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Llywodraeth Cymru
Welsh Government

Proposals to amend the Transmissible Spongiform Encephalopathies (England) Regulations 2010 and the Transmissible Spongiform Encephalopathies (Wales) Regulations 2008

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Background

Chapter 1: Purpose of the consultation

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. The European Food Safety Authority (EFSA) has advised that BSE is the only animal TSE that has been shown to be a risk to human health.

1.2 There are two forms of BSE: classical BSE, which is believed to be transmitted due to cattle eating contaminated feed primarily through deliberate or accidental inclusion of infective meat and bone meal; and atypical BSE, which is regarded by the World Organisation for Animal Health (OIE) as a condition believed to occur spontaneously in all cattle populations at a very low rate.

1.3 There are also two forms of scrapie. The first is classical scrapie, which is transmitted from mother to offspring immediately after birth or to other sheep and goats via fluids and tissues from an infected animal. Farmers are encouraged to breed sheep for genetic resistance to classical scrapie. Genetic resistance to classical scrapie in goats is very low. The second is atypical scrapie, which is considered by the OIE to be clinically, pathologically, biochemically and epidemiologically unrelated to classical scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep. No genetic resistance to atypical scrapie has been detected in sheep and no cases of atypical scrapie have been recorded in goats in the UK.

1.4 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, including BSE in cattle and scrapie in sheep and goats. The government seeks to implement TSE controls, in line with EU requirements, and in the interest of public health and animal health protection. The current domestic TSE legislation in England is the Transmissible Spongiform Encephalopathies (England) Regulations 2010, as amended (the 2010 Regulations) and in Wales the Transmissible Spongiform Encephalopathies (Wales) Regulations 2008, as amended (the 2008 Regulations).

1.5 On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU.

1.6 Defra, Welsh Government and the Food Standards Agency (FSA) are seeking your views on a number of proposals which would amend the 2010 Regulations in England and the 2008 Regulations in Wales (please see chapter 4). The Welsh Government and the Food Standards Agency (FSA) Wales have already undertaken a joint consultation in 2013 on two of these proposals (paragraphs 2.17- 2.19 refer). However, comments are still welcome on these proposed changes, as set out in Chapter 3.

1.7 We are confident that these proposals would have a net benefit to the farming, abattoir and feed industries. The purpose of this consultation is to seek feedback on the anticipated impact of our proposals from stakeholders in these industries and other interested parties.

1.8 The proposals on which we invite your comments would:

In England and Wales:

(i) achieve a more equitable sharing of the cost for BSE sampling of fallen stock cattle between industry and the taxpayer;

(ii) enable the feed industry to take advantage of an EU derogation permitting the use of poultry and pig processed animal protein (PAP) in feed for farmed fish[1];

(iii) clarify and make minor amendments to the controls on farms where classical scrapie has been confirmed, and remove requirements for restrictions on the movement of sheep and goats on holdings affected by atypical scrapie [2];

(iv) remove the requirement for abattoirs slaughtering cattle that require BSE testing to have a Required Method of Operation (RMOP)[3];

(v) amend the list of tissues from cattle that are designated as Specified Risk Material (SRM) to reflect changes to EU legislation[4];

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[1] Implemented in England and Wales on an administrative basis on 1 June 2013.

[2] Implemented in England and Wales on an administrative basis on 1 July 2013.

[3] Wales consulted on the proposal in 2013.

[4] Implemented in England and Wales on an administrative basis on 26 May 2015, 5 August 2015 and 1 July 2017. Paragraph 3.30 refers.

(vi) provide a statutory mechanism by which food business operators can apply for approval to use an alternative method of spinal cord removal, other than carcase splitting, for sheep and goats aged over 12 months of age;

(vii) clarify wording relating to the removal of SRM from sheep and goats in a slaughterhouse;

(viii) remove the requirement for written bilateral agreements between Member States to authorise the export of PAP derived from non-ruminant animals[5];

(ix) permit the use of meal from wild starfish and farmed aquatic invertebrates (which do not fall within the definition of 'aquatic animals') in feed for non-ruminant animals[6];

(x) enable the feed industry to take advantage of an EU derogation that will permit the use PAP derived from insects in feed for aquaculture[7];

(xi) enable the feed industry to take advantage of an EU derogation that will permit the import and export of PAP derived from ruminants[8]; and

(xii) make two technical amendments:
- To amend requirements for certification for animals falling within the pedigree category for BSE compensation; and
- To empower the Secretary of State to select slaughterhouses for the annual EU TSE sheep abattoir survey.

With regard to proposals (ii), (v), (viii), (ix), (x) and (xi), which originate from changes to EU legislation, Defra has worked closely with the FSA, and before these measures were voted upon in the EU we sought the views of the Advisory Committee on Dangerous Pathogens (ACDP), which advises on TSE risks, regarding any potential risk to public health arising from these proposals. As explained at Annex C, ACDP raised concerns in particular about proposals (v) and (xi).

The changes were agreed by the EU following majority votes from which the UK abstained, after which the ACDP's advice was referred to the cross departmental UK Zoonoses, Animal Diseases and Infections Group (UKZADI) which provides strategic co-ordination on public health interests and action. After considering the ACDP's

[5] Implemented in England and Wales on an administrative basis on 3 February 2016.

[6] Implemented in England and Wales on an administrative basis on 13 February 2016.

[7] Implemented in England and Wales on an administrative basis on 1 July 2017.

[8] Implemented in England and Wales on an administrative basis on 1 July 2017.

advice and concerns in the context of wider risk management, UKZADI noted that the changes to EU law already applied in the UK and recommended that Defra should seek the views of the public in an open consultation which sets out ACDP's concerns.

The views expressed by ACDP and UKZADI are set out at Annex C.

Key controls remain in force to protect public and animal health from the threat posed by BSE. Our vigilance continues to be maintained through:

- the ban on feeding certain animal proteins to farmed animals, which prevents the spread of BSE to animals through feed;
- removing specified risk material (SRM) – the most risky parts of animals – at slaughter to protects consumers from risk from food;
- carrying out active surveillance on fallen stock and other high risk animals (e.g. those found sick at abattoirs) to monitor the level of BSE over time and thereby check on the continued effectiveness of BSE controls; and
- vigilance for any signs of clinical infection. BSE remains a notifiable disease in the UK. All animals suspected of being infected with BSE are killed and tested for the disease and their carcases are destroyed.

In England:

(i) Increase the standard "table valuations" for compensation for sheep and goats killed on suspicion of being infected with a TSE or in pursuit of TSE eradication to better reflect replacement values; and remove the option for individual valuation.

In Wales:

(i) Amend the 2008 Regulations with regard to on-farm controls for classical scrapie to reflect the full range of options available in EU legislation[9];

(ii) amend the table of compensation categories for BSE; and

(iii) amend the 2008 Regulations with regard to the use of valuers for the purpose of TSE compensation for animals and animal products killed or destroyed on suspicion of being infected with a TSE or in pursuit of TSE eradication.

General Proposals:

[9] Implemented in Wales on an administrative basis on 1 July 2013.

The following legislation would be revoked:

(i) The Transmissible Spongiform Encephalopathies (No 2) (Amendment) Regulations 2008, which has been identified as obsolete by the Red Tape Challenge in England;
(ii) The Bovine Hides Regulations 1997 and the Selective Cull (Enforcement of Community Compensation Conditions) Regulations 1996 in Wales; and
(iii) The 2010 Regulations and its amending legislation in England and the 2008 Regulations, as amended, in Wales.

1.8 Full details of the above proposals are outlined in Chapter 3.

1.9 Our proposals would contribute to TSE controls that are based on scientific advice and are considered proportionate to the risk to public and animal health in line with the European Commission's TSE Roadmap 2, (2010-2015), which had a strategic goal to review the current animal feed ban and consider appropriate revisions to feed legislation in line with the principles of proportionate and precautionary response.

The TSE Roadmap 2 officially ended on 31 December 2015 but, in the absence of a new EU TSE strategy document, the Commission still wants TSE controls to be renegotiated in line with the outstanding items of the Roadmap. The aim is to continue to align TSE controls closer with the international standards of the World Organisation for Animal Health (OIE), if considered safe and backed up by scientific evidence.

1.10 Government supports a risk-based, proportionate approach that eliminates any unnecessary burdens. It strongly supported the objectives set out in the TSE Roadmap 2 document and continues to support the principle of the Commission bringing forward proposals for debate and potential regulatory change where there are grounds for reconsidering whether existing TSE control measures are disproportionate to the risk.

1.11 The BSE risk has diminished significantly (the most recent case in the UK was in September 2015) and the current levels of controls mean that the risk to the public remains very low. The 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. Cases of atypical BSE are excluded for the purpose of the OIE's official BSE risk status recognition. The OIE now recognise 25 EU Countries as having BSE negligible risk (NR) status. Also, on 26 May 2017 the OIE recognised Scotland /N Ireland as having BSE NR status, with the UK as a whole expected to follow by 2021.

1.12 These amendments would be brought into force in England by the Transmissible Spongiform Encephalopathies (England) Regulations 2018, which would consolidate the 2010 Regulations and all subsequent amendments, and in Wales by the

Transmissible Spongiform Encephalopathies (Wales) Regulations 2017, which would consolidate the 2008 Regulations and all subsequent amendments.

