EXPLANATORY MEMORANDUM TO

THE TSE (ENGLAND) (AMENDMENT) (No. 2) REGULATIONS 2005

2005 No. 2633

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 These Regulations amend the TSE (England) Regulations 2002 (S.I. 2002/843, as amended by S.I. 2002/1253, S.I. 2002/2860, S.I. 2003/1482, S.I. 2004/1518 and S.I. 2005/556. The Regulations provide a regime for the slaughter for human consumption, and testing, of cattle over thirty months of age. They also make some amendments required to address issues in the TSE (England) Regulations, which have arisen in areas of enforcement, identification and feed controls which need to be addressed as soon as possible, rather than in the consolidation of the regulations intended to revoke and replace the 2002 Regulations, which will come into force at a later date (see paragraph 7.3 below).

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 A consolidating instrument is in preparation and is expected to be made by the middle of December 2005.

4. Legislative Background

4.1 Regulation EC No. 999/2001 of the European Parliament and of the Council of 22 May 2001 lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopthies (TSEs) on an EU wide basis. The TSE (England) Regulations 2002 are the domestic legislation for the enforcement and administration of Regulation EC No. 999/2001.

5. Extent

5.1 This instrument applies to England.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 This instrument amends existing domestic TSE legislation, to, inter alia, set the criteria which abattoirs will have to meet if they wish to slaughter Over Thirty Month (OTM) cattle for human consumption following any replacement of the current OTM rule with a robust BSE testing regime. These requirements include a written agreement between the individual abattoir operator and the Meat Hygiene Service (MHS) in the form of a legally binding Required Methods of Operation (RMOP).

7.2 These requirements are based on the key components of the BSE testing system (see new Regulation 10A, set out in regulation 4 of the draft Regulations, and new Schedule 1A, set out in the Schedule to the draft Regulations) which have been identified by an Independent Advisory Group (IAG) set up by the FSA to advise on the robustness of the BSE testing system and endorsed by the FSA Board. The opportunity has also been taken to give effect to a number of other amendments to the TSE Regulations, some of which result from changes made to the EU TSE legislation (Council Regulation 999/2001) whilst others reflect the need to correct or clarify current legislation or are necessary to allow OTM animals into the food chain.

7.3 In addition to this Statutory Instrument, Defra has also consulted widely on an extensive consolidation of the TSE (England) Regulations 2002, with a view to their revocation and replacement with a more structured and less repetitive, set of Regulations. The consolidated legislation is due to come into force some time after the SI subject to this EM. Because of concerns over the timing of the consolidation and it's implementation in the devolved administrations, several provisions which were originally envisaged as part of the original consolidation exercise, have been incorporated into this amending SI. By far the most significant of these is the offence of consigning an OTM animal born before 1 August 1996 to an abattoir for slaughter for human consumption. All of the incorporated provisions have been subject to a full 90 day consultation period.

7.4 This instrument does not itself amend the OTM rule. the FSA has proposed parallel legislation which would replace the OTM rule with a prohibition on the placing on the market of products derived from cattle born or reared in the UK before 1 August 1996. Until the legislation relating to the OTM rule is changed, with limited exceptions, it will remain an offence to sell any meat for human consumption from OTM cattle.

7.5 Out of approximately 1400 stakeholders consulted in England, only 28 responses were received (2%). This pattern was repeated elsewhere in the UK. There was general support for the principles behind the proposed legislation, although some concerns expressed by the meat industry on the possible cost of any gold-plating of requirements by the Independent Advisory Group, which has been set up by the Food Standards Agency to provide advice on the robustness of the BSE testing system.

8. Impact

A Regulatory Impact Assessment is attached to this memorandum

9. Contact

Sinjini Mukherjee at Defra - Tel: 020 7904 6375 or e-mail: sinjini.mukherjee@defra.gsi.gov.uk can answer any queries regarding the instrument.

