EXECUTIVE NOTE

The Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006 (S.S.I. 2006/530)

1. The above instrument was made in exercise of the powers conferred by section 2(2) of the European Communities Act 1972. The instrument is subject to negative resolution procedure and due to come into force on 24 November 2006. It enforces Regulation (EC) No 999/2001 ("the Community TSE Regulation") and its amending instruments. The Community TSE Regulation and the amending instruments lay down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs).

2. The Community TSE Regulation is currently enforced by the TSE (Scotland) Regulations 2002 (SSI No. 255). Since the Regulations came into force in March 2002, more than 20 EU amending instruments have been introduced. In response, seven Scottish Statutory Instruments amending the TSE (Scotland) Regulations 2002 have been made. These Statutory Instruments have revoked or replaced a number of the original domestic regulations and inserted new regulations.

3. In order to prevent the existing regulations from becoming too unwieldy by the addition of further amendments, the new Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006 consolidate the existing provisions as well as providing for the enforcement of the most recent EU measures and the removal of some redundant provisions.

4. The consolidation, as well as updating the Regulations, will help provide transparency for those affected by the Regulations, as well as help with the consistency of operation and enforcement of the Regulations by industry and enforcement bodies.

5. These consolidated Regulations apply to Scotland only. Separate, but parallel, legislation has been enacted in England, Wales and Northern Ireland.

Policy Objectives

6. The purpose of this instrument is to consolidate and replace the TSE (Scotland) Regulations 2002, as amended and to introduce further amendments, in order to provide for continued implementation of the Community TSE Regulation.

7. The Community TSE Regulation contains provisions to reduce and eventually eradicate the incidence of BSE and scrapie (which are both TSEs). The purpose of the Regulation is to minimise the risk to the public and animals from TSEs and ensure that the public can be confident in the safety of meat and other products of animal origin. The controls cover four main areas:

Monitoring for TSEs (Schedule 2)

The Community TSE Regulation requires competent authorities to sample and test certain numbers of fallen stock and animals which are fit for human consumption. This surveillance provides information on the prevalence of BSE and scrapie and informs decisions on changes to the controls. Schedule 2 of these Regulations provides for the notification of fallen bovines and goats of certain ages (notification of sheep is

voluntary) and for the sampling and testing of specified bovine animals, including all of those over 30 months of age, which are intended for human consumption.

Eradication measures: (Schedules 3 and 4)

The Community TSE Regulation specifies the measures that must be taken when an animal is suspected of being affected by BSE or scrapie. It must be notified to Scottish Ministers, movement restrictions applied and the suspect animal killed and tested. If it is confirmed that it was affected with a TSE, associated animals (including the offspring of female animals) are identified and, in most cases, killed. For sheep and goats, some restrictions remain in place after the killing to ensure that the holding remains free of scrapie. Schedule 3 enforces these provisions in respect of bovine animals affected with BSE and Schedule 4 enforces them in respect of sheep and goats affected with scrapie and, in the event that it is found in sheep or goats, BSE.

Feedingstuffs: (Schedule 5)

The Community TSE Regulation prohibits the feeding to ruminants of processed animal protein and mammalian protein, other than specified products such as milk. It also prohibits the feeding of most processed animal protein to non-ruminants (other than products such as fishmeal which must be produced, handled and used in specified ways). These are the most important controls for protecting animal health, as they prevent infectivity from animals infected with a TSE being recycled in animal feed. These measures are enforced by Schedule 5 of the Regulations.

Specified Risk Material (SRM): (Schedule 6)

This term covers those animal tissues most likely to contain TSE infectivity, were the animal to be infected with a TSE. The Community TSE Regulation requires the removal and disposal of SRM from bovine animals, sheep and goats, a requirement which has been estimated to remove over 99% of any infectivity that might be present in a bovine animal, thus providing protection for consumers and ensuring that potentially infected material is not recycled in the animal feed chain. These measures are enforced by Schedule 6 of the Regulations.

8. The 2006 Regulations also extend the table valuation system, currently used for the calculation of compensation for bovines killed as BSE offspring, to include BSE suspects or cohorts culled following a veterinary tracing exercise. This brings arrangements into line with the rest of the UK and provides for a simpler and more streamlined process and reduced valuation costs.

