUBLIC OF IRELAND

Issue

1. Imperial College and DNV Consulting have undertaken a risk assessment of imported material originating from the Republic of Ireland, the largest exporter of bovine material to the UK. The results of this modelling work will be presented to the Committee on June 24th.
2. This is a further component to the review by the Food Standards Agency of the Over Thirty Month rule. Members will recall that results of earlier modelling work on the domestic position by Imperial College and DNV Consulting were presented to SEAC on 14th November 2002 and 11th February 2003.

Background

The FSA review

3. The OTM rule was introduced following a recommendation from the Committee, given on 24 March 1996, that cattle aged over 30 months be deboned in licensed plants and that obvious nervous and lymphatic tissue (including the 14 lymph nodes specified in EC trade legislation) and the vertebral column (excluding tail vertebrae) be treated as specified bovine offal.
4. The commitment to review the OTM rule was made in the Food Standards Agency's (FSA) review of BSE controls, published in December 2000. The 2000 review concluded that the OTM rule should be retained at that time, but recommended a further review in light of the decline in BSE and taking account of the number of cases born after the feed controls were tightened in August 1996. A brief outline of the OTM rule is attached at Annex I for information. As with previous FSA reviews, it is a science-based review. Discussions on risk management issues have involved stakeholders, with full public consultation relating to any proposals for change.

5. There are a number of strands to the review process:
 - the risk assessment;
 - consideration of risk management options; and
 - public consultation and recommendations.
6. As part of this process, Imperial College and the VLA provided epidemiological assessments of the number of BSE infected cattle (in GB and NI) that would enter the food chain at different stages in their incubation period. On the basis of the results from this modelling work, DNV Consulting provided an estimate of the potential human exposure through the food supply, by considering the infectivity of the individual tissues concerned. Results of the modelling were presented to SEAC on 14th November 2002 and 11th February 2003.
7. A further component of the OTM Rule Review relates to the risks associated with imported beef. Imperial College and DNV Consulting have undertaken a risk assessment of imported material originating from the Republic of Ireland, which is the largest exporter of bovine material to the UK. The results of this additional modelling work will be presented to the Committee on June 24th.
8. The FSA's review is now nearing conclusion. The public consultation period is due to end on 20 June, and the FSA Board are due to consider the recommendations of the review at their meeting on 10 July 2003, following which recommendations will be made to Ministers.
9. The outcome of the review will supersede the advice provided by the Committee in March 1996 on the treatment of cattle aged over 30 months (referred to in paragraph 3).

Options

10. The Core Stakeholder Group agreed two alternative options to the OTM rule should be considered:
 - allowing cattle born after 1 August 1996 into the food supply; or
 - allowing cattle of any age into the food supply.
11. EU-wide rules require a negative test result for BSE, and for the vertebral column, in addition to other SRM, to be removed from OTM cattle slaughtered for human consumption, before the carcass is released into the food supply.

Risk Assessment

12. The scientific input to the review is being provided by a joint FSA/SEAC Risk Assessment Group (RAG), under the chairmanship of Professor

Peter Smith. The work of RAG is at the core of the review process. The terms of reference for RAG are:

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.

Risk Management

13. Consideration of risk management issues are being undertaken by the Core Stakeholder Group, under the chairmanship of Sir John Krebs, Chairman of the FSA. This group has been formed, to advise the FSA, in light of the risk assessment, on whether or not the rule could be changed without unacceptable risk to consumers. The terms of reference for the Core Stakeholder Group are:

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 which 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.

Public Consultation

14. The public consultation process has included two public meetings: the first held on 4 July 2002, sought the full spectrum of stakeholders' views and concerns about the review. Those issues raised by stakeholders were taken into account as part of the review process.
15. A further stakeholder / public consultation meeting was held on 7 March 2003. At that meeting, stakeholder representatives discussed the latest scientific evidence and the potential impact on the options for change.
16. Following the end of the public consultation period (28 March – 20 June), the Board of the FSA will consider the proposal at their open meeting scheduled for 10 July, before making recommendations to Government Ministers.

Risk Assessment Modelling

SEAC 76: 14 November 2002

17. At the SEAC meeting on 14th November 2002, the Committee received presentations from Professor Neil Ferguson of Imperial College and Dr Mark Arnold of the VLA. The presentations provided Members with the methodology used and the results obtained from the modelling work undertaken by the two groups, to estimate the number of infected cattle (in GB) that would enter the food chain under a range of possible options being considered in the review. The presentations to the Committee followed similar presentations to the joint FSA / SEAC Risk Assessment Group (RAG) on November 12th, at which RAG accepted the work undertaken by the two groups.
18. Several key issues arising from the presentations were identified by the Chairman, i) that any relaxation to the current rule would result in an increase in risk, ii) it was assumed by both modelling groups that the diagnostic tests would only detect an infected animal towards the end of the incubation period, iii) it was assumed by both modelling groups that the future level of infection in animal feed would remain constant, and iv) the implications of the findings in respect of the risk to human health.
19. The Committee was informed that all the scenarios examined as possible options for changing the OTM rule would result in an increased risk in terms of infected animals entering the food chain, which was inevitable given that they would all allow older animals into the food chain and that the models assumed that BSE infection incidence would remain constant for future years. In conclusion, the Committee agreed with the general approach taken by the modellers to assess the risk of changing the OTM rule.

