

## **EXPLANATORY MEMORANDUM TO TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (WALES) REGULATIONS 2008**

This Explanatory Memorandum has been prepared by the Office of the Chief Veterinary Officer, Rural Affairs Department and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

### **Description**

1. The Transmissible Spongiform Encephalopathies (Wales) Regulations 2008 update and replace the existing Transmissible Spongiform Encephalopathies (Wales) Regulations 2006, which will be revoked. The new Regulations include changes that have been made in response to changes in European legislation, and due to increased knowledge of a technical, administrative or legal nature, in relation to implementation of the 2006 Regulations.

### **Matters of special interest to the Subordinate Legislation Committee**

2. There are no matters of special interest to the Committee.

### **Legislative Background**

3. The Transmissible Spongiform Encephalopathies (Wales) Regulations 2006 (hereafter known as the 2006 Regulations) came into force on 3<sup>rd</sup> May 2006. They provided the necessary powers to administer and enforce the provisions of Regulation (EC) No 999/2001, concerning the prevention, control and eradication of Transmissible Spongiform Encephalopathies (TSEs) (hereafter, known as the Community TSE Regulations).
4. Since the 2006 Regulations came into force there have been a number of amendments made to the EU legislation. These have generally been technical amendments updating the detailed requirements of TSE monitoring arrangements. There has also been a need to review the content of the main Regulations and the Schedules to the domestic legislation to ensure that any lessons learnt since May 2006 are incorporated into domestic legislation and wherever possible, to relax or remove controls that are no longer necessary or which are no longer proportionate to the risk to human and/or animal health.
5. Welsh Ministers have the power to make the legislation by virtue of their designation in relation to the implementation of EC law in veterinary and phytosanitary fields for the protection of public health (S.I. 1792/2008). The Welsh Ministers also make this instrument with Treasury consent pursuant to section 56 (1) and (2) of the Finance Act 1973. This permits a Government department to require the payment of fees or other charges for the provision of any services or facilities or the issue of any authorisation, certificate or other document, in pursuance of any Community obligation. The powers under section 56 are vested in Welsh Ministers by section 59(5)

of the Government of Wales Act 2006. Treasury consent was received on 4 December 2008.

### **Purpose and intended effect of the legislation**

6. TSEs are fatal brain diseases suffered by a variety of species, the most common of which is 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 164 deaths from definite and probable vCJD in the United Kingdom (UK) as at 4 July 2008.
7. 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, and under domestic law by the Transmissible Spongiform Encephalopathies (Wales) Regulations 2006.
8. Since the 2006 Regulations came into force, a number of amendments subsequently made to the EU legislation now need to become reflected in domestic legislation. Many clarify the requirements of the 2006 Regulations, do not impose any additional financial or administrative burden and their effect can be regarded as neutral. In some cases, the technical changes being made will result in a reduced burden on the livestock and meat industries. De-regulatory amendments are proposed by the Food Standards Agency (FSA), in relation to its responsibilities under the 2006 Regulations. Other de-regulatory amendments proposed include the incorporation of provisions currently contained within separate Statutory Instruments: namely, the Bovine Spongiform Encephalopathy (BSE) Compensation (Wales) Regulations 2006 and the Sheep and Goats Transmissible Spongiform Encephalopathy (TSE) Compensation (Wales) Regulations 2006.
9. The principal objectives for the amendments are:
  - following the outcome of a risk assessment and following EU Commission agreement, a more risk-based approach to BSE controls in abattoirs in any situation where the brain stem sample proves to be of inadequate quality for normal BSE testing. It is estimated that this will save the meat industry about £300,000 per annum;
  - to provide a new legal power to enable the Veterinary Laboratories Agency (VLA) to charge laboratories, that wish to carry out BSE tests, for the costs incurred by the VLA in their initial approval and in their subsequent quality assurance. The charges are based on VLA's estimate of their full economic costs. These charges are consistent with the specific TSE-related proposals made under the consultation on Responsibility and Cost Sharing (RCS) for Animal Health and Welfare in

Wales which concluded on 9 June 2008 and subsequently agreed by UK Rural Affairs Ministers;

- to provide the right of appeal on any decision to cull a BSE 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;
- to provide the right of appeal on any decision to cull a BSE 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;
- to include additional requirements with regard to the determination of compensation paid in respect of animals slaughtered because they have been fed, or have access to, any potentially TSE infective material;
- to formally lift certain export restrictions which have not been applied since June 2007, which were originally required by the EU as transitional measures for the lifting of the ban on the export of beef and bovine products from the UK;
- to relax controls on storing BSE tested carcasses in strict slaughter order, pending receipt of test results;
- to rationalise legislation on the ban on cattle born before August 1996, so that FSA legislation can be revoked; and,
- to include various other technical amendments.

