

**EXPLANATORY MEMORANDUM TO
THE BOVINE PRODUCTS (RESTRICTION ON PLACING ON THE MARKET)
(ENGLAND) (No. 2) REGULATIONS 2005**

2005 No. 3068

1. This explanatory memorandum has been prepared by the Food Standards Agency (FSA) and is laid before Parliament by Command of Her Majesty.

2. **Description**
 - 2.1 With limited exceptions, the over thirty months (OTM) rule prohibits the sale for human consumption of meat from cattle aged over thirty months at slaughter. The Bovine Products (Restriction on Placing on the Market) (England) Regulations 2005 (the POTM Regulations) replace the OTM rule by a prohibition on the placing on the market of products derived from bovine animals born or reared within the UK before 1st August 1996. That instrument thereby allows UK OTM cattle born on or after 1st August 1996 into the human food supply, provided they have received a negative test result for BSE. This instrument revokes and re-enacts with certain changes the POTM Regulations with effect from 1st January 2006.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None.

4. **Legislative Background**
 - 4.1 **The OTM rule legislation (the Fresh Meat (Beef Controls) (No. 2) Regulations 1996) is national legislation made under the Food Safety Act 1990. Subsequent Community legislation - Regulation 999/2001 - provides for EU-wide rules for controlling BSE. Because of its comprehensive nature, Regulation 999/2001 constitutes fully harmonised rules in the field of control and eradication of BSE, including consumer protection.**
 - 4.2 **There is no provision in Regulation 999/2001 for the UK to operate an OTM rule in the form of a ban on the sale for human consumption of meat from OTM cattle. Under the EU rules, such meat may legally be sold provided it is from an animal that had tested negative for BSE (and the specified risk material had been removed). The OTM rule is therefore inconsistent with the applicable EU law.**
 - 4.3 **The new policy of prohibiting UK cattle born before August 1996 from the food supply was subject to the same difficulty. The UK therefore requested action at EU level to legitimise a continued ban on such cattle.**
 - 4.4 **In response, within the powers delegated to it under Regulation 999/2001, the Commission adopted Decision 2005/598/EC of 2 August 2005. The POTM Regulations give effect to Article 1.1 of that Decision, which prohibits the placing on the market of products derived from bovine animals born or reared within the UK before 1st August 1996.**

4.5 The changes effected by the No. 2 Regulations are necessary in the light of the coming into force from 1st January 2006 of the Food Hygiene (England) (No. 2) Regulations 2005, which implement new EU food hygiene legislation. The POTM Regulations become out of date on 1st January 2006, as they refer in several places to the Fresh Meat (Hygiene and Inspection) Regulations 1995, which implement earlier EU meat hygiene legislation and are being revoked with effect from that date.

5. Extent

5.1 This instrument applies to England.

6. European Convention on Human Rights

No statement is required.

7. Policy background

- 7.1. The OTM rule was introduced in the UK in 1996 to strengthen the protection of public health from BSE. Other EU Member States have not operated a ban on OTM cattle, but since January 2001, and in line with Regulation 999/2001, have required OTM cattle slaughtered for human consumption to be tested for BSE, allowing only those receiving a negative result into the food supply.
- 7.2. In the light of the decline in BSE and the introduction of BSE testing, the FSA began a review of the OTM rule in July 2002. The review was informed by a detailed risk assessment overseen by a FSA/SEAC Risk Assessment Group (SEAC is the Government's BSE scientific advisory committee) chaired by Professor Peter Smith (SEAC Chairman at that time). The FSA was advised on whether replacing the OTM rule by testing would be acceptable and the options for doing so by a core stakeholder group (which included representatives from consumers, industry and enforcers, and observers from all relevant Government Departments and the Human BSE Foundation). Two public meetings were held; one at the start and one to give the opportunity for public discussion of the core stakeholder group's recommendations before they were finalised and issued for public consultation.
- 7.3. On the basis of the advice from the core stakeholder group and the results of public consultation, the FSA Board, at an open meeting on 10 July 2003, advised Ministers that a move to replace the OTM rule by testing would be justified on the grounds of public health risk and proportionality.
- 7.4. Following that advice, the FSA was asked by Health Ministers to reconsider the risk assessment in view of certain new information that had started to emerge, in particular about vCJD prevalence in the human population. The FSA/SEAC Risk Assessment Group was reconvened to undertake a fresh analysis, and SEAC was consulted.
- 7.5. Meanwhile, a failure by the Meat Hygiene Service (the body responsible for enforcing the testing requirements) to ensure that all 24 – 30 months casualty cattle were tested for BSE, as required under EU law, was uncovered in 2004. This failure was put to the Board, who commissioned an independent investigation. Professor Patrick Wall led a group to undertake this assignment, which reported in October 2004.

