

REVIEW OF THE OVER THIRTY MONTHS (OTM) RULE: ESTABLISHMENT OF AN EFFECTIVE BSE TESTING REGIME

Executive summary

1. This paper outlines the work undertaken to put in place a reliable BSE testing system for OTM cattle, following the Government's decision last December to replace the OTM Rule.
 - In May 2002 the Government announced a Review of the OTM Rule as a result of a significant decline in BSE. The central question of the Review was whether the BSE risk to public health was sufficiently low that the UK could move to a system of BSE testing.
 - In July 2003, following a comprehensive risk assessment and extensive public consultation, the FSA advised Ministers that a move to replace the OTM rule by testing would be justified on the grounds of public health risk and proportionality.
 - In July 2004, following an updated risk assessment, the FSA continued to advise Government that a move to replace the OTM rule by BSE testing of cattle born after 1 August 1996 would be justified.
 - At the same time, the FSA also recommended that Ministers should not change the OTM rule until an independent group had advised that the necessary arrangements had been made to ensure that all elements of a robust testing system had been put in place.
 - In December 2004 the Government accepted the FSA advice on rule change and announced that an essential first step would be for the FSA to advise Ministers on the establishment of a reliable and independently audited testing regime.
 - As a result, an Independent Advisory Group (IAG), chaired by Professor Patrick Wall, was set up by the FSA to oversee and advise on an effective testing regime.

2. The paper concludes by inviting the Board to **advise Ministers** that:

- a reliable BSE testing regime for OTM cattle has been successfully designed and trialled.
- arrangements are in place to ensure that, should the BSE testing regime be implemented, it would be able to operate across the UK to the highest standards

and to **agree**, in the event of rule change:

- that an OTM testing Implementation Review Group be set up, chaired by the FSA and involving all the UK Government departments concerned, to oversee implementation of the BSE testing regime for its first 12 months of operation before ceasing its activities, and report to the FSA Board (para 25)
- to recommend that rural affairs Departments keep the current OTMS scheme operational until such time as it is clear that there are sufficient fresh meat plants approved to meet the demand for the slaughter of OTM animals (para 16)
- to recommend that guidance on the new rules for emergency slaughter of bovine animals be distributed prior to any change in the OTM rule being implemented (para 17)
- to recommend that an MHS Area Official Veterinarian must visit every OTM fresh meat plant on both the first two working days of OTM BSE testing operations, and thereafter at regular intervals (para 28)

and to **note**:

- that an independent audit of the BSE testing system, to report six months following OTM rule change implementation, and arrangements for FSA ongoing audit which would supersede it, would in each case report both to the Implementation Review Group and to the Board; and that following the Implementation Review Group ceasing its activities, the latter audit body would continue to report direct to the Board (para 26).

TSE Division

Contacts:

Alan Harvey Tel: 020 7276 8303 (GTN 7276 8303)
Email: alan.harvey@foodstandards.gsi.gov.uk

Adrienne Conroy Tel: 020 7276 8379 (GTN 7276 8379)
Email: adrienne.conroy@foodstandards.gsi.gov.uk

REVIEW OF THE OVER THIRTY MONTHS (OTM) RULE: ESTABLISHMENT OF AN EFFECTIVE BSE TESTING REGIME

Issue

1. The establishment of an effective Bovine Spongiform Encephalopathy (BSE) testing regime, as a pre-requisite to the Over Thirty Months (OTM) rule being replaced.

Strategic aim

2. This work links to the FSA's aim to protect consumers by implementing and enforcing proportionate and effective BSE controls. The Agency also has a legal obligation to act proportionately when taking action to manage food risks.