9. The Regulations also implement Regulation (EC) 1492/2005 which introduces minor deregulatory provisions in relation to the approval of feed production and storage premises for animal feedstuffs containing fishmeal. EU-wide feed control measures have been in place for several years, but in the UK, feed controls were introduced much earlier. Combined with the exclusion of SRM, the ban on the feeding of specific processed animal protein to livestock has proved to be a very effective control measure in the UK. As a result, the number of clinical cases of BSE has declined in GB from over 37,000 in 1992 to 39 in 2005.

10. The European Commission recently published a TSE Roadmap, which outlines in general terms the way in which controls might alter in the future. It concludes that changes to the controls might be appropriate, provided that the positive trend in the incidence of TSEs continues, the changes have a sound scientific basis and consumer protection is maintained. In addition, our knowledge and understanding of TSEs continues to grow, the science is constantly developing and the prevalence of the TSEs changing. Changes at EU level, in the short and longer term, can therefore be expected and we wish to be able to take advantage of any relaxations as quickly as possible.

11. In making future changes, we wish to adopt good practice and consolidate the Regulations each time amendments are needed. However, because the legislation covers five distinct policy areas, each with a separate policy owner and different stakeholders, consolidation of the whole SSI is difficult and time-consuming. This makes it very difficult to ensure that the SSI is kept up to date. We have therefore presented the provisions in a format that :

(a) brings the common provisions and enforcement powers (granting of approvals, appeals, powers of entry, etc.) together in one section;

(b) deals with the individual policy areas in five separate Schedules (monitoring, eradication measures in bovines; eradication measures in sheep and goats; feedingstuffs; and SRM); and

(c) uses plain English and presents the provisions in a format that enables them to be easily understood by all who need to refer to them.

12. We consider that this approach provides an innovative solution to a difficult issue. It allows for the relevant Schedule to be revoked, consolidated and replaced without having to remake the whole set of Regulations each time. Thus policy owners will be able to amend their own Schedules when necessary, and without waiting until such time as the legal and administrative resources are available to co-ordinate changes to the whole Regulations. The burden on stakeholders and enforcement bodies will also be kept to a minimum as only those stakeholders who are interested in the particular policy area will need to be consulted on changes, and enforcement bodies can be confident that their enforcement powers will be consistent.

Consultation

13. The proposals, and draft Regulatory Impact Assessment were subject to a public consultation by the Scottish Executive issued on 27 June 2005. 166 organisations were consulted and there were 11 replies to the consultation. The Food Standards Agency Scotland issued a subsequent 12 week stakeholder consultation on 3 July 2006. 177 organisations were consulted and there were 3 replies to the consultation.

Financial Effects

14. A final Regulatory Impact Assessment is attached which shows the impact on business and the Executive. Expenditure on compensation is met centrally by DEFRA. There should be no major financial effects as a result of the Regulations and indeed some of the provisions, in relation to feed controls, are deregulatory.

Scottish Executive Environment and Rural Affairs Department
1 November 2006

REGULATORY IMPACT ASSESSMENT

Title of proposal

1. **The Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006**

Purpose and intended effect

Objective

2. To continue enforcement of the UK's obligations under Regulation (EC) No. 999/2001 (which lays down the rules for the prevention, control and eradication of certain TSEs).

3. To consolidate and restructure the existing domestic legislation[1] making the regulations easier to understand and use.

4. To update and amend the regulations to take account of changes in working practices/conditions since 2002. Separate, but parallel, legislation has been enacted in England, Wales and Northern Ireland.

Background

5. Bovine Spongiform Encephalopathy (BSE) was identified as a new disease of cattle in 1986. From July 1988 onwards Government introduced a series of controls designed to eradicate the disease in the national herd, prevent its transmission to other animal species and to protect consumers against any potential health risk.

6. At the peak of the BSE epidemic in cattle in 1992, over 37,000 clinical cases of BSE were found in the UK. By 1995 incidence of the disease in cattle had fallen to 14,300 cases and the economic cost of the epidemic was expected to fall rapidly. However, the announcement in March 1996 of a possible link between BSE and new variant CJD caused sales of domestic beef products to decline immediately by 40% and the loss of exports markets, resulting in the temporary closure of many abattoirs. The total economic loss to the UK resulting from BSE in the year following the announcement was estimated to be between £740million and £980million[2] (equivalent to between 0.1% and 0.2% of the UK's national income). The domestic market has since recovered and in 2005 only 39 clinical cases of BSE occurred in GB (including 1 in Scotland).

