Title: Impact Assessment (IA) Impact Assessment of the Transmissible Spongiform Encephalopathies (England) (Amendment) Regulations 2012 Date: 18/10/2012 IA No: Stage: Final DEFRA1426 Source of intervention: EU Lead department or agency: Type of measure: Secondary Department for Environment, Food and Rural Affairs (Defra) Other departments or agencies: Contact for enquiries: Katie Barnes 020 7238 6535 None katherine.barnes@defra.gsi.gov.uk **RPC Opinion:** Awaiting Scrutiny

Summary: Intervention and Options

Cost of Preferred (or more likely) Option						
Total Net Present Value Business Net Present Value Net cost to business per year (EANCB on 2009 prices) In scope of One-In, Measure qualifies as One-Out?						
£0.920m	-£0.031m	£0.003m	No	NA		

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

Regulation (EC) No.999/2001 (the EU TSE Regulation) lays down rules for the prevention, control and eradication of TSEs, e.g. BSE and scrapie. Classical scrapie controls in domestic legislation are not proportionate to risk and place an unnecessary burden on Government and industry. To balance costs of regulation for TSE controls against their wider benefits within the constraints of European legislation, we wish to avail ourselves of all the classical scrapie control options in the EU TSE Regulation, and to better reflect market values in determining BSE compensation and keep it aligned with that for other major notifiable cattle diseases. This requires amendments to the TSE (England) Regulations 2010.

What are the policy objectives and the intended effects?

Our objective is to protect the environment, society and the economy from the risks of animal disease through risk-based and proportionate management responses and to enhance the competitiveness and resilience of the food chain to ensure a secure, environmentally sustainable and healthy supply of food. Amending the TSE (England) Regulations 2010 (the 2010 Regulations) would enable us to reflect the more proportionate options available in EU legislation for controlling classical scrapie, and to maintain the existing alignment of compensation for BSE with that for other major notifiable cattle diseases.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

The Do Nothing/Business as Usual option (Option 0 - baseline) includes (i) killing and disposing of animals most genetically susceptible to classical scrapie in affected flocks and herds; (ii) allowing a discrepancy between compensation for BSE and that for other major notifiable cattle diseases; and (iii) not making minor technical amendments in the light of a review of the Regulations. The alternative policy option (Option 1) would amend the Regulations to (i) reflect the more proportionate approach of restricting flocks and herds with classical scrapie and testing animals from the holding for at least two years; (ii) align compensation for BSE with that for other major notifiable cattle diseases; and (iii) make minor technical amendments. Option 1 is preferred as it reflects the classical scrapie control options available in the EU TSE Regulation, better reflects market values in determining compensation and keeps it aligned with that for other major notifiable cattle diseases, and makes minor amendments in the light of a review of the Regulations.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: November 2016						
Does implementation go beyond minimum EU requirements? No						
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base. Micro < 20 Small Yes Yes Yes Yes						Large No
The state of the s					Non-t	raded:

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:	
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Summary: Analysis & Evidence

Description:

FULL ECONOMIC ASSESSMENT

Price Base	PV Base	Time Period	Net	Benefit (Present Val	ue (PV)) (£m)	
Year 2011	Year 2011	Years 10	Low: Optional	High: Optional	Best Estimate:	0.920

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate			0.007	0.062

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

Industry costs: Reduction in BSE compensation paid due to changes to some BSE compensation rates: £7,204.00.

Other key non-monetised costs by 'main affected groups'

Changed farmer incentives could lead to increased risk of persistence or spread of classical scrapie. However veterinary advice indicates that this risk is negligible, and would be mitigated by official monitoring and statutory controls.

BENEFITS (£m)	Total Tra (Constant Price)	TransitionAverage Annual) Years(excl. Transition) (Constant Price)		Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate			0.114	0.982

Description and scale of key monetised benefits by 'main affected groups'

Annual Government benefits: Savings on changes to classical scrapie controls: £97,000 (net of EU cofinancing); Savings resulting from changes to some BSE compensation rates: £6,100 (net of EU cofinancing); Savings on appeals against decisions to cull BSE cohort animals: £7,300. Total: £110,400. Industry benefits: Savings on work associated with genotyping and sourcing replacement stock on CSFS farms: £3,600. Total annual Government and industry benefits: £114,000.

Other key non-monetised benefits by 'main affected groups'

Environmental benefit: Between 18,045 kg and 25,195 kg of sheep and goat carcases from classical affected holdings not incinerated.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5

Assumptions are based on current disease levels for BSE and classical scrapie being maintained: (i) Classical scrapie controls assumes 4 sheep holdings restricted per year with average flock size of 354 of which 25% genetically susceptible, and 1 goat holding of 250 animals restricted per year; (ii) Genotyping costs based on the current contract; (iii) BSE compensation assumes similar values to animals killed in 2008-2010; (iv) Appeals against killing of cohort animals: Savings identified assume 5 fewer appeals per year.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0.007	Benefits: 0.004	Net: 0.003	No	NA

Evidence Base (for summary sheets)

Background

- 1. Transmissible spongiform encephalopathies (TSEs) are fatal brain diseases which include classical scrapie in sheep and goats and bovine spongiform encephalopathy (BSE) in cattle. Exposure to BSE through the consumption of infected meat is believed to be the primary cause of variant Creutzfeldt-Jakob Disease (vCJD) in humans. The European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control jointly advised in 2011 that BSE is the only animal TSE which has been shown to be a risk to human health, and that there is no epidemiological evidence to suggest that classical scrapie is a risk to human health.
- 2. The Government needs to implement TSE controls, in line with European Union (EU) requirements. The proposed amendments to the 2010 Regulations contribute to TSE controls which are based on scientific advice and are proportionate to the risk to public and animal health in line with the European Commission's TSE Roadmap.

Classical Scrapie

- 3. Classical scrapie has been recognised in the United Kingdom for over 250 years. The genetic make-up of sheep (polymorphism at the prion protein gene) determines their susceptibility to classical scrapie and genotyping and selective breeding have been used as control tools for the disease. In contrast to the genetic variability recognised in sheep, goats are uniformly susceptible to classical scrapie.
- 4. In 2007, the EU first agreed more proportionate controls for sheep flocks and goat herds with classical scrapie. It introduced the option of (i) reducing genotyping requirements to 50 sheep per flock; (ii) monitoring classical scrapie-affected sheep flocks and goat herds for two years following the detection of the latest case, instead of killing and destroying genetically susceptible animals over 3 months of age (approximately 25% of sheep and 100% of goats); (iii) allowing meat from genetically susceptible animals into the food chain subject to a negative post-mortem TSE test on animals over 18 months of age and the removal of specified risk material (SRM); and (iv) TSE testing all fallen animals over 18 months of age.
- 5. The French government challenged the proportionate controls on classical scrapie and the EU General Court suspended the contested provisions pending final judgement in the legal case (T-257/07). The UK intervened in the legal case in support of the Commission.
- 6. In its judgement of 9 September 2011, the EU General Court dismissed the French government's challenge and reinstated the suspended provisions. The Government proposes to update the 2010 Regulations to reflect the full range of options available for controlling classical scrapie, and to take the option of not killing and destroying genetically susceptible animals from classical scrapie-affected flocks and herds ("the monitoring option") as our default position for existing and future cases.
- 7. The French Government has appealed against the EU General Court's judgement on a point of law, but the Court has not re-suspended the previously contested provisions for classical scrapie. The Commission is continuing to review scrapie legislation and further changes (which will remove inconsistencies, extend the application of proportionality in controlling classical scrapie and remove restriction measures on holdings where atypical scrapie has been disgnosed) are expected to come into force in July 2013. It is therefore unlikely that the appeal will have any bearing on the future application of proportionate scrapie controls.

BSE Compensation

8. Since 2006 the compensation rates paid for BSE cattle under domestic TSE Regulations have been aligned with those paid under the Cattle Compensation (England) Order 2006 which sets out the table valuation system for compensation for bovines killed under the Animal Health Act 1981 in its application to bovine tuberculosis (BTb), brucellosis, and exotic bovine leukosis (EBL). Table valuations are determined on a monthly basis, using market data, and are published on the Defra website.

9. A recent review of the Order has identified some anomalies in the current system, which were addressed in the Cattle Compensation (England) Order 2012, which came into force on 1 July 2012. The Government wishes to consult on aligning the table valuations for cattle killed under the 2010 Regulations with the changes implemented in the Cattle Compensation (England) Order 2012. During the recent consultation on the proposed changes to cattle compensation under the Cattle Compensation (England) Order 2012, industry representatives expressed the view that the existing table valuation for calved dairy cattle is too broad as it covers all ages of calved animals. They advised that it is unfair to compensate owners of younger productive stock at the same level as owners of older unproductive animals. We therefore propose to split the category into two, with owners of younger stock being compensated at a higher level.

