

## **REGULATORY APPRAISAL**

### **FOOD, WALES**

#### **THE BOVINE PRODUCTS (RESTRICTION ON PLACING ON THE MARKET) (WALES) REGULATIONS 2005**

##### **Background**

1. The Over Thirty Month (OTM) rule was introduced in March 1996 following advice from the Spongiform Encephalopathy Advisory Committee (SEAC) on the link between variant Creutzfeldt Jakob Disease (vCJD) and Bovine Spongiform Encephalopathy (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.
2. The Over Thirty Month Slaughter Scheme (OTMS), on which the Department for Environment, Food and Rural Affairs (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. Defra and the European Commission fund the OTMS.
3. 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

4. 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

5. In the light of the decline in BSE and the introduction of BSE testing, the Food Standards Agency (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 Regulatory Appraisal, was issued for public consultation in March 2003<sup>1</sup>.

6. 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.
7. 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.
8. EU rules require the cohorts of BSE cases to be culled and kept out of the food supply. 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. UK 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.
9. The FSA Board met in July 2004 to consider revised risk estimates that took account of the developments since July 2003 and used a method and assumptions agreed by SEAC (as set out in an FSA Board paper<sup>2</sup>). On the basis of the revised estimates and 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.
10. In the light of the FSA advice, the UK 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; and
  - 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;

---

<sup>1</sup> The consultation package is available on the FSA website at:

[www.food.gov.uk/foodindustry/Consultations/completed\\_consultations/completeduk/otmreviewconsult303](http://www.food.gov.uk/foodindustry/Consultations/completed_consultations/completeduk/otmreviewconsult303)

<sup>2</sup> [www.food.gov.uk/multimedia/pdfs/fsa040706.pdf](http://www.food.gov.uk/multimedia/pdfs/fsa040706.pdf)

On 15 September 2005, the UK Government announced that it had accepted the Food Standards Agency advice and that new legislation to replace the OTM rule with BSE testing could be introduced.

### UK Beef Market

11. The Meat and Livestock Commission (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 in the foodservice sector.
12. 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 dead weight (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.
13. 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 World Organisation for Animal Health (OIE)<sup>3</sup> 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 (female parent of an animal) to survive for 6 months after the birth of the DBES<sup>4</sup> 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, Specified Risk Material (SRM), feed ban, cohort cull) and cattle born before 1 August 1996 were

---

<sup>3</sup> 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/>

<sup>4</sup> Date Based Export Scheme – the purpose of the Scheme is to allow the export of deboned beef and beef products from cattle born and raised in the UK after 1 August 1996.

kept out of the food and feed chains (because they have a higher incidence of BSE and would therefore increase risk).

14. An EU Food and Veterinary Office (FVO) inspection mission examined the UK's BSE measures from 6 - 15 June 2005. The final FVO mission report, which was published recently, is satisfactory and so opens the way for the Commission to propose legislation lifting the restrictions on UK beef exports from cattle born on or after 1 August 1996. If these Regulations are implemented 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.

### **Purpose and Intended Effect**

15. The Regulations will implement in Wales a move from OTM rule to BSE testing of cattle aged over thirty months at slaughter and born on or after 1 August 1996. The Regulations will revoke the OTM Rule and give effect to Article 1.1 of Commission Decision 2005/598/EC prohibiting the placing on the market of products derived from bovine animals born or reared within the UK before 1 August 1996 for any purpose. The Regulations also provide for offences, penalties and powers for authorised officers to inspect and seize suspected products.

### **Devolution**

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

### **Risk assessment**

#### Risk to human health

17. As noted in paragraph 5 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 para 7 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 to market for beef

18. 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 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.

## Options

19. 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.
20. 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, UK Rural Affairs Ministers decided to retain the ban on cattle born before 1 August 1996 (see paragraph 8). In July 2004, the FSA Board reconsidered its advice only in relation to cattle born on or after 1 August 1996. This Regulatory Appraisal therefore considers only two options:
  - Option 1: Do Nothing
  - Option 2: Make the Legislation
21. The UK Government has already agreed changes to the UK's BSE controls – this legislation gives effect to that decision in respect of Wales. It also implements Article 1.1 of Commission Decision 2005/598/EC in Wales and in that respect the “Do Nothing” option is not an option as it would lead ultimately to infraction proceedings against the National Assembly for Wales by the European Commission. Therefore, the “Make the Legislation” option, to implement the changes required to comply with European legislation, is being proposed.