1.13 Defra, the Welsh Government and the Food Standards Agency (FSA) are inviting views from stakeholders in England and Wales on the proposed amendments listed in paragraph 1.7 above to the 2010 Regulations (as amended) in England and to the 2008 Regulations (as amended) in Wales. Details on how to respond to this consultation are provided in Chapter 4.

Chapter 2: Previous stakeholder engagement

2.1 There has been significant and varied previous engagement on many of the issues proposed in this consultation document. Those applying to both England and Wales are outlined below.

Part 1: Proposed changes in England and Wales

(i) Sharing the cost of BSE sampling between the farming industry and the taxpayer

2.2 On 11 December 2006, Defra published a GB consultation document aimed to engage with all those who have an interest in developing policy on responsibility and cost sharing for animal health and welfare. The consultation set out the principles around which decisions on sharing responsibilities and costs could be made (Annex B refers). Most respondents welcomed the consultation as a positive step forward and agreed in general with the principle of responsibility and cost sharing.

2.3 Further consultations on the next step were held in England, Scotland and Wales in December 2007, inviting views from 375 stakeholders across GB on plans to share further responsibilities and costs for maintaining and improving animal health and welfare with livestock keepers and others associated with animal health and welfare. The consultation document detailed seven specific responsibilities and cost sharing proposals in respect of certain TSE related activities that government was funding but where the principal beneficiaries were specific livestock sectors or individuals participating in specific schemes. The proposals were to transfer responsibility for these activities or the cost of these activities to industry or, in the case of the scrapie proposals, to stop the activity if industry were unwilling to assume responsibility for it. Some respondents to this second consultation acknowledged that the cost of the TSE measures needed to be balanced more fairly between the taxpayer and industry. However, others felt that TSE controls were a public health issue that should be funded by the public purse. A number of respondents highlighted the need to apply the proposals evenly across industry and on a GB basis.

(ii). Proposal to permit the feeding of pig and poultry processed animal protein to farmed fish

2.4 In July 2010 Defra, the Welsh Government and the Food Standards Agency 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. The Commission proposed to continue stepwise changes to the TSE rules supported by scientific advice from EFSA, whilst maintaining a high level of food safety. 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. On the basis of the responses received, the UK government's agreed response supported the Commission's proposed approach.

2.5 In June 2011 Defra wrote to 70 organisations, including consumer and religious groups and the food and feed industries, seeking comments on the European Commission's proposal to amend the EU TSE Regulation to allow the feeding of pig and poultry Processed Animal Protein (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. The organisations were invited to comment on the scope, the practical aspects and the derogations in the proposal and to provide detailed information on the possible costs and benefits associated with any change. Twelve organisations provided comments expressing support for the proposals. A meeting in January 2013 between Defra and key stakeholders in the feed industry again showed support for the proposals but predicted that take-up of the derogation would be low because in the UK the available supplies of pig and poultry PAP are utilised in the pet food industry. Chapter 3, paragraph 3.8 refers. In addition, APHA wrote to stakeholders in July 2013 to notify them that this proposal had been implemented on an administrative basis.

(iii). Amendments to on-farm scrapie controls

2.6 All holdings in England and Wales, which were under movement restriction following the confirmation of classical or atypical scrapie, were notified of these amendments by letter after they came into force in EU law on 1 July 2013. The proposed amendments to classical scrapie controls, outlined in paragraph 3.15, were included in a consultation undertaken by the Welsh Government in 2013.

(iv). Removal of the requirement for abattoirs slaughtering cattle that require BSE testing to have a required method of operation (RMOP)

2.7 The BSE testing rules were relaxed in March 2013. This meant that there was no longer a requirement for routine testing of healthy animals from EU Member States. Industry representatives were informed through the industry stakeholder forum for Current and Future Meat Controls of the intention to eliminate the requirement of an approved RMOP in the next revision of the domestic regulations.

2.8 In 2013, the Welsh Government and Foods Standards Agency Wales, consulted on the proposed removal of the requirement for occupiers (FBOs) to have a RMOP in participating slaughterhouses. This was in response to the EU decision permitting

designated Member States to stop the testing of healthy bovine animals, which resulted in the requirement for an RMOP being disproportionate.

(v). Amendments to the definition of bovine specified risk material (SRM)

2.9 The FSA consulted with stakeholders about these changes prior to their adoption in EU law, while negotiations with the EU were still in progress. Following their adoption, Food Business Operators (FBOs) were notified of the dates when the amendments would come into force in EU law and when they would be implemented on an administrative basis in the UK. Both the Manual for Official Controls (MOC) and Meat Industry Guide (MIG) have been updated to take these changes into account.

(vi). Amendment to requirements for spinal cord removal from sheep and goats slaughtered for human consumption

2.10 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. Their work has included trials of alternative methods in June and November 2011. Chapter 3, paragraphs 3.33-3.35 refer.

(vii). Clarification on SRM removal in slaughterhouses

2.11 This issue came to light in the course of legal proceedings taken by the FSA against a Food Business Operator (FBO) in 2013. The proposed clarification of the existing legislation reflects the fact that the Court's judgement was given in favour of the FSA.

(viii). Removal of the requirement for written bilateral agreements to authorise the export of processed animal protein (PAP) derived from non-ruminant animals

2.12 Defra has frequently discussed this measure with industry and has provided regular updates on ongoing negotiations with the Commission. Industry is supportive of this proposal. No engagement has yet taken place with consumer organisations.

(ix). Extension to the scope of 'aquatic animals' permitted for use in processing fishmeal and inclusion in feed for aquaculture animals

2.13 This issue came to light when an application was made by industry in Wales to process polychaetes for inclusion of feed in aquaculture. Our proposal reflects the extended scope of organisms in EU legislation that may be processed as fishmeal. Whilst industry is considered to be supportive of this proposal, no engagement has taken place yet with consumer organisations.

(x). Proposal to enable the feed industry to use processed animal protein derived from insects in feed for aquaculture

2.14 The Commission has engaged with industry on the drafting of protocols for this proposal and Defra has provided industry stakeholders with regular updates on ongoing negotiations with the Commission. Industry is supportive of this proposal. No engagement has yet taken place with consumer organisations.

(xi). Proposal to permit the import and export of processed animal protein derived from ruminants

2.15 The Commission and Defra have consulted extensively with industry over the past three years regarding this proposal and have provided frequent updates to stakeholders. Industry is supportive of this proposal. No engagement has yet taken place with consumer organisations.

Part 2: Proposed changes in England

(i). Amendments to TSE compensation for sheep and goats

2.16 This amendment is proposed following a case that identified a weakness in the current TSE compensation system for sheep and goats. Defra co-operated with the farmer in agreeing a basis for the compensation package for his holding. The result of these discussions has been used as the basis for the proposed amendments to the 2010 Regulations.

Part 3: Proposed changes in Wales

(i). Amendment to domestic legislation regarding on-farm controls for classical scrapie

2.17 The consultation by the Welsh Government and Food Standards Agency in 2013 (see paragraph 2.8) also proposed amendments to on-farm classical scrapie controls in Wales, recognising a monitoring option available when a case of classical scrapie is confirmed on farm, and recommending this as the initial approach. The availability of options in relation to when classical scrapie is confirmed on farm was generally supported by industry who felt that the monitoring option provided a more proportionate and flexible approach to the risk posed. These proposals have already been introduced administratively since 2013.

(ii). Amendment to the table of compensation categories for BSE in Wales

2.18 The Welsh Government consulted on proposals to amend the table of compensation applicable for BSE compensation valuations in 2013. The purpose of this amendment was to provide clarity on the sales data which valuations are based on and to provide a more accurate series of compensation categories that would reflect the wide bovine market in Wales, providing a fairer compensation structure.

(iii). Amendment to the source of independent valuers for compensation purposes

2.19 The Welsh Government proposes to amend the 2008 Regulations with regard to the use of valuers for the purpose of providing compensation valuations for animals and animal products, to allow for the use of independent valuers appointed by the President of the Central Association of Agricultural Valuers (CAAV), in addition to those appointed by the President of the Royal Institute of Chartered Surveyors (RICS). This issue has not yet been consulted upon, and the Welsh Government are seeking views on the potential impact for animal owners, of widening the pool of potential independent and specialist valuers, for use only in cases where the table valuation of an animal has to be determined by this process as set out in the Welsh regulations.

Chapter 3: The proposed changes

Part 1: Proposed changes in England and Wales

(i). Sharing the cost of BSE sampling between the farming industry and the taxpayer

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

3.2 The carcases of fallen stock cattle that require BSE testing are transported to government approved sampling sites where trained staff takes a small sample of brain material for testing before the carcases are incinerated. The farming industry currently pays all the costs of transportation and destruction of the carcases by disposal sites, with the cost of taking fallen stock samples (at a price of £6.25 per sample), transporting the samples to the relevant laboratory, and the laboratory tests being borne by the taxpayer.

3.3 We propose to transfer the cost of taking fallen stock samples for mandatory BSE testing from the taxpayer to the farming businesses that already have to submit these carcases to such disposal sites for sampling and processing. This would result in a more equitable sharing of the cost of BSE surveillance between the farming industry and the taxpayer, by transferring the cost from the taxpayer to those farming businesses in England and Wales that receive and benefit from the EU BSE surveillance programme, while continuing to safeguard public and animal health (by monitoring for incidence) in a proportionate way. The taxpayer would continue to pay for the cost of transporting the samples to the government approved testing laboratory and for the testing itself.

