

# EPC(2) 08-05(p2) Annex B

To: Business Committee

From: Carwyn Jones AM

Minister for Environment, Planning and Countryside

## Explanatory Memorandum

Environmental Protection Wales

### THE GENETICALLY MODIFIED ORGANISMS (TRACEABILITY AND LABELLING) (WALES) REGULATIONS 2005

#### Summary

These Regulations make provision for the administration and enforcement of Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms (GMOs) and the traceability of food and feed products produced from GMOs. The Regulations allow inspectors authorised by the National Assembly for Wales to enter premises to carry out tests, take samples and/or require the provision of information. Where an inspector is satisfied that a product consisting of or containing GMOs or food or feed produced from GMOs has not been labelled in accordance with Regulation (EC) 1830/2003, the inspector is empowered to serve a notice withdrawing or prohibiting the movement of the product until labelling is corrected. The Regulation also provides for criminal offences and penalties relating to breach of requirements of Regulation (EC) 1830/2003 and for obstruction of inspectors. Specific defences to the offences are also set out in the Regulations.

1. This Memorandum is submitted to the Assembly's Environment, planning and Countryside Committee in relation to the Genetically Modified Organisms (Traceability and Labelling) (Wales) Regulations 2005, in accordance with Standing Order 24.6.
2. A copy of the Instrument is submitted with this Memorandum

#### Enabling Powers

3. The powers enabling this Instrument to be made are contained in section 2(2) of the European Communities Act 1972. The National Assembly for Wales has been designated, under section 2(2) of the 1972 Act, to make Regulations. for matters relating to the placing on the market, deliberate release and transboundary movement of GMOs, by virtue of the European Communities (Designation) (No. 4) Order 2003 (S.I. 2003/2901).

## Effect

4. The Regulations implement in Wales Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms (GMOs) and the traceability of food and feed products produced from GMOs. The objective of Regulation 1830/2003 is to create a harmonised EU framework for the traceability of products consisting of or containing GMOs and for the traceability of food and feed produced from GMOs at all stages of the production and distribution chain in order to facilitate effective labelling. Effective labelling will facilitate better consumer choice and risk management in relation to these products.
5. Regulation 1830/2003 is binding in its entirety and has been directly applicable in all Member States since 18 April 2004. Each UK competent authority is required to enforce and administer the requirements of the Council Regulation.
6. The Regulations will establish offences and penalties, and will empower inspectors to take enforcement action. Local Authority enforcement bodies, which already have responsibility for enforcement of the current Genetically Modified labelling requirements, will be responsible for ensuring compliance with the Regulations.
7. These Regulations are directly related to the Genetically Modified Food (Wales) Regulations 2004 and the Genetically Modified Feed (Wales) Regulations 2004, which implement Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, on which the Food Standards Agency (Wales) leads.

## Target Implementation

8. It is intended that this Instrument should come into force on 15 July 2005. Similar legislation was made in England on 8 October 2004 and in Scotland on 15 November 2004. It is anticipated that similar legislation will be made in Northern Ireland on 30 June 2005. The implementation of this Instrument has been delayed in Wales for several reasons. The initial Instrument produced by Defra, and upon which this Instrument is based, was reported for defective drafting by the Joint Committee on Statutory Instruments (JCSI). There was a subsequent delay whilst that Instrument was re-drafted before Directorate of Legal Services could produce a similar Welsh Instrument. In addition, development work on GM coexistence proposals and the need to concentrate resources on taking forward the Assembly's restrictive GM policy at the European level have led to the delay in bringing forward these Regulations in Wales.
9. Non-implementation of these Regulations would leave the Assembly and the UK in breach of its Community obligations and would leave a gap in the enforcement of these provisions. Consumers in Wales would be disadvantaged in comparison to their counterparts in the remainder of the UK and the Assembly would be open to substantial criticism. European Regulations are directly applicable to all Member States, and the Assembly is required to implement them as soon as possible.

## Financial Implications

10. There are no additional financial implications for the Assembly from the making of these Regulations.
11. Labelling provisions will impose some direct costs, although many businesses will already have systems in place for record keeping and providing information to the final consumer.
12. Costs to businesses will involve:
  - The direct cost of maintaining additional information regarding the use of GM material in food ingredients, passing this information along the supply chain, and providing information on GM content through labelling; and
  - The potential indirect cost for food manufacturers arising from voluntary sourcing of alternative supplies of non-GM derived ingredients in order to avoid the need to label products.