7. Regulation (EC) No. 999/2001 (the Community TSE Regulation) is the directly applicable EU legislation that provides a framework for the prevention, control and eradication of certain TSEs namely BSE and scrapie. In response to the introduction of the Community TSE Regulation and to consolidate domestic legislation enacted in

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1 The TSE (Scotland) Regulations 2002 (SI 2002 No. 255)

2 DTZ Pieda (1998) *Economic Impact of BSE on the UK Economy*, Report to the UK Agriculture Departments and HM Treasury

response to the BSE epidemic in the UK, the TSE (Scotland) Regulations were made in 2002.

8. These Regulations provided the necessary domestic powers to enforce and administer the Executive's obligations under the European legislation.

9. Since March 2002, more than 20 further EU measures have been introduced. These impact on the procedures that are used in the feeding, slaughter, export and import, placing on the market, inspection and movement of bovine, ovine and caprine animals. In response, seven Statutory Instruments amending the TSE (Scotland) Regulations 2002 have been made. These Statutory Instruments have revoked or replaced a number of the original domestic regulations and inserted new regulations.

Rationale for Executive intervention

10. Some areas in the domestic Regulations that require updating have not been addressed by the measures mentioned above. It has been decided that, in order to prevent the existing regulations from becoming too unwieldy by the addition of further amendments, they should be replaced in their entirety by new domestic TSE Regulations which consolidate the current regulations and their subsequent amendments. The benefits of consolidating as well as updating the Regulations are that this will help provide transparency for those affected by the Regulations, as well as help with the consistency of operation and enforcement of the Regulations by industry and the enforcement bodies.

11. A description of the main areas of the existing TSE Regulations that have been updated can be found in the Annex to this RIA.

Consultation

Within the Executive

12. SEERAD and Food Standards Agency Scotland (FSA(S)) are consolidating the regulations which will bring them into line with the other UK Agricultural Departments. The FSA(S) is the competent authority for Schedule 6 (specified risk material, mechanically recovered meat and slaughtering techniques) and the FSA's Meat Hygiene Service enforces Schedules 2 and 6. No new offences are being introduced with this provision.

Public consultation

13. A twelve week public consultation on the draft Regulations was carried out over the summer of 2005. FSA(S) also carried out a supplementary 12 week consultation earlier this year. The initial consultation was sent to 166 organisations in Scotland, including fresh meat abattoirs, industry and consumer organisations and local authorities. Only 11 responses were received for the initial consultation and 3 responses were received for the supplementary consultation. Respondees included representations from organisations such as the National Farmers Union of Scotland which covers a large number of farmers and businesses affected by the Regulations and local authorities. Overall, most respondents were in favour of consolidating and clarifying the domestic

TSE regulations (Option 4 below). A full summary of the comments received can be obtained on request from SEERAD[3].

Options

Option 1: Do Nothing

14. Failure to give legal effect to the amendments to the European TSE legislation would mean that the domestic legislation would contain outdated references to the European legislation. There is also the possibility that this could lead to insufficient enforcement powers in the domestic legislation, as more recent requirements in Regulation (EC) No 999/2001 will not be enforced, which could lead to Government facing infraction proceedings from the EU.

15. The Regulations would remain unconsolidated, making them difficult to follow. Areas of overlap would not be addressed and repetition of powers would remain in the legislation. Consolidated TSE legislation has been enacted in England, Wales and Northern Ireland. Scottish legislation would be inconsistent with the rest of the UK making it difficult for enforcement staff to follow guidance procedures.

16. For the reasons outlined above Option 1 is not a viable course of action.

Option 2: Use non-regulatory methods to enforce and administer TSE monitoring, control and eradication requirements

17. The agricultural industries affected by TSEs could, in theory, operate under guidance and a code of best practice developed either by industry or Government in association with the veterinary profession and others.

18. Whilst voluntary schemes, sometimes supported by codes of practice, can assist to regulate industry and safeguard public health, The Executive believes that such an approach in this area would not be advisable. The risk of contamination of herds and the subsequent potential increased danger to public health would not be justifiable. It is unlikely that a pure industry-run regulatory system would be feasible in the context of Government's obligations under Regulation (EC) No 999/2001. Some Government enforcement and monitoring controls would be required, which could lead to a duplication of resources and inefficiencies in the monitoring regime.

19. If the scheme was regulated by industry itself there are difficult questions of impartiality and liability should standards decline. To address this, the Executive could intervene and monitor, but without punitive measures it would be arguable that even with government surveillance there may be little impact on raising or maintaining standards.