## Benefits

22. 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.

23. The economic and social benefits of this option are set out below:

- 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;

<b>Forecast No. animals born after 01.08.96 to enter the food chain from 01/11/2005</b>					
<b>Year</b>	<b>England (59%)</b>	<b>Wales (12%)</b>	<b>Scotland (13%)</b>	<b>Northern Ireland (16%)</b>	<b>UK Total</b>
<b>2005/06</b>	125,522	25,530	27,658	34,040	212,750
<b>2006/07</b>	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; and
- Pet food manufacturers would have access to additional supplies.

## **Costs**

24. There are no additional financial implications for the Assembly from the making of these Regulations. The Welsh Assembly Government does not meet any of the costs of BSE testing – these are met by Defra. The OTM Scheme complements the OTM rule in providing an outlet for OTM cattle that cannot be sold for food. Cattle entering the scheme are slaughtered and destroyed and compensation is paid to the farmer. The OTM Scheme is funded by Defra and the European Commission. A detailed cost analysis is contained in paragraphs 26 – 38 with a summary of the costs to a typical business at paragraph 40.

### Impact on public health

25. 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

26. 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 UK Government currently bears the costs of sample analysis and is proposing to continue to do so after the OTM rule has been replaced.

27. 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 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 44). 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

28. 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

29. 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.
30. 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 and renderers

31. Replacing the OTM rule by testing will reduce the overall quantity of material requiring disposal through rendering and incineration, and 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 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.
32. 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 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.
33. 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 meat and bone meal (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.
34. Renderers will however continue to process OTMS and Older Cattle Disposal Scheme (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 23).



### Enforcement

35. Official supervision of new arrangements related to testing and the removal of vertebral column from OTM cattle would give rise to additional costs 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 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 Annex B attached).

### Independent Review and Audit

36. 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

37. 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 2005 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 the UK 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

38. 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 a proportion of current OTMS casualties born after August 1996 would not in fact be consigned for human consumption. The 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

39. The MLC 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 the UK Government of £5 million in 2005/06.

### Cost for a typical business

40. Costs for a typical business would depend on the facilities already available at individual premises and OTM cattle throughput. However, abattoirs and cutting plants will 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, 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 will benefit to the extent that the market provides a better return than the OTMS, less the additional costs to abattoirs of processing OTM cattle.

### Competition assessment

41. The competition filter questions have been considered. It is concluded that there is no significant adverse impact on competition. These Regulations are 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 will be to undercut the price and displace imported beef – currently sourced mainly from the Republic of Ireland.

## **Consultation**

### With Stakeholders

42. 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.
43. 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 that 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.
44. 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 one hundred abattoirs UK-wide including eight in Wales (out of a UK total of around 300 licensed to slaughter cattle) have expressed an interest in entering the 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.

## Public Consultation

45. 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.
46. A partial RA formed part of the formal consultation package on the Core Stakeholder Group's report and recommendations launched in March 2003. Around 60 responses were received. There was support for change but industry was 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.
47. 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 Regulatory Appraisal. In November 2003, Defra launched an OTM Rule Review area on their website to keep industry and other stakeholders informed of progress.
48. 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.
49. In December 2004 the UK Government announced the start of a managed transition towards replacing the OTM Rule with a BSE testing regime. Subsequently, the Food Standards Agency carried out a consultation in the UK from 9 March 2005 to 31 May 2005 on the Government's proposals. In Wales the Agency wrote to 329 stakeholders including consumer and industry representative bodies, farming unions and licensed red meat premises. They were invited to comment on the draft Regulations and the draft Regulatory Appraisal. (A list of consultees is attached at Annex A to the Regulatory Appraisal). 3 responses (from the National Farmers Union (Wales), Hybu Cig Cymru and the Farmers Union of Wales) were received in Wales with a total of 45 responses UK wide. All respondents to the exercise in Wales welcomed and supported the proposal. Generally across the UK the meat industry continues to favour rule change whilst consumer groups are more wary and stress the need for a reliable testing regime, robust enforcement of the new requirements and effective communication to the public.
50. Open meetings took place in London, Edinburgh, Belfast and Cardiff during July 2005 to discuss the proposed changes to the OTM rule. A representative of the FSA and Professor Patrick Wall, the chair of the independent group, which advised the

