

EXECUTIVE NOTE TO

THE TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (SCOTLAND)
AMENDMENT REGULATIONS 2008 (SSI 2008/166)

The above instrument is made under powers conferred by section 2(2) of the European Communities Act 1972(a) and of all other powers enabling them in that behalf. The instrument is subject to negative resolution procedure.

Issue

1. Following an amendment to the directly applicable Community TSE Regulations (EC No 999/2001), this instrument will enable the Food Standards Agency (FSA) to implement the changes to the rules on specified risk material (SRM) at approved meat establishments and at authorised butchers' premises in Scotland.
2. This 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 2008, 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 or as soon as possible afterwards in order to implement the changes to these public health protection measures.

Legislative Background

3. Regulation (EC) No. 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 Scotland through the Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006 (as amended) (the domestic TSE Regulations).
4. In particular, Annex V of the Community TSE Regulation contains the SRM controls. These controls are implemented in Scotland by Schedule 6 of the domestic TSE Regulations.
5. The European Commission adopted a proposal to increase the age at which bovine vertebral column (VC) is classified as SRM from 24 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.

Extent

6. The Regulations extend to Scotland only. Parallel legislation has been made in England, and is being proposed in Wales and Northern Ireland.

Policy Background

7. 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.
8. The main purpose of the Transmissible Spongiform Encephalopathies (Scotland) Amendment Regulations 2008 is to implement this change in Scotland. This amendment would return the VC SRM age limit in Scotland 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.
9. Some additional relatively minor amendments have also been included in the instrument. These are:
 - revocation of the Beef Bones Regulations 1999. 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.
10. Further changes have been made to the Regulations following consultation, including the introduction of some transitional arrangements. These would allow a short period during which currently 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 follow 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, 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.

Consultation

11. Approximately 170 stakeholders in Scotland were consulted over an eight week period, including industry representative organisations and operators of approved red meat establishments. Three responses were received, and none were unsupportive with regard to the proposed amendments. A summary of the responses may be found on the FSA website.

Guidance

13. The Agency will notify stakeholders when the change comes 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.

Sanctions

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

Impact

13. This instrument will have a positive impact on businesses. A Regulatory Impact Assessment is attached to this note.

FOOD STANDARDS AGENCY SCOTLAND

24 April 2008

Contact:

Karen McCallum-Smith, Food Standards Agency, St Magnus House, 25 Guild Street, Aberdeen, AB11 6NJ

Tel: 01224 285164

Karen.mccallum-smith@foodstandards.gsi.gov.uk

www.food.gov.uk

Final Regulatory Impact Assessment (RIA)

1. The Transmissible Spongiform Encephalopathies (Scotland) Amendment Regulations 2008

- 1.1. The proposal is for amendments to Schedules 6 and 7 of The Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006, and revocation of the Beef Bones Regulations 1999. Changes to EU rules need to be reflected in the domestic Regulations which provide enforcement powers in Scotland. EU rules for the prevention, control and eradication of Transmissible Spongiform Encephalopathies (TSEs) are enforced under domestic law by the Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006 (as amended) (the domestic Regulations).

2. Purpose & intended effect

2.1 The Objectives

- 2.1.1. The proposals are in line with the FSA strategic plan objective to deliver proportionate TSE controls based on scientific knowledge and compliance with EU law/obligations. The proposals will maintain proportionate consumer protection from BSE related risk without adding to industry or enforcement costs. The proposal on vertebral column specified risk material would see the age limit at which bovine vertebral column (VC) 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 1999 and on rules on EU trade will keep Scottish rules in line with Community law. The proposed amendment to Schedule 7 would update the references to the Community Regulations.

2.2. Devolution

- 2.2.1. The proposed amendments will apply in Scotland only. England, Wales and Northern Ireland will make separate but parallel amendments.

2.3. Background

- 2.3.1. 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), 22 of which were in Scotland.
- 2.3.2. 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 (Scotland) Regulations 2006 (as

amended) (the domestic Regulations) provide for the administration and enforcement of the Community TSE Regulations in Scotland.

- 2.3.3. 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 as such must be removed, stained and destroyed. It must not enter the human food or animal feed chains. This requirement is implemented in Scotland by the domestic Regulations.
- 2.3.4. In May 2006, following the UK attaining the same controlled BSE risk status as other Member States, 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 bovine vertebral column (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, and this meant that the age at which bovine VC was classified as SRM changed from 30 months to 24 months.
- 2.3.5 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 allow the removal of bovine VC from 24-30 month old animals in specifically authorised butcher shops.
- 2.3.6 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 vertebral column 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 an 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, and the proposal comes into force on 26 April 2008.