20. EU member states, and other countries around the world, would be unlikely to accept a voluntary regime as sufficient safeguard against TSEs and therefore would regard the UK as a high risk country for BSE. Member states and third countries would then take the necessary measures to protect their own livestock which is likely to include

3 Scottish Executive Library, K Spur, Saughton House, Broomhouse Drive, Edinburgh, EH11 3XD

restricting imports from the UK. This would be punitive for the UK meat and connected industries.

21. The EU Regulation requires that Member States make frequent inspections to verify compliance with Regulation (EC) 999/2001. It is likely that the Commission will take the view that Government would not be meeting its obligations under the European Regulation with a voluntary regime. This could lead to infraction proceedings which could lead to a substantial fine from the Commission for the UK.

22. Additionally, public confidence in Government BSE controls could be significantly dented if there appeared to be an indirect relaxation in controls.

23. For the reasons outlined above Option 2 is not a viable course of action.

Option 3: Update the Regulations only to reflect the subsequent amendments to the European legislation

24. Updating the Regulations for the amendments made to Regulation (EC) 999/2001, subsequent to the creation of the TSE (Scotland) Regulations 2002, would ensure that the domestic legislation is up to date in reflecting Government's obligations under the European TSE Regulation.

25. However, only updating the Regulations would not address such issues as the need to rationalise arrangements for appeals and would not cover changes required to reflect changed industry working practices. An update, based solely on the European amendments, would also leave unresolved the areas of repetition of powers both within the document and with domestic animal by-products legislation introduced after the 2002 TSE Regulations.

26. For the reasons outlined above the Executive does not believe that Option 3 is the best course of action with regards to the TSE Regulations.

Option 4: Consolidate, update and clarify the TSE Regulations

27. The preferred option is that the existing Regulations are consolidated, updated and restructured to reflect the EU measures introduced since the adoption of Regulation (EC) No 999/2001, allow the Regulations to reflect current working practices in the monitoring and eradication of TSEs, and make the Regulations easier to use for industry, government delivery agents, enforcement bodies and the public.

28. As the majority of the regulations in the 2006 Regulations are simply an update and consolidation of existing provisions, these should not have a significant economic impact on producers. However, there are some areas in the updated Regulations where there is likely to be some impact on producers. These are outlined and their impact discussed in greater detail in the sections on benefits and costs. These benefits and costs were highlighted to industry in the public consultation on the draft Regulations.

29. Both updating and consolidating the Regulations will mean that the new Regulations will have the correct references to the European legislation and will address issues that have come to light since the coming into force of the domestic TSE legislation. The updated Regulations better reflect the needs of Government and industry in the areas of monitoring, control and eradication of TSEs.

30. The restructuring of the Regulations brings the benefit of a more coherent structure, clarifies the Regulations and makes the Regulations easier to understand. By separating into Schedules the different and distinct areas in which the Regulations apply, it will also be easier to amend (and consolidate) the individual Schedules in line with changes to the EU legislation, rather than delaying until resources are available to consolidate the Regulations as a whole.

31. For the reasons given above, The Executive believes that Option 4 is the best course of action with regards to the TSE Regulations.

Costs and benefits

Sectors and groups affected

32. The provisions of the TSE Regulations 2006 primarily affect producers of feedingstuffs for animals, slaughterhouses, cutting plants, hide premises, tanneries and farmers of cattle, sheep and goats. Indirectly, however, they have a much wider impact, as the TSE legislation serves to protect public health, as well as animal health, against TSEs.

Benefits

Option 1

33. No benefits would occur if the do nothing option is followed.

Option 2

34. This option places the same requirements and obligations on industry as before, therefore no additional benefits would result from this option for industry. There would be some benefit to Government as enforcement costs would be reduced. However it is not possible to quantify this benefit as some monitoring and enforcement costs would remain in order for The Executive to meet their obligations under Regulation (EC) 999/2001.

Option 3

35. Updating the TSE Regulations to reflect the amendments to the European legislation has the benefit of ensuring that domestic legislation contains the most up to date references to the enabling European legislation. This is a non-quantifiable benefit.

Option 4

36. Fully updating and consolidating the TSE Regulations to take into account developments since the Regulations came into force, has the benefit given in Option 3 above, and additional benefits as described in the paragraphs below.

