

Consultation on Proposals to amend the Transmissible Spongiform Encephalopathies Regulations (NI) 2010

Department of Agriculture Environment & Rural Affairs

&

Food Standards Agency in Northern Ireland

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PART I - BACKGROUND

Introduction

- 1.1 Transmissible Spongiform Encephalopathies (TSEs) are fatal diseases of the brain which include Bovine Spongiform Encephalopathies (BSE) in cattle and Scrapie in sheep and goats.
- 1.2 TSEs are caused by pathogens known as prions and can be genetic, sporadic (atypical) or of infectious origin (classical). Transmission of these pathogens into the animal feed chain resulted in the emergence of classical BSE in the UK beef herd in 1986 and in significant consequences for the global beef industry. Sporadic or atypical cases of BSE, which are not related to an animal feed source, while extremely rare, are to be expected from time to time.
- 1.3 In July 2010, the European Commission outlined future steps regarding BSE/TSE in a plan known as the TSE Roadmap. This initiative outlined possible amendments to TSE rules with the objective of reviewing TSE measures to ensure that they were proportionate to the risk, while assuring a high level of food safety. Under this Roadmap, amendments to TSE rules have been taken forward on a stepwise approach supported by scientific advice from the European Food Safety Authority (EFSA) <http://www.efsa.europa.eu/>.
- 1.4 Regulation (EC) No. 999/2001 of the European Parliament and of the Council of 22 May 2001 (the EU TSE Regulations) lay down rules for the prevention, control and eradication of TSEs, including BSE and Scrapie. The Department seeks to implement TSE controls, in line with EU requirements, and in the interest of public health and animal health protection.
- 1.5 The current domestic TSE Regulation in Northern Ireland is the Transmissible Spongiform Encephalopathies Regulations (Northern Ireland) 2010 - <http://www.legislation.gov.uk/nisr/2010/406/contents/made> which provide the powers to administer and enforce the provisions of the EU Regulations in Northern Ireland.

Controls

- 1.6 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;
 - the removal and disposal of specified risk materials (SRM) – the most risky parts of susceptible animals – to protect consumers;
 - 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;
 - 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 carcasses are destroyed.

Purpose of the consultation

- 1.7 The Department of Agriculture, Environment and Rural Affairs (DAERA) and the Food Standards Agency in Northern Ireland (FSA) are seeking your views on a number of proposals to amend and replace the 2010 Regulations through consolidation.
- 1.8 Since the Transmissible Spongiform Encephalopathies Regulations (Northern Ireland) 2010 came into force, the EU has made a number of amendments to the EU TSE Regulation and reduced controls to reflect the reduced risk posed by BSE. These changes have been applied across the EU and have been implemented administratively in the United Kingdom pending the proposed update to domestic legislation. A number of minor amendments have also been proposed to clarify/reflect policy, operational and technical changes since the Regulations came into operation in December 2010.
- 1.9 The proposals on which we invite your comments would:-
- (i) enable the feed industry to take advantage of an EU derogation permitting the use of pig and poultry processed animal protein (PAP) in feed for farmed fish,
 - (ii) clarify on-farm classical scrapie controls,
 - (iii) remove requirement for restrictions on the movement of sheep and goats on holdings affected by atypical scrapie,
 - (iv) remove the unnecessary requirement for abattoirs slaughtering cattle that require BSE testing to have a Required Method of Operation (RMOP),
 - (v) provide a statutory mechanism by which food business operators can apply for approval to use an alternative method of spinal cord removal, other than carcass splitting, for sheep and goats over 12 months of age,
 - (vi) amend the list of tissues from cattle that are designated as Specified Risk Material (SRM) to reflect changes to EU legislation,
 - (vii) provide clarification on the removal of SRM from sheep in slaughterhouses,
 - (viii) amend the wording to permit the YL/YG stamp to be applied by someone other than an 'inspector' as per 11 (1) of Schedule 7,
 - (ix) update valuation and compensation procedures for sheep and goats to align with cattle procedures,
 - (x) remove the requirement for written bilateral agreements to authorise the removal of processed animal protein derived from non-ruminant animals,
 - (xi) 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,

- (xii) enable the feed industry to take advantage of an EU derogation that will permit the use of processed animal protein derived from insects in feed for aquaculture,
- (xiii) take advantage of an EU derogation that will permit the export of process animal protein from ruminants,
- (xiv) strengthen the arrangements for an independent appeals procedure,
- (xv) bring together the measures required by the veterinary inspector when a bovine is suspected with TSE and simplify enforcement action,
- (xvi) achieve a more equitable sharing of costs of BSE surveillance between the farming industry and the taxpayer,
- (xvii) revoke the 2010 Regulations and consolidate all these issues into one instrument – the Transmissible Spongiform Encephalopathies Regulations (Northern Ireland) 2018.