3.4 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. On this basis, the total annual cost of this proposal to the cattle farming industry in England and Wales would be £574,600 per year, with an equivalent saving to the taxpayer. The cost per holding would depend upon its number of fallen stock cattle aged over 48 months per year. As there are approximately 51,500 cattle holdings in England and Wales, the average would be two fallen stock cattle aged over 48 months per year, giving an average annual cost per holding of £12.50.

(ii) Proposal to permit the feeding of pig and poultry processed animal protein to farmed fish

3.5 In 2001, to prevent the spread of BSE, the EU introduced a general ban on the feeding of all processed animal protein (PAP) to farmed livestock. This prevents the spread of classical BSE in animals due to eating contaminated feed primarily through deliberate or accidental inclusion of infective meat and bone meal. 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:

Table 1: BSE cases recorded worldwide by the OIE since 2012

Year	Number of cases worldwide (including UK cases)	Number of cases in UK
2012	21	3
2013	7	3
2014	12	1
2015	7	2
2016	2	0
2017 (to 4 September)	3	0

Note: All three cases confirmed to date 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.

The EU is therefore considering ways to safely align the ban on the feeding of PAP to farmed livestock with the international standards of the World Organisation for Animal Health (OIE), which only prohibit meat-and-bone-meal (MBM) or greaves derived from ruminants from being fed to ruminants, to reduce unnecessary burdens on the industry and to reduce waste.

3.6 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 and was implemented in the UK on an administrative basis from that date. This was made possible after the EU validated a polymerase chain reaction (PCR) test capable of detecting very low levels of ruminant material in feed. Enforcement

authorities can test for and enforce PAP from ruminants to be banned from animal feed in the presence of pig and poultry PAP. Pigs, poultry and fish are not known to be able to contract or pass on BSE naturally. Pig and poultry PAPs are a potential high quality 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 the cause of vast amounts of deforestation around the world.

3.7 If anyone in England or Wales wishes to avail themselves of this derogation, all arrangements are in place for them to do so, on condition that they can demonstrate **to our satisfaction** that they can satisfy the EU's key requirements, as follows:

(i) 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;

(ii) 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.

3.8 However at present no feed manufacturers in the UK utilise this derogation. The feed industry has expressed support for this measure but has indicated that take-up is likely to be low because most pig and poultry PAP produced in the UK is used in pet food and that for commercial reasons this is expected to remain the case.

3.9 Our proposal would adopt in English and Welsh legislation the derogation that was implemented administratively across the UK on 1 June 2013. It would be proportionate to the risk to public and animal health in line with the goals of the TSE Roadmap 2 and with EFSA advice; would fulfil government's commitment to use all available derogations in EU law in England and Wales; and it would also ensure that the feed industry in England and Wales has the same opportunities as their counterparts in other Member States for the use of pig and poultry PAP in aquaculture feed, while continuing to enforce all prohibitions on the use of meat and bone meal in ruminant feed.

3.10 Manufacturers who adopt this option would be required to carry out additional tests costing approximately £98 per consignment. This is not a new charge and industry would only adopt this option if the benefits outweighed costs. The government incurred costs of approximately £25,000 in the setting up and rolling out of the validated test.

(iii). Amendments to on-farm scrapie controls[10]

3.11 Annex VII of the EU TSE Regulation lays down rules for the control of classical and atypical scrapie on holdings where the disease has been detected. Scrapie occurs at a low prevalence in the UK. EFSA has advised that scrapie has not been shown to be a risk to human health.

3.12 Classical scrapie has been recognised in the United Kingdom for over 250 years. The genetic make-up of sheep determines their susceptibility to classical scrapie, and genotyping and selective breeding have been used as control tools for the disease. However, goats do not exhibit a similar genetic variability and are believed to be generally susceptible to classical scrapie.

3.13 Where a case of classical scrapie is confirmed on a holding, the EU TSE Regulation provides options of killing and destroying or slaughtering all sheep and goats on the holding; or culling/slaughtering all goats and those sheep that are genetically susceptible to classical scrapie; or monitoring the holding, with no killing or destruction of sheep or goats.

3.14 In all cases where classical scrapie is confirmed, following initial action the holding is placed under movement restriction for two years following the detection of the last case. During this period all sheep and goats on the holding over 18 months of age that are slaughtered for human consumption, or that die or are killed other than for human consumption (‘fallen stock’) must be tested for TSEs. The government pays all costs of sampling, transportation of samples to government approved laboratories, and testing, and arranges and pays for the collection and destruction of the carcases of all ‘fallen stock’ sheep and goats over 18 months of age. Animals slaughtered for human consumption are sent to designated abattoirs where they are sampled and the carcases are retained until the test results are available. Carcases which test positive or inconclusive to scrapie are removed from the food chain and destroyed. Milk and milk products from sheep and goats from classical scrapie holdings with animals to be destroyed/ slaughtered, must not be fed to ruminants outside the holding where they were produced until the possibility of BSE on the holding has been ruled out. During this period the milk and milk products can only be used, stored and transported as feed for non-ruminants within the UK under strictly controlled conditions, and must not be exported as feed for non-ruminants.

3.15 In 2013 the EU TSE Regulation was rewritten and re-ordered in line with the latest EFSA advice, to clarify the control options available following the detection of classical scrapie on a holding. It introduced the following changes to on-farm controls:

[10] Amendments to classical scrapie controls already consulted upon by the Welsh Government in 2013 – paragraph 2.6 refers

(i) Where previously farmers on affected sheep holdings under monitoring restrictions have been advised to breed from rams that are genetically resistant to classical scrapie, it now would become a legal requirement. (NB: There are no similar breeding restrictions on goat holdings because goats are not recognised as genetically resistant to classical scrapie).

(ii) The existing ban on the feeding to ruminants outside the holding, of milk and milk products from animals present on the holding at the time the disease was confirmed, would be extended from the time when the possibility of BSE has been ruled out, to the end of the movement restriction period where the monitoring option has been applied, two years after the confirmation of the final case of classical scrapie on the holding. As it is not general practice for sheep and goat milk and milk products to be sold for feeding to ruminants on other holdings, the effects of this change upon the sheep and goat industry as a whole is expected to be negligible.

(iii) To prevent the possible spread of infection, common grazing would be prohibited during the lambing and kidding period for animals from holdings under classical scrapie controls. Approximately 10% - 20% of sheep and goat holdings use common grazing and could be affected by this change. The overall financial impact is not possible to quantify but it is expected that this change would only affect 10-20% of the very small number of holdings where classical scrapie is confirmed.

3.16 These measures were implemented across the UK on an administrative basis on 1 July 2013, pending amendments to domestic legislation. Our proposal to adopt these amendments in domestic legislation would continue to ensure that scrapie controls are proportionate to the risk to public and animal health in line with the goals of the TSE Roadmap 2 and EFSA advice.

3.17 Taking an assumption that two farms per year in England and Wales would be placed under classical scrapie controls and that each would be required to replace nine rams that are genetically susceptible to classical scrapie, it is estimated that the changes to classical scrapie controls would cost those farmers a total of £2,025 per year.

3.18 Atypical scrapie has been detected since 1998, primarily through the EU testing programme for the testing of fallen stock and healthy sheep slaughtered for human consumption at abattoirs. However, retrospective studies have indicated that it has been present in the UK since the late 1980s. The latest scientific advice from EFSA and the European Centre for Disease Prevention and Control (ECDC) dated 19 January 2011 indicates that unlike classical scrapie, which is transmissible between animals, atypical scrapie is unlikely to be naturally transmissible or has very low transmissibility.

3.19 Where a case of atypical scrapie is confirmed on a holding, it is placed under movement restriction and monitored for two years following the detection of the last case, with no killing or destruction of sheep or goats. Testing is carried out as described in paragraph 3.14.

3.20 In 2013 the EU TSE Regulation was rewritten and re-ordered in line with the latest EFSA advice, to clarify the control options available following the detection of atypical scrapie on a holding. It introduced the following changes to on-farm controls:

The following atypical scrapie controls would be removed:

(i) The prohibition on movement of animals on and off the holding, other than to slaughter, during the two year period following confirmation of the last case of atypical scrapie.

(ii) The prohibition on the export to Member States or third countries of live sheep and goats, and sheep and goat semen and embryos from holdings affected by atypical scrapie, in the two year period following the confirmation of the last case of atypical scrapie.

3.21 The existing requirements for sampling and testing animals aged over 18 months, which leave the holding directly for slaughter (but it does not apply to animals sent for slaughter via markets) or as fallen stock, would remain, to enable Member States to continue to gather scientific data on atypical scrapie.

3.22 These measures were implemented across the UK on an administrative basis on 1 July 2013, pending amendments to domestic legislation. Our proposal to adopt these amendments in domestic legislation would continue to ensure that scrapie controls are proportionate to the risk to public and animal health in line with the goals of the TSE Roadmap 2 and with EFSA advice.

3.23 There would be a positive impact upon holdings affected by atypical scrapie, which can move and sell their livestock without any requirement to identify them as coming from a holding affected by atypical scrapie or for any animals moved to another holding to be tested at slaughter.