Background

3. There are three main BSE controls. The principal one is the ban on specified risk material (SRM) going into the food chain, which removes over 99% of the infectivity in cattle. The second is the prohibition on mammalian meat and bone meal being fed to farm animals, reinforced in August 1996. The third is the OTM rule, which stops older animals from going for human consumption.
4. The OTM rule was introduced in 1996, following the establishment of a link between BSE and variant Creutzfeldt-Jakob Disease (vCJD). The BSE epidemic has since been in steep decline. There were 82 clinical cases in Great Britain (GB) last year, a reduction of over 99% since the peak year of 1992, and a significant reduction also since 1996 when over 8,000 BSE clinical cases were confirmed.
5. A history of the review of the OTM rule by the FSA is set out at Annex B. This describes how, with stakeholders being consulted, a two-stage rigorous science-based risk assessment was undertaken in 2003/4, and then endorsed by the Government's BSE scientific advisory committee, the Spongiform Encephalopathy Advisory Committee (SEAC). However SEAC also highlighted that, despite the use of pessimistic scenarios, 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. In the light of all this, the FSA Board advised in July 2004 firstly

that a move to replace the OTM rule by BSE testing of cattle born after 1 August 1996 would be justified on grounds of food-borne risk to consumers and proportionality. And secondly, that Ministers should not change the OTM rule until an Independent Group had advised that the necessary arrangements had been made to ensure that all elements of a robust testing system had been put in place. On 1 December 2004 the Government announced the start of a managed transition towards lifting the OTM rule, making clear that an essential first step would be the establishment of a reliable and independently audited testing regime, as advised by the FSA.

6. It was also stated in the announcement that cattle born before August 1996 will remain permanently excluded from the food chain.
7. The announcement also included a statement that the FSA had already set up an independent advisory group (IAG), under the chairmanship of Professor Patrick Wall, to advise on the testing regime. At a meeting later that same month, the Board approved an initial report from IAG. That set out the components recommended for an effective testing regime. The Board agreed that the next stage should be full trials of the system to assess whether or not it would be reliable. The trials were held March – June 2005.
8. The final report from IAG is attached at Annex A (membership and terms of reference are at Annex 2 to that report). IAG concluded the trials have demonstrated that all the key components of the recommended BSE testing regime operate effectively; and that it is robust if effectively implemented, complied with and enforced.
9. The Board will also recall that – in addition to advice from IAG - two other streams of assurance were seen as being necessary before advice could be offered on an effective testing system:
 - (a) a report from the European Commission's Food and Veterinary Office (FVO) on their June 2005 mission to scrutinise GB BSE controls
 - (b) the outcome from both the recent consultation exercise undertaken over rule change and the end July 2005 open meetings held to seek views from stakeholders and the public.These are now addressed in turn.

The report from the Food and Veterinary Office

10. In June 2005 the FVO undertook a mission to GB to report on the BSE controls (Northern Ireland BSE controls were judged to be satisfactory at an earlier mission). The final report is not yet available. However, at the meeting FVO held with the Department for Environment, Food and Rural Affairs (Defra) and the FSA at the conclusion of their mission in June, to outline and discuss their key findings, nothing untoward was revealed that would impact upon the questions that have been considered by IAG. We understand, from further discussions with the Commission and liaison with FVO, that they are likely to conclude that a satisfactory system has been put in place in order to assess the effectiveness of the testing regime if the OTM rule were to be replaced.

The July 2005 open meetings and earlier consultation

11. A formal written consultation exercise on the legislative proposal for OTM rule change was held between end February and end May 2005. In addition, open meetings took place in London, Edinburgh, Belfast and Cardiff at end July 2005 at which presentations on the background to the OTM rule review including the Government's announcement last year to accept the case in principle for rule change, and the emerging findings of IAG, were made both by FSA and Professor Patrick Wall. Questions and comment were invited from those who attended. There were no unexpected developments.

12. From the consultations, the meat industry continues to favour rule change, though concerns were identified about ensuring that suitable messages would be put across to consumers at the appropriate time; the retailers are also in favour but again stress the need to be proactive so as to maintain public confidence. Consumer groups are more wary. Some oppose rule change while others can accept the case for such a change on grounds of proportionality. All consumer groups argue that – if rule change were to happen – demonstrable reliability of the testing system would be all important. They too stress the need for effective communications.