1.10 Full details of the proposals are included in Part II.

1.11 The proposals would contribute to TSE controls which 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, 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

1.12 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 Roadmap 2. 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.

1.13 This consultation is for Northern Ireland. A similar review is been undertaken by Defra and the Devolved Administrations of Scotland and Wales.

1.14 We are therefore inviting views from stakeholders in Northern Ireland on the proposed amendments listed in Part II. An Impact Assessment which provides detail on the measures in terms of their impact on industry/stakeholders has also been included.

PART II – PROPOSED AMENDMENTS

2.1 Amendment to feed controls:

- (a) In 2001, to prevent the spread of BSE, the EU introduced a ban on the feeding of processed animal protein (PAP) to farmed livestock. This prevents the spread of BSE in animals through eating contaminated feed primarily through inclusion of infective meat and bone meal. Scientific evidence identified contaminated feed as the principal vector of BSE transmission. BSE incidence worldwide has declined in recent years and the EU is considering ways to safely align the ban with international standards, which only prohibits meat-and-bone meal or greaves from ruminants being fed to ruminants to reduce unnecessary burdens on the industry and to reduce waste.
- (b) In line with European Food Safety Authority (EFSA) advice, 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 has been made possible now that the EU has validated a polymerase chain reaction (PCR) test capable of detecting very low levels of ruminant material in feed. This means that pig and poultry PAP can now be safely differentiated from ruminant PAP, the latter remains banned from all livestock feed. Pigs, poultry and fish are not known to be able to contract or pass on BSE naturally. Pig and poultry PAP are a potential source of protein that may be cheaper and more sustainable than current protein sources such as fishmeal and soya, the prices for which are currently high.
- (c) It is proportionate to the risk to public and animal health in line with the goals of the TSE Roadmap 2 and with EFSA advice. It would ensure that the feed industry in the UK 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.
- (d) Our proposal would adopt this amendment in our domestic legislation.
- (e) If anyone wishes to avail of this derogation, they can do so on the condition they can demonstrate to the Department's satisfaction that they fulfil the EU's key requirements, as follows:
- That sufficiently effective measures are in place to prevent cross-contamination between ruminant and non-ruminant animal by-products, including physically separate, closed systems for feed production and physically separate facilities for storage, transport and packaging;
 - That regular sampling and analysis of non-ruminant PAP for feeding farmed fish, and for feed for farmed fish containing non-ruminant PAP, is carried out to confirm the absence of cross-contamination with ruminant PAP, using a scientifically validated test. The test results must be kept available to the Department for at least five years.
- (f) Although the feed industry expressed support for this measure, they do not anticipate much demand as most pig and poultry PAP produced is used in pet food, and that is expected to remain the case due to commercial reasons.

2.2 Amendments to on-farm classical scrapie controls:

- (a) Annex VII of the 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 sheep and goats in the UK. EFSA has advised that scrapie has not been shown to be a risk to human health.
- (b) 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. Goats are believed to be uniformly susceptible to classical scrapie.
- (c) Under the Department's current policy if an animal is confirmed positive for classical scrapie, the flock enters the Compulsory Scrapie Flock Scheme (CSFS). This scheme provides two controls where the Department can:
 - (i) cull the whole flock and pay compensation for all animals; or
 - (ii) genotype the flock in order to identify animals that are susceptible to classical scrapie and have these culled (culled sheep are rendered and do not enter the food chain). The flock is then subject to surveillance testing and movement restrictions for 2 years and compensation is payable for all culled sheep.
- (d) The action taken is considered on a case by case basis and will depend on which option the Departmental Veterinary Service recommends to provide the most appropriate solution to that case. This decision is based on flock size, level of outbreak, frequency of ARR allele (resistant genotype) and whether the flock is made up of a rare breed. Option (ii), the genotyping and cull option represents the current default option for handling classical scrapie cases in Northern Ireland. Whole flock culling is normally only used where large numbers of the flock are considered to be affected by the disease, or where the flock size is small.
- (e) In July 2013 Commission Regulation (EU) No 630/2013 amended (EC) No 999/2001. Where a case of classical scrapie is confirmed on a holding, the EU's amended regulation gives us the control options of:-
 - (i) killing and destroying or slaughtering all sheep and goats on the holding; or
 - (ii) culling / slaughtering all goats, and those sheep that are genetically susceptible to classical scrapie. or
 - (iii) monitor the holding, with no killing or destruction of sheep or goats provided certain criteria relating to the scarcity of resistant genotypes are met.
- (f) 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 TSE. The Department pays all costs of sampling; transportation of samples to approved laboratory, and testing, and arranges and pays for the collection and destruction of the carcasses of all 'fallen stock' sheep and goats over 18 months of age.
- (g) Animals slaughtered for human consumption are sent to designated abattoirs where they are sampled and the carcasses are retained until the test results are

available. Carcasses 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 relevant animals have been destroyed. In the case of option III, as susceptible animals remain in the flock, 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 while restrictions remain on the flock.

