Summary: Intervention & Options

Department /Agency:	Title: Impact Assessment of the Transmissible Spongiform Encephalopathies (England) Regulations 2008	
Stage: **OPTIONS**	Version: **2**	Date: **18 March 2008**
Related Publications:		

Available to view or download at:

http://www.defra.gov.uk/corporate/consult/tse-regs2007/index.htm

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

Rules for the prevention, control and eradication of Transmissible Spongiform Encephalopathies (TSEs) are regulated under domestic law by the Transmissible Spongiform Encephalopathies (No. 2) Regulations 2006 (as amended) (hereafter known as the 2006 Regulations). The Government proposes amendments to the Compulsory Scrapie Flocks Scheme (CSFS) which will provide scrapie controls in the UK that are flexible, meet the degree of risk involved, and place UK sheep and goat farmers on the same footing as their competitors in Member States. There are also related technical amendments.

What are the policy objectives and the intended effects?

To maintain protection for human and animal health while reducing scrapie controls and adminstrative costs, and improving market conditions for sheep and goat producers and for exporters, by amending domestic legislation in accordance with changes in EU legislation while seeking to minimise or reduce any burdens to these sections of the livestock and feedstuff industries.

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

- Continue current approach- using existing regulations (Do nothing).

- Apply the amended EU controls- change the existing regulations

(This is the preferred option as it would enable application and enforcement of the more flexible and cost effective EU controls.)

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

January 2010

Ministerial Sign-off **For consultation stage Impact Assessments:**

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

.....Date: 1 March 2008

Summary: Analysis & Evidence

Policy Option: 2	Description: Amend existing controls and change Regulations as soon as possible

COSTS

ANNUAL COSTS

One-off **(Transition)**	Yrs
£ 0	**8**
Average Annual Cost **(excluding one-off)**	
£ -2,400,000	

Description and scale of key monetised costs **by 'main affected groups'**

Annual cost to government : -£1,183,000 (a cost saving)
Annual cost to farmers : -£17,000 (a cost saving)
Annual cost to industry (schedule 2): -£297,000 (a cost saving)

Total Cost **(PV)** £ -10.7m

Other key non-monetised costs **by 'main affected groups'** **None**

BENEFITS

ANNUAL BENEFITS

One-off	Yrs
£ 0	**8**
Average Annual Benefit **(excluding one-off)**	
£ 0	

Description and scale of key monetised benefits **by 'main affected groups** **These changes to the TSE regulations will not impact on the benefits of the overall regulations in terms of disease control. The benefits are the same as those under the baseline option. Benefits of these changes are in terms of reduced costs as explained in the costs section above which then translate into an overall NPV benefit (see below).**

Total Benefit **(PV)** £ 0

Other key non-monetised benefits **by 'main affected groups'** **The benefits are the same as those under the baseline option.**

Key Assumptions/Sensitivities/Risks **Total number of revised controls in England. That there will be no costs to the public from reduced controls and no revised risk to human or animal health.**

Price Base	**Time Period**	Net Benefit Range **(NPV)** £ 10.7m	NET BENEFIT **(NPV Best estimate)** £ 10.7m

What is the geographic coverage of the policy/option?			**England**	
On what date will the policy be implemented?			**July 2008**	
Which organisation(s) will enforce the policy?			**Animal Health/LAs**	
What is the total annual cost of enforcement for these organisations?			**£ No increase**	
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?			**£ unknown**	
Will the proposal have a significant impact on competition?			**No**	
Annual cost (£-£) per organisation (excluding one-off)	**Micro** £0-£400	**Small** £0-£400	**Medium** na	**Large** na
Are any of these organisations exempt?	**No**	**No**	**N/A**	**N/A**

Impact on Admin Burdens Baseline **(2005 Prices)** **(Increase - Decrease)**

Increase **£ 0** **Decrease** **£ 500** Net Impact £

Key: Annual costs and benefits: Constant Prices (Net) Present Value

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

1. Introduction and legislative background

1.1 Transmissible Spongiform Encephalopathies (TSEs) are fatal brain diseases suffered by a variety of species, the most common of which are BSE (Bovine Spongiform Encephalopathy) in cattle, scrapie in sheep and goats, CWD (Chronic Wasting Disease) in deer and FSE (Feline Spongiform Encephalopathy) in cats. Exposure to BSE through the consumption of infected meat products is also thought to be the most likely cause of vCJD (variant Creutzfeldt-Jakob Disease) in humans. To date there have been 163 deaths from probable vCJD in the United Kingdom (UK) as at 3 March 2008.

1.2. Rules for the prevention, control and eradication of TSEs are regulated under EU law by Regulation (EC) No 999/2001 of the European Parliament and the Council, as amended from time to time (hereafter known as the Community TSE Regulations), and under domestic law by the Transmissible Spongiform Encephalopathies (No. 2) Regulations 2006 (hereafter known as the 2006 Regulations).

1.3. In the 22 months since the 2006 Regulations came into force, a number of relatively minor amendments have become necessary due to amendments to Regulation (EC) 999/2001. Many clarify the requirements of the 2006 Regulations and do not impose any burden, in other words their effect can be regarded as neutral.

1.4. The only substantial changes proposed are at Schedule 3 of the 2006 Regulations. A detailed consideration is given at Sections 2-7 below. Two small changes with lesser financial impacts are proposed at Schedules 2 and 8. Their impact is considered at Annex 2. The other amendments proposed, which are expected to have a minimal impact, are listed at Annex 3.

1.5 There are two further changes to the TSE legislation which may be required before the legislation is submitted to Parliament. The first relates to the conclusion of a separate consultation exercise on Responsibility and Cost Sharing (RCS) for Animal Health and Welfare. This change, if agreed by Defra Ministers, would allow for the charging of any private BSE testing laboratories wishing to become approved, for both the initial approval process and for the necessary quality assurance monitoring by the National Reference Laboratory for BSE (the Veterinary Laboratories Agency (VLA)). Further details of this particular measure can be found in the Impact assessment prepared for the RCS consultation at:
http://www.defra.gov.uk/corporate/consult/ahw-nextsteps/impact-assessment.pdf

1.6 The second possible change would be a technical amendment incorporating into the TSE legislation, certain provisions relating to the ban on pre-August 96 cattle from entering the food chain, currently contained in the Bovine Products (Restriction on Placing on the Market) (England) (No 2) Regulations 2005 as amended. This is FSA legislation which will be revoked once the TSE legislation has been amended. This is purely a de-regulatory measure with no impact on industry or consumers.

2. Schedule 3 of the 2006 Regulations: Detailed Consideration

Background

2.1. Sheep and goat farmers are small businesses. In England in 2006, there were over 50,000 holdings with 15.673 million sheep. The value of lamb and mutton produced in 2006 was £702 million.

2.2. Scrapie, a Transmissible Spongiform Encephalopathy (TSE), is a fatal disease of sheep and goats. It is a notifiable disease and can be transmitted within and between flocks and/or herds.

2.3. There is a theoretical risk that Bovine Spongiform Encephalopathy (BSE) might have been transmitted to sheep and if so it might be masked by scrapie. So flocks affected by scrapie could represent a reservoir of infection and potential public health risk.