13. The Human BSE Foundation, while recognising the proportionality argument, continues to oppose rule change.

14. In order to ensure a reliable testing regime, IAG have identified effective implementation, compliance and enforcement as critical factors. These are now addressed in turn.

IMPLEMENTATION

Sequence of events in run up to rule change

15. In preparing for any implementation, rural affairs Departments have been working closely with FSA, the Meat Hygiene Service (MHS) and the Department for Agriculture and Rural Development in Northern Ireland (DARD) Veterinary Service Veterinary Public Health Unit (VS-VPHU) for some time, on a contingency basis, on the practical issues. A sequence of anticipated events is set out below, in the event of a decision to proceed with OTM rule change:

- MHS to approve a number of abattoirs throughout Great Britain, sufficient to provide critical mass, ready to process OTM cattle.
- During the weeks following rule change, a steady stream of additional OTM plants to be approved
- Due to the small number of plants operating in NI, it is envisaged that the majority of these would gain approval prior to rule change.
- Meanwhile, the Over Thirty Month Slaughter Scheme (OTMS) - through which OTM animals are purchased for destruction throughout the UK - would continue to run in its present form for a period of time, and thus deal with any surplus supply
- OTMS be replaced in due course by an Older Cattle Disposal Scheme, for which only cattle born before August 1996 would be eligible (nb It has been decided by the Government that pre 1 August 1996 UK animals would never enter the food chain.)

Ensuring sufficient capacity

16. There remains an issue about whether the numbers of abattoirs authorised to process OTM animals for the food chain will have the capacity to meet demand on day one of the new regime. Rural affairs Departments plan to continue with OTMS during the initial stages of the new regime, but there are some doubts over how long such parallel running will apply. The Board is invited to agree to recommend that rural affairs Departments keep the current OTMS scheme operational until such time

as it is clear that there are sufficient fresh meat plants approved to meet the demand for the slaughter of OTM animals.

Guidance on casualty cattle

17. In July 2003, the Board recommended that further work be undertaken to clarify the definition of “casualty cattle” prior to rule change. IAG has now recommended that guidance on the new rules for emergency slaughter should be issued before a move to BSE testing of OTM cattle is made. Recent meetings have been held between FSA and the British Cattle Veterinary Association, who are helpfully producing guidance that will be widely distributed very shortly. The Board is invited to recommend that guidance on the new rules for emergency slaughter of bovine animals be distributed prior to any change in the OTM rule being implemented.

Cutting plants and the removal of vertebral column

18. Under EU law, vertebral column of UK cattle is designated SRM at 30 months and over. Following any OTM rule change vertebral column removed from such animals following slaughter would need to be taken out at cutting plants specifically licensed for this purpose. A number already remove vertebral column from the small number of OTM animals going for human consumption under the beef assurance scheme; in addition beef imported from the EU needs to have vertebral column removed at 12 months and over, under EU rules. Plant operators wishing to process OTM carcasses would first have to agree a Required Methods of Operation (RMOP) document, which would set out the required procedures and processes to apply at each cutting plant, with MHS or DARD. The Official Veterinary Surgeon (OVS) would need to be satisfied that each plant would have the appropriate facilities, equipment and suitably trained staff to enable it correctly to remove SRM vertebral column from these test-negative carcasses. There have already been a significant number of expressions of interest from UK cutting plants to process OTM carcasses in this way. FSA would actively take forward the specific approval of such premises, in conjunction with MHS/DARD.

COMPLIANCE

Areas of responsibility

19. Identifying who is responsible for what is critical to securing effective compliance.

Overall responsibility in GB for the day to day operation of the entire testing regime would fall to rural affairs Departments, with the MHS working to them under a service level agreement (the arrangements are slightly different in NI – para 22). Both farmers and meat plant operators of course have responsibilities which they would be expected to meet. The table below provides a breakdown of the various components in GB:

Activity	Where responsibility lies
1. Transport from farm to abattoir with correct identification documents	The farmer (but abattoir operators once at the abattoir, with verification and enforcement by MHS)
2. At the abattoir, activities such as identification and segregation of animals; taking samples; despatch of samples to laboratories; removal of specified risk material; retaining all body parts pending a successful test result	The abattoir operator, with MHS responsible for verification and enforcement
3. Retaining carcasses pending a test result	MHS to seal the chillers. MHS to control health marking of carcasses following BSE-negative test result
4. Identifying animals and all body parts following test results for release into the food chain or destruction as appropriate	Abattoir operators, with verification and enforcement by MHS

20. A diagrammatic representation of this process, indicating who has responsibility at each point in the chain in GB, is at Annex C. A similar process applies in NI.

