

REGULATORY APPRAISAL

ANIMALS, WALES

THE TSE (WALES) (AMENDMENT) REGULATIONS 2005

Background

1. EC Regulation 999/2001 (the Community TSE Regulation) lays down the rules for the prevention, control and eradication of certain Transmissible Spongiform Encephalopathies (TSEs) on an EU basis. Whilst the EC Regulation is directly applicable in all Member States, the rules for the enforcement and administration of the Regulation in Wales are set out in the TSE (Wales) Regulations 2002 (SI 1416/2002), which came into force in May 2002. Since that date, the Community TSE Regulation has been amended on several occasions but the changes have not been incorporated into domestic legislation. This means that the UK is not able to enforce the changed Specified Risk Material (SRM) requirements introduced by EC Regs 1494/2002, 1139/2003 and 1492/2004.
2. In June 2002, following a review of current precautionary measures in relation to BSE in sheep and goats, the Food Standards Agency (FSA) recommended to the European Commission that the whole intestine of all sheep and goats should be classified as SRM.
3. EC Regulation 1139/2003 extended the definition of SRM to include the ileum (the lowest part of the small intestine) of sheep and goats of all ages and tonsils of bovine animals less than six months. It was adopted by the Commission in June 2003 and came into force on 1 October 2003.
4. Although not initially supported by the Commission's Scientific Steering Committee, the Commission subsequently proposed that the ileum of all sheep and goats be classified as SRM.
5. Research has also identified that current methods of harvesting tongue do not remove all traces of tonsil, so the Commission is introducing a method of removing the tongue that should minimise contamination.
6. The changes introduced by EC Regulations 1494/2002 and 1492/2004 had the effect of excluding certain parts of bovine vertebral column from its designation as SRM, which simply reflect the practicalities of the de-boning process. These were adopted by the Commission in August 2002 and 2004 respectively.
7. During the boning process, specifically the removal of vertebral column, some of the parts of the vertebrae can be chipped and particles of bone may remain in carcase meat. These bone chips are not of any consequence in relation to the purpose of SRM rules, as vertebral column is removed because of its association with dorsal root ganglia (a group of nerve cell bodies located outside the central nervous system on the dorsal nerve root and being a part of the animal most likely to contain BSE

infectivity). The Commission has, therefore, amended the definition of SRM vertebral column on the basis of practicality in relation to boning practices.

Purpose and Intended Effect

8. The proposed legislation will amend the TSE (Wales) Regulations 2002 (S.I. 2002/1416) (W.142) to apply, in Wales, rules for the enforcement and administration of EC Regulations 1494/2002, 1139/2003 and 1494/2004 which are directly applicable in Member States. These Regulations will:

- extend the definition of Specified Risk Material (SRM) to include Commission Regulation (EC) No 1139/2003 relating to the ileum (the lowest part of the small intestine) of sheep and goats of all ages;
- extend the definition of SRM to include Commission Regulation (EC) No.1139/2003 relating to tonsils of bovine animals less than six months; and
- exclude certain parts of bovine vertebral column from its designation of SRM, which simply reflect the practicalities of the de-boning process as required by Commission Regulations (EC) No.1494/2002 and No.1494/2004.

Risk Assessment

a) Amendment of definition of SRM vertebral column to exclude the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae, median sacral crest and wings of the sacrum

9. The purpose of treating vertebral column from cattle over twelve months (30 months for UK cattle) of age as SRM is related to removal of dorsal root ganglia. The processes of the vertebral column, which might become chipped during removal, pose no additional risk to consumers.

b) Extension of EU SRM definition to include the ileum of sheep and goats of all ages

10. There is a theoretical risk that BSE may exist in sheep and goats. It is not possible, using routine methods, to distinguish between BSE and scrapie so it is possible that BSE is being masked by scrapie. In both diseases the level of infectivity in the ileum is significant from an early stage of infection. Its removal from the food chain has therefore been recommended as a precautionary measure.

c) Extension of the EU SRM definition to include the tonsils of cattle of all ages

11. The EU Scientific Steering Committee investigated the distribution of TSE infectivity in the tissues of ruminant animals and concluded that the tonsils of cattle of all ages pose a BSE risk and should therefore be regarded as SRM.

d) Harvesting of cattle tongues by transverse cut rostral to the lingual process of the basihyoid bone

12. Cattle tonsils are considered to pose a BSE risk and tonsil is present mainly at the back of the tongue. It is therefore necessary to minimise the possibility of tonsillar tissue remaining attached to tongues destined for the human food chain to ensure that potentially infective tonsil material does not enter the food chain via that route.

e) Rules governing dispatch of imported carcase meat for removal of vertebral column.

