

REGULATORY APPRAISAL

FOOD, WALES

THE BOVINE PRODUCTS (RESTRICTION ON PLACING ON THE MARKET) (NO.2) (WALES) REGULATIONS 2005

Background

1. The Over Thirty Month (OTM) rule was introduced in March 1996 following advice from the Spongiform Encephalopathy Advisory Committee (SEAC) on the link between variant Creutzfeldt Jakob Disease (vCJD) and Bovine Spongiform Encephalopathy (BSE). With limited exceptions, the OTM rule prohibits the sale for human consumption of meat from cattle aged over thirty months at slaughter. It is one of the three main BSE controls protecting public health. The others are removal of specified risk material (SRM), i.e. those parts of the carcass most likely to carry BSE infectivity and the ban on feeding mammalian meat and bone meal to all farm animals, which came fully into force on 1 August 1996. The basis of a control on cattle at thirty months has been that:
 - fewer than 100 BSE cases have developed clinical disease at under 30 months out of over 180,000 cases of BSE in the UK;
 - the majority of cases in UK cattle under 30 months old were born before 1994; and
 - BSE occurs at an average age of five years. Studies suggest that in the 12 months prior to the onset of clinical disease, cattle with BSE present a much higher risk due to the build up of infectivity.
2. Other Member States do not operate an OTM rule. Since 1 January 2001, EU legislation has required all cattle aged over 30 months to test negative for BSE before entering the food supply. In addition to the SRM requirements for under 30 months cattle, EU legislation also requires the vertebral column of UK OTM cattle entering the food supply to be removed and destroyed as SRM.
3. New EC legislation was needed to enable the UK to legislate and replace the OTM rule, as otherwise a restriction on cattle born before 1 August 1996 would have contravened EC law. The UK therefore asked the European Commission to make a provision for such a restriction. Suitable legislation was recently adopted in the form of a Commission Decision (2005/598/EC).
4. The Bovine Products (Restriction on Placing on the Market) (Wales) Regulations 2005 revoked the OTM Rule and gave effect to Article 1.1 of Commission Decision 2005/598/EC prohibiting the placing on the UK market of products derived from bovine animals born or reared within the UK before 1 August 1996 for any purpose. Only those OTM animals that have been tested negative for Bovine Spongiform Encephalopathy (BSE) will be allowed to enter the food chain.

Purpose and intended effect of the measure

5. These Regulations will revoke and re-enact The Bovine Products (Restriction on Placing on the Market) (Wales) Regulations.

6. The No.2 Regulations are required because of the effect of directly applicable EU food hygiene legislation, which comes into force from 1 January 2006. The Bovine Products (Restriction on Placing on the Market) (Wales) Regulations 2005 refer in several places to the Fresh Meat (Hygiene and Enforcement) Regulations 1995 (FMRs) which will be revoked from 1 January 2006 by the proposed Food Hygiene (Wales) Regulations 2005. These latter Regulations provide for the execution and enforcement of the new EU Hygiene Regulations, which apply directly across the UK from 1 January 2006, by replacing references to the FMRs with reference to the corresponding provisions in the new Food Hygiene (Wales) Regulations 2005. Some associated changes in terminology have also been made to adopt that used in the new hygiene legislation. Consequently, The Bovine Products (Restriction on Placing on the Market) (Wales) Regulations 2005 will also become out of date from 1 January 2006. It was not possible for the Bovine Products (Restriction on Placing on the Market) (Wales) Regulations 2005 and these No. 2 Regulations to be made at the same time, because the Food Hygiene (Wales) Regulations 2005, to which the No. 2 Regulations refer, have yet to be approved by the Assembly (these Regulations are scheduled to be considered by the Assembly in Plenary on 29 November 2005, but will not come into force until 1 January 2006. The No.2 Regulations will ensure that Article 1.1 of Commission Decision 2005/598/EC continues to have effect in relation to Wales.

Devolution

7. This is a devolved matter, which affects all parts of the UK. Separate, but parallel legislation will be introduced in England, Scotland and Northern Ireland from 1 January 2006.

Risk assessment

8. The No.2 Regulations ensure that Article 1.1 of EU Decision 2005/598/EC, which prohibits the placing on the market of products derived from bovine animals born and reared within the UK before 1 August 1996 for any purpose, continues to have effect in relation to Wales.
9. No additional risk has been identified given that the provisions of the No.2 Regulations continue, from 1 January 2006, the provisions set out in The Bovine Products (Restriction on Placing on the Market) (Wales) Regulations.

Options

10. In respect of this legislation, the 'Do Nothing' option is not an option, as it would ultimately 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 proposed.