Final Regulatory Impact Assessment

1. Title of Instrument

TSE (England)(Amendment)(No. 2) Regulations 2005

2. Purpose and intended effect of measure

(i) The objective

1. To provide the necessary legal powers in the TSE (England) Regulations 2002 to enforce a robust testing regime for the testing of Over Thirty Months (OTM) cattle for human consumption.

   To make relatively minor amendments to the TSE (England) Regulations 2002 required to address issues that have arisen in the areas of enforcement, identification, feed controls and offences.

   To make it an offence to consign cattle born or reared in the UK before 1 August 1996 to an abattoir for slaughter for human consumption

2. **Devolution:** This is a devolved matter which affects all parts of the UK. Separate, but parallel, legislation would be needed in Scotland, Wales and Northern Ireland.

(ii) The background

3. The discussion below relates solely to the changes proposed to the TSE (England) Regulations 2002 ("the 2002 Regulations") . A separate RIA, issued as part of the FSA's consultation on review of the OTM rule[1], has been prepared on the wider impacts of a change from the OTM rule to a testing system.

A: Legal requirement for an RMOP

4. In the light of the decline in BSE cases the Food Standards Agency (FSA) launched a review of the OTM rule in July 2002. In July 2003, following a scientific risk assessment, analysis of the risk assessment by a Core Stakeholder group, and a public consultation[1], the FSA advised Ministers that it would be justified to make moves towards replacing the OTM rule. The advice also stated that Ministers should not change the OTM rule until they were satisfied that the necessary

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

arrangements (which would include arrangements for BSE testing) had been made.

5. On 1 December 2004 following further advice from the FSA, the Government announced the start of a managed transition towards the lifting of the OTM rule and its replacement with a system of robust testing of cattle for BSE. The timing of any changeover is dependent on the FSA advising and Ministers agreeing that the testing regime is robust and on a number of other issues, such as recruitment of additional Meat and Hygiene Service (MHS) staff.

6. An Independent Advisory Group (IAG) has been set up by the FSA to advise on what arrangements would be required ahead of any change to the OTM rule. The IAG's initial work identified the key components of a robust testing system and the FSA Board subsequently endorsed these on 9 December 2004. The need for some flexibility, on the components relating to abattoirs, was acknowledged by the IAG to allow for differing facilities and processes at individual plants.

7. In order to assure that the testing of OTM cattle for human consumption is robust, the IAG concluded that a Required Methods of Operation (RMOP) should be agreed between the MHS and individual abattoir owners which reflected the requirements of the key components and their practical implementation. The IAG further recommended that the key components and the need for a mutually agreed RMOP should be set out clearly in legislation.

B: Other Measures

8. There have been some recent failures to comply with the Over Thirty Month (OTM) rule which prevents meat from OTM bovines being sold for human consumption. These have occurred following mistakes made by farmers, abattoirs and the Meat Hygiene Service. Whilst the requirements, as regards OTM bovine animals, on abattoirs and the MHS have been set out in legislation, they have not, historically, been set out for farmers.

9. Following a change to the OTM rule, bovine animals born or reared in the UK pre-August 1996 will continue to be excluded from the food chain. The Food Standards Agency in May 2005 recommended that, in order to strengthen enforcement of this exclusion, in addition to prohibiting abattoirs from processing such animals, it should be made an offence for anyone to consign cattle aged over thirty months to a slaughterhouse for human consumption. This S.I. incorporates this recommended change.

10. The 2004 FVO mission on BSE highlighted areas requiring improvement in the UK enforcement of the European TSE legislation. It was recommended in the FVO report summarising the mission, that further controls were needed in the area of animal feed, primarily

relating to the UK's implementation of the controls on fishmeal, which is banned from ruminant feed – notably to bring our current registration of feed manufacturers using fishmeal into line with the terms used in the EU legislation. EU legislation requires *authorisation* in these circumstances, and at farms using feed containing fishmeal where ruminants are present, official permission to do so needs to be granted after inspection of separation – the SI requires registration as a means of targeting necessary inspections.

11. The FVO also recommended that there should be compliance with the inspection Directive 95/53. This requires that information on the analysis of feed samples submitted by feed producers to laboratories, must be notified to the competent authority where the results indicate a breach of the ban. There is a specific provision for this in the draft legislation to back up existing administrative action and guidance, which has already been issued, to those submitting private samples.