- 7.6. At its meeting in July 2004, a summary of the updated SEAC advice was put to the Board, who also took into account the casualty testing failures. The Board concluded that the updated risk assessment continued to provide a basis on which to recommend that a move to replace the OTM rule by BSE testing of cattle born after 1 August 1996 would be justified. This recommendation was however subject to the putting in place of a robust BSE testing system.
- 7.7. The Board also took the view that appointing an independent group to oversee the implementation of testing would secure public confidence and ensure that a robust system was put in place. To that end, the FSA set up a new independent advisory group (IAG), again chaired by Professor Wall, which began its work in November 2004.
- 7.8. In the light of the FSA advice, the Government announced to Parliament on 1 December 2004 the start of a managed transition towards lifting the OTM rule and its replacement with a robust system for BSE testing for cattle born on or after 1st August 1996. The announcement made clear that the switch from the OTM rule to testing should happen only when the FSA has advised Ministers that the testing system is robust.
- 7.9. The IAG, having scrutinised the proposed testing system and overseen a number of trials of it, reported back to the FSA Board at its open meeting in August 2005. The Board agreed 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.
- 7.10. The Government announced on 15 September that the FSA's advice had been accepted and that new legislation to replace the OTM rule by BSE testing could be introduced.
- 7.11. Formal written consultation on both the process for implementing a move from the OTM rule to BSE testing of OTM cattle and the proposed legislation to effect the change was held between February and May 2005. In addition, the FSA held open meetings in London, Edinburgh, Belfast and Cardiff in July 2005, with 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 advice on the testing system being developed by the independent group.
- 7.12. The responses indicate wide support for the Government's approach to managing the transition to testing and agreement that a robust testing system needs to be in place before a change is implemented. Wide support was also expressed for the policy of rule change by the farming and meat industries and retailers, though concerns were identified about the need to maintain consumer confidence in the change. Consumer groups were 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. The Human BSE Foundation, while recognising the proportionality argument, continues to oppose rule change.
- 7.13. The consultation did not bring to light any need to amend the proposed legislation to implement OTM rule change.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

David Carruthers at the Food Standards Agency Tel: 020 7276 8305 or e-mail: david.carruthers@foodstandards.gsi.gov.uk can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

1. The Bovine Products (Restriction on Placing on the Market) (England) Regulations 2005 and the Bovine Products (Restriction on Placing on the Market) (England) (No 2) Regulations 2005.

2. Purpose and intended effect of measure

(i) The objective

2. Replacement of the Over Thirty Months (OTM) rule with an alternative control (BSE testing) that the Food Standards Agency has advised is proportionate to risk and continues to protect public health from exposure to meat from cattle infected with Bovine Spongiform Encephalopathy (BSE). Such a change would affect cattle farmers, the meat industry, animal by-product renderers and incinerators, retailers, beef importers and those involved with BSE testing and the transport of brain samples.

Devolution: This is a devolved matter which affects all parts of the UK. Separate, but parallel, legislation will be introduced in England, Scotland, Wales and Northern Ireland.

(ii) The Background

The BSE controls

3. The OTM rule was introduced in March 1996 following advice from the Spongiform Encephalopathy Advisory Committee (SEAC) on the link between variant CJD and BSE. With limited exceptions, the OTM rule prohibits the sale for human consumption of meat from cattle aged over thirty months at slaughter. It is one of the three main BSE controls protecting public health. The others are removal of specified risk material (SRM), i.e. those parts of the carcass most likely to carry BSE infectivity, and the ban on feeding mammalian meat and bone meal to all farm animals, which came fully into force on 1 August 1996. The basis of a control on cattle at thirty months has been that:
 - fewer than 100 BSE cases have developed clinical disease at under 30 months out of over 180,000 cases of BSE in the UK;
 - the majority of cases in UK cattle under 30 months old were born before 1994;
 - BSE occurs at an average age of five years. Studies suggest that in the 12 months prior to the onset of clinical disease, cattle with BSE present a much higher risk due to the build up of infectivity.
4. The Over Thirty Month Scheme (OTMS), on which Defra takes the lead, complements the OTM rule in providing an outlet for OTM cattle which cannot be sold for food. Cattle entering the scheme are slaughtered and destroyed and compensation is paid to the farmer. It currently costs on average £320 million a year.
5. Other Member States do not operate an OTM rule. Since 1 January 2001, EU legislation has required all cattle aged over 30 months to test negative for BSE before

entering the food supply. In addition to the SRM requirements for under 30 months cattle, EU legislation also requires the vertebral column of UK OTM cattle entering the food supply to be removed and destroyed as SRM.

BSE Epidemic

6. The UK BSE epidemic in cattle remains in steep decline - from a peak level of over 37,000 clinical cases in 1992 to some 343 confirmed cases (both test positives and clinical cases) in 2004, of which 90 were clinical cases. Of the cattle found to have the disease in 2004, all but 25 were born before August 1996.

