

EXPLANATORY MEMORANDUM TO
THE TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (ENGLAND) REGULATIONS
2010

2010 No. 801

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.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The purpose of the instrument is to amend arrangements for administering and enforcing Council Regulation (EC) No.999/2001 (the “EU TSE Regulation”) which lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs) such as bovine spongiform encephalopathy (BSE) in cattle and scrapie in sheep and goats. Three new offences are required to comply with the EU TSE Regulation with regard to the following:

- (i) Failing to sample for BSE, or failing to remove specified risk material from, eligible cattle which are slaughtered at places of slaughter other than slaughterhouses (“home slaughter”).
- (ii) Use of sheep or goat milk or milk products from a holding on which classical scrapie is confirmed, produced prior to the removal of all goats and genetically susceptible sheep, as feed for ruminants (except on the holding of origin) or exporting them or failing to comply with the requirements laid down in the Regulations regarding their storage and transportation.
- (iii) For the occupier of a premises approved under the Animal By-Products Regulations 2005 (S.I. 2005/2347) failing to comply with a direction from the Secretary of State to select and sample fallen sheep, goats and deer for TSE testing. Tested carcasses would have to be retained pending a negative test result unless they were disposed of by incineration or rendering followed by incineration.

2.2 The Ministry of Justice has cleared the new offences.

2.3 The instrument also includes a number of amendments to the 2008 Regulations, which are explained in detail in Sections 4 and 7 below.

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

None

4. Legislative Context

4.1 The Transmissible Spongiform Encephalopathies (England) Regulations 2008 (S.I. 2008/1881) (“the 2008 Regulations”) which came into force on 7 August 2008, updated and replaced the Transmissible Spongiform Encephalopathies (No 2) Regulations 2006 (S.I. 2006/1228) The 2008 Regulations, which provide the necessary powers to administer and enforce the provisions of the EU TSE Regulation, have since been amended by the Transmissible

Spongiform Encephalopathies (Fees) (England) Regulations 2008 (S.I.2008/2269) and the Transmissible Spongiform Encephalopathies (England) (Amendment) Regulations 2008 (S.I.2008 /3295).

4.2 The Transmissible Spongiform Encephalopathies (England) Regulations 2010 (“the 2010 Regulations”) update and replace the 2008 Regulations (as amended).

5. Territorial Extent and Application

This instrument applies to England.

6. European Convention on Human Rights

The Minister of State for Environment, Food and Rural Affairs has made the following statement regarding Human Rights:

In my view the provisions of the Transmissible Spongiform Encephalopathies (England) Regulations 2010 are compatible with the Convention on Human Rights.

7. Policy background

o What is being done and why

7.1 There have been a number of amendments to the EU TSE Regulation since the 2008 Regulations came into force. The amendments reflect the declining prevalence of BSE in cattle, new scientific advice and technical advances. The 2010 Regulations would amend the 2008 Regulations as follows:

- Creation of an offence requiring the sampling for BSE of, and the removal of specified risk material from, eligible cattle which are slaughtered at places of slaughter other than slaughterhouses (“home slaughter”). Failure to comply with these requirements would be an offence.
- An option for slaughterhouse operators to submit samples for BSE testing to laboratories approved in other Member States, in accordance with the Directive 2006/123/EC (the “EU Services Directive”).
- Removal of the requirement for abattoirs that do not handle cattle that require BSE testing to have an approved Required Method of Operation (RMOP).
- New powers for the Secretary of State to issue a direction to operators of animal by-product disposal plants to select and sample fallen sheep, goats and deer for TSE testing. Failure to comply with such a direction would be a new offence.
- The following new provisions, which are required in line with Commission Regulation (EC) No.103/2009, concerning the use of milk and milk products from sheep and goat holdings where TSE is suspected or confirmed:
 - New powers for inspectors to serve a notice to prohibit the movement of sheep or goat milk or milk products from a holding on which a TSE is suspected in sheep or goats, while permitting its use within the holding of origin.
 - Creation of an offence for using sheep or goat milk or milk products from a holding on which classical scrapie is confirmed, produced prior to the removal of all goats and genetically susceptible sheep, as feed for ruminants (except on the holding of origin) or for exporting them, or for failing to comply with the other requirements laid down in these paragraphs regarding their storage and transportation.

- New powers for inspectors to serve a notice to destroy sheep or goat milk or milk products produced between the dates of official suspicion and killing, on a holding on which BSE cannot be excluded after testing a sheep or goat. Defra will pay compensation as set out in Schedule 4.
 - Amendment requiring farmers to identify sheep and goats on holdings on which atypical scrapie is confirmed, as directed by the Secretary of State.
 - Amendment administering the derogation in the EU TSE Regulation allowing Member States to delay the killing of sheep flocks and goat herds in which classical scrapie has been confirmed, by enabling farmers to apply in writing to the Secretary of State setting out the reasons for the application.
 - Amendment permitting the feeding of fishmeal to unweaned ruminants in reconstituted milk replacer in line with Commission Regulation (EC) No. 956/2008, whilst maintaining the existing ban on feeding fishmeal to adult ruminants.
 - Amendment permitting the Secretary of State to permit the feeding to farmed animals, of feed materials of plant origin and feed containing such products, in which insignificant amounts of bone fragments of environmental origin had been detected, on the basis of a favourable risk assessment, in line with Commission Regulation (EC) No. 163/2009.
 - Amendment permitting the export of pet food containing processed animal proteins (PAP) of ruminant origin provided that it is produced and labelled in accordance with the Animal By-Product Regulations, in line with Commission Regulation (EC) No. 956/2008.
 - Plus other minor amendments.
- *Consolidation*

7.2 These 2010 Regulations consolidate the 2008 Regulations, its amendments, and incorporate subsequent amendments to the EU TSE Regulation.