(iv). Removal of the requirement for abattoirs slaughtering cattle that require BSE testing to have a required method of operation (RMOP)[11]

3.24 In 2005 a requirement was added to domestic TSE legislation for abattoirs slaughtering cattle that require BSE testing to have a Required Method of Operation (RMOP), which has been approved by either the Secretary of State (in England) or Welsh Ministers (in Wales). A RMOP is an agreement between the Official Veterinarian and the Food Business Operator in charge of the abattoir on the details

[11] Already consulted upon by the Welsh Government in 2013 – paragraph 2.8 refers.

of the slaughter process at abattoirs processing cattle slaughtered for human consumption, which require testing for BSE. This change was implemented on the advice of the FSA to enable the UK to introduce a system of BSE testing of older cattle to replace the Over Thirty Months Rule, which had banned the sale for human consumption of meat from cattle aged over thirty months at the time of slaughter since March 1996, to protect public health and maintain public confidence in cattle meat. The requirement for an approved RMOP, which exceeded the requirements of the EU TSE Regulation, was needed to ensure that abattoirs in GB slaughtering cattle requiring BSE testing would have robust sampling, retention and disposal systems that safeguarded human and animal health.

3.25 Commission Decision 2009/719 was amended on 4 February 2013 (Commission Decision 2013/76/EU) to give twenty-five Member States, including the UK, the option to end routine BSE testing of healthy cattle aged over 72 months slaughtered for human consumption, which were born in the UK and all other EU Member States except for Romania and Bulgaria, from 4 February 2013 (Commission Decision 2016/851/EU). The UK implemented this option on 1 March 2013. As a result, RMOPs for the occupier (Food Business Operator - FBO) of participating slaughterhouses were subsequently modified and their requirements made proportionate to the significantly reduced risk. 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) and a negligible number of healthy slaughtered animals aged over 30 months and ‘risk’ animals aged over 24 months born in Bulgaria, Romania and third countries, a reduction from about 300,000 cattle tested per year in GB to less than 5,000.

3.26 Our proposal would remove the legal requirement for a RMOP signed by the Secretary of State (in England) or the Welsh Ministers (in Wales) because it is no longer justified. This would also remove the offence provision currently applicable to an occupier for use of an abattoir without an approved RMOP. Abattoir operators would be expected to agree a Standard Operating Procedure (SOP) with the FSA, which will continue to maintain food safety and BSE controls.

3.27 This measure would not result in any additional costs or benefits to government or industry.

(v). Amendments to the definition of bovine specified risk material (SRM)

3.28 Specified Risk Material (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.

3.29 As explained at paragraph 1.11, 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.

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

(i) Changes to bovine mesentery**,** published in the Official Journal of the European Union on 6 May 2015, came into force on 26 May 2015. SRM was re-classified to allow the duodenum, the colon and the small intestine, except for its last four metres, back into the food and feed chains. This amendment was adopted in the UK on an administrative basis also on 26 May 2015. EFSA Opinion 3554, 2014 gave a quantitative assessment of the BSE infectious load that might enter the food and feed chain yearly if bovine intestine and mesentery from animals born and raised in the EU would be re-allowed for consumption. The results support the rationale for removal of the last four metres of the small intestine and the caecum in reducing over 90% of total infectivity associated with the intestine and mesentery in BSE infected cattle up to 36 months of age. This change effectively removes some material from SRM control (the duodenum, the colon and the small intestine except for the last four metres) 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.

(ii) 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. The changes were published in the Official Journal of the European Union on 15 July 2015 and came into force on 5 August 2015. This amendment was adopted in the UK on an administrative basis on the same day. EFSA Opinion 3554 indicated that 90% of the total infectivity amount in a BSE clinical case is associated with central and peripheral nervous system tissues. This has led to further changes. It also 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.

(iii) As a consequence of these amendments, the provisions in the EU TSE Regulation relating to the removal of SRM have been further amended. The vertebral column continues to be defined as specified risk material for BSE controlled risk countries such as the UK. In order to reduce administrative burden on operators, the European Union has modified the information to be provided on the label of carcase. As a control system, a red stripe shall be included on the label of carcases or whole cuts of carcases of bovine animals containing vertebral column, when 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 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.

3.31 We propose to adopt these amendments to SRM controls in domestic legislation. Table 2 below sets out what the requirements for SRM removal in England and Wales would be, following adoption of these proposals:

Table 2: Proposed requirements for SRM removal

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

3.32 As explained at paragraph 2.9, the FSA has carried out a consultation with key industry stakeholders to determine the impact on them following the legislative changes. However, more information is required to ascertain how these changes may affect industry. Also, because of the difficulty in removing all mesentery from the small intestine, some Member States, including the UK, have sought advice from the European Commission on the interpretation of the legislation. The Commission has since advised that it is for individual competent authorities to decide on what is appropriate. The FSA sought further advice from the ACDP TSE subgroup Committee, who recommended that a continued precautionary approach should be taken to ensure the complete removal of mesentery from the small intestine. The FSA subsequently instructed the industry and its Operations Group staff to follow the ACDP TSE subgroup's advice.

(vi). Amendment to requirements for spinal cord removal from sheep and goats slaughtered for human consumption

3.33 Under the EU TSE Regulation, the spinal cord of sheep and goats that 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 carcase is split to remove the spinal cord. However, UK industry contends that carcase splitting significantly reduces carcase value. Following representations from industry, a joint FSA/industry task group was set up in 2010 to investigate alternative removal methods that do not involve carcase 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 due to carcase damage. Additionally, the task group recognised that removal methods used in other Member States were unacceptable to the UK food safety authority as complete removal of the spinal cord could not be ensured or verified. To date, carcase splitting is the only method of spinal cord removal, which the UK meat processing industry and the FSA finds acceptable and effective.

3.34 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 English and Welsh legislation to provide the statutory mechanism by which food business operators 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 carcase would remain the default method for spinal cord removal.

3.35 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 to 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).

(vii). Clarification on SRM removal in slaughterhouses

3.36 As a result of issues raised during legal proceedings taken against a UK food business operator (FBO) in 2013 for failing to remove SRM from ewe carcases, the FSA is proposing changes to the legislation to clarify the provisions of paragraphs 8(1) and 9(1) of Schedule 7 of the 2010 Regulations (England) and the 2008 Regulations (Wales).

3.37 Questions had arisen as to whether the current provision required SRM to be removed from the carcase before post-mortem inspection and whether the spleen could remain inside the carcase at post-mortem inspection so long as it was 'contained in or attached to offal'. In response, the FSA confirmed the long standing position that, save for the permitted exceptions, all other SRM (including the spleen) is required to be removed from the carcase before post-mortem inspection.

3.38 The FSA's primary basis for the line it has taken is that Annex I, Section II, Chapter V point (r) of Regulation EC No. 854/2004 obliges the Official Veterinarian to declare meat unfit for human consumption where meat contains SRM, except as provided for under Community (now EU) legislation.

3.39 It was reported during the legal proceedings that the current wording of paragraphs 8(1) and 9(1) of Schedule 7 ought to be clarified to make the provisions clearer for both the FSA in its enforcement of the TSE legislation and the FBOs in understanding what the legislation requires of them.

(viii). Removal of the requirement for written bilateral agreements to authorise the export of processed animal protein (PAP) derived from non-ruminant animals

3.40 Previously, the EU TSE Regulation laid down the following rules for the authorisation of the export of PAP derived from non-ruminants (i.e. pigs and poultry) and products containing such PAP:

(i) They had to be destined for uses not prohibited by the EU TSE Regulation (i.e. feeding to non-ruminant species);

(ii) A written 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; and,

(iii) This bilateral agreement 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.

3.41 This requirement was originally intended to control the spread of BSE at a time when the disease was epidemic in the Union and when the European continent was the main part of the world affected by the epidemic. However, the BSE situation in the Union has since then significantly improved to the extent that 25 EU Member States are now recognised as having a negligible BSE risk status. As a result of the improvement in the BSE situation, the Commission agreed that the requirement for a written bilateral agreement, as described above, should be deleted. This requirement was subsequently 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 English and Welsh law on an administrative basis with effect from that date.

3.42 These changes should not change the BSE risk to food safety if the necessary controls are in place and enforced. Pig and poultry PAPs 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.

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

(i) The controls mirror those already in place for permitting the use of poultry and pig PAP in feed for farmed fish in the EU as described in paragraph 3.7 above.

(ii) 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.

(iii) 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.

(iv) 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.

(v) 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.

(vi) 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.

3.44 Our proposal would adopt in English and Welsh legislation the amendment to the EU TSE Regulation which allows industry the option of legally exporting non-ruminant PAPs 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).

3.45 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.

3.46 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. Paragraph 3.10 refers.

(ix). Extension to the scope of 'aquatic animals' permitted for use in processing fishmeal and inclusion in feed for aquaculture animals

3.47 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.* Therefore, since the definition of 'aquatic animals' laid down in Annex I to Regulation (EC) No 999/2001 does not cover invertebrates other than molluscs and crustaceans, the 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.

3.48 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 on an administrative basis on the same date.

3.49 Our proposal would implement this amendment in English and Welsh legislation. Defra and the Welsh Government would like to capture any significant impacts (costs or benefits) that you may foresee as a result of this change and so your views are being sought.