OTM Rule Review

7. In the light of the decline in BSE and the introduction of BSE testing, the FSA launched a review of the OTM rule in July 2002. The review comprised a scientific risk assessment undertaken by a FSA/SEAC Risk Assessment Group (RAG), which steered and peer reviewed mathematical modelling work commissioned by the FSA. A Core Stakeholder Group was formed to examine the results of the risk assessment and advise on whether the OTM rule might be replaced. They considered a number of factors including changes to the enforcement regime, the practicalities, the EU legal requirements for OTM beef entering the food chain (such as testing and the removal of vertebral column), public confidence and costs. The Core Stakeholder Group's recommendations were set out in a Report which, together with a partial RIA, was issued for public consultation in March 2003¹.
8. Following discussion of the results of the consultation by the FSA Board, the FSA advised Ministers in July 2003 that, "a move to replace the OTM rule by testing of all OTM cattle going through UK abattoirs is justified on the grounds of public health risk in relation to food and proportionality". The advice also stated that Ministers should not change the OTM rule until they were satisfied that the necessary arrangements (which would include arrangements for BSE testing) had been made.
9. Ministers subsequently asked the FSA to consider the implications for the risk assessment of developments that had occurred while they were considering its advice. A key development was the publication, in May 2004, of the results of a survey of human appendix tissue indicating that the public health impact of replacing the OTM rule, in terms of additional future vCJD cases, might be higher than the estimate considered in July 2003.
10. EU rules require the cohorts of BSE cases to be culled and kept out of the food supply (see paragraph 42). Due to the OTM rule, the UK has not routinely culled cohorts. A move towards replacement of the OTM rule with BSE testing would require cohorts of BSE cases in the UK to be culled. Rural Affairs Ministers decided not to proceed with a cull of cohort cattle born before August 1996, because of difficulties with tracing the cohorts of the large number of BSE cases born before that date. Consequently, cattle born before August 1996 will remain permanently excluded from the food supply.
11. The FSA Board met in July 2004 to consider revised risk estimates which took account of the developments since July 2003 and used a method and assumptions agreed by SEAC (as set out in an FSA Board paper²). On the basis of the revised estimates and

¹ The consultation package is available on the FSA website at:
www.food.gov.uk/foodindustry/Consultations/completed_consultations/completeduk/otmreviewconsult303

² www.food.gov.uk/multimedia/pdfs/fsa040706.pdf

advice from SEAC (see paragraph 17), they agreed to advise Ministers that replacing the OTM rule by testing for cattle born after July 1996 continued to be justified on grounds of the food borne risk to consumers and proportionality, subject to the putting in place of a robust testing system.

12. In the light of the FSA advice, the Government announced on 1 December 2004 the start of a managed transition towards lifting the OTM rule and its replacement with a robust system for BSE testing. The FSA appointed an Independent Advisory Group (IAG) to specify the requirements for a robust BSE testing regimen, oversee trials of the proposed regimen and report on whether it met the requirements specified. The IAG report was considered by the FSA Board at an Open meeting on 15 August 2005. The Board agreed 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.

UK Beef Market

13. The MLC predict that domestic beef supplies could be expected to rise by up to an estimated 23,000 tonnes in 2005 and 185,000 tonnes in 2006 if animals born after 1 August 1996 were allowed back into the food supply from 1 November 2005. The total UK market for beef in 2004 was around 1.2 million tonnes of which about 710,000 tonnes (farmgate value of £1,240m) is home produced and 520,000 tonnes (£795m) imported. The ability to absorb the additional beef from cattle aged over thirty months is dependent upon home produced cow beef being as acceptable to the retail sector and consumer as that currently imported and this in turn depends on there being no adverse public reaction to the re-introduction of OTM beef. The additional beef supplies are expected to be used mainly in the retail fresh meat sector, for the production of minced beef and processed products, and also the in the foodservice sector.
14. In 2004 520,000 tonnes of fresh/frozen and processed beef was imported, worth £795m. It is estimated that this may fall to 475,000 tonnes in 2005 if beef from animals born after 1 August 1996 is allowed back into the food supply by 1 November. Commercial cow prices at end July 2005 in Republic of Ireland were averaging 132p/kg deadweight (from around 95p/kg for poorest quality) against an EU average of about 135p/kg. These prices give an indication of those that might be expected on the UK market after an initial adjustment phase.

Exports

15. One of the industry's main concerns raised in the consultation was the adverse effect of a large volume of UK OTM beef entering the market while restrictions on exports remained in the form of the Date Based Export Scheme (DBES). In April 2003, Defra wrote to the Commission requesting a review of the Date Based Export Scheme and the UK's BSE-risk status. The European Food Safety Authority's (EFSA) Biohazards Panel was charged with reviewing the evidence provided, which included the modelling produced as part of the FSA's OTM rule review. The Panel's Opinions were published in May 2004. They concluded

- the UK should reach the OIE³ criterion for moderate risk status by the end of 2004;
 - removing the lower age limit (6 months) for cattle for export and the requirement for the dam to survive for 6 months after the birth of the DBES animal would not increase the risk; and
 - the risk to the consumer in the UK was comparable to other Member States provided the same protective measures were applied (i.e. testing, SRM, feed ban, cohort cull) and cattle born before 1 August 1996 were kept out of the food and feed chains (because they have a higher incidence of BSE and would therefore increase risk).
16. An EU Food and Veterinary Office (FVO) inspection mission examined the UK's BSE measures from 6 - 15 June 2005. If the final FVO mission report, due to be issued September 2005, is satisfactory, the way would be open for the Commission to propose legislation lifting the restrictions on UK beef exports from cattle born on or after 1 August 1996. If Ministers agree Option 2 and the process were to run smoothly from Commission proposals through to adoption of new EU legislation, current restrictions on exports could be lifted early in 2006.

(iii) Risk assessment

Risk to human health

17. As noted in paragraph 7 above, a scientific assessment of the risk to human health of replacing the OTM rule by testing was undertaken for the FSA by a FSA/SEAC Risk Assessment Group (RAG). This indicates that the amount of BSE infectivity entering the food supply following replacement of the OTM rule by testing would be a very small fraction of the total amount of infectivity that has already entered the food supply since the start of the BSE epidemic. Taking into account the appendix survey data referred to in paragraph 9 and using the assumptions and method agreed by SEAC, calculations of the additional vCJD cases that would result from replacing the OTM rule with testing give a range of between none and 2.5 over 60 years, with a central estimate of 0.5. SEAC however noted that significant scientific uncertainty surrounds these estimates.