20. Following the presentations by Imperial College and the VLA, Mr Philip Comer of DNV Consulting informed the Committee about how the results of the modelling would be used to estimate the potential exposure into the human food chain. DNV Consulting had been commissioned by the FSA to estimate the potential exposure to BSE infectivity from different tissues, and the ways in which this could enter the food chain. The Committee was informed that the results of the DNV work would be presented in terms of potential ingestion of BSE (bovine) infectious units by the UK population.
21. Detailed summaries of the Imperial College, VLA and DNV Consulting presentations, together with the main issues discussed by the Committee, are recorded in the closed session minutes of SEAC 76.

SEAC 77: 11 February 2003

22. At the SEAC meeting on 11 February 2003, the Committee received presentations from Professor Christl Donnelly of Imperial College and Mr Philip Comer of DNV Consulting. Professor Donnelly presented the Committee with updated results of the modelling work to estimate the number of infected animals entering the food supply in GB. In addition, the preliminary estimates of numbers of infected animals that would enter the food supply in Northern Ireland were also presented. The results utilised the DNV historical exposure estimates and the back-calculation model results, presented to the Committee in November 2002, to produce bovine ID₅₀ estimates. The presentations to the Committee followed similar presentations to the joint FSA / SEAC Risk Assessment Group (RAG) on February 7th, at which RAG accepted the work undertaken.
23. It was noted that under the same range of options, the risk (in terms of the absolute level of ID₅₀s) in Northern Ireland was estimated to be ten-fold less when compared to GB – though it should be noted that the total size of the NI herd is roughly ten-fold less than the GB herd.
24. The Chairman emphasised the point that even under the option to completely abandon the OTM rule, the risk of future exposure was significantly less than the risk of exposure in the past.
25. Mr Comer presented an update on the work undertaken by DNV Consulting for the FSA in relation to the review of the OTM rule. This was an update of the work presented to SEAC in November 2002, which examined the possible exposure to BSE infectivity by considering the infectivity present in different tissues that could enter the human food supply.
26. In conclusion, the Committee agreed with the general approach taken by the modellers. Detailed summaries of the Imperial College and DNV Consulting presentations, together with the main issues discussed by the Committee, are recorded in the closed session draft minutes of SEAC 77.

SEAC 78: 24 June 2003

27. The Core Stakeholder Group formed the view that whatever option is adopted for the future, there should not be an unacceptable discrepancy in risk between imported and home-produced beef. In order to assess the comparative risk between imported and home-produced beef, Imperial College and DNV Consulting are also undertaking further risk assessment modelling in respect of beef imported from the Republic of Ireland, which is by far the largest supplier of imported beef to the UK. It is anticipated that the results from the Republic of Ireland modelling work will be presented at the SEAC meeting on 24 June. This element of the modelling work should have already been extensively discussed at the RAG meeting on 20 June.

28. In addition, the Committee will be presented with an update of the Northern Ireland modelling results.

Advice sought from the Committee

29. Members are invited to agree that:

- the modelling work undertaken by Imperial College and DNV Consulting provides a sound basis for comparing the risks between imported and home produced beef.

THE OVER THIRTY MONTHS (OTM) RULE

Background

1. The generally applicable ban on the sale of beef from cattle aged over 30 months at slaughter (the Over 30 Month or OTM Rule) was introduced in 1996 after the probable link between BSE and the human disease variant CJD was established. This followed advice from SEAC that beef from OTM cattle should be deboned under official supervision. Deboning proved to be impractical and the OTM rule was introduced instead.
2. There are two exceptions to the OTM rule:
 - meat from Beef Assurance Scheme (BAS) herds may be sold for human consumption if the animal was no more than 42 months of age at slaughter; and
 - beef imported from 14 non-EU countries that traditionally supplied the UK and in which there was no history of BSE.
3. The UK's national 30-month limit was chosen for a number of reasons, as follows:
 - very few animals had shown signs of BSE onset at this age. In the two years before SEAC's recommendation in 1996 there had been only three clinically identified cases of BSE in cattle aged 30 months or younger.
 - data from experimental studies of the pathogenesis of scrapie in rodents had shown that infectivity was first detected in the central nervous system approximately half way through the incubation period. The mean age when signs appear in cattle is approximately 60 months, therefore 30 months should by analogy be a time at which infectivity is just emerging.
 - the earliest appearance of signs in cattle following experimental feeding with infected material is about 32 to 33 months.
4. Cattle too old for entry into the food supply are almost all disposed of through the Over Thirty Month Scheme (OTMS) under which farmers are paid compensation by Government for their unsaleable animals.

Previous review of the OTM Rule

5. The Food Standards Agency considered the Rule in its Review of BSE Controls. Its report, published on 20 December 2000, recommended that:
 - 30 months should remain the age at which controls are most appropriate; and
 - January 2002 was the earliest date on which a decision could be taken to announce the year of birth of animals that need not be subject to the rule.