



Department
for Environment
Food & Rural Affairs

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Consultation on the proposed Transmissible Spongiform Encephalopathies (England) (Amendment) Regulations 2012

Summary of responses to public consultation

January 2013

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Introduction

1. This document summarises responses to a Defra public consultation seeking views on the proposed Transmissible Spongiform Encephalopathies (England) (Amendment) Regulations 2013 (“the 2013 Regulations”). The consultation was circulated to 81 key stakeholders and was published on the Defra website. The consultation ran from 21 June to 13 September 2012. 10 responses were received.
2. Transmissible Spongiform Encephalopathies (TSEs) are fatal brain diseases which include classical scrapie in sheep and goats and bovine spongiform encephalopathy (BSE) in cattle. Exposure to BSE through the consumption of infected meat is believed to be the primary cause of variant Creutzfeldt-Jakob Disease (vCJD) in humans. The European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control jointly [advised](#) in 2011 that BSE is the only animal TSE which has been shown to be a risk to human health and that there is no epidemiological evidence to suggest that classical scrapie is a risk to human health.
3. The Government needs to implement TSE controls, in line with European Union (EU) requirements. The proposed amendments to the Transmissible Spongiform Encephalopathies (England) Regulations 2010 (“the 2010 Regulations”) contribute to TSE controls which are based on scientific advice and are proportionate to the risk to public and animal health in line with the European Commission’s [TSE Roadmap](#).
4. The consultation sought views on proposals to make the following amendments to the 2010 Regulations:
 - To harmonise compensation rates for cattle killed for BSE eradication under the 2010 Regulations with those for cattle killed for bovine tuberculosis, brucellosis and enzootic bovine leukosis under the Cattle Compensation (England) Order 2012, which came into force on 1 July 2012;
 - To reflect the full range of options available in EU legislation for controlling classical scrapie in sheep and goats, and to take the option of not killing and destroying genetically susceptible animals from classical scrapie-affected flocks and herds (“the monitoring option”) as our default position for existing and future cases;
 - To make a number of minor technical amendments which would fulfil Government requirements on better regulation, clarify enforcement procedures, limit unqualified appeals against killing of cattle under the 2010 Regulations, and remove an obligation and a redundant offence.

5. For each issue raised by the consultation document, this paper gives a summary of:
(a) the consultation proposal; (b) the consultation response; and (c) how Defra has responded to suggestions made by consultees.

6. A list of respondents is at Annex 1. A complete set of responses to the written consultation (other than where respondents requested confidentiality) are available from the Defra Information Resource Centre and can be supplied in response to personal callers or in response to phone or e-mail requests. An administrative charge will be made to cover photocopying and postage costs. Where possible, personal callers should give at least 24 hours notice of their requirements. To arrange this, please contact the Defra Information Resource Centre, Lower Ground Floor, Ergon House, Horseferry Road, London SW1P 2AL. Telephone 020 7238 6575. E-mail defra.library@defra.gsi.gov.uk

Part 1: Summary of consultation responses

Issue 1: Clarification of how notices may be served under the 2010 Regulations

1. **Consultation proposal:** Paragraph 2.1 of the [Consultation Document](#) set out proposal to add a new Regulation 15A which would clarify how notices under the 2010 Regulations may be served, e.g. by delivering it to a person, leaving it at the person's proper address, or sending it by post to the person's proper address.
2. **Consultation response:** Three respondents commented on this issue, all of whom agreed with the proposals but suggested that the new Regulation should include a requirement that the inspector receives acknowledgement of receipt.
3. **Defra response:** Defra agrees that this is a sensible suggestion. The draft Regulations will be amended to include a requirement for any person in receipt of a notice to immediately inform an inspector of its safe receipt.

Issue 2: TSE Monitoring

4. **Consultation proposal:** Paragraphs 2.2-2.3 of the Consultation Document set out two proposals with regard to TSE monitoring:
 - i. To remove the statutory requirement in Schedule 2, paragraph 1 of the 2010 Regulations for goat keepers to notify the Secretary of State about fallen goats aged 18 months and over. This requirement has been redundant since the method for selecting goat carcasses for TSE sampling changed on 4 January 2011.
 - ii. To expand the existing provision in Schedule 2, paragraph 10(1) of the 2010 Regulations allowing the Secretary of State to approve private laboratories to test bovine samples taken at abattoirs, to cover all bovine categories of rapid testing of samples for BSE. This is a technical proposal to enable private laboratories to test cattle sent for slaughter which are unfit for human consumption, e.g. because they die prior to slaughter.
5. **Consultation response:** All respondents who commented on this issue were in favour of proposal (i). Two respondents made representations regarding the requirement for goats to be tested for TSEs under the Scrapie Monitoring Scheme (SMS). Six respondents commented on proposal (ii). All were in favour, but one gave the proviso that their agreement was on condition that it would not lead to any additional costs of testing being passed to the producer for the collection of fallen stock or testing of animals sent for slaughter.

