

## **The Transmissible Spongiform Encephalopathies (Wales) Regulations**

**2018.**

This Explanatory Memorandum has been prepared by The Office of the Chief Veterinary Officer and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1

### **Minister's Declaration**

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Transmissible Spongiform Encephalopathies (Wales) Regulations 2018. I am satisfied that the benefits outweigh any costs.

***Lesley Griffiths***

**Cabinet Secretary for Energy, Planning & Rural Affairs**

**6 September 2018**

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# Part 1

## 1. Description

- 1.1 Transmissible Spongiform Encephalopathies (TSEs) are fatal brain diseases that include Bovine Spongiform Encephalopathy (BSE) in cattle and scrapie in sheep and goats. Exposure to BSE through the consumption of infected or contaminated meat is believed to be the primary cause of variant Creutzfeldt – Jakob disease (vCJD) in humans.
- 1.2 Regulation (EC) No. 999/2001 of the European Parliament and the Council, as amended ('the EU TSE Regulation') lays down rules for the prevention, control and eradication of TSEs. The Welsh Government needs to implement TSE controls, in line with EU requirements. The current domestic TSE legislation in Wales is the Transmissible Spongiform Encephalopathies (Wales) Regulations 2008, as amended.
- 1.3 Due to a number of amendments to the EU TSE Regulation, the Transmissible Spongiform Encephalopathies (Wales) Regulations 2008 need to be revoked and replaced with the Transmissible Spongiform Encephalopathies (Wales) Regulations 2018. These regulations provide the powers to administer and enforce the provisions of Regulation (EC) No.999/2001 in Wales.

## 2. Matters of special interest to the Constitutional and Legislative Affairs Committee

- 2.1 There are no matters of special interest which the Cabinet Secretary for Energy, Planning and Rural Affairs wishes to bring to the attention of the Committee.

## 3. Legislative background

- 3.1 The relevant legal power is Section 2(2) of the European Communities Act 1972. The Welsh Ministers have been designated for the purposes of Section 2(2) in relation to measures in the veterinary and phytosanitary fields for the protection of public health.
- 3.2 The Transmissible Spongiform Encephalopathies (Wales) Regulations 2018 instrument will be subject to 'negative procedure'.

## 4. Purpose & intended effect of the legislation

- 4.1 The Welsh Government policy objective is to have TSE controls which maintain consumer and animal health protection; are based on sound

scientific evidence; are proportionate to the known risk; and, are both practical and enforceable.

- 4.2 The proposed changes will bring Welsh legislation into line with similar legislation already in place or in the process of being introduced in England, Scotland and Northern Ireland.
- 4.3 The Transmissible Spongiform Encephalopathies (Wales) Regulations 2018 will reflect amendments to the EU TSE Regulation following the declining prevalence of BSE in cattle and the development of emerging scientific advice and technical advances. They will also address a number of technical points and clarifications arising out of practical experience with the 2008 Regulations.
- 4.4 There are a considerable number of developments and amendments proposed within the consolidated 2018 Regulations compared to the 2008 Regulations. However, the proposed amendments with the greatest potential impact are in Schedules 2, 3, 4, 6 and 7 of the 2008 Regulations. These are considered in more detail below and the impacts of each are considered within the attached Regulatory Impact Assessment (RIA).

#### **Schedule 2: TSE Monitoring and Approval of Laboratories**

- **Required Method of Operations** – Removal of the requirement for abattoirs in Wales slaughtering cattle that require BSE testing to have a Required Method of Operation (RMOP).
- **Home Slaughter** – Amendment to clarify the requirement of a cattle keeper home slaughtering a bovine animal aged over the testing threshold to arrange for both the animal to be sampled and to ensure delivery of the brainstem sample to an approved testing laboratory for BSE testing; and, to extend the retention and disposal requirements to cover home slaughter.
- **BSE Fallen Stock Sampling** – Proposal to transfer the cost of taking fallen stock samples for mandatory BSE testing from the taxpayer to the farming industry.

#### **Schedule 3: Control and Eradication of TSE in Bovine Animals**

- **Appeals against a decision to kill a cohort animal** – Proposal to limit unqualified appeals and prevent unnecessary delays to the culling process.
- **Compensation** – Update and amend the table of categories (increasing the number of categories) to be used to determine Table Valuations for compensation to be paid for bovine animals killed under this Schedule.
- **Compensation** – Amendment to the source of independent valuers for compensation payments for bovine animals.

#### **Schedule 4: Control and Eradication of TSE in Ovine and Caprine Animals**

- **Classical Scrapie Controls** – Amendments to provide for three available options for the control of classical scrapie in sheep flocks and goat herds, which introduce a monitoring and surveillance option.

#### **Schedule 6: Feedingstuffs**

- **Amendment to feed controls in Wales**
  - Amendment to allow for the feeding of pig and poultry Processed Animal Protein (PAP) to farmed fish.
  - To provide for the feeding of fishmeal to un-weaned ruminants in reconstituted milk replacer whilst maintaining the existing ban on feeding fishmeal to adult ruminants.
  - To provide for the export of pet food containing PAP of ruminant origin provided that it is produced and labelled in accordance with the Animal By-Product Regulations.
  - To provide for the use of 'aquatic animals' in processing fishmeal and inclusion in feed for aquaculture animals.
  - To enable the feed industry to use PAP derived from insects in feed for aquaculture animals.
- **Non-ruminant Processed Animal Protein (PAP)** – Removal of the requirement for written bilateral agreements to authorise the export of PAP derived from non-ruminant animals.
- **Ruminant Processed Animal Protein (PAP)** – To permit the export of PAP derived from ruminants.

#### **Other changes necessitated by changes to Annex IV of 999/2001**

There is a need to update Schedule 6 to align with the new Annex IV to the EU TSE Regulation which came into force on 17 January 2013.

Although the EU TSE Regulation is directly applicable, with the provisions continuing to apply, there is no enforcement mechanism in place, something which can only be done via statutory instrument.

#### **Schedule 7: Specified Risk Material, Mechanically Separated Meat and Slaughtering Techniques**

- **Specified Risk Material (SRM)** – Amendment to clarify that it is an offence to fail to remove SRM from ewe carcasses and to make it an offence not to remove SRM from cattle, sheep and goats slaughtered at 'other places of slaughter' (e.g. home slaughter).

- **Bovine Specified Risk Material** – Amendment to the definition of bovine SRM to be removed.
- **Mechanically separated meat** – Amendment to ensure alignment to the EU Regulation in terms of the definition of mechanically separated meat.
- **Requirements of method of spinal cord removal** – Amendment to provide for alternative methods of spinal cord removal to be used as an alternative to carcass splitting (currently the only method that the UK meat processing industry finds acceptable).

## 5. Technical amendments

- 5.1 There are also a number of minor technical amendments to be introduced by the 2018 Regulations (please see **Annex A**).

## 6. Consultation

- 6.1 The Welsh Government held a joint consultation with the Foods Standards Agency (FSA) in 2013, as original intention was to introduce a consolidated version of the Transmissible Spongiform Encephalopathy Regulations in Wales during 2013. Many of the proposed amendments are a result of changes to the directly applicable EU TSE Regulation, and as a result were implemented on an administrative basis across Wales. In these instances, individual engagement occurred with stakeholders to inform them of the changes.

Further to this, due to additional changes to EU legislation and the delay in the introduction of the Regulations, the Welsh Government consulted jointly with Defra and the FSA again on these issues in 2017. This consultation and the summary of responses can be found at the link below.  
<https://consult.defra.gov.uk/plant-and-animal-health/tseconsultation/>

The details of consultation activity undertaken in relation to each proposal are discussed further in the Regulatory Impact Assessment (RIA) below.

# Part 2 Regulatory Impact Assessment

## 7. General

The proposed revocation of the existing Transmissible Spongiform Encephalopathies (Wales) Regulations 2008 and their replacement with the Transmissible Spongiform Encephalopathies Wales Regulations 2018, introduce a significant number of amendments in line with European TSE requirements. Many of these are technical in nature and in response to a decline in the incidence of BSE (and subsequent risk to human health) so provide a simplification of existing controls. In line with EU requirements the Welsh Government has, along with other UK administrations, introduced these amendments where possible on an administrative basis, to provide for the associate benefits to the farming community and to ensure equal opportunities are afforded by those farmers in Wales as are available to the farming industry in other EU Member States. For the majority of those amendments, as a Member State, we have been required to introduce them, and there has been no option to deviate from that prescribed by the European Commission.

Where the amendments have already been introduced on an administrative basis, the introduction of the Transmissible Spongiform Encephalopathies (Wales) 2018 Regulations, are not expected to impose any further additional costs on either the farming industry or the public sector.

This section assesses the evidence associated with these various policy options, but in an attempt to be proportionate to the potential impact of the proposed changes, the level of assessment has been more focused towards those areas where the Welsh Government has had greater control over the policy implementation to be considered and where there has been a clear financial implication for either Government or industry. The level of assessment has been highlighted throughout.

The background and reasoning behind each proposal is outlined, including stakeholder engagement, followed by associated costs and benefits. The available options are then briefly outlined, and the formal recommendation of the Welsh Government is provided. A summary of each of the elements under consideration along with the options and an indication of the preferred option is provided in Table 1 overleaf.



<b>TABLE 1</b>	<b>Preferred Option =</b>	
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	<b>Title</b>	<b>Page</b>	<b>Option 1</b>	<b>Option 2</b>	<b>Recommendation</b>
<b>Proposed Amendment 1</b>	<b>Required Method of Operations</b> – Removal of the requirement for abattoirs in Wales slaughtering cattle that require BSE testing to have a Required Method of Operation (RMOP).	11	Do nothing	Remove the requirement for RMOPs	The Welsh Government recommends the removal of the requirement for RMOPs for those slaughterhouses in Wales where cattle requiring BSE testing.
<b>Proposed Amendment 2</b>	<b>Home Slaughter</b> – Amendment to clarify the requirement of a cattle keeper home slaughtering a bovine animal aged over the testing threshold to arrange for both the animal to be sampled and to ensure delivery of the brainstem sample to an approved testing laboratory for BSE testing; and, to extend the retention and disposal requirements to cover home slaughter.	12	Do nothing	Apply TSE controls to those who slaughter ‘at risk’ cattle for their own consumption – home slaughter	The Welsh Government recommends the application of all TSE controls for those who slaughter at risk cattle to be applied to those animals that are slaughtered on the owners premises for their own consumption.
<b>Proposed Amendment 3</b>	<b>BSE Fallen Stock Sampling</b> – Proposal to transfer the cost of taking fallen stock samples for mandatory BSE testing from the taxpayer to the farming industry.	13	Do nothing	Transfer sampling cost to industry	The Welsh Government, therefore, recommends the implementation of this change based on value for money for the taxpayer, and for consistency and simplicity for industry.
<b>Proposed Amendment 4</b>	<b>Appeals against a decision to kill a cohort animal</b> – Proposal to limit unqualified appeals and prevent unnecessary delays to the culling process.	16	Do nothing	Limit right of appeal against decision to kill cohort animals	We wish to introduce this amendment to limit unqualified appeals and prevent unnecessary delays to the culling process.
<b>Proposed Amendment 5</b>	<b>Compensation</b> – Update and amend the table of categories (increasing the number of	17	Do nothing	Revise compensation categories	The Welsh Government propose revising the compensation categories.

	categories) to be used to determine Table Valuations for compensation to be paid for bovine animals killed under this Schedule.				
<b>Proposed Amendment 6</b>	<b>Compensation</b> – Amendment to the source of independent valuers for compensation payments for bovine animals.	21	Do nothing	Increase the source of Independent Valuers for compensation purposes	The Welsh Government, therefore, recommends extending the source of valuers to those also appointed by CAAV in line with other animal disease compensation valuation methods applied in Wales.
<b>Proposed Amendment 7</b>	<b>Classical Scrapie Controls</b> – Amendments to provide for three available options for the control of classical scrapie in sheep flocks and goat herds, which introduce a monitoring and surveillance option.	22	Do nothing	The Surveillance (monitoring) Option	The Welsh Governments recommended option is the 'surveillance option' (Option 2), subject to the outcome of an epidemiological evaluation in each individual case.
<b>Proposed Amendment 8</b>	<b>Amendment to feed controls in Wales</b> – Amendment to allow for the feeding of pig and poultry Processed Animal Protein (PAP) to farmed fish.	34	Do nothing	Permit the feeding of Pig and Poultry PAP to farmed fish	The Welsh Government recommends amending TSE legislation in Wales to implement this permissive EU derogation.
<b>Proposed Amendment 9</b>	<b>Amendment to feed controls in Wales</b> – To provide for the use of 'aquatic animals' in processing fishmeal and inclusion in feed for aquaculture animals.	36	Do nothing	Extend the definition of 'aquatic animals'	The Welsh Government recommends the extension of the definition of 'aquatic animals' for fishmeal and feed for aquaculture animals in line with the EU recognised definition.