8. Consultation outcome

8.1 The consultation was sent to 604 organisations and private individuals, including industry stakeholders and consumer organisations. The consultation period lasted from 2 September to 2 December 2009. We received 19 responses to the consultation, 6 of which opposed the proposal for standard (fixed price) valuations for sheep and goats killed to control TSE. The commercial goat sector also registered strong concerns about EU controls on milk from sheep flocks and goat herds in which TSE is suspected or confirmed; and about the proportionality of EU requirements to kill goat herds in which classical scrapie is confirmed.

8.2 While the Government remains committed to the principle of table valuations for animals killed to control TSEs, it has decided not to proceed with the proposals for standard valuations for sheep and goats described in the consultation, at this time. The Government intends to continue to develop proposals for a compensation system for sheep and goats which is more closely linked to market data.

9. Guidance

Defra and FSA intend to update existing published guidance to reflect the changes arising from the 2010 Regulations as soon as possible.

10. Impact

10.1 The estimated impact on farming and meat businesses is as follows:

(i) Cost of BSE testing of “home slaughtered” cattle: £5,000 per annum. It is estimated that there are 100 home slaughtered cattle in England per annum. Testing and disposal costs per slaughtered animal are estimated to be £45.

(ii) Cost of restricting sheep and goat milk, following the confirmation of classical scrapie on a holding: £160,000 per annum. These restrictions on suspect TSE premises will reinforce the necessity for stringent biosecurity measures and incentivise good practice.

(iii) The new legislation would allow flexibility on how fallen sheep and goats are collected. Government currently provides a free service to farmers for the collection, sampling and disposal of these carcasses, via a Rural Payments Agency contract. Potential cost of industry paying, via private collectors, for collection and disposal of 10,000 fallen sheep and 500 goats sampled for the EU TSE testing programme: £140,000 per annum.

(iv) Saving to the meat industry as abattoirs that do not handle cattle that require BSE testing will not require an approved RMOP: £1,000 per abattoir. The meat industry has not been able to estimate how many abattoirs would make this saving.

There are no implications for charities or voluntary bodies.

10.2 The estimated impact on the public sector is:

(i) Cost of restricting sheep and goat milk, where BSE cannot be excluded: £4,000 per annum.

(ii) Potential saving on collection and disposal of fallen sheep and goats: £460,000 per annum (see impact on farming sector - Section 10.1(iii) above). The difference in the impact figures (between farming and public sector) arises because recent experience when the free collection service for fallen cattle ended in January 2009 indicates that we would expect individual farmers to secure a better deal than is available to Government.

10.3 An Impact Assessment is attached to this memorandum.

11. Regulating small business

The legislation applies to small business.

12. Monitoring & review

Policy on BSE and scrapie is kept under continuous review and is updated regularly in line with EU legislative developments.

13. Contact

Katie Barnes at the Department for Environment, Food and Rural Affairs Tel: 020 7238 6535 or email: katherine.barnes@defra.gsi.gov.uk can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency: Defra and FSA		Title: Impact Assessment of the Transmissible Spongiform Encephalopathies (England) Regulations 2010	
Stage: FINAL	Version: 1.0	Date: 24 February 2010	
Related Publications:			

Available to view or download at:

<http://www.defra.gov.uk/corporate/consult/tse-regs09/index.htm>

Contact for enquiries: Katie Barnes

Telephone: 020 7238 6535

What is the problem under consideration? Why is government intervention necessary?

Regulation (EC) No.999/2001 requires Member States to implement rules for the prevention control and eradication of transmissible spongiform encephalopathies (TSE). These rules are currently administered and enforced by the TSE (England) Regulations 2008 as amended. There have been a number of amendments to the EU Regulation in line with the EU TSE Roadmap and the Government proposes to amend the TSE (England) Regulations 2008 accordingly. Some other changes are proposed e.g. to reduce administrative procedures in abattoirs and to enable a sample of 10000 fallen sheep and 500 goats to be selected at animal by-products (ABP) premises as an alternative to the current free collection and disposal service.

What are the policy objectives and the intended effects?

Defra's policy objective is to have TSE controls which maintain consumer and animal health protection, are based on sound science, are proportionate to the known risk and are practical and enforceable. The TSE (England) Regulations 2010 include provisions which update the administrative requirements for abattoirs to reflect previous changes to BSE testing; introduce new controls on milk from sheep flocks and goat herds in which a TSE was suspected or confirmed; and introduce more proportionate feed controls.

What policy options have been considered? Please justify any preferred option.

Option 1 - Continue current approach using existing Regulations i.e. do nothing.

Option 2A - Apply amended EU controls - with Defra-funded collection and disposal of 10000 fallen sheep and 500 goats.

Option 2B - Apply amended EU controls - with the possibility of sampling 10000 sheep and 500 goat carcasses at ABP premises.

Following consultations on the options above, **Option 2B** is the preferred option. It enables EU controls to be updated and will allow flexibility in how fallen sheep and goats are selected.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

January 2011

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister:

Jim Fitzpatrick

.....Date: 8th March 2010

Summary: Analysis & Evidence

Policy Option: 2B

Description: Apply the amended EU controls, amend the existing Regulations as soon as possible, and adopt the NFSCo method of collection and disposal.

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups' A) <u>Government costs</u> : i) Sheep and goat milk restrictions where BSE cannot be excluded (£4k). B) <u>Industry costs</u> : i) BSE testing home slaughtered cattle (£5k); ii) Sheep and goat milk restrictions following confirmation of classical scrapie – (£160k); iii) Collection/disposal of fallen sheep and goat carcasses (£140k).
	One-off (Transition)	Yrs	
	£ 0		
	Average Annual Cost (excluding one-off)		
	£ 0.31m	Total Cost (PV)	£1.55m
Other key non-monetised costs by 'main affected groups'			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups' <u>Government</u> : Collection and disposal costs falling to zero under new collection and disposal scheme (£0.46m).
	One-off	Yrs	
	£ 0		
	Average Annual Benefit (excluding one-off)		
	£ 0.46m	Total Benefit (PV)	£ 2.3m
Other key non-monetised benefits by 'main affected groups' Animal health benefits for genetically susceptible sheep and goats in unaffected flocks and herds which receive milk or milk products from them, and which are at risk of infection with classical scrapie. RMOP changes could result in more slaughterhouses opting to slaughter eligible cattle aged 30 to 48 months because of the reduced administration burden on slaughterhouse operators.			

