

EXPLANATORY MEMORANDUM TO

THE TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (No.2) (AMENDMENT) REGULATIONS 2008

2008 No. 1180

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. **Description**

2.1. Following an amendment to the directly applicable Community TSE Regulations (EC No 999/2001), this instrument enables the Food Standards Agency (FSA) to implement the changes to the rules on specified risk material (SRM) at approved meat establishments and authorised butchers in England.

3. **Matters of special interest to the Joint Committee on Statutory Instruments.**

3.1. The instrument breaches the 21 day rule because the amendment is EU driven and the timescale for introduction is very tight. The Community Regulation comes into force on 26 April, 3 days after its publication in the Official Journal. The Regulation becomes binding on all Member States from that day. The domestic legislation must, therefore, be made and come into force on 26 April in order to implement the changes to these public health protection measures.

3.2. *Timing*

The instrument needs to come into force on 26 April. Until it comes into force, the change in SRM controls which could significantly reduce industry costs without increasing risk to consumers will not be implemented.

4. **Legislative background**

4.1. Regulation (EC) 999/2001 of the European Parliament and of the Council (the Community TSE Regulation) lays down the rules for prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE). These rules are currently implemented in England through the Transmissible Spongiform Encephalopathies (No. 2) Regulations 2006 (as amended) (the domestic TSE Regulations).

4.2. In particular, Annex V of the Community TSE Regulation contains the SRM controls, these controls are implemented in England by Schedule 6 of the domestic TSE Regulations.

4.3. The European Commission adopted a proposal to increase the age at which bovine vertebral column (VC) is classified as SRM from 24 months to 30 months on 22 April. The legislation amending the Community TSE Regulation was published on 23 April and comes into force in all Member States on 26 April. The amending Regulations will apply to animals slaughtered on or after 26 April.

5. **Territorial Extent and Application**

5.1 This instrument applies in England. Similar regulations are being introduced in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 Policy

7.1.1. The amendment to Annex V of the Community TSE Regulation that was published in the Official Journal on 23 April comes into force on 26 April. It increases the age at which bovine VC is classified as SRM from 24 months to 30 months.

7.1.2. The main purpose of the Transmissible Spongiform Encephalopathies (No. 2) (Amendment) Regulations 2008 is to implement this change in England. This amendment would return the VC SRM age limit in England to its position before May 2006, when UK SRM controls were harmonised with those in all other Member States as part of the process for lifting the export ban on UK beef and beef products. Some additional relatively minor amendments have also been included in the instrument. These are:

- Revocation of the Beef Bones Regulations 1997 (as amended). These Regulations currently impose a ban on the use of UK sourced beef bones in food manufacturing. This ban was kept in place when the ban on the retail sale of bone-in beef was lifted in 1999 and is the last remaining piece of national legislation introduced to protect consumers from BSE risk before the EU-wide legislation was adopted in 2001. The ban goes beyond the measures required under EU law and, with the other measures in place, makes little or no contribution to public health protection.
- Introduction of a provision implementing a current EU requirement that Member States wishing to export heads or un-split carcasses containing SRM must obtain the agreement of receiving Member States before dispatch.
- updating of some cross-references to the Community TSE legislation.
- Further changes have been made to the Regulations following consultation, this include introduction of some transitional arrangements. These would allow a short period during which current authorised butchers and all cutting plants could remove VC from 24-30 month bovines slaughtered before 26 April. The VC from these animals would still be required to be disposed of as SRM. These changes follows comments from industry (arising from the consultation but outside of the consultation period) about the potential impact on trade of the 24-30 month carcasses containing VC SRM which may already be in the distribution chain when the above Regulations come into force. In addition, a couple of technical changes were made to the Regulations in order to ensure the definition of SRM in the domestic Regulation is fully in line with that in the Community TSE Regulation.

7.2 Consultation

7.2.1. Over 900 stakeholders in England were consulted over a eight week period, including consumer organisations, industry representative organisations and operators of approved red meat establishments. Only 14 substantive responses were received, most of these were supportive of the proposed amendments. A summary of the responses can be found on the Agency's website. A respondent expressed concern that the consultation documents did not provide details on the risk to public health of the proposals to increase the age at which bovine vertebral column is classified as SRM and revocation of the Beef Bones Regulations 1997. Another expressed concern about the use of bovine bones in food manufacture. The Agency has therefore written directly to each of these respondents to clarify the issues they raised.