2.4. As a result EU controls were introduced in 2003. These require that sheep flocks with a confirmed case of scrapie are subject to either a whole flock cull or a genotype and selective cull, under which all the sheep in the flock are genotyped by taking a blood sample. Those sheep with genotypes that scientific research had shown to be more susceptible to infection by the form of scrapie now known as classical scrapie are culled.

2.5 Strict controls then apply to movements on and off the farm. Depending on its genotype, which determines the resistance to scrapie, a sheep:

- may be retained or sold for breeding,
- may be required to be sold for slaughter,
- or must be collected by Defra contractors and killed and destroyed as Specified Risk Material (SRM).

2.6 Current scientific knowledge suggests that goats are uniformly susceptible to scrapie regardless of their genotype. Therefore, the only option allowed in the EU Regulation introduced in 2003 for goat herds with a confirmed case of scrapie is to cull the whole herd.

3. The Compulsory Scrapie Flocks Scheme

3.1. The EU controls are applied via the Compulsory Scrapie Flocks Scheme (CSFS) throughout Great Britain, and the TSE (No 2) Regulations 2006 provide enforcement powers in England (Similar legislation applies in Scotland and Wales).

3.2. There are currently around 240 farms (440 flocks plus 3 goat herds) under the controls in Great Britain (GB) (of which 96 (156 flocks plus 3 goat herds) are in England). In 2006 Defra spent around £9m in Great Britain in applying the controls mainly for killing and destroying animals and compensating for them. The cost of applying the genotype and selective cull option to each flock is estimated at £55K and to cull the whole flock is £73K.

3.3. The scheme is administered by Animal Health with the Veterinary Laboratories Agency (VLA) undertaking TSE testing aspects. Local Authorities are responsible for monitoring movements from CSFS farms and for enforcement under the TSE regulations.

4. Changes in EU controls

4.1. The EU controls were introduced at a time when it was not possible to determine if a TSE was scrapie or BSE (theoretically scrapie could be masking BSE). However new diagnostic tests mean that this is now possible. The new diagnostic tests also confirmed the presence of a previously undetected form of scrapie, termed **atypical** scrapie to differentiate it from the form of scrapie known to have been in the national flock and herd for more than 200 years and now referred to as **classical** scrapie. Atypical scrapie has been found in sheep with genotypes that are resistant to classical scrapie as well as sheep with genotypes susceptible to classical scrapie. As a result, the EU Commission proposed a review and relaxation of the EU controls in relation to animals from flocks where BSE is excluded and to provide a suitable approach for dealing with atypical scrapie. Changes to the controls were agreed in April 2007. Amended EU Regulation 999/2001 applied from 17 July 2007. However as a result of a European Court of First Instance ruling, the relevant parts of the EU Regulation (EC) No.727/2007 that allowed Member States new flexibility in dealing with flocks and herds affected with classical scrapie has been suspended with effect from 28 September 2007.

4.2. The remaining changes to the controls following that suspension involve:

1. A monitored flock/herd option allowing flocks and herds with atypical scrapie to be monitored for a 2 year period, as an alternative to whole flock or herd cull. This option involves TSE testing of all fallen stock over 18 month of age and all animals over 18 months of age sent to slaughter in the UK for human consumption.

2. Reducing the period of restrictions in flocks affected by classical scrapie to 2 years (from 3 years).

5. Policy objective and effect

5.1. The UK's aim is to have scrapie controls that are flexible and reflect the degree of risk involved and we have been pressing for some time for changes to the EU controls to reflect this. The revised EU controls meet this objective with regard to atypical scrapie.

5.2. The effect of applying these amended controls is to help eradicate scrapie in affected flocks/herds in a way that is cost effective with regard to the risk of scrapie in a particular flock/herd affected with atypical scrapie

6. Businesses affected/assumptions

6.1. The business sectors affected are sheep and goat farms with suspected cases of classical and atypical scrapie. In England in 2005, 75 flocks from 44 holdings were entered into CSFS and in 2006, 49 flocks from 32 holdings. For a number of reasons including a decrease in the EU requirement for surveillance at abattoir and of fallen stock, and as a result of the work of the National Scrapie Plan since its inception in 2001, we estimate that the decrease in the number of cases of classical scrapie over the coming years will continue.

6.2. Where atypical scrapie has been found it is generally only an isolated case on a holding. Most cases are discovered by the EU Regulatory TSE surveillance of animals at abattoirs and fallen stock. Cases of atypical scrapie are expected to remain relatively constant and be found in single cases on farms as opposed to classical scrapie, where action may be taken on several flocks within the same farm unit.

6.3. Given the progressive reduction in the number of confirmed classical scrapie cases and the relatively stable number of confirmed atypical scrapie cases in recent years, we have assumed that there will be around 14 farms (22 flocks) with new classical scrapie cases in year 1 in England, declining to 6 farms (10 flocks) a year by year 8. We have assumed that there will be 15 farms (flocks) with atypical scrapie each year.

6.4. Based on the average number of animals in CSFS flocks to date, we have assumed that an average size flock is 500 adult animals, plus up to 700 lambs depending on the time of year. From information provided by sheep industry groups, we know that annual replacement rates (regardless of whether the flock is producing lambs for slaughter or breeding animals for use or sale) are somewhere between 20 and 30%. Therefore we have based our calculations on an annual adult replacement rate per flock of 25%. Depending on the nature and geographic location of a flock, the average adult mortality rate can vary between 2 and 5% per year. Therefore, we have assumed an overall average adult mortality rate of 3% per year.

7. Options

7.1. The proposed options are:

7.2 *Option 1 (Baseline)*

Apply current EU controls

This would not meet the objective of applying flexible controls that are cost effective in dealing with atypical scrapie. It would also be inconsistent with the latest EU regulation and would put our farmers with flocks affected with atypical scrapie at a disadvantage compared with those in other EU Member States.

Costs: Economic

Costs to Government

The current EU controls require either whole flock cull or genotype and selective cull where scrapie is confirmed in a sheep flock. (For a goat herd the only option is a whole herd cull).

As explained above, atypical scrapie is found in sheep with genotypes that are resistant to classical scrapie as well as in sheep with genotypes more susceptible to classical scrapie. Therefore, as a genotyping approach to control atypical scrapie in sheep is not practical, the whole flock is culled, the carcases are destroyed as Specified Risk Material and the farmer is compensated for these animals.

1. Whole flock cull of sheep flocks with atypical scrapie

Assuming that there will be 15 cases of atypical scrapie each year.

Average annual cost is 15 flocks x cost of Whole Flock Cull £73,000 = £1,095,000 (annex 1 table 4)

2. Genotyping and selective cull of sheep flocks with classical scrapie

For the sheep flocks that are affected with classical scrapie, genotype and selective cull action can be applied. As explained above, we expect that there would be 22 cases of classical scrapie in the first year, declining to 10 by year eight. It costs an average of £55,000 per flock to apply genotype and selective cull action.