(x). Proposal to enable the feed industry to use processed animal protein derived from insects in feed for aquaculture

3.50 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 as described at paragraphs 3.5 to 3.10. Such PAP has to be derived from slaughterhouses or cutting plants: therefore the use of PAP derived from insects in feed for aquaculture animals was not allowed.

3.51 Several Member States are now rearing insects for the production of PAP for petfood, 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.

3.52 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.

3.53 Based on the EFSA opinion, the Commission has 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.

3.54 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 domesticus*), Banded Cricket (*Gryllodes 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.

3.55 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.

3.56 Our proposal would adopt this amendment in English and Welsh legislation.

(xi). Proposal to permit the export of processed animal protein derived from ruminants

3.57 Previously the EU TSE Regulation prohibited the export of processed animal protein (PAP) derived from ruminants to third countries. This requirement was originally intended to control the spread of BSE at a time when the disease was epidemic in the Union and when the European continent was the main part of the world affected by the epidemic. However, as explained at paragraph 3.41 above, the BSE situation in the Union has since then significantly improved.

3.58 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 European Commission has also said it will consider the need for risk based checks on ruminant PAP leaving the EU to help ensure OIE rules which

prohibit the feeding of ruminant PAP to ruminants are adhered to and will consider intelligence reports of use of PAP for prohibited purposes in third countries to target those checks.

3.59 The EU legislation came into force on 1 July 2017 and was implemented across the UK on an administrative basis from that date.

3.60 Our proposal would adopt this amendment in English and Welsh legislation.

(xii). Technical amendments

3.61 We are proposing to carry out two technical amendments to the 2010 and 2008 Regulations. They are:

(i) To amend the 2010 and 2008 Regulations to replace the existing requirement for animals falling within the pedigree category for BSE compensation to have a zootechnical certificate, with a requirement for a pedigree certificate. This amendment is proposed following legal advice that a pedigree certificate provides all the information necessary to determine the pedigree status of the animal for compensation purposes.

(ii) To empower the Secretary of State to select slaughterhouses for the annual EU TSE sheep abattoir survey. Selected slaughterhouses will permit the taking of samples by veterinarians authorised by the SoS from the brains of 0.5% of that abattoir's throughput of sheep aged over 18 months of age or which have two erupted incisors; ensure that samples carcases are identified and retained until the test result is known; and dispose of all parts of the carcase of any animal which tests positive. This clarification is proposed following challenges to the existing selection system from selected slaughterhouses, one of which has resulted in a prosecution.

Part 2: Proposed changes in England

(i). Amendments to TSE compensation for sheep and goats

3.62 The EU TSE Regulation requires member states to pay compensation for animals killed as TSE suspects or in pursuit of TSE eradication. This is interpreted as compensation in lieu of market value as set out in Article 10 of Commission Regulation (EC) No. 1857/2006.

3.63 The 2010 Regulations currently offer low table valuations to farmers in respect of compensation for sheep and goats culled because of classical scrapie, with an alternative of individual valuations. We have found that individual valuations result in

disproportionately high levels of compensation, especially for goats, due to a lack of reliable market information.

3.64 The existing table values for sheep and goats have not been changed since 2002. There is difficulty in identifying realistic market values for sheep and goats, for the following reasons:

(i) Sheep sales tend to be seasonal and therefore sufficient market data is not available at certain times of year to calculate market values.

(ii) Very few dairy or breeding goats are sold at market. The majority of sales take place between owners and the prices are not published.

3.65 Between 2003 and 2011, the EU TSE Regulation offered the following options for holdings where classical scrapie was confirmed:

(i) Killing and destruction of all sheep and goats, with payment of compensation;

(ii) Killing and destruction of all genetically susceptible sheep, and all goats, with payment of compensation.

Compensation paid in respect of animals killed and destroyed on affected holdings during these years was a mixture of payment at table values and individual valuations. All payments in respect of goats, and the majority of payments in respect of sheep since 2008, were individual valuations.

3.66 In 2011, an option was introduced which gives an alternative to compulsory killing and destruction of goats and genetically susceptible sheep on affected holdings. It enables Member States to carry out an intensive monitoring regime on affected holdings for two years following the confirmation of the last case of classical scrapie on the holding. Although there is no mandatory killing of animals under this option, if additional cases are detected the Member State shall review the situation with a view to switching to killing goats and genetically susceptible sheep. This option has been the default in England since 2011.

3.67 At present, the EU TSE Regulation does not recognise any genetic resistance to classical scrapie in goats. Research is currently being undertaken on this issue. However it is likely to be several years before sufficient data becomes available to enable the EU to consider any amendment of their TSE Regulation in this respect.

3.68 The incidence of classical scrapie in GB has declined sharply in the past 16 years. In 2000, 568 cases were confirmed in sheep and goats in GB, compared with only 6 in 2016, all of which came from two affected holdings undergoing monitoring.

3.69 Since 2011, there has only been one case where it has been found necessary to cull a holding to control classical scrapie. In this case, which occurred in 2015, the farmer rejected the table values as being too low. An independent valuation of a sample of his stock indicated that compensation at individual valuation for the whole holding would not represent a reliable indicator of the value of the animals and would not be good value for the taxpayer. In the absence of market data, an offer was made to the farmer which took as a basis the values for replacement animals in the 46th edition of the John Nix Farm Management ePocketbook, which has for many years been acknowledged by industry as a useful guide on the prices farmers can expect to be paid. These values cover the cost of the animals only.

3.70 This valuation was accepted by the farmer, and was supported by HM Treasury because it represented the best value for money for both the farmer and taxpayer. As a condition of their agreement, HMT required that Defra (i) puts in place a consistent approach for dealing with similar issues in future (ii) and as part of this, considered how the 2010 Regulations could be amended to reduce incentives for farmers to reject the existing table values and seek an independent valuation.

3.71 To ensure value for money for the taxpayer and give the fairest possible deal to industry, we propose to amend the 2010 Regulations to increase the table valuations to reflect current prices and to remove the option in legislation for individual valuations.

3.72 Existing table values are as follows**:**

Table 3: Existing table values for sheep and goats killed on suspicion of infection with a TSE

Category	Table values for animals subsequently confirmed as being affected by a TSE	Table values for animals subsequently confirmed as not being affected by a TSE
Animals not at the end of their productive lives	£90.00	Market value up to £400.00
Animals at the end of their productive lives (i.e. cull animals)	£30.00	

Note: There is no table value for lambs or kids killed as suspects because, due to the length of the incubation period, scrapie is only diagnosed in animals aged over 12 months and usually over 18 months.

Table 4: Table values for sheep and goats killed in pursuit of TSE eradication following confirmation of a TSE on their holding:

Category	Table values
Male sheep or goat	£90.00
Female sheep or goat	£65.00
Lamb or kid aged under 12 months	£40.00

3.73 Proposed table values based on the values in the 46th and 47th editions of the John Nix Farm Management ePocketbook are as follows:

Table 5: Proposed table values for sheep killed on suspicion of infection with a TSE or killed in pursuit of TSE eradication following confirmation of a TSE on their holding:

Category	Table values
Males aged over 12 months	£480.00
Females aged over 12 months	£140.00
Lambs aged under 12 months	£75.00

Note: These figures take into account averages for the replacement values given by John Nix for spring lambing flocks and for upland spring lambing flocks (for which the prices are slightly lower).

Table 6: Proposed table values for goats killed on suspicion of infection with a TSE or killed in pursuit of TSE eradication following confirmation of a TSE on their holding:

Category	Table Values
Males aged over 6 months	£150.00
Females aged over 6 months	£220.00
Kids aged under 6 months	£80.00

Note: John Nix gives a single replacement figure of £200-240 for both males and females aged over 6 months: however because research suggests that sale prices for males vary from £85.00 to £250.00, the proposed value for males takes an average of these prices.

3.74 Based on the sharp decline in the incidence of classical scrapie in the UK since 2000 and the fact that Option 3 controls the disease on the majority of affected holdings, we expect no more than 3 goat or sheep holdings to require compensation over a ten year period and no more than 1 holding in any given year.

3.75 There would be a potential cost across all businesses as a result of receiving lower compensation under the revised table valuations. Most goat and sheep holdings are small or micro-businesses. It is estimated that the maximum potential cost in any one year, as the difference between individual valuations and the proposed table valuations, would be in the region of £265,000 for a holding of 2,000 goats.

Part 3: Proposed changes in Wales

(i). Amendment to domestic legislation regarding on-farm controls for classical scrapie[12]

3.76 The Welsh Government previously consulted on their proposals for amendment to on-farm classical scrapie controls applicable in Wales in 2013, to allow for Commission decisions and EU Regulatory changes and to provide more proportionate controls for sheep and goat herds with classical scrapie. The proposed amendment to the 2008 Regulation reflects the range of options now available.

3.77 Option 1: Following detection of classical scrapie in a sheep flock or goat herd, the holding is placed under movement restriction. All sheep and goats on the holding, and their semen and embryos, are either killed and destroyed or sent for slaughter for human consumption, subject to a negative test for TSE before their release into the food chain, with compensation paid to the owner. Only animals aged over 18 months are tested for TSEs and a random sample of 50 sheep aged over 3 months is genotyped.