<b>Proposed Amendment 10</b>	<b>Amendment to feed controls in Wales</b> –To enable the feed industry to use PAP derived from insects in feed for aquaculture animals.	37	Do nothing	Enable the feed industry to use PAP derived from insects in feed for aquaculture animals	The Welsh Government recommends the amendment of Welsh TSE legislation to provide for the use of PAP derived from insects in feed for aquaculture animals, in light of the scientific evidence that supports that the proposal is proportionate to the minimal risk level.
<b>Proposed Amendment 11</b>	<b>Non-ruminant Processed Animal Protein (PAP)</b> – Removal of the requirement for written bilateral agreements to authorise the export of PAP derived from non-ruminant animals.	39	Do nothing	Remove the requirements for written bilateral agreements for the export of non-ruminant PAP	The Welsh Government recommends Option 2.
<b>Proposed Amendment 12</b>	<b>Ruminant Processed Animal Protein (PAP)</b> – To permit the export of PAP derived from ruminants.	41	Do nothing	Remove the requirements for written bilateral agreements for the export of non-ruminant PAP	The Welsh Government recommends Option 2.
<b>Proposed Amendment 13</b>	<b>Bovine Specified Risk Material</b> – Amendment to the definition of bovine SRM to be removed.	42	Do nothing	Amendments to the definition and inclusion of bovine SRM	It is recommended that the Welsh Government implements the amendments to bovine SRM controls within the domestic TSE Regulations within Wales.
<b>Proposed Amendment 14</b>	<b>Requirements of method of spinal cord removal</b> – Amendment to provide for alternative methods of spinal cord removal to be used as an alternative to carcass splitting (currently the only method that the UK meat processing industry finds acceptable).	45	Do nothing	Amendment to the requirements for spinal cord removal from small ruminants slaughtered for human consumption	It is recommended that the Welsh Government implements the amendments within the Welsh domestic Regulations to provide for the amendment to the requirements for spinal cord removal from sheep and goats slaughtered for human consumption

## **8. Schedule 2: TSE Monitoring**

### **Proposed Amendment 1 - Required Method of Operations (RMOP)**

Implementing Decision 2013/76/EU permitted the UK to stop testing healthy slaughtered cattle for BSE from 4 February 2013. Welsh Ministers and the other UK administrations agreed to take advantage of this derogation and all administrations across the UK stopped testing healthy slaughtered cattle for BSE from 1 March 2013 on an administrative basis.

This means that the Required Method of Operation (RMOPs) prescribed to be held by abattoirs in Schedule 2 of the 2008 Regulations exceeds the requirement of the EU TSE Regulation. Also, many of the requirements are redundant following the decision to stop testing healthy slaughtered cattle for BSE. Schedule 2 of the 2018 Regulations will reflect the above decision and remove unnecessary requirements. Occupiers (Food Business Operators (FBOs)) of slaughterhouses will still need to comply with the remaining regulatory requirements contained in Schedule 2.

#### **Consultation**

This area was included in the 2013 joint consultation that the Welsh Government held with the Food Standards Agency (FSA). Five responses were received, all of which supported the European Commission proposal to stop testing healthy slaughtered cattle for BSE, and in light of these changes, agreed that the approved RMOP for Food Business Operators was no longer required.

The issue was further consulted on in the 2017 joint consultation that the Welsh Government held with Defra and the FSA. Four responses were received, three supporting the proposal and one querying the difference between RMOPs and the replacing Standard Operating Procedures (SOPs).

The only cattle from abattoirs now tested for BSE are '*risk*' animals aged over 48 months (emergency slaughtered cattle and those found to be sick at ante mortem), a negligible number of healthy slaughtered animals aged over 30 months and '*risk*' animals aged over 24 months born in Bulgaria and Romania, and third countries, which has resulted in a reduction from about 300,000 cattle tested per year in GB to about 5,000.

Our proposal would remove the legal requirement for an RMOP signed by Welsh Ministers because it is no longer justified. Abattoir operators would be expected to agree a Standard Operating Procedure (SOP) with the FSA, which would mirror the modified RMOP to maintain food safety and BSE controls.

#### **Costs & Benefits**

Neither RMOPs nor SOPs involve any costs to farmers, and would have no impact on food safety. It would merely result in a reduction in bureaucracy, which in turn would generate efficiencies for Food Business Operators at

abattoirs, as whilst the controls they had to adhere to would remain the same, the need for them to apply for Ministerial approval would be removed. As this measure would not result in any additional costs or benefits to either industry or Government, no detailed cost/benefit analysis has been carried out, and the only option considered has been to implement the removal of RMOPs.

### **Option 1 – Do nothing**

To do nothing would ensure that RMOPs that require approval from Welsh Ministers would continue to be required in slaughterhouses and cutting plants operating across Wales. These RMOPs would be disproportionate to the number of 'at risk' cattle slaughtered and would require implementation of TSE controls that are now obsolete in the view of the Commission.

### **Option 2 – Remove the requirement for RMOPs**

To remove the requirement for RMOPs would reduce the level of bureaucracy applied to the slaughter process, in eliminating the need for Welsh Ministers to approve the procedures. They would be replaced with SOPs which maintain public health protection levels, yet provide a more proportionate level of delivering on these controls.

#### **Recommendation**

The Welsh Government recommends the implementation of **Option 2** and for the removal of the requirement for RMOPs for those slaughterhouses in Wales where cattle requiring BSE testing to be introduced.

### **Proposed Amendment 2 - Home Slaughter**

In the context of keepers that slaughter cattle on their premises for their own consumption (i.e. home-slaughtered), the European Commission has advised that the EU TSE Regulation requires the BSE testing of all relevant cattle aged over the testing threshold. Although the 2008 Regulations provide powers for inspectors to issue notices to enforce the EU TSE Regulation, they do not contain a clear obligation for cattle keepers carrying out home-slaughtering to comply with BSE testing requirements. The following changes in the 2018 Regulations are therefore introduced:

- A new paragraph in Schedule 2, to require a cattle keeper home-slaughtering a bovine animal aged over the testing threshold to arrange for both the animal to be sampled and to ensure delivery of the brainstem sample to an approved testing laboratory for BSE testing. The Animal and Plant Health Agency (APHA) offer a private commercial service to receive bovine heads at its Regional Post Mortem Examination facilities for sampling and despatch as required. Cattle keepers can access this service via their private veterinary surgeon.

- Also, there is an extension of the retention and disposal requirements to cover home slaughter and clarification that an “insufficient test result” includes situations in which approved testing laboratories do not receive brainstem samples.

## **Consultation**

These proposals were also included in the 2013 consultation, for which there were no comments received. The changes support enforcement of the EU TSE Regulation which requires cattle keepers who slaughter animals for home consumption to comply with TSE rules.

## **Costs & Benefits**

It is difficult to assess the number of cattle slaughtered in other places of slaughter, but the number is expected to be minimal. There is no alternative option for this other than to introduce this requirement, as to not implement would mean that EU TSE Requirements were not being adhered to. As a result, no detailed cost/benefit analysis has been carried out, but the number of animals affected by this would be minimal, and there would be benefits in relation to enhanced food safety and assurance.

### **Option 1 – Do nothing**

To do nothing would put the Welsh Government at risk of not having enforcement powers over those who slaughter ‘at risk’ cattle in other places of slaughter, including those who choose to home slaughter, but do not adhere to those TSE controls prescribed by the EU TSE Regulation. This is not an option, as this places a risk to human health, and would mean we were operating outside of EU requirements.

### **Option 2 – Apply TSE controls to those who slaughter ‘at risk’ cattle for their own consumption – home slaughter**

This option would bring domestic regulations in Wales in line with EU TSE Regulation requirements and ensure a consistent application of TSE measures across industry, giving the Welsh Government the provisions to enforce these requirements. It would also ensure enhanced food safety measures are adhered to, protecting human health.

### **Recommendation**

The Welsh Government recommends the implementation of **Option 2** and the application of all TSE controls for those who slaughter at risk cattle to be applied to those animals that are slaughtered on the owners premises for their own consumption.

## **Proposed Amendment 3 - BSE Fallen Stock Sampling**

To establish national incidences of BSE, it is an EU requirement that all EU-born cattle (excluding those born in Romania or Bulgaria) over 48 months of age that die or are killed other than for human consumption (so called 'fallen stock') are tested for BSE. For fallen stock cattle born in Romania and Bulgaria or outside the EU the qualifying age for testing is 24 months but there are a negligible number of these cattle in the UK.

The carcasses of fallen cattle that require BSE testing are transported to approved sampling sites where trained staff take a small sample of brain material for testing before the carcasses are incinerated. The farming industry currently pays all the costs of transportation and destruction of the carcasses by disposal sites, with the cost of actual sampling borne by the taxpayer at a price of £6.25 per sample.

The proposal is to transfer the cost of taking fallen stock samples for mandatory BSE testing from the taxpayer to the farming industry (in this case to those holdings on which the fallen stock have died). This would result in a more equitable sharing of the cost of BSE surveillance between the farming industry and the taxpayer. This also recognises that farming businesses in England and Wales benefit from the EU BSE surveillance programme, while continuing to safeguard public and animal health in a proportionate way. Government would continue to pay for the cost of transporting the samples to the contracted approved testing laboratory and for the testing itself.

It is planned that all UK administrations will introduce the transfer of charges on 1<sup>st</sup> October 2018.

## **Consultation**

This proposal is UK wide and was consulted on in the 2017 consultation jointly held with Defra and the FSA. Nine of the eleven respondents, opposed this proposal on the grounds that TSEs are notifiable disease, the controls of which are prescribed by Government, and as such should be funded by Government, in order to protect public health. Two respondents supported the proposal.

## **Cost and benefits**

Approximately 1.4% of the national herd are sampled and tested per year as fallen stock aged over 48 months. Over the financial years 2013-14, 2014-15 and 2015-16, the average number of samples taken annually in England and Wales was 91,937.

### Costs

At a cost of £6.25 per sample, the total annual cost of this proposal to the cattle farming industry in England in Wales would be £574,600 per year. The actual cost per holding would be dependent upon the number of fallen stock cattle aged over 48 months per year, but as an average, with 10,688 cattle holdings in Wales in 2016 requiring 19,031 fallen stock samples, this would equate to two fallen stock cattle aged over 48 months per year per holding. This would give an average annual cost per holding of £12.50 and an overall cost to the farming

industry in Wales of £118,943.49. On average, holdings with less than 100 animals could be expected to have at most one fallen bovine requiring sampling per year at a maximum cost of £6.25. Holdings with 100-149 animals per year would have 1-2 fallen bovines requiring sampling at a maximum cost of £12.50, and holdings with over 150 animals would have 4-5 fallen bovines per year at a maximum cost of £31.25. Therefore, even for larger holdings, the proposed addition to farms' total annual production costs is expected to be very small and would not be expected to lead to any impacts on their competitive positions.