37. Currently there is a legal requirement for abattoir operators to sample over 30 month bovine animals which are slaughtered for human consumption, but there is no equivalent requirement for them to sample the small number of over 24 month bovines that the EU Regulation requires to be sampled and tested. However, this sampling is being done in practice. Providing a legal basis for abattoir operators' responsibilities for brainstem sampling and correlation of carcases to samples etc. has the benefit of reducing the risk of legal challenges on enforcement decisions and subsequent extra costs to Government. It also avoids challenge for failure to comply with EU state aid rules.

38. Consolidating the appeals procedures into a single provision that applies across the whole of the Regulations contributes to the overall social benefit of clarifying the Regulations, improving their ease of use for both industry, the public and Government, and could lead to a reduction in business and administration costs for both industry and Government (depending on the number of future appeals).

39. Under the previous legislation, slaughterhouses and cutting plants required a licence to remove spinal cord which is SRM from sheep and goats. The Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006 no longer contain a requirement for slaughterhouses to be licensed, with the benefit of slightly reducing the administrative burden for affected slaughterhouses, but the Regulations do require the authorisation (but not the licensing) of cutting plants, in line with EU requirements.

40. Adjusting the controls to permit the use of low-risk MMBM in non-pasture fertilisers has a potential economic benefit in that it could return some limited value of this product to producers and an environmental benefit in that it reduces the amount of this material being disposed of by landfill or incineration. The release assessment[4] quoted the total amount of MBM produced in GB in 2003 as 360,022 tonnes, 5% of which went for petfood, 45% to combustion, and 50% to landfill. 1996 figures (i.e. before the ban in agricultural fertilisers) suggest that around 0.05% of MBM was used in fertilisers production, with earlier average content of around 1% during the 1980s. In the present situation, with 50% of available MBM going to landfill per year, it is difficult to predict the actual amount which will be used in agricultural fertilisers as a result of the proposed de-regulation in this area.

41. The restructuring of the Regulations, so that the general provisions on the powers of inspectors, procedures for approvals, appeals etc are set out in the main body of the Regulations and the specific provisions regarding monitoring, control and eradication, feedingstuffs, and SRM are set out in Schedules, has a social benefit in that they clarify the Regulations. The restructuring also attempts to make it easier for both industry and enforcers to see the requirements of the Regulations. It is not possible to quantify this benefit.

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4 Paper presented to SEAC on 21 April 2005

42. The new provision for SEERAD to arrange a valuation in exceptional circumstances will enable clear cases of overpayment to be addressed, benefiting the taxpayer and discouraging use of the scheme for fraudulent purposes or financial gain. The new table valuation system was introduced in the TSE (Scotland) Amendment (No. 2) Regulations 2006 (SSI No. 231) for valuations under the Offspring Cull. This system is now extended to the calculation of compensation for BSE suspects and cohorts, in line with the rest of the UK. This provides for a simpler and more streamlined process and reduces valuation costs.

43. In 2004-05 approximately £6,000 was paid in compensation for BSE suspects in Scotland. The financial effect of the change to the compensation arrangements is difficult to judge, particularly against the background of declining BSE incidence.

Costs

Option 1

44. Following the 'do nothing' option could potentially lead to costs arising from legal action taken against Government, either by the Commission, for inadequate enforcement of the UK's obligations under the European TSE legislation, or by individuals challenging present requirements.

45. Not amending the domestic Regulations to reflect the simplification and moderation of certain feed rules in European legislation would lead to continued economic costs to industry of meeting the old requirements and the unnecessary cost to government of maintaining the enforcement regime.

46. The 'do nothing' option also leads to costs in terms of the forgone benefits highlighted in options 3 and 4 above.

Option 2

47. Transferring enforcement of TSE controls from Government to industry would result in a greater cost burden for industry. Industry would need to take on the responsibility of inspecting and monitoring the regime. This would entail employing and training inspectors, arranging contracts with testing laboratories and setting up IT systems to record data/results. In addition, there would be administrative costs from running the regime. It is not possible to quantify these costs precisely as it is likely that industry could decide on different systems to those currently in operation. At present the FSA meets the cost of the enforcement of SRM controls by the Meat Hygiene Service, this costs around £15m annually. UK Government meets the costs relating to control and eradication of TSEs and the annual programme of monitoring which are in the region of £4m in UK. It is likely that a significant proportion of these costs would fall to industry under this option.