The average annual cost is estimated to be £880,000 (Annex 1 table 3)

The estimated average annual cost to Government is £1,975,000 under Option 1.

Costs to farmer:

Genotype and selective cull of sheep flocks with classical scrapie

22 flocks under Genotype and selective cull action

1. Farmer's time gathering animals, dealing with NSPAC paperwork -2 days, £260 per flock

2. Farmer's time sourcing replacement animals for approximately 50% of adult flock that either must be sold for slaughter or killed and destroyed as SRM after genotype and selective cull action. They will spend the time sourcing replacements. This is a labour intensive action of one working week on average: £650 per flock

Total of 1. & 2. £910 per flock

Average annual cost: £14,560 (Annex 1 Table 1)

Whole flock cull of sheep flocks with atypical scrapie

3. In the 15 holdings affected by atypical scrapie, farmers will have to spend approximately half a day on additional paper work relating to CSFS during the year e.g. additional record

keeping in dealing with legal notices and other CSFS administration paper work: £65 per flock

4. In the 15 holdings affected by atypical scrapie, farmers will have to source replacement animals after whole flock cull action. They will spend time sourcing replacements. This is a labour intensive action of one working week on average: £650 per flock

Total 3. & 4. £715 per flock

Average annual cost: £10,725 (Annex 1 table 2)

***Total average annual cost to farmers = £25,285**

Total economic costs of Option 1 are therefore estimated at £2,000,285 per annum.

Costs: environmental

Atypical scrapie:

If we applied a whole flock cull to atypical flocks then there would be an increase in the number of animals incinerated. Assuming 20 rams and 480 ewes in 15 flocks and action required when two thirds of them have 700 lambs on the ground.

Rams (110 -130kg per animal)x 20 rams x 15 flocks =300 Rams

Weight incinerated = 33,000-39,000kg

Ewes (60-85 kg per animal) 480 ewes x 15 flocks = 7,200 ewes

Weight incinerated = 432,000-612,000kg

Lambs (25-35kg per animal) 700 animals x 10 flocks = 7,000 lambs

Weight incinerated = 175,000-245,000kg

Total 14,500 sheep (maximum weight) = **640 - 890 tonnes**

Classical scrapie:

22 flocks with 500 adults (20 Rams and 480 ewes) and possibly 700 lambs per flock will be genotyped and susceptible animals culled and destroyed.

Assume 35% of adult flock would have been destroyed because of unsuitable genotypes under genotype and cull action = 7 Rams and 161 ewes per flock

Assume 50% of the 22 flocks which come under scrapie controls involve lambs that are taken and destroyed without genotyping.

(assume weights of 60-70kg for a ewe, 110-130kg for ram. and 25-35kg for a lamb).

Rams (110 -130kg per animal)x 7 rams x 22 flocks =154 Rams

Weight incinerated (154x [110 -130kg per animal]) = 16,940-20,020kg

Ewes (60-85 kg per animal) 161 ewes x 22 flocks = 3,542 ewes

Weight incinerated (3,542x[60-85 kg per animal]) = 212,520-301,070kg

Lambs (25-35kg per animal) 700 animals x 11 flocks = 7,700 lambs

Weight incinerated (7,700x[25-35kg per animal]) = 192,500-269,500kg

Total 11,396 sheep (maximum weight) = **422 – 590 tonnes**

The total weight of sheep that would be incinerated under Option 1 is therefore between **1,062 and 1,480 tonnes** in the first year

Benefits: Government

This option will reduce sources of TSE infection from known scrapie-affected flocks and prevent transmission to other flocks thus reducing the level of scrapie infection in the national flock and saving the taxpayer the cost of dealing with flocks that may otherwise have become infected. This option reduces a theoretical risk to human and animal health from BSE masked as scrapie.

Benefits: Farmer

This option will eliminate scrapie on farms with known infection and reduce the risk of re-occurrence. This will reduce a theoretical risk to human and animal health from BSE masked as scrapie and therefore help to preserve consumer confidence in sheep meat.

7.3 *Option 2*

Apply amended EU controls and change SI as soon as possible

This would meet the policy objective. It would enable us to apply the controls in a flexible and cost effective way, in line with EU legislation, and enable us to enforce them.

Under this option we assume all the classical cases would be subject to the Genotype and selective cull option and atypical scrapie cases will be subject to the Monitored flock option. The split in the first year would therefore be:

Classical scrapie cases - Genotype and selective cull option	= 22 flocks
Atypical scrapie cases - Monitored Flock option	= 15 farms

Costs: Economic (in addition to the costs and benefits of Option 1)

Costs to Government

Atypical scrapie -Monitored flocks

1. There will be an additional cost to Government in collecting fallen stock from atypical scrapie flocks that now come under CSFS control measures

- 3% adult mortality = 15 animals per flock x 15 flocks per year = 225 fallen stock per year.

The average cost of collecting a fallen stock carcase, removing the head and incinerating the carcase, delivering the head to a VLA laboratory, removing the brain sample at the VLA laboratory and testing for the presence of TSE including discriminatory test for BSE is approximately £200.

Cost per flock is £3,000.

- The average annual cost to Government is estimated at £85,000 (Annex 1 table 7)

2. There will be an additional cost to Government of TSE testing the difference between all annual culls from atypical scrapie flocks monitored under option 2 and TSE testing the sample of annual culls that would be required if the flock was restocked after whole flock cull under option 1. On average 125 – 100 = 25 animals per flock.

Cost per flock £2,000

- The average annual cost to Government is estimated at £56,000. (Annex 1 Table 6)

There are not expected to be additional costs to delivery agents- Animal Health or VLA -or to Local Authorities who enforce the legislation as any extra burden in dealing with atypical scrapie will be offset by the reduction in the restriction period from three years to two years in genotyping and selective cull cases.

There will be no costs to other Departments.

Total annual cost to Government = £140,600

Cost to farmers

It is not expected that farmers with detected or reported cases of classical scrapie in their flocks will incur any additional one-off costs arising from the new controls. At present owners of flocks with classical scrapie are required to submit a sample of annual culls slaughtered for the food chain for TSE testing (100 animals per average flock size).

Atypical Scrapie- Monitored Flocks

1. As indicated above, we assume that there will be around 15 farms/flocks with atypical scrapie coming under the controls per year – they will be restricted and monitored for 2 years which will involve sending over 18 month fallen stock and annual culls for slaughter for TSE testing. (They will be able to send animals off for breeding in the UK but not to other Member States). Farmers are not expected to incur any additional one-off costs.
2. Regarding annual costs – they will incur nothing for collection of fallen stock as Government pays for this, but will have additional costs for annual culls as follows:

- 25 additional annual culls for human consumption now required to be tested. 2 hours farmers time gathering animals and completing NSPAC paper work in connection with the collection : £33 per flock, :

3. Farmers will also have to spend approximately half a day on additional paper work relating to CSFS during the year e.g. additional record keeping in dealing with legal notices and other CSFS administration paper work. £65 per flock

- Total 2 & 3 = £98 per flock

Total average annual cost to farmers = £2,756 (Annex 1 table 5)

Saved Costs to Government

Classical scrapie cases

1. There will be benefits to the taxpayer from reduced expenditure in collecting fallen stock from flocks with classical cases of scrapie as a result of the reduction of the restriction period from three to two years.