Key Assumptions/Sensitivities/Risks

Price Base Year 2009	Time Period Years 5	Net Benefit Range (NPV) £ 0.75m	NET BENEFIT (NPV Best estimate) £ 0.75m	
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What is the geographic coverage of the policy/option?		England		
On what date will the policy be implemented?		April 2010		
Which organisation(s) will enforce the policy?		AH/MHS/LAs		
What is the total annual cost of enforcement for these organisations?		No new costs		
Does enforcement comply with Hampton principles?		Yes		
Will implementation go beyond minimum EU requirements?		No		
What is the value of the proposed offsetting measure per year?		£ N/A		
What is the value of changes in greenhouse gas emissions?		£N/A		
Will the proposal have a significant impact on competition?		No		
Annual cost (£-£) per organisation (excluding one-off)	Micro [£]	Small [£]	Medium [£]	Large [£]
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)		(Increase - Decrease)	
Increase of £ to	Decrease of £	Net Impact	£

Key:

Annual costs and benefits: Constant Prices

(Net) Present Value

Evidence Base (for summary sheets)

1. Introduction and legislative background

1.1 Transmissible spongiform encephalopathies (TSEs) are fatal brain diseases which include classical and atypical scrapie in sheep and goats and bovine spongiform encephalopathy (BSE) in cattle. Exposure to BSE through the consumption of infected meat is believed to be the primary cause of variant Creutzfeldt-Jakob Disease (vCJD) in humans. There had been 167 human deaths from definite or probable vCJD in the UK to 1 February 2010.

1.2 The Transmissible Spongiform Encephalopathies (England) Regulations 2008 came into force on 7 August 2008. They provide the necessary powers to administer and enforce the provisions of Regulation (EC) No.999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (the EU TSE Regulation).

1.3 There have been a number of amendments to the EU TSE Regulation since the 2008 Regulations came into force. Defra and the Food Standards Agency (FSA) have also reviewed the Schedules to ensure that they are appropriate and that any lessons learned are incorporated.

1.4 The amendments with the greatest impact, arising from the consultation on the new TSE (England) Regulations, are in Schedules 2, 4 and 7 of the 2008 Regulations. These are considered in more detail below. Other amendments, which are expected to have a negligible impact, are listed at Annex 1.

1.5 While the Government remains committed to the principle of table valuations for animals killed to control TSEs, it has decided not to proceed with the proposals for standard valuations for sheep and goats described in the consultation, at this time. The Government intends to continue to develop proposals for a compensation system linked more closely to market data, with the concomitant requirement for a separate impact assessment for such a system.

2. Schedules 2, 4 & 7 of the 2008 Regulations: Detailed consideration

Background

2.1 The European Commission has advised that the EU TSE Regulation requires the BSE testing of all cattle aged over the testing threshold. This includes cattle slaughtered in slaughterhouses and cattle which keepers slaughter on their premises for their own consumption (home-slaughtered). The 2008 Regulations require slaughterhouse operators to collect and submit samples from cattle aged over the testing threshold for BSE testing. Although the 2008 Regulations provide powers for inspectors to issue notices to enforce the EU TSE Regulation, they do not contain a clear obligation for cattle keepers carrying out home-slaughtering to comply with BSE testing requirements. We are making the following changes to the 2008 Regulations:

1. Amending paragraph 3 of Schedule 2 of the 2008 Regulations to require a cattle keeper home-slaughtering a bovine animal aged over the testing threshold to arrange both to sample the animal and to deliver the brainstem sample to an approved testing laboratory for BSE testing; and
2. Extending the retention and disposal requirements in paragraph 6 of Schedule 2 to cover home slaughter. We are also taking the opportunity to clarify that an “insufficient test result” includes situations in which approved testing laboratories do not receive brainstem samples.

2.2 The EU TSE Regulation requires that specified risk material (SRM) is removed at slaughterhouses or, as appropriate, “other places of slaughter” (i.e. home slaughter). To

administer this requirement we are inserting a new paragraph in Schedule 7 of the Regulations making it an offence not to remove SRM from cattle, sheep and goats slaughtered at “other places of slaughter” (i.e. from a home-slaughtered animal).

2.3 On 1 January 2009, the age threshold for BSE testing healthy cattle born in the EU15 slaughtered for human consumption was raised from 30 to 48 months. Schedule 2 of the current Regulations requires that all slaughterhouses in which cattle aged over 30 months are slaughtered for human consumption have an approved Required Method of Operation (RMOP). It also requires the RMOP to describe the system for removing vertebral column as SRM. Following the agreement of the FSA Board, we are removing the requirement for slaughterhouses, which do not slaughter cattle eligible for BSE testing, to have an approved RMOP. We are also removing the requirement for RMOPs to describe the system for removing vertebral column as SRM.

2.4 Currently the EU TSE Regulation requires the UK to test an annual quota of 10,000 fallen sheep and 500 fallen goats aged over 18 months. This involves considerably less than 1% of fallen sheep carcasses and relatively few fallen goats. The fallen sheep and goat surveys are currently administered by the Rural Payments Agency (RPA) via contracts and Defra provides a free service to farmers for the collection, sampling and disposal of sheep and goat carcasses volunteered into the survey. Defra would like greater flexibility in establishing systems to ensure better compliance with EU requirements to test a random, annual sample of fallen sheep and goats for TSE in future. We are amending paragraph 6(6) of Schedule 2, Part 1 of the 2008 Regulations to require premises approved under the Animal By-Products (ABP) Regulations to comply with a direction from the Secretary of State to select fallen sheep or goats for TSE sampling and to sample them. Tested carcasses would have to be retained pending a negative test result, unless they were disposed of by incineration or rendering followed by incineration in accordance with the ABP Regulations. These provisions would also apply to any future requirement to sample deer for TSE. Defra will discuss any future changes to the current system with stakeholders.