## **Implementation**

- 10.** Failure to implement these Regulations could potentially be seen as inadequate transposition of EU legislation and could result in infraction proceedings. There is also a risk that it could lead to a lack of clarity and confusion as to the current requirements in force in the UK, which may have the effect of increasing non-compliance with the provisions of TSE legislation.

## **Consultation**

- 11.** A 12 week consultation was carried out on the proposed amendments to the TSE Regulations. The consultation period ran from 18<sup>th</sup> June 2008 to 12<sup>th</sup> September 2008. The consultation included a partial Regulatory Impact Assessment which covered proposed amendments to the Compulsory Scrapie Flocks Scheme (CSFS).
- 12.** It should be noted that there is an on-going legal case between France and the European Commission concerning amendments to European Union

TSE legislation replacing compulsory genotyping (not goats) and culling of scrapie-affected flocks/ herds with the option of monitoring and slaughter.

13. The partial Regulatory Impact Assessment prepared for the consultation, reflected the position at the time regarding this issue, so includes costs relating to the option of monitoring and slaughter for human consumption of classical scrapie affected flocks/ herds which replaced compulsory genotyping and culling as set out in Regulation (EC) 746/2008.
14. Subsequently, there have been further developments regarding the legal case between France and the European Commission. On 30<sup>th</sup> October the Court of First Instance suspended the classical scrapie provisions in Regulation (EC) 746/2008 pending judgement in the legal case.
15. As a result of this suspension, the provisions within the partial regulatory assessment relating to classical scrapie are not included in the Transmissible Spongiform Encephalopathies (Wales) Regulations 2008.

### **Regulatory Impact Assessment**

16. This partial Regulatory Impact Assessment specifically covers proposed amendments relating to the Compulsory Scrapie Flocks Scheme (CSFS) and their impact in Wales. It is proposed to amend the CSFS to provide scrapie controls in Wales (and GB) that are flexible, meet the degree of risk involved, and place UK sheep and goat farmers on the same footing as their competitors in Members States. There are also technical amendments.
17. The policy objective is to maintain protection for human and animal health while reducing scrapie controls and administrative costs, 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 burdens to these sections of the livestock and feedstuff industries.

### **Options**

18. The following options have been considered;

Option 1 – Do nothing and continue current approach using existing regulations

Option 2 – Change the existing regulations and apply the amended EU controls.

A detailed analysis of each option is contained in Annex A. All figures which form the basis of this analysis are available at Annex B. In summary Option 2 is the favoured option as the analysis demonstrates that 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.

**19.** It should be noted that the proposed amendments to the TSE Regulations will not impact on the benefits of the overall regulations in terms of disease control, namely;

- **Benefits to Government & Public:** Reducing the 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 tax payer the cost of dealing with flocks that may otherwise have become infected. It reduces the theoretical risk to human and animal health from BSE masked as scrapie.
- **Benefit to Farmers:** Eliminating scrapie on farms with known infection and reduce the risk of re-occurrence. This will reduce the risk to human and animal health from BSE masked as scrapie and therefore help to preserve consumer confidence in sheep meat.

**20.** The additional benefits of the proposed changes are in terms of reduced costs as set out above in paragraph 6.

### **Risk Assessment**

**21.** Failure to implement these Regulations could potentially be seen as inadequate transposition of EU legislation and could result in infraction proceedings. There is also a risk that this could lead to a lack of clarity and confusion as to the current requirements in force in the UK, which may have the effect of increasing non-compliance with the provisions of TSE legislation and possible consequential implications for disease control.