It should be noted, however, that the total cost will vary from year to year depending on the number of fallen stock, which in turn depends on the national cattle herd and its age structure. The national cattle herd is in long term decline and the age structure is shaped by the age of cattle at slaughter (usually about 15 to 24 months) and the ages at which bovines are culled. It is extremely unlikely, therefore, that this identified cost to the farming industry would exceed these calculated averages by any significant amount.

In addition, with farmers now being able to choose their sampling site based on this cost, there is potential for sampling sites to become more competitive and for this sampling cost and the subsequent cost to the farming industry to fall below the current price of £6.25 per sample.

There is not envisaged to be any administrative charge on this, as the sampling sites currently invoice the farming industry for removing the fallen stock from farms and for disposal, so will add the sampling cost to this single invoice. This will, however, reduce the number of invoices issued by the sampling sites, who will no longer have to invoice Government separately for these costs, so will drive efficiencies and potential cost savings for approved sampling sites across the UK.

(NB. In relation to VAT, businesses typically charge VAT on their outputs, but claim it back on their input costs. Any VAT paid by farmers in relation to the cost of providing the sample could be claimed back and are not therefore included here as a business cost).

### Benefits

The transfer of costs for sampling to industry would equate to the equivalent reduction in cost to the Welsh Government and, therefore, the taxpayer of the same magnitude as the increase in costs to the farming industry (approx. £118,943.00).

### **Option 1: Do nothing**

All other UK administrations intend to implement this cost transfer on 1<sup>st</sup> October 2018. Should this cost not be applied in Wales at the same time, there is a risk that some English farm businesses might decide to use Welsh sampling centres to take advantage of the free sampling service, and that Welsh taxpayers would therefore be contributing more towards TSE controls for England. Differing systems operating between administrations would also cause confusion for farm

businesses and sampling sites, potentially adding to their costs for different invoice methods depending on where the cattle being sampled died.

## **Option 2: Transfer sampling cost to industry**

Government will continue to pay for the cost of transporting samples to contracted approved testing laboratories and for the testing itself. The cost of sampling would be transferred to farm businesses. The cost per sample is £6.25 with the average cost shown above based on two animals per farm. There is no evidence to suggest that the transfer of costs as proposed would deter farm businesses from disposing of their fallen stock in the recognised way.

### **Recommendation**

The Welsh Government, therefore, recommends the implementation of **Option2** and for the charge for sampling costs to be transferred to Industry. This change is based on value for money for the taxpayer, and for consistency and simplicity for industry.

## **9. Schedule 3: Control and eradication of TSE in bovine animals**

### **Proposed Amendment 4 - Appeals against a decision to kill a cohort animal**

Paragraph 5 (2) of Schedule 3, of the 2008 Regulations currently permit the owners of BSE cohort animals (cattle born up to twelve months before or after a confirmed case, which were reared and shared feed with that animal) to submit a general appeal against a decision to kill a cohort animal. The 2018 Regulations introduce a paragraph to limit unqualified appeals and prevent unnecessary delays to the culling process.

### **Consultation**

In the 2013 consultation, support for proposals to limit the appeals process against a decision to kill cohort animals was given “in principle”. While the rationale behind the proposal to limit unqualified appeals was understood, there was a question as to why cohort culling was still taking place. This proposal is intended to limit unjustified and unqualified appeals which place an unnecessary administrative and financial burden upon Government and upon public funds. Under the proposed amendment, the owners of cohort cattle would continue to have the right to query in writing any decision to cull their animals, and APHA would respond and offer guidance

### **Costs & Benefits**

In light of the declining incidence of BSE and fewer instances of the culling of cohorts following the identification of index animals, there has been a subsequent decline in the number of appeals against decisions to kill cohort animals. The proposed amendment to the requirements for appealing against such a decision

will reduce the number of ineligible appeals being made in the first instance. This is not envisaged to pose any cost to industry, as only those appeals that could demonstrate they did not have access to the same feed as the index animal and those bulls housed continually in semen collection centres are currently considered cohorts so would be successful in their relevant appeals. Therefore, this amendment is not reducing the number of eligible appeals, merely reducing those from the outset that would prove ineligible, and thus encouraging efficiencies to be generated within the system. This should instead reduce the times owners have to wait for decisions for genuine appeal outcomes and reduce unnecessary costs to Government of an inefficient appeals system.

### **Option 1: Do nothing**

The current wording prescribes that the owner of a cohort animal which is to be killed can appeal against the Government decision. This provides for genuine reasons to be argued as to why an animal should not be considered a cohort of the index animal, for example, 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. However, as it does not specify requirements of appeal, owners may incorrectly appeal against decisions on the basis of other reasons that would not prove an animal was not in a cohort. This delays culling animals that are required to be killed under legislation.

### **Option 2: Limit right of appeal against decision to kill cohort animals**

Under the 2018 Regulations, appeals against decisions to kill BSE cohort animals will be limited to the following specific criteria in the legislation:

- 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.
- 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.

### **Recommendation**

The Welsh Government recommends the implementation of **Option 2** and for the introduction of the amendment to limit unqualified appeals and prevent unnecessary delays to the culling process.

### **Proposed Amendment 5 - Increase of compensation categories**

Schedule 3, Paragraph 8 of the 2008 Regulations sets out the requirements for Welsh Ministers to pay compensation for animals killed under this Schedule. Table valuations are determined on a monthly basis, using market data, which enables accurate average market values to be used in determining compensation for BSE cases, cohorts and offspring. The 2018 Regulations

update the compensation table, increasing the number of cattle categories, in order to ensure a more accurate table valuation can be applied to those cattle, as shown in table 2 below.

**Table 2**  
**Categories for BSE compensation as set out in the TSE Regulations 2018**

<b>Male</b>	<b>Female</b>
<b>Beef Sector – non-pedigree animal</b>	
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, breeding bulls	Over 20 months, calved
Over 20 months, <i>non-breeding bulls</i>	Over 20 months, not calved
<b>Dairy Sector – non-pedigree animal</b>	
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	
<b>Beef Sector – pedigree animal</b>	
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	
<b>Dairy Sector – pedigree animal</b>	
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 changes:

- Introduce categories for young pedigree beef animals 0-6 months of age.
- 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.
- Clarify the period over which sales data is collected to calculate table values, i.e. 1 month sales data collection period, lasting from the 21<sup>st</sup> of the month to the 20<sup>th</sup> of the following month for non-pedigree cattle and a rolling period of 6 months lasting from the 21<sup>st</sup> of the month until the 20<sup>th</sup> of the sixth following month for pedigree cattle.
- 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.

- Limit compensation payments to cattle with the legally required ID documentation.
- 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.
- 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.
- Reduce compensation for owners of herds with BTb breakdowns disclosed through significantly overdue tests (this amendment is not relevant for cattle affected by BSE).

## **Consultation**

One respondent to the 2013 consultation did not agree to the proposed changes to the BSE compensation table, as they did not feel that the proposed levels of compensation would reflect the true market value for healthy cattle. However, cattle killed for BSE (infected cattle, those suspected of infection and cattle killed to eradicate BSE) are automatically excluded from the food chain and, therefore, their value is greatly reduced. The effect of the proposed change upon BSE compensation paid by the Welsh Government is expected to be very minor, as the disease is in decline and very few cattle are now killed for BSE each year.

Only two respondents answered the question in the 2017 consultation, one fully in support of the increased table categories and one suggesting that individual valuation should be used for all bovines killed for BSE control purposes.

### **Option 1: Do nothing**

The 'do nothing' option would allow the compensation system for bovine culls associated with BSE controls to continue as normal, using the existing table valuation with limited categories, with little transparency on the sales data which provides those valuations. Of those respondents who were not supportive of the proposal to revise the compensation table valuations, they were not necessarily supportive of the use of the existing valuation table either, but instead were proposing the use of independent valuations.

### **Option 2: Revise compensation categories**

The advantage of the revised table is that compensation for BSE cattle will be paid at rates which more accurately reflect the value of the animals on the open market. The new system would be more transparent in relation to how the valuations are calculated. It is envisaged this would reduce reliance on independent valuations, which will be used when owners do not agree with their table valuation. As a result, there should be fewer delays to the culling and compensation process, providing efficiencies to both Government and industry.

In addition, the time period for the data is specified as one month sales data collection (from 21<sup>st</sup> of the month to the 20<sup>th</sup> of the following month) for non-pedigree cattle and 6 months rolling market data (from 21<sup>st</sup> of the month to 20<sup>th</sup> of the 6<sup>th</sup> month following) for pedigree cattle. This ensures the accuracy of the data used reflects the sale price of the animal at that time, reducing the impact of seasonal fluctuations and other anomalies, or at least allowing them to be identified more clearly.

As such, there is no cost to industry from this option. There has been no detailed analysis of who might gain or lose out from the increased number of compensation categories, as there is such limited evidence available. There has only been one case of BSE which has required compensation payments for cattle in Wales since 2014, and we can estimate that the potential for impact is also minimal due to such a decline in incidence. Also, should owners disagree with their position within the compensation table, the option to apply for independent valuation is then available.

There is, however, a benefit to Government and the tax payer, as a more accurate value for each cull will be realised, and the process to do so should now be more efficient.

#### **Recommendation**

The Welsh Government recommends the implementation of **Option 2**. The proposed option does not have a significant impact on cattle owners, as should there be disagreement the table valuation is accurate, they are fully entitled to opt for an independent valuation of their animal. The use of independent valuation does delay the cull process and may delay payment of compensation to the owner.

#### **Proposed Amendment 6 - Amendment to the source of independent valuers for compensation payments for bovine animals**

As prescribed within the EU TSE Regulation, compensation must be paid for animals killed as TSE suspects or in pursuit of TSE eradication. Table valuations are offered in respect of compensation and are the default position. The TSE Regulations provide for independent valuation of animals and animal products for those instances where the table valuation applied is not agreed with. Under the 2008 Regulations, when the Welsh Ministers and the owner can not agree on a valuer, the President of the Royal Institute of Chartered Surveyors (RICS) may appoint an independent valuer. The 2018 Regulations propose to widen the pool of potential independent and specialist valuers by also allowing for the use of valuers appointed by the President of the Central Association of Agricultural Valuers (CAAV).

The purpose of this proposal would be to increase the quantity of independent valuers that could be utilised and would allow relevant valuers to be identified,

including those who might specialise in the valuation of milk and milk products. The use of valuers as nominated by the President of CAAV as appointed by the Welsh Ministers, is currently used for cattle valuations for bovine Tuberculosis in Wales.

A detailed cost benefit analysis of this proposal has not been undertaken, however, as independent valuers are only to be used in circumstances where the valuation tables may be rejected and a valuer cannot be mutually agreed, combined with the declining incidence of disease, this should only be implemented in a minimal number of cases. There would be potential benefits to both affected animal owners and to the taxpayer who fund compensation, in that the amount of compensation awarded by the independent valuer should be more specialised to the individual case, and a wider pool of valuers, should reduce any delays in the valuation process.

### **Option 1 – Do Nothing**

To maintain the status quo and only allow the President of RICS to appoint independent valuers, would result in no changes to the process, but would limit the availability of expert valuers that may be used, and cause possible delay should there be a large number of cohorts required to be valued and culled in relation to an index case.

### **Option 2 – Increase the source of Independent Valuers for compensation purposes**

This option would widen the pool of independent and expert valuers that could be called upon to be appointed for valuation purposes. This would provide benefits to the industry and Government, although their use should only be in rare incidences.

#### **Recommendation**

The Welsh Government, therefore, recommends **Option 2** and extending the source of valuers to those also appointed by CAAV in line with other animal disease compensation valuation methods applied in Wales.