Benefits

11. The Regulations maintain the benefits arising from the Bovine Products (Restriction on Placing on the Market) (Wales) Regulations.
12. The longer term reduction in the amount of animal carcass material requiring to be disposed of (around 50% of the carcass would be consumed instead) would provide an environmental benefit.
13. The economic and social benefits of this option are set out below:

- Significant savings in Exchequer costs from reductions in OTMS expenditure net of additional costs, which are estimated to increase from some £60m in 2005/06 compared to the cost in 2004/05, to £337m after all cattle born before August 1996 have been disposed of. The disposal scheme for cattle born before August 1996 (the Older Cattle Disposal Scheme (OCDS)) will be in place for three years after which the only costs to the exchequer in relation to these cattle would be for the disposal of residual SRM;
- UK fully compliant with EU BSE controls and risk of infraction proceedings removed;
- Farmers allowed to sell OTM cattle born on or after 1 August 1996 for human consumption;
- An eventual end to the requirement to dispose of OTM cattle via rendering and incineration (only up to 716,000 cattle born before August 1996 would remain to be disposed of if the OTM rule were changed from 1 November 2005, instead of the some 715,000 cattle disposed of annually through OTMS);
- The estimated forecast OTMS compensation payment is £52.5m for 212,750 post August 1996 cattle in 2005/06 (see Table below). The equivalent value on the EU market (Irish Republic) for these cows at current prices (July 2005) is £76.5m, representing a benefit to the farmer of £24m. In 2006/07 the benefit is estimated at £49m;

Forecast No. animals born after 01.08.96 to enter the food chain from 01/11/2005						
Year	England (59%)	Wales (12%)	Scotland (13%)	Northern (16%)	Ireland	UK Total
2005/06	125,522	25,530	27,658	34,040		212,750
2006/07	257,240	52,320	56,680	69,760		436,000

- A possible benefit to consumers via the availability of cheaper (cull cow) OTM beef for manufacturing. Currently only beef from prime stock is available to UK food manufacturers; and
- Pet food manufacturers would have access to additional supplies.

Costs

14. There are no additional financial implications for the Assembly or local authorities in Wales as a result of the making of these Regulations.

Consultation

With Stakeholders

15. In December 2004 the UK Government announced the start of a managed transition towards replacing the OTM Rule with a BSE testing regime. Subsequently, the Food Standards Agency carried out a consultation in the UK from 9 March 2005 to 31 May 2005 on the UK Government's proposals. In Wales the Agency wrote to 329 stakeholders including consumer and industry representative bodies, farming unions and licensed red meat premises (a list of consultees is attached at Annex A). They were invited to comment on the draft Regulations and the draft Regulatory Appraisal.

3 responses were received in Wales, from the National Farmers Union (Wales), Hybu Cig Cymru and the Farmers Union of Wales, with a total of 45 responses UK wide. All respondents to the exercise in Wales welcomed and supported the proposal. Generally across the UK the meat industry continues to favour rule change whilst consumer groups are more wary and stress the need for a reliable testing regime, robust enforcement of the new requirements and effective communication to the public.

16. Also open meetings took place in London, Edinburgh, Belfast and Cardiff during July 2005 to discuss the proposed changes to the OTM rule. A representative of the FSA and Professor Patrick Wall, the Chair of the independent group, which advised the FSA on the robustness of the testing regime, gave presentations on the background to the OTM rule review. This included the UK Government's announcement last year to accept the case in principle for rule change and the emerging findings of the independent group. In Cardiff some 390 invitations were issued to, amongst others, Assembly Members, consumer, industry and farming representatives. Public notices were placed in key newspapers to raise awareness of the meeting. Over 40 delegates attended the meeting and participated in a Question and Answer session after the presentations. The general consensus was one of support and there were no unexpected developments arising from the open meetings.

With Subject Committee

17. The Regulations were first notified to the Health and Social Services via the list of forthcoming legislation on 1 September 2005 (HSS (2)-1005(p.3b), item no: FSA 26 (03)), but were not identified for detailed scrutiny.

Enforcement and sanctions

18. The legislation is enforced at licensed slaughterhouses and cutting plants by the Meat Hygiene Service (MHS) in Great Britain and by the Department for Agriculture and Rural Development (DARD) in Northern Ireland. Sanctions will be applied for non-compliance. The penalty for placing on the market any product (apart from milk) from an animal slaughtered in the UK and born or reared in the UK before 1 August 1996, on summary conviction would be a fine not exceeding the statutory maximum (currently £5,000), a three months prison term or both and, on indictment, an unlimited fine or up to two years in prison or both.