- Cost saving per flock per year is £3,000-

average annual cost saving £100,500 (Annex 1 table 11)

Atypical scrapie

2. There will be cost savings from not culling all atypical scrapie affected flocks (estimated 15 flocks pa).

- Cost saving per flock £73,000

  Average annual cost saving £1,095,000 (annex 1 table 12)

Saved costs to farmers

Classical scrapie cases

Sheep and goat farms with confirmed cases of classical scrapie will benefit. Current members of the scheme whose flocks have been genotyped with culling of susceptible genotypes will be subject to a reduction in the period of restrictions from three years to two years. There is a lot of paper work involved in CSFS. Farmers have to deal with legal notices, genotype and slaughter certificates, collection notices and correspondence with NSPAC and the owner should benefit by not having to spend two days in total on dealing with this administrative burden.

1. There are 156 flocks in England currently under genotype and selective cull action for which there will be a one-off reduction in the three year period of restrictions to two years of restrictions.

- Farmer's time gathering animals, dealing with NSPAC paperwork -2 days :

£260 per flock,

£40,510 annual cost saving in the first year only (Annex 1 table 9)

New Classical scrapie cases from August 2007

2. The farmers whose flocks enter the CSFS from August 2007 will also benefit from being subject to scrapie controls for 2 years instead of 3 years.

  - Farmer's time gathering animals and dealing with NSPAC paper work :

£260 per flock (2 days work),

average annual cost saving £4,155.(Annex 1 table 8)

Atypical scrapie

3. Flocks with atypical scrapie will no longer need to be culled out.

  - Farmers cost savings £715 per flock,

  Average annual cost saving £10,725 (Annex 1 table 10)

Saved costs: Environmental

Reduced levels of culling will mean less transport of animals for destruction and reduction in the number of carcases incinerated. However, we do not consider this to be a significant cost saving. The gross body weight range of the total amount of sheep, 14,500 animals*, that would be incinerated annually under current policy (Option 1) is between 640 and 890 Tonnes only compared to option 2. Atypical scrapie flocks would not be culled and destroyed under option 2. There would be no change in the amount of sheep from classical scrapie genotyped flocks between option 1 and option 2. (There should be no need to cull and destroy animals in the second year of restrictions in classical scrapie genotyped flocks as the remaining animals and progeny should be of the required genotype)

**(During the outbreak of Foot-and-Mouth disease in 2001 almost 3.5 million sheep were incinerated)*

Benefits (additional to Option 1)

Benefits to farmers and government are the same as under Option 1.

Conclusion

Annual costs and benefits

Cost Option 1 (baseline)	**£ 2.00million**	Benefit Option 1 (baseline)	**Protection of human and animal health**
Additional Cost Option 2	**-£1.20 million**	Additional Benefit Option 2	**None**

NB: Totals may not exactly equal the sum of individual figures due to rounding.

Option 2 will achieve the same level of benefit as option 1 (e.g. it has the same level of protection of human and animal health) but at a lower cost to farmers and taxpayers.

8. Additional information sought

8.1 The following amendments to the Regulations may also have a minimal impact. To refine this Impact Assessment, additional information on these issues is being sought as part of the consultation exercise.

8.2 Schedule 6, Paragraph 20: This amendment enhances the existing control of vegetable ingredients (e.g. extruded wheat discs) which are produced in premises where processed animal proteins are in use (usually petfood plants), and are therefore potentially subject to cross-contamination which would make them unsuitable for incorporation into ruminant feed - these ingredients are currently controlled by labelling or accompanying documentation so that farmed animal feed compounders cannot unwittingly incorporate possibly contaminated feed ingredients in end products destined to be fed to TSE susceptible animals. The proposed amendment is intended to extend the existing control to unfinished feed products not actually specified as petfood but which contain these ingredients. We believe that the impact of this amendment on businesses will be small, as the group of products in the petfood industry which contain such ingredients but are not actually designated as petfood is not believed to be large.

Producers are invited to answer the following questions:

- **Can you quantify the categories of product that will be affected?**
- **What will be the cost to your business of compliance with this measure?**

8.3 Schedule 8, Paragraph 1: The amendments to this paragraph reflect changes to the Community TSE Regulation, removing the prohibition on exporting meat and products from bovine animals born or reared in the UK after 31 July 1996 and slaughtered before 15 June 2005, and vertebral column from bovine animals born or reared in the UK after 31 July 1996 and slaughtered before 2 May 2006, and products derived from such vertebral column. These were transitional measures introduced when the Community ban on the export of beef from the UK was lifted on 2 May 2006. They were lifted by the EU on 29 June 2007 when it is estimated that such produce would no longer be available.

The removal of these measures is a benefit to Defra and Animal Health. It is estimated that the cost to the public sector of carrying out surveillance to ensure that the requirements of Schedule 7 were fulfilled, was approximately £150,000 between 2 May 2006 and 29 June 2007. This works out at approximately £130,000 per annum.

It is also a benefit of the meat industry as exporters will no longer be required to check the origin and slaughter dates of beef and bovine products prior to export.

As part of the consultation exercise, consultees in the meat industry are invited to answer the following questions:

- **What will be the saving per year to your business due to the removal of the requirement to check the origin and slaughter dates of beef and bovine products prior to export?**

- **Or will the future benefit of this measure be nominal because all products from animals slaughtered before 15 June 2005 will long since have been consumed on the domestic market?**

9. Benefits to Government Departments

9.1 There will be no benefits to other Government departments in England. (Scottish Executive and Welsh Assembly Government Department for Sustainability and Rural Development will be making similar changes in Scotland and Wales)

10. Competition

10.2 There will not be any direct or indirect limits to the number or range of farms in the industry caused by the proposed change in legislation. The proposed new legislation will not change farms incentive or ability to compete with each other.

11. Administrative Burdens

11.1 The Administrative burdens baseline in 2005 included a small amount for the provisions in the TSE regulations relating to enforcement of the scrapie controls of £2,179 per year. We expect that this will reduce to around £1,700 per yr as a result of this option, a saving of approximately £500 per year.