21. In addition, in GB the LGC laboratories at Teddington, Runcorn and Edinburgh would carry out the testing of samples, under a contract with Defra on behalf of all GB rural affairs Departments. These laboratories are already testing samples from

all OTM animals born since 1 August 1996, to meet EU surveillance requirements. Transport of samples to LGC would be the abattoir operator's responsibility. Overnight turn round of sample test results to abattoirs would be LGC's responsibility.

22. In Northern Ireland, responsibility for the testing regime would lie with DARD and meat plant operations would be similarly supervised by DARD's Veterinary Service – Veterinary Public Health Unit (VS-VPHU). Testing would be carried out by DARD's Veterinary Science Division. Removal of vertebral column from test-negative OTM animals at cutting plants would be supervised by DARD VS-VPHU under a service level agreement with FSA NI.

23. Responsibility for oversight of the removal of vertebral column at cutting plants would fall to FSA (see para 18)

Establishment of a new Implementation Review Group

24. IAG in its report recommends that the FSA should set up and lead an Implementation Review Group involving all the Government Departments and Agencies concerned, to oversee the implementation of the testing regime and to ensure it is rolled out successfully across the UK. Board members may recall that, in a statement to Parliament by the Secretary of State for Rural Affairs on 1 December 2004, it was announced that "Ministers have also agreed that the Food Standards Agency should be responsible for the on-going audit and review of the testing system. This role in relation to testing will be in addition to the Agency's continuing responsibility, as an independent body set up to protect the public's health and consumer interests in relation to food, for monitoring developments and advising Government on the scientific evidence on the food-borne BSE risk to consumers."

25. Taking all this into account, the FSA proposes to establish an Implementation Review Group along the lines of the IAG recommendation. The duration of this group would be time limited, operating for no more than one year following the introduction of rule change. Its role would essentially be to review, scrutinise and advise upon the roll-out of OTM testing implementation, thus helping to ensure that the reliable testing regime identified by IAG is effectively implemented, complied with and enforced, as IAG recommend. This group would operate on a UK basis with

representatives from rural affairs Departments including DARD, and the MHS. We propose the group should report to the Board of the FSA.

26. Ongoing audit and review of the entire testing regime arrangements would be undertaken by FSA, again with the aim of helping to ensure effective compliance. The FSA would initially commission an independent audit of the BSE testing regime which would report its findings during the first six months following implementation, including via interim reports with a final report to the Implementation Review Group at the end of that period. Meanwhile an extension of the FSA audit mechanism would be put in place once the independent auditors had concluded their task, again to help secure compliance. One of the functions of the Implementation Review Group would be to consider recommendations from the various audit reports, and task those responsible with any identified necessary action. After the Implementation Review Group had ceased its activities, ongoing audit reports would continue to be submitted to the Board of the FSA.

MHS strengthening and professional overview

27. Following a review of veterinary supervision arrangements, the MHS are reconfiguring their line management chain to include Area Official Veterinarians (AOVs), a new position in the operational reporting structure to enhance control in those plants that would process OTM cattle in the event of rule change. AOVs would provide a further degree of scrutiny and support, being based off site, to MHS staff working at each OTM-approved plant. They would assume responsibility for a number of such plants, with each OVS reporting direct to the AOV on veterinary and technical matters at such plants. Thus AOVs would be in position to help ensure consistency of standards. AOVs would have a direct responsibility for approving the RMOPs which would contain all the required procedures and processes customised for each particular abattoir. RMOPs would also be checked by a lead veterinary adviser in MHS HQ, to ensure consistency across the country.