12. The S.I. also makes a number of relatively minor changes the 2002 Regulations to reflect changes made to Regulation (EC) 999/2001 and to clarify enforcement measures. These are highlighted below:

Definition of "the Community Transitional Measures" in regulation 3

13. Regulation (EC) 932/2005 which extends the application of the transitional measures, including SRM controls, has been added to the list, contained in the definition of "the Community Transitional Measures" in the 2002 Regulations, of instrument which amend Regulation (EC) 999/2001. This ensures that these measures continue to have legal force in domestic legislation.

Definition of 'inspector' in regulation 3

14. Under the current testing regime, all parts of the carcase of a tested animal, including the hide, should be traceable and should remain under official control. Standard practice is that hides are generally sent to hide markets or tanneries for treatment to prevent loss of value of the hide. This amendment re-defines 'inspector' to include a person appointed by the Meat and Livestock Commission (MLC) at hide markets or tanneries, who would be responsible for official controls at these premises.

Definition of 'local authority' in regulation 3

15. Parts of the present TSE (England) 2002 Regulations rely on local authorities for enforcement. This amendment adds district councils in non-metropolitan counties to the definition of local authority.

Definition of 'vertebral column' in regulation 3

16. European requirements for the monitoring and control of TSEs are set out in Regulation (EC) 999/2001. The TSE (England) Regulations 2002 reflected these requirements and set out the monitoring and control regimes for TSEs in England. The definition of vertebral column in the European TSE regulations has been amended and modified since the initial publication of the European Regulations. This amendment would reflect these changes.

Addition of 'Young Goat Stamp' to regulation 3

17. Under the current regulatory system, a sheep or goat under the age of twelve months, or without a permanent incisor tooth erupted, is marked with a 'Young Lamb stamp'. This has led to difficulties distinguishing between young lamb and young goat carcases. To address this concern, the FSA have proposed the introduction of a 'Young Goat stamp' to aid identification. Regulations 38, 41 (1) and (2), 46 (1) and 47 (1) of the 2002 Regulations also need to be amended to reflect the use of the new stamp.

Powers of slaughter under feed controls under regulation 29B

18. At present an ambiguity exists in regulation 29B about when an inspector is authorised to destroy an animal suspected of having been fed prohibited feed. The proposed amendment makes it clear that, where a notice to destroy an animal has been issued and the recipient of the notice appeals against it, an inspector cannot take action to destroy the animal unless the Secretary of State confirms the notice.

Removal of SRM under regulation 33 (1) & 33 (10)

19. The current legislation (Reg. 33 (10)) allows only BAS animals (the only GB produced OTM animals currently allowed into the food chain) to be consigned to a cutting plant for removal of vertebral column.. Current regulation 33 (1) is being altered to enable all bovine carcase meat containing vertebral column (which is SRM) to be consigned to a cutting plant licensed for removal of SRM bovine vertebral column, to reflect the European requirements and allow the processing of OTM meat to take place. Reg. 33 (10) is being deleted.

Removal of SRM in sheep and goats under regulation 33 (2)

20. Regulation 33 (2) of the 2002 Regulations, concerns the removal of SRM in sheep and goats. The present requirement, for animals with one or more permanent incisor teeth erupted, is that the head, spleen and tonsils are removed in the slaughterhouse, reflecting the SRM definition at the time the original Regulation was made. This no longer accords with the definition of SRM in the European legislation and the

present regulation should be amended to reflect the European requirements. As the definition of SRM is set out in the directly applicable EU Regulation there is no need to repeat it here, with the exception of the item that is excluded i.e. spinal cord.

Removal of SRM spinal cord under regulation 37

21. Current regulation 37 of the 2002 Regulations makes reference to bovine animals. However, this regulation deals specifically with the removal of SRM spinal cord from sheep and goats. It should therefore be amended to remove references to bovine animals.