## **10. Schedule 4: Control and Eradication of TSE in Ovine and Caprine Animals**

### **Proposed Amendment 7 - Classical Scrapie Controls**

In 2007, the EU introduced more proportionate controls for sheep flocks and goat herds affected by classical scrapie. The French Government challenged the EU's legislative amendments in Case T-257/07. The EU General Court suspended the contested provisions pending final judgment in the legal case. In its judgment of 9 September 2011, the EU Court dismissed the French Government's challenge and reinstated the suspended provisions. The 2018 Regulations reflect that there are three options available for the control of classical scrapie in sheep flocks and goat herds:

- Whole flock cull;
- Genotype and cull (sheep only); and
- Surveillance (monitoring) (***the new option***).

The Competent Authority must select one of these options for implementation following a case of classical scrapie and this must be reviewed each time a new case of classical scrapie is detected in a restricted flock/herd.

In line with other UK administrations, the Welsh Government has chosen to implement a derogation available to allow a Member State to “replace the killing and complete destruction” of relevant animals “by their slaughtering for human consumption”. Any such animals sent for slaughter and over 18 months of age must be tested and found free of TSE before being released into the food chain. Furthermore, classical scrapie is not considered a human health risk, and the destruction of fit and healthy animals is considered a waste of valuable protein that impacts on waste disposal and the environment through the required subsequent processing.

The proposed 2018 Regulations reflect the derogation in the EU TSE Regulation that allows Member States to delay the killing of sheep flocks and goat herds in which classical scrapie has been confirmed, by enabling farmers to apply in writing to Welsh Ministers setting out the reasons for the application.

The current classical scrapie controls in the UK, as specified by the EU TSE Regulation, are considered disproportionate to the known risk and, therefore, 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 and in line with the other UK administrations, changes are introduced as detailed below.

The additional option of surveillance (monitoring) is now available for implementation in flocks where an initial case of classical scrapie is confirmed, and in the UK is considered the most proportionate initial response to the risk of classical scrapie in terms of public and animal health. It arguably reduces the overall burden of disease controls and results in the greatest savings to Government and could be considered to improve the balance of animal health responsibility between taxpayers and the industry, for controlling this disease.

New provisions included in the 2018 Regulations, required in line with Commission Regulation (EC) No.103/2009 concerning the use of milk and milk products from sheep and goat holdings where TSE is suspected or confirmed, are:

- Powers for inspectors to serve a notice to prohibit the movement of sheep or goat milk or milk products from a holding on which a TSE is suspected in sheep or goats, while permitting its use within the holding of origin.
- Creation of an offence for using sheep or goat milk or milk products from a holding on which classical scrapie is confirmed, produced prior to the removal of all goats and genetically susceptible sheep, as feed for

ruminants (except on the holding of origin) or for exporting them, or for failing to comply with the other requirements laid down in these paragraphs regarding their storage and transportation.

- New powers for inspectors to serve a notice to destroy sheep or goat milk or milk products produced between the dates of official suspicion and killing, on a holding on which BSE cannot be excluded after testing a sheep or goat. Welsh Government will pay compensation.

## **Costs & Benefits**

The costs and benefits associated with each option are contained within the option narratives below. It should be noted, however, the evidence used within these narratives are as at 2012, which is when the decision to implement this policy position on an administrative basis across Wales was taken, and is as such the evidence required at that point in time. The incidence of classical scrapie has declined across Wales since 2012, due to the policy actions prescribed.

### **Option 1: Genotype and kill (applicable to sheep only), implementing recent changes introduced by the EU TSE Regulation and substituting “kill” with slaughter for human consumption**

Following detection of classical scrapie in a sheep flock, the sheep flock and relevant land and buildings are placed under restriction and a notice is served advising the owner of a decision to implement the Genotype and Cull option.

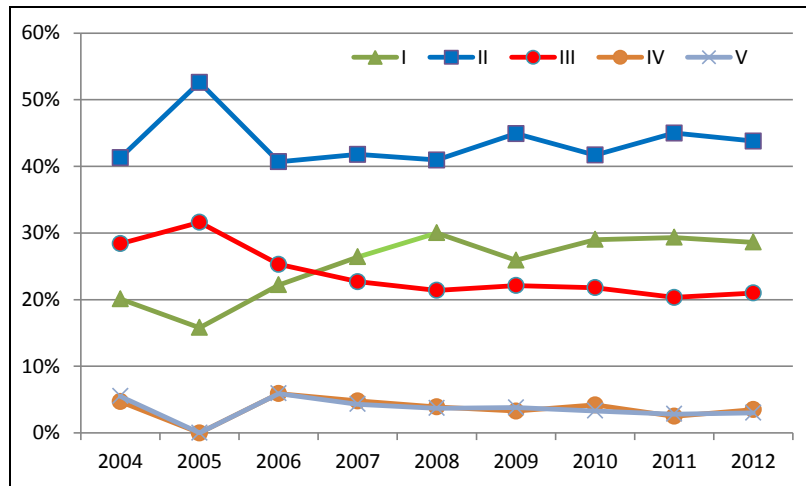
The Welsh Government pays for the blood sampling and genotyping of all sheep over three months old intended for breeding. There is a labour cost to industry for assisting with mandatory blood sampling of the sheep. The Welsh Government pays for the killing, disposal (destruction) and compensation of animals that require killing and destruction, i.e. genotypes (T) 3 & 5, please see table 3 below. This is typically 25% of a sheep flock. The flock owner is required to send for slaughter any T4 sheep, adding another 5% - 7% of the flock needing to be culled. However, the paying of compensation for this cohort of animals could significantly reduce as killing and destruction is being substituted with slaughter for human consumption and the Government has taken the view that compensation is not payable under these circumstances. However, the capacity at abattoirs for handling this type of animal is limited and in average and larger sized flocks, animals may still have to be killed and destroyed with compensation payable.

There is a labour cost to industry for delivering mandatory sorting, collection and presentation of, or arranging slaughter for, susceptible stock. Government pays for the cost of transporting animals to be killed, the cost of TSE testing a proportion of animals requiring killing and destruction over 18 months of age, and the cost of supervision and auditing by APHA. The Government pays for sampling and TSE testing of any sheep over 18 months of age sent for slaughter.

For those animals that have to be slaughtered but were intended for sale as breeding animals, there is a financial loss to the industry in revenue as market slaughter values are consistently lower than breeding values, exacerbated where the animals are of registered pedigree. Flock owners are subject to limited market availability and subsequent low prices for stock that they have to sell as culls to slaughter.

In total it may be expected that 30% - 40% of all sheep in a flock would be susceptible and requiring killing/slaughter.

**Figure 1: Percentage contribution of the five NSP types to selected scrapie negatives for genotyping for the period 2004-2012**



Levels of resistance in sheep to classical scrapie were defined by the National Scrapie Plan, with ARR/ARR or Type 1 being the most resistant and genotypes with no ARR alleles (Types 3 and 5), the least resistant.

**Table 3: Scrapie Genotypes as defined by the National Scrapie Plan**

Type 1	Type 2	Type 3	Type 4	Type 5
Resistant	Semi-Resistant	Susceptible	Carry a resistant gene but still considered susceptible	Susceptible
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		

Once the genotyping and culling/slaughter action has been completed, including the removal/sale of lambs that remained ungenotyped, a movement restriction

continues to apply for two years, and is restarted if additional cases are detected, during which the following controls apply:

- The Government pays for the collection, brain sampling, disposal and TSE testing of all fallen stock sheep and goats over 18 months of age, which must be TSE tested, although ARR/ARR (Type 1) are excluded from this requirement. Government will continue to arrange and pay for carcase collection, sampling, testing and disposal.
- The Government pays for the transport of all '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 an APHA laboratory for TSE testing.
- 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 that all animal housing has been thoroughly cleaned and disinfected following destocking.
- Only semen from Type 1 rams, and Type 1 or 2 embryos, may be used on the holding.
- Sheep known to be Type 1 may be moved or sold from the holding without restriction. Sheep of unknown genotype and Type 2 ewes may be sent direct to slaughter. However, ewes known to be Type 2 may be moved to other holdings that 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 that 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.
- Government pays APHA to monitor compliance with the rules.
- The Government provides financial support for genotyping of replacement stock and for the purchase of replacement rams for breeding purposes. There is a case for market failure in this context as replacement sheep, especially of the hill type breeds, are no longer sold with a known genotype and finding replacement sheep can be very difficult. Sheep breeding societies generally no longer require members to carry out genotyping of their breeding stock or for this to be declared at sales.
- There is a labour cost to industry in restocking.

The **advantages** of Option 1 are that it very effectively controls classical scrapie by killing or requiring slaughter of genetically susceptible stock on affected holdings, thereby providing short and medium term protection against re-emergence and dissemination of classical scrapie from known contaminated potential sources. It largely removes the risk of susceptible sheep being sold to

slaughter and inadvertently or deliberately diverted for breeding, thereby preventing potential dissemination of disease. It provides a nucleus breeding flock of resistant sheep and this will continue to mitigate against reinfection long after movement restrictions have ceased, especially for those flocks breeding their own replacement sheep.

The **disadvantages** of Option 1 are that it is considered a disproportionate response to the risk posed by the disease to animal and human health and that it is a more costly option to both Government and flock owners. Government pays for the cost of sampling, genotyping, compensation of genetically susceptible animals that have to be killed where numbers exceed available slaughter capacity (i.e. most medium and larger sized flocks), the cost of replacement sheep genotype sampling and testing (limited) and the purchase cost of replacement rams (within a ceiling). There are costs to industry for the loss of stock, for the time spent on genotyping and subsequent sorting, for the time spent in sourcing replacement animals and in not being able to pursue their preferred breeding policy due to limited availability of suitable breeding rams.

There are additional costs for industry in those animals that are no longer saleable as breeding stock or on the open market and have to be sent for slaughter at reduced values. It is now near impossible for flock owners to find replacement stock of suitable genotype in the open market and it has proved difficult to source such sheep directly from potential sellers by private arrangement.

## **Option 2 – The Surveillance (monitoring) Option**

Under this option:

- A maximum of 50 sheep per flock would be genotyped at government expense, targeted at breeding rams. Any further genotyping will be at the discretion of the keeper.
- Sheep known as genetically most susceptible (T 3 and T 5) will no longer be collected from the farm for killing and disposal with compensation; or required to be sent for slaughter at a market loss. However, these animals should ideally not be used for breeding. Owners will be advised to send any sheep of known susceptibility to slaughter to reduce the likelihood of new classical scrapie cases in the future;
- Government financial support for genotyping replacement ewes is expected to reduce significantly and would still be needed for the genotyping of replacement rams.
- All animals over 18 months of age intended for human consumption (rather than a proportion) will be collected and have to be sent to participating abattoirs for TSE testing, at government expense.
- Affected holdings would remain under a movement restriction period for two years following the detection of the last case. These controls are almost

identical to those listed under Option 1 above and only those controls that are significantly different are listed.

- Goats may not be brought onto restricted premises. Replacement female sheep may only be sourced from a premises fully complying with the genotype and kill/slaughter option whilst under restriction or with genotypes 1 & 2 only.
- No embryos, semen or ova may be dispatched from the holding;
- All sheep and goats on the holding shall be subject to common grazing restrictions during the lambing and kidding period.