7.3. *Guidance*

- 7.3.1. The Agency will notify stakeholders when the change will come into force and update the 'Meat Industry Guide to Food Hygiene and Other Regulations' to take account of the changes after the instrument comes into force.

7.4 *Sanctions*

- 7.4.1 The Agency will remain responsible for enforcement, sanctions and monitoring for Schedule 6 of the Regulations at approved meat establishments.

8. Impact

- 8.1 The instrument will have a positive impact on UK businesses. An Impact Assessment is attached to this memorandum.

9. Contact

Mrs Olukayode Odukoya at the Food Standards Agency Tel: 020 7276 8333 or e-mail: olukayode.odukoya@foodstandards.gsi.gov.uk can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency: Food Standards Agency	Title: Impact Assessment of The Transmissible Spongiform Encephalopathies (TSE) Regulations 2008	
Stage: Consultation	Version: 3	Date: 24 April 2008
Related Publications:		

Available to view or download at:

<http://www.food.gov.uk>

Contact for enquiries: Kenny Odukoya

Telephone: 020 7276 8333

What is the problem under consideration? Why is government intervention necessary?

Changes to EU rules need to be reflected in the domestic Regulations which provide enforcement powers in England. EU rules for the prevention, control and eradication of Transmissible Spongiform Encephalopathies (TSEs) are enforced under domestic law by the TSE Regulations (No 2) 2006 (as amended) (the domestic Regulations). The proposals will maintain proportionate consumer protection from BSE related risk without adding to industry or enforcement costs.

What are the policy objectives and the intended effects?

In line with our strategic plan objective to deliver proportionate TSE controls based on scientific knowledge and compliance with EU law/obligations, the proposal on vertebral column SRM would see the age limit at which bovine vertebral column is classified as Specified Risk Material (SRM) increase from 24 to 30 months (the UK position before May 2006). Proposals on revocation of the Beef Bones Regulations 1997 and on rules on EU trade will keep UK rules in line with Community law. Proposed amendment to Schedule 7 would update the references to the Community Regulations

What policy options have been considered? Please justify any preferred option.

- (1) Maintain the current Regulations (Do nothing)
- (2) Adopt the proposed changes (amend the Regulations)

Following consultation, the preferred option, Option 2 was chosen.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? April 2010

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Dawn PrimaroloDate: **24th April 2008**

Summary: Analysis & Evidence

Policy Option: 2	Description: Amend existing SRM controls and change Regulations as soon as they come into force in Member States
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COSTS	ANNUAL COSTS	Description and scale of key monetised costs by 'main affected groups'	
	One-off (Transition) Yrs		
	£ 0		
	Average Annual Cost (excluding one-off)		
	£ 0	Total Cost (PV)	£ 0
Other key non-monetised costs by 'main affected groups'			

BENEFITS	ANNUAL BENEFITS	Description and scale of key monetised benefits by 'main affected groups' Cutting plants (CPs) and authorised butchers will no longer be required to remove, stain and dispose of vertebral column (VC) of 24-30 months bovines as SRM. The Meat Hygiene Service and local authorities will no longer need to enforce SRM controls in relation to VC from 24-30 months bovines in CPs and butchers respectively.	
	One-off Yrs		
	£ 0		1
	Average Annual Benefit (excluding one-off)		
	£ 2 million	Total Benefit (PV)	£ 2 million
Other key non-monetised benefits by 'main affected groups' Bones (including vertebral column) from cattle deboned in the UK could be used in the manufacture of processed food products instead of being disposed off as animal by-product. Butchers, cutting plants and slaughterhouses would benefit. In addition, there would be an increase in consumer choice.			

