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Summary of responses to the consultation on the proposed Transmissible Spongiform Encephalopathies Regulations 2008 - 3 April to 26 June 2008

July 2008



FOOD
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AGENCY


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Department for Environment
Food and Rural Affairs

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1. Introduction

1. On 3 April 2008, Defra launched a joint consultation with the Food Standards Agency on proposals to revoke and replace the existing Transmissible Spongiform Encephalopathies (No. 2) Regulations 2006 with the Transmissible Spongiform Encephalopathies (England) Regulations 2008. The proposed new Regulations include amendments that have been made in response to changes to EU legislation (EU Council Regulation 999/2001) and as a result of experience gained in administering the 2006 Regulations since they came into force.

2. The main consultation launched on 3 April did not cover those provisions of EC Regulation 727/2007 relating to classical scrapie, which were suspended by an interim judgement of the European Court of Justice (ECJ) in September 2007. However, the European Commission subsequently secured Member States' agreement to a proposal that would reintroduce those provisions. A supplementary consultation covering the proposals was launched on 8 May 2008 because the Government would like to make amendments to the Compulsory Scrapie Flocks Scheme (CSFS) to apply the more flexible provisions as soon as possible. However, the relevant new EU legislation has not yet been published in the Official Journal. This means that the proposals in the supplementary consultation cannot be included at this stage.

3. Both consultations closed on 26 June 2008. The consultation packages are available to view online at <http://Defraweb/corporate/consult/tseregs-2008/index.htm>.

Analysis of responses

4. This summary does not cover comments received in respect of the supplementary consultation. This is because the relevant EU legislation will not be published until the end of July at the earliest. A separate summary of responses on issues covered by the supplementary consultation will be published following the publication of the EU legislation.

5. Ten responses to the main consultation were received from the following bodies:

The British Cattle Veterinary Association (BCVA)
The Country Land and Business Association (CLA)
The Local Authorities' Co-Ordinator of Regulatory Services (LACORS)
The National Farmers' Union (NFU)
The Pet Food Manufacturers' Association (PFMA)
The Road Haulage Association Ltd (RHA)
The Society for General Microbiology
SPAR (UK) Ltd
The Trading Standards Institute
Vegetarian Economy & Green Agriculture (VEGA)

5. Of these, two had no comments. The comments of the other eight consultees can be summarised as follows:

Regulation 8

Country Land and Business Association

Accepts the need for this provision but asks that an adequate consultation period be included before any amendments to the RMOP are introduced.

National Farmers' Union

In full agreement that the RMOP should be adapted to take into account changes of a technical or scientific nature. This is a positive step.

Regulation 13

Trading Standards Institute and Local Authorities Co-Ordinators of Regulatory Services

Support clarification of Powers of Entry and welcome the proposal to enable the use of a Warrant issued by a JP to enter premises. This is in line with other legislation enforced by local authorities.

National Sheep Association

Content for the regulations on powers of entry to be clarified as indicated.

National Farmers' Union

Accepts the amendment with regard to powers of entry.

Regulation 15

Trading Standards Institute

Supports the proposal to improve powers of recall when feedingstuffs are found to contain animal products.

Schedule 2

British Cattle Veterinary Association

(i) Can see no reason for not making it an offence to submit brain stem material from an unidentified bovine.

(ii) Welcomes the proposed modification in the 1 before and 2 after rule for 'no test' results. This will reduce unnecessary financial and material waste.

Country Land and Business Association

(i) Argues that making the submission of an unidentified brain stem sample for testing an offence is not the right way to deal with the problem because the problem is not the submitting of a sample but the presence on the line of an unidentified animal, or submitting a sample that cannot be linked to a specific animal. The wording in the Consultation Document may prevent the sampling of animals without identification but where results may be useful for epidemiological purposes. Suggests that the point be revisited and the wording changed.

(ii) Welcomes the change of attitude on "no-tests". The CLA pointed out that the position taken was disproportionate back in May 2005. It should also be pointed out that this disproportionate stance has cost the industry £1.2 million. In a cost sharing environment, the cost of such disproportionate regulation must be kept in mind when apportioning costs between industry and the taxpayer.

Government response to Country Land and Business Association

(i) There are unlikely to be any epidemiological implications in not sampling and testing for BSE any unidentified cattle. In any case, such cattle should not be slaughtered for the food chain. This measure is being introduced because of the potentially serious consequences of abattoir operators allowing a breakdown in correlation between tested brain stem and retained carcass. This could lead to an animal testing positive for BSE entering the food chain. Such breakdowns can be demonstrated by using DNA testing of brain stem and carcass.

