EXPLANATORY MEMORANDUM TO

THE TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (No.2) (AMENDMENT) REGULATIONS 2007

2007 No. 1998

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 will enable the Food Standards Agency (FSA) to enforce the rules on specified risk materials (SRM) at approved meat establishments and Local Authorities at authorised butchers' premises 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 came into force on 1 July 2007, 3 days after its publication. The Regulation became binding on all Member States from that day, the domestic legislation must therefore be made as soon as possible after 1 July in order to implement the changes to these public health protection measures.

3.2. Timing

3.2.1. The instrument needs to come into force on 14 July 2007. Unless we do so, it will not be possible to enforce SRM controls, potentially exposing consumers to greater levels of risk.

4. Legislative background

4.1. *Background*

4.1.1. Prior to 1 July Annex XI to the Community TSE Regulations (Regulation (EC) No. 999/2001 as amended) contained the SRM controls and the transitional measures put in place while risk assessments on potential factors for the appearance of BSE and their development over time were undertaken in countries outside the European Community. These controls are implemented in English law by Schedule 6 of the Transmissible Spongiform Encephalopathies (No 2) Regulations 2006 (S.I. No. 2006/1228).

4.1.2. The European Commission has now adopted new simplified categories for the classification of BSE risk in Member States and countries outside the European Community, which are more closely linked to the OIE risk classification categories recently adopted by the Commission. The effect of this is that the transitional arrangements contained in Annex XI to the Community TSE Regulation have been revoked and replaced by a new Annex V.

4.1.3. The new Annex V to the Community legislation contains SRM controls that were previously contained in Annex XI. This requires a number of changes to the domestic legislation. The majority of these simply change the cross references to the Community legislation. There is no significant change to the SRM controls themselves. Without these changes being made it will not be possible to legally enforce the Community SRM controls in England.

4.2. *Scrutiny History*

4.2.1. Scrutiny histories that were produced for the European Scrutiny Committee in the House of Common and European Union Committee in the House of Lords during negotiation of Regulation (EC) 999/2001 (as amended) and Regulation (EC) 722/2007 are attached at Appendix 1.

5. Territorial Extent and Application

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

6. European Convention on Human Rights

6.1. 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*

Regulation (EC) 999/2001 of the European Parliament and of the Council (Community TSE Regulations) lays down the rules for prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE) and forms the legal basis for the domestic TSE Regulations.

(a) Annex XI to the Community TSE Regulations contained the transitional SRM controls which were put in place while risk assessments were undertaken in countries outside the European Community.

(b) The European Commission has recently adopted new simplified categories for the classification of BSE risk in Member States and countries outside the Community, these are more closely linked to the OIE risk classification categories. As a result, Annex XI has been repealed and replaced by a new Annex V.

(c) The new Annex V which was recently published in the Official Journal, came into force on 1 July and contains SRM controls that were contained in Annex XI. The domestic legislation is now being amended so that the cross references to the Community legislation will be to the new Annex V and come into force as soon as possible after 1 July. There is no significant change to the SRM controls themselves. The majority of the changes are technical and should not impact on businesses. Only one change may impact on businesses and this is as follows:

(i) mechanically recovered meat: this is now known as mechanically separated meat in line with the Community food hygiene legislation. In addition, the Community legislation has been modified slightly to prohibit the use of bone in cuts of bovine, ovine and caprine animals for production of MSM. This simply corrects an anomaly; in the previous Regulation, the prohibition

referred to only recovery from bones, but because the potential risk from MSM production from bones and bone in cuts is the same, the prohibition will now apply to both. While we are not aware of any businesses currently producing MSM from bone in cuts, it is possible some are and would therefore have to change current practices in order to comply with the new legislation.

7.2 *Consultation*

7.2.1. Around 970 stakeholders in England were consulted over a two week period, including industry representative organisations and operators of approved red meat establishments. Only 2 substantive responses were received, both were supportive of the proposed amendments. A summary of the responses is attached to this memorandum and may be found on our website.