6. **Defra response:** (i) Respondents' comments on the SMS are outwith the terms of the consultation and will be referred to the Defra policy team dealing with intra-community trade for a separate response. (ii) This proposal would not result in any change to the current system of financing the testing of fallen cattle.

Issue 3: Control and eradication of BSE in cattle

7. **Consultation proposal:** Paragraphs 2.4-2.5 of the Consultation Document set out the current provisions in Schedule 3, paragraph 5(2) of the 2010 Regulations for the owners of BSE cohort cattle to submit a general appeal against a decision to slaughter a cohort animal, and the proposal to limit appeals to specific criteria under which the owner believes that the animal is not part of a BSE cohort because it did not have access to the same feed as the confirmed BSE case, or the owner contends that the cohort animal is exempted from culling because it is a bull which is continuously kept at, and will not be removed from, a semen collection centre, and will be killed at the end of its productive life.
8. **Consultation response:** Five respondents commented on this proposal:
- i. One supported the proposal on the grounds that preventing unnecessary delays in the culling process and limiting unqualified appeals safeguards public and animal health.
 - ii. Three opposed the proposal, stating that farmers should continue to have the right of appeal because the circumstances of each case of BSE, and the decision to cull, will be different.
 - iii. One queried how owners can provide reliable evidence to support their case.
 - iv. One questioned why cohort culling is still taking place, given that it is possible to allow a Member State to defer the killing and complete destruction of cohort animals until the end of their productive lives.
9. **Defra response:**
- i. This proposal is intended to limit unjustified and unqualified appeals which place an unnecessary administrative and financial burden upon Government and upon public funds. Public and animal health are safeguarded because BSE cohorts are placed under movement restriction as soon as a case of BSE has been confirmed, and their passports are taken to prevent unauthorised movement prior to slaughter.
 - ii. Under the proposed amendment, the owners of cohort cattle would continue to have the right to query in writing any decision to cull their animals, and AHVLA would respond and offer guidance. The intention of the amendment is to limit the formal appeal procedure to cases where the grounds of appeal would, if successful, result in the cattle being excluded from the cohort. As only three cases of BSE have been confirmed in the UK in 2012, the number

of animals affected by this change in current and future years is expected to be very small.

- iii. We would expect farmers to provide evidence to support any appeal on the basis that an animal has not received the same feed as a BSE case, especially in the first twelve months of its life, or that the animal is a bull which is continuously kept at, and will not be removed from, a semen collection centre, and will be killed at the end of its productive life.
- iv. Our current policy with regard to the culling of cohorts is in line with the proposals contained in Defra's 2007 veterinary assessment of the risk of replacing the culling of BSE cohorts with permanent restriction. As BSE case numbers have reduced since then, and we wish to take all possible advantage of EU derogations, we intend to review the assessment and will publish an update in due course.

Defra will proceed with the proposal.

Issue 4: BSE Compensation

10. **Consultation proposal:** Paragraph 2.6 of the Consultation Document set out the requirements under Schedule 3, paragraph 8 of the 2010 Regulations for the Secretary of State to pay compensation in respect of cattle killed on suspicion of being infected with BSE and for cattle killed in pursuit of BSE eradication. Since 2006, BSE compensation rates have been aligned with those laid down in the Cattle Compensation (England) Order 2006 (“the 2006 Order”) for bovines killed under the Animal Health Act 1981 in its application to bovine tuberculosis (BTb), brucellosis and enzootic bovine leukosis (EBL).
11. Paragraphs 2.7 and 2.8 described the updates and revisions to the 2006 Order in the Cattle Compensation (England) Order 2012 (“the 2012 Order”) and the proposal to maintain the existing harmonised approach to cattle compensation by aligning the 2010 Regulations with the 2012 Order. This would increase the number of cattle categories in the valuation table from 47 to 51, correct certain anomalies in the text, and make other changes only relevant to compensation for BTb. Consultees were asked if they had any comments on the proposed changes to the categories for table valuation for BSE compensation.
12. **Consultation response:** Four respondents commented on this issue. All supported the proposal to maintain the existing harmonised approach to cattle compensation, but two raised concerns in relation to the application of the table valuation system, in particular they felt that the level of compensation paid for pedigree cattle did not always reflect the true market value for healthy cattle. One raised concerns over the proposal to limit compensation to cattle with the legally required ID documentation, since failure to provide documentation may be caused by other delay factors.