1. Main costs of enforcing the new Regulations have been identified as:

- The cost of monitoring the accuracy of traceability and labelling;
- Any potential testing products for GM content; and
- The cost of imposing penalties for non-compliance.

1. Since 1999, regulations have been in force requiring the labelling of GM food ingredients. The new food Regulations extend the range of food ingredients to be labelled. Local Authorities are responsible for monitoring and enforcing compliance with food labelling requirements and they will pick up responsibility for labelling under the new feed labelling requirements.
2. Although there were no responses from local authorities in Wales to the joint Food Standards Agency (Wales) and National Assembly for Wales public consultation exercise, one county council in England, which is specifically setting up facilities for testing, has estimated an annual running cost of £50k. However, Local Authorities Co-ordinators for Regulatory Services (LACORS UK) has indicated that this example is one extreme of the spectrum and they are not expecting other authorities to act in this way. It is not anticipated that additional costs will be incurred by local authorities. However, local authorities are being encouraged to collate information in relation to expenditure on enforcement of these Regulations, as enforcement activity will be considered as part of the European Commission's review of the Regulations.

### Regulatory Appraisal

3. A Regulatory Appraisal has been prepared in relation to this Instrument and is attached. The Regulatory Appraisal jointly covers the Traceability and Labelling Regulations and the Food and Feed Regulations (i.e. the Genetically Modified Animal Feed (Wales) Regulations 2004 and the Genetically Modified Food (Wales) Regulations 2004). This approach has been taken because these Regulations are closely related and the level of crossover between them is such that a joint Regulatory Appraisal increases the transparency.

## Consultation

### With Stakeholders

4. A joint Welsh Assembly Government and Food Standards Agency Wales consultation was undertaken between 29 April 2004 and 28 June 2004. The joint consultation encompassed the Genetically Modified Food (Wales) Regulations 2004, the Genetically Modified Animal Feed (Wales) Regulations 2004, the Genetically Modified Organisms (Traceability and Labelling) (Wales) Regulations 2005 and the Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2005. A full list of consultees is attached at Annex A.
5. One substantive response was received in relation to the Traceability and Labelling Regulations. The response asked for clarification of the role of the enforcement bodies and costs to business. These issues were addressed in the final Regulatory Appraisal. Fifty-five responses in total were received to parallel consultations in the other UK administrations, of which 21 were comments on the Regulatory Appraisal. Interested parties were asked whether they agreed with the analysis of costs and benefits presented in the Regulatory Appraisal and whether there were any significant areas of benefits and/or costs not covered by the Regulatory Appraisal. Responses from interested parties have been incorporated into the final Regulatory Appraisal.
6. Following stakeholder comments, the Regulatory Appraisal was simplified to make it more understandable, a large amount of complex information was removed and more basic text introduced. In addition, an introductory summary was included. Respondents were unable to provide input in relation to direct and indirect costs incurred and have stated that this will be monitored over the forthcoming year. There were no changes in policy that required changes to be made to the draft Regulations.

### With Subject Committee

7. The Regulations were notified to the Environment, Planning and Countryside Committee in May 2004, when the consultation papers issued, and on 6 October 2004, via the list of forthcoming legislation (EPC(2)-09-04 (P.4) Annex 1 Item No. 26). A request to scrutinise the regulations was made at the Committee's meeting on 13 April 2005 and consequently the Regulations have been tabled for EPC Committee scrutiny on 22 June 2005.

### Recommended Procedure

8. Subject to the views of the Business Committee I recommend that the legislation Regulations proceed to Plenary under the Standard procedure to give Members the opportunity to debate the issue.

### Compliance

9. I confirm that the proposed legislation will (as far as is applicable):

- have due regard to the principal of equality of opportunity for all people (Government of Wales Act 1998, section 120);
- be compatible with the Assembly's scheme for sustainable development (section 121);
- be compatible with Community law (section 106);
- be compatible with the Assembly's human rights obligations (section 107); and
- be compatible with any international obligation binding the UK Government and the Assembly (section 108).