- (h) Options (i) and (ii) by way of derogation, that instead of susceptible sheep and all goats being killed and destroyed, they may be slaughtered for human consumption provided that this is within the territory of the Member State and all animals over 18 months of age have tested negative for TSE before entering the human food chain. Lambs and kids are exempt from genotyping provided they are slaughtered for human consumption before they reach the age of 3 months.
- (i) Further derogations for option (ii) allow for a delay of up to three months where the initial confirmed case is close to the lambing season. This is on the condition that the ewes, goats and new-born are kept isolated from sheep and goats from other holdings. Or a delay for up to three years where sheep and goats are kept together, where the level of scrapie resistance in sheep is low, where there are epidemiological reasons, economic factors or other considerations such as in circumstances of rare breeds.
- (j) Under option (iii) Member States may decide not to kill and destroy animals where it is difficult to obtain replacement animals of a known genotype.
- (k) The Department will make use of the available derogations and will consider the most efficient and cost effective way of dealing with an outbreak. The Department will continue to use the most appropriate option on a case by case basis, although the culling/slaughtering of susceptible animals will continue to be the default position for handling scrapie cases in Northern Ireland.
- (l) The amended EU regulation introduces the following changes to on farm controls following the detection of classical scrapie on a holding:-
 - (i) Where previously farmers on affected sheep holdings 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 universally susceptible 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 for the monitoring option, 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.
- (m) 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 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.

2.3 Amendments to restrictions on the movement of sheep and goats on holdings affected by atypical scrapie:

- (a) Atypical Scrapie has been detected since 1998, primarily through the EU testing programme for 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 atypical scrapie is likely not to be transmissible or has very low transmissibility, unlike classical scrapie which is transmissible between animals.
- (b) Current policy is that where a case of atypical scrapie is confirmed on a holding, it is placed under movement restriction, monitored for two years with no killing or destruction of sheep and goats.
- (c) The amended EU regulation relaxes previous movement restrictions and accepts it is now unnecessary to restrict the movement of animals where a case of atypical scrapie has been confirmed. 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 provided they meet the other export requirements.
- (d) The existing requirements for sampling and testing animals aged over 18 months, which leave the holding for slaughter or as fallen stock, would remain, to enable Member States to continue to gather scientific data on atypical scrapie.
- (e) 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.
- (f) 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 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.

2.4 BSE testing in abattoirs - Remove the requirement for abattoirs to have a Required Method of Operation (RMOP):

- (a) In 2005, a requirement was added to the domestic TSE legislation for abattoirs slaughtering cattle which require BSE testing, to have in place a Required Method of Operation (RMOP) approved by the Department. A RMOP is 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. This change was implemented at that time on the advice of the FSA to enable the UK to introduce a system of BSE testing of older cattle. The intention was to replace the Over Thirty Months Rule, which had banned the sale of meat from cattle aged over thirty months at the time of slaughter since March 1996, and which was designed to protect public health and maintain public confidence in beef. The requirement for an approved RMOP was needed to ensure that abattoirs in the UK, slaughtering cattle requiring BSE testing, would have robust sampling, retention and disposal systems that safeguarded public and animal health.
- (b) 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.
- (c) The UK implemented this option on 1 March 2013. As a result, RMOPs for the occupier (Food Business Operator (FBO)) of slaughterhouses exceeded the requirement of the EU TSE Regulation and were 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 small number of healthy slaughtered animals aged over 30 months and 'risk' animals aged over 24 months born in Bulgaria, Romania, and third countries. Approximately 5,000 cattle are currently tested per year in GB and 1,000 in NI.
- (d) Our proposal would remove the legal requirement for a RMOP, approved by the Department, because it is no longer justified. Abattoir operators would be required to agree a Standard Operating Procedure (SOP) with the Department which would mirror the modified RMOP to maintain food safety and BSE controls.
- (e) The measures would not result in any additional cost to Government or Industry.