Offences under Schedule 6A

22. In response to Regulation (EC) 1492/2004 which amended the European TSE Regulations to make breeding programmes compulsory following the confirmation of scrapie in sheep, an amendment was made to the domestic regulations inserting Schedule 6A into the 2002 Regulations which transposed these requirements. Paragraphs 8, 10, 11 and 12 of the schedule create offences but there is no statement in the schedule as to the sanctions for such an offence. Regulation 99 does not apply by reason of paragraph (1) of that regulation. A further Part is therefore required in the Schedule to set out the sanctions to apply if an offence is committed under the Schedule.

(iii) Risk assessment

23. Failure to set in place the necessary legislative framework for a testing regime for OTM animals may delay the decision to replace the OTM rule. The Exchequer costs of purchase and destruction of OTM cattle under the OTM rule currently amount to some £320m a year. A delay on the OTM decision would prolong this expense. A delay to the lifting of the OTM rule would also set back the process of removing the beef export ban.

24. The impact of the proposals for a robust testing system is limited to firms that voluntarily make the decision to participate in the OTM trade. Plants are being trained to take samples free of charge, and Defra propose to pay for laboratory costs and for MHS supervision. The costs to abattoirs of taking a sample, transporting that sample, and retaining and correlating carcases and body parts to that sample, will be small compared with the value of the carcase. For further details of costs, please see separate RIA issued by the FSA.

25. Failure to address the points relating to the feed ban and the recommendations made by the FVO, described above, could contribute to the European Commission delaying bringing forward a proposal to lift the beef export ban.

26. Failure to establish an offence of consigning cattle born or reared in the UK before 1 August 1996 to an abattoir for slaughter for human consumption would lead to criticism by the FSA who have stated this is a pre-requisite for replacing the OTM rule with a BSE testing regime. It could also mean that the FSA would not be able to advise Ministers that the OTM Rule should be changed.

27. Not addressing the various issues in the domestic legislation, highlighted above, would continue to leave district councils without enforcement powers, allow difficulties in identification to persist between young goat and lamb carcases, leave the SRM provisions out of line with European guidance and continue inconsistencies in sanctions for offences.

3. Options

Option 1: Do Nothing

A: Legal requirement for an RMOP

28. Under the 'do nothing' option a legal basis for the RMOP will not be established. This is a pre-requisite for lifting the OTM rule. Without a legal basis for the RMOP the testing regime for OTM cattle could not be adequately enforced and it is highly unlikely that the OTM rule would be replaced.

B: Other Measures

29. Failure to add Regulation (EC) 932/2005 to the definition of "the Community Transitional Measures" could lead to issues arising in the enforcement of controls based on the transitional measures of the EU TSE legislation.

30. Failure to add a reference to the MLC in the definition of "inspector" would mean that these officials would not be able to oversee the controls at hide premises. This would mean that hides would not be permitted to move from slaughterhouses whilst test results are pending for OTM animals. Similarly, continuing to omit district councils from the definition of "local authority" in the domestic legislation would prevent them from taking action under the Regulations.

31. Not making the recommended change to the definition of 'vertebral column' would mean that the definition would not correlate with the European definition. Not to address this issue in the domestic legislation could also lead to problems in the future in trade with our EU partners. Linked to this issue, failure to amend regulation 33 (1) would mean it would not be possible to consign OTM carcases to cutting plants for vertebral column removal . Not amending Regulations 33 (2) and 37 would mean that the regulations would not reflect present

industry practice, as plant operators and the MHS are already working to the European definitions.

32. Not introducing a separate stamp to identify between young goat and young lamb carcases would allow difficulties in distinguishing between young lamb and young goat carcases to persist.

33. Failure to insert a section on offences into Schedule 6A would allow a potential gap in enforcement to continue.

34. Although the UK considers the ban on fishmeal in ruminant feed to be unjustified there has been no change in this respect to the European legislation. Not making adjustments to the feed ban relating to fish meal and its use could lead to the UK's implementation of the overall feed ban being seen by the EU Food and Veterinary Offices (FVO) as inadequate because of perceived shortcomings in this area. This in turn could lead to the rule change being delayed or postponed and could also have a negative impact on efforts to lift the beef export ban.