(ii) The change in attitude referred to was at the level of the EU. At the time that OTM cattle were allowed back into the food chain (late 2005) it was the written opinion of the EU Commission which led to the application of the one before and two after (1b2a) rule to cattle receiving a 'no test' result. Following subsequent lobbying by the UK, the EU agreed to a relaxation of the 1b2a rule in late 2007, and this was immediately applied to OTM slaughter in the UK. There are therefore no links to the current cost sharing proposals made by Government.

National Farmers' Union

(i) Notwithstanding that the continued rapid decline in the number of bovines testing positive for BSE is a good thing for the UK, the NFU feel it is important that the testing is done to enable the UK to progress towards its target of having a negligible BSE status and to keep consumer confidence. The NFU agree that when any testing is carried out it is important that these samples and results are easily identified, traced and analysed.

(ii) The NFU see the risk based approach to "no tests" in abattoirs is a positive step forward by using evidence based solutions in a positive way without compromising public health and reducing costs and wastage from the red meat supply chain.

Schedule 3

British Cattle Veterinary Association

(i) The introduction of a right to appeal on a decision to cull a cohort is welcomed.

(ii) Will the introduction of the owner paying for the valuation of a cohort animal lead to increased valuations? It is not clear if the owner can appoint his own valuer or if this will be a government appointed valuer in which case would there be a set fee?

Government response to British Cattle Veterinary Association

(ii) Producers have the option of agreeing the valuer with the Secretary of State, without incurring valuation fees. This proposal is in line with current arrangements for scrapie valuations.

Country Land and Business Association

(i) With regard to the appeal process over any decision to cull a cohort animal: suggests that it be specifically stated that the person appointed by the Secretary of State to hear an appellant would not be from the same Department but genuinely independent: otherwise the system falls into disrepute.

(ii) With regard to the clarification that compensation relates to the date of valuation, not the date of slaughter: suggests that, as the keeper has to feed

and house the animal between the dates of valuation and slaughter, if slaughter is more than ten days after valuation, the keeper should be able to ask for the animal to be revalued.

Government response to Country Land and Business Association

(i) The appeals procedure proposed is that described in regulation 10 of the current regulations. This is consistent with the appeals procedure in the Animal By-Products Regulations. The appellant is at leave to challenge the Secretary of State's final determination in the Courts.

(ii) For BSE suspects and offspring and cohorts, the two dates are expected to be the same. Although there may be a delay between valuation and slaughter of cohorts slaughtered in an OCDS abattoir, this is unlikely to be protracted due to the requirement to cull these animals as soon as possible and the possibility of alternative arrangements e.g. on-farm killing. Also as the compensation table values generally apply, the 10 day proposal will only make a difference if valuation and slaughter occur in different months, as the animal's compensation category is fixed at the point the notice of intention to slaughter is served.

National Farmers' Union

(i) Accepts the amendments with regard to appeals.

(ii) Agree with the control of movements with regard to cohorts, alongside a mechanism to apply any appeal process on taking potential cohorts which is clear and evidence based following an inspection.

(iii) Seeks to secure the right for individual valuation of livestock that are compulsorily slaughtered. This is a long held policy position of the NFU, but importantly it is one that ensures that the correct price is paid for any stock that is taken.

(iv) Acknowledge the need for Defra to clarify the point at which the valuation is to be based, is concerned that this does not take account of delays that might occur for example due to a lack of capacity in the slaughter house, leading to additional costs to farmers. Whatever system is implemented it must provide the opportunity for a right to appeal for either farmers or the Government if appropriate where there has been an undue or unforeseen delay to the removal of identified animals.

(v) The NFU does not expect the farmer to pay for the valuation of animals, but see some credibility in there being a bond or fee to enter into any appeal process, which is returned if an appeal is successful.

Government Response to National Farmers' Union

(iii) The table valuation system addresses previous issues with over-compensation (when individual valuations are used); is based on large amounts of contemporaneous market data; is objective, transparent and quick to operate; and provides consistency in the compensation paid for endemic cattle diseases.

(iv) For BSE suspects and offspring and cohorts, the two dates are expected to be the same. Although there may be a delay between valuation and slaughter of cohorts slaughtered in an OCDS abattoir, this is unlikely to be protracted due to the requirement to cull these animals as soon as possible and the possibility of alternative arrangements e.g. on-farm killing. Also as the compensation table values generally apply, the 10 day proposal will only make a difference if valuation and slaughter occur in different months, as the animal's compensation category is fixed at the point the notice of intention to slaughter is served.

