

REGULATORY APPRAISAL

ENVIRONMENTAL PROTECTION, WALES

THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) (WALES) (AMENDMENT) REGULATIONS 2005

Background

1. The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 implement in Wales Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms. Directive 2001/18/EC establishes a common system in the EU for the regulation of approvals of GMOs. It encompasses both contained use of GMOs, for example uses in controlled experimental trials, and deliberate releases of GMOs, for example the cultivation of a GM crop variety. This system follows a case-by-case, evidence-based approach to GMO assessments, under which a GMO will not receive approval for use unless it has been demonstrated that it does not pose an increased risk to human health or the environment.
2. Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed lays down specific Community procedures and provisions for the assessment, authorisation, supervision and labelling of GM food and feed. This aims to provide the basis for ensuring a high level of protection to human life and health, the environment and consumer interest in relation to GM food and feed, whilst ensuring the effective functioning of the internal market. The Food and Feed Regulation has been in force since 7 November 2003 and has been applicable in Member States since 18 April 2004.

Purpose and intended effect of the measure

3. These Regulations amend the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 (S.I. 2002/3188). Consequential amendments are required to the 2002 Regulations to reflect amendments made by Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (the Food and Feed Regulation) to Directive 2001/18/EC on the deliberate release into the environment of GMOs (the Deliberate Release Directive).
4. The amendment Regulations make provision for GM food and feed products that are authorised under Regulation (EC) 1829/2003 to be marketed without the requirement to obtain a separate marketing consent under the Environmental Protection Act 1990 or to undergo an additional risk assessment under the Act.
5. The amendment Regulations make provision, until 18 April 2007, for the marketing of products for use directly in food or feed or for processing, which contain trace amounts of one or more GMOs that have not been authorised for use under Directive 2001/18/EC. That is, products that contain traces of an unauthorised GMO (or mixture of GMOs) up to a maximum level of 0.5% are

exempt from the requirements of the Act – to obtain a marketing consent or to undergo a risk assessment – providing that:

- the trace presence is adventitious or technically unavoidable;
- the GMO holds a favourable risk assessment;
- the application for the authorisation of the GMO has not already been rejected; and
- detection methods for the GMO are made publicly available.

Risk Assessment

6. With the exception of leaving the Assembly susceptible to infraction proceedings being brought by the European Commission, there would be no risk of a harmful effect from failure to implement the amendment Regulations.

Options

7. 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 recommended.

Benefits

8. Introducing the amendment Regulations will bring the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 up to date with the latest EU legislation. It will also bring Wales' GMO legislation into harmony with the other UK administrations' GMO legislation.

Costs

9. As these are consequential amendments, no additional costs will arise from their implementation for the Assembly.

10. There are no financial implications for the public or other stakeholders associated with the making of these Regulations.

Competition Assessment

11. These Regulations will have a minor impact on the business sector – the Regulations will allow applicants (i.e. biotech companies) to apply for deliberate release and marketing consents directly under the Food and Feed Regulations, as opposed to seeking these under Directive 2001/18/EC. This removes the requirement on the applicant to duplicate authorisations and risk assessment procedures.

Consultation

With Stakeholders

12. A joint Welsh Assembly Government and Food Standards Agency Wales consultation was undertaken between 29 April and 28 June 2004 (a list of the consultees is attached at Annex 1). The joint consultation encompassed the GM Food (Wales) Regulations 2004, the GM Animal Feed (Wales) Regulations 2004, the GMO (Traceability and Labelling) (Wales) Regulations 2005 and the GMO (Deliberate Release) (Amendment) (Wales) Regulations 2005. Nothing contentious was raised about the Deliberate Release (Amendment) Regulations and consequently no amendments were necessary.

With Subject Committee

13. The Environment, Planning and Countryside Committee was notified of the Regulations in May 2004, when the joint consultation package issued. No comments were received from the Committee as a result of this consultation. The Regulations also appeared on the list of forthcoming legislation (EPC(2)-09-04(p.4) Annex 1, item no: 33) submitted to the Committee on 6 October 2004, but were not identified for detailed scrutiny.

Review

14. The amendment Regulations will not be reviewed per se, however the Food and Feed EC Regulation contains specific review provisions, on which the Commission is tasked to report to the European Parliament and the Council by November 2005. Although the review report may cover any aspect of the Regulations, the Commission has been specifically asked to report on the operation of the 0.5% transitional threshold in relation to GM food and feed.

Summary

15. There are no costs in making this legislation. The amendment Regulations will update the domestic Deliberate Release legislation for it to come in line with new GM food and feed rules.

ANNEX 1

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