35. Not creating an offence for farmers to send born before 1 August 1996 bovines to a slaughterhouse for human consumption could contribute to failures in the system of animal identification, potentially allowing some of these animals into the food chain. This would lead to serious criticism of the testing system and could damage confidence in the domestic beef market. The creation of this offence is also one of the pre-requisites for OTM rule change. Without it, it is highly unlikely that the OTM rule would be replaced.

36. For the above reasons Option 1 (Do nothing) is not a viable course of action.

Option 2: Amend domestic TSE legislation

A: Legal requirement for an RMOP

37. Amending the domestic TSE legislation would give legal effect to the Required Methods of Operation (RMOP) between a slaughterhouse and the MHS. This is a key requirement that the IAG has highlighted as part of a robust testing system. Ensuring that the appropriate enforcement powers are in place would form an essential element to the replacement of the OTM rule with a robust testing regime.

B: Other Measures

38. Making the amendments to the definitions in the TSE regulations continues to give legal force to required controls under the European transitional measures; corrects omissions in the area of enforcement, allowing district councils to take action under the TSE Regulations;

and, enables abattoirs to send hides to hide markets under MLC control.

39. Changing the definition of “vertebral column” brings it in line with European legislation and amending Regulations 36 and 37 corrects anomalies and updates the rules governing SRM removal in line with European legislation, reducing the risk of action against the UK by the Commission. The revision to Regulation 33 (1) allows the OTM carcases to be consigned to cutting plants for the removal of SRM vertebral column, subject to the plant having the appropriate licence.

40. The addition of the term ‘Young Goat Stamp’ and amendments to Regulation 38 if the 2002 Regualtions, and related regulations 41, 46 and 47, allows the FSA to introduce the use of such a stamp which would improve the means of identifying these carcases.

41. Adding a section on offences to Schedule 6A corrects an oversight in the previous legislation.

42. Creating a new offence for consigning a pre-August 96 animal to a human consumption slaughterhouse would strengthen enforcement powers in this area and potentially reduce the likelihood of failures in the cattle identification system occurring.

4. Benefits

Option 1: Do Nothing

43. No additional benefits would occur if the ‘do nothing’ option was followed.

Option 2: Amend domestic TSE legislation

44. The economic, social and environmental benefits of this option are set out below.

A: Legal requirement for an RMOP

45. By defining clearly the requirements that abattoirs must meet in order to participate in the OTM trade, the regulation improves information in the market and will allow abattoirs to make a commercial decision to enter the trade with a greater degree of information.

46. A demonstrably robust testing system would have the benefit of increasing public confidence in OTM meat and would facilitate the growth of this market to pre-1996 levels. An increase in public confidence domestically would also serve to boost wider confidence in UK OTM meat in Europe and could hasten the lifting of the export ban.

47. The benefits above do not take into account the overall benefits of a decision to lift the OTM rule. The OTM rule cannot be replaced by testing unless Ministers agree that the testing system is robust, on the back of advice from the FSA, who will be advised by the IAG. Such a decision would result in significant savings in Exchequer, allow the market to determine the value of OTM animals, which is expected to lead to improved returns to producers and all parts of the meat industry and possibly benefit consumers via the availability of cheaper OTM beef for manufacturing. A full analysis of these benefits is available in the FSA's RIA on the replacement of the OTM rule[2].

B: Other Measures

48. Adding Regulation (EC) 932/2005 to the list of amending regulations in the definition of "the Community Transitional Measures" has the benefit of removing any risk of challenge to the legal basis of controls based on the transitional measures of Regulation (EC) 999/2001.

49. Updating the definition of 'vertebral column' and the requirements of SRM removal has the political benefit of bringing domestic legislation back into line with European legislation thereby avoiding possible confusion and potential future barriers to trade.

50. Allowing OTM carcases to be sent to appropriately licensed cutting plants for vertebral column to be removed will mean that rule change can take place without legal impediment.