48. Further costs, which are difficult to quantify, are the potential additional risk to public if codes of practice and industry self-regulation proved to be less stringent than present controls and the potential economic cost from any reduction in consumer confidence (see paragraph 6 above).

Option 3

49. Failing to provide a legal basis for abattoir operators' responsibility for brainstem sampling for certain over 24 month bovines would allow the risk of legal challenge to this arrangement to persist and could lead to subsequent extra costs to Government if the current arrangements are overturned. A change to these arrangements could lead to possible infringement of EU state aid rules and costs arising from infraction proceedings. Similarly, a lack of adequate appeals procedures in the legislation could be challenged which, if successful, would lead to extra costs for Government.

50. Not adjusting the compensation rates for the CSFS, or for cattle, would lead to cost in terms of the forgone benefits discussed in the benefits of Option 4 above.

Option 4

51. Since 1 June 2004, the sampling of bovine animals, for BSE testing, and the transportation of samples has been the responsibility of the abattoir operator rather than UK Government. Although there was no previous legal basis for this, the 2006 Regulations reflect that practice and there is now a requirement on operators to take samples 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 UK Government offers free of charge to abattoirs. This provision therefore, does not impose an additional cost burden on industry but formalises in legislation existing practice.

52. 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 the impact of this change 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. Therefore, the cost for no-tests in casualty animals can be expected to be in the region of £4,800 per annum for the whole GB industry.

53. The current training requirements for slaughterhouse staff removing SRM has been extended so that all training is recorded. This requirement will also now apply to cutting plant staff involved in SRM removal. This extension of training requirements should be cost neutral as it is regarded as good practice and should already be occurring in these premises.

54. Where provisions have been clarified, for example, on the timing of SRM removal and on the definition of the terms "mechanically recovered meat", these have no cost impact as no change is required to working practices or procedures.

Competition assessment

55. The TSE Regulations affect farmers of TSE susceptible animals, slaughterhouses, cutting plants, hide premises, animal feed producers and some of those who process animal by-products. These industries consist of a large number of small and mid-sized firms and a number of large firms, none of which dominate the marketplace. Consolidating and updating the TSE Regulations would not significantly impact the structure of these industries. There would be no substantially different effect on firms, nor any change caused to market structures as a result of the revised Regulations. None of the measures prevent entry into the market by new firms and none would lead to higher ongoing costs compared to existing firms for new or potential entrants to the market.

Enforcement, sanctions and monitoring

56. Schedules 2 & 6 of the consolidated Regulations would be enforced at licensed slaughterhouses and cutting plants by the Meat Hygiene Service in Great Britain on behalf of Scottish Ministers and the Food Standards Agency (Scotland) respectively. The Meat and Livestock Commission would enforce the controls of Schedule 2 in hide markets and tanneries on behalf of Scottish Ministers. Local authorities are responsible for enforcing the Regulations at all other premises.

57. On summary conviction, for an offence under these Regulations, a person would be liable to a fine or to imprisonment for a maximum of three months or both. On conviction on indictment, a person would be liable to a fine or imprisonment for a maximum of two years or both.

58. The consolidated TSE Regulations will be reviewed on an ongoing basis and amended as required to reflect changes in European legislation and changes in industry practices.

Implementation and delivery plan

59. The 2006 Regulations by and large continue the existing system set up by the 2002 TSE Regulations. When the new Regulations are made, Defra will write to the main industry organisations to inform them. The State Veterinary Service, Meat Hygiene Service and local authorities will also be informed of the new Regulations so that updates can be made to instructions and other official documentation as appropriate. In particular, guidance and instructions on the changes made to the provisions on animal feed will be made available to industry and enforcement bodies before the Regulations come into force.

Post-implementation review

60. The 2006 Regulations will be subject to on-going review in order to respond to any changes required as a result of further amendments to the EU Regulation.

