

REGULATORY APPRAISAL

FOOD, WALES

THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (AMENDMENT) (NO.2) (WALES) REGULATIONS 2005

Background

1. The Plastic Materials and Articles in Contact with Food Regulations 1998, as amended, set overall migration limits for the substances that may be used in the manufacture of food contact plastics. They establish a positive list of monomers (small molecules that become chemically bonded to other monomers to form a polymer) and starting substances permitted for use in manufacturing food contact plastics and establish an incomplete list of additives already approved by some EU Member States. They provide for any specific migration limits conditional on their use and lay down basic rules for testing the migration from food contact plastics.
2. The updating of the lists of monomers and additives that can be used in the manufacture of plastic materials and articles intended to come into contact with food is routine. New scientific data is regularly taken into account in the assessment of the risk that may be posed by the presence of these substances in food.

Purpose and Intended Effect of the Measure

3. The proposed legislation will implement European Commission Directive 2004/19/EC that amends Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs. Directive 2004/19/EC makes routine amendments to the Community list of permitted monomers and additives and makes provision for a date to be set by which the European Commission shall establish a positive list of additives that may be used in the manufacture of food contact plastics.
4. The new Directive specifically seeks to:
 - routinely amend the Community list of permitted monomers in Annex II and the incomplete list of additives in Annex III to Directive 2002/72/EC to include new substances and amend the entries for others. These changes reflect the published expert risk assessment for the substances conducted at European level. Among these amendments is the transfer of certain monomers and other starting substances (chemicals which start the process of polymerisation) from the list in Annex II B (authorised only until 31 December 2004) to the list in Annex II A (authorised without time limit);
 - set a date, 31 December 2007, by which the European Commission must announce the date for closing the list of additives used in the manufacture of food contact plastics as the first step in creating a positive list of these additives. Thus, the Commission shall establish by 31 December 2007 a provisional list of additives containing those that are already authorised in

one or more Member States and for which the necessary data stipulated by the European Food Safety Authority (EFSA) has been submitted so that each substance may continue to be used pending evaluation by the EFSA;

- introduce a requirement of Member States that by 31 December 2006 they shall provide for the submission of the required data to the EFSA for any additive that is to be entered on the provisional list; and
 - introduce other provisions to ensure that additives used in the manufacture of food contact plastics that are also authorised food additives shall not migrate into foodstuffs in quantities having a technological function in the final foodstuffs; in excess of the amounts permitted by food additives rules; or, where they are not authorised as an additive in a particular food, in excess of the amount permitted by Directive 2002/72/EC, as amended.
5. In the current Plastic Materials and Articles in Contact with Food Regulations 1998, Annex II A to Directive 2002/72/EC is replicated in Section A of Part I of Schedule 1, and Annex II B is reproduced in Section B. The deadline for implementing Directive 2004/19 into national measures is not until 1 September 2005. However, as a consequence, from 1 January 2005 until they are amended, the 1998 Regulations will be out of step with EC law. This is because until the amendment comes into force, it will technically be an offence to use those time limited monomers still listed in Section B of Part 1 of Schedule 1, which have in fact been given permanent authorisations and are now listed in Annex II A of the Directive. Therefore, between 1 January 2005 and the coming into force of the new amending Regulations, when the permanent authorisations in 2004/19/EC are implemented, the Foods Standards Agency are content for enforcement authorities to take a relaxed approach to enforcing provisions in relation to those monomers in Section B of Part I of Schedule 1 of the 1998 Regulations.

Risk Assessment

6. Directive 2004/19/EC reflects improved scientific knowledge of particular chemicals in relation to human health and changes the lists of substances that may be used in manufacturing food contact plastics. Some substances have been deleted from the Community list of monomers and additives either because satisfactory data has not been submitted by applicants for completion of the necessary risk assessment by the EFSA, or because risk assessments have deemed that the substances should no longer be used.
7. The European Food Safety Authority (EFSA) carries out risk assessments and gives its opinion on the safe use of substances used in the manufacture of food contact plastics based on dossiers submitted by industry that support a request for their approval for use in manufacturing a plastic food contact material or substance. These opinions are given in consideration of the protection of public health from any harmful effects that may arise from consumption of food into which the substance may have migrated. Any resulting limits on use that are contained in EFSA's opinions have margins of

safety to ensure that the health of consumers who may eat contaminated foodstuff would not be affected over their lifetime. The resulting European Commission proposals contain additional safety margins that are added to determine the level of a substance that may be allowed to migrate into the food.