12. Enforcement

12.1 Enforcement will be risked based and proportionate in accordance with Hampton principles.

13. Race, Equality and Gender Impacts

13.1 There will be no additional race equality or gender impacts resulting from this option.

14. Small Firms Impact Test

14.1 A Small Firms Impact test will be carried out during the consultation period by consulting key representatives of the sheep industry who are small businesses to gauge their views on the impact of the measures. The impact is not expected to be significant as only a very small number of businesses will be affected by the controls.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	**Yes**	**No**
Small Firms Impact Test	**No**	**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**

Annexes

ANNEX 1: Schedule 3 calculations

Cost Calculations

NB Present Value = PV = Total cost / (1 + discount rate)^(no years -1)

OPTION 1

Table 1Cost to farmer of classical scrapie flocks genotype and cull

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	22	£910.00	£20,020	1	£20,020
2	20	£910.00	£18,460	1.035	£17,836
3	19	£910.00	£16,900	1.071225	£15,776
4	17	£910.00	£15,340	1.108717875	£13,836
5	15	£910.00	£13,780	1.147523001	£12,008
6	13	£910.00	£12,220	1.187686306	£10,289
7	12	£910.00	£10,660	1.229255326	£8,672
8	10	£910.00	£9,100	1.272279263	£7,153
				TOTAL	**£105,590**
				av annual	£14,560

Table 2 Cost to farmer of whole flock cull of atypical scrapie flocks

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	15	£715.00	£10,725	1	£10,725
2	15	£715.00	£10,725	1.035	£10,362
3	15	£715.00	£10,725	1.071225	£10,012
4	15	£715.00	£10,725	1.108717875	£9,673
5	15	£715.00	£10,725	1.147523001	£9,346
6	15	£715.00	£10,725	1.187686306	£9,030
7	15	£715.00	£10,725	1.229255326	£8,725
8	15	£715.00	£10,725	1.272279263	£8,430
				TOTAL	**£76,303**
				av annual	£10,725

TOTAL COSTS TO FARMERS (PV over 8 years)	**£181,893**
Average total costs to farmers	£25,285

Table 3 Cost to Government of genotyping and selective cull of sheep flocks with classical scrapie

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	22	£55,000	£1,210,000	1	£1,210,000
2	20	£55,000	£1,115,714	1.035	£1,077,985
3	19	£55,000	£1,021,429	1.071225	£953,515
4	17	£55,000	£927,143	1.108717875	£836,230
5	15	£55,000	£832,857	1.147523001	£725,787
6	13	£55,000	£738,571	1.187686306	£621,857
7	12	£55,000	£644,286	1.229255326	£524,127
8	10	£55,000	£550,000	1.272279263	£432,295
				TOTAL	**£6,381,795**
				av annual	£880,000

Table 4 Additional cost to Government to cull whole flock with atypical scrapie

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	15	£73,000	£1,095,000	1	£1,095,000
2	15	£73,000	£1,095,000	1.035	£1,057,971
3	15	£73,000	£1,095,000	1.071225	£1,022,194
4	15	£73,000	£1,095,000	1.108717875	£987,627
5	15	£73,000	£1,095,000	1.147523001	£954,229
6	15	£73,000	£1,095,000	1.187686306	£921,961
7	15	£73,000	£1,095,000	1.229255326	£890,783
8	15	£73,000	£1,095,000	1.272279263	£860,660
				TOTAL	**£7,790,426**
				av annual	£1,095,000

TOTAL COSTS TO GOVT (PV over 8 years) **£14,172,221**
Average total costs to govt **£1,975,000**

TOTAL COSTS	
PV	**£14,354,114**
Average over 8 years	**£2,000,285**

OPTION 2

COSTS

Table 5 Cost to farmer of TSE testing annual culls from atypical flocks and CSFS paper work

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	15	£98.00	£1,470	1	£1,470
2	30	£98.00	£2,940	1.035	£2,841
3	30	£98.00	£2,940	1.071225	£2,745
4	30	£98.00	£2,940	1.108717875	£2,652
5	30	£98.00	£2,940	1.147523001	£2,562
6	30	£98.00	£2,940	1.187686306	£2,475

7	30	£98.00	£2,940	1.229255326	£2,392
8	30	£98.00	£2,940	1.272279263	£2,311
				TOTAL	**£19,447**
				av annual	£2,756

TOTAL COSTS TO FARMERS (PV over 8 years)	**£19,447**
Average total costs to farmers	£2,756
Max cost to a farmer (for cost to typical business)	£130

Table 6 Additional cost to Government of TSE testing the difference between all annual culls from atypical scrapie flocks monitored under option 2 and TSE testing the sample of annual culls that would be required if the flock was restocked after whole herd cull under option 1

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	15	£2,000	£30,000	1	£30,000
2	30	£2,000	£60,000	1.035	£57,971
3	30	£2,000	£60,000	1.071225	£56,011
4	30	£2,000	£60,000	1.108717875	£54,117
5	30	£2,000	£60,000	1.147523001	£52,287
6	30	£2,000	£60,000	1.187686306	£50,518
7	30	£2,000	£60,000	1.229255326	£48,810
8	30	£2,000	£60,000	1.272279263	£47,159
				TOTAL	**£396,873**
				av annual	£56,250

Table 7 Additional cost to Government to collect and TSE test all fallen stock from flocks with atypical scrapie monitored under option 2

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	15	£3,000	£45,000	1	£45,000
2	30	£3,000	£90,000	1.035	£86,957
3	30	£3,000	£90,000	1.071225	£84,016
4	30	£3,000	£90,000	1.108717875	£81,175
5	30	£3,000	£90,000	1.147523001	£78,430
6	30	£3,000	£90,000	1.187686306	£75,778
7	30	£3,000	£90,000	1.229255326	£73,215
8	30	£3,000	£90,000	1.272279263	£70,739
				TOTAL	**£595,309**
				av annual	£84,375

TOTAL COSTS TO GOVT (PV over 8 years)	**£992,182**
Average total costs to govt	**£140,625**

TOTAL COSTS PV	**£1,069,479**
Average over 8 years	**£151,581**

COST SAVINGS

Table 8 Benefit from only having two years of restrictions instead of three years in which farmer is required to gather animals and deal with CSFS paper work e.g. slaughter and genotype certificates. There would be minimal additional work in monitored flocks and it would be BAU for them as far as atypical cases are concerned.

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	22	-£259.68	-£5,713	1	-£5,713
2	20	-£259.68	-£5,268	1.035	-£5,090
3	19	-£259.68	-£4,823	1.071225	-£4,502
4	17	-£259.68	-£4,377	1.108717875	-£3,948
5	15	-£259.68	-£3,932	1.147523001	-£3,427
6	13	-£259.68	-£3,487	1.187686306	-£2,936
7	12	-£259.68	-£3,042	1.229255326	-£2,475
8	10	-£259.68	-£2,597	1.272279263	-£2,041
				TOTAL	**-£30,131**
				av annual	-£4,155

Table 9 One-off Benefit from only having two years of restrictions instead of three years in which farmer is required to gather animals and deal with CSFS paper work e.g. slaughter and genotype certificates for the flocks currently under CSFS .

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	156	-£259.68	-£40,510	1	-£40,510
2	0	-£259.68	£0	1.035	£0
3	0	-£259.68	£0	1.071225	£0
4	0	-£259.68	£0	1.108717875	£0
5	0	-£259.68	£0	1.147523001	£0
6	0	-£259.68	£0	1.187686306	£0
7	0	-£259.68	£0	1.229255326	£0
8	0	-£259.68	£0	1.272279263	£0
				TOTAL	**-£40,510**
				av annual	-£5,064

Table 10 Benefit to farmer of cost saved from not having whole flock cull of atypical scrapie flocks

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	15	-£715.00	-£10,725	1	-£10,725
2	15	-£715.00	-£10,725	1.035	-£10,362
3	15	-£715.00	-£10,725	1.071225	-£10,012
4	15	-£715.00	-£10,725	1.108717875	-£9,673
5	15	-£715.00	-£10,725	1.147523001	-£9,346
6	15	-£715.00	-£10,725	1.187686306	-£9,030
7	15	-£715.00	-£10,725	1.229255326	-£8,725
8	15	-£715.00	-£10,725	1.272279263	-£8,430
				TOTAL	**-£76,303**
				av annual	-£10,725

TOTAL COST SAVINGS TO FARMERS (PV over 8 years)	**-£146,945**
Average total cost savings to farmers	**-£19,944**

Table 11 Benefit to Government in not collecting fallen stock in third year of restriction period as it is now reduced to two years.