28. Any plant wishing to process OTM cattle for the food chain, as part of a stringent approval process would have to undergo an assessment of the testing arrangements over 2 slaughter days, which would be subject to a pass or fail verdict. The AOV would play a key role in assessing the test result. The intention is that AOVs would be in place to cover those abattoirs that would initially take part, in the event of a decision to change to BSE testing. In particular, they would pay visits to such plants

to scrutinise and support operations both on the day the plants would begin BSE testing OTM animals and on the following working day, when BSE test-negative carcasses and related body parts would be released into the food chain. This would be an important step in helping ensure that any OTM testing operations were successfully launched. The Board is invited to recommend that an AOV must visit every OTM fresh meat plant on both the first two working days of OTM BSE testing operations, and thereafter at regular intervals.

29. In addition, MHS have confirmed that the arrangements as outlined will not affect their ability to maintain existing standards of compliance with the Transmissible Spongiform Encephalopathies (TSE) controls at other under-thirty-month meat plants. Nor will there be any reduction in all the other official controls that the MHS undertakes on a day to day basis.

30. Approval procedures in NI would mirror those in GB. However, due to the smaller number of premises involved, the role of the MHS AOV and HQ veterinary adviser would be amalgamated and undertaken by a DARD Divisional Veterinary Officer.

ENFORCEMENT

Over age animals

31. The Board have been made aware of plans for new legislation concerning over age animals. Defra have consulted interested parties on a proposal to make it an offence for a producer to send animals born before 1 August 1996 – the cut-off date that would apply should OTM rule change be introduced - for slaughter for human consumption. Defra aim to introduce this legislation by end October 2005, prior to any OTM rule change. This would help underpin an effective testing system.

MHS/DARD activity

32. The MHS already operate in the front line as FSA's enforcement arm, in relation to the BSE controls. DARD fulfil a similar function in NI. Their role is essentially to provide targeted enforcement proportionate to the level of risk. Following any OTM rule change, their interventions to ensure compliance would include the ultimate sanction of withholding permission from operators wishing to start processing OTM cattle, or withholding the health mark from animals in cases of serious non-

compliance. As mentioned, any plant wishing to process OTM cattle for the food chain, as part of a stringent approval process, would have to undergo an assessment of the testing arrangements over 2 slaughter days, which would be subject to a pass or fail verdict. In addition, following plant approval, MHS/DARD, in fulfilling ongoing enforcement responsibilities, would have at their disposal a number of other enforcement tools eg issue of enforcement notices, reduction of line speed, etc.

33. Should major issues non of compliance emerge, the MHS would have the option - upon serving of appropriate notices - to suspend the RMOP thereby making it an offence for the operator to continue OTM processing.

Resources

34. In the event of rule change, Defra have agreed to meet all the costs associated with implementation. On specifics, Defra would provide funding direct to MHS/DARD to ensure that adequate numbers of MHS/DARD staff would be in place, suitably trained, to inspect, verify and where necessary enforce the controls on OTM cattle subject to BSE testing at abattoirs. Defra would fund MHS/DARD to undertake checks, according to the agreed frequency in relation to the removal of vertebral column from test-negative animals at cutting plants (para 18). In addition, Defra would provide funding to support the operation of the new Implementation Review Group (para 25), together with the new audit arrangements across the UK (para 26).

Timeline

35. In the event of advice going forward from the Board that an effective BSE testing regime for OTM cattle has been successfully designed and trialled, timelines describing the processes involved (a) with the making of legislation and associated Ministerial clearance and (b) in practical terms, associated with 'roll out' are described at Annex D. It means the earliest that implementation could take effect on a common date across the UK would probably be towards the end of 2005.