Problem under consideration

10. The EU TSE Regulation lays down rules for competent authorities in Member States relating to the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs) such as BSE and scrapie. The current controls for classical scrapie in domestic legislation are not proportionate to risk and place an unnecessary burden on Government and industry. To balance the costs of regulation for TSE controls against their wider benefits within the constraints of European legislation, we wish to avail ourselves of all the options for classical scrapie control available in the EU TSE Regulation, and to better reflect market values in determining compensation for BSE and keep it aligned with that for other major notifiable cattle diseases. This requires amendments to the TSE (England) Regulations 2010.

Rationale for intervention

- 11. Under the Government's Coalition Agreement, we are committed to tackling the budget deficit and ensure that taxpayers' money is spent responsibly and reducing the regulatory burden on farmers by moving to a risk-based system of regulation. Specifically the TSE work is covered by two priorities in the Defra Business Plan:
 - Support and develop British farming, and encourage sustainable food production; and
 - Prepare and manage risk from animal disease.
- 12. This Impact Assessment presents one policy option in addition to 'do nothing/business as usual'. The amendments being proposed in Option 1 (as outlined in Paragraph 13 below) are necessary to enable us to balance the costs of regulation for TSE controls against their wider benefits within the constraints of European legislation. In theory it would be possible to carry out some elements of Option 1 and keep the 'do nothing' option for others. However, as demonstrated in paragraphs 29-53 below, retaining any element of the 'do nothing' option would result in smaller benefits than carrying out all elements of Option 1.
- 13. The proposed amendments can be divided into three elements:
 - (i) <u>Classical scrapie:</u> The option in the EU TSE Regulation for monitoring holdings affected by classical scrapie, as opposed to genotyping of sheep followed by killing and destruction of classical scrapie susceptible animals, is the most proportionate response to the risk of classical scrapie to public and animal health. It would reduce the overall burden and result in the greatest savings to Government, and would improve the balance of animal health responsibility for controlling the disease between taxpayer and industry.
 - (ii) <u>Cattle compensation:</u> The Cattle Compensation (England) Order 2006 has been updated and revised to correct certain anomalies in the text, increase the number of compensation categories from 47 to 51, and make other changes with regard to compensation for BTb. We are proposing to maintain the existing harmonised approach to cattle compensation by aligning the 2010 Regulations with the Cattle Compensation (England) Order 2012. This will ensure we better reflect market values in determining compensation for BSE and keep it aligned with that for other major notifiable cattle diseases.

- (iii) <u>Technical amendments:</u> The proposed technical amendments will fulfil Government requirements on better regulation, clarify enforcement procedures, limit unqualified appeals against killing of cattle under the 2010 Regulations, and remove an obligation and an offence.
- 14. The individual costs and savings for classical scrapie and BSE under Option 0 and Option 1 are identified at Tables 16, 17 and 18.

Policy objective

15. Our objective is to protect the environment, society and the economy from the risks of animal disease through risk-based and proportionate management responses and to enhance the competitiveness and resilience of the food chain to ensure a secure, environmentally sustainable and healthy supply of food. Amending the 2010 Regulations would enable us to reflect the more proportionate options available in EU legislation for controlling classical scrapie, and to better reflect market values in determining compensation for BSE and maintain its existing alignment with that for other major notifiable cattle diseases.

Description of options considered (including do nothing)

16. The baseline option is:

Option 0 - Do Nothing: Business as Usual

Schedule 4: Classical Scrapie Controls: Genotype and Kill

- 17. Following detection of classical scrapie in a sheep flock or goat herd, the holding is placed under movement restriction and the Government pays for the blood sampling and genotyping of all sheep over three months old. There is a labour cost to industry of assisting with mandatory genotyping. Government pays for the killing, compensation and disposal of all initial cull animals which are genetically susceptible to classical scrapie (typically about 25% of a sheep flock and all goats). This includes the cost of transporting animals to be killed, the cost of TSE testing initial cull animals over 18 months of age, and the cost of supervision by the Animal Health Veterinary Laboratories Agency (AHVLA). Initial movement restrictions remain in place until AHVLA has removed the most genetically susceptible animals.
- 18. Once the initial genotyping and culling action has been completed, there is a movement restriction period for two years following the detection of the last case during which the following controls apply:
 - (i) All sheep and goats on the holding must be identified.
 - (ii) The Government pays for the collection, brain sampling and disposal and TSE testing of all fallen animals over 18 months of age.
 - (iii) The Government pays for the transport of a quota of 'annual cull' animals over 18 months of age to pre-arranged abattoirs; for them to be sampled by the Food Standards Agency (FSA) Operations Group; and for these samples to be dispatched to the AHVLA laboratory in Newcastle for TSE testing.
 - (iv) Only Type 1 rams and Type 1 or 2 ewes may be introduced onto the holding. Goats may be introduced, provided that no Type 3, 4 or 5 sheep are present on the holding and all animal housing has been thoroughly cleaned and disinfected following destocking.
 - (v) Only semen from Type 1 rams, and Type 1 or 2 embryos, may be used on the holding.
 - (vi) Sheep known to be Type 1 may be moved from the holding without restriction. Sheep known to be Type 2 or 4 may only be moved from the holding to go directly for slaughter or destruction: however, ewes known to be Type 2 may also be moved to other holdings which are under movement restriction following confirmation of classical scrapie. Goats may be moved to holdings which are subject to intensified TSE monitoring, including the testing of all goats over 18 months of age which are slaughtered for human consumption, or die or are killed on the holding other than for human consumption. No other movements off the holding are allowed, except by a formal arrangement to allow the fattening of store lambs or kids.
 - (vii) Government pays AHVLA to monitor compliance with the rules.
 - (viii) The Government also provides 'assistance payments' for genotyping of replacement stock, and for the purchase of replacement rams for breeding purposes.
 - (ix) There is a labour cost to industry of restocking.

Table 1: Scrapie Genotypes as defined by the National Scrapie Plan

Type 1	Type 2	Type 3	Type 4	Type 5
ARR/ARR	ARR/AHQ	AHQ/AHQ	ARR/VRQ	AHQ/VRQ
	ARR/ARH	AHQ/ARH		ARH/VRQ
	ARR/ARQ	AHQ/ARQ		ARQ/VRQ
		ARH/ARH		VRQ/VRQ
		ARH/ARQ		
		ARQ/ARQ		

This table sets out levels of resistance to classical scrapie as defined by the <u>National Scrapie Plan</u>, with ARR/ARR or Type 1 being the most resistant and genotypes with no ARR alleles (Types 3 and 5), the least resistant.

19. The <u>advantages</u> of Option 0 are that it controls classical scrapie by culling genetically susceptible stock on affected holdings, and that genetically susceptible animals from affected holdings are not allowed into the food chain.

The <u>disadvantages</u> of Option 0 are that it is a disproportionate response to the risk posed by the disease to animal health and that it is not the most cost effective solution. Government has to pay for the cost of genotyping, of compensation for genetically susceptible animals, and for replacement rams. There are costs to industry for the loss of stock and for the time spent on genotyping and sourcing replacement animals. Scrapie is not known to pose a risk to public health.

Schedule 3: Cattle Compensation

20. Schedule 3, Paragraph 8 of the 2010 Regulations sets out the requirements for the Secretary of State to pay compensation in respect of cattle killed on suspicion of being infected with a TSE and for cattle killed in pursuit of BSE eradication. Paragraphs 4 and 5 set out the requirement to kill offspring aged two years and under of confirmed cases, and cohort animals (cattle born up to twelve months before or after the confirmed case which were reared and shared feed with it), in pursuit of BSE eradication. Paragraph 9 sets out the categories for compensation, as shown in Table 2. Since 2006, the cattle categories and compensation rates for BSE have been aligned with those for BTb, brucellosis and EBL under the Cattle Compensation (England) Order 2006.

Table 2: Categories for BSE compensation as set out in the TSE Regulations 2010 and the Cattle Compensation Order 2006

Categories	
Male	Female
Beef Sector — non-pedigree animal	remaie
Up to and including 3 months	Up to and including 3 months
Over 3 months up to and including 6 months	Over 3 months up to and including 6 months
Over 6 months up to and including 9 months	Over 6 months up to and including 9 months
Over 9 months up to and including 12 months	Over 9 months up to and including 12 months
Over 12 months up to and including 16 months	Over 12 months up to and including 16 months
Over 16 months up to and including 20 months	Over 16 months up to and including 20 months
Over 20 months	Over 20 months
Breeding bulls	Calved
Other	Not Calved
Dairy Sector — non-pedigree animal	
Up to and including 3 months	Up to and including 3 months
Over 3 months up to and including 6 months	Over 3 months up to and including 6 months
Over 6 months up to and including 12	Over 6 months up to and including 12
months	months
Over 12 months up to and including 16 months	Over 12 months up to and including 16 months
Over 16 months up to and including 20 months	Over 16 months up to and including 20 months
Over 20 months	Over 20 months
	Calved
	Not Calved
Beef Sector — pedigree animal	
6 months up to and including 12 months	6 months up to and including 12 months
Over 12 months up to and including 24 months	Over 12 months up to and including 24 months
	Over 24 months (not calved)
	Calved under 36 months
	Over 24 months
	Calved 36 months and over
Dairy Sector — pedigree animal	
Up to and including 2 months	Up to and including 2 months
Over 2 months up to and including 12 months	Over 2 months up to and including 10 months
Over 12 months up to and including 24 months	Over 10 months up to and including 18 months
Over 24 months	Over 18 months (not calved)
	Calved under 36 months
	Calved 36 months and over

The valuations are calculated and published monthly, using market data, and are published on the Defra website.