1. The information in this Memorandum has been cleared with the Directorate of Legal Services and the Assembly Compliance Officer (ACO).
2. Drafting Lawyer: Mr Sean Bradley, ext. 3202
3. Head of Division: Mrs Norma Barry, ext. 6228
4. Policy Contact: Mr Martin Williams, ext. 3452

CARWYN JONES JUNE 2005

MINISTER FOR ENVIRONMENT, PLANNING AND COUNTRYSIDE

ANNEX A

### Consultation List

AMs	MEPs (Wales)
MPs (Wales)	Abergavenny Fine Foods
ACCAC	ADAS Wales
Advisory Committee on Genetic Modification	Advisory Committee on Releases into the Environment
Age Concern Cymru	Agriculture and Environment Biotechnology Commission
Alderwicks Soft Drinks	All Wales Dietetic Advisory Committee
Aqua Prima Ltd	Arfon Meat Company
Association of Civic Hosts	B. Sidoli & Sons Ltd
Bar and Restaurant Foods Ltd	BBC Radio Cymru
BBC Wales	Beggan Farm Partnership
BEN (Black Environment Network) -	Berwyn Bakery

Biotrace Limited	Blaenau Gwent CBC
Brecon Beacons National Park	Brecon Beacons Natural Waters
Brecon Support Group for Sufferers of Food/ Environmental Intolerances	Brewster et Hugette White
Bridgend County Borough Council	British Assoc of Shooting & Conservation
British Institute for Allergy and Environmental Therapy	British Meat Processors' Association
British Retail Consortium	British Soft Drinks Association
Brookfield Foods Limited	Business Connect Heart of Wales
Cadbury Schweppes European Beverages	Caerphilly County Borough Council
Campaign for Real Milk	Campaign for the Protection of Rural Wales
Campden and Chorleywood Food Research Association Group	Cardiff Business Technology Centre
Cardiff Chamber of Commerce	Cardiff County Council
Cardiff Scientific Services	Carmarthen Water Ltd
Carmarthenshire County Council	CBI Wales
Celtic Dimensions	Centre for Research into Environment + Health
Ceredigion County Council	Cerist Natural Mineral Water Co
Chairman, Welsh Food Advisory Committee	Champion FM
Chartered Institute of Environmental Health in Wales	Chester, Ellesmere Port and North Wales Chamber of Commerce
Children's Commissioner for Wales	City and County of Swansea
City of Cardiff	Clark's Original Pies
Coed Cymru	Commission for Racial Equality
Conwy County Borough Council	Conwy Mussel Company
Co-operative Group (CWS) Ltd	Council of National Parks
Country Land and Business Association (Wales)	Countryside Alliance Wales
Countryside Council for Wales	Crystal Falls
Cyngor Gwynedd	Daily Post
Dailycer Chestergate	Dairy Strategy Group

DARD (NI)	Decantae Mineral Water
Dee Dairy Services	DEFRA
Denbighshire County Council	Department of Food Science & Technology
Diabetes UK Cymru	Dr H Fullerton
EJ Jones and Son Ltd	ELWa
Environment Agency	Environmental Data Services Ltd
Eppyut Hill and Beulah Face Sheep Society	ESTYN
Eurofins Scientific	European Commission
Eversheds (Wales)	Farm Assured Welsh Livestock
Farmers For Action	Farmers' Union of Wales
Federation of Field Sports of the EEC	Federation of Small Businesses
Fforwm Dwyieithrwydd Cymru (North Wales Bilingual Forum)	Five Year Freeze
Flintshire County Council	Food and Drink Federation
Food Centre for Wales	Food Quality Panel
Food Safe	Food Safety Microbiology Laboratory
Forestry Commission (Wales)	Forum Products Ltd
Friends of the Earth (Wales)	G C Hahn & Co Ltd
Gelatine Products Ltd	Gelpak Ltd
Glamorgan Gem	GM Co-ordination Team, Edinburgh
GM Free Cymru	Good Food Distributors
Gower Spring Water Co	Graig Farm Organics
Greenpeace	Guild of Welsh Lamb and Beef Suppliers
Gwent Healthcare NHS Trust	Gwynedd County Council
Halo Foods Ltd	HCIMA
Headland Foods	HEES
Hybu Cig Cymru	Iceland Frozen Foods
IGER	Institute of Consumer Sciences
Institutes of Rural Health	International Federation for Home Economics