FSA on the robustness of the testing regime, gave presentations on the background to the OTM rule review. This included the Government's announcement last year to accept the case in principle for rule change and the emerging findings of the independent group. In Cardiff some 390 invitations were issued to, amongst others, Assembly Members, consumer, industry and farming representatives. Public notices were placed in key newspapers to raise awareness of the meeting. Over 40 delegates attended the meeting and participated in a Question and Answer session after the presentations. The general consensus was one of support and there were no unexpected developments arising from the open meetings.

#### With Subject Committee

51. The Regulations were notified to the Health and Social Services Committee in 2003 and most recently via the list of forthcoming legislation on 13 July 2005 (HSS(2)-09-05(p.2b), item no: FSA26 (03)) but were not identified for detailed scrutiny.

#### **Enforcement and Sanctions**

52. The legislation will be enforced at licensed slaughterhouses and cutting plants by the Meat Hygiene Service (MHS) in Great Britain and by the Department for Agriculture and Rural Development (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.

#### **Monitoring and Review**

53. 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.

54. The entire testing system, including MHS and DARD enforcement, would also be subject to an independent review 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 Implementation Review Group (IRG).

55. As a check on the risk assessment, numbers of BSE positive cattle will be monitored against predictions from the risk assessment model.

## Contact Point

Mike Pender  
Food Standards Agency Wales  
11<sup>th</sup> Floor, Southgate House  
Wood St  
Cardiff  
CF10 1EW

Tel: 029 20678904

Fax: 029 20678918

Email: [mike.pender@foodstandards.gsi.gov.uk](mailto:mike.pender@foodstandards.gsi.gov.uk)

## ANNEX A

<b>Company Name</b>
Abergavenny Fine Foods
ADAS Wales
Age Concern Cymru
Agricultural Industries Confederation (AIC)
All Wales Dietetic Advisory Committee
Arfon Meat Company
Association of Civic Hosts
B. Sidoli & Sons Ltd
Bar and Restaurant Foods Ltd
BBC Radio Cymru
BBC Wales
BBC Wales
Be Safe Not Sorry
Beggan Farm Partnership
BEN (Black Environment Network) - Swansea Office
BEN (Black Environment Network) - Swansea Office
Berwyn Bakery
Biotrace Limited
Blaenau Gwent CBC
Brecon Support Group for Sufferers of Food/Environmental Intolerances
Bridgend CBC
Bridgend County Borough Council
British Assoc of Shooting & Conservation
British Institute for Allergy and Environmental Therapy
British Meat Processors' Association
British Retail Consortium
British Veterinary Association North
British Veterinary Association South
Brookfield Foods Limited
Business Connect Heart of Wales
Caerphilly CBC
Caerphilly CBC
Caerphilly County Borough Council
Campaign for Protection of Rural Wales
Campden and Chorleywood Food Research Association Group
Cardiff Chamber of Commerce
Cardiff County Council
Cardiff Scientific Services
Cardigan Bay Fishermen's Assoc Ltd
Carmarthenshire CC
Carmarthenshire College

Carmarthenshire County Council
CBS Technologies Ltd
Celtic Dimensions
Centre for Research into Environment + Health
Ceredigion CC
Ceredigion County Council
Ceredigion County Council
Chairman, Welsh Food Advisory Committee
Champion FM
Chartered Institute of Environmental Health in Wales
Chartered Institute of Environmental Health in Wales
Children's Commissioner for Wales
Children's Commissioner for Wales
Cig Mon Group
City and County of Swansea
City of Cardiff
Clark's Original Pies
Co-operative Group (CWS) Ltd
Coleg Llysfasi Ruthin
Commission for Racial Equality
Communicable Disease Surveillance Centre Wales
Conwy County Borough Council
Conwy County Borough Council
Country Land and Business Owners Association
Country Land and Business Owners Association
Countryside Alliance Wales
Countryside Council for Wales
Countryside Council for Wales
Countryside Division
Crystal Falls
Cyngor Gwynedd
Daily Post
Dailycer Chestergate
Dairy Strategy Group
Dee Dairy Services
Denbighshire CC
Denbighshire CC
Denbighshire CC
Department of Food Science & Technology - ISSUE BY EMAIL ONLY
Diabetes UK Cymru
E T Jones, Sons & Daughter
EJ Jones and Son Ltd
Environment, Planning and Countryside Committee
Environmental Data Services Ltd
Eppyut Hill and Beulah Face Sheep Society