The <u>disadvantage</u> of Option 0 is that compensation for BSE cattle would not be paid at rates which accurately reflect the value of the animals on the open market and appropriate data would not be used when determining the average compensation value. If we do not take the opportunity to align the statutory compensation system for BSE with the similar amendments made under the Cattle

Compensation (England) Order 2012, BSE compensation would be paid at different rates, which would increase the complexity of the system for farmers.

Schedule 3: Appeals against decisions to kill BSE cohort animals

21. Under the 2010 Regulations, owners are permitted to submit a general appeal against a decision to kill a BSE cohort animal.

The <u>advantage</u> is that the owner of a cohort animal which is to be killed can appeal against the Government decision, e.g. because the animal did not have access to the same feed as the confirmed BSE case or because it is a bull housed continuously in a semen collection centre.

The <u>disadvantage</u> is that the wording of Schedule 3, paragraph 5.2(b) does not restrict the criteria for making an appeal. This means that an owner can appeal against a decision to kill without giving a reason for doing so. This can cause unnecessary delays in the culling process and waste the staff time expended in processing the appeal.

Option 1: Monitoring Option for Classical Scrapie controls, alignment of BSE compensation rates with the Cattle Compensation (England) Order 2012, and minor technical amendments

Proposed Amendments to Schedule 4: Classical Scrapie Controls: Monitoring Option

22. Under this option:

- (i) A maximum of 50 sheep over three months of age per flock would be genotyped.
- (ii) Genetically susceptible animals would not be killed and destroyed, and could be sent for slaughter for human consumption subject to a negative test for TSE if over 18 months of age.
- (iii) Assistance payments for genotyping replacement ewes, and for purchasing replacement rams, would cease, but would still be available for the genotyping of replacement rams.
- 23. Affected holdings would remain under a movement restriction period for two years following the detection of the last case during which the following controls would apply:
 - (i) All sheep and goats on the holding must be identified;
 - (ii) Instead of genotyping all sheep over three months old, Government will arrange and pay for a maximum sample of 50 sheep per flock to be genotyped. Any further genotyping will be at the discretion of the keeper;
 - (iii) Sheep which have been identified as genetically susceptible (Type 3 and Type 5) will no longer be collected from the farm for killing and disposed of with compensation. However, these animals should not be used for breeding. Owners are advised to send them to slaughter to reduce the likelihood of new classical scrapie cases;
 - (iv) All lambs and kids may be sent for slaughter for human consumption;
 - (v) Sheep and goats over 18 months of age may also be slaughtered for human consumption but they need to be TSE tested, which is arranged and paid for by Government. This means that these animals have to be sent to selected abattoirs where they can be sampled for testing. Government will organise and pay for transport of these cull animals to the abattoir;
 - (vi) Sheep and goats over 18 months of age which die or are killed on the farm other than for human consumption continue to require TSE testing. Government will continue to arrange and pay for carcase collection, sampling, testing and disposal;
 - (vii) No other movements off the holding are allowed, except for slaughter or by a formal arrangement to allow the fattening of store lambs or kids. Sheep known to be Type 1 may be moved to other holdings which are under movement restriction following confirmation of classical scrapie;
 - (viii) Replacement goats and female sheep may be sourced from any unrestricted premises without regard for genotype. However, owners are advised to source genetically more resistant sheep (not Type 3 or 5) to reduce the likelihood of new classical scrapie cases;
 - (ix) Male sheep may only be brought onto the holding if they are Type 1. Government will continue to offer financial assistance for genotyping in order to source replacement rams;
 - (x) No embryos or ova may be dispatched from the holding;
 - (xi) Only semen from Type 1 rams, and Type 1 or 2 embryos, may be used on the holding;
 - (xii) All sheep and goats on the holding shall be subject to common grazing restrictions, based on a reasoned consideration of all the epidemiological factors.

24. The advantages of Option 1 are that:

(i) It confirms in domestic legislation how we implement the classical scrapie control options available in the EU TSE Regulation. The monitoring option is a proportionate response to the risk posed by the disease to animal and public health. Classical scrapie is not known to be a risk to human health, and the prevalence of the disease has reduced considerably in recent years. Only a very few holdings are now affected every year.

- (ii) It is the most cost effective solution and would result in the greatest savings to Government and industry. Government would not have to pay for costly genotyping and culling action on affected holdings, and keepers would not suffer losses resulting from the culling of stock and the time spent on genotyping and the sourcing of new stock. During the monitoring period, all animals over 18 months of age on affected holdings must test negative for TSE prior to entering the food chain, and all fallen animals over 18 months of age must be tested for TSE.
- (iii) It aims to improve the balance of responsibility for controlling classical scrapie between the taxpayer and industry. Government will continue to operate and pay for the controls on affected holdings and for the genotyping of replacement rams. Keepers will have an increased incentive to control classical scrapie on their holdings and avoid the possibility of further cases, which would cause the two year monitoring period to be extended, by only purchasing female animals known to be Type 1, 2 or 4, breeding new stock for genetic resistance, and sending genetically susceptible animals to slaughter.

In the non-formal consultation on the TSE Roadmap in September 2010, key stakeholders in the sheep and goat industry expressed their support for the monitoring option as a more proportionate response to classical scrapie controls.

The <u>disadvantages</u> of Option 1 are that:

- (i) There is an increase in the risk that classical scrapie may persist on affected holdings if keepers fail to take responsibility for managing the disease, including the removal of the most susceptible animals, purchasing animals which have been bred for genetic resistance, and breeding for genetic resistance.
- (ii) There is only a slight increase in the risk that classical scrapie may spread to new holdings if keepers on affected holdings fail to comply with the movement restrictions. As shown in Table 4, only a small number of holdings are affected per year. The possibility of a single additional holding per year being affected as a result of this risk is extremely low, and no costings for this possibility have been included in this Impact Assessment.

Both of these risks can be mitigated by official monitoring of keepers' compliance with the restrictions and by financial assistance from the Government with the genotyping of replacement rams for affected flocks.

Proposed Amendments to Schedule 3: Cattle Compensation

25. The Cattle Compensation (England) Order 2006 has been updated and revised to increase the number of cattle categories from 47 to 51 (a net effect of four additional categories), correct certain anomalies in the text, and make other changes only relevant to compensation for BTb. The Cattle Compensation (England) Order 2012 came into force on 1 July 2012.

The main relevant changes are to:

- (i) Introduce categories for young pedigree beef animals 0-6 months of age;
- (ii) Revise the text so that it is clear that only animals with a full pedigree certificate receive pedigree compensation and that owners of steers will not receive compensation at pedigree rates;
- (iii) Clarify the period over which sales data is collected to calculate table values, i.e. 1 month sales data collection period, lasting from the 21st of the month to the 20th of the following month for non-pedigree cattle and a rolling period of 6 months lasting from the 21st of the month until the 20th of the sixth following month for pedigree cattle;
- (iv) Define the sales price data used to calculate the average market price for compensation purposes, i.e. data in relation to domestic cattle from store markets, prime markets, rearing calf sales, breeding sale and dispersal sales in Great Britain.
- (v) Limit compensation payments to cattle with the legally required ID documentation;
- (vi) Split the current single category for non-pedigree dairy calved females into two age bands, over 20 months up to 84 months and over 84 months, so that compensation more accurately reflects market values;

- (vii) Split the current single category for pedigree dairy calved females into two age bands, over 36 months up to 84 months and over 84 months, so that compensation more accurately reflects market values; and
- (viii) Reduce compensation for owners of herds with BTb breakdowns disclosed through significantly overdue tests (this amendment is not relevant for cattle affected by BSE)

Under this option, the 2010 Regulations would be aligned with the Cattle Compensation (England) Order 2012. The valuation table would be amended as shown in Table 3. New and amended categories are shown in italics.