The advantages of Option 2 are that:

- The surveillance option is considered the most proportionate available response to protect animal and public health from the risk or potential risk posed by classical scrapie. Classical scrapie is not known to be a risk to human health, and the indicative prevalence of the disease has reduced considerably in recent years. Only a few holdings are detected every year although many remain untested. Precautionary principle safeguards are provided in that during the surveillance period, all animals over 18 months of age must test negative for TSEs prior to release into the food chain for human consumption.
- It is the least costly option to Government. Although Government will have to implement Option 1 (G&C) in flocks where disease is established in the flock/herd and uncontrolled, Government would not have to pay for costly genotyping and subsequent culling and destruction on an estimated 50% of affected flocks. This estimate is based on historical experience of monitoring and testing scrapie positive flocks.
- Keepers would not suffer the immediate losses resulting from the compulsory culling of stock and the time spent on genotyping, sorting of genotypes and the associated sourcing of new stock although they should be encouraged to take steps to control the disease themselves as part of their flock management.
- It is expected that approximately a third to half of the restricted flocks and herds will be able to be released from scrapie related controls 3-9 months earlier when compared to Option 1.
- This option 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 (but not the consequences) on affected holdings and for the genotyping of replacement rams. Keepers may have an increased incentive to control classical scrapie on their holdings themselves to avoid an extension of restrictions caused by the possibility of further cases and to avoid the additional financial implications of falling into the Genotype and Cull scenario, Option 1.

## **Consultation**

One respondent felt that compensation should be paid for any milk destroyed if BSE was subsequently ruled out. Another respondent suggested that there was no evidence that the consumption of milk or milk products from sheep or goats has human health implications and that any milk produced from healthy animals remaining in the herd/flock should be allowed to enter the food chain.

The majority of respondents were in favour of a more proportionate response to classical scrapie detection on farms. However, one respondent did suggest that the surveillance/monitoring option requires flexibility in order to ensure that businesses, who were suffering under this option, are not financially disadvantaged. It was also suggested that leaving premises on extended restriction and limiting testing, could undermine any valuable work already undertaken. Another respondent recognised that the surveillance/monitoring option would retain the intention of creating a genetically resistant flock and limit the transmission of scrapie between animals and flocks, whilst being less wasteful and reducing costs to Government.

The majority of the respondents welcomed the Welsh Government proposal to support farmers enrolled in the surveillance/monitoring option that wish to breed scrapie resistance into their flocks. One respondent, who although supportive of the proposal, raised concerns that the culling of all rams apart from Type 1 would mean that some breeds could not participate (as Type 1 rams were not available to certain breeds) and suggested that in these circumstances, Type 2 and Type 3 rams are not culled.

Despite being introduced on an administrative basis in Wales on 1 July 2013, pending the amendment to Welsh legislation, this issue was consulted on again in the 2017 joint consultation between the Welsh Government, Defra and the FSA. Four consultees responded, with three giving their full support and one querying as to why there were differing systems between England and Wales, but not opposing the Welsh proposal. The scheme implemented in Wales is more generous and flexible, as the Welsh Government offers assistance payments for the genotyping of replacement rams under the monitoring and surveillance option in order to facilitate the development of genetic resistance within Welsh flocks.

## **Costs and benefits of each option**

### **Option 1 - Do Nothing: Business as Usual (allowing for the option to send animals to slaughter)**

This is the “Do Nothing” option against which proposals for Option 2 are measured. The introduction of slaughter as an alternative to killing and destruction has associated benefits.

The calculations below use the following evidence and assumptions:

- The incidence of detected classical scrapie in Wales has declined since 2002 (Table 4). Annual numbers of confirmed classical scrapie cases are now usually very small.

**Table 4 : Classical Scrapie in Wales: 2002-2012**

<b>Year</b>	<b>Cases (sheep)</b>	<b>Holdings</b>	<b>Cases (goats)</b>	<b>Holdings</b>
<b>2002</b>	<b>111</b>	<b>31</b>		
<b>2003</b>	<b>127</b>	<b>40</b>		
<b>2004</b>	<b>116</b>	<b>53</b>		
<b>2005</b>	<b>161</b>	<b>73</b>		
<b>2006</b>	<b>71</b>	<b>42</b>		
<b>2007</b>	<b>18</b>	<b>16</b>	<b>3</b>	<b>1</b>
<b>2008</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>1</b>
<b>2009</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>1</b>
<b>2010</b>	<b>1</b>	<b>1</b>	<b>6</b>	<b>1</b>
<b>2011</b>	<b>1</b>	<b>1</b>		
<b>2012</b>	<b>2</b>	<b>1</b>		
	<b><u>609</u></b>	<b><u>261</u></b>	<b><u>13</u></b>	<b>4*</b>

- The total number of holdings does not necessarily reflect the number of farms, e.g. all goat cases occurred in the same herd.
- 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 culling, have also declined, thus reducing the costs of sheep genotyping, the compensation payable to farmers and the associated cost to Government.

Incidence of classical scrapie is now very low across GB, and the number of new cases emerging over the next ten years is expected to remain very low, provided that the national flock genotype profile does not deteriorate significantly or a new adapted strain does not emerge. This in turn would mean that the number of holdings to be placed under restriction, the number of sheep on those holdings requiring genotyping, of goats and susceptible sheep on those holdings requiring culling, are also expected to remain very low. However, two issues may affect this assumption:

- On 1 January 2011, the method of collecting 10,000 fallen sheep samples and 500 fallen goat samples for the EU required annual UK TSE survey, changed. Previously, keepers had volunteered carcasses of fallen animals for the survey, and samples came from a relatively small number of holdings. Since this date carcasses 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 through this survey, however, in 2011, only 3 cases (1 in Wales; 2 in England) had been confirmed in GB as part of this survey,

which is comparable to the detection rate in the previous three years. In 2012, 2 cases were detected, both of which originated in Wales.

- 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 therefore not possible to predict whether or not there may be another occurrence of a large number of cases from individual flocks and herds over the next ten years.

The assumption on the number of holdings and the number of animals on those holdings, as shown in Table 3 below, is based upon the type and size of sheep holdings in Wales, placed under restriction during 2011 and 2012 and reflects what could be expected to fall under CSFS controls per year. Only one goat holding is expected fall under CSFS controls over the next ten years and we therefore indicate this as a proportion per year.

**Table 3: Assumption for number and size of holdings in Wales that can be expected under the Compulsory Scrapie Flocks Scheme in an average year**

<b>Expected holdings in Wales newly restricted under the Compulsory Scrapie Flocks Scheme and averaged over ten years</b>	<b>Number of breeding animals on holding</b>	<b>Number in addition to basic breeding numbers at time of controls being applied</b>	<b>Number of scrapie susceptible animals (25% of sheep &gt; 3 months and all goats &gt; 3 months)</b>
Holding 1 (sheep)	1200	1500	250
Holding 2 (sheep)	550	950	110
<b>TOTAL (SHEEP)</b>	1750	2450	--
Holding 3 (goats*)	1000 / 10	750 / 10	1750 / 10

The expenditure identified in Option 1, and the cash savings to the Welsh Government identified under Option 2, 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 31/10/2012, which was €1 = £0.80645

## Option 2 - Surveillance option: Savings to Government under Option 2

NB: All calculations exclude APHA supervision costs, which will be the same under both Option 1 and Option 2.

### Total savings to Government under Option 2

	Savings in an average year under Option 2	Less net EU income	Savings in an average year under Option 2 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

### Costs and savings to the farming industry under Option 2

	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)

### Recommended Option

The Welsh Governments recommended option is the 'surveillance option' (**Option 2**), subject to the outcome of an epidemiological evaluation in each individual case. This provides for the lowest cost to government, whilst still complying with EU Reg 999/2001. Of the available options it is the most proportionate to the risk of classical scrapie to public and animal health. It will

change the balance between the taxpayer and industry of animal health responsibility for controlling scrapie by decreasing overall costs to Government and increasing costs to some farmers, especially those selling breeding animals as part of their business model. Since 2011 this option has been implemented on an administrative basis in Wales.

## Amending Domestic Regulations

In 2008, the Welsh Government consulted on amending the domestic TSE Regulations in line with the suspended measures. The consultation stage GB Impact Assessment (IA) calculated a net benefit (NPV) of £2.8m over 8 years for Option 1. The three respondents (NFU, NSA and CLA) supported the proposed approach. Given the deregulatory nature of “Option 1” this concession has been applied on an administrative basis.

Option 2 offers a positive impact upon the small number of farms in Wales which are affected by classical scrapie, which will be able to sell their animals for human consumption. Approximately 484 animals per year are killed, destroyed and compensated under the alternative options, which would not be killed and destroyed under Option 2. All supported the proposals to adopt proportionate controls for classical scrapie.

## 11. Schedule 6 - Feedingstuffs

Protection of the food and feed chain through strict feed controls is vital to the control and eradication of TSEs. In 2001, the EU introduced a general ban on the feeding of all PAP to farmed livestock, as scientific evidence has identified contaminated feed as the principal vector of BSE transmission. However, BSE incidence worldwide has declined dramatically in recent years – the World Organisation for Animal Health (OIE) records the following cases worldwide since 2012:

### BSE Cases recorded worldwide by the OIE since 2012

Year	Number of cases worldwide (included in the UK)	Number of cases in the UK
2012	21	3
2013	7	3
2014	12	1
2015	7	2
2016	2	0
2017	3	0

*(N.B. All three cases confirmed in 2017 were atypical BSE. The most recent cases of classical BSE were in France and Spain in 2016. The most recent case of classical BSE in the UK was in 2015).*

This declining incidence combined with continued developments in technology and improved scientific knowledge of the actual risks of certain feed components, have resulted in various amendments to the EU Regulation in relation to those feeding stuffs permitted and the controls associated with them.

The 2018 Regulations reflect permission for the feeding of fishmeal to un-weaned ruminants in reconstituted milk replacer in line with Commission Regulation (EC) No 956/2008, whilst maintaining the existing ban on feeding fishmeal to adult ruminants.

The 2018 Regulations permit Welsh Ministers to allow the feeding of materials of plant origin and feed containing such products, in which insignificant amounts of bone fragments of environmental (non-ruminant) origin had been detected, to farmed animals, on the basis of a favourable risk assessment, in line with Commission Regulation (EC) No. 163/2009.

The 2018 Regulations reflect the export of pet food containing processed animal proteins (PAP) of ruminant origin, provided that it is produced and labelled in accordance with the Animal By-Product Regulations, in line with Commission Regulation (EC) No.956/2008.

### **Proposed Amendment 8 - Amendment to allow for the feeding of pig and poultry Processed Animal Protein (PAP) to farmed fish**

In line with the European Food Safety Authority's (EFSA) advice, progress has been made on re-introducing the feeding of pig and poultry PAP under strict conditions. This has been made possible now that the EU has validated a polymerase chain reaction (PCR) test capable of detecting very low levels of ruminant material in feed. This means that pig and poultry PAP can now be safely differentiated from ruminant PAP (which remains banned from all livestock feed). Pigs, poultry and fish are not known to be able to contract or pass on BSE naturally. Pig and poultry PAP are a potential source of protein that may be cheaper and more sustainable than current protein sources such as fishmeal and soya, the prices for which are currently high, and which cause vast deforestation around the world.

As a result, and following independent scientific advice from EFSA, EU legislation, which permits the feeding of pig and poultry PAP to farmed fish, came into force on 1 June 2013. If anyone in England or Wales wishes to avail themselves of this derogation, all arrangements are in place for them to do so. The condition is that they must demonstrate that they can satisfy the EU's key requirements, as follows:

- That sufficiently effective measures are in place to prevent cross-contamination between ruminant and non-ruminant animal by-products, including physically separate, closed systems for feed production and physically separate facilities for storage, transport and packaging.
- That regular sampling and analysis of non-ruminant PAP for feeding farmed fish, and for feed for farmed fish containing non-ruminant PAP, is carried out to confirm the absence of cross-contamination with ruminant PAP, using a scientifically validated test. The test results must be kept available to the Animal and Plant Health Agency (APHA) for at least five years.

Full guidance on the feed ban is available in the [Guidance note on feed controls in the Transmissible Spongiform Encephalopathies Regulations](#).