3.78 Option 2: Following detection of classical scrapie in a sheep flock, the holding is placed under movement restriction and the government pays for the blood sampling and genotyping of all sheep over three months old. Government pays for the killing, compensation and disposal of all sheep that are genetically susceptible to classical scrapie (typically about 25% of a flock) and for all sheep aged over 18 months to be tested for TSE. Alternatively, these animals may be sent direct to slaughter for human consumption, subject to a negative test for TSE before the carcases are released into the food chain. The owner is compensated for all animals killed and destroyed.

N.B. This option does not apply to goat holdings unless goats are co-located with sheep, because there is little or no genetic resistance to classical scrapie in goats.

3.79 Under Options 1 and 2, the milk and milk products derived from animals to be destroyed or slaughtered and which were present on the holding between the date of confirmation of the case of TSE and the date of the completion of killing or slaughter, or derived from the infected flock/herd shall not be used for the feeding of ruminants outside the holding until all movement restrictions are lifted, and may only be sold as feed for non-ruminants within the UK.

3.80 Under Options 1 and 2, once the initial genotyping and culling action has been completed, there is a movement restriction period for two years following the detection of the last case during which the following controls apply:

[12] Already adopted in English domestic legislation by the Transmissible Spongiform Encephalopathies (England) (Amendment) Regulations 2013

(i) The government pays for the collection, brain sampling and disposal and TSE testing of all fallen animals aged over 18 months.

(ii) Government pays for the transport to abattoirs of ‘annual cull’ animals aged over 18 months which are slaughtered under normal farm management. Animals must be sent to abattoirs where brain sampling can be carried out.

(iii) Government pays the FSA Operations Group to sample a quota of ‘annual cull’ animals aged over 18 months at pre-arranged abattoirs and for these samples to be dispatched to a laboratory under government contract for TSE testing.

(iv) Government pays APHA to monitor compliance with the rules.

(v) The government also provides ‘assistance payments’ for genotyping of replacement stock, and for the purchase of replacement rams for breeding purposes.

3.81 Option 3: Following detection of classical scrapie in a sheep flock or goat herd, the holding is placed under movement restriction. Under this option, there is no initial cull of sheep or goats: instead the holding is placed under an intensified monitoring regime. Assistance payments are available for the genotyping of replacement rams.

3.82 Affected holdings remain under a movement restriction period for two years following the detection of the last case during which the following controls apply:

(i) Government arrange and pay for a maximum sample of 50 sheep aged over 3 months per flock to be genotyped. Any further genotyping is at the discretion of the keeper.

(ii) Owners are not permitted to breed from rams which have been identified as susceptible to classical scrapie (Types 2, 3, 4 and 5) and are required to send genetically susceptible rams to slaughter to reduce the likelihood of future cases of classical scrapie.

(iii) All lambs and kids may be sent for slaughter for human consumption.

(iv) Sheep and goats over 18 months of age may also be slaughtered for human consumption but, with the exception of sheep known to be genetically resistant to classical scrapie (Type 1), they need to be tested for TSEs, which is arranged and paid for by government. This means that these animals have to be sent to selected abattoirs where they can be sampled for testing. government organises and pays for transport of these cull animals to the abattoir.

(v) Sheep and goats over 18 months of age which die or are killed on the farm other than for human consumption (fallen stock) require TSE testing.

government arranges and pays for carcase collection, sampling, testing and disposal.

(vi) No movements off the farm are allowed during the restriction period, except for animals sent direct to slaughter or by a formal arrangement to allow the fattening of store lambs. Sheep known to be Type 1 may be moved to other holdings which are under movement restriction following confirmation of classical scrapie.

(vii) Replacement female sheep may be sourced from any unrestricted premises. However, owners are limited to source genetically more resistant animals (Types 1, 2 and 4 but not Types 3 or 5) to reduce the likelihood of new classical scrapie cases;

(viii) Male sheep may only be brought onto the farm if they are Type 1. government offers financial assistance for genotyping in order to source replacement rams.

(ix) To prevent the possible spread of infection, common grazing is prohibited during the lambing and kidding period for animals from holdings under classical scrapie controls.

3.83 In Wales, the default control option following confirmation of classical scrapie on a sheep or goat holding is Option 3 (monitoring/surveillance with no killing or destruction of animals).

3.84 When additional classical scrapie cases are detected in a holding where option 3 is being applied, the EU TSE Regulation requires that the relevance of the reasons and criteria founding the decision to apply Option 3 to this holding must be reassessed. A Veterinary Risk Assessment is carried out by APHA which considers the risk of further cases of classical scrapie on the holding and examines the potential costs and effects of a series of options for future action, which may range from continuation of monitoring under Option 3 to a complete cull of the holding with a cleansing and disinfection programme. If it is concluded that applying Option 3 does not ensure a proper control of the outbreak, we must consider switching the management of this holding from Option 3 to either Option 1 or Option 2.

3.85 This approach was implemented by the Welsh Government on 1 July 2013, pending an amendment to domestic legislation. Our proposal would make the full range of options in EU legislation for control of classical scrapie available in Welsh domestic legislation.

(ii). Amendments to the table of compensation categories for BSE in Wales[13]

3.86 Schedule 3, Paragraph 8 of the 2008 Regulations sets out the requirements for Welsh Ministers to pay compensation for animals killed under Schedule 3, for the purpose of the control and eradication of BSE. The amount of compensation paid to owners of eligible bovines in Wales is also prescribed within the 2008 Regulation, and is set at the average price paid in Great Britain for that age and category of animal.

3.87 As previously consulted on in 2013 in Wales, the Welsh Government plans to update the table of categories to provide a more accurate means of establishing a valuation, more reflective of the market. The proposed amendment will increase the number of cattle categories from the current 47 to 51, the main changes of which are:

(i) Introduce new categories for young pedigree beef animals 0-6 months of age;

(ii) Revise the text, so it is clear that only animas with a full pedigree certificate receive pedigree compensation and owners of steers will not receive compensation at pedigree rates;

(iii) Clarify the period over which sales data is collected to calculate table values, i.e. 1 month sales data collection period, lasting from the 21st of the month until the 20th of the following month for non-pedigree cattle and a rolling period of 6 months lasting from the 21st of the month until the 20th of the sixth following month for pedigree cattle;

(iv) Define the sales price data used to calculate the average market price for compensation purposes, i.e. data in relation to domestic cattle from store markets, prime markets, rearing calf sales, breeding sales and dispersal sales in Great Britain;

(v) Limit compensation payments to cattle with all of the legally required ID documentation;

(vi) Split the current single category for non-pedigree dairy calved females into two age bands, over 20 months up to 84 months, and over 84 months, so that compensation more accurately reflects market values; and,

(vii) Split the current single category for pedigree dairy calved females into two age bands, over 36 months up to 84 months, and over 84 months, so that compensation more accurately reflects market values.

[13] Already adopted in English domestic legislation by the Transmissible Spongiform Encephalopathies (England) (Amendment) Regulations 2013.

Table 7: Proposed table of categories for BSE compensation in Wales

(New and amended categories are shown in italics)

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

(iii). Amendment to the source of independent valuers for compensation purposes

3.88 As prescribed within the EU TSE Regulation, compensation must be paid for animals killed as TSE suspects or in pursuit of TSE eradication. This is interpreted as compensation in lieu of market value as set out in Article 10 of Commission Regulation (EC) No. 1857/2006.

3.89 For all animals, table valuations are offered in respect of compensation. Table valuations are the default position, and should always be the starting point when determining compensation levels to be paid. Only where there is insufficient data to calculate the relevant table value for cattle should the alternative option of an independent valuer be utilised. For other animals, a different procedure applies. Under the 2008 domestic regulations, where a table valuation is not applicable or suitable, the owner of the animal may request an independent valuer at their own cost, to give a valuation for their animals. The valuer must be agreed upon by both the owner and Welsh Ministers. Where such agreement cannot be reached, the Welsh Ministers will be appointed by the President of the Royal Institution of Chartered Surveyors (RICS) to appoint a valuer for this purpose.

3.90 The Welsh Government proposes to extend the potential valuers that could be used, by including valuers appointed by the President of the Central Association of Agricultural Valuers (CAAV). This would increase the quantity of independent and specialist 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 the CAAV as appointed by Welsh Ministers, is currently used for cattle valuations for bovine Tuberculosis in Wales.

3.91 As independent valuers are only to be used in circumstances where the valuation tables may be rejected (not applicable to cattle) and a valuer cannot mutually be agreed, combined with declining incidence of disease this should only be implemented in a minimal number of cases. There would be a potential benefit to both affected animal owners and to taxpayers who fund compensation, in that the amount of compensation awarded by the independent valuer should be more specialised to the individual case.