Year	Number flocks (Classical Scrapie)	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
Current flocks	156	-£3,000	-£468,000		
				1	-£468,000
1	22	-£3,000	-£66,000	1.035	-£63,768
2	20	-£3,000	-£60,000	1.071225	-£56,011
3	18	-£3,000	-£54,000	1.108717875	-£48,705
4	16	-£3,000	-£48,000	1.147523001	-£41,829
5	14	-£3,000	-£42,000	1.187686306	-£35,363
6	12	-£3,000	-£36,000	1.229255326	-£29,286
7	10	-£3,000	-£30,000	1.272279263	-£23,580
				TOTAL	**-£766,542**
				av annual	-£100,500

Table 12 Benefit to government from not having to cull whole flock with atypical scrapie

Year	Number flocks	Cost per flock	Total cost (number flocks x cost per flock)	Discounting	PV
1	15	-£73,000	-£1,095,000		
				1	-£1,095,000
2	15	-£73,000	-£1,095,000		
				1.035	-£1,057,971
3	15	-£73,000	-£1,095,000		
				1.071225	-£1,022,194
4	15	-£73,000	-£1,095,000	1.108717875	-£987,627
5	15	-£73,000	-£1,095,000	1.147523001	-£954,229
6	15	-£73,000	-£1,095,000	1.187686306	-£921,961
7	15	-£73,000	-£1,095,000	1.229255326	-£890,783
8	15	-£73,000	-£1,095,000	1.272279263	-£860,660
				TOTAL	**-£7,790,426**
				av annual	-£1,095,000

TOTAL COST SAVINGS TO GOVT (PV over 8 years)	**-£9,466,669**
Average total cost saving to govt	**-£1,323,365**

TOTAL COST SAVINGS	**-£9,613,614**
Average over 8 years	**-£1,343,309**

Total net costs to farmers PV	**-£127,498**
Total net costs to govt PV	**-£8,474,488**

TOTAL	**-£8,601,986**
Annual net costs to farmers	**-£17,187**
Annual net costs to govt	**-£1,182,740**
TOTAL	**-£1,199,928**

NB: These totals include the reduced costs from removing portal controls as set out in annex 2.

ANNEX 2: SCHEDULE 2 AND SCHEDULE 8 CALCULATIONS

SCHEDULE 2

Poor quality brainstem samples where the obex cannot be adequately identified are classified as "no-tests". Up until recently (see below) the UK authorities had applied a worst case scenario to these "no-test" samples (i.e. treating them as though they were samples from cattle which would have tested positive for BSE) . This resulted in the destruction of up to 4 animals on each occasion of a "no-test" result (because of the requirement to dispose of the previous and two subsequent animals in the slaughter line in addition to the affected carcase, commonly known as the 'one before and two after rule' – (1b2a) to positively tested cattle). We estimate that this rule when applied to "no-test" samples has cost the UK meat industry about £1.2 million since the OTM rule was changed in November 2005.

Given the continued rapid decline in the number of cattle testing positive for BSE (and hence the increased odds against any "no test" animal testing positive for BSE), the Veterinary Laboratories Agency (VLA) was asked by Defra to conduct a comprehensive risk assessment on BSE including the application of the 1b2a rule in the event of a "no-test" result. The outcome from this research led to Defra writing to the EU Commission seeking a more proportionate and risk based approach to "no-test" samples. On the basis of advice from the VLA, we proposed that "no-test" samples should be subject to multiple testing and that the 1b2a rule would only be applied if a positive or inconclusive result was found, or if there was insufficient brain stem material for testing. However, the carcase and body parts from the original "no-test" animal or batch would still need to be destroyed. This move was supported by the Food Standards Agency.

Following agreement to this approach by the EU Commission in late 2007, the new system of multiple testing began on 7 January 2008. As a result of this change, Schedule 2, Part 1, paragraph 5, sub-paragraph (3) of the 2006 Regulations will need to be amended to clarify the application of the 1b2a rule to "no test" samples.

Estimate of annual savings to the OTM meat industry in England resulting from this measure:

55 Approved OTM abattoirs in England have had 243 "no-test" results in 28 months since testing began in November 05.

This gives an average of 8.68 "no-test results" per month.

Therefore in 12 months this gives an average of 104.16 "no-test results" per annum.

When the "1b2a" rule is applied to a "no-test" result, the following are destroyed (in addition to the carcase and hide of the BSE positive animal):

Three bovine carcases
Three bovine hides
Batched edible (red) offals, tripes and fat for all cattle slaughtered that day

The non-application of the "1b2a" rule per "no-test" result will therefore save 312.48 bovine carcases and hides per annum, plus associated offals, tripes and fats, and disposal costs. The costs associated with batched offals, tripes, fats, and disposal costs, will vary according the size of the day's kill.

Average market value of meat, edible offals, and hides per bovine, plus disposal costs	£950.00
Multiplied by 312.48 =	£296,856.00

Rounded to approximately £297,000 per annum saving for the OTM meat industry in England.

Discounted over 8 years this equates to a saving of £2.1m

SCHEDULE 8

(See Evidence Base, Paragraph 8.3)

3192 hours spent on portal checks between 2.5.2006 and 29.6.2007.
Grades involved: Animal Health Officer (AHO) and Senior Animal Health Officer (SAHO), no breakdown between grades available.

Assume a 50% split:
AHO 1596 hours divided by 7.4 = 216 days
SAHO 1596 hours divided by 7.4 = 216 days

Actual salary rates cannot be obtained without a considerable additional work as a substantial number of staff around the country were involved in portal surveillance.

Defra Ready Reckoner assumes availability 215 days per year, so figures rounded to 1 x AHO and 1 x SAHO for a year. Also 1 x Executive Officer (EO) at London salary rates for a year working on portal surveillance records as a full time job.

Costs assumed to be saved over the next 14 months using 07/08 rates (assuming 1.9% salary increase)

SAHO (National rate)	£24,890
ALSC/PCSPS @ 19.5%	£ 4,853
ERNIC @ 8%	£ 1,991
AHO (National rate)	£39,523
ALSC/PCSPS @ 19.5%	£ 7,707
ERNIC @ 7%	£ 2,767
EO (Core Defra – London rate including ALSC/PCSPS and ERNIC)	£32,848
Central Service overhead: £6745 per staff member per year	£20,235
Accommodation overhead for EO @ 23.94%	£ 7,864
	£142,678

Allowances – Portal surveillance staff worked to a shift pattern so it is unlikely that overtime was involved. (Impossible to be 100% certain without checking with every Animal Health Office but nothing has been counted).