(v) In most cases the table valuation system will apply. Where it does not, producers have the option of agreeing the valuer with the Secretary of State, without incurring valuation fees. This proposal is in line with current arrangements for scrapie valuations.

Schedule 4

National Farmers' Union

(i) Scrapie is no longer a public health issue, therefore the schemes should be discontinued and members should decide if they wish to continue with the scheme on the basis that they fund it or close it.

(ii) The NFU will always rely on a science based approach with regard to TSE controls and in the absence of confirmed information on the prevalence of Atypical Scrapie we must have a flexible approach to its control, whichever options are considered it is important that producers have the ability to appeal any decisions and that this appeals process is simple and workable.

Government response to National Farmers' Union

(i) While there is no evidence that atypical or classical scrapie are a risk to public health, and the risk of BSE in sheep and goats is considered to be very low, if present at all, controls on sheep flocks and goat herds with atypical or classical scrapie are still required by EU law (Regulation EC 999/2001 as amended). At present the only options are to implement a whole flock/herd cull or genotype based controls appropriate for classical scrapie.

(ii) Science is of fundamental importance to Defra's policies on BSE, Sheep TSEs and Animal By-Products. Defra coordinates and funds research into TSEs to inform UK policy for public health and animal disease control. This is in addition to the funds spent on other aspects of TSEs such as disease surveillance and scrapie control measures. Defra works closely with the Food Standards Agency (FSA) which leads on policy relating to food safety. The Spongiform Encephalopathy Advisory Committee (SEAC) is the main scientific advisory committee providing advice to UK Ministers on matters relating to TSEs.

Schedule 5

Pet Food Manufacturers' Association (PFMA)

(i) So far as they are aware, their members do not manufacture pet food and livestock feed at the same plant or at the same facility.

(ii) Unable to comment on the effect of this proposal on other production sites.

Schedule 6

Country Land and Business Association

Members have had issues with contamination of feed at the manufacturers. One member took delivery of a load of 'vegetable waste' for feeding to cattle, which turned out to be contaminated with prawns. Suggests that the Regulation should make it clear that the responsibility for ensuring that feedstuffs and their ingredients are not contaminated, and for the costs of compensation and disposal, rests with the supplier, rather than the recipient.

Government response to the Country Land and Business Association

The CLA's example related to contamination of vegetable food waste from a factory. Supply of this description is more relevantly controlled under the

Animal By-Products Regulations 2005. Under the related controls and guidance on former foodstuffs, appropriate HACCP arrangements at the factory for separate handling to prevent the sort of contamination described need to be in place and agreed with the Local Authority. The responsibility for getting these arrangements right rests clearly with the supplier. The supply of a feedingstuff containing prawns, as in the quoted example, or most other animal proteins intended for feeding to cattle, is of course already an offence under the TSE Regulations, and the expense of any recall/disposal required by an inspector would fall upon the supplier as the CLA suggest it should.

National Farmers' Union (NFU)

(i) In agreement that notices served on persons in possession of animal proteins and products containing animal proteins, as well as product recalls for animal proteins and products containing animal proteins need to be done at the earliest point in the supply chain this must be done at the mills and suppliers before they get to producers. If these products to get on to farms then the notices and recalls do need to take place on any producers who are in possession of these products.

(ii) No objections with regard to the proposed changes to the regulation with regard to 'raw pet food consisting of animal proteins' on farms in controlled circumstances.

(iii) Agree that traceability of products is vital, this involves clear labeling and documentation prior to any access to the farm gate to avoid any possible contamination incidents from occurring.

(iv) Seeks to secure the right for individual valuation of livestock that are compulsorily slaughtered. This is a long held policy position of the NFU, but importantly it is one that ensures that the correct price is paid for any stock that is taken.

(v) Acknowledge the need for Defra to clarify the point at which the valuation is to be based, is concerned that this does not take account of delays that might occur for example due to a lack of capacity in the slaughter house, leading to additional costs to farmers. Whatever system is implemented it must provide the opportunity for a right to appeal for either farmers or the Government if appropriate where there has been an undue or unforeseen delay to the removal of identified animals.

Government response to the National Farmers' Union

(iv) The table valuation system addresses previous issues with over-compensation (when individual valuations are used); is based on large amounts of contemporaneous market data; is objective, transparent and quick to operate; and provides consistency in the compensation paid for endemic cattle diseases.

(v) Under this Schedule, the onus would be on the owner or person in charge of the animals to arrange for killing and disposal – so they would be responsible for any delays incurred in this process. In addition, the payment of compensation under this Schedule is discretionary.