2.5 Alternative methods of spinal cord removal from sheep and goats over 12 months of age:

- (a) Under the EU TSE Regulation, spinal cord of sheep and goats which are aged over 12 months, or have one permanent incisor erupted, is deemed to be specified risk material (SRM) and must be completely removed and disposed of as Category 1 animal by-product by rendering and incineration. Existing UK implementing legislation requires that the carcass is split to remove the spinal cord. However, the UK industry contends that carcass splitting significantly reduces carcass value.
- (b) Following representations from industry, a joint FSA/industry task group was set up in 2010 to investigate alternative removal methods that do not involve carcass splitting. The task group set up trials in June and November 2011 looking at possible alternative methods in the UK; however, these proved to be unsuccessful due to carcass damage and the decreased likelihood of complete removal of the spinal cord. Additionally, the task group determined 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 achieved effectively. To date, carcass splitting is the only method of spinal cord removal, which the UK meat processing industry and the FSA finds acceptable and effective. The FSA remains prepared to consider alternative removal methods provided they can be shown to be effective and safe.
- (c) We are proposing to include a new provision in our domestic 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. In the absence of an effective alternative, splitting of the carcass will remain the default method for spinal cord removal.

2.6 Amendments to the list of tissues from cattle that are designated Specified Risk Material (SRM) to reflect changes to EU legislation:

- (a) 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 the extremely unlikely event that an animal infected with BSE is slaughtered for human consumption, SRM controls are estimated to remove almost all potential infectivity. The current list of SRM material can be found in Chapter 2.7 of the Manual for Official Controls –
(<http://www.food.gov.uk/enforcement/approved-premises-official-controls/manual>)
- (b) In October 2014, the European Commission presented two proposed amendments to Annex V of the TSE Regulations, namely, to:
 - (i) amend the list of SRM; and
 - (ii) to repeal the requirement for EU Member States and regions with a negligible BSE risk to remove SRM.
- (c) During the negotiations, the FSA consulted with stakeholders about the proposed changes.
- (d) The change to the definition of SRM came into force in EU law on 26 May 2015.
- (e) This amendment reclassifies the definition of bovine SRM so that, for cattle in EU countries with a controlled risk status, the last four metres of the small intestine, the first part of the large intestine (the caecum) and the membranes which anchor the intestines (the mesentery) will continue to be defined as SRM. The remainder of the intestines will be removed from the current SRM list. Intestines imported from non-EU countries with a negligible BSE risk status are not currently defined as SRM and may be consumed, e.g. sausage casings. This policy will now be extended to intestines from EU countries with a negligible BSE risk status.
- (f) The controls for EU Member States and regions with a negligible BSE risk status came into force on 5 August 2015.
- (g) The second amendment permits a wider range of previously SRM designated tissues back into the food and feed chains, and brings EU Regulations closer into line with OIE requirements which apply to third countries. For Member States and regions with negligible BSE risk status, SRM from bovine animals over 12 months old will continue to include the skull, brain, eyes and the spinal cord.
- (h) 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 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. The UK has been classified by the OIE as having 'Controlled Risk' status since 2008. Because the UK's most recently born case of classical BSE was born in 2009, the UK as a whole will be eligible to apply for negligible risk status in 2020. However, as Northern Ireland currently satisfies the conditions to apply for negligible risk status, the Department made application to the OIE in September 2016 for Negligible Risk status on a regionalised basis. Notification of the risk

classification upgrade to negligible risk status – the safest level - was confirmed by the OIE at a meeting in Paris on 25 May 2017.

- (i) As a consequence of the amendments described in paragraph 2.6(b) above, certain provisions relating to the removal of specified risk material set out in Annex V to Regulation (EC) No 999/2001 have been further amended. Where the vertebral column continues to be defined as specified risk material, the European Union has modified the information to be provided on the label. As a control system, a red stripe shall be included on the label of carcasses or whole cuts of carcasses of bovine animals containing vertebral column, when the removal of the vertebral column is required. This amendment will also apply to products of bovine origin imported into the European Union from third countries. These further changes came into force in EU law on 1 July 2017 and were implemented in the UK on an administrative basis from the same date.
- (j) Point 7 of Annex V has been amended so that only Member States with controlled or undetermined BSE risk are required to harvest at the slaughterhouse tongues of bovine animals of all ages intended for human or animal consumption by a transverse cut rostral to the lingual process of the basihyoid bone.
- (k) Additionally point 11.3(b) of Annex V has been modified as follows - where applicable, specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which the removal of the vertebral column is required, shall be added on the commercial document relating to consignments of meat. Where applicable, that specific information shall be added to the Common Veterinary Entry Document (CVED) referred to in Article 2(1) of Commission Regulation (EC) No 136/2004 (1) in the case of imports.