No overheads for AHOs/SAHOs as they were working on detached duty, at ports.

As a result of portal surveillance, 111 backward traces were carried out. Some backward traces were carried out by SAHOs/AHOs, others were delegated to EOs/Administrative Officer(AO)s. Not possible to assess how long each backward trace took: they involve sending requests to exporters for documentation, proof of dates of slaughter, etc. Follow-up letters are sent if the first is not answered. Occasionally a visit to the exporters' premises may be necessary. Regular returns were sent to London with details of surveillance and traces undertaken.

Assume 2 hour for each backward trace, also allowing an element for making returns to London, and divide equally between SAHO, AHO, EO and AO.
For ease of division, say 112 x 2 =224 divided by 4 = 56 hours per grade.
The Ready Reckoner calculates costs at 215 days per year, 7.4 hours per day for National staff. 215 x 7.4 = 1591 divided by 56 = 3.5% of a working year per grade.

Annual rates:

SAHO (National rate)	£24,890
ALSC/PCSPS @ 19.5%	£ 4,853
ERNIC @ 8%	£ 1,991
AHO (National rate)	£39,523
ALSC/PCSPS @ 19.5%	£ 7,707
ERNIC @ 7%	£ 2,767
EO (National rate – includes ALSC/PCSPS and ERNIC)	£29,692
AO (National rate – includes ALSC/PCSPS and ERNIC)	£22,796
Central Service overhead: £6745 per staff member per year	£26,980
	£161,199

Accommodation overheads – All Regions @ 15.17%	£ 24,454
	£185,653
£185,653 x 3.5%: Cost of backward traces	£ 6,498
Grand total cost of portal surveillance over 14 months	£149,176
£149,176 divided by 14 months and multiplied by 12 months	£127,865

Rounded to a saving of **£128,000** per annum.

Benefit to Government of ending portal surveillance

Year	Total cost pa	Discounting	PV
1	-£127,865	1	-£127,865
2	-£127,865	1.035	-£123,541
3	-£127,865	1.071225	-£119,363
4	-£127,865	1.108717875	-£115,327
5	-£127,865	1.147523001	-£111,427
6	-£127,865	1.187686306	-£107,659
7	-£127,865	1.229255326	-£104,018
8	-£127,865	1.272279263	-£100,501
		TOTAL	**-£909,702**
		av annual	-£127,865

ANNEX 3: PROPOSED TECHNICAL AMENDMENTS TO THE REGULATIONS AND TO SCHEDULES 1, 2, 5 AND 6

Regulation 2, paragraph 1 This amendment sets out the two Commission Decisions which are to be read with the Community TSE Regulation (Regulation (EC) No 999/2001): 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 for any purpose and exempting such animals from certain control and eradication measures laid down in Regulation (EC) No 999/2001) and 2007/453/EC (which establishes the BSE status of Member States or third countries or regions thereof according to their BSE risk). This is an administrative amendment and has no impacts.

Regulation 8, Paragraph 2 This amendment enables the Secretary of State to amend an approval, authorisation, licence or registration granted under the Regulations if he considers such amendment necessary to reflect technical or scientific developments. This covers amendments to a Required Method of Operation (RMOP) as defined by Schedule 2, part 1 and is a technical amendment to enable changes to be made to cover, for instance, new techniques in brain stem sampling and packaging of samples.

Regulation 10 The amendments to this Regulation clarify the procedure for appeals under the Regulations to the Secretary of State.

Regulation 13 The amendments to this Regulation provide a new requirement for Inspectors appointed by the Secretary of State to produce documentary evidence before entering premises for the purpose of ensuring that the Community TSE Regulation and the 2006 Regulation are being complied with, and defines Inspectors' powers of entry in terms of the types of premises which can be entered.

Regulation 15 As it stands at present, Regulation 15 (1) (c) enables an Inspector to serve notices on suppliers, and persons in possession, of animal proteins and feedingstuffs which may contain animal protein, which means that Regulation 15 (3) (g), relating to feed recalls, is inconsistent if it only applies to persons in possession. This would cause problems if feed had to be recalled. The proposed amendment, adding a reference to suppliers at Regulation 15 (1) (c), rectifies this anomaly and improves the power of enforcement.

Schedule 2

Paragraph 3: There have been incidents when it has not been possible to identify the animal from which a sample was taken, either because the sample pot was not clearly marked or because two samples were placed in the same pot. This amendment clarifies the existing requirement.

Paragraph 5: The amendment to paragraph 5 (6) clarifies the existing requirement that it is the responsibility of the inspector appointed by the Meat Hygiene Service, not of the owner or occupier of a slaughterhouse, to select an animal for testing.

Schedule 3

Paragraph 3: This amendment provides that, if a veterinary inspector suspects that a bovine animal is affected with TSE, he has the power to restrict the movements of animals on other holdings, as well as on the holding where the suspect animal is restricted. Such restrictions would remain in force until the final results of tests on the suspected animal are known. This power would be used if the available epidemiological information indicates that the holding where the animal was present when TSE was suspected is unlikely to have been the holding where the animal could have exposed to the TSE – for instance, if an animal had recently been moved to a new holding. We do not anticipate that this power would be needed often, and any impact (loss of income while the farmer is unable to move restricted animals) would be minimal

compared with the size of the national cattle herd, which in the June 2006 Agricultural Survey was estimated to be 5.3 million for England, and the size of the national sheep flock, which in the June 2006 Agricultural Survey was estimated to be 15.7 million for England.

Paragraph 5: This amendment provides a right of appeal against any decision to cull a cohort animal following an inspector's rejection of evidence alleging that the animal did not have access to the same feed as an animal affected with BSE. We do not anticipate there being any significant number of appeals and therefore there should be little or no impact.

Paragraph 9: This amendment clarifies that the compensation payable under the published calendar month standard values is the average price paid in Great Britain for that age and category of animal in the six months (pedigree) or month (non-pedigree) before the date of its valuation (rather than the date of slaughter or death). The age and category are determined at the point the notice of intention to slaughter is served. This amendment avoids any confusion if, for example, an animal's value is determined in a calendar month before that in which it is slaughtered (Schedule 2, clause 8(a)) or dies (Schedule 2, clause 8(b)).

Schedule 5

This is a new schedule which clarifies the procedures to be followed if TSE is suspected in an animal which is not bovine, ovine or caprine. These measures have been added to cover future eventualities: to date, the only non-bovine, ovine or caprine animals detected with TSE in the UK have been domestic cats and exotic species in zoos.

Schedule 6

Paragraphs 2 and 3: These amendments give the Secretary of State the power to control raw petfood, direct from a butcher, on a livestock farm (in addition to the existing powers to control petfood containing animal protein). There is no quantifiable financial burden, only a requirement for raw petfood intended for feeding to pets on livestock farms to be kept and used in such a way as to prevent livestock access.

