

PROPOSED AMENDMENTS TO THE DOMESTIC TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (NO 2) REGULATIONS 2006 (AS AMENDED)

Summary of consultation responses from stakeholders by issue:

1. The consultation on proposed Amendments to the Domestic Transmissible Spongiform Encephalopathies Regulations 2006 (as amended) was launched on 26 October 2007 and closed on 21 December 2007.
2. The FSA is grateful to those stakeholders who responded.
3. The key proposals on which the consultation sought views were:
 - Proposal to increase the age at which bovine vertebral column (VC) is classified as specified risk material (SRM).
 - Proposal to revoke the Beef Bones Regulations 1997.
 - Proposal to introduce a provision to allow enforcement of EU Rules on Trade.
 - Proposal to amend Schedule 7 to correct references to EU legislation.
4. The Food Standards Agency's considered responses to stakeholders' comments are given in the last column of the table.

Summary of responses to the FSA Consultation on proposed amendments to the Transmissible Spongiform Encephalopathies (No.2) Regulations 2006 (as amended)

No.	Respondent	Method of response	Summary of response	FSA response
A. Proposal to increase the age at which bovine VC is classified as SRM				
1.	Traditional Breeds Meat Marketing Co. Ltd	E-mail	(a) Change is welcome to everyone in the trade. (b) Urge FSA to press for further increase in age limit to 42 months in stages as it is still a major impediment to finishing rare and traditional breeds.	(a) Noted. (b) Both the FSA and EU are continuing to research the risk associated with TSE. The Agency notes your suggestion.
2	The Chartered Institution of Wastes Management	E-mail	No comment, response.	Noted.
3	Stafford Borough Council	Letter + follow-up e-mail	(a) SBC is in full support of the proposed amendments. (b) Proposed change will have positive financial impact as there will no longer be a requirement to authorise butchers. Savings of around £52.65 per visit will be made.	(a) Noted. (b) Noted.
4.	Country Land & Business Association (CLA)	E-mail	Welcome proposed change and hopes this will be the start of a continuing 'roll back' of these regulations. The regulations cause considerable problems and expense to those producing quality beef from cattle that mature more slowly.	Noted. However, current restriction on bovine vertebral column of over thirty months (OTM) animals would continue to apply.

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5.	Crystal Springs Farm	E-mail	<p>(a) The changes have a financial impact of £65/HD cost saving and also a marketing advantage on bone-in cuts.</p> <p>(b) There are no likely benefits or drawbacks in food safety terms.</p> <p>(c) Explore a higher limit than the 30 months limit which the UK has had for 10 years.</p>	<p>(a) Noted.</p> <p>(b) Noted.</p> <p>(c) Noted. Both the FSA and EU are continuing to research the risk associated with TSE. Your suggestion has been noted.</p>
6.	Kirklees Council	Letter	<p>(a) Welcome the proposed change.</p> <p>(b) The proposed change would remove the burden for Butchers to separate the VC waste product as category 1 waste. This would be a cost saving to the food business operator.</p> <p>(c) Removal of requirement to authorise butchers to remove VC SRM would benefit both the business operators and the local authority.</p> <p>(d) Does not think there are any drawbacks to these proposals.</p>	<p>(a) Noted.</p> <p>(b) Noted.</p> <p>(c) Agreed.</p> <p>(d) Noted.</p>
7.	Society for General Microbiology	E-mail	<p>(a) Given the level of consideration on the proposal to change the age at which bovine VC is classified as SRM, support the view that additional risk to consumers from the proposal is negligible.</p> <p>(b) Welcome the change.</p>	<p>(a) Agreed.</p> <p>(b) Noted.</p>