Risk of infraction proceedings

18. Replacing the OTM rule would bring the UK into line with EU legislation and so remove the risk of infraction proceedings.

Risk to market for beef

19. The industry has previously expressed concern that the market could collapse if the supply of UK beef were suddenly increased, particularly as exports historically provided the main outlet for cull-cow beef. However in the last three years there has been a fundamental change in the EU beef market. As EU production has fallen and intervention stores emptied at the same time as EU beef consumption has increased, the EU has become a net importer of beef. The EU import requirement for 2004 was

³ OIE is the World Organisation for Animal Health. OIE standards are recognised by the World Trade Organisation as reference international sanitary rules. On 10 March 2005, EFSA published a further statement from the Biohazards Panel. This stated that the Panel had confirmed that, according to the OIE classification, the UK could be considered a country with a moderate risk status in terms of BSE for its whole cattle population. The text of the full statement can be found on the EFSA website at <http://www.efsa.eu.int/>

200,000 tonnes and is expected to rise to 280,000 tonnes in 2005 and 400,000 tonnes in 2006 (if the OTM rule remained in place). Given that the increase in UK production resulting from the arrival of post August 1996 OTM cattle onto the market is less than 2% of total EU production and well within the import requirement, the disturbance to the EU market is expected to be minimal. For this reason the Commission will not introduce any market support measure but will monitor the UK market as post August 1996 cattle are re-introduced and, in the unlikely event of a substantial fall in prices, take any corrective action through standard Beef Management Committee procedures. Most producers will benefit from a substantial rise in value for their post August 1996 OTM cattle.

3. Options

20. The Core Stakeholder Group considered various options for changing the OTM rule for which risk assessment modelling had been undertaken. These options included a new age-based rule, a date-based rule and completely replacing the rule. They concluded that two options should be considered – either allowing cattle born on or after 1 August 1996 or cattle of any age into the food supply. In July 2003, the FSA Board considered these two options as well as alternative birth-date options put forward during the consultation. These alternative options would have fixed birth dates of either 1 October 1998 (when more reliable cattle identification procedures were introduced) or 1 January 2001 (when a complete EU-wide ban on processed animal protein in animal feed came into effect) as the starting point for cattle allowed into the food supply.
21. The Board concluded that complete replacement of the rule was justified. They considered that the later birth-date options referred to above would cost significantly more than the options recommended by the Core Stakeholder Group, because they would require the destruction of large numbers of additional cattle, but would not provide a commensurate benefit in terms of reduction in risk to public health. Subsequently however, Rural Affairs Ministers decided to retain the ban on cattle born before 1 August 1996 (see paragraph 10). In July 2004, the FSA Board reconsidered its advice only in relation to cattle born on or after 1 August 1996. This RIA therefore considers only two options.

Option 1

- retain the OTM rule (which also applies to imported carcase meat but not to meat in imported meat products). This is the 'do-nothing' option.

Option 2

- allow UK cattle born on or after 1 August 1996 into the food supply, with all such cattle aged over 30 months at slaughter subject to BSE testing and removal of vertebral column as SRM (as required by EU legislation);
- allow imported beef from cattle (and beef from imported cattle) slaughtered at any age into the food supply subject to the EU rules on testing and removal of SRM.

4. Benefits

Option 1

22. There are no environmental benefits or benefits to the livestock or meat industries.

23. The economic and social benefits of this option are:
- Exceptionally high level of public health protection maintained.
 - For each vCJD case prevented there would be a saving on the cost of the suffering of the patients and their families. There would also be savings on the National Health Service costs associated with vCJD estimated to be in the range of £30,000-£40,000 per case. A Government funded compensation scheme provides for payments to be made to families of up to 250 vCJD cases up to an overall maximum of £67.5 million. By 1 August 2005, payments have been made on claims submitted in 152 cases, totalling in value around £31.2 million. As at the end of July 2005, there were 157 vCJD cases of whom 7 were still alive.

Option 2

24. The longer term reduction in the amount of animal carcass material requiring to be disposed of (around 50% of the carcass would be consumed instead) would provide an environmental benefit.
25. The economic and social benefits of this option are:
- Significant savings in Exchequer costs from reductions in OTMS expenditure net of additional costs, which are estimated to increase from some £60m in 2005/06 compared to the cost in 2004/05, to £337m after all cattle born before August 1996 have been disposed of. The disposal scheme for cattle born before August 1996 (the Older Cattle Disposal Scheme (OCDS)) will be in place for three years after which the only costs to the exchequer in relation to these cattle would be for the disposal of residual SRM.
 - UK fully compliant with EU BSE controls and risk of infraction proceedings removed;
 - Farmers allowed to sell OTM cattle born on or after 1 August 1996 for human consumption;
 - An eventual end to the requirement to dispose of OTM cattle via rendering and incineration (only up to 716,000 cattle born before August 1996 would remain to be disposed of if the OTM rule were changed from 1 November 2005, instead of the some 715,000 cattle disposed of annually through OTMS);
 - The estimated forecast OTMS compensation payment is £52.5m for 212,750 post August 1996 cattle in 2005/06 (see Table below). The equivalent value on the EU market (Irish Republic) for these cows at current prices (July 2005) is £76.5m, representing a benefit to the farmer of £24m. In 2006/07 the benefit is estimated at £49m.