## **Consultation**

In July 2010, the Welsh Government, Defra and the FSA held a short public consultation on the European Commission's TSE Roadmap 2, which set out the actions on TSE measures envisaged by the Commission in the period 2010-2015, including possible future policy options for projected revisions to the feed ban. Nineteen stakeholders responded to the consultation. Whilst industry representatives mostly favoured the Commission's proposed relaxation of the ban on feeding pig and poultry protein to non-ruminants, consumers favoured a more cautious approach.

In June 2011, Government wrote to 70 organisations, including consumer and religious groups and the food and feed industries, seeking further comment on this proposal to amend the EU TSE Regulation to allow the feeding of pig and poultry PAP to pigs, poultry or fish subject to a ban on intra-species recycling of terrestrial animal PAP, subject to tight channelling and testing controls. Twelve organisations provided comments expressing support for the proposals. However, take-up of the derogation was expected to be low because in the UK the available supplies of pig and poultry PAP are utilised by the pet food industry.

## **Costs & Benefits**

At present, no feed manufactures in the UK utilise this derogation. The feed industry has expressed support for this measure but has indicated that take-up will be low as the pet food industry uses PAP in the UK. For commercial reasons, this is expected to remain the case.

Manufacturers who adopt this option would be required to carry out additional tests costing approx. £98 per consignment. However, this is not a new charge and industry would only adopt this option if the benefits outweighed the costs. There are only three major fish feed producers in the UK. The Government incurred costs of approx. £25,000 in the setting up and rolling out of the validated tests.

The benefit to adopting the proposal in Welsh legislation is that it would provide industry with this derogation, affording Welsh Industry the same opportunities available to competitors in other Member States.

### **Option 1 – Do nothing**

This would prevent industry in Wales from taking advantage of the EU derogation should they wish to allow the use of pig and poultry PAP in aquaculture feed.

### **Option 2 – Permit the feeding of Pig and Poultry PAP to farmed fish**

This would fulfil Government's commitment to implement EU legislation exactly, and to use all available derogations within EU law. It would also ensure that the

feed industry in Wales has the same opportunities as their counterparts in other Member States and in England, whilst continuing to enforce all prohibitions to the use of meat and bone meal in ruminant feed.

### **Recommendation**

The amendments proposed are already being implemented on an administrative basis in line with changes to the EU TSE Regulation which came into force on 1 June 2013 and are directly applicable in domestic law. All protocols, controls and guidance required by the EU were in place by this date, including roll-out of the EU validated DNA-based test (PCR test), which is able to detect the presence of ruminant, pig or poultry material in feed.

It is therefore recommended that the Welsh Government implements **Option 2** and amends TSE legislation in Wales to implement this permissive EU derogation. This proposal would be proportionate to the risk to public and animal health in line with the European Commission's TSE Roadmap 2, which was published in 2010 and outlines various future policy options for a managed relaxation in the TSE controls over the period 2010-2015. The Commission's objective is to continue to review the measures, to ensure that they are proportionate to the reducing risk, while assuring a high level of food safety. Amendments to EU TSE rules are taken following a stepwise approach supported by scientific advice from EFSA.

### **Safeguards**

Industry would have to ensure that Animal By Products (ABP) used for the production of pig and poultry PAP intended to be used for farmed fish, must be derived from non-ruminant protein. Slaughterhouses would have to ensure that ruminants and non-ruminants would have to be slaughtered on separate lines and separate storage, transport and packing facilities.

### **Proposed Amendment 9 - Extension to the scope of 'aquatic animals' permitted for use in processing fishmeal and inclusion in feed for aquaculture animals**

Point 1(e) (ii) of Annex I to Regulation (EC) No 999/2001 defines 'aquatic animals' by reference to the definition laid down in Article 3(1)(e) of Council Directive 2006/88/EC (2) as (i) fish belonging to the superclass *Agnatha* and to the classes *Chondrichthyes* and *Osteichthyes*, (ii) mollusc belonging to the Phylum *Mollusca*, and (iii) crustacean belonging to the Subphylum *Crustacea*. This definition of 'aquatic animals' does not cover invertebrates other than molluscs and crustaceans, and thus requirements of point (a) of Section A and of point (a) of Section E of Chapter IV of Annex IV to that Regulation did not allow the use of wild starfish and farmed aquatic invertebrates, other than molluscs and crustaceans, for the production of fishmeal.

As the use of meal produced from wild starfish and farmed aquatic invertebrates, other than molluscs and crustaceans, in feed for non-ruminant animals is not considered to represent a higher risk for the transmission of TSEs than the use of fishmeal in such feed, the EU TSE Regulation has been amended in order to add the

possibility of using starfish or farmed aquatic invertebrates, other than molluscs and crustaceans, for the production of fishmeal and thereby feed for aquaculture. This amendment came into force in EU law on 13 February 2017 and was adopted in the UK, including in Wales on an administrative basis on the same date.

## **Consultation**

The proposal to amend Welsh legislation to allow for this amendment to the definition of 'aquatic animals' was consulted on in the 2017 consultation, jointly held by the Welsh Government with Defra and the FSA. Only one consultee responded to this question, and this was in support of the proposal.

## **Costs & Benefits**

It is expected that there is limited interest for industry for this proposal, although the extension of available sources of feed for aquaculture animals that are not reliant on soya or fishmeal would prove beneficial, providing a greater protein content in a more sustainable manner, whilst maintaining TSE controls.

## **Option 1 – Do nothing**

If this proposal is not introduced in Wales, we would not be taking full advantage of the extension of the definition of aquatic animals and limiting the available options for feed for aquaculture animals.

## **Option 2 – Extend the definition of 'aquatic animals'**

This option has already been implemented in Wales on an administrative basis since 13 February 2017. In extending the definition of aquatic animals that can be processed for fishmeal and for the inclusion in feed for aquaculture animals, the Welsh Government would be ensuring a wider scope of potential feed. It would also permit relevant industries to process such aquatic animals for such feed purposes, including the processing of star fish and polychaetes, should they wish, provided they meet all other TSE production controls.

### **Recommendation**

The Welsh Government recommends the implementation of **Option 2** extension of the definition of 'aquatic animals' for fishmeal and feed for aquaculture animals in line with the EU recognised definition.

## **Proposed Amendment 10 - Proposal to enable the feed industry to use Processed Animal Protein (PAP) derived from insects in feed for aquaculture**

Previously, the EU TSE Regulation prohibited the feeding of non-ruminant PAP to non-ruminant farmed animals except under certain derogations, e.g. the feeding of non-ruminant PAP to aquaculture animals. Such PAP has to be derived from slaughterhouses or cutting plants. Thus the use of PAP derived from insects in feed for aquaculture animals was not allowed.

Several Member States are now rearing insects for the production of PAP for pet food, using their own national control schemes. Studies have shown that farmed insects could represent a sustainable alternative to conventional sources of animal proteins for feed for non-ruminant farmed animals.

On 8 October 2015, EFSA published a scientific opinion on a risk profile related to production and consumption of insects as food and feed. The opinion concludes that the occurrence of prions in non-processed insects is expected to be equal or lower to current protein sources, as long as insects are fed on substrates that do not harbour material of ruminant or human origin (i.e. human manure). As the processing of insects may further reduce the occurrence of biological hazards, that statement is also valid when it comes to processed animal proteins derived from insects.

Based on the EFSA opinion, the Commission amended the EU TSE Regulation to permit the use of PAP derived from insects of certain species, reared within the EU and produced in processing plants dedicated exclusively to the production of products derived from farmed insects, and compound feed containing such PAP, to be authorised for feeding to aquaculture animals. The permitted insect species should not be pathogenic or have other adverse effects on plant, animal or human health; they should not be recognised as vectors of human, animal or plant pathogens and they should not be protected or defined as invasive alien species.

The permitted insect species named in the proposal are House Fly (*Musca domestica*), Black Soldier Fly (*Hermetia illucens*), Yellow Mealworm (*Tenebrio molitor*), Lesser Mealworm (*Alphitobius diaperinus*), House Cricket (*Acheta domestica*), Banded Cricket (*Gryllobates sigillatus*) and Field Cricket (*Gryllus assimilis*). This list may be amended in the future based on an assessment of the animal health, public health, plant health or environmental risks of the insect species concerned.

This proposal came into force in the EU on 1 July 2017 and was implemented on an administrative basis across the UK on the same date.

## **Consultation**

The proposal to enable the feed industry to use PAP derived from insects in feed for aquaculture was consulted on in the joint consultation held by the Welsh Government, Defra and the FSA. Only one consultee replied to this proposal, and was supportive of its adoption within Welsh legislation.

## **Costs & Benefits**

Any costs to those industries wishing to process PAP derived from insects in feed for aquaculture animals, would be of their choice, and are yet to be established. However, the benefits include that this would now be an option for feed producers within Wales should they wish to adopt the measure. In addition, the benefit includes that a more sustainable option for feed for aquaculture animals would now be available, with less environmental impacts.

## **Option 1 – Do Nothing**

If this proposal is not introduced in Wales, we would not be taking full advantage of the extension of the available feed options of PAP for aquaculture animals. This would limit the opportunities available to our industry in Wales, and would not afford them the opportunities available to their competitors in other Member States.

### **Option 2 – Permit Industry to use PAP derived from insects in feed for aquaculture**

This option has already been implemented in Wales on an administrative basis since 1 July 2017. In permitting the use of PAP derived from insects to produce feed for aquaculture, Welsh industry would be able to consider a wider range of options for feed for aquaculture, permitting the use of a more sustainable and potentially higher protein source of feed, than existing alternatives.

#### **Recommendation**

The Welsh Government recommends the implementation of **Option 2** and for the amendment of Welsh TSE legislation to provide for the use of PAP derived from insects in feed for aquaculture animals, in light of the scientific evidence that supports that the proposal is proportionate to the minimal risk level.

### **Proposed Amendment 11 - Removal of the requirement for written bilateral agreements to authorise the export of Processed Animal Protein (PAP) derived from non-ruminant animals**

Previously, the EU TSE Regulation laid down strict rules for the authorisation of the export of PAP derived from non-ruminants (i.e. pigs and poultry) and products containing such PAP, including that a written bilateral agreement had to be concluded, prior to the export, between the competent authority of the exporting Member State, or the Commission, and the competent authority of the importing third country. This bilateral agreement also had to contain an undertaking from the importing third country to respect the intended use of the PAP and not to re-export it, or the products containing such PAP, for uses prohibited by the EU TSE Regulation.

This requirement was originally intended to control the spread of BSE at a time when the disease was epidemic in the Union. However, the BSE situation in the Union has since then significantly improved, with 25 EU Member States now recognised as having a negligible BSE risk status. The Commission has since agreed that the requirement for a written bilateral agreement should be removed by an amendment to the EU TSE Regulation, which was published on 13 January 2016 and came into force in EU law on 3 February 2016. It was implemented in Welsh law on an administrative basis with effect from that date.

These changes should not change the BSE risk to food safety if the necessary controls are in place and enforced. Pig and poultry PAP are not known to be able to contract or pass on BSE naturally. Export of pet food comprising PAPs was exempted from the need for bilateral agreements and prohibition on ruminant PAP and the requirements have not changed.

Subject to approval by the Animal and Plant Health Agency (APHA) for industry to export non-ruminant PAP, the following conditions would apply:

- The controls mirror those already in place for permitting the use of poultry and pig PAP in feed for farmed fish in the EU.
- Non-ruminant PAP intended for export would need to be derived either from slaughterhouses which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants, or from cutting plants which do not bone or cut up ruminant meat. The competent authority is defined by the EU TSE Regulation as the central authority of a Member State competent to ensure compliance with the requirements of the Regulation, or any authority to which that competence has been delegated.
- By way of derogation from that specific condition, the competent authority may authorise the slaughter of ruminants in a slaughterhouse producing pig and poultry animal by-products intended to be used for the production of PAP.
- That authorisation may be granted only where the competent authority is satisfied, following an inspection, that measures aimed to prevent cross-contamination between ruminant and non-ruminant by-products are effective.
- Notably strict separation requirements would apply to the collection, transport and processing of products in order to avoid any risk of cross-contamination with ruminant material.
- In addition, regular sampling and analysis of the non-ruminant PAP and the compound feed containing it would be required by business operators, in order to verify the absence of cross-contamination with other animal by-products.