Table 3: Categories for BSE compensation as set out in the proposed TSE (England) (Amendment) Regulations 2012 and the Cattle Compensation (England) Order 2012

Male	Female
Beef Sector – non-pedigree animal	
Up to and including 3 months	Up to and including 3 months
Over 3 months up to and including 6 months	Over 3 months up to and including 6 months
Over 6 months up to and including 9 months	Over 6 months up to and including 9 months
Over 9 months up to and including 12	Over 9 months up to and including 12
months	months
Over 12 months up to and including 16 months	Over 12 months up to and including 16 months
Over 16 months up to and including 20 months	Over 16 months up to and including 20 months
Over 20 months, breeding bulls	Over 20 months, calved
Over 20 months, non-breeding bulls	Over 20 months, not calved
Dairy Sector – non-pedigree animal	
Up to and including 3 months	Up to and including 3 months
Over 3 months up to and including 6 months	Over 3 months up to and including 6 months
Over 6 months up to and including 12 months	Over 6 months up to and including 12 months
Over 12 months up to and including 16 months	Over 12 months up to and including 16 months
Over 16 months up to and including 20 months	Over 16 months up to and including 20 months
Over 20 months	Over 20 months up to and including 84 months, calved
	Over 20 months up to and including 84 months, not calved
	Over 84 months
Beef Sector – pedigree animal	
Up to and including 6 months	Up to and including 6 months
Over 6 months up to and including 12 months	Over 6 months up to and including 12 months
Over 12 months up to and including 24 months	Over 12 months up to and including 24 months
Over 24 months	Over 24 months, not calved
	Over 24 months up to and including 36 months, calved
	Over 36 months, calved
Dairy Sector – pedigree animal	
Up to and including 2 months	Up to and including 2 months
Over 2 months up to and including 12 months	Over 2 months up to and including 10 months
Over 12 months up to and including 24 months	Over 10 months up to and including 18 months
Over 24 months	Over 18 months, not calved
	Over 18 months up to and including 36 months, calved
	Over 36 months up to and including 84 months, calved
	Over 84 months, calved

The <u>advantage</u> of Option 1 is that compensation for BSE cattle would be paid at rates which more accurately reflect the value of the animals on the open market and to ensure that appropriate data is being used when determining the average compensation value. This option takes the opportunity to align the statutory compensation system for BSE with changes made for other notifiable diseases through approved changes included in the Cattle Compensation (England) Order 2012, which would create a single compensation system for major notifiable cattle diseases and would be the simplest system for farmers.

Proposed Amendments to Schedule 3: Appeals against decisions to kill BSE cohort animals

- 26. Under Option 1, appeals against decisions to kill BSE cohort animals would be limited to the following specific criteria in the legislation:
 - (i) Where the owner believes that the animal is not part of a BSE cohort because it did not have access to the same feed as the confirmed BSE case; and
 - (ii) Where the owner contends that the cohort animal is exempted from culling because it is a bull which is continuously kept at, and will not be removed from, a semen collection centre, and will be killed at the end of its productive life.

This amendment would require the owners of BSE cohort cattle to state a reason for appealing against a decision to cull their animals, i.e. that they fulfil a criterion which might enable them to be exempted from a cull, before invoking the full appeal process. Cases which fulfil the specific criteria would be counted as legitimate and would go to appeal. In cases which do not meet the criteria, the owners of cohort cattle would continue to have the existing right to query in writing any decision to cull their animals, and AHVLA would offer guidance.

27. The <u>advantage</u> to this option is that it would limit unqualified appeals and prevent unnecessary delays to the culling process. It is estimated that, on average, five appeals per year are on unjustifiable or inappropriate grounds, resulting in wasted staff time.

Minor Technical Amendments

28. A number of minor technical amendments to the regulations, none of which have any financial impact, are listed in Annex 2.

Monetised and non-monetised costs and benefits of each option, rationale and evidence

Option 0 - Do Nothing: Business as Usual

29. This is the Do Nothing option against which proposals for Option 1 are measured. It therefore has no associated benefits. The costs are given to show how the savings under Option 1 are calculated.

Schedule 4: Classical Scrapie Controls: Genotype and Kill

- 30. The calculations below use the following assumptions:
 - (i) The incidence of classical scrapie in England has declined since 2002 (Table 4). Annual numbers of confirmed classical scrapie cases are now usually very small.

Table 4: Classical Scrapie in England: 2002-2011

Year	Sheep: Number of cases	Sheep: Number of holdings	Goats: Number of cases	Goats: Number of holdings
2002	237	77	0	0
2003	276	100	1	1
2004	183	73	0	0
2005	113	52	4	2
2006	112	47	20	4
2007	23	19	62	2
2008	6	6	35	3
2009	4	3	4	2
2010	0	0	1	1
2011 (to 30 September)	121	4	0	0

- (ii) As classical scrapie case numbers have declined, the numbers of goats and sheep requiring genotyping, and the numbers of goats and classical scrapie susceptible sheep requiring killing and destruction, have also declined, thus reducing the costs of sheep genotyping and the compensation payable to farmers.
- (iii) Incidence of the disease is now very low, and the number of new classical scrapie cases emerging over the next ten years is expected to remain constant, provided that the national flock genotype profile does not deteriorate significantly over the next ten years. This in turn would mean that the number of holdings to be placed under restriction, of goats and sheep on those holdings requiring genotyping, and of goats and classical scrapie susceptible sheep on those holdings requiring killing and destruction, are also expected to remain constant. However, two issues may affect this assumption.
 - a) On 1 January 2011, the method of collecting 10,000 fallen sheep samples and 500 fallen goat samples for the EU's annual UK TSE survey changed. Previously, keepers had volunteered carcases of fallen animals for the survey, and samples came from a relatively small number of holdings. Since this date carcases for testing have been selected at random at disposal sites and come from a far wider selection of holdings. It is possible that this change could increase the number of classical scrapie cases detected under the survey in 2011 and future years: however, in 2011 only 5 cases were confirmed in GB under the survey, which is comparable with past years.
 - b) As Table 4 demonstrates, although only four holdings were affected in the first nine months of 2011, there were 116 cases to date on a single farm. This is an exceptional occurrence, and January-September 2012 has again shown lower case numbers. However, as flocks and herds can vary enormously in size and value, and there is a continued risk of a high level of

infection on a single holding, it is not possible to predict whether or not there may be another occurrence on this scale during the next ten years.

31. For an average year, the assumption on the number of holdings and the number of animals on those holdings as shown in Table 5 is based upon the three sheep holdings placed under restriction during the first three quarters of 2011 <u>less</u> the single holding with 116 cases, which is not a typical holding, plus an estimate of one sheep and one goat holding placed under restriction during the final quarter of the year.

Table 5: Assumption for number and size of holdings in England newly restricted under the Compulsory Scrapie Flocks Scheme in an average year

Holdings in England newly restricted under the Compulsory Scrapie Flocks Scheme	Number of animals on holding	Number of animals over 3 months old on holding	Number of scrapie susceptible animals (25% of sheep over 3 months and all goats over 3 months)
Holding 1 (sheep)	267	214	54
Holding 2 (sheep)	550	440	110
Holding 3 (sheep)	49	40	10
Holding 4 (sheep)	550	440	110
GRAND TOTAL (SHEEP)	1416	1134	284
Holding 5 (goats)	250	200	200
GRAND TOTAL (SHEEP AND GOATS)	1666	1334	484

32. The expenditure identified in Option 0, and the cash savings to Government identified under Option 1, would be offset by income from the EU Veterinary Fund, which provides co-financing of €15 for each rapid TSE test, €4 for each genotyping test kit, and 50% of the average value of all sheep and goats killed in the UK in a calendar year in pursuit of scrapie eradication, up to a maximum of €70 per animal. However, approximately 70% of marginal EU expenditure in the UK is paid for by the UK exchequer via the abatement mechanism (Fontainebleau rebate). The benefits in this Impact Assessment have therefore been adjusted to take account of this such that only 30% of these EU subsidies are treated as net benefits to the UK.

EU subsidies are converted to sterling using the exchange rate on 30 September 2011, which was €1 = £0.86665.

- 33. Under Option 0, the annual costs to Government in an average year would be as follows:
 - (i) Genotyping: 1134 genotyping tests at £15.00 each + £1.00 equipment cost = £18,144.00, in respect of which net EU income (after abatement) = £1,179.34. Net cost to Government: £16,964.66.

Tagging of all affected animals: 1666 tags at £1.00 each = £1,666.00

(ii) Killing, Compensation and Disposal (Initial Cull):

Compensation: Assume:

9 adult males at £500.00 each = £4,500.00 148 adult females at £125.00 each = £18,500.00 327 lambs and kids aged 3-12 months at £75.00 each = £24,525.00 £47,525.00

Net EU income (after abatement): £47,525.00 divided by 484 animals: assume an average of £98.192 per animal \times 50% = £49.096 income per animal = £23,762.464, rounded to £23,762.50 \times 30% = £7,128.75. Net cost to Government: £40,396.25.

Slaughter and incineration costs for 484 animals at £9.00 each = £4,356.00

Transport to approved abattoirs for killing:

Average hire cost per vehicle per collection visit: £83.00
Average mileage per collection visit: £482.00
Total average cost per collection visit: £565.00

The cost for vehicle hire takes into account the depreciation in its value due to wear and tear.

Based on the sizes of the holdings restricted in January-September 2011, it is assumed that seven collection visits would be required for the five holdings in Table 5. £565.00 x 7 = £3,955.00.

Rapid TSE test costs at £20.50 per test plus £2.05 staff costs = £22.55 per animal x 484 = £10,914.20, in respect of which net EU income (after abatement) = £1,887.56. Net cost to Government: £9,026.64.

(iii) Assistance payments: During the two-year restriction period, affected farms are eligible for 'assistance' payments for genotyping replacement stock and for up to £500.00 for purchasing each replacement ram for breeding. This applies both to genetically susceptible rams which are killed and destroyed (i.e. Type 3 and 5) and to rams known to be genetically resistant or less susceptible to classical scrapie (i.e. Type 1, 2 or 4), which are slaughtered for human consumption. Based on the flocks restricted in January-September 2011, it is assumed that 26 rams would be replaced from the flocks in Table 5.