2.7 Clarification on Specified Risk Material (SRM) removal in slaughterhouses:

- (a) 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 carcasses, the FSA is proposing changes to the legislation to clarify the provisions of paragraphs 8(1) and 9(1) of Schedule 7 of the TSE Regulations (Northern Ireland) 2010.
- (b) Questions had arisen as to whether the current provision required SRM to be removed from the carcass before post-mortem inspection and whether the spleen could remain inside the carcass 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 carcass before post-mortem inspection.
- (c) 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.
- (d) 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.

2.8 Amendment to the requirements for the application of the young lamb (YL) and young goat (YG) stamp:

- (a) Under the current requirements in Schedule 7 paragraph 11(1) only an 'inspector' may apply the YL/YG stamp and an offence occurs under Schedule 7 paragraph 11 (3) if someone other than an inspector applies the stamp.
- (b) The amendment would include the option of permitting the occupier of the premises to apply the YL/YG stamp under paragraph 11(1).
- (c) Paragraph 11(1) of Schedule 7 requires that the YL/YG stamp may be applied only by an 'inspector'. This was introduced at a time when there were systems in place in all NI slaughterhouses approved for the slaughter of sheep for DAERA officials to examine the dentition of sheep presented for slaughter. The YL/YG stamp was applied by DAERA inspectors at the post mortem inspection point on the basis of those examinations.
- (d) These examinations have for some time, been carried out by slaughterhouse staff employed by the food business operator (FBO) and these have been subsequently verified at a risk based frequency by DAERA officials. As these are primarily FBO examinations, it is necessary to include the option of permitting the occupier of the premises to apply the YL/YG stamp.
- (e) Consequently paragraph 11(3) should be reworded to facilitate this amendment - It is an offence to stamp a young lamb or a young goat carcass with a stamp that is, or resembles a young lamb or a young goat stamp unless the animal satisfies the requirements of subparagraph (1). It is also an offence for any person, other than those permitted under subparagraph (1) to apply the stamp mark or a mark resembling the stamp, or to possess the equipment for applying it.
- (f) It is considered necessary to retain the dimensions of the YL/YG stamp described in paragraph 11(2) and the offence of applying the stamp to an ineligible carcass in paragraph 11(4).

2.9 Update valuation and compensation procedures for sheep and goats to align with cattle procedures:

- (a) 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.
- (b) The TSE Regulations (Northern Ireland) 2010, (Schedule 4 paragraph 25), provides guidance of compensation and offers table valuations to farmers in respect of compensation for sheep and goats culled due to classical scrapie with an alternative of an individual market valuation. The table values have not changed since 2006.
- (c) We are proposing to remove the valuation table. The reasoning behind this proposal is that compensation tables become outdated, giving low table values and is not based on current reliable market prices.
- (d) We are proposing to align the compensation for sheep and goats with that for cattle procedures (Regulation 11) which will be based on market value.
- (e) The incidence of scrapie in Northern Ireland has declined sharply in the past 10 years. In 2006, 18 cases were confirmed. There have been no cases in the past 2 years.

2.10 Remove the requirement for written bilateral agreements to authorise the removal of Processed Animal Protein (PAP) derived from non-ruminant animals:

- (a) 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;
 - (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.
- (b) 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 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 UK law on an administrative basis with effect from that date.
- (c) To maintain food safety, controls would be in place that 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 2.1(c) above. Subject to authorisation by the Department's Veterinary Service to export non-ruminant PAP, the following conditions would apply:
 - (i) 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;
 - (ii) 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;
 - (iii) 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;

- (iv) 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;
- (v) 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.
- (d) Our proposal would adopt in domestic 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 Department's Veterinary Service.
- (e) 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 demand to export poultry PAP or feather meal, from dedicated slaughter and processing plants.

2.11 Amendment to EU rules to extend the scope of ‘aquatic animals’ permitted for use in processing fishmeal and inclusion in feed for aquaculture animals:

- (a) The EU TSE Regulation permits the use of aquatic animals in fishmeal in feed for aquaculture. Because the definition of ‘aquatic animals’ did not include wild starfish and farmed aquatic invertebrates other than molluscs and crustaceans, and the use of meal produced from these animals in feed for non-ruminants 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 to permit the use of starfish or farmed aquatic invertebrates, other than molluscs and crustaceans, for the production of fishmeal and thereby feed for aquaculture.
- (b) This amendment came into force in EU law on 13 February 2017 and was adopted in the UK on an administrative basis from that date. Our proposal would adopt this amendment in domestic legislation. 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 the Government’s commitment to use all available derogations in EU law; and would ensure that the feed industry in the UK has the same opportunities as their counterparts in other Member States for the wild starfish and aquatic invertebrates in aquaculture feed, while continuing to enforce all prohibitions on the use of ruminant protein in ruminant feed.