Defra response: Cattle killed for BSE are automatically excluded from the food chain and therefore their value is greatly reduced (i.e. salvage value). The proposed new compensation categories take into account feedback received from industry and are intended to compensate farmers for cattle killed for BSE at a higher rate than their salvage value. The effect of the proposed changes upon BSE compensation is expected to be very minor, as the disease is in decline and very few cattle are now killed for BSE per year. Discretion is allowed for the late provision of ID documentation for fully tagged animals whose passports have been lost or stolen, so long as the farmer/keeper has applied for a replacement. However there is no provision for compensation for animals which have neither ear tags nor passports.

Defra will therefore proceed with the proposal.

Issue 5: Control and eradication of TSE in sheep and goats

13. **Consultation proposal:** Paragraphs 2.9-2.11 of the consultation document described the requirements under Schedule 4, paragraphs 6 and 7 of the 2010 Regulations following detection of classical scrapie in a sheep flock or goat herd, under which the holding is placed under a movement restriction and all sheep over three months old are blood sampled and genotyped at Government expense. All sheep over three months old which are genetically susceptible to classical scrapie, and all goats over three months old, are killed, with Government compensating the owner and paying all costs of slaughter and disposal. A movement restriction period, with a range of controls, would then apply to the holding until two years have elapsed since the confirmation of the last classical scrapie case (“the genotype and cull option”).
14. Paragraph 2.11 describes how, following the decision by the EU General Court to reinstate options in the EU TSE Regulation for more proportionate controls on holdings where classical scrapie has been diagnosed, the Government proposes to update the 2010 Regulations to reflect the full range of options now available, and to adopt the option of not killing and destroying genetically susceptible animals from classical scrapie-affected flocks and herds (“the monitoring option”) as our default position for existing and future cases. The monitoring option was adopted by Defra as its default option on 19 October 2011. Paragraphs 2.12-2.13 set out the arrangements for affected holdings under the monitoring option and the range of controls which would apply during the movement restriction period. Consultees were asked if they had any comments on the proposed amendments to controls for holdings on which classical scrapie had been confirmed.
15. Paragraph 2.14 set out the proposal to insert an ambulatory clause in the 2010 Regulations to align the periods of time which the Secretary of State may delay the killing of a goat herd in which TSE has been confirmed, with those given in current and future revisions to the EU TSE Regulation.

16. Consultation response: Nine respondents commented on this issue. All were in support of the proposals to amend the Regulations. The following issues were raised:

- i. One expressed concern over the statement in the consultation document and Impact Assessment that EFSA and the European Centre for Disease Prevention and Control jointly advised in 2011 that BSE is the only animal TSE which has been shown to be a risk to human health and that there is no epidemiological evidence to suggest that classical scrapie is a risk to human health. The respondent suggested that the statement should read that, at present, the only TSE agent demonstrated to be zoonotic is the Classical BSE agent: however, the epidemiological evidence in relation to sporadic CJD cannot be regarded as definitive, and the possibility that a small proportion of cases are zoonotic cannot be excluded.
- ii. Two raised some technical queries on the EU's requirements regarding the movement of certain categories of sheep from infected holdings.
- iii. One raised concerns that, as cull goats in some areas of the country have little or no value, there is a danger that a large herd in which classical scrapie is diagnosed could be forced out of business with heavy financial losses.
- iv. One sought clarification for the arrangements for hill and upland farmers selling store lambs.
- v. One sought a review of the EU rules on classical scrapie in small ruminants, including SRM controls, and restrictions on dairying, and sought reassurance that any milk produced on scrapie infected farms from non-suspect animals would not be restricted from the market place.