13. Prior to EC Regulation 1139/2003, half and quarter bovine carcases containing SRM vertebral column could be traded between member states providing vertebral column is removed in the receiving country. The Regulations now enable half carcases cut into no more than 3 wholesale cuts to be traded, bringing it into line with current trading practice.

14. These Regulations will apply in Wales only. Separate, but parallel, Regulations came into force in England, Scotland and Northern Ireland on 4 April 2005, 22 March 2005 and 5 April 2005 respectively.

Options

15. In respect of this legislation, the “Do nothing option” is not an option as it ultimately would lead to infraction proceedings against the National Assembly for Wales by the European Commission. Therefore, the “Make the legislation” option, to implement the changes required to comply with European legislation, is being implemented.

Benefits

16. EC Regulations 1494/2002 and 1492/2004 remove the requirement to treat certain parts of the vertebral column as SRM. The benefits of the SRM vertebral column change is a recognition of the practicalities involved in the boning process whilst still maintaining a consumer protection.

17. EC Regulation 1139/2003 extends the definition of specified risk material to further reduce the possibility of infective material entering the food chain. The Regulations also require bovine tongue to be removed in a particular way to minimise contamination with SRM. The benefit of these changes is further reduction in the level of risk to consumers from possible exposure to BSE infectivity.

Costs

18. There are no additional financial implications for the Assembly from the making of these Regulations.

Compliance costs

19. The proposed measures would affect licensed red meat slaughterhouses and cutting plants, tongue processors and beef importers. We do not anticipate there will be any additional costs related to compliance, indeed in respect of removal of vertebral column there may be some reduction in cost. This possible reduction in cost cannot be quantified.

20. One associated cost the Agency considered is that of disposal of the SRM and consultees were invited to provide further information on disposal costs as part of the consultation exercise. This costing is dependent on the "actual" price differential between disposal of SRM and non SRM. However, no significant increase in cost was identified in the responses to the consultation.

Enforcement costs

21. The Community TSE Regulations are enforced, in licensed abattoirs and cutting plants in GB by the Meat Hygiene Service (MHS) on behalf of the Agency. The cost of enforcement of these Regulations is borne by the Food Standards Agency. In most cases no additional enforcement costs have been identified. In cases where additional MHS supervision is necessary, leading to an increase in costs, these have been absorbed within the overall cost of enforcement of SRM controls, which are met by the FSA.
22. There is no indication that the changes set out above will affect small businesses to a lesser or greater extent than medium sized or large ones. Equally there are no costs to consumers.

Equity and Fairness

23. No issues of equity and fairness have been identified.

Consultation with small business – the Small Firms' Impact Test

24. The Community TSE Regulations apply across the industry, including small businesses. There is no indication that the changes set out in this RA will affect small businesses to a lesser or greater extent than medium sized or large ones.

Enforcement, Sanctions, Monitoring and Review

25. If these measures are not incorporated into the TSE (Wales) Regulations 2002, then it will not be possible to fully enforce the directly applicable Community SRM controls in Wales.

Consultation

With Stakeholders

26. The Food Standards Agency Wales carried out a 12-week consultation from 5 November to 1 February 2005. Eighty six stakeholders including consumer and industry representative bodies, farming unions and licensed red meat premises were invited to comment on the draft Regulations and the draft Regulatory Appraisal (a list of consultees is attached at Annex A).
27. Three responses were received in Wales from the Institute of Food Science and Technology, the National Sheep Association and Hybu Cig Cymru, whilst 41 responses were received UK wide. The comments were supportive of the proposed changes and no objections to the proposal were raised, as respondents envisaged they would not give rise to any

difficulties. No changes were made to the Regulations as a result of the consultation exercise.