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8.	Meat and Livestock Commission (MLC)	E-mail	<p>(a) Proposed change will allow for greater flexibility of trade and consumer choice.</p> <p>(b) The potential financial impact should be positive, although we are unable to quantify, it is likely to be small.</p> <p>(c) The proposals are thought to have a negligible impact on food safety risk. The proposal restores the previous position.</p>	<p>(a) Agreed.</p> <p>(b) Noted.</p> <p>(c) Agreed.</p>
9.	British Meat Processors Association (BMPA)	Letter	<p>(a) Fully supportive of the proposed change given that it should not have been made except that it was needed to deliver the lifting of the export ban.</p> <p>(b) The proposed change would benefit butchers who can not sell 24 – 30 months bovine under the current rules.</p> <p>(c) Disappointed at EP scrutiny delay</p>	<p>(a) Noted.</p> <p>(b) Agreed. The proposed change would mean butchers would be able to sell bone-in beef from bovine under 30 months.</p> <p>(c) The Agency's letter of 18 December 2007 to BMPA explains that; the Agency shortened its consultation to 8 weeks in order to be able to implement the proposed changes as soon as the EU legislation came into force. However, the timescale was dependent upon the referral of the proposal to the EP by the Commission and the FSA was not in a position to influence this stage of the proceedings. Unfortunately, we understand that due to the requirement</p>

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				to translate the proposal into all the 22 languages, the Commission could not refer the document containing the proposal to the EP until 30 November 2007, at which time the EP had ceased to take referrals in the lead up to Christmas.
10.	Foodaware: The Consumers Food Group	E-mail	Welcome the proposed change which is in line with the revised risk assessment following recommendations of the EC Standing Committee on the Food Chain and Animal Health.	Noted.
11.	Local Authorities Coordinators of Regulatory Services (LACORS)	E-mail	(a) Supports the proposed change. (b) Pleased that proposed change would lead to the authorisation of butchers shops for the removal of vertebral column being unnecessary.	(a) Noted. (b) Noted.
12.	National Beef Association	E-mail	(a) Supports the proposed change given bovine age limit used to be 30 months in the UK. (b) The lower age limit has no benefit for public health, but imposes considerable financial burdens on the beef supply chain. It has resulted in a two tiered pricing system, the disruption caused to wholesalers and retail butchers by the one move and two wholesale cuts rule and the devaluation of over 24 month cattle and	(a) Noted. (b) Noted.

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			<p>beef cuts. A considerable proportion of cattle presented for slaughter are over 24 months due to normal production practices.</p> <p>(c) Delay in EP procedures is unacceptable.</p> <p>(d) There is a significant drop in price paid for cattle over 30 months of age (an average £200/head dead weight). Aware that France is seeking a national measure under article 6 of the TSE Regulations and think that the UK should be doing likewise, bearing in mind that we had different controls measures, including a much earlier effective feed ban.</p>	<p>(c) The Agency's letter of 22 January to NBA explains that the Agency shortened its consultation to 8 weeks in order to be able to implement the proposed changes as soon as the EU legislation came into force. However, the timescale was dependent upon the referral of the proposal to the EP by the Commission and the FSA was not in a position to influence this stage of the proceedings. Unfortunately, we understand that due to the requirement to translate the proposal into all the 22 languages, the Commission could not refer the document containing the proposal to the EP until 30 November 2007, at which time the EP had ceased to take referrals in the lead up to Christmas.</p> <p>(d) As explained in our letter of 22 January, there is a difference in the situation in France and what you suggest we do in the UK. France has taken a more stringent line than the EU legislation requires in relation to TSE monitoring in sheep, early implementation of bovine vertebral column age limit would result in a less stringent regime (in the UK) than currently required by EU law.</p>

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13.	Department Of Health Infectious Disease and Blood Policy Branch	Email	Concerned that the consultation documents do not provide details of the potential risk to human health posed by the proposal. Therefore recommends that the issue be referred to SEAC for its expert advice on the risk to human health.	<p>As mentioned in our letter of 15 January, the Agency consults SEAC for risk assessment advice in relation to TSEs. In 2005 SEAC (at the request of the Agency) reviewed an assessment of the BSE exposure risk from vertebral column. Their conclusion at that time was that the risk from vertebral column in under 30 months cattle is very low and the difference in risk from vertebral column as SRM from 30 months or 12 months cattle at slaughter is very small, verging on negligible, even for any subgroup of individuals who may consume much of the beef on the bone in supply at the time.</p> <p>In addition, EFSA Biohazard Panel published an opinion in May 2007 in which their risk assessment provided evidence to support a change in the age at which bovine VC is classified as SRM. Until May 2006, the age at which bovine VC was SRM was 30 months and this was only harmonised with the rest of the EU at 24 months when UK rules were harmonised with the rest of Europe on the lifting of the beef export ban.</p>
B. Proposal to revoke the Beef Bones Regulations 1997				
1.	Country Land & Business Association (CLA)	E-mail	(a) Revocation of the Beef Bones Regulations is entirely sensible.	(a) Noted.