51. Introducing the Young Goat stamp benefits government, industry and consumers as it increases the ability to identify young lamb and young goat carcases, preventing the substitution of lower value young goat carcases for higher value young lamb carcases and enabling inspectors to take action in cases where such substitution is attempted.

52. Introducing an offence of consigning animals born before 1 August 1996 to a slaughterhouse for human consumption places a clear responsibility on the farmer. This additional layer of protection helps ensure these higher risk animals do not enter the food chain which represents a social benefit in terms of maintaining consumer confidence in the domestic beef market. This complements the responsibility already placed on abattoir operators.

5. Costs

Option 1: Do Nothing

53. The economic, social and environmental costs of this option are set out below.

[2] Available at www.food.gov.uk

A: Legal requirement for an RMOP

54. Under the 'do nothing' option it is unlikely that there would be a rule change which would lead to continuing costs for the Exchequer for the purchase and destruction of OTM cattle, currently amounting to some £320m a year. This equally applies to the RMOP requirement and the pre 1 August 1996 offence.

B: Other Measures

55. Not giving the MLC the authority to act as inspectors in hide markets and tanneries could prevent abattoirs from moving hides to these premises, causing a loss in value of the hide and to the abattoir.

56. Failing to amend Regulation 33(1) would mean vertebral column couldn't legally removed, preventing the industry taking commercial advantage of rule change. Failing to address the enforcement issues on the powers of district councils, identification of young lamb and goat carcases and the offences in Schedule 6A has the social cost of allowing deficiencies in the current system to persist.

57. Failure to implement the changes to feed regulations to reflect EU regulations and the recommendations of the FVO could mean that Member States, and other countries around the world, would regard the present regime as insufficient. This may have a negative impact on the European Commission bringing forward a proposal to lift the beef export ban or could result in a lack of support from member states in any subsequent vote on a Commission proposal, representing a cost to industry from continued lack of access to these markets.

Option 2: Amend domestic TSE legislation

A: Legal requirement for an RMOP

58. From 19 April 2002, when the 2002 Regulations came into force, until 31 May 2004, sampling of bovine animals and transportation of such samples to the testing laboratory was paid for by Government. Since 1 June 2004, sampling and the transportation of samples has been the responsibility of the abattoir operator. This change was required because of EU State Aid rules, limiting the amount of aid Member States can contribute toward BSE testing. Accordingly the regulations have been updated to reflect this current practice and a new provision inserted to ensure that samples are taken in accordance with the procedures required by the European TSE legislation. Currently approximately two-thirds of abattoirs in GB that slaughter cattle have received training in the taking of brain-stem samples, which Defra offers free of charge to abattoirs. This provision therefore, does not impose an additional cost burden on industry but formalises in legislation existing practice.

59. Linked to the above change is a new provision which restricts entitlement to compensation for carcases that are destroyed when there is a failure to obtain a negative BSE test result (a “no-test” result) because, for example, an abattoir has failed to take an adequate brain stem sample or samples have failed to arrive at the testing laboratory. This is a change from the previous situation. However its impact is expected to be limited. Based on figures from 2004, only 2 samples, out of a total of 2,263 samples taken from 24 – 30 month casualties (0.09%) received a ‘no-test’ result. This cost would be in the region of £4,800 per annum for industry until the Over Thirty Month rule is replaced by testing when much larger number of cattle eligible for the food chain will need to be tested.

60. Any other costs associated with BSE testing OTM cattle slaughtered for human consumption apart from the laboratory and enforcement costs would fall to industry. Costs for a typical business would depend on the facilities already available at individual premises and OTM cattle throughput. The actual unit cost to industry 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.

61. All animals which require testing under this amendment are currently tested through the Over Thirty Month Scheme (OTMS). Therefore cost to government for the analysis of samples will be unaffected by this S.I.. However, there are additional MHS / MLC enforcement costs which would need to be paid by Defra.