Isle of Anglesey County Council	Kwik Save Group Ltd
LACORS (Welsh Officer)	Lady Moran
Liverpool Daily Post and Echo Ltd (Welsh Edition)	Llanwenog Sheep Society
Lleyn Sheep Society	Lucas Meyer (UK) Ltd
M/S J R W & S Rogers	Marcher Gold
Martin Forsyth	Meat and Livestock Commission
Meat and Livestock Commission's Consumer's Committee	Meridian Foods
Merthyr Tydfil CBC	Messrs Davies
Mid Wales Manufacturing Group	Milk Development Council
Minton, Treharne & Davies Ltd	Monmouthshire CC
Monmouthshire Food Initiatives Officer	Monmouthshire Trading Standards Dept
Montgomery Spring Water Co	Mr D Staniforth
Mr Ivor Lewis	Mr O M Owen
Mr R Lewis	Mrs H E James
Mrs J MacDonald	Ms G Ashmore
National Assembly for Wales – Brussels Office	National Assoc. of Head Teachers - Cymru
National Britannia	National Farmers' Union (Wales)
National Federation of Women's Institutes - Wales	Neath Port Talbot County Borough Council
Neuadd Brycheiniog	Newport County Borough Council
NHS Staff College	North East Wales NHS Trust
North Wales/Borderlands Tourism Alliance	Organic Farming Centre for Wales
PB Gelatins UK Ltd	Pembrokeshire Coast National Park Authority
Pembrokeshire County Council	Pembrokeshire Spring Water Co
Peters Food Service Ltd	PHA Cymru
PHLS - CDSC Wales	PHLS in Wales
Plas Gwyn	Powys CC
Powys Food Futures Group	Prince's Gate Spring Water
Process Drying Ltd	Procheck Food Safety Ltd



PRP Training Ltd	PTP Quality Training
Public Analyst's Laboratory	Public Health Protection Division 1
Rachel's Dairy	Radnor Hills Natural Mineral Water Co
RCT Trading Standards Dept	Red Dragon FM
Red Star BioProducts	RHM Frozen Foods Limited
Rhondda Cynon Taff County Borough Council	Royal Institute of Chartered Surveyors (Wales) (
Royal National Institute for the Blind	Royal Welsh Agricultural Society
RSPB	Ruddock & Sherratt
Sainsbury's Supermarkets Limited	School of Environmental Sciences
Scientific Services	SCIMAC
Senior Assistant Trading Standards Officer	Severn Trent Laboratories
Snowdonia National Park Authority	Society of Directors of Public Protection
Soil Association	Somerfield Stores Ltd.
South Wales Evening Post	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 Cafe	The Institute of Plumbing
The Organic Working Group	The Speciality Sauce Co. Ltd
The Western Mail	The Woodland Trust, Lincolnshire
Tillery Valley Foods Ltd	TMCI (UK) Ltd
Torfaen County Borough Council	Tovali Ltd
Trading Standards Institute (Wales)	Twin Chef Foods
Ty Nant Spring Water	UKASTA Wales
UNISON	Universities (Wales)
Vale of Glamorgan Council	Vaynol Arms
Vydex Nutrition	Wales Assembly of Women

Wales Centre For Health	Wales Council for the Blind
Wales Council for the Deaf	Wales Countryside and Wildlife Link
Wales European Centre	Wales Heart Research Institute
Wales Pensioners	Wales Social Partners Unit
Wales tourist Board	Wales TUC Cymru
Wales Young Farmers' Club	WCVA
WDA	Welsh Agricultural Organisation Society
Welsh Assembly of Women	Welsh Beekeepers' Association
Welsh Black Cattle Society	Welsh Consumer Council
Welsh Council of the Institution of Environmental Health Officers	Welsh Development Agency
Welsh Food Advisory Committee	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	Whitbread Holdings PLC
Wildlife Trusts	Women in Agriculture
Womens Farming Union	Womens National Commission
Woodward Food Service	Wrexham CBC
Wrexham Licensed Vicuallers Association	Wrexham Town Centre Forum
WWF Cymru	Zorba Foods