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			(b) The revocation will do away with the ridiculous situation of UK sourced beef bones being replaced by imported bones from countries with little or poor health records.	(b) Noted.
2.	Crystal Springs Farm	E-mail	Removing the ban on the use of UK beef bones will remove the cost of disposal, it will however, provide potential income.	Noted.
3.	Society for General Microbiology	E-mail	<p>(a) Support proposal. As the EC TSE regulations apparently do not require this measure, there is no good reason why revocation from the English Regulations should not be carried out.</p> <p>(b) An upper age limit on the animals whose bones are processed should be considered.</p>	<p>(a) Noted.</p> <p>(b) As there is a lack of data on the presence of TSE infectivity in bones, there is no scientific basis on which the FSA could consider an upper age limit. There is already a prohibition on cattle born or reared in the UK before 1 August 1996 entering the food chain.</p>
4.	Meat and Livestock Commission	E-mail	<p>(a) The proposal to revoke the Beef Bones Regulations 1997 is welcomed.</p> <p>(b) Removal of the manufacturing ban on the use of UK beef bones will allow for greater flexibility of trade and consumer choice.</p> <p>(c) Hope that the revocation will create a market for UK beef bones although the</p>	<p>(a) Noted.</p> <p>(b) Noted.</p> <p>(c) Noted.</p>

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			value is likely to be negligible, it may assist in defraying disposal costs.	
5.	Local Authorities Coordinators of Regulatory Services (LACORS)	E-mail	Support the proposal to revoke the beef bones regulations.	Noted.
6.	National Beef Association	E-mail	Supports the proposal to revoke the Beef Bones Regulations 1997.	Noted.

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7.	Human BSE Foundation	Questionnaire	<p>(a) I see quite a few references to allowing bone and bone marrow to be used in manufacturing food or used in food processing. Who is this food for?</p> <p>(b) Does the resulting food have clear labels which indicate that it contains this material?</p>	<p>(a) Beef bones containing bone marrow are used in stocks and soups.</p> <p>(b) Food labelling rules do not require the labelling of “bones” or “beef bones” on the ingredient list of beef stock. The ingredient list is a declaration of all the ingredients added/present in the food. As bones are not present in the final food, they do not need to be declared. Although there are no requirements to indicate bone and bone marrow on the label, consumers wishing to avoid products made with beef bones can contact the manufacturer directly for further information. The current restrictions prohibit the use in food only of UK bones but not imported bones, which may come from countries with a BSE risk similar to that in the UK.</p>

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8.	The Department of Health Infectious Disease and Blood Policy Branch	E-mail	Concerned that the consultation documents do not provide details of the potential risk to human health posed by the proposal. SEAC advice dates from 2003, therefore recommends that the issue be referred to SEAC for its expert advice on the risk to human health.	The SEAC Secretariat has been consulted and has confirmed that a literature search produced no new information that would alter SEAC's stated view. There is therefore no basis for seeking an updated opinion from SEAC.