Paragraph 4: This amendment empowers an inspector appointed by the Secretary of State to seize the passport of a bovine animal which he has reasonable grounds to believe has been fed or has had access to any potentially TSE infective material. There is no impact from this change, which strengthens the inspector's powers to control animals under restriction, in addition to serving movement restriction notice.

Paragraph 5: This amendment ensures that, where an inspector appointed by the Secretary of State has ordered the slaughter of TSE susceptible animals, following a breach of the feed ban, he may ensure that all such animals are killed and disposed of. This makes the inspector's powers clear if a slaughter notice is not complied with by the owner by the date specified in the notice. There is no impact from this change, only a clarification of the enforcement powers.

Paragraph 6: These amendments relate to the way in which compensation is paid in respect of animals slaughtered because they have been fed, or have access to, any potentially TSE infective material. At present compensation is paid according to the market value of the animal: under the proposed amendment, compensation for bovine animals will be paid according to the values established in accordance with paragraphs 9 and 10 of Schedule 2, and for ovine and caprine animals paid according to the values established in accordance with paragraphs 24 and 25 of Schedule 3. This amendment brings the compensation payable in such cases into line with that paid in respect of BSE suspects. It is obviously inequitable to pay a higher rate of compensation for animals slaughtered under Schedule 5, than for animals slaughtered under Schedule 2. However the impact is expected to be small, as relatively few animals are slaughtered under Schedule 5, and compensation may not be payable at all in cases where the owner is directly culpable for a breach of the feed ban.

Due to breaches of the feed ban, 288 cattle and 149 sheep have been slaughtered in 2007, 35 cattle in 2005 and 20 cattle in 2004. These cases were due to contact with animal by-products on-farm, and not to failures in the livestock feed supply chain. No compensation has been paid in any of these cases due to the culpability of the owners/keepers for the situation. Compared

with the size of the national cattle herd which in the June 2006 Agricultural Survey was estimated to be 5.3 million for England, and the size of the national sheep flock, which in the June 2006 Agricultural Survey was estimated to be 15.7 million for England, any financial effects of this measure are expected to be minimal.

Paragraph 12: These amendments relate to the regulation of plants which process blood products or blood meal of non-ruminant origin for feed purposes, as well as ruminant blood (not eligible for feed), and the need for effective separation of these processes within the same plant. The Community TSE Regulations already require plants wishing to carry out both activities to have a control system ensuring separation, which has to be permitted by the competent authority. The only change proposed is that such 'permission' would be granted by means of authorisation, with consequently improved powers of enforcement. At present there are no processors in Great Britain who want to process non-ruminant blood products or blood meal for feed, who also process ruminant blood at the same establishment – the authorisation provision will facilitate proper enforcement, if such a proposal is made in future.

This application procedure is already in force: the only change is that it is now an application for authorisation rather than an application for approval. There will therefore be no additional financial or regulatory burden to industry arising from this measure.

Schedule 7

Between 26 October and 21 December 2007 the Food Standards Agency consulted on the following proposals to amend Schedule 6 (renumbered Schedule 7 in the draft Regulations) of the domestic TSE Regulations:

(i) changes arising from the Commission's proposal to increase the age at which bovine vertebral column (VC) is classified as specified risk material (SRM);
(ii) revocation of the Beef Bones Regulations 1997;
(iii) introduction of a provision to allow enforcement of EU rules on trade; and
(iv) changes to Schedule 7 (renumbered Schedule 8 in the draft Regulations) to correct references to EU legislation.

Full details of the consultation, including a partial Impact Assessment, are available on the Food Standards Agency's website at:
http://www.food.gov.uk/consultations/consulteng/2007/tseamends02eng07 and a summary of responses received is available at:
http://www.food.gov.uk/multimedia/pdfs/consultationresponse/tse06amend02engresp.pdf.

The EU proposal to increase the age at which bovine VC is classified as SRM is currently subject to a three month scrutiny period by the European Parliament. The scrutiny is expected to close at the end of April 2008, if the proposal is adopted, the Community TSE Regulations will be amended to reflect the change. The change would be implemented in UK as soon as possible after it comes into force and following its publication in the Official Journal.

EC Regulation 1923/2006, Article 3 para 1(b) point (n), introduced a definition of "mechanical separated meat". This means the identical definition in the domestic Regulations (which is identical) is no longer necessary and has therefore been omitted from the new Schedule 7. In addition the extension of prohibition on the production of MSM to bone in cuts from bovine, ovine and caprine animals first introduced into the Community TSE Regulations by Regulation (EC) 722/2007 becomes applicable in England.

These changes are expected to be implemented in an amending Regulation in May 2008, and will be incorporated into the TSE (England) Regulation 2008 which is the subject of this consultation exercise.

Annex 4: Outcome of Impact Tests not referred to in the Evidence Base

Legal Aid

The proposed amendments to the Regulations do not create new criminal sanctions or civil penalties.

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. There may be individual winners and losers in terms of increased or reduced trade opportunities, and therefore some change to the carbon footprint of individual businesses, but the overall impact for the industry as a whole is unlikely to alter substantially.

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 1998.

Rural Proofing

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

Annex 5: Glossary

Acronym	Term	Definition
(none)	**Atypical scrapie**	**Previously undetected form of scrapie which been found in sheep with genotypes that are resistant to classical scrapie as well as sheep with genotypes susceptible to classical scrapie.**
BSE	**Bovine Spongiform Encephalopathy**	**TSE in cattle.**
(none)	**Classical scrapie**	**The form of scrapie known to have been in the national flock and herd for more than 200 years.**
CSFS	**Compulsory Scrapie Flocks Scheme**	**Compulsory slaughter scheme for flocks in which scrapie is diagnosed.**
CWD	**Chronic Wasting Disease**	**TSE in deer.**
FSE	**Feline Spongiform Encephalopathy**	**TSE in cats (domestic cats and zoo animals).**
(none)	**Genotyping**	**A test on the DNA of a sheep's blood sample to determine its genetic resistance – or susceptibility – to scrapie.**
MHS	**Meat Hygiene Service**	**The Government body responsible for the protection of public health and animal health and welfare in Great Britain, through proportionate enforcement of legislation in approved fresh meat premises.**
NSPAC	**National Scrapie Plan Administration Centre, Worcester**	**Administrative centre for the NSP.**
NSP	**National Scrapie Plan**	**A joint initiative of British agricultural departments, launched in 2001 with the principle objective of increasing the level of resistance to TSEs in the national flock.**
(none)	**Scrapie**	**TSE in sheep and goats.**
(none)	**Selective cull**	**Culling in a CSFS flock of the sheep which have scrapie-susceptible genotypes.**
SRM	**Specified Risk Material**	**The parts of an animal deemed to TSE-infective.**
TSEs	**Transmissible Spongiform Encephalopathies**	**Fatal brain diseases suffered by a variety of species, including cattle, sheep, goats, deer and cats.**
vCJD	**Variant Creutzfeldt-Jakob Disease**	**TSE-like disease in humans.**
VLA	**Veterinary Laboratories Agency, Weybridge**	**The EU and UK reference laboratory for testing for TSEs.**