Key Assumptions/Sensitivities/Risks

Price Base Year 2007	Time Period Years 1	Net Benefit Range (NPV) £	NET BENEFIT (NPV Best estimate) £ 2 million
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What is the geographic coverage of the policy/option?	England				
On what date will the policy be implemented?	29/04/ 2008				
Which organisation(s) will enforce the policy?	MHS/LAs				
What is the total annual cost of enforcement for these organisations?	£ Small decrease				
Does enforcement comply with Hampton principles?	Yes				
Will implementation go beyond minimum EU requirements?	No				
What is the value of the proposed offsetting measure per year?	£ negligible				
What is the value of changes in greenhouse gas emissions?	£ N/A				
Will the proposal have a significant impact on competition?	No				
Annual cost (£-£) per organisation (excluding one-off)	<table style="width: 100%; border: none;"> <tr> <td style="width: 25%; text-align: center;">Micro -£3,500</td> <td style="width: 25%; text-align: center;">Small -£3,500</td> <td style="width: 25%; text-align: center;">Medium</td> <td style="width: 25%; text-align: center;">Large</td> </tr> </table>	Micro -£3,500	Small -£3,500	Medium	Large
Micro -£3,500	Small -£3,500	Medium	Large		
Are any of these organisations exempt?	<table style="width: 100%; border: none;"> <tr> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%; text-align: center;">No</td> </tr> </table>	No	No	No	No
No	No	No	No		

Impact on Admin Burdens Baseline (2005 Prices)				(Increase - Decrease)
Increase	£	Decrease	£ 130,000	Net £ -130,000

Key: Annual costs and benefits: Constant Prices (Net) Present Value

Evidence Base (for summary sheets)

1. Introduction and legislative background

(a) Transmissible Spongiform Encephalopathies (TSEs) are fatal brain diseases suffered by a variety of species, the most common of which are BSE (Bovine Spongiform Encephalopathy) in cattle and Scrapie in sheep and goats. Exposure to BSE through the consumption of infected meat products is thought to be the most likely cause of vCJD (variant Creutzfeldt-Jakob Disease) in humans. As at 3 January 2008, there have been 161 deaths from probable vCJD in the United Kingdom (UK).

(b) Measures for the prevention, control and eradication of TSEs within the European Union are provided by Regulation (EC) No 999/2001 of the European Parliament and the Council (the Community TSE Regulations). The Transmissible Spongiform Encephalopathies (No. 2) Regulations 2006 (as amended) (the domestic Regulations) provide for the administration and enforcement of the Community TSE Regulations in England.

(c) Under Regulation (EC) 999/2001 (as amended), the vertebral column of bovine animals over 24 months of age at slaughter is designated specified risk material (SRM) and must therefore be removed, stained and destroyed. As such it must not enter the human food or animal feed chains. This requirement is implemented in England by the domestic Regulations.

(d) In May 2006, following the UK attaining the same controlled BSE risk status as other Member States (MS), SRM controls in the UK were harmonised with those applicable in other Member States, when the ban on the export of UK beef and beef products was lifted. Prior to that time, the UK had a derogation to classify VC as SRM only in animals over 30 months of age at slaughter. The Spongiform Encephalopathies Advisory Committee (SEAC), the UK independent advisory committee advised at that time that there was negligible risk benefit in moving to 24 months. When harmonisation took place in May 2006, the 24 months limit became applicable to the UK, this meant that the age at which bovine VC was classified as SRM changed from 30 months to 24 months.

(e) To help reduce the impact of this change on industry the Food Standards Agency (FSA) agreed to take advantage of a derogation provided under EU law to also allow the removal of bovine VC from 24-30 month old animals in specifically authorised butcher shops.

(f) As part of the EU TSE road map, which aims at maintaining a high level of consumer protection while reviewing SRM rules based on new and evolving scientific knowledge, the European Food Safety Authority (EFSA) Biohazard panel was invited to provide an opinion on the assessment of the likelihood of the infectivity in SRM derived from infected cattle at different age groups. The Opinion published on 11 May 2007 provided evidence to support a change to increase the age at which bovine VC is classified as SRM. Following publication of the opinion, the Commission put forward a formal proposal to the Standing Committee on the Food Chain and Animal Health (SCoFCAH). On 3 October SCoFCAH voted unanimously in favour of the increase in the age at which bovine VC is classified as SRM from 24 to 30 months. The proposal has been subjected to a three month scrutiny period by the European Parliament and Council. In both cases, the outcome of the scrutiny procedure was positive, the proposal should therefore now come into force at the end of April 2008.