With Subject Committee

28. There has been no prior scrutiny of the proposed Regulations by the Health and Social Services Committee. However, the Regulations were notified to the Committee via the list of forthcoming legislation on 24 November 2004 (HSS(2)-14-05 (p.2b) item no. FSA 23/04), but were not identified for detailed scrutiny.

Summary and Recommendation

29. This will allow the Government to fulfil its Community obligation to implement the provisions of EC Regulations 1494/2002, 1139/2003 and 1492/2004, which will ensure further reduction in the level of risk to consumers from possible exposure to BSE infectivity and reflect the practicalities of the de-boning process for industry.

Contact point:

Ms Jayne Griffiths
Food Standards Agency Wales
11th Floor, Southgate House, Wood St, Cardiff CF10 1EW
Tel: 029 20678908
Fax: 029 2068918
Email: jayne.griffiths@foodstandards.gsi.gov.uk

CONSULTATION LIST / RHESTR YMGYNGHORI

Red Meat Slaughterhouses and Cutting Plants

Associated Meat Co Ltd
BWL George
Cardigan Abattoir Ltd
Cig Mon Meats Ltd
Cig Oen Caron
Competitive Meats
Conwy Valley Meats
D & J Thomas
Dawn Pac
Direct Meat Supplies
D T Havard
E T Jones, Sons & Daughter
Fairfield Meat Co Ltd
Food Technology Centre, Coleg Menai
Fribro Foods Ltd
G R Evans
Hamer International Ltd
Hughes Meats
I & B Jones
J Williams & Son
J E Tudor & Sons Ltd
J O Evans
Jones Bros
Marks Meats Ltd
Messrs B & B Webster
Mid Glamorgan Provisions
Mr L H Phillips
O Roberts A'l Faib
Oriel Jones & Sons Ltd
Owen G Owen Ltd
Pembrokeshire Meat Company
R G B Webster & Sons Ltd
R W Kennard
St Merryn Meat Ltd
Stanley Jones
T H Sutcliffe
T J Thomas
Towers Thompson
T W M Ltd
Tywyn Wholesale Meat Co Ltd
W Lloyd Williams
W A James
Weddel Swift
Weeks Wholesale Meat Co Ltd

Other Organisations

Cate Barrow
Judith Nelson
Mr S A Kidwai
Mr Richard Wood
Mr Paul Handby
Julian Salmon
John Lloyd Jones
Moss Jones
Mr Arwyn Owen
ADAS Wales
Agricultural Industries Confederation (AIC)
Association of Muslim Professionals
British Retail Consortium
Chartered Institute of Environmental Health in Wales
Country Land and Business Owners Association
Countryside Council for Wales
Farm Assured Welsh Livestock
Farmers' Union of Wales

Gwyn Evans	Federation of Small Businesses (North Wales)
Gethin Williams	Federation of Small Businesses (South Wales)
Alan Horine	Guild of Welsh Lamb and Beef Suppliers
Gwyn Howells	Hybu Cig Cymru
Jane Randall-Smith	Institutes of Rural Health
Ms Susan Perkins	LACORS (Welsh Officer)
Miss Meinir Green	Llanwenog Sheep Society
Mrs G Roberts	Lleyn Sheep Society
Mrs Mary James	National Farmers Union (Wales)
John Taylor	National Federation of Meat and Food Traders
Rhian Connick	National Federation of Womens Institutes - Wales
Helen Davies	National Sheep Association (Wales)
Gerwyn Probert	Plas Gwyn
Mr David Walters	Royal Welsh Agricultural Society
Mr Tony Edwards	State Veterinary Service
Tim Keohane	Teeswater Sheep Breeders Association
Lowri Jones	Trading Standards Institute (Wales)
Mr Arwyn Davies	Wales Young Farmers' Club
Mr Wynfford James	WDA Agri-Food Development
Jo Glenn	WDA Food Directorate
Christine Carberry	Welsh Assembly Government
Jean Sullivan	Welsh Black Cattle Society
Dafydd Morris	Welsh Food Alliance
Professor Mike Harris	Welsh Highland Shepherds
Don Thomas	Welsh Institute of Rural Studies
Mr Sandy Blair	Welsh Lamb and Beef Promotions
Joan Irving	Welsh Local Government Association
Gillian Van Der Meer	Womens Farming Union
	Women's Food & Farming Union