2.5 Following an opinion from the European Food Safety Authority (EFSA) in November 2008, the EU adopted new controls on milk from sheep and goat flocks in which TSE was suspected, classical scrapie was confirmed or BSE could not be excluded. The main impact is the ban on using milk or milk products from holdings on which TSE is suspected, other than on the holding, until the test result has been confirmed. Sheep or goat milk or milk products can still be used on the holding during this period. A potential impact is the requirement to destroy milk or milk products on holdings on which BSE cannot be excluded in a sheep or goat. Following the confirmation of classical scrapie there are restrictions on the use of milk/milk products in animal feed.

We are making the following changes to the 2008 Regulations to administer these controls:

1. Amending Regulation 15 and Paragraph 4 of Schedule 4 to require an inspector to serve a notice to prohibit the movement of sheep or goat milk or milk products from a holding on which a TSE is suspected in sheep or goats;
2. Amending Regulation 16 to allow inspectors to licence milk or milk products to premises for storage pending the outcome of the confirmatory tests, which are expected to take up to 12 working days from receipt at the laboratory. Sheep or goat milk or milk products can still be used on the holding during this period. Restrictions will be lifted if a TSE is not confirmed or if the TSE is confirmed as atypical scrapie. Defra will not pay for any consequential loss as a result of these restrictions (other than where BSE cannot

subsequently be excluded following testing, and milk or milk products are compulsorily destroyed);

3. Amending Paragraphs 6 and 7 of Schedule 4 to add new requirements for sheep or goat milk or milk products from a holding on which classical scrapie is confirmed, produced prior to the removal of genetically susceptible sheep/all goats. It will be an offence to use such milk/milk products as feed for ruminants (except on the holding of origin). If such milk/milk products are used for feed for non-ruminants it will be an offence:
 - to export the feed from the UK;
 - to fail to comply with the documentation and packaging requirements;
 - to bring such feed on to a premises with ruminants for storage or use; and
 - to fail to comply with the requirements for transport and cleaning and disinfection of vehicles.

The number of classical scrapie affected herds/flocks with genetically susceptible animals in England is very small (2) and we are not aware that there is any significant use of milk/milk products from such herds for animal feed outside the holding of origin.

4. Amending Paragraph 8 of Schedule 4 to add a new requirement for an inspector to serve a notice of intention to destroy sheep or goat milk or milk products on a holding on which BSE cannot be excluded following a test on a sheep or goat. This will apply to milk/milk products on the holding produced from the point of official suspicion to the point at which the herd or flock is culled. Defra will pay compensation at market value for milk or milk products compulsorily destroyed. The owner will be required to arrange and pay for the valuation.
5. Amending Regulation 14 to provide powers for inspectors to seize and dispose of milk and milk products. Regulation 15 will also be amended to allow inspectors to serve notices to require the disposal of milk or milk products.

3. Options

3.1 The proposed options considered were:

3.2 Option 1 (Baseline)

Continue current approach using existing Regulations i.e. do nothing

Costs to Government

Fallen Sheep and Goat Surveillance

Cost of collection and disposal of 10,000 fallen sheep and 500 goats

- GB RPA collection and disposal cost = £90/sheep or goat
- Number of collections = 10,500
- Total cost = 10,500 x £90 = £945,000.

Costs to Industry

None identified

Costs : Environmental

The environmental costs are negligible.

Benefits : Government

Option 1 provides for human and animal health controls on TSEs

Benefits : Industry

Option 1 provides for human and animal health controls on TSEs

3.3 Option 2A and 2B

Apply the amended EU controls and amend the existing Regulations as soon as possible with

Option 2A - Government paying, via RPA contracts, for collection and disposal of 10,000 fallen sheep and 500 goats;

Option 2B – Industry paying, via NFSCo or other collector, for collection and disposal of 10,000 fallen sheep and 500 goats.

Figures 1 and 2 summarise the costs, benefits, and the overall net benefit of the two options.

Figure 1: Summary table of costs and benefits of option 2A

Option 2A – Government costs	
Milk restrictions where BSE cannot be excluded	£4k
Average annual government cost	£4k
Option 2A - Industry costs	
BSE testing home slaughtered animals	£5k
Milk restrictions following confirmation of classical scrapie	£0.16m
Average annual industry cost	0.16m
Total average annual cost of option 2A	£0.17m
Total cost over 5 years	£0.84m
Option 2A – Government benefit	
Total average annual benefit of option 2A	£0
Total benefit over 5 years	£0
Net benefit over 5 years	-£0.84m

Figure 2: Costs and benefits of option 2B

Option 2B – Government costs	
Milk restrictions where BSE cannot be excluded	£4k
Average annual government cost	£4k
Option 2B – Industry costs	
BSE testing home slaughtered animals	£5k
Milk restrictions following confirmation of classical scrapie	£0.16m
Collection and disposal of fallen sheep and goat carcasses e.g. £27/Adult Sheep & £35/Adult Goat based on advice from NFSCo	£0.14m
Average annual industry cost	£0.31
Total average annual cost of option 2B	£0.31m
Total cost over 5 years	£1.55m
Option 2B – Government benefit	
Collection and disposal costs for fallen sheep and goats falling to zero under new scheme	£0.46m
Total average annual benefit of option 2B	£0.46m
Total benefit over 5 years	£2.3m
Net benefit over 5 years	£0.75m

Both Options 2A and 2B are measured against the costs and benefits of the baseline (Option 1). Therefore, any costs and benefits of option 2A and 2B are additional to the costs and benefits of the baseline option. The difference between options 2A and 2B is purely down to the method of collection and disposal of 10,000 fallen sheep and 500 goats. Option 2A assumes the continuation of the RPA method of collection and disposal. Option 2B assumes that industry pays as normal to send carcasses for disposal at ABP premises and that brainstem samples are taken from a 10,000 sample of sheep and a 500 sample of goats at a range of disposal sites without a free collection and disposal service funded by taxpayers.