Pet Food Manufacturers' Association (PFMA)

(i) Inclusion of raw pet food under Schedule 6 would be a clarification of the current requirements with regard to pet food containing animal protein.

(ii) Difficult to comment on Schedule 6 Paragraph 20 without having seen the proposed Regulations.

Trading Standards Institute and Local Authorities Co-Ordinators of Regulatory Services

Proposed clarification and technical changes should make enforcement more straightforward and bring it into line with other legislation.

Local Authorities Co-Ordinators of Regulatory Services

Notes new powers for inspectors to seize passports of cattle under movement restrictions.

Schedule 7

National Farmers' Union

Encouraged by the joint campaign to get the VC removal age lifted in cattle. However would like a more pragmatic approach to be taken with regard to SRM removal in all species especially Sheep, this is based on the scientific evidence on the prevalence of BSE within the EU. The NFU would like the FSA, Defra and the industry to lobby the EU to amend the regulation to remove the need to remove spinal cord in lambs as this has costs which far outweighs the benefits of this particular technique.

Government response to the National Farmers' Union

The Food Standards Agency is very aware of the industry's concern that the splitting of carcasses reduces their value by 20 - 50%, and that the Community TSE Regulations only require that spinal cord is removed and do not specify the method of removal. As a consequence a number of FBOs in other Member States remove the spinal cord by other methods without splitting the carcass, suction being the most common. The UK has resisted using this method in the past because of concerns about the effectiveness of the method. These concerns have also been noted by Missions by the EU Food and Veterinary Office to a number of Member States where up to 25% of the carcasses examined have contained spinal cord. In addition on a number of occasions consignments of unsplit sheep and goat carcasses have also been found to have spinal cord present.

However Agency officials will shortly be visiting France and Holland to see the 'suction' and 'blowing' methods of removal. In addition the French have developed a new suction method which is claimed to be extremely effective. On return from these visits the Agency will engage with the industry on possible ways forward.

Society for General Microbiology

The proposal to revoke the Beef Bones Regulations, allowing bovine bone marrow back into the human food chain, would seem reasonable because:

- a) no infectivity has been found in bone marrow when injected into cattle (although it has in mice)
- b) bone marrow infectivity would be expected to be at a low level and the number of cases of vCJD has been very low
- c) bone marrow going into the human food chain would come from cattle whose brains had tested negative for BSE.

However:

- a) bone marrow would be expected to carry infection unless scientific evidence was produced to show that this was not the case

b) infectivity would be expected to be present in bone marrow at a different point in the development of the disease from the brain, although this is not the precise finding of BSE experiments in mice

c) as oral infection in cattle peaks in the first month of life and decreases towards the seventh month, and as newborn mice can be infected with exceptionally low doses of infectivity, SRM and bone marrow from cattle should not be used in the formation of feed for calves.

Trading Standards Institute

Welcomes the decision to end the requirement for butchers to be licensed to remove SRM from over 24 month old beef.

General comments

British Cattle Veterinary Association

(i) Welcomes the general tenor of the consultation that enables simplification, clarification and de-regulation of what has become a complex, piece-meal area of legislation.

(ii) With regard to the implementation of the VLA charges to testing laboratories for initial approval and annual quality assurance together with the proposed analysis charge being paid direct by abattoirs, BCVA would suggest that in theory this is acceptable unless the charges become so excessive that the price passed back to the abattoir is potentially so great as to cause small local abattoirs to go out of business.

However, it is felt that transference of costs is more likely to ultimately impinge more heavily at the farm-gate end of the supply chain whereas a shared responsibility would be more equitable.

(iii) Other technical changes to legislation affecting the bringing of animal proteins onto livestock farms especially with regard to pet-foods are logical although difficult to enforce. The risks with such actions, of course, go further than TSE considerations.

Country Land and Business Association

(i) Supports the process outlined in the EU's TSE Roadmap and is in favour of any proportionate measures that will lead to cutting back the bureaucracy and regulation that has grossly overburdened the industry.

(ii) The incorporation of the Bovine and Bovine Products (Restriction and Placing on the Market) (England) (No 2) Regulations 2005 into the proposed Regulations is not 'de-regulatory' because "merely piling the rules into one heap does not reduce the number of rules; neither does it reduce the cost of these rules to the industry".

Local Authorities Co-Ordinators of Regulatory Services

(i) Has already responded to the responsibility and cost sharing consultation and feel that it is not appropriate for them to comment on the proposal to charge for BSE testing, which is more an industry matter.

(ii) However suggests that there should be strict controls on the testing of over 30 month beef before allowing it into the food chain.