7.3. *Guidance*

7.3.1. The Agency will update the meat industry guide 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 and Local Authorities will be responsible for enforcing it at authorised butcher's shops.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

8.2 The instrument will not have significant impact on businesses.

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.

Appendix 1

COMMISSION REGULATION (EC) No 722/2007 (Defra lead) { Commission Regulation (EC) No 722/2007 of 25 June 2007 amending Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies}

Legislation	Commission Regulation (EC) No 722/2007
Adopted	25 June 2007
Official Journal	L164 of 26 June 2007, pp 7-23
Explanatory Memoranda	NO EM PRODUCED AS THIS IS A COMMISSION REGULATION

COUNCIL REGULATION (EC) No 1923/2006 (Defra lead) {Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies}

Legislation	Council Regulation (EC) No 1923/2006
Adopted	18 December 2006
Official Journal	L404 of 30 December 2006, pp 1-8
Explanatory Memoranda	EM 15784/04 of 31 January 2005

EXPLANATORY MEMORANDUM 15784/04 OF 31 January 2005

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords
Not Cleared, further information requested	Date: 10 February 2005 Report No:7 Session 2004 – 2005	Sifted in Chairman's sift of 8 February 2005. Letter of 17 March to Ben Bradshaw MP, Minister for Nature Conservation & Fisheries, Defra; replies 6 April and 24 May. Cleared by letter of 5 July to Ben Bradshaw MP
SCRUTINY OVERRIDE LETTER SENT ON 24-05-05		

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO A SPECIAL REPORT NO 14/2001 BY THE COURT OF AUDITORS CONCERNING THE FOLLOW-UP ON THE COURT'S SPECIAL REPORT NO. 19/98 ON BSE.

EUROPEAN PARLIAMENT AND COUNCIL REGULATION 999/2001 (LAST AMENDED BY COMMISSION REGULATION 1326/2001)

Legislation	European Parliament and Council Regulation (EC) No. 999/2001
Adopted	22 May 2001
Official Journal	L 147 of 31 May 2001 (Page 1)
Explanatory Memoranda	5196/99 of 1 February 1999 SEM 5196/99 of 28 November 2000

EXPLANATORY MEMORANDUM 5196/99

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Legally and politically important – not cleared; further information requested	Date : 17 March 1999 Report ref: (19751) HC 34-xiii (Session 1998/99) Paragraph 2	Referred to Sub-Committee (List B)	Date: 8 February 1999 Sub- Committee D
		Cleared without report (List C)	Date: 19 March 1999

SUPPLEMENTARY EXPLANATORY MEMORANDUM 5196/99

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Legally and politically important – for debate in European Standing Committee A	Date: 29 November 2000 Report ref: (19751) HC 23-xxxi (Session 1999-2000) Paragraph 1	Referred to Sub-Committee (List B)	Date: 28 November 2000 Sub- Committee D
Debated in European Standing Committee A	Date: 14 February 2001	Cleared without report (List C)	Date: 20 December 2000

COUNCIL REGULATION 820/97

Legislation	Council Regulation (EC) No 820/97
Adopted	21 April 1997
Official Journal	L117 of 7 May 1997 (Page 1)
Explanatory Memoranda	10495/96 (Proposal 1) of 25 October 1996 10495/96 (Proposal 2) of 25 October 1996 SEM 10495/96 of 3 February 1997 SEM 10495/96 (Proposal 1) of 10 March 1997 SEM 10495/96 (Proposal 2) of 10 March 1997

EXPLANATORY MEMORANDUM 10495/96 PROPOSALS 1 AND 2

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Politically important -for debate	Date : 30 October 1996 Report ref : (17535) HC 36-i (Session 1996-1997) Paragraph 5	Referred to Sub-Committee (List B)	Date : 28 October 1996 Sub-Committee D
Debated in European Standing Committee A	Date : 13 November 1996	Cleared without report (List C)	Date : 26 November 1996

SUPPLEMENTARY EXPLANATORY MEMORANDUM 10495/96

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Politically important – not for debate	Date : 5 February 1997 Report ref : (17535) HC 36-xii (Session 1996-1997) Paragraph 7	Cleared without report (List A)	Date : 3 February 1997