Forecast No. animals born after 01.08.96 to enter the food chain from 01/11/2005					
Year	England (59%)	Wales (12%)	Scotland (13%)	Northern Ireland (16%)	UK Total
2005/06	125,522	25,530	27,658	34,040	212,750
2006/07	257,240	52,320	56,680	69,760	436,000

- A possible benefit to consumers via the availability of cheaper (cull cow) OTM beef for manufacturing. Currently only beef from prime stock is available to UK food manufacturers.
- Pet food manufacturers would have access to additional supplies.

5. Costs

Option 1

26. The continued need to incinerate the remains of some 800,000 cattle per year represents an environmental cost.
27. The economic and social costs of this option are:
 - The Exchequer costs of purchase and destruction of OTM cattle currently amount to some £320m per year;
 - Currently the OTM rule also represents a cost to producers because they are being denied access to a strong EU cow beef market. This cost, in terms of the higher value that would be derived from the market, is currently estimated to be £24m in 2005/06 and £49m in 2006/07 (see paragraph 25 above).

Option 2

28. The economic and social costs of this option are set out below.
 - *Impact on public health*
29. The FSA review concluded this option would provide slightly less public health protection compared with Option 1, giving rise to the possibility of a small number of additional vCJD cases (see paragraph 17).
 - *Costs to industry associated with BSE testing*
30. The additional costs associated with BSE testing OTM cattle slaughtered for human consumption (apart from sample analysis) would fall to industry. All animals which would require testing after a rule change are currently being tested when they are slaughtered under the OTMS. The Government currently bears the costs of sample analysis and is proposing to continue to do so after the OTM rule has been replaced.
31. The actual unit cost to industry of BSE testing will be dependent on throughput, but Defra estimate that the cost, including taking samples, consumables, packaging and transportation of the sample but excluding test kit and the test itself to average around £10 per animal tested. There would also be costs of the additional processing and staff required to operate the testing system which are estimated to be up to £5 million or so per annum. Some respondents to the consultation, however, considered industry costs would be far greater. Nevertheless, these costs are unlikely to be significant in relation to the value of the carcass and have not precluded slaughterhouses from expressing an interest in entering OTM trade (see paragraph 49). Whether or not to handle OTM cattle would be a commercial decision for operators. If costs in individual circumstances were to prove uneconomic, abattoir operators would exercise their option not to handle OTM animals. Any additional capital costs would depend on whether physical alterations were required to individual premises to provide any new facilities needed.

- *Removal of vertebral column*

32. SRM controls require the removal of vertebral column, including dorsal root ganglia, of cattle aged over 30 months. Removal and disposal would give rise to a cost, as would the need to maintain traceability of carcasses between slaughter and SRM removal in a cutting plant. Although the vast majority of beef is sold off the bone, additional industry costs might average at up to £2 per animal but would be greatly dependent on throughput and whether the cutting plant was on the same site as the slaughterhouse, totalling at most £1 million per annum.

- *Tanneries and hide markets*

33. EU rules require that all parts of the tested animal are held under official control until the test result is known. Hides taken from tested cattle will usually be transported on the day of slaughter from the originating abattoir to a hide market or tannery, prior to the test result being known. Although the hide premises operator will be allowed to carry out initial processing of the hides while they remain under official control, the hides will not be permitted to leave the premises or be further processed until the BSE test result is known. Under normal conditions the test result will be available on the day following the day of slaughter. On receipt of a negative result the hides will be released from official control into free circulation.
34. From discussions with hide industry representatives it is not anticipated that this requirement will impose additional burdens on hide processors, as bovine hides are processed by salting or icing for a number of days following receipt from the originating abattoir. Hide processors will, however, be required to agree and sign a protocol setting out the arrangements for handling, identification and detention of tested hides.

- *Incinerators & renderers.*

35. Replacing the OTM rule by testing will reduce the overall quantity of material requiring disposal through rendering and incineration, but would alter the amount of material going to the different rendering streams. The large reduction in OTMS (Category 1) rendering would be partially offset by an increased need for rendering the Category 1 and Category 3 by-products arising from the slaughtering of OTM animals entering the food chain. One immediate effect may also be an increased proportion of material requiring incineration. This is explained below.
36. As with all carcass parts, by-products derived from BSE tested cattle will need to be held under official control until the BSE test result is known, unless they are consigned for incineration at a category 1 approved premises or rendered at a plant all of whose output is subsequently incinerated. Some abattoirs are likely to consign material for disposal as above rather than retain it on site pending receipt of test results. This is due to logistical or smell nuisance problems associated with on-site storage and decomposition of the material.
37. However, some renderers who would otherwise be able to take this material once a BSE - negative test result has been received, may not be able to do so if the material was consigned before the result is received as they landfill the MBM they produce. Landfill is not permitted for material for which there is no or an inconclusive test result. This may lead to some movement from rendering to incineration as the disposal route.
38. Renderers will however continue to process OTMS and OCDS by-products, as destruction by incineration (either directly or of the rendered products) of this material is

already required. The amount of OTMS/OCDS material requiring disposal via dedicated rendering lines in the year following replacement of the OTM rule will depend on the uptake of the OCDS in the first year of its three year duration but is estimated to be around 240 kilotonnes (see paragraph 24).