2. Proposal on VC age limit:

Of all the 13 comments received on this proposal, 11 were in support of the proposed change, 1 expressed no opinion on it and 1 concerned that the consultation document did not provide details on the risk to public health of the proposal, we have therefore written to the stakeholder to clarify the issue.

- (a) This amendment would allow cutting plants and butchers to be able to operate in the way they did before SRM controls were first harmonised in May 2006. Cutting plants and authorised butchers would make some savings on SRM disposal as they would no longer need to stain and dispose of up to 30 month VC as SRM. This is estimated by the Meat and Livestock Commission (MLC) to be around £3500 per butcher per year. There are 509 authorised butchers in England so the potential savings to butchers of approximately £1.8 million could accrue.
- (b) Cutting plants should also benefit from reduced costs as a result of the change, but we are unable to estimate the value of this.
- (c) The industry have maintained that the rule change in May 2006 has caused a two tier market for animals less than 24 months of age and those between 24 -30 months of age with a decrease in price being paid for the latter. The Meat Trades Journal of 12 October 2007 estimated this at 25p/kg (dead weight), and that this could mean an additional cost of up to £100 per animal. The return to the 30 month age limit would remove this price differential.
- (d) In addition, local authorities will make some savings as they would no longer be required to authorise butchers for VC SRM removal. This is estimated at around £60 per inspection visit and it is assumed that 2 visits are made per annum; the total savings therefore is:
 $£60 \times 2 \times 509 \cong £61,000$ per annum.
- (e) An important unquantifiable benefit is the removal of the restrictions on movement of bone in beef carcasses. This will allow much more flexibility in the market and allow much greater movement between cutting plants, wholesalers and butchers thereby aiding businesses. In addition, butchers will once again be able to trade in beef on the bone (e.g. t-bone steaks) from traditional breeds of slower maturing cattle.
- (f) Further more, the proposal would allow (in addition to sale of bone in cuts from bovine up to 24 months) bone in cuts from 24 – 30 month to be sold to the public thereby increasing consumer choice, with negligible increase in BSE risk.

3. Proposal on EU rules on trade:

The only comment received on the proposal was neither for nor against it. Although we requested for information on potential up take of this provision and the impact it would have on industry, none of the response received provided any such information. Whilst the Agency is aware that the proposal could impose an insignificant administrative burden on the industry, we are unable to quantify the burden.

- (a) This amendment implements an existing Community requirement on intra-Community trade that is not included in the current domestic regulations but would now be included in Schedule 6. This will have a minor impact on Food Business Operators (FBOs). If an FBO wishes to export bovine heads or meat containing SRM (un-split sheep carcasses over 12 months of age, for example) to another MS they must ask the FSA to obtain the required agreement of the competent authority in the receiving Member State to receive the material.
- (b) We appreciate that this procedure may impose a small administrative burden on businesses. However this is not a new requirement as it was already included in the EU legislation, it is just a case of correcting the domestic legislation to ensure it reflects the EU rules. We do not believe the procedures will be onerous for businesses. The FSA has only received one request from a business wanting to trade carcasses containing SRM to a Member State over

the last four years and we are not aware of any businesses currently making use of the provision.

4. Proposal to revoke the Beef Bone Regulations 1997:

Of all the 8 comments received on this proposal, 6 were in support of the proposed change, 2 expressed some concern, we have since written to the stakeholders concerned to clarify the issues.

- (a) The Beef Bones Regulations¹ impose a ban on the use of UK beef bones in manufactured and processed food, and are the last remaining piece of national legislation introduced to protect consumers from BSE before the Community TSE Regulations were adopted. Much of the public health risk linked with beef bones comes from the dorsal root ganglia associated with vertebral column which are subject to the EU SRM controls. The beef bones ban goes beyond the measures required by the Community TSE Regulations and can no longer be considered to make a significant contribution to public health protection (see Annex 7 of the consultation documents).
- (b) Revocation of the ban would mean the bones could be used in manufactured and processed food. We have been unable to quantify the benefit of this proposal. However, enquiries made from time to time as to the use of UK beef bones indicate a market for UK beef bones.