### **Competition Impacts**

**22.** 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. The rest of the UK and all the EU Member States are required to transpose this regulation

### **Race, Equality and Gender impacts**

**23.** There will be no additional race equality or gender impacts resulting from the preferred option.

## **Annex A: Detailed consideration of Schedule 4 of the 2006 Regulations**

### **Background**

1. 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. 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.
3. 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.
4. Strict controls then apply to movements on and off the farm. Depending on its genotype, which determines the resistance to scrapie, a sheep:
  - a) may be retained or sold for breeding,
  - b) may be required to be sold for slaughter,
  - c) or must be collected by Defra contractors and killed and destroyed as Specified Risk Material (SRM).
5. 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.

### **The Compulsory Scrapie Flocks Scheme**

6. The EU controls are applied via the Compulsory Scrapie Flocks Scheme (CSFS) throughout Great Britain (GB), and the 2006 Regulations provide enforcement powers in Wales (Similar legislation applies in England and Scotland).
7. There are currently around 240 farms (440 flocks plus 3 goat herds) under the controls in Great Britain (GB). 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.

8. 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.

### **Changes in EU controls**

9. 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. Certain provisions with regard to classical scrapie were suspended on 28 September 2007 by order of the Court of First Instance of the European Communities. On 30 April 2008, the European Commission achieved a qualified majority for a proposal to reinstate these provisions. The proposal should take effect in EU law in August 2008.

10. The changes to the controls involve:

- A monitored flock/herd option allowing flocks and herds with classical or 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.
- Reducing the period of restrictions in flocks affected by classical scrapie to 2 years (from 3 years).

## **Business Affected /Assumptions**

11. The business sectors affected are sheep and goat farms with suspected cases of classical and atypical scrapie. In Wales in 2005, 126 flocks from 68 holdings were entered into CSFS and in 2007, 29 flocks from 10 holdings. For a number of reasons including the Welsh Ewe-Genotyping Scheme, 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 will continue.
12. 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.
13. 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 10 holdings (29 flocks) with new classical scrapie cases in year 1 in Wales declining to 0 holdings (0 flocks) by year 8. We have assumed that there will be 15 flocks with atypical scrapie each year.
14. 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.

### **OPTION 1: Do nothing and continue current approach using existing Regulations**

15. In respect of this legislation, failure to implement the proposed amendments could be seen as inadequate transposition and could ultimately lead to infraction proceedings against the Welsh Assembly Government by the European Commission. In addition, applying current controls 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.

### **Option 1: Economic & Environmental Costs**

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).

The economic costs (including the cost to the farmer and cost to government) for Option 1 are set out below. The tables supporting these calculations can be viewed at Annex B within Tables 1, 2, 3 & 4. All figures are approximate.

#### **Cost to farmer of classical scrapie flocks genotype and cull (Annex B, Table 1)**

Table 1 shows that the average annual cost to farmers is approximately **£6,700**

Assumptions;

- a) 29 flocks under Genotype and selective cull action
- b) Farmer's time gathering animals, dealing with NSPAC paperwork – 2 days, £260 per flock
- c) 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
- d) The total cost per flock is  $£260 + £650 = £910$
- e) The average cost has been calculated over a period of 8 years

#### **Cost to farmer of whole flock cull of atypical scrapie flocks (Annex B, Table 2)**

Table 2 shows that the average annual cost to farmers is approximately **£11,000**

Assumptions;

- a) 15 holdings affected by atypical scrapie.
- b) 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

- c) 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
- d) The total cost per flock is £65 + £650 = £715
- e) The average cost has been calculated over a period of 8 years

The **total** average cost to the farmer of option 1 is approximately **£17,000**

### **Cost to Government of genotyping and selective cull of sheep flocks with classical scrapie (Annex B, Table 3)**

Table 3 shows that the average annual cost to Government is approximately **£ 400,000**

Assumptions;

- a) We would expect that there would be 29 holdings affected by classical scrapie in year 1, declining to 0 by year eight.
- b) It costs an average of £55,000 per flock to apply genotype and selective cull action.
- c) The average cost has been calculated over a period of 8 years.

### **Additional Cost to Government to cull whole flock with atypical scrapie (Annex B, Table 4)**

Table 4 shows that the average cost to Government is approximately **£1,000,000**

Assumptions;

- a) 15 holdings affected by atypical scrapie each year
- b) It costs an average of £73,000 per flock to apply whole flock cull action
- c) The average cost has been calculated over a period of 8 years.