26 assistance payments for replacement rams at £500 each = £13,000.

Genotyping of replacement stock: Up to 5 genotyping tests are available for replacements in respect of every sheep killed. It is assumed that, of the 284 sheep killed under Option 0, in an average year, 5 tests would be required for every replacement. $284 \times 5 = 1420$ tests at £15.00 each + £1.00 staff cost = £22,720, in respect of which net EU income (after abatement)= £1,476.77. Net cost to Government: £21,243.23.

(iv) A quota of annual cull animals on affected farms must be killed at a designated abattoir and sampled for TSE testing, as laid down in Annex III of the EU TSE Regulations:

Table 6: Testing of annual cull animals as laid down in the EU TSE Regulations, Annex III, Chapter II, Paragraph 5

Number of animals over 18 months of age or which have more than two permanent incisors erupted through the gum, killed for destruction in the herd or flock	Minimum sample size
70 or less	All eligible animals
80	68
90	73
100	78
120	86
140	92
160	97
180	101
200	105
250	112
300	117
350	121
400	124
450	127
500 or more	150

The assumptions for annual culls are as follows:

- (i) 25% of each flock would be culled as being genetically susceptible;
- (ii) 20% of the remainder would be slaughtered as annual culls.

Table 7 shows the requirement to test the annual culls in an average year, from the sheep farms in Table 5:

Table 7: Annual culls to be tested in an average year under Option 0

	Number of animals on holding	Reduced by 25% culled as genetically susceptible	Of which 20% to go to annual cull	Minimum sample size of annual culls required to be tested under Annex III
Holding 1 (sheep)	267	200	40	40
Holding 2 (sheep)	550	413	83	68
Holding 3 (sheep)	49	37	8	8
Holding 4 (sheep)	550	413	83	68
Grand Total (Sheep)	1416	1062	214	184

Sampling of annual culls is undertaken at approved abattoirs by the Food Standards Agency at a cost of £28.23 per sample. 184 samples at £28.23 = £5,194.32.

Rapid TSE tests for 184 annual cull animals at £20.50 per test plus £2.05 staff costs = £22.55 per animal = £4,149.20, in respect of which net EU income (after abatement) = £717.59. Net cost to Government: £3,431.61.

- 34. The costs to industry in an average year are estimated as follows:
 - (i) Time spent by keeper assembling animals for genotyping and dealing with associated paperwork: 2 days, £260 per flock
 - (ii) Time spent by keeper 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 cost per flock: £910.00. 4 flocks at £910.00 each = £3,640.00.

35. The baseline costs to Government and industry for classical scrapie controls in an average year under Option 0 can therefore be summarised as follows:

Table 8: Option 0: Do Nothing: Baseline costs for Classical Scrapie controls

				Gross baseline costs in an		Baseline costs in an average year net of EU
			Unit	average year under	Less net	income under Option
	Unit type	Number	cost	Option 0	EU income	0
Genotyping tests: Sheep	Test + equipment cost	1134	£16.00	£18,144.00	£1,179.34	£16,964.66
Tagging of all animals on classical scrapie affected	0001		210.00	2.10,11.1100	21,110.01	210,00 1100
farms	Ear tag	1666	£1.00	£1,666.00	£0.00	£1,666.00
Initial Cull: Compensation	Per animal - average	484	£98.192	£47,525.00	£7,128.75	£40,396.25
Initial Cull: Slaughter and Incineration: Sheep and goats	Per animal	484	£9.00	£4,356.00	£0.00	£4,356.00
Initial Cull: Transport to incinerators	Visit + average mileage	7	£565.00	£3,955.00	£0.00	£3,955.00
Initial Cull: Rapid TSE Tests	Test + staff cost	484	£22.55	£10,914.20	£1,887.56	£9,026.64
Assistance Payments: Purchasing replacement rams	Payment	26	£500.00	£13,000.00	£0.00	£13,000.00
Assistance Payments: Genotyping tests	Test + equipment cost	1420	£16.00	£22,720.00	£1,476.77	£21,243.23
Sampling of annual culls	Test	184	£28.23	£5,194.32	£0.00	£5,194.32
Testing of annual culls	Test + staff cost	184	£22.55	£4,149.20	£717.59	£3,431.61
Classical Scrapie costs to Government under Option 0				£131,623.72	£12,390.01	£119,233.71
Industry: Time spent assembling animals for genotyping and sourcing						
replacement animals	Per farm	4	£910.00	£3,640.00	£0.00	£3,640.00
Classical Scrapie costs to Government and Industry under Option 0				£135,263.72	£12,390.01	£122,873.71

NB: All calculations exclude AHVLA supervision costs, which will be the same under both Option 0 and Option 1.

Net EU income is after the contribution from the UK exchequer (Fontainebleau abatement) – see paragraph 32.

Schedule 3: Cattle Compensation

36. The incidence of BSE has declined sharply since 2000. Annual numbers of BSE cases are very small compared to the numbers killed for BTb, and continue to reduce. Table 9 demonstrates how the numbers of confirmed BSE cases in England have reduced since 2000, while BTb numbers have risen and remain high.

Year **BSE BTb**

Table 9: Historical trends in BSE and BTb cases in England

- 37. Given the fall in annual BSE cases since 2000, it would not be representative of future years to take the past ten years' figures into account. For this reason, calculations for Option 0 and Option 1 have taken into account figures for 2008, 2009 and 2010.
- 38. The EU Veterinary Fund pays 50% of the average value of cattle slaughtered in pursuit of BSE eradication in a Member State, up to a maximum of €500 per animal. As explained at paragraph 32, approximately 70% of these EU subsidies are paid by the UK exchequer. The benefits in this Impact Assessment have therefore been adjusted to take this into account such that only 30% of EU marginal expenditure in the UK is treated as a net benefit.

EU income is converted to sterling using the exchange rate on 30 September 2011, which was €1 = £0.86665.

- 39. For an average year, the following assumptions have been taken into account:
 - (i) As BSE case numbers have fallen over the past ten years, the numbers of offspring and cohort animals requiring killing and destruction have also fallen thus reducing the compensation payable to farmers. However, the number of animals to be killed and destroyed will fluctuate from year to year because BSE cohorts can vary in size and value, depending upon the age of a confirmed case (the older the case, the greater likelihood that cohort animals have already been slaughtered) and the size and number of the farm(s) on which it lived during the first twelve months of its life. The amount of compensation payable will also depend upon the value of the animals killed and destroyed. Following the devolution of budgets in April 2011, there is the additional complication that a confirmed case in England may have cohort animals or offspring in Scotland or Wales, and vice versa.
 - (ii) Incidence of the disease is now very low and is expected to continue at this level for some years to come. For this reason, the number of new BSE cases emerging over the next ten years is expected to

remain constant. This in turn would mean that the numbers of cohort animals and offspring are also expected to remain constant.

- (iii) Confirmed BSE cases are growing older. This means that, over the next ten years, the ages of cohort animals (which make up the greater part of the animals killed and destroyed) are also expected to increase.
- (iv) The requirements for culling of cohort animals and offspring has changed during the past ten years. Between 29 March 1996 and 2 May 2006, all offspring of confirmed BSE cases (whatever their age) had to be killed and destroyed. Since 2 May 2006, this requirement has reduced to the killing and destruction of offspring under two years old. The killing and destruction of cohort animals born on or after 1 August 1996 has been required since the Over Thirty Month rule was replaced on 7 November 2005.
- 40. The number of confirmed cases, cohort animals and offspring in England in 2008, 2009, and 2010 are summarised as shown in Table 10:

Table 10: Confirmed cases, cohort animals and offspring, 2008-2010

Year	Confirmed BSE cases	Offspring	Cohorts	Compensation Paid	Less net EU income	Cost to Government net of EU income
2008	25	Not recorded	116	£171,575	£15,805.02	£155,769.98
2009	9	6	63	£120,627	£11,995.67	£108,631.33
2010	11	15	148	£203,317	£23,462.24	£179,854.76

NB: Net EU income is after the contribution from the UK exchequer (the Fontainebleau abatement – see paragraph 32).

Schedule 3: Appeals against decisions to kill BSE cohort animals

41. There are on average five unqualified appeals in an average year. The staff costs incurred are estimated as shown in Table 11:

Table 11: Staff costs per case for unqualified appeals against the killing of BSE cohort animals

Grade	Hours spent on appeal	Annual Salary	Hourly salary spent on appeal	NI (0.15% of pay costs) spent on appeal	Annual General Overhead	Annual IBM Support	Annual Shared Services Costs	Annual Accommodation Overhead	Total Annual Non Pay costs	Total Non Pay Costs spent on appeal	Total Pay and Non Pay costs spent on appeal
VA (London)	3.5	£74,731	£168.97	£0.25	£11,579	£648	£3,618	£3,600	£19,445	£43.96	£213.18
VO (Elsewhere)	12	£63,584	£479.58	£0.72	£11,579	£648	£3,618	£3,600	£19,445	£146.66	£626.96
DVM/ROD (Elsewhere)	8	£78,290	£393.66	£0.59	£11,579	£648	£3,618	£3,600	£19,445	£97.77	£492.03
EO (Elsewhere)	2	£31,803	£39.98	£0.06	£11,579	£648	£3,618	£3,600	£19,445	£24.44	£64.48
AO (Elsewhere)	2	£23,648	£29.73	£0.04	£11,579	£648	£3,618	£3,600	£19,445	£24.44	£54.22
Total Cost											£1,450.87

On this basis, unqualified appeals currently cost Government a total of £7,254 in an average year. There are no costs to farmers because the appeals process is carried out at Government expense.