The largest impact in terms of costs and benefits is due to restrictions imposed on milk, and changes in the method of collection and disposal of 10,000 fallen sheep and 500 fallen goats. Amendments to the regulation such as the BSE testing of home slaughtered cattle lead to much smaller costs, while another amendment, reducing the need for RMOP, has unquantifiable costs.

Option 2A and 2B will provide benefits to animal health. The milk restrictions on suspect TSE premises will reinforce the necessity for stringent biosecurity measures and incentivise good practice. These measures will, in turn, yield increased protection of animal health.

A benefit of option 2B is due to the change in the method of collection and disposal of 10,000 sheep and 500 goats. This leads to an increased cost to industry of £0.14m per annum, but as the government doesn't have to pay for collection and disposal, there is a government benefit of £0.46m per annum. Even though, as before, there is a trade off of cost and benefit between government and Industry, the government actually receives a larger benefit from the change in method of collection and disposal than the industry loses as a cost. The difference in the figures arises because we would expect individual farmers to secure a better deal than is available to government, bearing in mind recent experience when the free collection service for fallen cattle ended in January 2009. Therefore, there is an overall economic benefit to this amendment in the regulation. This amendment is the biggest factor in reaching the £0.75m annual benefit of option 2B. Defra currently provide a free service to farmers, administered under a RPA contract, for the collection, sampling and disposal of sheep and goat carcasses accepted into the survey. This involves considerably less than 1% of fallen sheep carcasses and relatively few fallen goats. Carcasses are currently volunteered by farmers but the survey would be more representative if carcasses could be collected on a random basis at disposal sites. Defra would like greater flexibility in establishing systems to ensure compliance with EU requirements to test an annual quota of fallen sheep and goats for TSE in future. This option would take a similar approach to that adopted for the fallen cattle survey, with farmers paying for collection and disposal in the natural course of disposing of their fallen sheep and goats. Defra could require ABP premises to select a certain number of sheep per week, pay for them to be sampled and sent to the Veterinary Laboratories Agency (VLA) laboratory at Newcastle for analysis. Defra would continue to cover the cost of taking brain samples and testing them at the VLA Newcastle laboratory under all options.

A significant cost to the industry involves the cost of milk restrictions following a suspected case of TSE in goats and sheep. While awaiting the results of the tests, the farmer is banned from using milk or milk products other than on the holding where TSE is suspected. As milk perishes quickly, the milk that is held on the farm for the 2 week restriction period will spoil and cannot be sold by the farmer. There is no requirement for compensation to be paid for this milk and therefore the industry bears the full cost of the milk restriction. It is assumed that milk is disposed of on farm as category 2 animal by-product without significant costs to industry. The cost to industry is calculated in table 2. The annual industry cost of restrictions on goats and sheep milk is assumed to stay constant over 5 years.

Table 1: Annual industry cost due to milk restrictions (Option 2A & 2B)

Size of goat herd	1,000
Number of scrapie cases per herd per year	5
Number of herds affected in England per year	2
Milk yield per goat per week (Litres)	18
Total milk yield per week (Litres)	18,000
Price per litre	£0.40
Number of weeks restricted per suspected case	2
Total amount of goats milk restricted	360,000
Annual industry cost of restrictions on goats milk	£144,000
Size of sheep flock	800
Number of scrapie cases per flock per year	1
Number of flocks affected in England per year	1
Milk yield per sheep per week (Litres)	10.5
Total milk yield per week (Litres)	8,400
Price per litre	£0.90
Number of weeks restricted per suspected case	2
Total amount of sheep milk restricted	16,800
Annual industry cost of restrictions on sheep milk	£15,120
Total industry cost of restrictions on goat and sheep milk	£159,120

Milk restrictions also apply in a case where BSE cannot be excluded. This involves destroying milk or milk products on holdings on which BSE cannot be excluded. It is assumed that milk is disposed of on farm as category 2 animal by-product without significant costs to government. However, in this case, the government would then have to compensate farmers for the milk or milk products destroyed. The cost to government is worked out in table 2. It is clear at the bottom of the table that the cost due to restrictions on milk when BSE cannot be excluded is relatively small as such cases are rare.

Table 2: Annual government cost due to milk restrictions where BSE cannot be excluded (Option 2A & 2B)

Milk restrictions	
Size of goat herd	1,000
Number of goat herds in which BSE cannot be excluded in England per year	0.14285714
Milk yield per goat per week (Litres)	18
Total milk yield per week (Litres)	18,000
Price per litre	£0.40
Number of weeks restricted per suspected case	2
Total amount of goats milk restricted	36,000
Annual cost of restrictions on goats milk (BSE cannot be excluded)	£2,057
Size of sheep flock	800
Number of sheep flocks in which BSE cannot be excluded in England per year	0.14285714
Milk yield per sheep per week	10.5
Total milk yield per week (Litres)	8,400
Price per litre	£0.90
Number of weeks restricted per suspected case	2
Total amount of sheep milk restricted (Litres)	16,800
Annual cost of restrictions on sheep milk (BSE cannot be excluded)	£2,160
Total annual government cost of restrictions on milk where BSE cannot be excluded	£4,217

Another industry cost is the cost of BSE testing home slaughtered cattle. It is estimated that there are 100 home slaughtered cattle in England per annum. Testing and disposal costs per

slaughtered animal are estimated to be £45. Therefore, the cost to industry for BSE testing home slaughtered animals is approximately £5k a year.