Part 4: General proposals

(i). Revocations

3.92 We propose to use the TSE (England) Regulations and the TSE (Wales) Regulations to revoke the following legislation:

(i) To revoke the following Statutory Instruments which will be replaced by the consolidated Transmissible Spongiform Encephalopathies (England)

Regulations 2016 or the consolidated Transmissible Spongiform Encephalopathies (Wales) Regulations 2016:

The Transmissible Spongiform Encephalopathies (England) Regulations 2010	S.I. 2010/801
The Animal By-Products (Enforcement) and Transmissible Spongiform Encephalopathies (England) (Amendment) Regulations 2011	S.I. 2011/2681
The Transmissible Spongiform Encephalopathies (England) (Amendment) Regulations 2013	S.I. 2013/336
Transmissible Spongiform Encephalopathies (Wales) Regulations 2008	S.I. 2008/3154 (W.282)
Transmissible Spongiform Encephalopathies (Wales) Amendment Regulations 2008	S.I. 2008/3266 (W.288)
Transmissible Spongiform Encephalopathies (Wales) (Amendment) Regulations 2010	S.I. 2010/1822

(ii) To revoke the following Statutory Instrument which has been identified as obsolete by the Red Tape Challenge:

The Transmissible Spongiform Encephalopathies (No 2) (Amendment) Regulations 2008	S.I. 2008/1180

(iii) To revoke the additional Statutory Instruments in Wales, which have been identified as obsolete:

The Selective Cull (Enforcement of Community Compensation Conditions) Regulations 1996 (in respect of Wales)	S.I. 1996/3186
The Bovine Hides Regulations 1997 (in respect of Wales)	S.I. 1997/813

Chapter 4: Tell us what you think

4.1 Your comments are invited on the following questions. Please feel free to answer many or as few as you like.

Part 1: Proposed changes in England and Wales:

(i). Sharing the cost of BSE sampling between the farming industry and the taxpayer (paragraphs 3.1-3.4)

1) Have you any comments on the proposal to transfer the cost of sampling fallen stock cattle from the taxpayer to the businesses in England and Wales, which benefit from the service?

(ii). Proposal to permit the feeding of pig and poultry processed animal protein to farmed fish (paragraphs 3.5-3.10)

2) At present no feed manufacturers in the UK utilise the derogation to use pig and poultry processed animal protein (PAP) in feed for farmed fish which was introduced on 1 June 2013. If you work in the farmed fish industry in England or Wales, do you intend to take up this derogation in the future? What would your reasons be for doing so or not doing so?

3) Have you any other comments on the derogation to use pig and poultry processed animal protein in feed for farmed fish in England and Wales?

(iii). Amendments to on-farm scrapie controls (paragraphs 3.11-3.23)

4) What are your views on the amendments to on-farm controls for holdings in England and Wales where classical scrapie or atypical has been confirmed?

5) If you are in the sheep or goat industry in England or Wales, what effects, if any, have these changes had upon your business since they were introduced?

(iv). Removal of the requirement for abattoirs slaughtering cattle that require BSE testing to have a required method of operation (RMOP) (paragraphs 3.24-3.27)

6) Have you any comments on the proposal to remove the requirement for abattoirs in England slaughtering cattle that require BSE testing to have a Required Method of Operation?

(v). Amendments to the definition of bovine specified risk material (SRM) (paragraphs 3.28-3.32)

7) If you work in the meat industry in England or Wales, have you implement the change introduced on 26 May 2015, which permits the utilisation of the duodenum, the colon and the small intestine (except for the last four metres)? If not, do you plan to take up this measure in the future? What would your reasons be for doing so or not doing so?

8) The FSA would like to capture any significant impacts (costs or benefits) that you may foresee as a result of the amendments to Annex V of the TSE Regulations.

(vi). Amendment to requirements for spinal cord removal from sheep and goats slaughtered for human consumption (paragraphs 3.33-3.35)

9) If you work in the meat industry in England and Wales, would your business be interested in implementing an alternative method of spinal cord removal for sheep and goats aged over 12 months, should an effective alternative become available? Have you any idea of the cost, including any supporting evidence, to your business of implementing an alternative method, e.g. in purchase of new equipment and training of staff?

10) Have you any other comments on the criteria to be taken into account when consideration is being given to an alternative method of spinal cord removal?

(vii). Clarification on SRM removal in slaughterhouses (paragraphs 3.36-3.39)

11) Have you any comments on the proposed changes to wording relating to the removal of SRM in a slaughterhouse?

(viii). Removal of the requirement for written bilateral agreements to authorise the export of PAP derived from non- ruminant animals (paragraphs 3.40-3.46)

12) Have you any comments on the proposal to remove the requirement for written bilateral agreements for the export of non-ruminant processed animal protein?

13) Defra and the Welsh Government would like to capture any significant impacts (costs or benefits) that you may foresee as a result of this proposal. If you work in the feed industry in England or Wales, would you expect this proposal to open up new markets for your business?

(ix). Extension to the scope of ‘aquatic animals’ permitted for use in processing fishmeal and inclusion in feed for aquaculture animals (paragraphs 3.47-3.49)

14) Have you any comments on the proposal to extend the definition of aquatic animals used for feed in aquaculture?

15) If you work in the feed industry in England and Wales, and your business makes feed for farmed fish, would you expect your business to utilise meal produced from wild starfish and farmed aquatic invertebrates? What would your reasons be for doing so or not doing so?

16) Defra and the Welsh Government would like to capture any significant impacts (costs or benefits) that you may foresee as a result of this proposal. Would you be able to quantify the annual potential benefit to your business?

17) Are there any environmental or health concerns of which we need to be aware?

(x). Proposal to enable the feed industry to use processed animal protein derived from insects in feed for aquaculture (paragraphs 3.50-3.56)

18) Have you any comments on the proposal to permit the use of PAP derived from insects in feed for aquaculture?

19) If you work in the feed industry in England or Wales, and your business makes feed for farmed fish, would you take up this option in the future if it passes into EU and domestic law? What would your reasons be for doing so or not doing so?

20) Defra and the Welsh Government would like to capture any significant impacts (costs or benefits) that you may foresee as a result of this proposal. Would you be able to quantify the annual potential benefit to your business?

(xi). Proposal to permit the import and export of processed animal protein derived from ruminants (paragraphs 3.57-3.60)

21) Have you any comments on the proposal to amend English and Welsh legislation for the import and export of ruminant PAP?

22) If you work in an industry in England and Wales which produces ruminant PAP, do you expect to take advantage of the proposed amendment to export non-ruminant PAP? What would your reasons be for doing so or not doing so?

23) Defra and the Welsh Government would like to capture any significant impacts (costs or benefits) that you may foresee as a result of this proposal. Would you be able to quantify the annual potential benefit to your business?

(xiii). Technical amendments (paragraph 3.61)

24) Have you any comments on the proposal to amend the 2010 Regulations to replace the existing requirement for animals falling within the pedigree category for BSE compensation to have a zootechnical certificate, with a requirement for a pedigree certificate?

25) What are your views on the proposal to empower the Secretary of State to select slaughterhouses for the annual EU TSE sheep abattoir survey?

Part 2: Proposed changes in England

(i). Amendments to TSE compensation for sheep and goats (paragraphs 3.62-3.75)

26) Do you consider that the proposed table values represent realistic replacement values for sheep and goats killed as TSE suspects or in pursuit of TSE eradication? Please give evidence to support your view.

Part 3: Proposed changes in Wales

(i) Amendment to domestic legislation regarding on-farm controls for classical scrapie (paragraphs 3.76-3.85)

27) What are your views on the proposed amendment to Welsh domestic legislation regarding on-farm controls for classical scrapie, which were introduced administratively in Wales on 1 July 2013?

Since 1 July 2013, what effect has the introduction of the monitoring option had upon your business where classical scrapie has been detected?

(ii). Amendments to the table of compensation categories for BSE in Wales (paragraphs 3.86-3.87)

28) Do you consider that the proposed additional table categories will provide greater accuracy and increase fairness in the assignment of valuations for TSE compensation purposes in Wales?

(iii). Amendment to the source of independent valuers for compensation purposes (paragraphs 3.88-3.91)

29) Do you consider that the inclusion of independent valuers as appointed by the President of the Central Association of Agricultural Valuers will provide a more specific valuation or additional flexibility in valuation of animals and animal products for the purposes of TSE compensation in Wales?

Part 4: General proposals

(i). Revocations (paragraph 3.92)

30) Have you any comments on our proposal to revoke the Transmissible Spongiform Encephalopathies (No 2) (Amendment) Regulations 2008 and in Wales the Bovine Hides Regulations 1997 and the Selective Cull (Enforcement of Community Compensation Conditions) Regulations 1996?

(ii) General comments

31) Have you any other comments not covered by the above?

(iii) How to reply

4.1 A list of interested organisations Defra has approached directly for views will be published on the Defra section of the government website. We welcome views from all interested parties or individuals by **29 December, 2017.**

4.2 You can respond to this consultation in one of three ways.

Online by completing the questionnaire at

https://consult.defra.gov.uk/plant-and-animal-health/tseconsultation

- **Email** to TSERegs2018.consultation@defra.gsi.gov.uk
- **Post** to Defra at:

  Animal By-Products and TSEs Team
  Area 5A, Nobel House
  17 Smith Square
  London
  SW1P 3JR

4.3 Our preferred method is online because it is the fastest and most cost-effective way for us to collate, analyse and summarise responses.

4.4 Responses to this consultation are also welcomed in the medium of Welsh.

4.5 Responses received by the deadline will be analysed and a summary will be placed on the consultation section of the government web site.

4.6 In line with Defra's and the Welsh Government's policy of openness, copies of the responses we receive will be publicly available, at the end of the consultation period, for at least 6 months. If you do not consent to this, you must clearly request that your response be treated confidentially. Any confidentiality disclaimer generated by your IT system in an e-mail response will not be treated as such a request. You should also be aware that there may be circumstances in which Defra and the Welsh Government will be required to release information to comply with their obligations under the Freedom of Information Act and the Environmental Information Regulations.