Eurofins Scientific
European Commission
Eversheds (Wales)
Farm Assured Welsh Livestock
Farm Assured Welsh Livestock
Farmers For Action
Farmers Markets in Wales
Farmers' Union of Wales
Farmers' Union of Wales
Federation of Small Businesses (North Wales)
Federation of Small Businesses (South Wales)
Fforwm Dwyieithrwydd Cymru (North Wales Bilingual Forum)
Five Year Freeze
Flintshire County Council
Flintshire County Council
Food and Drink Federation
Food Centre for Wales
Food Consultancy
Food Quality Panel
Food Safe
Food Safety Microbiology Laboratory
Forum Products Ltd
Friends of the Earth Cymru
G C Hahn & Co Ltd
Gelatine Products Ltd
Gelpak Ltd
Glamorgan Gem
Good Food Distributors
Graig Farm Organics
Greysones
Guild of Welsh Lamb and Beef Suppliers
Gwent Healthcare NHS Trust
Gwynedd CC
Gwynedd CC
Halo Foods Ltd
HCIMA
Headland Foods
Health & Social Services Committee
HEES
Hospital Caterers Association
Hybu Cig Cymru
Iceland Frozen Foods
Institute of Consumer Sciences
Institute of Consumer Sciences
Institute of Grassland and Environmental Research

Institute of Rural Studies (Wales)
Institutes of Rural Health
International Federation for Home Economics
Isle of Anglesey County Council
Kwik Save Group Ltd
LACORS
LACORS (Welsh Officer)
Liverpool Daily Post and Echo Ltd (Welsh Edition)
Llanwenog Sheep Society
Lleyn Sheep Society
Marcher Gold
Meat and Livestock Commission
Meat and Livestock Commission's Consumer's Committee
Medicines and Healthcare Products Regulatory Agency (MHRA)
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Meridian Foods
Merthyr Tydfil CBC
Messrs TG, P & S Jones
Mid Wales Manufacturing Group
Minton, Treharne & Davies Ltd
Monmouthshire CC
Monmouthshire County Council
Monmouthshire Food Initiatives Officer
Mr R Lewis
National Association of Health Stores
National Britannia
National Farmers Union (Wales)
National Farmers Union (Wales)
National Farmers Union (Wales)
National Federation of Meat and Food Traders
National Federation of Womens Institutes - Wales
National Sheep Association (Wales)
Neath Port Talbot CBC
Neath Port Talbot CBC
Neuadd Brycheiniog
Newport CBC
NHS Staff College
North East Wales NHS Trust

North Wales/Borderlands Tourism Alliance
PB Gelatins UK Ltd
Pembrokeshire County Council
Pencoed College
Peters Food Service Ltd
PHA Cymru
PHLS in Wales
PHLS in Wales
PHLS in Wales
Plas Gwyn
Port Health Services
Powys CC
Powys Food Futures Group
Process Drying Ltd
Procheck Food Safety Ltd
PRP Training Ltd
PTP Quality Training
Public Analyst's Laboratory
Rachel's Dairy
Radnor Hills Natural Mineral Water Co
RCT Trading Standards Dept
Red Dragon FM
Red Meat Strategy Group
Red Star BioProducts
RHM Frozen Foods Limited
Rhondda Cynon Taff CBC
Rhondda Cynon Taff CBC
Rhondda Cynon Taff CBC
Rhondda Cynon Taff CBC
Royal Institute of Chartered Surveyors (Wales) (formally agricultural auctioneers)
Royal Institute of Chartered Surveyors Wales
Royal National Institute for the Blind
Royal Welsh Agricultural Society
Royal Welsh Agricultural Society
Ruddock & Sherratt
Sainsbury's Supermarkets Limited
School of Applied Sciences
School of Environmental Sciences
SEAC
Senior Assistant Trading Standards Officer
Severn Trent Laboratories
Society of Directors of Public Protection - North Wales
Society of Directors of Public Protection Wales - Trading Standards Group
Somerfield Stores Ltd.
South Caernarfon Creameries Ltd