- *Beef labelling*

39. Labelling beef as being Over Thirty Months is not required under beef labelling requirements set out in EU Regulations and is not the practice in other EU countries where OTM beef is in free circulation.

- *Enforcement*

40. Enforcement of the new arrangements related to testing and the removal of vertebral column from OTM cattle will give rise to additional costs to Government incurred by the Meat Hygiene Service (MHS) in Great Britain and the Department of Agriculture and Rural Development (DARD) in Northern Ireland. In addition, the extent of routine monitoring of current SRM controls would increase simply because a larger number of cattle would be slaughtered in fresh meat slaughterhouses. Also, it is impractical to require all abattoirs to retain hides on site until test results are received which means that a system of official control must be extended to hide markets and tanneries. Defra will use Meat and Livestock Commission (MLC) staff for this purpose. Additional enforcement costs to Government are difficult to quantify because the number and location of abattoirs which will be approved to process OTM cattle for human consumption is not known, and the costs of MHS supervision, particularly of vertebral column removal, remain unconfirmed. However, enforcement costs could be in the region of £22 million in 2005/06 (see summary of costs table at paragraph 63).

- *Independent Review and audit*

41. Defra have agreed to meet the FSA's costs of implementation, including the FSA's new responsibility for the review and audit of the BSE testing regime for cattle aged over 30 months slaughtered for human consumption. An independent audit of the testing regime over the first six months following implementation (indicative estimate of £50,000) will be superseded by an ongoing audit and review of the testing regime undertaken by the FSA (indicative estimate of £50,000 pa). These will be overseen by an Implementation Review Group (IRG) which will run for the first year following implementation. The IRG will be chaired by the FSA and report to the FSA Board. Thereafter, the FSA audit reports will be considered by the FSA Board.

- *Cohort cull*

42. Under EU rules, all cattle born within a year of the birth of a BSE case in its herd of birth must be slaughtered if they have been exposed to the same feed. In addition, any cattle reared in the first year of their lives with the BSE case in the first year of its life must be culled. Historically, the UK has not culled cohorts because the OTM rule has meant that UK cattle aged over thirty months have been excluded from the food supply and ultimately incinerated under the OTMS at the end of their productive lives. However, following OTM rule replacement, any cohort animal born after August 1996 will need to be culled. Depending on the age of the BSE case and the size of the natal herd and rearing group, there may be up to about 200 cattle in a cohort or all cattle in the cohort may already be dead. A cull of the backlog of cattle born after August 1996

within cohorts of all BSE cases born after 1 August 1995 took place between 1 March and 30 June 2005. Since then, cohorts have been culled as BSE cases born on or after 1 August 1995 have been confirmed. Farmers receive compensation for their cattle based on individual valuations. The backlog cull cost Government around £6 million and the on-going cull is expected to cost about £1m in 2005/06 financial year with costs falling in future years as the number of BSE cases declines.

- *Collection and disposal of additional fallen stock*

43. Farmers receive compensation under the OTMS for cattle slaughtered on farm for welfare reasons but deemed by a vet as fit for human consumption. However, they pay for the transport of these cattle to incinerators or renderers. Following OTM rule replacement it is expected that a proportion of current OTMS casualties born after August 1996 would not be suitable for human consumption. Such cattle would then need to be treated as fallen stock which are collected, tested and incinerated at the expense of Defra/DARD. The additional cost to Government is estimated to be £12 million in 2005/06.

- *Possible market support and MLC promotion*

44. The Meat and Livestock Commission have produced a report on the likely impact of post August 1996 born cattle re-entering the food chain. There is a degree of confidence that, provided there is no consumer or retailer resistance to substituting imported beef with cow beef, the domestic market is well able to absorb the additional 23,000 tonnes in 2005 and 185,000 tonnes in 2006 through import substitution. Import requirement is likely to drop from 520,000 tonnes in 2004 to 475,000 tonnes in 2005 and further to 380,000 tonnes in 2006. The EU Commission have indicated that they will not fund any specific market support scheme to underpin the market following the re-introduction of UK cow beef on the grounds that the EU is also short of beef for manufacturing. The increase in supplies will be welcomed. If however there were a substantial fall in price then they would respond through Beef Management Committee procedures in the normal way. An opening up of export markets at the same time or soon after would also provide a safety valve. Both this and the maintenance of domestic consumption may be encouraged by a well targeted MLC promotion campaign – at a one-off cost to Government of £5 million in 2005/06.

Costs for a typical business

45. Costs for a typical business would depend on the facilities already available at individual premises and OTM cattle throughput. However, abattoirs and cutting plants would be able to choose not to handle OTM cattle. Major accommodation works would not typically be required for a plant to engage in the OTM trade, the main requirements being sufficient lairage capacity to segregate cattle into appropriate batches, to provide a space for sampling and suitable facilities for holding carcasses awaiting test results. As noted above (paragraphs 31 & 32), for all plants taking on OTM work, handling OTM carcasses would involve higher costs in relation to testing and additional processing and SRM removal. Slaughterhouses would be expected to pass on all or part of these additional costs to producers. Additional industry costs for testing and removal of vertebral column may be about £12 per animal but would depend on capital outlay at abattoirs and OTM cattle throughput. Producers would benefit to the extent that the market provides a better return than the OTMS, less the additional costs to abattoirs of processing OTM cattle.