Annex A: Glossary

Acronym	Term	Definition
ABP	Animal By-Products	Entire animal bodies, parts of animals, products of animal origin or other products obtained from animals that are not fit or intended for human consumption, including oocytes, embryos and semen.
ACDP	Advisory Committee on Dangerous Pathogens	An expert committee of the Department of Health which advises on TSE risks.
AHWS	Animal Health and Welfare Strategy for Great Britain	The route map for work to improve the health and welfare of kept animals in England, Scotland and Wales.
APHA	Animal and Plant Health Agency	Defra agency, formed on 1 October 2014 following the merger of the Animal Health and Veterinary Laboratories Agency (AHVLA) with the Food and Environment Research Agency (Fera).
(none)	Atypical Scrapie	A TSE in sheep and goats which, unlike classical scrapie (which is a contagious disease) is considered to be a fatal brain disease which occurs spontaneously and could be little or not contagious at all.
BSE	Bovine Spongiform Encephalopathy	A TSE in cattle, a fatal brain disease believed to be transmitted via infected feed. Exposure to BSE through the consumption of infected meat is believed to be the primary cause of variant Creutzfeldt-Jakob Disease (vCJD) in humans.
(none)	Classical Scrapie	A contagious TSE in sheep and goats, a fatal brain disease to which certain genetic types of sheep, and all goats, are more susceptible.

EC	European Commission	The executive body of the European Union.
ECDC	European Centre for Disease Control	An independent agency of the European Union whose mission is to strengthen Europe's defenses against infectious diseases.
EFSA	European Food Safety Authority	The EU risk assessment body for food and feed safety.
EU	European Union	The economic and political union of 28 Member States.
(none)	Fallen stock	Animals which die or are killed other than for human consumption.
FBO	Food Business Operator	The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.
(none)	EU TSE Regulation	Regulation (EC) No. 999/2001 of the European Parliament and the Council, as amended, which lays down rules for the prevention, control and eradication of TSEs, including BSE in cattle and scrapie in sheep and goats.
FSA	Food Standards Agency	Non-ministerial government department, responsible for protecting public health in relation to food.
(none)	Non-Ruminants	Pigs and chickens are non-ruminant, monogastric animals that digest food in one stomach, similar to humans.
OIE	World Organisation for Animal Health (formerly Office International des Epizooties)	The intergovernmental organisation responsible for improving animal health worldwide.

PAP	Processed Animal Protein	A protein source derived from animals and intended or suitable for inclusion into feed and feedingstuffs.
PCR	Polymerase chain reaction	A biochemical technology in molecular biology to amplify a single or few copies of a piece of DNA or RNA by several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence.
(none)	Red Tape Challenge	A cross-government programme to tackle the stock of unnecessary and over-complicated regulation.
RMOP	Required Method of Operation	An agreement between the Official Veterinarian and the Food Business Operator on the details of the slaughter process at abattoirs processing cattle slaughtered for human consumption, which require testing for BSE.
(none)	Ruminants	Any of various even-toed hoofed mammals of the suborder Ruminantia. Ruminants usually have a stomach divided into four compartments (called the rumen, reticulum, omasum, and abomasum), and chew a cud consisting of regurgitated, partially digested food. Ruminants include cattle, sheep, goats, deer, giraffes, antelopes, and camels, and their relatives.
(none)	Scrapie	A TSE in sheep and goats. See separate entries for classical scrapie and atypical scrapie.

SRM	Specific Risk Material	Parts of the bodies of animals susceptible to TSE identified as higher risk for carrying infection, that are defined by the EU TSE regulation and that have to be removed and disposed of as (very high risk) Category 1 animal by-product.
TSE	Transmissible Spongiform Encephalopathy	Fatal brain disease suffered by a variety of species, including cattle, sheep, goats, deer, cats, and certain bovine and feline exotic species. See separate entries for BSE, classical scrapie and atypical scrapie.
(none)	TSE Roadmap 2	The European Commission's strategy paper on TSEs for 2010 to 2015.
UKZADI	The UK Zoonoses, Animal Diseases and Infections Group	A cross-Departmental group which provides strategic co-ordination on public health interests and action.
vCJD	Variant Creutzfeldt-Jakob Disease	The human form of BSE, believed to be caused by exposure to BSE through the consumption of infected or contaminated meat.
(none)	Zoonoses	Diseases that can be transmitted to humans from animals.

Annex B: Principles of consultation on responsibility and cost sharing for animal health and welfare, December 2006 - March 2007 (paragraph 2.2 refers)

1. Preserving public safety and maintaining confidence both nationally and internationally in UK food production.

2. Preserving the principles of the Animal Health and Welfare Strategy for Great Britain (AHWS) – especially that prevention is better than cure.

3. Maintaining and improving capability to deliver policies.

4. Sharing responsibilities so that achievement of animal health and welfare outcomes is effective and efficient.

5. Sharing costs only where the activity provides a clear benefit or service to industry, taking account of affordability and of the impact on competitiveness.

6. Focus cost sharing where it is most likely to reduce disease risk.

7. Responsibilities should be shared at least where costs are shared.

8. Accountability for both industry and government.

9. The regulatory burden should be reduced and measures simplified wherever possible.

10. Consistency with EC and international developments.

Annex C: Potential risks to public health: advice received from the Advisory Committee on Dangerous Pathogens (ACDP) and the UK Zoonoses, Animal Diseases and Infections Group (UKZADI)

Prior to this consultation we sought independent expert advice to clarify whether any of the amendments to EU legislation included in our proposed changes to TSE legislation in England and Wales would result in any risks to public health.

We initially sought views from the Advisory Committee on Dangerous Pathogens (ACDP). Their opinion on the risks to public health from our proposals can be summarised as follows:

Proposed changes in England and Wales: Summary of ACDP advice

(ii) Proposal to permit the feeding of pig and poultry processed animal protein to farmed fish (paragraphs 3.11-3.23)

The ACDP concluded that the barrier between fish and mammals was likely to be such that transmission of disease was unlikely and, therefore, that there was little public health risk.

(v) Amendments to the definition of bovine Specified Risk Material (SRM) (paragraphs 3.28-3.32)

Noting that little or no new published scientific work had taken place in the last two years to inform the understanding of risk, the ACDP felt that that the Government should consider the need for further research and risk assessment. A risk management decision was needed on this issue.

(viii) Removal of the requirement for written bilateral agreements to authorise the export of PAP derived from non-ruminant animals (paragraphs 3.40-3.46)

This was considered to be a proposed alteration of risk management and outside the competence of the ACDP.

(ix) Extension to the scope of 'aquatic animals' permitted for use in processing fishmeal and inclusion in feed for aquaculture animals (paragraphs 3.47-3.49)

The ACDP agreed that the widening of the scope of the marine animals that can be included would be unlikely to change substantially any public health risk.

(x) Proposal to enable the feed industry to use processed animal protein derived from insects in feed for aquaculture (paragraphs 3.50-3.56)

Based on the EFSA scientific opinion of 8 October 2015 (see paragraph 3.53) and on the restricted range of both insect species and permissible substrates, upon which those insects would be fed, the ACDP saw little public health risk in allowing this.

(xi) Proposal to permit the import and export of processed animal protein derived from ruminants (paragraphs 3.57-3.60)

The ACDP felt that the level of public health risk associated with ruminant derived PAP was well established already that in exporting ruminant derived PAP from a national herd believed still to contain animals with the transmissible agent, there was a risk that a third country may use the PAP in such a way that recycling of affected ruminants may occur, similar to the way that it had occurred in the UK, historically, giving rise to the BSE and vCJD epidemics. A risk management decision was needed on this issue.

The ACDP's advice was referred to the UK Zoonoses, Animal Diseases & Infections Group (UKZADI). Their feedback is summarised below:

Proposed changes in England and Wales: Summary of UKZADI advice

1. UKZADI accepted the ACDP advice that from a purely scientific standpoint there are risks and uncertainties which justify a precautionary approach. However, this advice had to be applied in the real world context in which decisions on risk management have to be made. In particular it was important to recognise that trade in both material previously considered to be SRM and PAP is happening at a global level under international OIE rules (into which the UK feeds into via the EU) and that the former material is already imported and able to enter the food chain in the UK.

2. UKZADI accepted that the BSE risk continues to diminish in line with predictions which recognise that there may be occasional cases at the tail end of the epidemic and recognised that the UK could have confidence in our disease surveillance programme and enforcement of controls and noted ACDP views that the government should consider

further research and risk assessment. However, such consideration would need to take account of how long the work would take, the theoretical nature of any modelling and the likelihood that the results would show the risks remained very small.

3. The devolved administrations on the committee noted that they would need to implement EU rules as required under the devolution arrangements. In conclusion, UKZADI therefore accepted that there was no practical legal means by which we can maintain pre 2015 SRM controls or ban exports of PAP and recognised that there were measures in place to mitigate the risks.

4. In the light of these points UKZADI recommended that Ministers should be advised to consult on bringing UK law in line with EU law, taking care to ensure the consultation is open and balanced in recognition of all of the factors identified above.