Review

19. The functioning of the system for BSE testing of OTM cattle is subject to continuous monitoring by the MHS and DARD as part of their enforcement function.
20. The entire testing system, including MHS and DARD enforcement, is also subject to an independent review covering the first 6 months following implementation. Thereafter, the FSA will be responsible for ongoing audit and review of the testing regime. For the first year following implementation, both will be overseen by the IRG.
21. As a check on the risk assessment, numbers of BSE positive cattle will be monitored against predictions from the risk assessment model.

ANNEX A

Company Name
Abergavenny Fine Foods
ADAS Wales
Age Concern Cymru
Agricultural Industries Confederation (AIC)
All Wales Dietetic Advisory Committee
Arfon Meat Company
Association of Civic Hosts
B. Sidoli & Sons Ltd
Bar and Restaurant Foods Ltd
BBC Radio Cymru
BBC Wales
BBC Wales
Be Safe Not Sorry
Beggan Farm Partnership
BEN (Black Environment Network) - Swansea Office
BEN (Black Environment Network) - Swansea Office
Berwyn Bakery
Biotrace Limited
Blaenau Gwent CBC
Brecon Support Group for Sufferers of Food/Environmental Intolerances
Bridgend CBC
Bridgend County Borough Council
British Assoc of Shooting & Conservation
British Institute for Allergy and Environmental Therapy
British Meat Processors' Association
British Retail Consortium
British Veterinary Association North
British Veterinary Association South
Brookfield Foods Limited
Business Connect Heart of Wales
Caerphilly CBC
Caerphilly CBC
Caerphilly County Borough Council
Campaign for Protection of Rural Wales
Campden and Chorleywood Food Research Association Group
Cardiff Chamber of Commerce
Cardiff County Council
Cardiff Scientific Services
Cardigan Bay Fishermen's Assoc Ltd
Carmarthenshire CC
Carmarthenshire College
Carmarthenshire County Council

CBS Technologies Ltd
Celtic Dimensions
Centre for Research into Environment + Health
Ceredigion CC
Ceredigion County Council
Ceredigion County Council
Chairman, Welsh Food Advisory Committee
Champion FM
Chartered Institute of Environmental Health in Wales
Chartered Institute of Environmental Health in Wales
Children's Commissioner for Wales
Children's Commissioner for Wales
Cig Mon Group
City and County of Swansea
City of Cardiff
Clark's Original Pies
Co-operative Group (CWS) Ltd
Coleg Llysfasi Ruthin
Commission for Racial Equality
Communicable Disease Surveillance Centre Wales
Conwy County Borough Council
Conwy County Borough Council
Country Land and Business Owners Association
Country Land and Business Owners Association
Countryside Alliance Wales
Countryside Council for Wales
Countryside Council for Wales
Countryside Division
Crystal Falls
Cyngor Gwynedd
Daily Post
Dailycer Chestergate
Dairy Strategy Group
Dee Dairy Services
Denbighshire CC
Denbighshire CC
Denbighshire CC
Department of Food Science & Technology - ISSUE BY EMAIL ONLY
Diabetes UK Cymru
E T Jones, Sons & Daughter
EJ Jones and Son Ltd
Environment, Planning and Countryside Committee
Environmental Data Services Ltd
Eppyut Hill and Beulah Face Sheep Society
Eurofins Scientific

European Commission
Eversheds (Wales)
Farm Assured Welsh Livestock
Farm Assured Welsh Livestock
Farmers For Action
Farmers Markets in Wales
Farmers' Union of Wales
Farmers' Union of Wales
Federation of Small Businesses (North Wales)
Federation of Small Businesses (South Wales)
Fforwm Dwyieithrwydd Cymru (North Wales Bilingual Forum)
Five Year Freeze
Flintshire County Council
Flintshire County Council
Food and Drink Federation
Food Centre for Wales
Food Consultancy
Food Quality Panel
Food Safe
Food Safety Microbiology Laboratory
Forum Products Ltd
Friends of the Earth Cymru
G C Hahn & Co Ltd
Gelatine Products Ltd
Gelpak Ltd
Glamorgan Gem
Good Food Distributors
Graig Farm Organics
Greysones
Guild of Welsh Lamb and Beef Suppliers
Gwent Healthcare NHS Trust
Gwynedd CC
Gwynedd CC
Halo Foods Ltd
HCIMA
Headland Foods
Health & Social Services Committee
HEES
Hospital Caterers Association
Hybu Cig Cymru
Iceland Frozen Foods
Institute of Consumer Sciences
Institute of Consumer Sciences
Institute of Grassland and Environmental Research
Institute of Rural Studies (Wales)