Summary and recommendation

61. The analysis of the costs and benefits given above lead to the recommendation that Option 4 should be followed.

Summary costs and benefits table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1	None	Cost associated with risk of infraction proceedings against the UK and challenge to requirements of TSE monitoring regime
2	Reduction in administrative costs for government	Economic cost to industry in the region of £19m Potential significant economic and social costs from loss of public confidence in TSE controls
3	Non-quantifiable benefit of having the correct references to EU legislation in the domestic legislation.	Cost associated with risk of challenge to requirements of TSE monitoring regime and the appeals procedure in the regulations
4	Same benefit as in Option 3 above, and also: Non-quantifiable social benefit of clarifying the Regulations and making them easier to use Environmental benefit from any reduction in the amount of MBM going to landfill Benefit to industry from slight reduction in administrative burden on SRM spinal cord Savings to taxpayer from adjustment of CSFS rates: approx £0.75m	Cost to cattle industry for 'no-test' over 24 month casualties of approx. £4,800 Cost to sheep / goat industry for new CSFS rates: approx £0.75m

Declaration

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

Signed **ROSS FINNIE**

Date **1st November 2006**

Minister's Name Ross Finnie
Title: Minister for Environment and Rural Development
Department Environment and Rural Affairs

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Room 358
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1 November 2006

Annex

63. Until 1 June 2004, if a bovine animal needed to be sampled for BSE testing, the head of the animal was removed at the abattoir and then transported to the Veterinary Laboratories Agency (VLA). Defra funded the transport of cattle heads from abattoirs to the VLA where brain stem samples were taken and further transported to laboratories for testing. This service was withdrawn, following discussions with industry, in order to meet the EU rules which limit to €40 the contribution Member States can make towards the costs of testing animals for human consumption.

64. Since then, the sampling of bovine animals slaughtered for human consumption which require a BSE test has been the responsibility of the individual abattoir operator. Training in the brain stem sampling process has been available, free of charge, for abattoirs since July 2003. This change in responsibility for the sampling of bovine animals needs to be reflected in domestic legislation for enforcement purposes.

65. As well as the adjustment to the TSE Regulations to reflect the changed responsibility for the sampling, there was also a need to harmonise compensation arrangements in the case of 'no-test' results for sampled bovine animals. The TSE (Scotland) (Amendment) (No. 2) Regulations 2005 limited the automatic payment of compensation for OTM bovine carcases destroyed under the monitoring requirements of the TSE Regulations to those destroyed due to the receipt of a positive result. The same principle needed to be extended to carcases of 24 – 30 month bovine animals.

66. The feed ban issues to be addressed include adjusting the UK's domestic controls on rendered mammalian material (mammalian meat & bonemeal (MMBM)) in fertilisers, which since 1996 has been banned from all agricultural use. These controls now need to take into account the EU Animal By-Products Regulation, (EC) No 1774/2002, which permits the use of certain rendered material on non-pasture land.

67. A risk-assessment (release assessment stage) on the use of rendered MMBM in fertilisers was carried out for Government by the Veterinary Laboratories Agency. The assessment was considered by the Spongiform Encephalopathy Advisory Committee (SEAC) on 21 April 2005. SEAC was generally content with the approach used and assumptions made in the assessment. SEAC recommended that a watching brief should be maintained to ensure that potentially infected material cannot be used for fertiliser production, as little is known about the persistence of TSE agents in soil. The controls in the Animal By-Products Regulation prevent potentially infected material being used in fertiliser production and the national rules have been relaxed to allow the use of low risk material for the production of fertilisers for use on non-pasture land.

68. Regulation (EC) No. 1234/2003, adopted in September 2003, and Regulation (EC) No 1292/2005, adopted on 5 August 2005, simplified some of the rules on the use, production and handling of fishmeal, dicalcium phosphate, and hydrolysed proteins, and these changes are reflected in the 2006 Regulations by de-regulating: to remove the requirements for the registration of related bulk stores and separate approval of producers of these products. Approval is now a requirement of the Animal By-Products Regulation.

69. The same EU Regulation also moderated the controls on the feeding of blood products and bloodmeal to farmed fish and this change is reflected in the 2006 Regulations.

70. A feature of the 2006 Regulations is that compensation for TSE-susceptible animals required to be slaughtered will not be automatically payable if the owner is directly responsible for their exposure to a TSE. The new provisions link the decision on whether compensation will be payable to the appeals procedure.

71. The TSE (Scotand) Regulations 2002 contain a requirement for slaughterhouses removing SRM spinal cord from sheep and goats to be licensed for this purpose. Following a review of procedures, it has been decided not to continue with this requirement. However, the requirement for cutting plants to be authorised for this purpose remains in place, as required by the Community TSE Regulation.

72. Within the 2002 Regulations there are also currently a number of provisions relating to appeals procedures against notices issued under different regulations. Following a review of these procedures, it has been decided to consolidate the appeals procedures into a single provision based on the appeals structure used elsewhere in animal health regulations.