South Wales Evening Post
State Veterinary Service
Stork MPS (Meat Processing Systems)
Suffolk Sire Reference Scheme Limited
Sunday Times
SUSTAIN
Swansea Local Health Group
T/A Source Foods
Teeswater Sheep Breeders Association
Tesco Stores Ltd
The Association of Public Analysts
The Federation of Bakers
The Highway Cafe
The Organic Working Group
The Speciality Sauce Co. Ltd
The Western Mail
Tillery Valley Foods Ltd
TMCI (UK) Ltd
Torfaen CBC
Torfaen County Borough Council
Torfaen County Borough Council
Tovali Ltd
Trading Standards Institute (Wales)
Twin Chef Foods
UNISON
University of the Third Age
University of Wales Aberystwyth
UWIC
UWIC
Vale of Glamorgan Council
Vale of Glamorgan Council
Vaynol Arms
Vydex Nutrition
Wales and Border Counties Pig Breeders Association
Wales Assembly of Women
Wales Centre For Health
Wales Centre for Health
Wales Council for the Blind
Wales Council for the Deaf
Wales Council for Voluntary Action
Wales Pensioners
Wales Social Partners Unit
Wales Young Farmers' Club
WDA Agri-Food Development
WDA Agri-Food Partnership

WDA Food Directorate
WDA Food Directorate
WDA Food Directorate
Welsh Agricultural Organisation Society
Welsh Assembly Government
Welsh Assembly Government
Welsh Assembly Government-Public Health Protection
Welsh Assembly of Women
Welsh Black Cattle Society
Welsh Consumer Council
Welsh Development Agency
Welsh Food Alliance
Welsh Food Laboratories
Welsh Food Microbiological Forum
Welsh Food Promotions
Welsh Highland Shepherds
Welsh Institute of Rural Studies
Welsh Lamb and Beef Promotions
Welsh Local Government Association
Welsh Local Government Association
Whitbread Holdings PLC
Women in Agriculture
Women's Food & Farming Union
Women's Food and Farmin Union Livestock Committee
Womens Farming Union
Womens National Commission
Woodward Food Service
Wrexham CBC
Wrexham Licensed Vicuallers Association
Wrexham Town Centre Forum
Zorba Foods

## ANNEX B

### Summary of Costs

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
<b>1. Keep the OTM Rule</b>	OTMS compensation and disposal gross costs of £282.3m million **see separate table below	Exceptionally high level of public health protection maintained
<b>2. Allow cattle born after 1 August 1996 to be slaughtered for human consumption</b>	<ul style="list-style-type: none"> <li>• Additional enforcement cost of £22m, of which               <ul style="list-style-type: none"> <li>➢ vertebral column removal £3m</li> <li>➢ additional MHS recruitment and supervision costs related to testing £14m</li> <li>➢ additional MHS recruitment and supervision costs related to removal of SRM from OTM cattle £4m</li> <li>➢ additional DARD costs £0.7m</li> <li>➢ MLC costs related to hide controls at hide markets and tanneries £0.5m</li> </ul> </li> <li>• Policy costs (<i>not yet fully quantified</i>) of which               <ul style="list-style-type: none"> <li>➢ post-implementation audit £0.1m</li> <li>➢ cohort cull £7m (backlog included; £1m per annum thereafter)</li> <li>➢ collection and disposal of additional fallen stock (previously OTMS casualties) £10m</li> <li>➢ MLC promotion (includes exports) £5m</li> <li>➢ compensation and disposal costs of pre August 1996 cattle over 3 year duration of OCDS. (<i>Figures not yet available</i>)</li> </ul> </li> </ul>	<p>Very high level of public health protection maintained.</p> <p>Gross savings on OTMS compensation and disposal costs of £282.3 million after pre August 1996 cattle have been disposed of.</p> <p>A significant and increasing proportion of OTM cattle able to be sold for food instead of being destroyed.</p> <p>Risk of initiation of infraction procedures removed.</p>

