

## ~~Initial/Partial/Full~~ Regulatory Impact Assessment on

### **1. TITLE OF PROPOSAL**

OVER 30 MONTHS RULE REVIEW

### **2. Purpose and intended effect of measure**

#### **(i) The Objective:**

To consider whether the Over Thirty Months (OTM) rule is still an appropriate, proportionate public health measure in light of the decline in BSE since its introduction.

#### **(ii) Devolution**

The review has been conducted on a UK-wide basis but deals with a subject that is devolved.

#### **(iii) The Background:**

The OTM rule was introduced in March 1996. It forms part of a package of measures to protect public health, and was brought in following advice from the Spongiform Encephalopathy Advisory Committee (SEAC) on the link between variant CJD and BSE. SEAC had advised that OTM cattle should be deboned under official supervision in licensed cutting plants but, for practical reasons, it was decided to exclude OTM cattle from the food chain. With limited exemptions, the OTM rule prohibits the sale for human consumption of meat from cattle aged over thirty months at slaughter, and is one of the three main BSE controls. Since its introduction the OTM rule is estimated to have cut the volume of infected cattle in the last year of the BSE incubation period entering the food supply by over 99%.

The UK BSE epidemic in cattle is now in steep decline - from a peak level of over 37,000 clinical cases in 1992 to just over a thousand BSE positive results, including 471 clinical cases, reported last year (2002).

The question therefore arises of whether the OTM rule is still a necessary and proportionate measure to apply, given the other protection measures that are also in place in the UK and elsewhere in the EU, or whether alternative controls could replace it.

The Over Thirty Month Scheme (OTMS), on which Defra takes the lead, complements the 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 in the region of £400m a year.

Other Member States do not operate an OTM rule. However, since 1 January 2001, EU legislation has required all cattle entering the food supply aged over 30 months to be tested first for BSE. In addition, the EU legislation requires the vertebral column of OTM cattle in the UK to be removed and destroyed as Specified Risk Material (SRM).

#### **(iv) Risk assessment**

As part of the Review process a comprehensive scientific risk assessment has been undertaken by a FSA/SEAC Risk Assessment Group (RAG) chaired by Professor Peter Smith (Chairman SEAC). The RAG has been steering and providing peer review of the scientific input to the Review for which the Agency commissioned mathematical modelling work on the BSE epidemic. Further modelling looked at the small amount of infectivity entering the food supply after the SRM controls have been applied. By looking at the overall amount of BSE infectivity entering the food supply, this work has enabled the effect of different options on future risk to be assessed and compared with the current and previous risks.

Imperial College, DNV and the VLA have undertaken this modelling which so far covers Great Britain and Northern Ireland. The risk from imported OTM beef will also be assessed by undertaking similar modelling for the Republic of Ireland, by far the largest supplier of imported beef to the UK.

### **(v) Business sectors affected**

The OTM rule was introduced as a public health protection measure. It impacts on cattle farmers, the meat industry, renderers and incinerators involved in the destruction of OTM cattle, retailers and beef importers. The alternative options would affect the same sectors and those involved with BSE testing and the transport of brain samples.

### **(vi) Issues of equity and fairness**

The current OTMS provides a payment to farmers for OTM animals which, because of the OTM rule, they are not able to sell. Under options 2 or 3 below, it would be replaced, either partly or wholly, by the ability to sell those animals for their market value. If the market value of those cattle is less than the amount of compensation payable under the OTMS, removal of the compensation and reintroduction of the animals to the market would result in a reduction in subsidy to farmers (this issue is further discussed under section 5).

## **3. Options**

In considering the options, the Food Standards Agency's primary concern was to ensure an appropriate level of public health protection. Any move away from the current regime had to take into account the existing European regime for OTM cattle. The cost of the OTMS was also taken into consideration.

### **Option 1:**

- Retain the OTM rule.

### **Option 2:**

Modify the rule, and apply the EU regime (testing and vertebral column removal) to OTM cattle subsequently slaughtered for human consumption. A number of possibilities were considered but, for a number of reasons, the Core Stakeholder Group concluded that two options should be considered further:

- replace the OTM rule with a ban on the slaughter for human consumption of cattle born before 01.08.96 when the feed ban is considered effective; all OTM cattle born after 01.08.96 to be subject to testing and vertebral column removal;

or

### **Option 3:**

- replace the OTM rule with the EU regime applicable to OTM cattle, namely testing and vertebral column removal.

In addition to options 2 and 3, it is possible that withdrawal of OTM casualty cattle from human consumption may also be recommended.