8. The European Commission routinely makes proposals to amend these technical limits, or levels of migration, and refines definitions that are included in its lists of authorised substances as scientific understanding of the substances and their health effects improves. Substances that are deemed to cause unacceptable risk to consumer health, particularly among more vulnerable people, will be prohibited from use. Thus, Member States routinely amend their national Regulations and this is the case for implementation of this Directive. As well as putting in place restrictions on the use of substances, the measures provide the means for authorities to act when risks arise to human health and for consumers to have better information about the products that they buy. Once in place the measures ensure that the industry has only one set of rules to abide by instead of different rules in different EU Member States.
9. Transposition of this Directive is essential if our consumers are to have the same level of health protection as other EU Member States, from the potentially harmful effects of excessive levels of substances that might migrate into their food. Industry welcomes the creation of harmonised EU rules that govern the manufacture of their products. This ensures they compete on level terms to meet common standards of health protection across the EU. Industry also recognises that these harmonised measures play a key part in maintaining consumer confidence in the safety of its products.
10. Failure to fully implement this Directive would leave UK consumers with less protection than elsewhere in the EU. Even without implementation in the UK, industry would work to these rules anyway, as the international nature of their business would necessitate the adherence to the stricter limits applying elsewhere in the EU.

Options

11. 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 the European legislation, is being implemented.

Benefits

Economic

12. As most businesses involved operate on a European and even global basis, their concern would be to ensure continuing access to the wider EU market for their products. Full implementation ensures that manufacturers and suppliers of the materials and articles that are subject to these rules enjoy

the benefits of a set of rules that are applied throughout the single market of the EU and that those rules move closer to full harmonisation across Europe.

Social

13. By implementing these measures in full, the Government ensures that UK consumers benefit from increased health protection from the migration into food of potentially harmful substances used in the manufacture of food contact plastics. These measures reflect the independent views of an EU expert scientific committee after assessment of chemical migration and toxicity data coupled with estimates of consumer exposure to the chemical migrant.

Environmental

14. The environmental impact of this proposal is negligible.

Costs

15. As part of the public consultation exercise, business was asked to comment upon any financial impact arising from the proposed legislation. No comments were received in Wales and in England, the consultation outcome confirmed that the measures proposed in the proposed legislation have no specific extra requirements that lay any new financial burdens on the industry.

16. There are no additional financial implications to local authorities or the Assembly arising from these Regulations. There are no compliance costs for charities and voluntary organisations. The business sectors most likely to be affected are the manufacturers of food contact plastic materials and articles, their raw materials suppliers and downstream users. These are largely international companies or their subsidiaries that operate in an international, often global market. These proposals do not specifically impact on ethnic communities nor rural areas.

Issues Of Equity and Fairness

17. The Regulations extend harmonisation across the EU for substances that may be used, and the conditions that apply to their use, in the manufacture of plastic food contact materials and articles. The proposed measures should have equal effect across the European food contact plastics industry and its commercial customers. In addition, UK consumers will have the same health protection as consumers in the rest of the EU from the effect of consumption of excessive amounts of the substances dealt with in these proposals.

Competition Assessment

18. Industry and businesses have been closely involved at European level in the development of these proposals and have not raised any issues that indicate a disadvantage to any particular business sector. The proposals apply equally to all plastic materials and articles intended to be brought into contact with food and will not therefore disadvantage any particular business sector, nor company.

Enforcement and Sanctions

19. Local authorities will carry out enforcement. There will be no significant resource implications for them from these Regulations. However, the Food Standards Agency routinely monitors foodstuffs on sale to the public to ensure compliance with the Regulations. The results of this work are published and are openly available. Where safety margins are eroded the Agency will work with industry to restore them. Where safety levels are breached the Agency will inform the enforcement authorities so that they may take appropriate action.

Monitoring and Review

20. The Food Standards Agency will consider any comments organisations or individuals may make in the light of experience of the amendments to the existing Regulations.

Consultation

With Stakeholders

21. The Food Standards Agency in Wales carried out a thirteen week consultation with stakeholders on the provisions relating to regenerated cellulose film (a thin sheet material derived from unrecycled wood or cotton) between 10 December 2004 to 18 March 2005. Stakeholders included: all Assembly Members; and consumer and industry representative bodies (a full list of consultees is attached at Annex A) and were invited to comment on the draft Regulations and the draft Regulatory Appraisal.

22. Parallel consultations were carried out in England, Scotland and Northern Ireland. No comments were received from stakeholders in Wales. In England, the consultation outcome confirmed that the measures proposed in the proposed legislation have no specific extra requirements that lay any new financial burdens. No policy changes to the draft Regulations were identified as a consequence of the public consultation.

With Subject Committee

23. 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 6 October 2004 (HSS(2)-11-04, item no: FS 19 (04)) and in successive meetings. The Regulations were not identified for detailed scrutiny.