Option 1 - Monitoring Option for Classical Scrapie controls, alignment of BSE compensation rates with the Cattle Compensation Order 2012, and minor technical amendments

Proposed amendments to Schedule 4: Classical Scrapie Controls: Monitoring Option

- 42. Under this option, the Government would make savings on the following:
 - (i) Genotyping tests would be reduced to 50 animals per farm.
 - (ii) There would be no 'initial cull' of classical scrapie susceptible animals, which means that no compensation would be payable, and there would be no costs for transport of animals for killing and destruction, or for sampling and TSE testing of animals over 18 months of age.
- 43. As explained at paragraph 32, the expenditure identified in Option 1 would be offset by income from the EU Veterinary Fund, which provides co-financing of €15 for each rapid TSE test, €4 for each genotyping test kit, and 50% of the average value of all sheep and goats killed in the UK in a calendar year in pursuit of scrapie eradication, up to a maximum of €70 per animal. Net costs and benefits of these subsidies are shown in this IA after taking account of the UK abatement (Fontainebleau rebate mechanism)

EU income is converted to sterling using the exchange rate on 30 September 2011, which was €1 = £0.86665.

The costs to Government under Option 1 are estimated as follows:

<u>Genotyping</u>: Genotyping of whole flocks would be replaced by genotyping of 50 sheep per flock. 4 flocks: 200 genotyping tests at £15.00 each + £1.00 equipment cost = £3,200, in respect of which net EU income (after abatement) = £208.00. Net cost to Government: £2,992.00.

Tagging of all affected animals: 1666 tags at £1.00 each = £1,666.00

<u>Killing, Compensation and Disposal (Initial Cull):</u> No further killing, compensation and disposal would be required as genetically susceptible animals could be sent for slaughter for human consumption.

<u>Assistance payments</u>: There would no longer be a case for 'assistance' payments for genotyping replacement ewes and lambs and for purchasing replacement rams. This saving would be partially offset by assistance payments for genotyping of rams intended for breeding to encourage farmers to control classical scrapie in affected holdings.

Option 0 estimates that 26 rams for breeding would require replacement in an average year and that five genotyping tests would be required to source each replacement. $26 \times 5 = 130$ tests at £15.00 each + £1.00 equipment cost = £2,080.00, in respect of which net EU income (after abatement) = £135.20. Net cost to Government: £1,944.80.

<u>Testing of annual culls</u>: All annual cull animals on affected farms would have to be tested. The assumption is that 20% of the whole flock/herd would be slaughtered as annual culls in an average year.

Table 12: Annual culls to be tested in an average year under Option 1

	Number of animals on holding	Annual culls tested under Option 0	Annual culls tested under Option 1 (20% of whole flock/herd)
Holding 1 (sheep)	267	40	53
Holding 2 (sheep)	550	68	110
Holding 3 (sheep)	49	8	10
Estimate for 1 October-31 December 2011: Holding 4 (sheep)	550	68	110
Grand total (sheep)	1416	184	283
Estimate for 1 October-31 December 2011: Holding 5 (goats)	250	0	50
Grand total (sheep and goats)	1666	184	333

The costs for sampling and testing 333 annual cull animals per year would be:

Sampling of annual culls is undertaken at approved abattoirs by the Food Standards Agency at a cost of £28.23 per sample: 333 samples = £9,400.59.

Rapid TSE tests for 333 annual cull animals at £20.50 per test plus £2.05 staff costs = £22.55 per animal x 333 = £7,509.15, in respect of which net EU income (after abatement) = £1,298.68. Net cost to Government: £6,210.47.

<u>Environmental benefit:</u> In an average year, it is estimated that 484 sheep and goat carcases would not be incinerated.

9 @110 -130kg per animal: Weight incinerated = 990 - 1,170kg

148 @ 60-85kg per animal: Weight incinerated = 8,880 - 12,580kg

327 @ 25-35kg per animal: Weight incinerated = 8,175 - 11,445 kg

The total weight of animals that would not be incinerated under Option 1 is therefore between 18,045 and 25,195 kg.

44. The total costs to Government for classical scrapie controls under Option 1 in an average year can therefore be summarised as follows:

Table 13: Option 1: Monitoring Option: Costs for Classical Scrapie controls

	Unit type	Number	Unit cost	Gross costs in an average year under Option 1	Less net EU income	Costs in an average year net of EU income under Option 1
	Test +					
Genotyping tests	staff cost	200	£16.00	£3,200.00	£208.00	£2,992.00
Tagging of animals on classical scrapie	_					
affected farms	Ear tag	1666	£1.00	£1,666.00	£0.00	£1,666.00
Assistance Payments: Genotyping Tests	Test + staff cost	130	£16.00	£2,080.00	£135.20	£1,944.80
Sampling of annual culls	Test	333	£28.23	£9,400.59	£0.00	£9,400.59
Testing of annual culls	Test + staff cost	333	£22.55	£7,509.15	£1,298.68	£6,210.47
Total costs to Government				£23,855.74	£1,641.87	£22,213.87

NB: All calculations exclude AHVLA supervision costs, which will be the same under both Option 0 and Option 1.

EU income is net of the contribution from the UK exchequer (see paragraph 32).

Proposed Amendments to Schedule 3: Cattle Compensation

- 45. As the majority of animals killed as BSE suspects and as cohort animals tend to be 84 months of age or over, it is expected that, of the proposed changes to cattle compensation described at paragraph 25, the amendment which would have the greatest effect upon BSE compensation is the proposal to split the categories for dairy calved animals into two age bands: over 20 months up to 84 months, and over 84 months. The overall effect of the proposed changes upon BSE compensation in any year would depend upon the numbers, ages and categories of the animals killed.
- 46. The figures in Table 10 have been analysed to identify the animals which would be affected by the proposed changes in compensation rates. The result of the analysis is shown at Table 14. In 2008, a larger number of dairy animals over 84 months of age were killed, which under Option 1 would reduce the compensation paid. In 2009, the dairy animals killed were between 20 and 84 months of age, which under Option 1 would slightly increase the compensation paid, and in 2010, the numbers of dairy animals in the two categories offset each other, leaving the compensation payable under Option 1 virtually unchanged from Option 0.

Table 14: Historic Compensation payments for BSE, 2008-2010, and comparison with the proposed system

Year	Total BSE compensation – Option 0	Total BSE Compensation – Option 1	Difference between existing and proposed systems
2008	£171,575	£147,252	-£24,323
2009	£120,627	£123,813	£3,186
2010	£203,317	£202,841	-£476
Averages	£165,173	£157,969	-£7,204

- 47. Using these estimates generates an average annual fall in compensation payments over the three years of £7,204.00 which is a cost imposed on farmers as this is the fall in the compensation that they would receive. In contrast, the Government would experience a benefit of £7,204.00 as it will have reduced its compensation payments to farmers by this amount. However, this calculation takes into account an unexpected increase in the number of offspring and cohort animals killed in 2010, which was significantly higher than the number of offspring and cohort animals killed in 2011. As we can expect lower numbers of offspring and cohort animals in future years, the actual fall in compensation payments in future years could also be lower.
- 48. Only certain categories of cattle would be affected by the proposed changes. It is therefore not definite how much of the average figure of £7,204.00 would be offset by the EU income.
- 49. An average of 116 offspring and cohorts have been slaughtered per year in the past three years. Taking the assumption that an average of 50% of animals slaughtered in a calendar year would be affected by the proposed changes, 58 animals per year would receive compensation of an average of £124.00 per year more under the current system than under the new system. £124.00 x 58 x 50% x 30% = EU income (after abatement) of £1,078.80.