## **4. Benefits**

### **Option 1:**

- Exceptionally high level of public health protection maintained.

### **Option 2:**

- More proportionate public health protection than option 1.
- Significant savings in Exchequer costs from savings in a significant proportion of OTMS costs (currently about £400 million a year) net of the costs of additional testing.
- UK brought closer into line with EU-wide mechanism and becoming fully compliant without further change, as cattle born before August 1996 die or are culled. Infraction proceedings therefore less likely.
- Farmers allowed to sell OTM cattle born after 01.08.96 for human consumption.
- A significant proportion of the some 800,000 animals processed annually under OTMS (over half from 2004/5 and increasing thereafter) would no longer be wasted.
- A possible benefit to consumers in the availability of cheaper OTM beef (although OTM beef is likely to be used in products of which it may represent a small proportion of the cost).

### **Option 3:**

- More proportionate public health protection measure than option 1
- Significant savings in Exchequer costs from savings in the full cost of the OTMS net of the costs of additional testing.
- UK brought into line with EU-wide mechanism: avoids risk of infraction proceedings.
- Farmers allowed to sell all OTM cattle for human consumption.
- The 800,000 animals processed annually under OTMS would no longer be wasted.
- A possible benefit to consumers in the availability of cheaper OTM beef (although OTM beef is likely to be used in products of which it may represent a small proportion of the cost).

## **5. Costs for business, charities and voluntary organisations**

### **(i) Compliance costs**

#### **Option 1:**

The National Farmers' Union estimated (at the time the FSA review of BSE controls was published in December 2000) that the cost to industry of the OTM rule was about £95 million a year in terms of the difference between the compensation and what they would have received if market prices had remained unchanged. However, it is uncertain what would have happened to market prices in the absence of the OTMS and Defra now considers that for most cattle entering the Scheme (chiefly old dairy cows) the OTMS price is above the price producers would be likely to receive from the market.

#### **Option 2 and 3:**

Replacing the OTM rule with the EU system would allow farmers to sell OTM cattle for food, rather than for destruction and so represents a reduction in regulation. There would, however, be a very small increase in the public health risk from exposure to BSE infectivity from consumption of beef which might possibly lead to additional cases of vCJD. The EU system of testing of and removal of vertebral column from OTM cattle would be new requirements on industry which have associated costs.

#### *Withdrawal of the OTMS*

Running the OTMS is a Defra responsibility. In theory, the compensation is intended to reflect a fair payment for what producers would have received had they been able to sell their animals. To the extent that the OTMS price is above the market value of the animals, the OTMS represents a subsidy to producers. The extent of the loss to producers if the OTMS were wholly or partly withdrawn is unquantifiable, as it would depend on the payment rate at the time the Scheme was abolished and the market price for OTM cattle at that time. It is, however, estimated that a reduction in returns on OTM cattle of 20% would reduce the cash incomes of dairy farmers by 3% on average. This equates to just under 1% of total farm costs. Cattle farms would also be affected, although to a lesser extent. There would be substantial variations between individual producers around these average positions.

Any losses to producers would be expected to be relatively short-term, as in the longer term, and assuming the Date Based Export Scheme can be amended and eventually abolished, market prices for OTM cattle could be expected to recover to levels close to the average for the EU as a whole. Defra is discussing market management issues with the Commission and with an industry stakeholder group.

#### *BSE testing*

EU state aid rules limit Government funding of BSE testing of cattle for human consumption to 40 Euros (about £27) per test. The government proposes to fund the laboratory costs of carrying out BSE tests. Industry would have to meet the other costs associated with testing (taking samples, despatch of samples to testing laboratory, storage of carcasses pending receipt of test results, ensuring traceability etc.). Planning for the introduction of BSE testing of OTM cattle at abattoirs is being co-ordinated by Defra, working with FSA, the Meat Hygiene Service and an industry stakeholder group.

The view of industry representatives, as expressed in the Core Stakeholder Group, is that the costs of sampling and transport of samples to the laboratory, and of ensuring traceability of carcasses, are unlikely to be significant in relation to the value of the carcase. As an indication, Defra currently estimate the cost of BSE testing in OTMS abattoirs, including the laboratory testing cost, to be about £50 per test. On that basis, the cost of taking the sample and transporting it to the laboratory would be expected to be just over £20 per test.

The industry's main concern is that the test results are returned within 24 hours to avoid a build-up of carcass material from the tested animals at the abattoir awaiting release on receipt of the results, which would be very disruptive of operations. The system has however been shown to work elsewhere in Europe and there is also already considerable experience with testing of OTMS animals in the UK. There is therefore no reason to suppose that the system could not be made to work here.

