

## **Explanatory Memorandum to the Transmissible Spongiform Encephalopathies (Wales) (Amendment) (No 2) Regulations 2007**

This Explanatory Memorandum has been prepared by the Food Standards Agency Wales and is laid before the National Assembly for Wales.

### **(i) Description**

This instrument revokes and replaces the Transmissible Spongiform Encephalopathies (Wales) (Amendment) Regulations 2007 (S.I. 2007/2043 (W.168), which came into force on 18 July 2007. It corrects errors in the text and enables the current control arrangements on specified risk materials (SRM) to continue in Wales. The errors that have been identified are errors in the text of the Regulations, which unfortunately had not previously been identified. In particular, the references to the powers to grant, suspend or revoke approvals, authorisations, licences or registrations within the Regulations, which are to be conferred on the Food Standards Agency (in relation to authorisation of cutting plants) and on local authorities (in relation to authorisation and registration of butcher shops) need to be corrected. In addition the current Welsh text refers to bovine animals who are “over 30 months” at slaughter, but it should refer to bovine animals that are “30 months or less at slaughter”. This inconsistency may result in butchers unknowingly breaching the Community TSE Regulations, by failing to remove specified risk material (SRM) from bovine animals who are 30 months or less at slaughter.

The control arrangements are designed to prevent parts of the animal most likely to contain BSE infectivity from entering the food or animal feed chain. The new Regulations reflect the European Commission’s adoption of new simplified categories for the classification of BSE risk in Member States and countries outside the Community as set out in Commission Regulation (EC) No 722/2007.

### **(ii) Matters of special interest to the Subordinate Legislation Committee**

As the Commission Regulation came into force on 1 July 2007 the new SI is required to come into force as soon as possible to ensure the continuation of current controls. The UK would be in breach of a Community requirement in not having the relevant prohibition in effect. For this reason the instrument breaches the 21 day rule. The risk of not implementing the legislation with immediate effect will lead to inconsistency of enforcement across the UK thus reducing the public health measures in relation to BSE. The Minister for Assembly Business and Communication has written to the Presiding Officer to notify him of the breach.

### **(iii) Legislative Background**

The powers enabling this instrument to be made are contained in section 2(2) of the European Communities Act 1972. They have been designated by virtue of the European Communities (Designation) (No 2) Order 2003 (SI 2003/1246) to Welsh Ministers in respect of measures in veterinary fields for the protection of public health. This Instrument is subject to the negative resolution procedure.

(iv) **Purpose and intended effect of the legislation**

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.

Annex XI to the Community TSE Regulations contained the specified risk material (SRM) controls and the transitional measures put in place while the risk assessments on potential factors for the appearance of BSE and their development over time were undertaken in countries outside the European Community.

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.

The new EC Regulation which was published in the Official Journal on 26 June, came into force on 1 July and contains SRM controls that were previously 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 must come into force as soon as possible after 1 July. There is no significant change to the SRM controls themselves. A number of consequential changes need to be made and these are:

- Para 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.
- Para 5 (which implements point 6 of the new Annex V) – this 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.
- 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 carcasses containing SRM vertebral column must include on the commercial document relating to the consignment of meat being transported information on the number of carcasses from which removal of vertebral column as SRM is required, and the number that do not require removal as SRM.

If Wales, along with the rest of the UK, did not implement this Regulation it would be in breach of a Community requirement. In addition, the risk of not implementing the legislation with immediate effect in Wales could reduce the public health measures in relation to BSE.

**(v) Implementation**

These Regulations were made on 27 July 2007 and are intended to come into force on 31 July 2007. Failure to implement the legislation as soon as possible would lead to inconsistency of enforcement across the UK and reduce the public health measures in relation to BSE. If the UK did not implement this Decision it would be in breach of a Community requirement. Parallel legislation came into force in England on 14 July 2007 and in Scotland and Northern Ireland on 18 July 2007.

**(vi) Consultation**

A two week consultation on the proposed Regulations took place between 25 June and 9 July 2007 in Wales. The consultation was not held for the usual 12 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 and our intention is to implement the requirements as soon as possible.

**(vii) Regulatory Impact Assessment**

a) Options

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 Wales are:

- i. Option 1 - do nothing; and
- ii. Option 2 - amend current Schedule 6 to reflect changes in the Community legislations.

Option 1 (doing nothing) would mean that no amendments are made to the domestic TSE legislation so the Food Standards Agency 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.

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. There are no issues of equity of fairness.

b) Benefits

The benefit of making this amending Regulation and therefore continuing the control arrangements in Wales will be the ability to enforce consistently across the UK and the maintenance of public health measures in respect of BSE.

c) Costs

The sector affected by this proposed Regulation is operators of approved meat establishments. We consider that the proposal will have no impact on racial equality, social or environmental issues. There are no additional financial implications for the Welsh Assembly Government or Local Authorities arising from making these Regulations.

Of the changes identified at para (iv) above only the amendment to the prohibition relating to MSM is likely to have potential financial impact on the meat industry. Although consultees were invited to identify these potential costs no detail has been provided. Whilst the level of impact is therefore unknown, the Agency consider it is unlikely to be significant.

d) Competition Assessment

No impact.

e) Consultation

Forty stakeholders were consulted in Wales and around 1000 across the UK over a two week period between 25 June and 9 July 2007. These included industry representative organisations, farming unions and consumer organisations.

Only one substantive response was received in Wales, from Hybu Cig Cymru, which was supportive of the proposed amendments.

f) Post Implementation Review

The Meat Hygiene Service and Local Authorities will monitor control arrangements to ensure implementation is effective and as required by Community legislation.

g) Summary and recommendation

The proposed Regulations would ensure continued compliance with Community TSE legislation and continue the current SRM controls, thus ensuring protection of public health in relation to BSE.

It is recommended that the Community Regulation be implemented in Wales by the Transmissible Spongiform Encephalopathies (Wales) (Amendment) (No 2) Regulations 2007.

(viii) **Contact details**

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