(iii) Notes that most of the changes result from EU legislation and that there are not expected to be any additional enforcement costs as a result of these proposals.

National Farmers' Union

- (i) The NFU believe that TSE testing is a public health matter and should be covered by public expenditure.
- (ii) Defra should have discussions with the testing labs with regard to the subject of them having to pay costs. The NFU state that these costs should not be passed back to producers.
- (iii) Defra should fund all TSE surveillance work on fallen stock including older animals after 31 December 2008.
- (iv) Scrapie Regulations should be relaxed as there are no public health implications, thereby cutting costs to both producers and Government.

Government response to comments on responsibility and cost sharing by the British Cattle Veterinary Association and the National Farmers' Union

These issues are being taken forward as part of the current consultation on responsibility and cost sharing.

Government response to comments on Scrapie regulations by the National Farmers' Union

While there is no evidence that atypical or classical scrapie are a risk to public health, and the risk of BSE in sheep and goats is considered to be very low, if present at all, controls on sheep flocks and goat herds with atypical or classical scrapie are still required by EU law (Regulation EC 999/2001 as amended). Changes to the EU rules governing the control measures which are required on farms affected with atypical or classical scrapie have recently been agreed and it is anticipated that these changes will take effect from August 2008. If these changes take effect the competent authority will then have the option to monitor affected flocks / herds for two years from the date of the last case of atypical or classical scrapie. At present the only options are to implement a whole flock/herd cull or genotype based controls appropriate for classical scrapie.

Application of the monitoring option will reduce costs for both producers and Government. Fewer flocks and herds will be subject to compulsory controls for classical scrapie because the voluntary and compulsory control measures for classical scrapie which have been implemented since 2001 have significantly reduced the number of detected cases of classical scrapie. The number of farms affected with atypical scrapie is low and the detected prevalence is relatively static.

Pet Food Manufacturers' Association (PFMA)

Generally supportive of any proportionate measure that can reduce cross contamination.

Society for General Microbiology

- (i) The proposed changes to the existing Regulations are reasonable but cannot be absolutely guaranteed to be risk-free. Probably they represent little microbiological risk to humans.
- (ii) It is necessary to continue with most existing regulations because the presence of BARBs means that BSE cannot be relied upon to have disappeared from a herd simply because it does not contain any cattle that are old enough.

(iii) For every case with BSE symptoms detected at slaughter, a further four or five will also be infected and will go into the food chain. It is therefore necessary to:

- a) test the brain tissue of slaughtered cattle (but realise that the tests are not sensitive enough to pick up all infected cattle)
- b) not use potentially highly infected tissues in the human food chain – evidence concerning human risk is currently poor
- c) continue to remove SRM from material sold for human or animal consumption.

Vegetarian Economy and Green Agriculture (VEGA)

(i) Agree with the proposed amendments, provided the public good is relentlessly championed over any relaxation of the controls and costs incurred by an industry guilty of substantial harm caused to the national economy and wellbeing.

(ii) The industry must therefore be required any levies to ensure that it is indemnified against all extra charges and claims for damages and injury incurred in maintenance of good hygiene and care of livestock (as compared with the running of, say, the bakery and fruit and vegetable sectors). If insurance assessors are not willing to accept such responsibilities and policing, the failing enterprises and their premises must be shut down, even if the bill is not primarily intended for human consumption. These stipulations may entail due diligence on conditions of slaughter for imported meat and other products derived from animals, as well as for hunted and farmed wildlife.

(iii) These conditions would emphasize to the public the true cost of cheap food policies and support the unequivocal recommendations- from DEFRA Ministers and other experts- cut down consumption of alternatives less tainted. The ills of intensification, factory-style productions, and killing (and fast-running slaughter-lines and hurried inspection) would thus be reduced.

(iv) In surveillance of activities in premises in which animals are kept, handled, or killed local lay authorities must be allowed independent entry for either their or deputed lay or professional assessors to investigate complaints from the public as cruelty, nuisance or spread disease in the relevant environs.

Government response to Vegetarian Economy and Green Agriculture

Local Authorities are responsible for enforcing standards of animal hygiene and welfare.

The Way Forward

6. The Government thanks all consultees who responded to the consultation and has taken careful consideration of their views. The Government's priority remains to protect public and animal health and for TSE-related controls to be proportionate to the risks. The Government intends to proceed with its proposals as outlined in the initial consultation.

7. Schedule 4 of the Regulations will not now be amended as proposed in the supplementary consultation. This is because the relevant EU legislation is not now expected to be published until the end of July. However, the Regulations will be amended later this year to reflect the new, more flexible provisions once they have come into effect.