Other costs would depend on whether physical alterations need to be made to premises, e.g. to provide facilities for testing or extra chiller space for retained carcasses. However, it would be a commercial decision for the operator whether or not it was worth putting in extra facilities if needed. If the costs were uneconomic, abattoir operators would have the option of deciding not to handle OTM animals (which would be likely to be a specific market). It will be difficult to identify the potential industry costs of testing with any precision until more is known about the likely interest in slaughtering OTM animals and whether this is likely to be restricted to a few specialist abattoirs or may become more widespread.

Official supervision of a new requirement in abattoirs (by MHS in GB and the Department of Agriculture and Rural Development (DARD) in Northern Ireland) would also give rise to additional enforcement costs.

#### *Removal of vertebral column*

The requirement to remove vertebral column from OTM cattle would also give rise to costs of maintaining traceability of carcasses until the vertebral column had been removed in a cutting plant and then removing it and disposing of it as SRM. At present, however, there is no difference between the disposal costs of SRM and low risk animal by-products, so the requirement to dispose of vertebral column as SRM would not give rise to additional costs.

Official supervision of a new requirement in abattoirs (by MHS in GB and the Department of Agriculture and Rural Development (DARD) in Northern Ireland) would also give rise to additional enforcement costs.

#### *Possible additional vCJD cases*

The best estimate from the risk assessment is that, on the basis of a pessimistic assumption of a total number of vCJD cases of 5000, for both options 2 and 3, the number of additional vCJD cases due to additional BSE exposure in the period 2004-09 would be considerably less than one over the next 60 years. Under the most pessimistic assumptions, the risk assessment suggests that option 2 would result in less than 1 extra vCJD case and option 3 less than 2 extra vCJD cases over the next 60 years.

#### **(ii) Costs for a typical business**

The costs for a typical business would depend on the facilities already available at individual slaughterhouses, OTM cattle throughput and the outcome of the contingency planning work on the arrangements for BSE testing currently being co-ordinated by Defra.

The costs for farmers would depend on the market prices for OTM cattle compared with the level of payments received from the OTMS.

### **6. Consultation with small business: the small firms impact test**

We consulted the Small Business Service and a number of trade associations. Their initial feedback was that the possible impact would depend on which option was chosen and, if the rule were to be changed, they would like clear guidance on the option to be adopted and the timing of implementation.

### **7. Competition assessment**

We have considered the competition filter questions and have concluded that there is no significant impact on competition as a result of these options.

## **8. Enforcement and Sanctions**

The OTM requirements would be enforced at licensed slaughterhouses by the Meat Hygiene Service in Great Britain and by DARD in Northern Ireland. Sanctions would be set out in implementing legislation. Sanctions are also included in existing TSE legislation and Trades Descriptions Act.

## **9. Monitoring and review**

The Core Stakeholder Group have recommended that any testing system put in place should be reviewed 6 months after implementation.

## **10. Consultation**

### **(i) Within Government**

Agriculture Departments (Defra, SEERAD, NAW and DARD, NI) and Department of Health attended meetings and were copied papers.

### **(ii) Public Consultation**

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.

The 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. This partial RIA forms part of the formal consultation package. Following consultation, proposals will be discussed by the FSA Board at a public meeting before making recommendations to Ministers. If, on the basis of the FSA's advice, Ministers decide that changes to the OTM rule should be made, a second round of public consultation would be needed on draft legislation to introduce the changes.

## **11. Summary and recommendation**

The costs below relate to the operation of the OTMS and testing. Industry comments are sought on the impact on the market and on the wider costs of testing including impact on abattoir operations.

<b>Option</b>	<b>Total Cost for the period 2004/5 to 2005/6</b>	<b>Total Benefit for the period 2004/5 to 2005/6</b>
1 Keep the OTM Rule	OTMS costs of £736 million	Exceptionally level of public health protection maintained
2 Allow cattle born after 01.08.96 to be slaughtered for human consumption	Additional costs of testing and vertebral column removal  A small chance of one additional vCJD case	Proportionate public health protection  Net savings on OTMS costs of £360 million  A significant and increasing proportion of OTM cattle able to sold for food instead of being destroyed  Reduced risk of infraction costs
3 Allow all cattle to be slaughtered for human consumption	Additional costs of testing and vertebral column removal  A small chance of one additional vCJD case	Proportionate public health protection  Net savings on OTMS costs of £640 million  All OTM cattle able to sold for food instead of being destroyed  Risk of infraction costs avoided

**12. Declaration**

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

Signed .....

Date

Minister's name (s), Title , Department (s)

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