IAG detailed proposals to be taken forward

36. In their report, IAG have made several detailed recommendations to ensure effective roll out and implementation of any BSE testing regime. Many have already been

actioned, as part of the contingency planning for OTM rule change by rural affairs Departments, MHS, DARD VS-VPHU and FSA (para 15). A number are addressed within this paper. It is proposed that the Implementation Review Group (see para 25) should be tasked with addressing, in depth, the detail of these recommendations from IAG, and confirming to the FSA Board that they have been appropriately actioned.

Discussion and conclusions

37. The question is whether the Board can now advise Ministers that an effective BSE testing regime for OTM cattle has been successfully designed and trialled, and arrangements are in place to ensure that, should the BSE testing regime be implemented, it would be able to operate to the highest standards. At the July 2005 Board meeting, it became clear that three streams of assurance would be necessary before such advice could go forward:

- a) a positive report from the independent advisory group in relation to the reliability of the testing system
- b) that the report from the FVO outlining their findings from their recent assignment to scrutinise GB BSE controls (NI BSE controls were judged to be satisfactory at an earlier mission) would not be inconsistent with any advice from IAG on an effective testing system
- c) no major new issues being identified from the July 2005 open meetings and consultations with stakeholders and the public.

38. Taking each of these three in turn, the Board's conditions would appear to have been satisfied. First, the IAG, following a comprehensive in-depth review, have concluded that all the key components of the recommended BSE testing regime operate effectively; and that it is reliable if effectively implemented, complied with and enforced. Implementation depends critically on the provision of sufficient trained MHS/DARD staff and continuing audit and review.

39. A new management tier of AOVs have been recruited and these will be supported by sufficient numbers of other trained MHS staff. Similar staffing arrangements have been implemented by DARD VS-VPHU. A full 2 day assessment of each and every abattoir wishing to undertake slaughter of OTM animals would have to take place first, and be successful, before operations could commence. It is seen as imperative

that Defra plan for OTMS plants continuing, for the time being, should there be excess demand over capacity, and this is covered by a Board recommendation (para 16). In addition, arrangements are being put in place to enable a thorough ongoing audit and review of the entire BSE testing system to be provided by FSA. The whole implementation process would be scrutinised by an Implementation Review Group, chaired by the FSA, reporting to the Board and involving all the Government departments concerned.

40. Secondly, we are aware that the FVO have assessed the proposed testing arrangements, including visiting a trial, and are likely to conclude that a satisfactory system has been put in place in order to assess the effectiveness of any BSE testing regime.

41. Finally, the open meetings to engage stakeholders and the public have revealed no significant new issues, but have helpfully underlined the importance of having in place an effective communications strategy, in the event of a decision to proceed with rule change. This complements a similar recommendation from the IAG. The FSA Communications Directorate will work up a communications plan, in conjunction with Rural Affairs and Health Departments, that will encompass not only consumer groups but also other key stakeholders.

Recommendation

42. The Board is invited to **advise Ministers** that:

- a reliable BSE testing regime for OTM cattle has been successfully designed and trialled.
- arrangements are in place to ensure that, should the BSE testing regime be implemented, it would be able to operate across the UK to the highest standards

and to **agree**, in the event of rule change:

- that an OTM testing Implementation Review Group be set up, chaired by the FSA and involving all the UK Government departments concerned, to oversee

implementation of the BSE testing regime for its first 12 months of operation before ceasing its activities, and report to the FSA Board (para 25)

- to recommend that rural affairs Departments keep the current OTMS scheme operational until such time as it is clear that there are sufficient fresh meat plants approved to meet the demand for the slaughter of OTM animals (para 16)
- to recommend that guidance on the new rules for emergency slaughter of bovine animals be distributed prior to any change in the OTM rule being implemented (para 17)
- to recommend that an MHS Area Official Veterinarian must visit every OTM fresh meat plant on both the first two working days of OTM BSE testing operations, and thereafter at regular intervals (para 28)

and to **note**:

- that an independent audit of the BSE testing system, to report six months following OTM rule change implementation, and arrangements for FSA ongoing audit which would supersede it, would in each case report both to the Implementation Review Group and to the Board; and that following the Implementation Review Group ceasing its activities, the latter audit body would continue to report direct to the Board (para 26).