Summary

3.4 Option 2B has a net benefit of £0.75m over 5 years relative to the baseline option (Option 1). Option 2A has a negative net benefit of -£0.84m over 5 years relative to the baseline option. The difference between the two options is due to the two different methods of collection and disposal of 10,000 fallen sheep and 500 fallen goats. The collection and disposal costs in option 2B are far cheaper than those in option 2A. Option 2A has a negative net benefit over 5 years relative to the baseline, mostly because of the milk restrictions on farms where TSE is suspected. Option 2B also has this large cost, however, the cheaper collection and disposal costs more than offsets these costs and gives option 2B its positive net benefit. It is difficult to assess whether option 2A is a more beneficial option than the baseline option. Although this impact assessment attributes option 2A with a negative net benefit relative to the baseline, this does not take into account the unquantifiable benefits related to option 2A.

Results of consultation

3.5 One respondent estimated that the saving as a result of the removal of the requirement for an abattoir which does not slaughter cattle requiring BSE testing, to produce an RMOP would result in a one-off saving of £1000. However, we have no data on the number of premises which might benefit from this provision. Another respondent noted the potential for consequential losses as a result of loss of established markets following the application of restrictions on milk from herds and flocks in which TSE was suspected. However these are difficult to quantify. Other than these comments, the consultation did not present any new data.

3.6 As outlined in paragraph 1.5, while the Government remains committed to the principle of table valuations for animals killed to control TSEs, it has decided not to proceed with the proposals for standard valuations for sheep and goats described in the consultation, at this time. The Government intends to continue to develop proposals for a compensation system linked more closely to market data, with the concomitant requirement for a separate impact assessment for such a system

Recommendation

3.6 Following consultation, **Option 2B** is the adopted policy. It will enable application and enforcement of EU controls as updated by recent EU legislation. It will also enable fallen sheep and goat carcasses to be selected at ABP premises after the RPA contracts expire. Defra will discuss any future changes to the current system with stakeholders.

4. Benefits to Government Departments

4.1 There will be no benefits to other Government departments in England. (The Scottish Government, Welsh Assembly Government and Northern Ireland Assembly will be making similar changes in Scotland, Wales and Northern Ireland).

5. Competition

5.1 There will not be any direct or indirect limits to the number or range of farms in the industry caused by the proposed changes to the Regulations. The proposed Regulations will not change farmers' incentives or abilities to compete with each other.

6. Administrative Burdens

6.1 Any impact upon existing administrative burdens is expected to be too negligible to quantify.

7. Enforcement

7.1 Enforcement will be risk based and proportionate in accordance with Hampton principles. <http://www.defra.gov.uk/corporate/enforcement/enforce-policy-rev0808.pdf>

8. Race, Equality and Gender Impacts

8.1 There will be no race, equality or gender impacts resulting from the proposed changes to the Regulations

9. Small Firms Impact Test

9.1 A Small Firms Impact test was carried out during the consultation. The new measures must apply to small and medium enterprises (SMEs) but the additional impact is not expected to be significant as only a very small number of SMEs will be affected by the new measures. The new measures could be met by SMEs within their normal working practices.

Specific Impact Tests: Checklist

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	Yes
Sustainable Development	No	Yes
Carbon Assessment	No	Yes
Other Environment	No	Yes
Health Impact Assessment	No	Yes
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Annex 1: Proposed Technical Amendments

Transmissible Spongiform Encephalopathy (England) Regulations 2008

Regulation 21

The new Regulations update the definition of "animal by-product"

in regulation 3 of the Animal By-Products (Identification) Regulations 1995 as follows:

- The definition as "animal by-product," of products derived from bovine animals born or reared in the UK before 1 August 1996 refer to paragraph 1 of Schedule 8 to the proposed Regulations.
- The definition as "animal by-product," of carcasses, or parts of carcasses, of bovine animals which have been slaughtered for human consumption, other than in accordance with an approved RMOP, and thus require disposal, refer to regulation 15 of the new Regulations.

Schedule 1

Schedule 1 lists the pieces of EU legislation which, whenever amended, automatically fall within the provisions of the new Regulations. This means that the new Regulations continue to administer the corresponding EU legislation even if it is amended. The new Schedule includes the following Commission Decisions:

- Commission Decision 2007/411/EC which prohibits the placing on the market of products derived from bovine animals born or reared within the United Kingdom before 1 August 1996. No amendments to this Decision are currently proposed.
- Commission Decision 2007/453/EC establishing the BSE status of Member States or third countries according to their BSE risk. This Decision has been amended by Commission Decision 2008/829/EC and by Commission Decision 2009/830/EC.
- Commission Decision 2009/719/EC authorising certain Member States to revise their annual BSE monitoring programmes. This Decision has been amended by Commission Decision 2010/66/EC. Optional increases in the BSE testing age of cattle slaughtered for human consumption, resulting from any future amendments of Commission Decision 2009/719/EC would only be implemented if they were agreed by Defra and Health Ministers on the basis of advice from the FSA.

Schedule 2

Paragraph 2 (1) of Schedule 2. This paragraph is amended to clarify the definition of a bovine animal which was born or reared in the UK before 1 August 1996 and that it is an offence to slaughter these animals for human consumption.

Paragraphs 3(1)(c) and 4(3) of Schedule 2, Part 1. This amendment enables slaughterhouses to send brain stem samples from cattle to suitably designated laboratories in other Member States for BSE testing, as required by the EU Services Directive 2006/123/EC. There are two private companies with a total of four laboratories in Great Britain approved to carry out BSE testing of cattle slaughtered for human consumption. Thus we believe that the likelihood of slaughterhouses choosing to send samples for testing outside the UK is remote.

Paragraph 6(6) of Schedule 2, Part 1. This paragraph is amended to retain an equivalent provision to those currently in Paragraph 5 of Schedule 5 of the 2008 Regulations, which requires the retention of deer carcasses sampled for TSE and the disposal of any carcasses testing positive for a TSE. The provision in Schedule 5 has been deleted as it relates to a specific EU requirement that is no longer applicable.

