



FOOD STANDARDS AGENCY REVIEW OF THE OVER THIRTY MONTH RULE

BACKGROUND TO PRESENTATION BY MR PHILIP COMER

Issue

1. The FSA is conducting a review of the Over Thirty Month (OTM) rule. As part of this process, Imperial College and the VLA provided epidemiological assessments of the number of BSE infected cattle (in GB) entering the food chain at different stages in their incubation period. On the basis of the results from the modelling work undertaken by Imperial College and the VLA, DNV Consulting have been commissioned by the FSA to estimate the potential human exposure through the food chain, by considering the infectivity of the individual tissues concerned. The results of the additional modelling work will be presented to the Committee on 11th February.

Background

The FSA review

2. 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.
3. 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. Subsequent discussion on risk management issues will involve stakeholders and there will be full public consultation on any proposals for change.
4. There are a number of strands to the review process:

- the risk assessment;
- consideration of risk management options; and
- public consultation and recommendations.

The review is now well underway and is expected to conclude by July 2003, provided that the risk assessments on which the review depends have been completed according to the timetable.

5. 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 2).

Options

6. Options being considered range from 'no change' to full implementation of the EU cattle testing scheme at the age of 30 months for animals entering the food chain. Between these parameters, various intermediate options are also being considered. No decisions have yet been taken. Nothing has been ruled in and nothing has been ruled out.

Risk Assessment

7. 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

8. 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

9. The public consultation process includes 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 will be taken into account as part of the review process. The intention is that a wider stakeholder group will meet in public, in the spring of 2003, to consider the emerging options and advise on whether any issues may have been omitted. A full public consultation should follow shortly thereafter on the review recommendations. Proposals will then be put to the Board of the FSA for consideration, who, in turn, will advise Ministers.

Risk Assessment Modelling

10. 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.
11. 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.
12. 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.
13. Imperial College are also undertaking further risk assessment modelling to consider the position of infected cattle entering the food chain in Northern Ireland. It is anticipated that the results from the Northern Ireland modelling work will be presented at the SEAC meeting on February 11th. This element of the modelling work should have already been extensively discussed at the RAG meeting on February 7th.
14. 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.

15. The results of the additional modelling work undertaken by DNV Consulting will be presented to the Committee on February 11th. This element of the modelling work will have already been extensively discussed at the RAG meeting on February 7th. The results may also be presented to the FSA's Core Stakeholder Group on February 11th, immediately before the presentation to SEAC on the same day.
16. Detailed summaries of the Imperial College, VLA and DNV Consulting presentations, together with the main issues discussed by the Committee, are recorded in the draft closed session minutes of SEAC 76 (Paper No. 77/1).

Advice sought from the Committee

Members are invited to agree that:

- the modelling work undertaken by Imperial College, VLA and DNV Consulting provides a sound basis for consideration of the measures now appropriate for managing the risk posed by OTM cattle.

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.

*

* Argentina, Australia, Botswana, Brazil, Mauritius, Namibia, New Zealand, Paraguay, Poland, South Africa, Swaziland, Uruguay, United States of America and Zimbabwe.

The Food Standards Agency advised on 9 May 2002 that OTM beef from Poland, South Africa and Zimbabwe may pose a slightly higher BSE risk than other legally sold beef. The European Commission (EC) have classified Poland as likely to present a BSE risk and the first case of BSE in Poland was confirmed on 2 May 2002. No EC risk assessments have been completed in respect of South Africa or Zimbabwe. The eleven other exempt countries, according to EC classification, are highly unlikely to present a BSE risk or to have a risk which is classified as unlikely but which cannot be excluded.

- 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 human food chain 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.