2.4. Rationale for Government intervention

- 2.4.1. Changes to EU rules need to be reflected in the domestic Regulations which provide enforcement powers in Scotland. EU rules for the prevention, control and eradication of Transmissible Spongiform Encephalopathies (TSEs) are enforced under domestic law by the Transmissible Spongiform Encephalopathies

(Scotland) Regulations 2006 (as amended) (the domestic Regulations). The proposals will maintain proportionate consumer protection from BSE related risk without adding to industry or enforcement costs.

3. Consultation

- 3.1. A public consultation on the proposed amendments to the domestic Regulation took place between 26 October and 21 December 2007. Of the 170 stakeholders consulted, only 3 substantive responses were received, and these were supportive of the proposed amendments.

4. Options

4.1. Changes as a result of amendments to the Community TSE Regulation

- 4.1.1 The Community TSE Regulation provides measures for the prevention, control and eradication of TSEs within the EU, and sets out the definition of SRM and the requirements on where and how it must be removed. These measures are binding on all Member States. The Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006 (as amended) provide for the administration and enforcement of the Community TSE Regulation in Scotland. The options considered to implement the amendment to the Community TSE Regulation in Scotland are:

- i. Option 1 - do nothing; and
- ii. Option 2 - amend existing SRM controls and change domestic Regulations to reflect changes to Community Regulation as soon as they come into force in Member States.

4.1.2. Analysis of options

- i. Option 1 (doing nothing) would mean that no amendments are made to the domestic TSE legislation so that Scotland would not be compliant with Community obligations. This would also mean that domestic SRM rules would not be in line with EU rules, thereby leaving industry and consumers in Scotland disadvantaged in relation to those in other Member States.
- ii. Option 2 would ensure continuing compliance with Community legislation. It would ensure that SRM rules in Scotland are in line with EU rules and would assist the Scottish industry as it will reinstate the position before May 2006. This will also increase consumer choice as consumers will once more have the option of buying bone-in beef sourced from 24-30 month old cattle. There are no significant additional administrative costs or economic, social or environmental impacts associated with this option.

5. Costs and benefits

5.1. Sector and groups affected

- 5.1.1. The meat industry, principally operators of approved red meat establishments and butchers, and consumers.
- 5.1.2. We consider that the proposal will have no impact on racial equality, social or environmental issues.

5.2. Costs and Benefits

A: Proposal on age limit for vertebral column SRM

Costs

Option 1

- 5.2.1. Doing nothing would mean that no amendments are made to the domestic TSE legislation so that Scotland would not be compliant with Community obligations, and domestic SRM rules would not be in line with EU rules, thereby leaving industry and consumers in Scotland disadvantaged in relation to those in other Member States.

Option 2

- 5.2.2. There are no costs attached to Option 2.

Benefits

Option 1

- 5.2.3. There are no benefits attached to Option 1.

Option 2

- 5.2.4. This amendment would allow cutting plants and butchers 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 24-30 month bovine vertebral column as SRM. This cost is estimated by the Meat and Livestock Commission (MLC) at around £3500 per butcher per year. There are 127 authorised butchers in Scotland so potential savings to butchers of approximately £444,500 could accrue.

- 5.2.5. Cutting plants should also benefit from reduced costs as a result of the change, but we are unable to estimate the value of this.
- 5.2.6. The industry has maintained that the rule change in May 2006 has caused a two tier market, with a decrease in the price paid for animals aged from 24 to 30 months. The requirement to de-bone 24-30 month beef has led to additional cost to producers, and therefore a price penalty on 24 – 30 month old prime beef animals. The Meat Trades Journal of 12 October 2007 estimated this at 25p/kg (dead weight), and that this could work out to up to £100 per animal. The return to the 30 month age limit would remove this price differential.
- 5.2.7. In addition, the 32 Scottish local authorities will make some savings as they would no longer be required to authorise butchers for bovine VC SRM removal. The saving is estimated at around £60 per inspection visit and it is assumed that 2 visits are made per annum. On this basis the total savings are:
 $£60 \times 2 \times 32 = £3840$.
- 5.2.8. An important unquantifiable benefit is the removal of the restrictions on movement of bone-in beef carcasses from animals less than 30 months at slaughter. 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. 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.

B: Proposal on EU rules on trade

Costs

Option 1

- 5.2.9. Doing nothing would mean that the domestic legislation failed fully to reflect Community legislation.