Institutes of Rural Health
International Federation for Home Economics
Isle of Anglesey County Council
Kwik Save Group Ltd
LACORS
LACORS (Welsh Officer)
Liverpool Daily Post and Echo Ltd (Welsh Edition)
Llanwenog Sheep Society
Lleyn Sheep Society
Marcher Gold
Meat and Livestock Commission
Meat and Livestock Commission's Consumer's Committee
Medicines and Healthcare Products Regulatory Agency (MHRA)
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Meridian Foods
Merthyr Tydfil CBC
Messrs TG, P & S Jones
Mid Wales Manufacturing Group
Minton, Treharne & Davies Ltd
Monmouthshire CC
Monmouthshire County Council
Monmouthshire Food Initiatives Officer
Mr R Lewis
National Association of Health Stores
National Britannia
National Farmers Union (Wales)
National Farmers Union (Wales)
National Farmers Union (Wales)
National Federation of Meat and Food Traders
National Federation of Womens Institutes - Wales
National Sheep Association (Wales)
Neath Port Talbot CBC
Neath Port Talbot CBC
Neuadd Brycheiniog
Newport CBC
NHS Staff College
North East Wales NHS Trust
North Wales/Borderlands Tourism Alliance

PB Gelatins UK Ltd
Pembrokeshire County Council
Pencoed College
Peters Food Service Ltd
PHA Cymru
PHLS in Wales
PHLS in Wales
PHLS in Wales
Plas Gwyn
Port Health Services
Powys CC
Powys Food Futures Group
Process Drying Ltd
Procheck Food Safety Ltd
PRP Training Ltd
PTP Quality Training
Public Analyst's Laboratory
Rachel's Dairy
Radnor Hills Natural Mineral Water Co
RCT Trading Standards Dept
Red Dragon FM
Red Meat Strategy Group
Red Star BioProducts
RHM Frozen Foods Limited
Rhondda Cynon Taff CBC
Rhondda Cynon Taff CBC
Rhondda Cynon Taff CBC
Rhondda Cynon Taff CBC
Royal Institute of Chartered Surveyors (Wales) (formally agricultural auctioneers)
Royal Institute of Chartered Surveyors Wales
Royal National Institute for the Blind
Royal Welsh Agricultural Society
Royal Welsh Agricultural Society
Ruddock & Sherratt
Sainsbury's Supermarkets Limited
School of Applied Sciences
School of Environmental Sciences
SEAC
Senior Assistant Trading Standards Officer
Severn Trent Laboratories
Society of Directors of Public Protection - North Wales
Society of Directors of Public Protection Wales - Trading Standards Group
Somerfield Stores Ltd.
South Caernarfon Creameries Ltd
South Wales Evening Post

State Veterinary Service
Stork MPS (Meat Processing Systems)
Suffolk Sire Reference Scheme Limited
Sunday Times
SUSTAIN
Swansea Local Health Group
T/A Source Foods
Teeswater Sheep Breeders Association
Tesco Stores Ltd
The Association of Public Analysts
The Federation of Bakers
The Highway Café
The Organic Working Group
The Speciality Sauce Co. Ltd
The Western Mail
Tillery Valley Foods Ltd
TMCI (UK) Ltd
Torfaen CBC
Torfaen County Borough Council
Torfaen County Borough Council
Tovali Ltd
Trading Standards Institute (Wales)
Twin Chef Foods
UNISON
University of the Third Age
University of Wales Aberystwyth
UWIC
UWIC
Vale of Glamorgan Council
Vale of Glamorgan Council
Vaynol Arms
Vydex Nutrition
Wales and Border Counties Pig Breeders Association
Wales Assembly of Women
Wales Centre For Health
Wales Centre for Health
Wales Council for the Blind
Wales Council for the Deaf
Wales Council for Voluntary Action
Wales Pensioners
Wales Social Partners Unit
Wales Young Farmers' Club
WDA Agri-Food Development
WDA Agri-Food Partnership
WDA Food Directorate

WDA Food Directorate
WDA Food Directorate
Welsh Agricultural Organisation Society
Welsh Assembly Government
Welsh Assembly Government
Welsh Assembly Government-Public Health Protection
Welsh Assembly of Women
Welsh Black Cattle Society
Welsh Consumer Council
Welsh Development Agency
Welsh Food Alliance
Welsh Food Laboratories
Welsh Food Microbiological Forum
Welsh Food Promotions
Welsh Highland Shepherds
Welsh Institute of Rural Studies
Welsh Lamb and Beef Promotions
Welsh Local Government Association
Welsh Local Government Association
Whitbread Holdings PLC
Women in Agriculture
Women's Food & Farming Union
Women's Food and Farming Union Livestock Committee
Womens Farming Union
Womens National Commission
Woodward Food Service
Wrexham CBC
Wrexham Licensed Victuallers Association
Wrexham Town Centre Forum
Zorba Foods