Paragraph 6(7) of Schedule 2, Part 1. This paragraph has been deleted as the contract for Agricultural and Horticultural Development Board to carry out this work terminated on 31 March 2009. Animal Health is now responsible for carrying out official TSE controls at hide markets and tanneries.

Paragraph 1(E) of Schedule 2, Part 1. This paragraph has been amended to clarify that the exemption in paragraph 1E applies to animals which die in the Isle of Wight, even if their carcasses are disposed of on the mainland. It also extends the exemption to the Isles of Scilly and Lundy Island. This is a technical change as the Government-funded fallen stock collection service which operated prior to 12 January 2009 did not cover these two areas, which are also categorised as “remote areas” under the ABP Regulations 2005.

Paragraph 10 of Schedule 2, Part 2. This has been amended to refer to cattle which require BSE testing.

Paragraph 5 of Schedule 2, Part 1. Regulation (EC) No.716/96 provided for the Older Cattle Disposal Scheme (OCDS) which ceased to exist on 1 January 2009. A reference to this Regulation in Paragraph 5 of Schedule 2, Part 1 of the 2008 Regulations has been removed.

Schedule 3

Paragraph 3(5) of Schedule 3. Under the 2008 Regulations, where a bovine animal suspected of being affected with BSE was not killed immediately, the keeper was obliged to dispose of its milk in such a way that it could not be consumed by humans or animals, other than the suspect’s own calf or animal kept for research purposes. We have removed this requirement as the results of FSA-funded research, together with previous epidemiological and experimental research provided no evidence for the transmission of BSE via milk. However, the food ban will remain as the EC Food

Hygiene Regulation 853/2004 requires that raw milk for human consumption must come from animals which are in a good general state of health.

Paragraph 5 of Schedule 3 This has been amended to clarify the existing procedures for appealing against the inspector's decision to kill a cohort animal. It has also been amended to clarify the option of deferring the killing of a cohort animal which is a bull kept permanently in a semen collection centre, until the end of its productive life.

Schedule 4

Paragraph 9(6) of Schedule 4. To help monitor compliance with existing atypical scrapie controls, we have amended paragraph 9(6) of Schedule 4 to require the owner to identify the sheep and goat as directed by the Secretary of State (e.g. using a dedicated tag which marks the animal as not for export) and to make it an offence to remove this identification unless permitted by the Secretary of State.

Paragraph 15 of Schedule 4. This has been clarified to require subsequent occupiers of premises, to comply with a notice served on a previous occupier.

Paragraphs 6 and 7 of Schedule 4

In 2008 the European Court of First Instance suspended the option of replacing the killing and destruction of genetically susceptible sheep and all goats, following the confirmation of classical scrapie in a flock or herd, with testing of fallen sheep/goats and abattoir culls aged over 18 months. The EU TSE Regulation contains a derogation allowing Member States to delay killing for up to 5 breeding years where the frequency of the ARR allele within the breed or holding is low or absent or where a delay is necessary to avoid inbreeding. Regulation (EC) No.103/2009 reduced the delay in dairy herds or flocks from 5 breeding years to 18 months and it requires that all breeding rams on the premises are NSP Type 1 (ARR/ARR). The movement restrictions referred to in paragraphs 16, 17 and 18 of Schedule 4 of the 2008 Regulations apply to the holding while culling is being delayed. We are currently using the EU derogation to delay the culling of goat herds in which classical scrapie has been confirmed.

New paragraph in Schedule 4. To enable us to operate more transparently, we have introduced a provision allowing farmers wishing to take advantage of the derogation, to apply in writing to the Secretary of State setting out the reasons for the application. Animal Health will consider applications on behalf of the Secretary of State. The appeals process applies to applications approved in part or refused. We also propose introducing a provision allowing the Secretary of State to apply the derogation directly.

Paragraph 21 of Schedule 4. This has been corrected to refer to progeny.

Schedule 5

Paragraph 5 of Schedule 5. This has been removed as the survey for TSEs in farmed and wild red deer required by Commission Decision 2007/182/EC has been completed. This is linked to the changes in Paragraph 6(6) of Schedule 2, which retain an equivalent provision to those currently in Schedule 5.

Schedule 6

Paragraph 1 of Schedule 6, Part 1. This paragraph has been amended to permit the feeding of fishmeal to unweaned ruminants in reconstituted milk replacer in line with Regulation (EC) No.956/2008. Farms wishing to bring such milk replacer containing fishmeal on to their premises where ruminant animals are kept (and feed it to unweaned ruminants) must register with Animal Health on behalf of the Secretary of State. This mirrors the requirements for feeding feed containing fishmeal to non-ruminants (e.g. pigs and poultry). Milk replacer powder containing fishmeal must be produced in mills authorised by Animal Health (AH) on behalf of the Secretary of State and labelled and transported in accordance with Regulation (EC) No.956/2008. Again this mirrors the requirements for producing feed containing fishmeal for non-ruminants (e.g. pigs and poultry). We believe that the impact on feed businesses will be very small as the feed industry has advised that there is no significant demand for producing this type of product in England.

Paragraph 1(1) and Paragraph 2(3)(f) of Schedule 6, Part 1. This amendment extends the current provision allowing AH on behalf of the Secretary of State to permit the use of root crops and feedingstuffs containing such products in which insignificant amounts of bone fragments had been detected, on the basis of a favourable veterinary risk assessment (i.e. whether the feed poses a significant risk of generating new TSE infections), to all feed materials of plant origin. This is in line with Regulation (EC) No.162/2009 which covers the unavoidable presence of insignificant amounts of animal bone fragments (e.g. soil, rodents, birds) in crops and reflects the sensitivity of current detection methods. The risk assessment would consider the amount (e.g. using qualitative laboratory techniques) and probable source (e.g. using production and tracing data and species-specific laboratory tests) of the bone fragments. It would also consider the final destination of the feed (e.g. whether for ruminants or non-ruminants). For feed produced in Great Britain, AH would assess the risk with technical input from the VLA, the National Reference Laboratory for animal protein in feed. We believe that the impact on businesses will be very small as the feed testing programme to date suggests that this type of contamination is very rare.