Net benefit to Government: £6,125.20

Net cost to industry: £7,204.00

Proposed Amendments to Schedule 3: Appeals against decisions to kill BSE cohort animals

- 50. If the criterion for appeals against decisions to kill BSE cohort animals is limited to specific decisions relating to access to feed or housing in a semen collection centre, Government would be saved the cost of an average of 5 unqualified appeals per year. It is estimated that each appeal incurs approximately £1,451 in staff costs. It therefore follows that this change would save Government a total of £7,254 per year. No change is expected in the level of AHVLA staff costs for providing advice to the owners of cohort cattle which do not fulfil the specific criteria. There would be no additional costs to farmers as a result of this change because all cattle killed under the BSE cohort cull receive compensation in line with market values (paragraphs 8-9, 20-21, 25, 36-40 and 45-49 refer).
- 51. The savings to Government for BSE in an average year which would be affected by the proposed changes, can therefore be summarised as shown in Table 15:

Table 15: Option 1: BSE Savings to Government

Unit type	Number	Unit cost	Savings to Government	Less Net EU income	Savings to Government net of EU income
Average					
total compensation					
year	N/A	N/A	£7,204.00	£1,078.80	£6,125.20
Appeal	5	£1,451.00	£7,254.00	£0.00	£7,254.00
11	·	, , , , , , , , , , , , , , , , , , , ,	,	C4 070 00	£13,379.20
	Average change to total compensation in an average year	Average change to total compensation in an average year N/A	Average change to total compensation in an average year N/A N/A	Unit type Number Unit cost Government Average change to total compensation in an average year N/A N/A £7,204.00	Unit type Number Unit cost Government EU income Average change to total compensation in an average year N/A N/A £7,204.00 £1,078.80 Appeal 5 £1,451.00 £7,254.00 £0.00

NB: EU income is net of the contribution from the UK exchequer (see paragraph 32).

Savings and costs to Government and industry under Option 1 compared with Option 0

52. Tables 16 and 17 summarise the savings to Government under Option 1, shown as the balance between the costs identified under Option 0 and Option 1 (Tables 8 and 13 for classical scrapie, Tables 11, 14 and 15 and paragraphs 45-51 for BSE).

Table 16: Classical Scrapie: Savings to Government under Option 1

	Gross baseline costs in an average year under Option 0	Less net EU income	Baseline costs in an average year less net EU income under Option 0	Gross costs in an average year under Option 1	Less net EU income	Costs in an average year less net EU income under Option 1	Gross savings in an average year under Option 1	Less net EU income	Savings in an average year less net EU income under Option 1
Genotyping tests: Sheep	£18,144.00	£1,179.34	£16,964.66	£3,200.00	£208.00	£2,992.00	£14,944.00	£971.34	040 070 00
Tagging of all animals on classsical scrapie affected farms	£1,666.00	£1,179.34 £0.00	£1,666.00	£1,666.00	£0.00	£2,992.00 £1.666.00	£14,944.00	£0.00	£13,972.66 £0.00
Initial Cull:	£1,000.00	20.00	£1,000.00	£1,000.00	20.00	£1,000.00	20.00	20.00	20.00
Compensation	£47,525.00	£7,128.75	£40,396.25	£0.00	£0.00	£0.00	£47,525.00	£7,128.75	£40,396.25
Initial Cull: Slaughter and Incineration: Sheep and goats	£4,356.00	£0.00	£4,356.00	£0.00	£0.00	£0.00	£4,356.00	£0.00	£4,356.00
Initial Cull: Transport to incinerators	£3,955.00	£0.00	£3,955.00	£0.00	£0.00	£0.00	£3,955.00	£0.00	£3,955.00
Initial Cull: Rapid TSE Tests	£10,914.20	£1,887.56	£9,026.64	£0.00	£0.00	£0.00	£10,914.20	£1,887.56	£9,026.64
Assistance Payments: Purchasing replacement rams	£13,000.00	£0.00	£13,000.00	£0.00	£0.00	£0.00	£13,000.00	£0.00	£13,000.00
Assistance Payments: Genotyping Tests	£22,720.00	£1,476.77	£21,243.23	£2,080.00	£135.20	£1,944.80	£20,640.00	£1,341.57	£19,298.43
Sampling of annual culls	£5,194.32	£0.00	£5,194.32	£9,400.59	£0.00	£9,400.59	-£4,206.27	£0.00	-£4,206.27
Testing of annual culls	£4,149.20	£717.59	£3,431.61	£7,509.15	£1,298.68	£6,210.47	-£3,359.95	-£581.09	-£2,778.86
TOTAL	£131,623.72	£12,390.01	£119,233.71	£23,855.74	£1,641.87	£22,213.87	£107,767.98	£10,748.14	£97,019.84

NB: All calculations exclude AHVLA supervision costs, which will be the same under both Option 0 and Option 1.

EU income is net of the contribution from the UK exchequer (see paragraph 32).

Table 17: Total savings to Government under Option 1

	Savings in an average year under Option 1	Less net EU income	Savings in an average year under Option 1 net of EU income
Classical Scrapie: Total savings to Government under Option 1	£107,767.98	£10,748.14	£97,019.84
BSE: Total savings to Government under Option 1	£14,458.00	£1,078.80	£13,379.20
Total BSE and Classical Scrapie savings to Government under Option 1	£122,225.98	£11,826.94	£110,399.04

NB: EU income is net of the contribution from the UK exchequer (see paragraph 32).

53. Costs and savings to industry under Option 1 are summarised in Table 18:

Table 18: Costs and savings to the farming industry under Option 1

	Savings to the farming industry in an average year	Costs to the farming industry in an average year	Costs and savings to industry in an average year
BSE Compensation	£0.00	£7,204.00	£7,204.00 (costs)
Classical Scrapie: Time spent assembling animals for genotyping and sourcing			
replacement animals	£3,640.00	£0.00	£3,640.00 (savings)
BSE and classical scrapie costs to the farming industry under Option 1	£3,640.00	£7,204.00	£3,564.00 (costs)

Direct costs and benefits to business calculations (following OIOO (One-In, One Out) methodology)

- 54. Option 1 would result in additional annual costs to the cattle industry of £7,204.00 and annual savings to the sheep and goat industries of £3,640.00. The overall impact would be a net cost to the farming industry as a whole of £3,564.00.
- 55. The additional cost relates to the proposed alignment of the TSE (England) (Amendment) Regulations 2012 with the Cattle Compensation (England) Order 2012. The requirement to pay compensation for animals killed in pursuit of TSE eradication derives from an instruction to Member States in the EU TSE Regulation. This is interpreted as compensation in lieu of market value as per article 10 of Commission Regulation (EC) No 1857/2006.
- 56. The proposed changes to the valuation table are necessary to correct some anomalies in the current statutory compensation system for BSE and to align it with compensation for BTb, brucellosis and EBL under the Cattle Compensation (England) Order 2012. The changes are not intended to penalise farmers, but are intended to ensure that farmers are compensated at rates which more accurately reflect the value of their animals on the open market and to ensure that appropriate data is being used when determining the average compensation value.
- 57. As Option 1 would implement the minimum requirements of the EU TSE Regulation, the TSE (England) (Amendment) Regulations 2012 are exempt from both the OIOO restrictions as well as the moratorium on microbusiness regulation. This is because regulations which are required to implement EU or other international obligations are not within the scope of OIOO.

Wider Impacts

Economic/Financial Impacts

Schedule 4: Classical Scrapie Controls

58. Option 1 would have a positive impact upon the small number of farms in England which are affected by classical scrapie, which will be able to sell their animals for human consumption. Approximately 484 animals per year, which are killed, destroyed and compensated under Option 0, would not be killed and destroyed under Option 1.

Wider Impacts

- 59. There are no expected impacts upon the wider economy or upon domestic competition under Option 1.
- 60. There are no expected impacts upon innovation or upon other Departments under Option 1.

Social Impacts

61. There are no expected social impacts under Option 1.

Environmental Impacts

62. 484 sheep and goat carcases, with a total weight between 18,045 kg and 25,195 kg, would not be incinerated in an average year under Option 1. The environmental impact from this benefit has not been quantified as it is de minimis.

Impact upon Small Businesses

63. A Small Business Impact Test was carried out as part of the consultation process. Comments from respondents did not identify any significant impact upon cattle, sheep and goat farmers resulting from the proposed changes.

Summary and agreed approach with description of implementation plan

64. After taking all feedback received into account, Option 1 is our agreed approach. This option reflects the classical scrapie control options available in Regulation (EC) No.999/2001 and is a proportionate response to the risk of classical scrapie to public and animal health. It will also maintain the existing harmonised approach to cattle compensation by aligning the 2010 Regulations with the Cattle

Compensation (England) Order 2012, ensuring we better reflect market values in determining compensation for BSE and keep it aligned with that for other major notifiable cattle diseases, and will fulfil Government requirements on better regulation, clarify enforcement procedures, limit unqualified appeals against killing of cattle under the 2010 Regulations, and remove an obligation and an offence. It will result in net savings to Government of an estimated £110,399 per year and additional net costs to industry of an estimated £3,564.00 per year (annual costs of £7,204 to the cattle industry less annual savings to the sheep and goat industry of £3,640).

- 65. The proportionate controls for classical scrapie have already been adopted as the default option in England on 18 October 2011, using an ambulatory reference in the 2010 Regulations. The 2012 Regulations will amend the 2010 Regulations to reflect the full range of classical scrapie control options available in the EU TSE Regulation. The table valuations for compensation for cattle killed under the 2010 Regulations will be aligned with the changes implemented in the Cattle Compensation Order (England) 2012, as soon as the 2012 Regulations come into force. The technical amendments will be implemented at the same time.
- 66. Table 19 summarises the costs and benefits over a 10 year horizon and forms the basis of the cost and benefit data that appears on the summary pages at the beginning of this Impact Assessment.