Consultation with Small Business (The Small Firms Impact Test)

24. The companies involved in this area are represented through their national trade bodies to those at European level. The Small Business Bureau has been consulted, they indicated that there might be some financial implications for small businesses arising from this proposal. However, they were unable to provide any specific data or information. The Food Standards Agency has not, through its contacts been able to identify any information supporting this view.

Summary and Recommendations

25. The Agency believes that the advantages of full implementation of the proposals will benefit industry, enforcement authorities and consumers. The measures proposed are important in providing essential consumer health protection and improved product information. They also provide businesses with harmonised rules and greater transparency in the authorisation of new substances for use in materials and articles in contact with food.

Contact Point

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ANNEX A

Company Name	Contact
ADAS Wales	Cate Barrow - Food Business Development Manager
Bar and Restaurant Foods Ltd	Mr Mark Dukes
Brecon Support Group for Sufferers of	Ms H Bradley
British Institute for Allergy and Environmental	The Secretary
British Retail Consortium	Mr Richard Wood
Brookfield Foods Limited	Mr M Howard
Carmarthen Water Ltd	
Cerist Natural Mineral Water Co	
Chairman, Welsh Food Advisory Committee	Mrs Ann Hemingway, Chair
Chartered Institute of Environmental Health in	Julie Barratt, Director
Chartered Institute of Environmental Health in	Mr Paul Handby, Development Co-ordinator
Clark's Original Pies	Ceri J Baillie
Co-operative Group (CWS) Ltd	Wendy Cave
Crystal Falls	
Decantae Mineral Water	Mr Ian Spooner
Dee Dairy Services	Mrs J Higginbothom
Environmental Data Services Ltd	Dr Phillip Lightowlers
Eurofins Scientific	Mr R A Ennion
Farmers' Union of Wales	Mr Arwyn Owen, Director of Policy
Federation of Small Businesses (North Wales)	Gwyn Evans, Chairman
G C Hahn & Co Ltd	The Secretary
Gelpak Ltd	Mr Harris
Good Food Distributors	Mr K F Powell
Gower Spring Water Co	
Halo Foods Ltd	Elizabeth Williams
Health & Social Services Committee	Jane Hutt AM
Health & Social Services Committee	Ann Jones AM
Health & Social Services Committee	Jonathan Morgan AM
Health & Social Services Committee	Rhidri Glyn Thomas AM
Health & Social Services Committee	David Melding AM, Chair
Health & Social Services Committee	Jocelyn Davies AM
Health & Social Services Committee	John Griffiths AM
Health & Social Services Committee	Val Lloyd AM
Iceland Frozen Foods	Peter Lee
International Federation for Home Economics	Ms Jane Lloyd Hughes
Kwik Save Group Ltd	David Hill
LACORS (Welsh Officer)	Ms Susan Perkins
Member - Welsh Food Advisory Committee	Dr David Casemore
Member - Welsh Food Advisory Committee	Professor SM Griffiths
Member - Welsh Food Advisory Committee	Professor Robert Pickard
Member - Welsh Food Advisory Committee	Mrs Gilli Davies

Member - Welsh Food Advisory Committee	Mrs Dilwen Phillips
Member - Welsh Food Advisory Committee	Dr Robert Bell
Member - Welsh Food Advisory Committee	Professor James Parry
Member - Welsh Food Advisory Committee	Mr David Smith
Meridian Foods	Mrs Brenda Davies
Montgomery Spring Water Co	Richard Whittall
National Farmers Union (Wales)	Mrs Mary James
Pembrokeshire Spring Water Co	Charles King
Peters Food Service Ltd	David Jackson
Prince's Gate Spring Water	Glyn Jones
Public Analyst's Laboratory	Mr Trevor Johnson
Rachel's Dairy	Joanna Tett
Radnor Hills Natural Mineral Water Co	Jean Farmer
RHM Frozen Foods Limited	C R Taylor
Ruddock & Sherratt	R A Ennion
Severn Trent Laboratories	Jill Finch
The Association of Public Analysts	Paul Lenartowicz - Vice President
The Speciality Sauce Co. Ltd	Chris Price-Jones
Ty Nant Spring Water	Mr N S Taylor
Wales Young Farmers' Club	Lowri Jones
WDA Food Directorate	Mr Paul O' Donovan, Project Manager
Welsh Consumer Council	Viv Sugar, Chair
Welsh Food Laboratories	Mr Norman Biggs
Welsh Food Microbiological Forum	Mrs Ceri Edwards, Secretary
Welsh Local Government Association	Mr Sandy Blair
Woodward Food Service	Tim Goff