C. Proposal to introduce a provision to allow enforcement of EU rules on trade

1.	Meat and Livestock Commission	E-mail	No position is adopted on the proposal on EU rules on trade. Given that the responsibility for food safety now rests with food business operators the EU should consider whether the restrictions on trade should be reviewed and greater responsibility passed to food business operators.	Proposal does not place restriction on trade.
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D. Proposal to amend Schedule 7 to correct references to EU legislation

1.	Meat and Livestock Commission	E-mail	Amending domestic legislation to reflect changes in Community legislations to ensure continuing compliance with Community legislation would seem the most sensible option.	Noted.
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E. Comments on other TSE issues				
1.	Crystal Springs Farm	E-mail	(a) Remove carcass splitting in older sheep as ovine BSE has now been discounted.	(a) In the Agency's view, the most effective way of removing spinal cord SRM in sheep and of verifying its removal is still splitting. It has been found that where suction method is used, in some cases 20 – 25% of carcasses still contained spinal cord SRM. Although BSE has not been found to naturally occur in sheep, it is known that some sheep consumed the same feed that is thought to have caused the spread of BSE in cattle. In addition, sheep have been infected with BSE under laboratory conditions; it is possible therefore that BSE has occurred in sheep but that it has been masked by or diagnosed as Scrapie. In addition, another brain disease in sheep, atypical scrapie, has recently been identified. This disease is a TSE like "classical scrapie" and BSE but is distinct from both. Atypical scrapie is thought to be relatively widespread in the UK, in fact, more widespread than classical scrapie. It is SEAC's view that although atypical scrapie is not BSE, and there is no evidence that it can be transmitted to humans, a human health risk cannot be ruled out. SEAC have advised further research into whether atypical scrapie might be a risk to human and the Agency is currently undertaking this.

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			(b) Bring 1996 cattle into the food chain as they can now be tested for BSE.	(b) Community legislation prohibits cattle born or reared in UK before 1 August 1996 from entering the food chain – date of introduction of re-enforced feed ban.
2.	Meat and Livestock Commission	E-mail	The age of the youngest cases of BSE continues to increase according to the statistics published by DEFRA. It may therefore be opportune to review the appropriateness of the current controls on a risk assessment basis and in particular the age at which material is classified as SRM.	Both the FSA and EU are continuing to research the risk associated with TSE. The Agency notes your suggestion.
3.	British Meat Processors Association	Letter	It is high time there was a review of both the TSE Regulations and the domestic rules/guidance implementing those regulations. For too long the TSE controls have been disproportionate to the risk and whilst the VC changes are a good step, further progress with both the EU road map and the UK implementation are needed. We need to urgently address both the regulations and the enforcement regime which has built on the back of the current rules.	The FSA and the Rural Affairs Departments are taking an active part in European negotiation of changes to the BSE surveillance programme in line with the TSE Roadmap. In 2007, the European Commission started discussing eligibility criteria for Member States wishing to apply for more proportionate BSE surveillance programme. Following the views of a majority of Member States, the Commission decided to progress with a uniform approach to a reduced BSE surveillance programme for eligible Member States. In January 2008, the Commission asked the European Food Safety Authority to consider a number of options for reducing surveillance by increasing the testing age limits. The Commission continues to negotiate the eligibility criteria with Member States in parallel.

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				<p>The UK has in agreement with the Commission recently modified the application of the “1 before 2 after” rule in cases where a poor quality brain stem sample classified as a “no test” yields conclusive negative result following the application of 3 rapid post mortem tests.</p> <p>FSA has begun to reduce official levels of supervision of SRM controls and as part of the process, we are introducing a more proportionate enforcement regime.</p>
4.	National Beef Association	E-mail	<p>Urge that immediate consideration is given to reviewing UK BSE control measures. This debate is now starting in EU within the context of the TSE Roadmap and against the background of rapidly declining BSE incidence.</p>	<p>The FSA and the Rural Affairs Departments are taking an active part in European negotiation of changes to the BSE surveillance programme in line with the TSE Roadmap. In 2007, the European Commission started discussing eligibility criteria for Member States wishing to apply for more proportionate BSE surveillance programme. Following the views of a majority of Member States, the Commission decided to progress with a uniform approach to a reduced BSE surveillance programme for eligible Member States. In January 2008, the Commission asked the European Food Safety Authority to consider a number of options for reducing surveillance by increasing the testing age limits. The Commission continues to negotiate the</p>

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