2.12 To take advantage of an EU derogation that will permit the use of Processed Animal Protein (PAP) derived from insects in feed for aquaculture:

- (a) 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 2.1(a)-(e). Such PAP has to be derived from slaughterhouses or cutting plants: therefore PAP derived from insects in feed for aquaculture animals is currently not allowed.
- (b) 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.
- (c) Based on a recent scientific opinion from EFSA, 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 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.
- (d) The permitted insect species named in the proposal are House Fly (*Musca domestica*), Black Soldier Fly (*Hermetia illucens*), Yellow Mealworm (*Tenebrio molitor*), Lesser Mealworm (*Alphitobius diaperinus*), House Cricket (*Acheta domestica*), Banded Cricket (*Grylodes 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.
- (e) The EU legislation came into force on 1 July 2017 and was implemented across the UK on an administrative basis from that date. Our proposal would adopt this amendment in our domestic legislation.

2.13 To take advantage of an EU derogation that will permit the export of Processed Animal Protein (PAP) derived from ruminants:

- (a) Previously the EU TSE Regulation prohibited the export of 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 Europe was the main part of the world affected by the epidemic. However, the BSE situation in the Union has since then significantly improved with twenty three Member States now recognised as having negligible BSE risk status by the OIE.
- (b) The European 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.
- (c) The 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.
- (d) The EU legislation came into force on 1 July 2107 and was implemented across the UK on an administrative basis from that date. Our proposal would adopt this amendment in our domestic legislation.

2.14 Appeals – Strengthening arrangements for Independent Appeals Procedure:

- (a) The Examiner of Statutory Rules queried the Department's legislative independent appeals procedures, advising that there was no system for a person to make an independent appeal against the decision taken by the Department regarding non-compliance of the Regulations. In response the Department included an additional paragraph in the Animal By-Products (Enforcement) Regulations (Northern Ireland) 2015 and proposes to support and strengthen an independent appeals procedure in the TSE Regulations (Northern Ireland) 2010 by including a new paragraph (Regulation 10(6) in our 2018 domestic Regulation) which will state:

“A person who is aggrieved by the final determination of the Department under paragraph (5) may, within 21 days of the notification of the determination, appeal against that determination to a court of summary jurisdiction.

2.15 Schedule 3 – Paragraph 3 Slaughter of a Suspect Animal – Re-Instatement of paragraph:

- (a) Schedule 3 of the TSE Regulations (NI) 2010 outlines the policy and implementing procedures for dealing with TSE in a bovine animal.
- (b) When amendments were made to the TSE Regulations (NI) 2008, paragraph 3 (1)5 (below) was inadvertently taken out. This paragraph provides the necessary controls/requirements for a veterinary inspector in respect of dealing with milk following the slaughter of a suspect animal.
- (c) Inspectors have sufficient powers to seize and destroy milk or milk products under regulation 14 of our 2010 Regulations. However in order to ensure enforcement of the Regulations is carried out fully and accurately we propose to re-instate the paragraph below into Schedule 3 at paragraph 3 (1)5. This will bring together, under one paragraph, the measures required by the veterinary inspector when a bovine is suspected with TSE and simplify enforcement action.

3.- (1)(5) If the animal to which sub-paragraph (1) applies is not killed immediately, the keeper must dispose of its milk in such a way that it cannot be consumed by a human or an animal other than its own calf or an animal kept for research purposes and any contravention of this sub-paragraph is an offence.