## **Consultation**

The proposal to remove the requirement for bilateral agreements to authorise the export of PAP derived from non-ruminant animals was consulted on in the joint consultation held by the Welsh Government, Defra and the FSA in 2017. Two consultees responded to the question and were supportive of the proposal.

## **Costs & Benefits**

Industry would continue to pay the existing test cost of £98.00 per consignment to verify the absence of cross-contamination with other animal by-products. But this is an existing cost that they would pay regardless of whether the written bilateral agreement exists or not.

There would be potential benefits to industry from this amendment if the removal of the requirement for bilateral agreements enables the negotiation of new export markets for non-ruminant PAP. We expect there to be demand to export poultry PAP or feather meal from dedicated slaughter and processing plants.

## **Option 1 – Do nothing**

This is not a viable option, as the Welsh Government would be operating outside of the EU TSE requirements, and would not be able to trade effectively with other Member States, who would not be required to enter into such written agreements.

### **Option 2 – Remove the requirements for written bilateral agreements for the export of non-ruminant PAP**

This option would ensure safeguard measures are maintained whilst facilitating effective trade of non-ruminant PAP with other Member States and England.

#### **Recommendation**

The Welsh Government recommends the implementation of **Option 2** and for the adoption in Welsh legislation the amendment to the EU TSE Regulation which allows industry the option of legally exporting non-ruminant PAP and products containing such protein, without the need for a written agreement prior to their exportation. Exports of non-ruminant PAP would remain subject to authorisation by the Animal and Plant Health Agency (APHA).

### **Proposed Amendment 12 - Proposal to permit the export of Processed Animal Protein (PAP) derived from ruminants**

Previously the EU TSE Regulation prohibited the export of processed animal protein (PAP) derived from ruminants to third countries. As explained previously, the BSE situation in the Union has since then significantly improved. The Commission has therefore removed the prohibition on the export of PAP derived from ruminants, subject to certain conditions to ensure that the products exported do not contain meat-and-bone meal, which carries a higher BSE risk. The PAP derived from ruminants would be transported in sealed containers directly from the producing processing plant to the point of exit from the EU via a border, in order to permit official controls.

The EU legislation came into force on 1 July 2017 and was implemented in Wales on an administrative basis from that date.

#### **Consultation**

The proposal to permit the export of PAP derived from ruminants to third countries was consulted on in the joint consultation held between the Welsh Government, Defra and the FSA in 2017. Four consultees responded to this, raising concerns regarding how we would safeguard against the re-import of this ruminant PAP in animal feed.

#### **Costs & Benefits**

Industry would be required to continue to administer the test per consignment to demonstrate there is no cross-contamination with any other animal by-product, at a cost of £98 per consignment. This is not a new fee (the fee has applied since 2013 following the introduction of allowing pig and poultry PAP to be fed to farmed fish.

This is a permissive derogation and Industry would only take up this cost if the benefits outweighed the costs. This recommendation would, however, permit new export markets to be negotiated and developed, providing potential benefits for industry producing PAP.

#### **Option 1 – Do nothing**

This is not a viable option, as the Welsh Government would be operating outside of the EU TSE requirements, and would not be able to trade effectively with third countries, reducing opportunities available to PAP producing industries in Wales.

#### **Option 2 – Remove the requirements for written bilateral agreements for the export of non-ruminant PAP**

This option would ensure safeguard measures are maintained whilst allowing for new export opportunities to be negotiated by Welsh industries.

#### **Recommendation**

Despite the concerns raised, the only available option for the Welsh Government to implement is **Option 2** and the proposed amendment, as it is a direct requirement of the EU. However, there are sufficient checks and controls required within the EU TSE Regulation that should provide effective safeguards against cross-contamination and the potential introduction of ruminant PAP into ruminant feed sources. Hence, it is recommended that the Welsh Government amend domestic legislation in line with the EU TSE Regulation to provide for the export of ruminant PAP.

### **12. Schedule 7 - Specified Risk Material, mechanically separated meat and slaughtering techniques**

#### **Proposed Amendment 13 - Bovine Specified Risk Material – Amendment to the definition of bovine Specified Risk Material to be removed**

The World Organisation for Animal Health (OIE) determines countries' BSE risk status according to the date of birth of their most recently born case of classical BSE. To be eligible to apply for negligible BSE risk status, a territory must not have had any cases of classical BSE born in the previous eleven years. Scotland and Northern Ireland have 'Negligible BSE Risk' status as zones of the UK while England and Wales have 'Controlled BSE Risk' status. The UK as a whole is currently expected to achieve Negligible Risk Status in 2021. The BSE risk status of a country determines what level of TSE controls it must implement including the Specified Risk Material (SRM) to be removed.

SRM comprises the parts of cattle most likely to carry BSE, which must be removed in the slaughterhouse or cutting plant and stained and disposed of to ensure that it does not enter the human or animal food chain. In cattle, the SRM controls are estimated to remove almost all potential infectivity in the unlikely event of an animal infected with BSE, but not yet showing any clinical signs,

being slaughtered for human consumption. The current list of SRM material can be found in Chapter 2.7 of the Manual of Official Controls, <http://www.food.gov.uk/enforcement/approved-premises-official-controls/manual>

The following amendments have been made to the EU TSE Regulation:

- SRM was reclassified to allow the duodenum, the colon and small intestine (except for the last four metres) back into the food and feed chains. This amendment came into force on 26 May 2015, and was adopted on an administrative basis in Wales (and across the UK) on this date. This change effectively removes some material from SRM control for BSE controlled risk countries like the UK and will allow UK industry to utilise these parts of the animal which they would previously have had to dispose of.
- Changes that permit EU Member States with a BSE negligible risk status a wider range of previously SRM designated tissues back into the food and feed chains. This includes the tonsils, intestine and vertebral column, but the skull, brain, eyes and spinal cord, (excluding the mandible) will continue to remain SRM designated tissues. These changes came into force across Europe on 15 July 2015 and were adopted in Wales on an administrative basis (along with the rest of the UK) on this date. This brings EU Regulations closer into line with OIE requirements which apply to third countries and means that these materials will no longer be SRM for EU BSE negligible risk countries. Although this will not directly impact on England and Wales before 2021 which is the earliest negligible risk status can be achieved, this will allow material previously considered to be SRM from other Member States and Scotland and Northern Ireland (who have achieved negligible BSE risk status as zones of the UK) to circulate within the internal market.
- Amendments to the control systems in order to reduce the administrative burden on operators have also been introduced at a European level, amending the information to be provided on the label of a carcass. A red stripe shall now be included on the label of carcasses or whole cuts of carcasses of bovine animals containing vertebral column, to indicate that the removal of the vertebral column is required. This amendment applies to products of bovine origin imported into the European Union from third countries. These changes came into force in EU law on 1 July 2017 and were implemented in England and Wales on an administrative basis on the same date. The amendment to domestic regulations are required in order to provide for effective enforcement provisions in relation to these changes.
- The primary controls currently in place relating to the removal of certain SRM and the feed ban, combined with continuing surveillance and secondary controls continue to do much to control risks to the food chain.

The proposed amendment to requirements for SRM removal are as set out below:

	<b>EU Negligible Risk</b>	<b>EU Non-Negligible Risk</b>	<b>International (OIE Standards) Negligible Risk</b>	<b>International (OIE Standards) Non-Negligible Risk</b>
<b>Tonsils</b>	Not SRM	All ages	Not SRM	All ages
<b>Intestine</b>	Not SRM	All ages – last four metres of small intestine (includes distal ileum), caecum and the mesentery	Not SRM	All ages – Distal ileum of small intestine
<b>Skull, brain, eyes and spinal cord (Exc. Mandible)</b>	Over 12 months	Over 12 months	Not SRM	Over 12 months (undetermined risk) or 30 months (controlled risk)
<b>Vertebral column</b>	Not SRM	Over 30 months	Not SRM	Over 12 months (undetermined risk)

## Consultation

For all SRM changes, for which the FSA are the competent authority, the FSA consulted directly with stakeholders about these changes prior to their adoption in EU law, during the negotiations process. Food Business Operators (FBOs) were notified of dates when the amendments would come into force in EU law and when they would be implemented on an administrative basis in the UK.

These amendments were also consulted on in the 2017 joint consultation held. Only one consultee responded, outlining that the change was not permitted in abattoirs because the mesentery and mesocolon could not be removed. The complete removal of mesentery and its fat from the small intestine is not easily achievable, so the harvesting of small intestines for human consumption is not currently allowed in the UK. Only methods which the FSA considers effective, safe and efficient will be authorised.

## Costs & Benefits

The costs associated with minimising the material identified as SRM for industry will be negligible, as in effect, it permits more products to be entered into the food and feed chains. There are instead intended benefits in bringing domestic legislation in line with European requirements, as this will allow material previously considered to be SRM from those Member States (and Scotland and Northern Ireland) with a negligible BSE risk status to circulate within the UK. Provided Wales and England achieve negligible risk status (as planned for 2021), industry within Wales will also be able to benefit from these amendments.

## Option 1 – Do nothing

This is not a viable option. The Welsh Government must acknowledge and implement the TSE controls prescribed in the EU TSE Regulation. If we do not recognise these amendments within the Welsh domestic legislation, there would

be no enforcement provisions available to the FSA to ensure adherence to these requirements.

## **Option 2 – Amendments to the definition and inclusion of bovine SRM**

This is the preferred option, as it would bring Welsh legislation in line with EU requirements, and ensure sufficient powers for the FSA to enforce these requirements across Wales.

### **Recommendation**

The Welsh Government recommends the implementation of Option 1 and for the amendments to bovine SRM controls within the domestic TSE Regulations within Wales.

## **Proposed Amendment 14 - Requirements of spinal cord removal**

Under the EU TSE Regulation, the spinal cord of sheep and goats which are aged over 12 months, or have one permanent incisor erupted, is deemed to be specified risk material (SRM) and must be removed. Existing UK implementing legislation requires that the carcass is split to remove the spinal cord. However, UK industry contends that carcass splitting significantly reduces carcass value. Consequently, and following representations from industry, a joint FSA/industry task group was set up in 2010 to investigate alternative removal methods that do not involve carcass splitting. The task group set up trials in June and November 2011 looking at possible alternative methods in the UK, however, these proved to be unsuccessful. Additionally, the task group determined that removal methods used in other Member States were unacceptable to the UK meat processing industry. To date, carcass splitting is the only method of spinal cord removal, which the UK meat processing industry finds acceptable.

The FSA remains prepared to consider alternative removal methods provided they can be shown to be effective and safe. To this end, we are proposing to include a new provision in the Transmissible Spongiform Encephalopathies (Wales) Regulations 2018 to provide the statutory mechanism by which FBOs can apply to the FSA for approval to use an alternative method of spinal cord removal for sheep and goats, should an effective alternative become available. Splitting of the carcass would remain the default method for spinal cord removal.

Adoption of any alternative methods for spinal cord removal would be on a voluntary basis. As with any other significant change to operating processes within approved establishments, there would be a cost for the business in seeking approval to use an alternative method. There would also be a cost to business from purchasing new equipment for any alternative method of spinal cord removal. However, as this is a permissive derogation, industry would only take this up if the benefits outweighed costs (i.e. the cost of a new method for removing the spinal cord is less than the current one).

We would wish Welsh FBOs to have the same ability as those in England (to apply to FSA for approval to use an alternative spinal cord removal process should one become available and meet FSA requirements).