5. Proposed amendment to Schedule 7 Regulations:

The only comment received on the proposal was in support of the proposed change.

Paragraph 2 of Schedule 7 is being amended to refer to the correct section in the Community Regulations. Currently that paragraph refers to annex XI of the Community Regulations, which has been revoked and replaced with a new annex V. This change will not impose additional burdens on industry or any other stakeholders as the requirements of the regulation are unchanged.

6. General view

The proposed amendments to the Regulations would provide industry savings to the UK of around £2 million per annum. In addition, there is a potential small reduction in enforcement costs and an increase in consumer choice.

¹ [Beef Bones Regulations 1997 \(SI No. 2959\)](#), as amended by the [Beef Bones \(Amendment\) \(England\) Regulations 1999 \(SI No. 3371\)](#)

Specific Impact Tests: Checklist

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	No

EU Annex

The European Community legislation, Regulation EC 999/2001 (as amended) lays down the rules for prevention, control and eradication of certain TSE. These rules are implemented in the UK by the Transmissible Spongiform Encephalopathies (No 2) Regulations 2006 (as amended) (the Regulations); and require the removal of specified risk material (SRM) which are those parts of cattle that are most likely to contain infectivity in infected animals. SRM is removed at slaughterhouses, cutting plants or authorised butcher's shops (as specified in the Regulations), stained and sent for destruction. This measure is estimated to remove almost all of infectivity from infected animals if such an animal was to enter the food chain. However, the risk of an infected animal entering the food chain is very small. No animal showing symptoms of BSE is permitted to enter the food chain.

Furthermore, there is also a requirement for BSE testing in older cattle. Cattle aged over 30 months at slaughter must test negative for BSE before they are allowed to enter the food supply. Any cattle that do not test negative are banned from the food chain and destroyed. All cattle born before the introduction of the reinforced feed ban in August 1996 continue to be excluded from the food chain. There is also control on animal feed.

These TSE controls are based on current scientific knowledge and are designed to reduce the risk to consumers to an extremely low level. The EU has drawn up a TSE road map which sets out its short, medium and long term BSE strategy for future policy development. These include different areas such as the definition of SRM, the age of testing and the feed ban.

Competition Assessment

The proposals would not distort competition.

The change in age limit and revocation of the Beef Bone Regulations are deregulatory measures that should increase competition in the relevant sectors while the rules on trade aim to create a level-playing field across the EU and will help foster EU-wide competition. The proposal on VC age change will eliminate the present price differential between under 24 month beef and over 24 month beef which the industry believes has existed since the harmonisation measures were introduced in May 2006.

Small Firms Impact Test

The proposal on VC age limit will be beneficial to small businesses and would provide a saving of around £2 million per annum to the meat industry (through reduction in burden on butchers) as estimated by the Meat and Livestock Commission. The FSA worked closely with key industry representative organisations such as the Association of Independent Meat Suppliers, National Farmers Union, Independent Meat Traders Association, British Meat Processors Association and National Federation of Meat and Food Traders in taking the proposal to increase age limit at which bovine vertebral column is classified as SRM forward. These organisations strongly support the proposal and have advised that it would particularly benefit small to medium sized businesses although no figures were provided.

Sustainable development

The proposed amendment to the Regulations is in accordance with the shared UK (and Agency's) principles of sustainable development. The proposals would have positive economic impact, and help to sustain local, specialised businesses. However, there would be no significant social (as risk to public health would be negligible) or environmental impact.

Race equality issues

The proposed amendment to the Regulations would not impose any restriction or involve any requirement which a person of a particular racial background would find difficult to comply with. The rules apply equally to all individuals and businesses involved in the activities covered by the proposed amendment irrespective of their race.

Gender equality issues

The proposed amendment to the Regulations would not impose any restriction or involve any requirement which a person of a particular gender would find difficult to comply with. The rules apply equally to all individuals and businesses involved in the activities covered by the proposed amendment to the Regulations.

Disability equality issues

The proposed amendment to the Regulations would not impose any restriction or involve any requirement which a person of a particular disability would find difficult to comply with. The rules apply equally to all individuals and businesses involved in the activities covered by the proposed amendment to the Regulations.

We therefore believe that the benefits of implementing the proposals significantly outweigh the costs.