The total average cost to the Government of Option 1 is approximately **£1,500,000**

### **CONCLUSION**

The total economic costs of Option 1 are approximately **£1,520,000**

## ***OPTION 1: Environmental Costs***

### 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:

29 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 168 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 29 flocks = 203 Rams  
Weight incinerated (203x [110 -130kg per animal]) = 22,330 -26,390kg  
Ewes (60-85 kg per animal) 168 ewes x 29 flocks = 4,872 ewes  
Weight incinerated (4,872 x[60-85 kg per animal]) = 292,320 -414,120kg  
Lambs (25-35kg per animal) 700 animals x 15 flocks = 10,500 lambs  
Weight incinerated (10,500 x[25-35kg per animal]) = 262,500-367,500kg  
Total 15,575 sheep (maximum weight) = **577 – 808 tonnes**

The total weight of sheep that would be incinerated under Option 1 is therefore between **1,217 and 1,698 tonnes** in the first year

***OPTION 1: Benefits to 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.

***OPTION 1: Benefits to 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.

## **OPTION 2: Change The Existing Regulations And Apply The Amended Eu Controls.**

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.

The economic costs (including the cost to the farmer and cost to government) for Option 2 are set out below. The tables supporting these calculations can be viewed at Annex B within Tables 5,6,7,8 and 9. All figures are approximate.

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

#### **OPTION 2: Cost to farmers**

#### **Cost to farmer of TSE testing annual culls from atypical flocks and CSFS paper work (Annex B, Table 5)**

Table 5 shows that the average annual cost to farmers is approximately **£3,000**

Assumptions;

- a) 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.
- b) Regarding annual costs – farmers 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.
- c) 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.
- d) The total cost per flock is £98 (£33 + £65)
- e) The average cost has been calculated over a period of 8 years.

### **Cost to farmer of TSE testing additional 25 annual culls in classical scrapie monitored flocks (Classical genotyped flocks BAU) (Annex B, Table 6)**

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). The EU Regulation now requires all such animals to be TSE tested when the monitored flock option is applied to a classical scrapie flock.

Table 6 shows that the average annual cost to the farmer is approximately **£100**

The total average annual cost to the farmer is approximately **£3000**

### ***OPTION 2: Costs to Government***

#### **Cost to Government of TSE testing additional 25 annual culls in classical scrapie monitored flocks (Annex B, Table 7)**

There will be an additional cost to Government in arranging and carrying out an additional 25 tests on average for each flock monitored instead of genotyped and selectively culled.

Table 7 shows that the average annual additional cost to Government is approximately **£7,000**

Assumptions;

- a) Animal Health Central Operations: £30 per flock
- b) Meat Hygiene Service (MHS) sample removal: £700 per flock
- c) VLA TSE test: £1,250 per flock
- d) Total cost to government per flock : £1,980

#### **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 (Annex B, Table 8)**

Table 8 shows that the average cost to Government is estimated at approximately **£56,000**

Assumptions;

- a) on average there will be  $125 - 100 = 25$  animals per flock
- b) cost per flock = £2,000

**Additional Cost to Government to collect and TSE test all fallen stock from flocks with atypical scrapie monitored under Option 2 (Annex B, Table 9)**

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

Table 9 shows that the average annual cost to Government is approximately **£84,000**

Assumptions;

- a) 3% adult mortality = 15 animals per flock x 15 flocks per year = 225 fallen stock per year.
- b) The average cost of collecting a fallen stock carcass, removing the head and incinerating the carcass, 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.
- c) Cost per flock is £3,000
- d) Average costs have been calculated over a period of 8 years

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.

The total average annual cost to the Government is approximately **£148,000**

**CONCLUSION**

The total economic costs of Option 2 are approximately **£151,000**

## **Saved Costs to Government**

### **Classical scrapie cases**

As we will be monitoring approximately half the new cases rather than genotyping and selectively culling them, there will be benefits to the taxpayer from reduced expenditure on culling of animals and compensating for them. Genotype and selective cull costs approximately £55,000 per flock.