6. Equity and Fairness

46. There is no greater impact by gender, age, disability, or by race. Without a knowledge of which abattoirs will wish to take part in the new arrangements, and their location, it is not possible to say whether there will be any greater regional or devolved administration impact. Any impact on particular income groups is unlikely to be significant.

7. Consultation with small business: the Small Firms' Impact Test

47. FSA consulted the Small Business Service and a number of trade associations in face to face discussions prior to the launch of the formal consultation on the Core Stakeholder Group report in March 2003. Their initial feedback was that the possible impact would depend on which option was chosen and, if the OTM rule were to be changed, they would like clear guidance and information on the timing of implementation. A number of organisations representing small business interests responded to the formal consultation e.g. AIMS, Crofters Commission, Family Farmers Association, Tenant Farmers Association. Overall their views reflected those of the industry as a whole. Consumers and small business interests are represented on Defra's Stakeholder Group which has been looking at preparations for the possible introduction of large scale BSE testing of OTM cattle slaughtered for human consumption.
48. Organisations representing small business interests that responded to the formal consultation launched in March 2005 include AIMS, the Rare Breeds Survival Trust and Scottish Crofting Foundation. The National Federation of Meat & Food Traders did not anticipate many smaller slaughterhouse operators would handle OTM cattle, while not doubting that butchers and slaughterers would welcome the opportunity to handle prime beef cattle aged up to 42 months. Trials of the BSE testing system to be implemented were held at a number of abattoirs across the UK, including at small abattoirs with low throughput. These trials demonstrated that the testing system could be successfully operated in abattoirs of this size.
49. It is impossible to know precisely how many abattoirs will be approved to handle OTM cattle. Industry have indicated that it is likely that a few large abattoirs would specialise in older cull cows, but a larger range of abattoirs may be prepared to handle prime beef cattle aged under 42 months. Around 100 abattoirs (out of a UK total of around 300 licensed to slaughter cattle) have expressed an interest in entering OTM trade. Some small abattoirs may offer a local service for cattle of all ages. Abattoirs would take a commercial decision based on the costs of implementing the requirements for testing and the removal of vertebral column and returns from the market. Given the excess of slaughtering capacity in the UK, it is unlikely in the longer term that there would be insufficient abattoirs willing to handle OTM cattle although there could be short term difficulties.

8. Competition assessment

50. The competition filter questions have been considered. It is concluded that there is no significant adverse impact on competition. Option 2 is essentially deregulatory in nature and should improve competition in the beef slaughtering and manufacturing sectors by increasing domestic supplies and providing a wider range of cattle specification (cow beef) than is currently available. It should return the UK to a situation similar to that which prevailed before 1996. Any slaughtering business would be eligible to handle OTM cattle. The structure of the industry and the run down of the OTM scheme

releasing capacity should provide keen competition. Those that are able to achieve economies of scale will be at an advantage. In a full year Option 2 should lead to an increase in domestic beef supplies of about 185,000 tonnes (of which about 7,000 tonnes would be from prime cattle and the remainder would be cow beef). This represents an increase in domestic production of about 22%. The main consequence would be to undercut the price and displace imported beef – currently sourced mainly from the Republic of Ireland.

9. Enforcement and Sanctions

51. The legislation will be enforced at licensed slaughterhouses and cutting plants by the MHS in Great Britain and by DARD in Northern Ireland. Sanctions will be applied for non-compliance. The penalty for placing on the market any product (apart from milk) from an animal slaughtered in the UK and born or reared in the UK before 1 August 1996, on summary conviction would be a fine not exceeding the statutory maximum (currently £5,000), a three months prison term or both and on indictment, an unlimited fine or up to two years in prison or both.

10. Monitoring and review

52. The functioning of the system for BSE testing of OTM cattle will be subject to continuous monitoring by the MHS and DARD as part of their enforcement function.
53. The entire testing system, including MHS and DARD enforcement, will be subject to an independent audit covering the first 6 months following implementation. Thereafter, the FSA will be responsible for ongoing audit and review of the testing regime. For the first year following implementation, both will be overseen by the IRG (see paragraph 41).
54. As a check on the risk assessment, numbers of BSE positive cattle will be monitored against predictions from the risk assessment model.
55. In July 2005, the Commission issued the "TSE Roadmap", which provides an overview of changes to the BSE controls, including the current regimes for testing animals for BSE, in the short, medium and long term. The Roadmap will be used as a basis for discussion with Member States, the European Parliament and other stakeholders on possible changes to the controls that could be made while maintaining the current high level of consumer protection.

11. Consultation

(i) Within Government

56. Following the FSA's advice to Ministers in July 2003, the FSA and Defra dealt with a number of queries concerning the risk assessment and implementation issues from the Parliamentary Secretary (Public Health) and the Chief Medical Officer. The FSA Chairman, Chief Veterinary Officer and Chief Scientific Officer met the UK CMOs to discuss the risk assessment. Following that meeting, CMOs advised their respective Ministers of their views. The FSA Chairman also met the Parliamentary Secretary (Public Health), the Secretary of State for Health and the Welsh Assembly Minister for Health. The Minister for Food has met the Parliamentary Secretary (Public Health).
57. The Rural Affairs Departments (Defra, SEERAD, WAG and DARD, NI) and FSA have had regular official level meetings as part of the preparations for the introduction of BSE testing of cattle aged over thirty months slaughtered for human consumption.