17. Defra response:

- i. The EFSA report was comprehensive in considering all aspect of the evidence for an epidemiological or molecular link between human and animal TSEs and came to the conclusion that BSE was the only zoonotic TSE. In the case of other TSEs, there was an element of uncertainty which prevented the BioHaz Panel and the ECDC from ruling out the possibility of any other zoonotic TSE strain but there was no evidence for such a strain and the uncertainties were fully discussed. Semi-quantitative assessment of the uncertainty allowed the BioHaz Panel to infer it was not likely to significantly affect the baseline level of 1 in 50 000 fatalities attributable to human TSE. At a population level the existence of a zoonotic animal TSE strain other than BSE is similarly not likely to give an increased risk of human TSE cases.
- ii. Under the monitoring option, the rules for the movement of animals from affected holdings are more stringent than for holdings where the option to genotype and cull has been applied. Annex VII of the Commission Decision (EC) 999/2001 is currently being revised to simplify the complex

requirements for holdings affected by classical and atypical scrapie. The revised arrangements are to come into force in mid-2013, and we will, of course, consult on them in due course.

- iii. In the light of the low incidence of classical scrapie in the UK, and EFSA advice that there is no epidemiological evidence to suggest that classical scrapie is a risk to human health, our policy is to take minimum action to control outbreaks of the disease. We believe that the monitoring option is the most proportionate and cost effective response to the disease and is in line with our policy of taking advantage of all EU derogations.
- iv. and v. These issues are outwith the terms of the consultation and will be replied to separately by the appropriate Defra and Food Standards Agency officials.

Defra will proceed with the proposal.

Issue 6: Production of protein and feedingstuffs

18. **Consultation proposal:** Paragraph 2.15 of the consultation document set out the proposal to insert an ambulatory clause in the 2010 Regulations to align its requirements for the export of fishmeal, products containing fishmeal and petfood, with the requirements set out in the EU TSE Regulation.

19. **Consultation response:** No comments were received.

20. **Defra response:** Defra will proceed with the proposal.

Issue 7: Small Firms Impact Test

21. **Consultation proposal:** As part of the consultation process, we carried out a Small Firms Impact Test to assess the potential impact of our proposals upon small businesses. To do this, we needed the views of small businesses in the cattle, sheep and goat industries and of their key representatives.

22. **Consultation response:** Four respondents commented on this issue.

- i. One commented that sheep and goat holdings which routinely sell breeding animals or store animals for fattening could be disadvantaged by the reduction in support for affected holdings. This could be seen as a strong incentive to continue breeding sheep in favour of Type 1 genotypes, but the likely situation is that few farmers will wish to take such action when they perceive that the risk of scrapie has significantly declined. More information should be given to farmers and their representative bodies about the current reported level of TSEs in sheep and goats and they should be urged to

continue to genotype breeding sheep of high genetic merit to ensure that only animals with a reduced susceptibility to scrapie are used in large scale breeding programmes.

- ii. Two commented that, given the low incidences of scrapie in the UK, it is very difficult to provide precise figures on the costs of the proposed changes. Restrictions by their very nature have a negative impact on producers as they inhibit a farmer ability to trade freely. It is essential that control options are proportionate and based on sound scientific evidence with farmers being adequately compensated for any loss.
- iii. One commented that, on condition that the regulation amendments do not transfer any of the costs to the producer/finisher, then no significant impact is anticipated. Further evaluation for the phasing out of restrictions would be welcomed: it was accepted however that testing, at this time, protects the market value of British meat.
- iv. One expressed concern that the proposals could have an adverse effect upon the goat export industry, and could, as a secondary consequence, jeopardise the sheep export industry.

23. Defra response:

- i. We agree that farmers need strong targeted information on the risk posed by TSEs to encourage them to breed for low susceptibility to classical scrapie. Data on classical scrapie cases confirmed in Great Britain is available on the AHVLA website at http://vla.defra.gov.uk/science/docs/sci_tse_stats_active.pdf and http://vla.defra.gov.uk/science/docs/sci_tse_stats_sheep.pdf, both of which are updated monthly.
- ii. Our proposal to amend the 2010 Regulations to include the monitoring option would enable us to take advantage of the most proportionate option available for holdings affected by classical scrapie, which takes account of the latest scientific advice. Restrictions upon movements from affected holdings are unfortunately necessary to prevent the spread of the disease.
- iii. The comments were noted.
- iv. These comments are related to the Scrapie Monitoring Scheme, which is not affected by Defra proposals for the TSE (England) (Amendment) Regulations 2013. We have passed the comments to the relevant policy team for response.

Annex 1: List of Respondents

Scottish Agricultural College

Trading Standards Institute

National Sheep Association

Goat Veterinary Association

National Farmers Union

National Beef Association

British Veterinary Association

Country Land and Business Association

Two private individuals