2.16 Share the cost of BSE sampling of fallen stock cattle between the farming industry and the taxpayer:

- (a) To establish national incidences of BSE it is an EU requirement that all EU-born cattle (excluding Romania and Bulgaria) over 48 months of age that die or are killed other than for human consumption (so called 'fallen stock') are tested for BSE. For fallen stock cattle born in Romania and Bulgaria or outside the EU the qualifying age for testing is 24 months, there are a small number of these cattle in the UK.
- (b) Farming businesses have to submit the carcasses of fallen cattle aged over 48 months to approved TSE Sampling sites for sampling and destruction in accordance with the TSE Regulations. Trained staff at the TSE sampling sites take a small sample of brain material for testing before the carcasses are incinerated. Currently the cost of sampling, transportation of samples to the testing laboratory and for the testing itself is all borne by the taxpayer; the Department currently pay the TSE sampling site operators £6.50 for taking each brain stem sample.
- (c) We propose to cease paying the £6.50 to the TSE sampling site operators. The TSE sampling sites may absorb this cost or charge farm businesses this amount for carrying out the service (i.e. removing the brain stem sample before sending it to the testing laboratory), within the collection/disposal charge for the animal. This will transfer the cost of taking brain stem samples from fallen cattle, for mandatory BSE testing, from the taxpayer to the farming industry. Farming businesses already have to submit the carcasses of fallen cattle aged over 48 months to such sites for sampling and destruction. Transferring the sampling cost from the taxpayer to the farming industry would result in a more equitable sharing of the cost of BSE surveillance between the taxpayer and the farming industry, who 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 approved testing laboratory and for the testing itself.

2.17 Revocation:

- (a) To revoke the following Statutory Rule, this will be replaced by the Transmissible Spongiform Encephalopathies Regulations (Northern Ireland) 2018.

The Transmissible Spongiform Encephalopathies Regulations (Northern Ireland) 2010	SR 2010 No. 406
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PART III – LIST OF QUESTIONS

(a) Your comments are invited on the following questions:-

2.1 Amendment to feed controls:

Q1: If you work in the farmed fish industry do you intend to take up this derogation in the future?

Q2: Do you have any other comments on the proposal to adopt the EU derogation to permit the use of poultry and pig processed animal protein (PAP) in feed for farmed fish?

2.2 Amendments to on-farm classical scrapie controls:

Q3: Do you have any comments on the amendments to on-farm controls for holdings where classical scrapie has been confirmed?

2.3 Amendments to restrictions on the movement of sheep and goats on holdings affected by atypical scrapie:

Q4: Do you have any comments on the amendments to on-farm controls for holdings where atypical scrapie has been confirmed?

2.4 BSE testing in abattoirs - Remove the requirement for abattoirs to have a Required Method of Operation (RMOP):

Q5: Do you have any comments on the proposal to remove the requirement for abattoirs slaughtering cattle that require BSE testing to have an approved RMOP?

2.5 Alternative methods of spinal cord removal from sheep and goats over 12 months of age:

Q6: Is your business likely to 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?

Q7: Have you any idea of the cost, including any supporting evidence to your business of implementing an alternative method?

2.6 Amendments to the list of tissues from cattle that are designated Specified Risk Material (SRM) to reflect changes to EU legislation:

Q8: Do you have any comments on the proposals to implement the changes made to the EU TSE legislation regarding SRM controls.

Q9: The FSA would like to gather any significant impacts (costs or benefits) that you may foresee – can you provide details?

2.7 Clarification on Specified Risk Material (SRM) removal in slaughterhouses:

Q10: Do you have any comments on the proposal to change the wording relating to the removal of SRM in a slaughterhouse?

2.8 Amendment to the requirements for the application of the young lamb (YL) and young goat (YG) stamp:

Q11. Do you have any comments on the proposal to permit the occupier of the premises to be included as an option for applying the YL/YG stamp?

2.9 Update valuation and compensation procedures for sheep and goats to align with cattle procedures:

Q12: Do you have any comments on the proposal to change the procedure in paragraphs 25 and 26 of Schedule 4 of the 2010 Regulations with regard to scrapie compensation for sheep and goats killed following confirmation of TSE, removing the valuation table?

2.10 Remove the requirement for written bilateral agreements to authorise the removal of Processed Animal Protein (PAP) derived from non-ruminant animals:

Q13: Have you any comments on the proposal to remove the requirement for written bilateral agreements for the export of non-ruminant PAP?

Q14: If you work in the feed industry, would you expect this proposal to open up new markets for your business?

2.11 Amendment to EU rules to extend the scope of 'aquatic animals' permitted for use in processing fishmeal and inclusion in feed for aquaculture animals:

Q15: Have you any comments on the proposal to extend the definition of aquatic animals used for feed in aquaculture?

Q16: If you work in the feed industry, and your business makes feed for farmed fish, would you expect your business to utilise meal produced from wild starfish and farmed aquatic invertebrates?

2.12 To take advantage of an EU derogation that will permit the use of Processed Animal Protein (PAP) derived from insects in feed for aquaculture:

Q17: Have you any comments on the proposal to permit the use of PAP derived from insects in feed for aquaculture?

Q18: If you work in the farmed fish industry would you take advantage of this amendment? Please give your reasons.

2.13 To take advantage of an EU derogation that will permit the export of Processed Animal Protein (PAP) derived from ruminants:

Q19: Have you any comments on the proposal to amend the EU rules for the export of ruminant PAP?