(ii) Public Consultation

58. The FSA's OTM Rule Review was launched at a public meeting on 2 July 2002. A second public meeting took place on 7 March 2003 as part of the consultation process. The Agency was assisted in its consideration of risk management options by a Core Stakeholder Group. Membership included consumer, farming, meat industry and enforcement representatives from across the UK.
59. A partial RIA formed part of the formal consultation package on the Core Stakeholder Group's report and recommendations issued in March 2003. Around 60 responses were received. There was support for change but industry were keen that it be phased in to avoid market collapse. Consumer organisations felt that assurances were needed on a number of questions before changes were made. Following completion of the 12 week formal consultation process, recommendations were discussed by the FSA Board at a public meeting on 10 July 2003. The Agency's subsequent advice was sent to Ministers on 16 July 2003 and was made available to the public on the FSA's website together with other relevant information and documents. The FSA Board considered revised risk estimates at a public meeting on 6 July 2004 and the FSA's subsequent advice to Ministers was again made available to the public on the FSA's website together with the relevant documentation.
60. As part of contingency planning arrangements, Defra have held a series of stakeholder meetings looking at preparations for the possible introduction of large scale BSE testing of OTM cattle slaughtered for human consumption and other associated measures such as possible market support which had been the focus of the industry's comments on the RIA. In November 2003, Defra launched an OTM Rule Review area on their website to keep industry and other stakeholders informed of progress.
61. The FSA has carried out the process of developing its advice on the robustness of testing in an open and transparent way, involving stakeholders. A meeting with stakeholder representatives was held on 7 December 2004 both to update stakeholders of developments on the OTM review and to invite feedback on the independent group's initial recommendations.
62. Following Ministers' decision to start a managed transition from the OTM rule to BSE testing, a second round of formal written public consultation on draft legislation to introduce the change took place between March and May 2005. There were around 45 responses. In addition, around 350 members of the public attended open meetings held in London, Edinburgh, Belfast and Cardiff which took place at the end of July 2005. The London meeting was also webcast. The meetings had presentations on the background to the OTM rule review, emerging findings from the Independent Advisory Group and provided an opportunity for comments and questions from those attending. Responses to these consultations indicated that the meat industry continues to favour OTM rule replacement and were no longer concerned about market collapse, though they, and retailers stressed the need to retain consumer confidence. Consumer groups while remaining generally concerned about OTM rule replacement welcomed the work of the Independent Advisory Group and the FSA's role in the audit and review following implementation of OTM rule replacement.

12. Summary of costs

63. The following costs relate to the operation of OTMS and testing funded by the Government.

Option	Total Cost per annum Economic, environmental, social	Total Benefit per annum Economic, environmental, social
1. Keep the OTM Rule	<ul style="list-style-type: none"> OTMS compensation and disposal gross costs of £282.3m **see separate table below 	<ul style="list-style-type: none"> Exceptionally high level of public health protection maintained
2. Allow cattle born after 1 August 1996 to be slaughtered for human consumption	<ul style="list-style-type: none"> Additional enforcement cost of £22m, of which <ul style="list-style-type: none"> ➤ vertebral column removal £3m ➤ additional MHS recruitment and supervision costs related to testing £14m ➤ additional MHS recruitment and supervision costs related to removal of SRM from OTM cattle £4m ➤ additional DARD costs £0.7m ➤ MLC costs related to hide controls at hide markets and tanneries £0.5m Policy costs (<i>see paragraph 64</i>) of which <ul style="list-style-type: none"> ➤ post-implementation audit £0.1m ➤ cohort cull £7m (backlog included; £1m per annum thereafter) ➤ collection and disposal of additional fallen stock (previously OTMS casualties) £12m ➤ MLC promotion (includes exports) £5m (one-off cost) ➤ compensation and disposal costs of pre August 1996 cattle over 3 year duration of OCDS. 	<ul style="list-style-type: none"> Very high level of public health protection maintained. Gross savings on OTMS compensation and disposal costs of £282.3m million after pre August 1996 cattle have been disposed of. A significant and increasing proportion of OTM cattle able to be sold for food instead of being destroyed. Risk of initiation of infraction procedures removed.

** Option 1

Direct OTMS Costs 2005/06 (Compensation and Disposal only) if no change to OTM rule and OTMS i.e. excluding approximately £20m administrative costs					
	%	No. Animals	Compensation	Disposal	Total Costs
UK TOTAL		715,000	£189.2m	£93.1m	£282.3m
England	59%	421,850	£111.6m	£54.9m	£166.5m
Wales	12%	85,800	£22.7m	£11.2m	£33.9m
Scotland	13%	92,950	£24.6m	£12.1m	£36.7m
Northern Ireland	16%	114,400	£30.3m	£14.9m	£45.2m

64. All costs are broad guidelines only. MHS costs are very dependent on number, throughput and location of abattoirs and cutting plants that decide to enter OTM trade and may in practice be lower; the cost of the post-implementation audit is dependent on the precise scope of the work undertaken; and the cost of the OCDS is dependent on the payment rate and number of eligible cattle born before 01.08.96.

13. Recommendation

65. The FSA has advised the adoption of Option 2.

14. Declaration

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Caroline Flint

29th September 2005

Parliamentary Under Secretary of State, Department of Health.

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