<u>B: Other Measures</u>

62. It is not expected that amending the TSE Regulations to address the various issues highlighted above, will generate additional costs. However, the Community TSE Regulations currently require that all bovine carcases that do **not** require the vertebral column to be removed as SRM, be identified by a blue stripe label applied in the slaughterhouse. This provision is not currently implemented in England, but will be once OTM cattle can be slaughtered for human consumption. Although this provision does not necessarily require an additional label, as information on the labels currently in use can be applied to a blue stripe label, a small additional cost may be incurred by slaughterhouses.

63. The regulation making it an offence to consign an animal born before 1 August 1996 would not incur additional costs for producers. These animals currently are not eligible for human consumption and after any change to the OTM rule should not be sent to a human consumption

slaughterhouse. The new offence provides a legal basis to enforce this control and should not involve any change to producers' procedures.

64. The changes relating to feed manufacturers using fishmeal, from registration to authorisation, mainly reflect a regularisation of the terms used in domestic legislation with those used in EU legislation. Registration is already carried out against a background of inspection. Therefore this change is cost neutral to industry. Registration of farms using feed containing fishmeal where ruminants are present involves a notification by affected farmers to the competent authority. Of around 15,000 premises with both ruminants and non-ruminants present in England, it is estimated, on the basis of previous on-farm inspections, that around 10% may be using fishmeal in feed and need to register.

6. Equity and Fairness

65. There is no unequal impact by gender, age, disability, or by race. Defra expects a fairly even geographical spread of participating slaughterhouses and cutting plants. It is not expected that any impact on particular income groups will be significant.

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

66. 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. The discussions and issues raised at these meetings can be accessed from the Defra website[3]. As at end January 2005 165 slaughterhouses had been trained to take brain stem samples, of which approximately 40 are low throughput. Some or all of these may be interested in handling OTM cattle.

67. All red meat slaughterhouses and cutting plants regardless of size, throughput or intention to participate in the trade, have received the consultation papers.

68. We have discussed the proposal with the Small Business Service (SBS), who have agreed that there is no requirement to carry out stage one of the Small Firms Impact Test since the proposals are unlikely to impact disproportionately on small firms.

8. Competition Assessment

69. The competition filter questions have been considered. It has been concluded that there is no significant adverse impact on competition. Any slaughtering business would be eligible to handle OTM cattle, providing they meet the criteria in the proposed legislation. Entry

[3] http://defra.gov.uk/animalh/bse/publichealth/otm/review/index.html

requirements to the trade are not particularly onerous, nor disproportionate. The structure of the industry and the run down of the OTM scheme has the potential to release capacity and should provide keen competition. The additional amendments, to address current issues in the TSE Regulations, will not affect competition as for the most part they are technical changes which do not filter down to firms.

9. Enforcement and Sanctions

70. Legislation would be enforced at licensed slaughterhouses and cutting plants by the Meat Hygiene Service in England. The Meat and Livestock Commission would enforce controls in hide markets. Sanctions would be applied for non-compliance.

10. Monitoring and Review

71. The functioning of the system for BSE testing of OTM cattle would be subject to continuous monitoring by the MHS and DARD as part of their enforcement function. Defra would remain responsible for ensuring a satisfactory system of laboratory testing. The entire testing system, would also be subject to an independent review covering the first year following implementation and an ongoing external audit by the Food Standards Agency.

11. Consultation

i) Within government

72. The Devolved Administrations, FSA and the Meat Hygiene Service have been consulted on these proposals.

ii) Public Consultation

73. Defra regularly meet with stakeholders from industry and consumer groups. All aspects of these regulations have been subject to a full public consultation exercise.

12. Summary and Recommendation

Option	Total cost per annum Economic, environmental, social	Total benefit per annum Economic, environmental, social
1. Do Nothing	Continued OTMS cost of £320m	No additional benefit
2. Amend legislation	Testing costs of £15m to industry	Improved returns to producers and all parts of the meat industry and possibly benefits

		to consumers via the availability of cheaper OTM beef for manufacturing, these benefits currently cannot be quantified

13. Declaration

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

Signed: *Ben Bradshaw*

Date: 19th September 2005

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