EXECUTIVE NOTE

THE TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (SCOTLAND) AMENDMENT REGULATIONS 2007 SSI 2007/357

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

Legislative Background

3. Prior to 1 July, Annex XI to the Community TSE Regulation (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 Scottish law by Schedule 6 of the Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006 (S.S.I. No. 2006/530).

4. 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 The effect of this is that the transitional arrangements contained in Annex XI to the Community TSE Regulation have been revoked and replaced by a new Annex V.

5. 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 legally to enforce the Community SRM controls in Scotland.

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. 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.

8. 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.

9. 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.

10. 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 outlined in the following paragraph.

11. Mechanically recovered meat 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 only to 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.

Consultation

12. Approximately 170 stakeholders in Scotland were consulted over a two 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 is attached to this note, and may be found on the FSA website.

Guidance

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

Impact

13. This instrument will not have significant impact on businesses. A Regulatory Impact Assessment is attached to this note.

FOOD STANDARDS AGENCY SCOTLAND

13 July 2007

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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 Encephalopathies (Scotland) Regulations 2006.

2. 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 arrangement in Scotland to continue as required by Community legislation.

2.2. Devolution

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

2.3. Background

2.3.1. Annex XI to the Community TSE Regulation contains the SRM controls and the transitional measures put in place while risk assessments were undertaken in countries outside the European Community. It forms the legal basis for the 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 OIE risk classification categories. The effect of this is that the transitional arrangements contained in Annex XI of the Community TSE Regulation are to be revoked and replaced by a new Annex V.

2.3.3. The new Annex V to the Community Regulation will contain SRM controls that are currently contained in Annex XI. This will mean a number of consequential changes will need to be made to the domestic legislation. The majority of these will simply change the cross references to the Community legislation. **There is no significant change to the SRM controls themselves.**

2.3.4. Of the changes listed below, only the first one is likely to impact on some Food Business Operators (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 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 FBO to comply with point 11(3)(b) of Annex V to 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 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 leave 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 they come into force.

4. Options

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

4.1.1 The Community TSE Regulation sets 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 the amendment to the Community TSE Regulation in Scotland are:

i. Option 1 - do nothing; and

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

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 to the Community TSE Regulation. This will leave the UK (as the Member State) 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 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

Costs

Option 1

5.2.1. Doing nothing would mean that there is no legal basis for enforcing SRM controls and would breach our Community obligation to enforce SRM controls stipulated in the new Annex V of the Community TSE Regulation. This will leave the UK (as the Member State) open to infraction proceedings by the Commission for failing to comply with these requirements.

Option 2

5.2.2. Of the three changes 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 to be significant.

Benefits

Option 1

5.2.3. There are no benefits attached to Option 1.

Option 2

5.2.4. This would ensure continuing compliance with Community legislation. It would maintain the current system of SRM controls.

6. Small Firms Impact Test

6.1. The proposed changes are not expected to have significant impact specific to small businesses. The consultation included trade associations which represent small, medium and large businesses, and also included the Federation of Small Businesses Scotland. The consultation was issued to Local Authorities, who were asked specifically to ensure that any meat plants which they have approved for the production of MSM were made aware of the consultation. None of the responses to the consultation suggested that the proposed changes would have an 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. There will be no changes to competition.

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, an Executive Agency of the FSA, will remain responsible for enforcing and monitoring compliance with SRM controls in slaughterhouses and cutting plants, and Local Authorities will remain responsible for enforcement and monitoring in butcher shops and any stand-alone meat preparations plants producing MSM. Failure to comply with the requirements relating to SRM controls will continue to be offences.

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 Executive 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 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: SHONA ROBISON

Date: 16th July 2007