Total benefit in first year is  $15 \times £55,000 = £ 825,000$

Average annual cost saving £206,250 (Annex B, Table 10)

There will be benefits to the taxpayer from reduced expenditure on 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 is £3,000

Total benefit in first year is  $29 \times £3,000 = 87,000$

Average annual cost saving is £22,125 (Annex B, Table 11)

There will be an animal health benefit in reducing the sources of TSE infection thus avoiding costly action to tackle cases that may otherwise have occurred if the new regulation had not been implemented.

For classical scrapie, the estimated net present cost saving over 8 years to the Government is approximately **£1,800,000**

### **Atypical scrapie**

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 is approximately £1,095,000 (Annex B table 12)

## **Saved costs to farmers**

### **Classical scrapie cases**

Sheep and goat farms with confirmed cases of classical scrapie will benefit. 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 the administrative burden.

### **New Classical scrapie cases from August 2008**

The farmers whose flocks enter the CSFS from August 2008 will also benefit from being subject to scrapie controls for 2 years instead of 3 years.

Farmers time gathering animals and dealing with NSPAC paperwork: £260 per flock (2 days work)

Total benefit in Year 3 is  $29 \times £259.68 = £7,530.72$

Average annual cost saving is approximately £974 (Annex B, Table 13)

### **Classical scrapie – Monitored Flocks**

Those whose flocks are subject to the new monitored flock option will benefit from not having animals killed and destroyed so enabling them to retain them for breeding or send them to fattening or slaughter. They will save the time they would have had to spend sourcing replacements and selling off those replacements found to be of unsuitable genotype for up to 50% of their flock that was compulsory culled and destroyed with compensation paid or required to be sold for slaughter. There is a labour intensive action of one working week on average £649.20

Total benefit in year 1 is  $15 \times £649.20 = £9,738$

Average annual cost saving is approximately £2,435 (Annex B, Table 14)

For Classical scrapie, the estimated net present cost saving (over 8 years) to the farmers is approximately £27,000

### **Atypical scrapie**

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

- Farmers cost savings £715 per flock,

Average annual cost saving is approximately £10,725 (Annex B, Table 15)

### **Saved costs: Environmental**

Reduced levels of culling will mean less transport of animals for destruction and reduction in the number of carcasses incinerated. However, we do not consider this to be a significant cost saving as total amount of sheep body weight saved that would be incinerated annually under current policy (Option 1) is between approximately 1,217 and 1,698 tonnes. 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

Comparison of the cost of complying with TSE proposals (a negative cost indicates a cost saving).

	<b>Option 1</b>	<b>Option 2</b>
<b>Cost to Government</b>		
Present Value	10,933,866	-8,514,646
Average annual cost	1,500,625	-1,175,325
<b>Cost to Farmer</b>		
Present Value	128,313	-82,395
Average annual cost	17,436	-11,255
<b>Total Cost</b>		
Present Value	11,062,180	-8,597,040
Average annual cost	1,518,061	-1,186,580

**NB: All figures are approximate. 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 annual 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?**

Regulation 12(2): 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?**

### **Other Government Departments**

9.1 The department for Environment & Rural Affairs in England and Scottish Executive will be making similar changes in England and Scotland

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1.	Cost to farmer of classical scrapie flocks genotype and cull
2.	Cost to farmer of whole flock cull of atypical scrapie flocks
3.	Cost to Government of Genotyping and selective cull of sheep flocks with classical scrapie
4.	Additional cost to Government to cull whole flock with atypical scrapie
5.	Cost to farmer of TSE testing annual culls from atypical flocks and CSFS paper work
6.	Cost to farmer of TSE testing additional 25 annual culls in classical scrapie monitored flocks (classical genotyped flocks BAU)
7.	Cost to Government of TSE testing additional 25 annual culls in classical scrapie monitored flocks
8.	Additional cost to Government of 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
9.	Additional cost to Government to collect and TSE test all fallen stock from flocks with atypical scrapie monitored under Option 2
10.	Benefit to Government of reduced expenditure on culling of animals and compensating for them
11.	Benefit to Government in not collecting fallen stock in third year of restriction period (as under this option the restriction period is reduced to two years)
12.	Benefit to Government from not having to cull whole flock with atypical scrapie
13.	Benefit of 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.
14.	Benefit of flocks monitored not having to source replacements for animals that would otherwise have been killed under genotype option.
15.	Benefit to farmer of cost saved from not having whole flock cull of atypical scrapie flocks