Q20: If you work in an industry which produces ruminant PAP, do you expect to take advantage of this amendment?

2.14 Appeals – Strengthening arrangements for Independent Appeals Procedure:

Q21: Do you have any comments on the proposal to include a new paragraph in the Regulations to strengthen the arrangements for an independent appeals procedure?

2.15 Schedule 3 – Paragraph 3 Slaughter of a Suspect Animal – Re-Instatement of paragraph:

Q22: Do you have any comments on re-instating the paragraph into Schedule 3 (paragraph 3 (1)5), which will bring together, under one paragraph, the measures required by the veterinary inspector when a bovine is suspected with TSE?

2.16 Share the cost of BSE sampling of fallen stock cattle between the farming industry and the taxpayer:

Q23: Have you any comments on the proposal to transfer the cost of sampling fallen cattle over 48 months of age from the taxpayer to the farming businesses which will allow a more equitable sharing of the cost of BSE surveillance between the farming industry and the taxpayer?

Q24: If you do not agree with sampling costs being transferred from the taxpayer to industry, can you propose an alternative way for how costs should be shared?

2.17 Revocation:

Q25: Have you any comments on our proposal to revoke the Transmissible Spongiform Encephalopathies Regulations (Northern Ireland) 2010?

PART IV – HOW TO RESPOND

4.1 We invite your comments on proposals to amend the Transmissible Spongiform Encephalopathies Regulations (Northern Ireland) 2010.

4.2 You can view and respond to this consultation online at the Northern Ireland Hub – Citizen Space at:

<https://consultations.nidirect.gov.uk/daera-animal-health-welfare-policy-division/tse-consultation>

4.3 If you are unable to respond to the consultation on line, written responses will also be accepted and should be sent to:

Mr Malcolm Hanna
Department of Agriculture, Environment and Rural Affairs
Room 720, Dundonald House
Upper Newtownards Road,
Ballymiscaw,
Belfast,
BT4 3SB

or e-mail to: malcolm.hanna@daera-ni.gov.uk

Telephone contact no: 02890 520932

4.4 The closing date for responses is 22 April 2018.

4.5 Copies of the consultation can be made available on request or in alternative formats e.g. large print.

Freedom of Information Act 2000 – confidentiality of consultations

4.6 The Department will publish a summary of responses following completion of the consultation. Your response and all other responses to the consultation may be disclosed on request.

4.7 The Freedom of Information Act gives the public a right of access to any information held by a public authority, namely the Department of Agriculture and Rural Development in this case. This right of access to information includes information provided in response to a consultation. The Department cannot automatically consider as confidential information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity, should be made public or be treated as confidential. If you do not wish information about your identity to be made public please include an explanation in your response.

PART V – LIST OF STAKEHOLDERS CONSULTED

- Animal Health & Welfare NI (AHWNI)
- Belfast Zoo
- British Veterinary Association (BVA)
- Butchers
- Cattle Breed Societies
- Countryside Services Ltd
- Craft Meat
- Dairy UK
- External Agencies (Departmental Guidance)
- Elite Butchers Association
- Farmers for Action
- Food Groups
- Food Standards Agency (FSA)
- General Consumer Council
- Goat Breed Societies
- Livestock and Meat Commission (LMC)
- Local Councils in Northern Ireland (11)
- Meat Plants & Outlets
- National Beef Association – NI Region (NBA)
- National Sheep Association – NI Region (NSA)
- Northern Ireland Agricultural Producers Association (NIAPA)
- Northern Ireland Beef Breed Liaison Group
- Northern Ireland Food & Drink Association (NIFDA)
- Northern Ireland Grain Trade Association (NIGTA)
- Northern Ireland Goat Club
- Northern Ireland Livestock Auctioneers Association (NIAA)
- Northern Ireland Local Government Association (NILGA)
- Northern Ireland Master Butchers' Association
- Northern Ireland Meat Exporters' Association (NIMEA)
- Northern Ireland Sheep Breeders Development Group
- Pet Food Manufactures
- Pharmaceutical Companies
- Rare Breed Society
- Rare Breed Survival Trust
- Regal Food Processors Ltd
- Renderers
- Royal College of Veterinary Surgeons (RCVS)
- Section 75 Groups
- Severely Disadvantaged Areas Group
- Sheep Breed Societies
- Society of Local Government Chief Executives (SOLACE)
- TSE Sampling Sites
- Ulster Farmers Union
- United Dairy Farmers Ltd
- United Kingdom Renderers' Association (UKRA)
- Vet NI
- Young Farmers Club of Ulster