Option 2

- 5.2.10. This amendment implements a Community requirement on intra-Community trade that is not included in the current domestic regulations but would now be included in Schedule 6. It relates to a pre-existing requirement, the impact of which has not previously been assessed. The requirement 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.

5.2.11. 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, but rather 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 wishing 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. Although our recent consultation included a request for information on the potential uptake of this provision and the impact on industry, none of the responses received provided such information.

Benefits

Option 1

5.2.12. There are no benefits attached to option 1: the Community Regulation containing this requirement on intra-Community trade is binding across the Community.

Option 2

5.2.13. Amending the domestic legislation would ensure that the domestic TSE Regulation fully reflects the Community requirement.

C: Proposal to revoke the Beef Bones Regulations 1999

Costs

Option 1

5.2.14. Doing nothing would mean that Scotland would retain a ban on the use of UK beef bones in manufactured and processed food. The Beef Bones Regulations 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 the vertebral column, which is subject to the EU SRM controls. The beef bones ban goes beyond the measures required by the Community TSE Regulations.

Option 2

5.2.15. There are no costs attached to option 2: the beef bones ban can no longer be considered to make a significant contribution to public health protection.

Benefits

Option 1

5.2.16. There are no benefits attached to this option: the beef bones ban can no longer be considered to make a significant contribution to public health protection.

Option 2

5.2.17. 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 indicates a market for UK beef bones.

D: Proposed amendment to paragraph 2 of Schedule 7

Costs

Option 1

5.2.18. Doing nothing would mean that the domestic Regulations would not accurately refer to the Community Regulation. Currently paragraph 2 refers to Annex XI of the Community Regulation, which has been revoked and replaced with Annex V.

Option 2

5.2.19. There are no costs attached to the proposal to amend paragraph 2 of Schedule 7 to refer to the correct section in the Community Regulation. The amendment will not impose additional burdens on industry or any other stakeholders as the requirements of the Regulation are unchanged.

Benefits

Option 1

5.2.20. There are no benefits attached to Option 1.

Option 2

5.2.21. Amendment of paragraph 2 of Schedule 7 would ensure that the domestic Regulations are in line with the Community Regulation. Currently that paragraph refers to Annex XI of the Community Regulation, which has been revoked and replaced with Annex V.

Small Firms Impact Test

- 6.1. The proposed change to the age threshold for removal of vertebral column will be beneficial to small businesses, and would provide a saving of around £444,500 per annum in the meat industry (through the reduction in burden on butchers), as estimated by the Meat and Livestock Commission. The FSA worked closely with industry representative organisations in taking forward the proposal to increase the age at which bovine vertebral column is classified as SRM. These organisations strongly support the proposal, and have advised that it would particularly benefit small to medium sized businesses, although no figures were provided.

7. Test Run of Business Forms

- 7.1 No new or additional forms will be introduced.

8. Competition Assessment

- 8.1. The proposals will not distort competition. The change in age threshold for removal of vertebral column, and the revocation of the Beef Bones Regulations are both 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.

9. Enforcement, sanctions and monitoring

- 9.1. The current enforcement, sanctions and monitoring system will remain in place. The Food Standards Agency (FSA) will remain the Competent Authority with ultimate responsibility for enforcement, sanctions and monitoring. The Meat Hygiene Service (MHS), an Executive Agency of the FSA, will remain responsible for enforcing and monitoring compliance with SRM controls in slaughterhouses and cutting plants. However, since cutting plants and authorised butchers will no longer need to remove, stain and destroy vertebral column from 24-30 month bovine carcasses, the MHS will no longer be required to audit cutting plants in this regard, and Local Authorities will no longer be required to authorise butcher shops and enforce SRM rules at those shops.

10. Implementation and delivery plan

The MHS and local authorities will monitor the control arrangements to ensure implementation is effective and as required by Community legislation.

11. Post-implementation review

The MHS and local authorities will monitor the control arrangements to ensure implementation is effective and as required by Community legislation. In line with

Scottish Government guidance we will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment that will be completed within 10 years.

12. Summary and Recommendation

The proposed Regulations would ensure compliance with TSE Community legislation and will maintain proportionate consumer protection from BSE related risk while providing industry savings, a small reduction in enforcement costs, and an increase in consumer choice.

13. Declaration and publication

I have read the Regulatory Impact Assessment and am satisfied that the benefits justify the costs.

Signed: S. ROBISON

Date: 24 April 2008