SUPPLEMENTARY EXPLANATORY MEMORANDUM 10495/96 PROPOSALS 1 & 2

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Legally and politically important – not for debate at this stage	Date : 12 March 1997 Report ref : (17535) HC 36-xvii (Session 1996-1997) Paragraph 3	Referred to Sub-Committee (List D)	Date : 10 March 1997 Sub-Committee B
		Cleared by a letter to the Minister (List F)	Date: 11 June 1997

Comments: The Committee recommended that only if the Proposal was adopted with legal base of Article 43, the UK should not withhold its agreement. However, if Article 100a was use, the Committee would consider recommending a further debate. The then Parliamentary Secretary (Angela Browning) wrote to the Chairman on 24 March 1997 to confirm that the proposal had been agreed at the Agriculture Council on 17 March 1997 on the basis of Article 43. The Committee considered the letter at its meeting on 23 July 1997.

EUROPEAN PARLIAMENT AND COUNCIL REGULATION 1760/2000

Legislation	Council Regulation (EC) No. 1760/2000
Adopted	17 July 2000
Official Journal	L 204 of 11 August 2000 (Page 1)
Explanatory Memoranda	12030/99 of 25 November 1999 SEM 12030/99 of 31 January 2000 8799/00 of 15 June 2000

EXPLANATORY MEMORANDUM 12030/99

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Legally and politically important – not cleared; further information and a Regulatory Impact Assessment requested	Date : 1 December 1999 Report ref: (20604 and 20627) HC 23-ii (Session 1999-2000) Paragraph 1	Cleared without report (List A)	Date : 23 November 1999

SUPPLEMENTARY EXPLANATORY MEMORANDUM 12030/99

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Legally and politically important – not cleared; awaiting further information	Date : 9 February 1999 Report refs: (20627 and 20854) HC 23-viii (Session 1999-2000) Paragraph 1	Cleared without report (List A)	Date : 8 February 1999

EXPLANATORY MEMORANDUM 8799/00

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Not legally or politically important	Date: 21 June 2000	Cleared (List A)	Date: 20 June 2000

COUNCIL DECISION 2000/766/EC

Legislation	Council Decision 2000/766/EC
Adopted	4 December 2000
Official Journal	L 306 of 7 December 2000 (Page 32)
Explanatory Memorandum	14181/00 of 7 February 2001

EXPLANATORY MEMORANDUM 14181/00

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Politically important – cleared	Date : 14 February 2001 Report ref: (21959) HC 28-vi (Session 2000-01) Paragraph 13	Referred to Sub-Committee (List B)	Date: 20 February 2001 Sub- Committee D
		Cleared by Sub – Committee D	Date: 18 July 2001

Final Regulatory Impact Assessment (RIA)

1. Title of the Proposal

1.1. The proposal is for an amendment to Schedule 6 of The Transmissible Spongiform Encephalophathies (No. 2) Regulations 2006.

Purpose & intended effect

2.1 The Objectives

2.1.1. The objectives of the proposed amendments to the regulations are to enable the current SRM controls arrangements in England to continue as required by Community legislation.

2.2. Devolution

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

2.3. Background

2.3.1. Annex XI to the Community TSE Regulations previously contained the SRM controls and the transitional measures put in place while risk assessments were undertaken in countries outside the European Community. It was the legal basis for current Schedule 6 to the domestic TSE Regulations.

2.3.2. The European Commission has adopted new simplified categories for the classification of BSE risk in Member States and countries outside the European Community, which are more closely linked to the World Organisation for Animal Health (OIE) risk classification categories. The effect of this is that the transitional arrangements contained in Annex XI of the Community TSE Regulations have been revoked and replaced by a new Annex V.