Table 19: Summary of Costs and Benefits (£m)

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Total
At											
constant											
prices											
Benefit	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.036
to											
industry											
Cost to	(0.007)	(0.007)	(0.007)	(0.007)	(0.007)	(0.007)	(0.007)	(0.007)	(0.007)	(0.007)	(0.072)
industry											
Benefit	0.110	0.110	0.110	0.110	0.110	0.110	0.110	0.110	0.110	0.110	1.104
to govt											
Total net	0.107	0.107	0.107	0.107	0.107	0.107	0.107	0.107	0.107	0.107	1.068
benefit											
Present											
Value											
Benefit	0.114	0.110	0.106	0.103	0.099	0.096	0.093	0.090	0.087	0.084	0.982
to											
industry											
and govt											
Cost to	(0.007)	(0.007)	(0.007)	(0.006)	(0.006)	(0.006)	(0.006)	(0.006)	(0.005)	(0.005)	(0.062)
industry											
Total net	0.107	0.103	0.100	0,096	0.093	0,090	0.087	0.084	0.081	0.078	0.920
benefit											

N.B. In this table the parenthesis indicate that costs are to be deducted from benefits to give the net benefit.

Annex 1 -Post Implementation Review

Basis of the review:

The basis of the review will be to assess the impact of, and better quantify, the preferred option, by 30 November 2016, as laid down in Regulation 24 of the TSE (England) Regulations 2010, as amended by the Animal By-Products (Enforcement) and TSE (England) (Amendment) Regulations 2012.

Review Objective:

The objective of the review is (i) to assess the performance of the monitoring option (Option 1) for classical scrapie, to ensure that it remains the most proportionate response to classical scrapie in England, delivers the expected, risk based level of protection to animal and consumer health, and represents the best use of taxpayers' money; and (ii) to assess the impact of the changes to BSE compensation.

Review approach and rationale:

The scope of the review will include (i) assessment of the genotyping and TSE testing data accumulated since October 2011, including the numbers of annual cull animals slaughtered and tested, taking into account the numbers and sizes of any holdings taken into the Compulsory Scrapie Flocks Scheme since then. This information will help us to evaluate the performance of the monitoring option and to develop future policy for classical scrapie holdings; and (ii) assessment of compensation payments made in respect of BSE cohort animals and offspring. This information will help us to evaluate the level of impact from the changes to BSE compensation in the Cattle Compensation (England) Order 2012.

Baseline:

The baseline will be a continuation of the policy under Option 0 for the genotyping of sheep and the culling and TSE testing of classical scrapie susceptible sheep and all goats on classical scrapie holdings; and payment of BSE compensation under the TSE (England) Regulations 2010 and the Cattle Compensation (England) Order 2006.

Success Criteria:

The success criteria are (i) the establishment of a risk-based monitoring system to control classical scrapie on affected holdings, which will provide a proportionate response to the disease and continues to protect public and animal health; (ii) that the prevalence of classical scrapie in England remains constant or reduces under the monitoring system; and (iii) the maintenance of a single system which ensures a consistent approach to the calculation of compensation rates for BSE and other major cattle diseases.

Monitoring Information Arrangements:

The monitoring arrangements are set out below:

- AHVLA records of names, locations and sizes of flocks and herds under CSFS restriction;
- AHVLA test data for annual culls;
- AHVLA records of genotyping tests at affected farms;
- AHVLA data for compensation paid in respect of BSE cohort and offspring cattle.

Reasons for not planning a review:

N/A

Annex 2 - Minor technical amendments to the TSE (England) Regulations 2010, included in the TSE (England) (Amendment) Regulations 2012

- Regulation 15 sets out the circumstances in which inspectors may serve a notice under the
 Regulations; what prohibitions and/or requirements the notice may contain; and lays down that the
 notice must state how it is complied with, and the time limits for serving a notice. It is proposed to
 add a new Regulation 15A which clarifies how notices under the Regulations may be served, e.g. by
 delivering it to a person, leaving it at the person's proper address, or sending it by post to the
 person's proper address. A notice may specify that a person in receipt of it must immediately inform
 an inspector of its safe receipt.
- Schedule 2, Paragraph 1 includes a statutory requirement for goat keepers to notify the Secretary of State about fallen goats aged eighteen months and over. This requirement ceased on 31 December 2010. Since that date, carcases have been randomly selected for TSE sampling at animal byproducts plants, based on quotas provided by AHVLA. It is therefore proposed that this requirement, and the associated offence for failing to report a fallen goat, should be removed.
- Schedule 2, Paragraph 10 (1) currently allows the Secretary of State (SoS) to approve private
 laboratories to test bovine samples taken at abattoirs. It is proposed to expand this provision to
 cover the approval of private laboratories for all bovine categories of rapid testing of samples for
 TSEs. This is necessary as technically approved laboratories could not test cattle other than healthy
 slaughter, and sometimes these laboratories are expected to test 'fallen stock', e.g. which died in
 lairage.
- Schedule 4, Sub-Paragraphs 11 (3) and (4) set out the length of time which the Secretary of State may delay the killing of a goat herd in which TSE has been confirmed, as five years for meat herds and eighteen months for dairy herds. Currently, the EU TSE Regulation sets the length of the deferral period as five years for meat herds, and extends the deferral period to 31 December 2012 for dairy herds where the index case was confirmed before 1 July 2011. We propose to insert an ambulatory clause to align the deferral periods in Schedule 4, Sub-Paragraphs 11(3) and (4) with current and future revisions to the EU TSE Regulation.
- Under Schedule 6, Paragraph 18 (3) it is currently an offence to export fishmeal, products containing
 fishmeal and petfood without an agreement in writing between the Secretary of State and the third
 country receiving the products. This exceeds the requirements of the EU TSE Regulation, which
 does not require written agreement. We propose to insert an ambulatory clause which would align
 the requirements of the 2010 Regulations with the conditions and exemptions for these products as
 currently set out in Annex IV, Part II of the EU TSE Regulation and with any future revisions.

Annex 3 - Glossary

Acronym	Term	Definition				
AHVLA	Animal Health Veterinary Laboratory Agency	Defra agency, formed on 1 April 2011 following the merger of Animal Health and the Veterinary Laboratories Agency (VLA).				
(none)	Allele	An alternative form of a gene that is located at a specific position on a specific chromosone. These DNA codings determine distinct traits that can be passed from parents to offspring.				
(none)	Brucellosis	An infectious disease that occurs from contact with animals carrying Brucella bacteria.				
BSE	Bovine Spongiform Encephalopathy	TSE in cattle.				
BTb	Bovine Tuberculosis	A chronic infectious disease which affects a broad range of mammalian hosts including humans, cattle, deer, llamas, pigs, domestic cats, mustelids (mammals of the weasel family), rodents, and wild carnivores including badgers and foxes.				
(none)	Classical Scrapie	A TSE in sheep, to which certain genotypes are susceptible.				
(none)	Cohort	Group of cattle born up to twelve months before or after a confirmed case of BSE, which shared feed with it.				
(none)	Cohort animal	An animal from a cohort.				
CSFS	Compulsory Scrapie Flocks Scheme	A compulsory programme which requires disease control action to be taken in flocks or herds which have had a confirmed case of classical or atypical scrapie.				
EBL	Enzootic Bovine Leukosis	A viral disease in adult cattle.				
EC	European Commission	The executive body of the European Union.				
EFSA	European Food Safety Authority	The EU risk assessment body for food and feed safety.				
EU	European Union	The economic and political union of 27 Member States.				
(none)	EU General Court	A jurisdictional instance of the Court of the European Union: an independent court attached to the European Court of Justice.				
(none)	Fallen animals	Animals which die or are killed other than for human consumption.				
FSA	Food Standards Agency	Non-Ministerial Government Department, responsible for protecting public health in relation to food.				
(none)	Genotyping	A test on a sheep's DNA to determine its genetic resistance or susceptibility to scrapie. Usually carried out using blood samples.				
(none)	Lairage	Animal handling facilities at sale yards or abattoirs.				
NSP	National Scrapie Plan	A joint initiative of British agricultural departments, launched in 2001 with the principal objective of increasing the level of resistance to TSEs in the national sheep flock.				
(none)	Offspring	Offspring of a confirmed BSE cow.				
(none)	Polymorphism	An occurrence in which two or more clearly different phenotypes exist in the same population of a species.				

(none)	Prion protein	A small glycoprotein found in high quantity in the brains of animals infected with certain degenerative neurological diseases, such as scrapie, BSE, and CJD.
(none)	Scrapie	TSE in sheep and goats.
SRM	Specialised Risk Material	The tissue in TSE-infected animals that contains the agent that may transmit the disease. In diseased animals, the infective agent is concentrated in certain tissues such as the brain and spinal cord.
(none)	TB Reactor	An animal which has failed the tuberculin skin test.
TSE	Transmissible Spongiform Encephalopathy	Fatal brain disease suffered by a variety of species, including cattle, sheep, goats, deer and cats.
(none)	TSE Roadmap	The European Commission's strategy paper on TSEs.
vCJD	Variant Creutzfeldt-Jakob Disease	TSE-like disease in humans.