## **Consultation**

The devaluation of carcasses as a result of carcase splitting has long been a concern of industry. Since 2010, the FSA and representatives of the meat industry have collaborated on a task group to investigate methods of removing the spinal cord from sheep and goats aged over 12 months that do not involve splitting the carcase.

Five consultees responded to the issue of alternative methods of spinal cord removal in the 2017 joint consultation. All of these supported the proposal to extend the availability of alternative methods.

## **Costs & benefits**

Adoption of any alternative method for spinal cord removal would be on a voluntary basis. As with any other significant change to operating processes within approved establishments, there would be a cost to businesses in seeking approval to use an alternative method of spinal cord removal. There would also be a cost to business from purchasing new equipment for any alternative method of spinal cord removal. However, this is a permissive derogation, industry would only take this up if the benefits outweighed the costs (i.e. the cost of a new method for removing the spinal cord is less than the current one).

## **Option 1 – Do nothing**

If the Welsh Government chose not to include this amendment to the domestic TSE legislation, the domestic provisions would not reflect the full options available at a European level. This would put Welsh industry at a disadvantage in terms of the options available to them compared to their counterparts in other Member States. Carcasses would have to continue to be split and industry would suffer from the reduced value this has on those carcasses

## **Option 2 – Amendment to the requirements for spinal cord removal from small ruminants slaughtered for human consumption**

Provided alternative removal methods of the spinal cord can be found and the FSA approve to be safe and effective, the domestic regulations in Wales should be amended to allow for such methods to be implemented across Wales. This would afford Welsh industry the same opportunities and derogations that apply to other Member States.

## **Recommendation**

It is recommended that the Welsh Government implements **Option 1** and for the amendments within the Welsh domestic Regulations to provide for the amendment to the requirements for spinal cord removal from sheep and goats

slaughtered for human consumption. This would provide for an alternative method to carcase splitting to be introduced to remove the spinal cord of small ruminants. The FSA would still need to consider and approve any alternative method of spinal cord removal before it could be implemented, and carcase splitting will remain the default position until such an alternative method can be demonstrated and is accepted by the FSA.

### 13. Minor Technical Amendments

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

### 14. Public consultations

The Welsh Government jointly consulted with FSA on proposed changes in September 2013. The feedback is reflected above next, to the proposed changes.

Due to the delay in laying the SI a subsequent consultation was carried out with Defra and the FSA between October and December 2017. The feedback has reflected above next to the proposed changes.

### 15. Wider Impacts

#### Competition Assessment

The competition filter test for <b>Livestock Keepers</b>	
Question	Yes/No
<b>Q1:</b> In the market(s) affected by the new regulation, does any firm have more than 10% market share?	<b>No</b>
<b>Q2:</b> In the market(s) affected by the new regulation, does any firm have more than 20% market share?	<b>No</b>
<b>Q3:</b> In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	<b>No</b>
<b>Q4:</b> Would the costs of the regulation affect some firms substantially more than others?	<b>No</b>
<b>Q5:</b> Is the regulation likely to affect the market structure, changing the number or size of businesses/organisation?	<b>No</b>
<b>Q6:</b> Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	<b>No</b>
<b>Q7:</b> Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	<b>No</b>
<b>Q8:</b> Is the sector characterised by rapid technological change?	<b>No</b>
<b>Q9:</b> Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	<b>No</b>

The competition filter test for <b>Food Business Operators</b>	
Question	Yes/No
<b>Q1:</b> In the market(s) affected by the new regulation, does any firm have more than 10% market share?	<b>No</b>
<b>Q2:</b> In the market(s) affected by the new regulation, does any firm have more than 20% market share?	<b>No</b>
<b>Q3:</b> In the market(s) affected by the new regulation, do the largest three firms together have at least	<b>No</b>

The competition filter test for <b>Food Business Operators</b>	
Question	Yes/No
50% market share?	
<b>Q4:</b> Would the costs of the regulation affect some firms substantially more than others?	<b>No</b>
<b>Q5:</b> Is the regulation likely to affect the market structure, changing the number or size of businesses/organisation?	<b>No</b>
<b>Q6:</b> Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	<b>Possibly</b> – should individual slaughterhouses choose to avail themselves of some of the feed control derogations; they would have to pay some initial start up costs. This would be their choice however, and it is anticipated this would only be undertaken should the benefits for that company outweigh the costs
<b>Q7:</b> Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	<b>No</b>
<b>Q8:</b> Is the sector characterised by rapid technological change?	<b>No</b>
<b>Q9:</b> Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	<b>No</b>

There are no expected impacts upon the wider economy or upon domestic competition under the preferred option.

There are no expected impacts upon innovation or upon other Departments under the preferred option.

## 16. Social Impacts

There are no expected social impacts under the preferred option.

## Impact of the proposed legislation on the duties of the Welsh Ministers as set out in the Government of Wales Act 2006.

### 17. Equality of opportunity and Welsh Language

No issues relating to these duties are considered to arise from the making of these Regulations. An equality impact assessment has been undertaken in relation to these proposals.

### 18. Sustainable Development

The proposed amendments to the Regulations are in accordance with the Welsh Governments principles of sustainable development.

### 19. Carbon Impact Assessment

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

## **20. 16. Other Environmental Issues**

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

## Annex A

### **Proposed Technical Amendments**

### **Transmissible Spongiform Encephalopathy (Wales) Regulations 2018**

#### **Regulations 14, 15 and 16 (of the 2008 Regulations)**

Regulation 14 (Powers of inspectors), 15 (Notices) and 16 (Notices restricting movement) will be revoked and new provisions brought into force to provide powers for inspectors to seize and dispose of milk and milk products, to issue notices prohibiting the movement of milk and milk products and to licence the movement of restricted products. This is linked to the proposed changes in Schedule 4. It is also proposed that a new regulation be added, 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.

#### **Schedule 2 (TSE Monitoring)**

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

- a new paragraph in Schedule 2, to require a cattle keeper home-slaughtering a bovine animal aged over the testing threshold to arrange both to sample the animal and to deliver the brainstem sample to an approved testing laboratory for BSE testing. APHA offers a private service to receive bovine heads at its Regional Laboratories. Cattle keepers can access this service via their private veterinary surgeon.
- extension of the retention and disposal requirements in Schedule 2 Part 1 to cover home slaughter and also clarifying that an "insufficient test result" includes situations in which approved testing laboratories do not receive brainstem samples.

Schedule 2 includes a statutory requirement for goat keepers to notify Welsh Ministers about fallen goats aged eighteen months and over. This requirement ceased on 31 December 2010 and, since that date, carcasses have been randomly selected for TSE sampling at animal by-products plants, based on quotas provided by APHA. This requirement - and the associated offence for failing to report a fallen goat – will therefore be removed.

Schedule 2 will be amended to clarify the definition of a bovine animal that was born or reared in the UK before 1 August 1996, and that it is an offence to slaughter these animals for human consumption.

Remove from Schedule 2 the requirement for slaughterhouses, which do not slaughter cattle eligible for BSE testing, to have an approved Required Method of Operation (RMOP). The requirement for RMOPs to describe the system for removing vertebral column as Specified Risk Material (SRM) is also removed.

Schedule 2 currently allows Welsh Ministers 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 categories of bovines requiring rapid testing of samples for BSE. 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', eg. that died in lairage.

The reference to Regulation (EC) No.716/96 will be removed from Schedule 2, as it provided for the Older Cattle Disposal Scheme, which ceased to exist on 1 January 2009.

Provision of enforcement power in Schedule 2, Part 1 of the 2008 Regulations, to require, if necessary, premises approved under the Animal By-Products (ABP) Regulations to comply with a direction from the Welsh Ministers to select fallen sheep or goats for TSE sampling and to sample them. The system, which requires tested carcasses to be retained pending a negative test result unless they are disposed of by incineration or rendering followed by incineration in accordance with the ABP Regulations, has been in operation since January 2011. These provisions would also apply to any future requirement to sample deer for TSE.

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

The paragraph is deleted from Schedule 2, as the contract for Agricultural and Horticultural Development Board to carry out this work terminated on 31 March 2009. Animal Health Veterinary Laboratories Agency is now responsible for carrying out official TSE controls at hide markets and tanneries.

Schedule 2 will be amended to refer explicitly to cattle that require BSE testing.

Schedule 2 will be amended to refer explicitly to a BSE test result.

### **Schedule 3**

Currently, where a bovine animal suspected of being affected with BSE is not killed immediately, the keeper is obliged under the Regulations to dispose of its milk in such a way that it cannot be consumed by humans or animals, other than

the suspect's own calf or animals kept for research purposes. This requirement will be removed, as the results of FSA-funded research, together with previous epidemiological and experimental research, provided no evidence for the transmission of BSE via milk. However, the food ban will effectively remain, as the EC Food Hygiene Regulation 853/2004 requires that raw milk for human consumption must come from animals that are in a good general state of health.

#### **Schedule 4**

A new requirement will be added for an inspector to serve a notice of intention to destroy sheep or goat milk or milk products on a holding on which BSE cannot be excluded following a test on a sheep or goat. This will apply to milk/milk products on the holding produced from the point of official suspicion to the point at which the herd or flock is culled.

To help monitor compliance with existing atypical scrapie controls, Schedule 4 will be amended to require the owner to identify the sheep and goats as directed by the Welsh Ministers (e.g. using a dedicated tag which marks the animal as not for export) and to make it an offence to remove this identification unless permitted by the Welsh Ministers.

Schedule 4 will be clarified to require subsequent occupiers of premises to comply with a notice served on a previous occupier.

Schedule 4 will be corrected to refer to progeny.

#### **Schedule 5**

Schedule 5 will be amended as the survey for TSEs in farmed and wild red deer required by Commission Decision 2007/182/EC has been completed. This is linked to the changes in Schedule 2, which retain an equivalent provision to that currently in Schedule 5. However, we will amend Part 1 of Schedule 2 of the 2008 Regulations to retain an equivalent provision, in case it is required in the future.

#### **Schedule 6**

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

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

In September 2008, the EU adopted Regulation (EC) No.956/2008, which made a change to the requirements for packaging of feed for non-ruminants (e.g. pigs/poultry) containing fishmeal. This required the packaging to be “*clearly marked*” with the words “*contains fishmeal must not be fed to ruminants*”, rather than simply for the “*label*” to “*clearly indicate*” these words. This followed reports of the use of detachable labels, such that bags were no longer properly identified as containing fishmeal if the label became detached. The requirement for the declaration to be printed or stuck directly (i.e. “*marked*”) on the bag is already legally binding because of the ambulatory clause in Schedule 1.

There will be an amendment to require written consent from an inspector when using equipment used to produce milk replacer containing fishmeal, to produce feed for weaned ruminants.

There will be an amendment to exempt the export of pet food containing processed animal protein of ruminant origin from the general ban on exporting processed animal protein of ruminant origin to third countries. This is in line with Regulation (EC) No.956/2008. We do not have figures on the potential for export of pet food that contains processed animal protein of ruminant origin to third countries.

It is currently an offence to export fishmeal, products containing fishmeal and pet food, without an agreement in writing between Welsh Ministers 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 new 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.

## **Schedule 8**

Amendments will be made to clarify the definition of a bovine animal that was born or reared in the UK before 1 August 1996. This is linked to the changes being proposed in Schedule 2.

It is believed that all the hides derived from cattle born or reared in the UK before 1 August 1996, killed under the Older Cattle Disposal Scheme (OCDS), have now been tanned to leather and the Agricultural and Horticultural Development Board no longer require powers of inspectors at hide markets and tanneries in relation to OCDS hides, so this requirement has been removed. Animal and Plant Health Agency inspectors are responsible for carrying out other official TSE controls at hide markets and tanneries.

A new paragraph will be added to Schedule 8 of the new Regulations, which will provide a cross-reference to offences relating to placing on the market and export in Schedules 3, 4 and 6.