2.3.3. The new Annex V to the Community legislation contains SRM controls that were previously contained in Annex XI. Therefore a number of consequential changes are being made to the domestic legislation. The majority of these simply change the cross references to the Community legislation. **There is no significant change to the SRM controls themselves.**

2.3.4 Of all the changes listed below, only the first one is likely to impact on some FBOs. The changes are:

a) In Paragraph 4, which implements point 5 of the new Annex V of the Community Regulation, in line with the Hygiene legislation, mechanically recovered meat (MRM) is now known as mechanically separated meat (MSM). The definition of MSM in the Community Regulation has been modified slightly and means the prohibition at paragraph 4(1) of Schedule 6 to the domestic legislation is now modified to exclude the use of bone in cuts of bovine, ovine and caprine animals for production of MSM. This corrects an anomaly, as in the previous Regulation the prohibition referred only to recovery from bones, but as the potential risk from MSM production from bones and bone in cuts is the same, the prohibition now applies to both.

b) Paragraph 5, which implements point 6 of the new Annex V, retains the prohibition on pithing. However the prohibition will cease to apply if and when **all** member states are classified as countries with negligible BSE risk. There is no immediate prospect of this occurring.

c) Paragraph 9(3) requires the Food Business Operator (FBO) to comply with point 11(3)(b) of the Community TSE Regulation. Point 11(3)(b) has an updated reference to current hygiene legislation. This confirms that the FBO consigning beef carcases containing SRM vertebral column must include on the commercial document relating to the consignment of meat being transported information on the number of carcases from which removal of vertebral column as SRM is required, and the number that do not require removal as SRM.

2.4. Rationale for Government intervention

2.4.1. The regulations are required to ensure continued compliance with EC requirements in relation to SRM controls.

3. Consultation

3.1. Criterion 1 of the Cabinet Office Code of Practice states that a written consultation must be held for a minimum of 12 weeks for at least once during the development of the policy. The consultation was held for 2 weeks because the proposal is EU driven and the timescale for the introduction of the legislation is very tight. The new Community Regulation came into force on 1 July 2007. This did not allow enough time for the normal consultation period as we must implement the changes to these important public health protection measures as soon as possible after 1 July 2007.

4. Options

4.1. Changes as a result of amendment to Community TSE Regulations

The Community TSE Regulations set out the definition of SRM and the requirements on where and how it must be removed. These requirements are binding on all Member States. The options considered to implement amendment to the Community TSE Regulations in England are:

i. Option 1 - do nothing; and

ii. Option 2 - amend current Schedule 6 to reflect changes in the Community legislations.

4.1.2. Analysis of options

i. Option 1 (doing nothing) would mean that no amendments are made to the domestic TSE legislation so the FSA would be unable to fulfil its Community obligation to enforce SRM controls as stipulated in the new Annex V of Community TSE Regulations. This will leave the UK open to infraction proceedings by the Commission for failing to comply with these requirements.

ii. Option 2 would ensure continuing compliance with Community legislation. It would maintain the current system of SRM controls. 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. Operators of approved red meat establishments.

5.1.2. We consider that the proposal will have no impact on racial equality, social or environmental issues.

5.2. Costs and Benefits

5.2.1. Of the three changes identified in paragraph 2.3.4 only the amendment to the prohibition relating to MSM is likely to have a potential financial impact on the meat industry. Although the level of impact is unknown, it is unlikely for it to be significant.

6. Small Firms Impact Test

6.1. The proposed changes are not expected to have significant impact specific to small businesses.

7. Test Run of Business Forms

7.1 No changes to the administration of the system for SRM controls are intended as a result of the proposed amendments. No new or additional forms will be introduced.

8. Competition Assessment

8.1. No impact.

9. Enforcement, sanctions and monitoring

9.1. The current enforcement, sanctions and monitoring system will remain in place.

10. Implementation and delivery plan

The changes being made to the Regulations will be reflected in the meat industry guide and manual of official controls.

11. Post-implementation review

The MHS and Local Authority will continue to monitor the control arrangements to ensure implementation is effective and, as required by Community legislation.

12. Summary and Recommendation

The proposed Regulations would ensure continued compliance with Community TSE legislation and continue the current SRM controls.

13. Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed *Dawn Primarolo*
Date *11th July 2007*

Dawn Primarolo
Minister for Public Health
Department for Health