Paragraph 8(3) of Schedule 6, Part 2. In September 2008, the EU adopted Regulation (EC) No.956/2008 which made a change to the requirements for packaging of feed for non-ruminants (e.g. pigs/poultry) containing fishmeal. This required the packaging to be “clearly marked” with the words “contains fishmeal must

not be fed to ruminants”, rather than simply for the “label” to “clearly indicate” these words. This followed reports of the use of detachable labels such that bags were no longer properly identified as containing fishmeal if the label became detached. The new requirement for the declaration to be printed or stuck directly (i.e. “marked”) on the bag is already legally binding because of the ambulatory clause in Schedule 1.

Paragraph 14 of Schedule 6, Part 2. We have amended this paragraph to require written consent from an inspector when using equipment used to produce milk replacer containing fishmeal, to produce feed for weaned ruminants.

Paragraph 17(1) of Schedule 6, Part 2. This amendment exempts the export of petfood containing processed animal protein of ruminant origin, from the general ban on exporting processed animal protein of ruminant origin to third countries. This is in line with Regulation (EC) No.956/2008. We do not have figures on the potential export of petfood which contains processed animal protein of ruminant origin to third countries.

Schedule 7

Paragraph 3(3). The definition of “mechanically separated meat” in of the 2008 Regulations is superfluous and has been deleted because “mechanically separated meat” automatically has the same meaning as the EU TSE Regulation. The prohibition on production of mechanically separated meat is covered by the direct reference to the EU TSE Regulation in Paragraph 3(1) of Schedule 7.

Paragraph 16. This has been deleted as the OCDS ceased to exist on 1 January 2009.

Schedule 8

Paragraphs 1A and 1B. We have amended these paragraphs to clarify the definition of a bovine animal which was born or reared in the UK before 1 August 1996. This is linked to the changes at Paragraph 2(1) of Schedule 2.

Paragraph 1A(3). This has been deleted as the Agricultural and Horticultural Development Board no longer require powers of inspectors at hide markets and tanneries in relation to OCDS hides. AH is responsible for carrying out other official TSE controls at hide markets and tanneries.

We have added a new paragraph to Schedule 8 which provides a cross-reference to offences relating to placing on the market and export in Schedules 3, 4 and 6.

Annex 2: Outcome of Impact Tests Not Referred to in the Evidence Base

Legal Aid

No increase anticipated.

Sustainable Development

The proposed amendments to the Regulations are in accordance with the shared UK principles of sustainable development

Carbon Impact Assessment

The proposed amendments to the Regulations will have no significant effect on carbon emissions as the nature and scale of cattle, sheep and goat production and marketing is likely to remain the same.

Other Environmental Issues

As the nature and scale of cattle, sheep and goat production and marketing is likely to remain the same, the proposed amendments to the Regulations have no implications in relation to climate change, waste management, landscapes, water and floods, habitat and wildlife or noise pollution.

Health Impact Assessment

The proposed amendments to the Regulations will not directly impact on health or well being and will not result in health inequalities.

Race/Disability/Gender

There are no limitations on meeting the requirements of the proposed amendments to the Regulations on the grounds of race, disability or gender. The proposed amendments to the Regulations do not impose any restriction or involve any requirement which a person of a particular racial background, disability or gender would find difficult to comply with. Conditions apply equally to all individuals and businesses involved in the activities covered by the proposed amendments to the Regulations.

Human Rights

The proposed amendments to the Regulations are consistent with the Human Rights Act 1988.

Rural Proofing

The majority of producers and many of the suppliers are based in rural areas and the proposed amendments to the Regulations are designed to facilitate their activities.

Annex 3: Glossary

Acronym	Term	Definition
ABP	Animal By-Products	As per Animal By-Products Regulations 2005.
AH	Animal Health	An executive agency of Defra.
BSE	Bovine Spongiform Encephalopathy	Fatal brain disease in cattle. Exposure to meat from BSE-infected cattle is believed to be the primary cause of vCJD in humans.
Defra	Department for Environment, Food and Rural Affairs	
EFSA	European Food Safety Authority	As per Regulation (EC) No.178/2002.
EU	European Union	An economic and political union of 27 Member States.
FSA	Food Standards Agency	
LA	Local Authority	Local Authority in England.
MHS	Meat Hygiene Service	An executive agency of the Food Standards Agency.
NFSCo	National Fallen Stock Company	A not for profit, farmer led organisation that aims to provide a national service for the collection and disposal of fallen stock that farmers use from choice.
NSP	National Scrapie Plan	The programme for breeding for genetic resistance to classical scrapie in sheep flocks.
OCDS	Older Cattle Disposal Scheme	An exceptional market support measure providing for disposal of, and compensation for, cattle born or reared in the UK before August 1996. It replaced the Over Thirty Month Scheme on 23 January 2006 and ended on 31 December 2008.
RMOP	Required Methods of Operation	Document agreed between the Meat Hygiene Service and abattoir operators describing how the plant will process eligible cattle for human consumption. It is a legal instrument required by law.
RPA	Rural Payments Agency	An executive agency of Defra.
TSE	Transmissible Spongiform	Fatal brain disease including scrapie in sheep and goats and BSE in cattle.

	Encephalopathy	
SRM	Specified risk material	Defined tissues which pose the greatest risk of TSE infectivity in an infected animal.
vCJD	Variant Creutzfeldt-Jakob Disease	Fatal brain disease in humans. Exposure to BSE through eating infected meat is believed to be the primary cause.
VLA	Veterinary Laboratories Agency	An executive agency of Defra.