

REGULATORY APPRAISAL

FOOD, WALES

THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (WALES) REGULATIONS 2006

Background

1. A new European Regulation No. (EC) 1895/2005 completely replaces two EC Directives, 2002/16/EC and 2004/13/EC, on the use of certain epoxy derivatives (chemical composites) in materials and articles intended to come into contact with food and consequently updates the provisions of those Directives. It is necessary to provide for the enforcement of that European Regulation, for the application of penalties where offenders are convicted by the Courts, and for removing current national provisions that enacted the now revoked EC Directives on these substances. Those older enacting provisions are contained within The Plastic Materials and Articles in Contact with Food Regulations 1998.
2. Removing the provisions on epoxy derivatives from The Plastic Materials and Articles in Contact with Food Regulations 1998 will cause extensive amendment of those Regulations that also enact the provisions of EC Directive 2002/72/EC on food contact plastics. That Directive has also been amended several times, so not only would this proposal be a major further amendment to the 1998 Regulations, but it would follow five other sets of amending Regulations to the 1998 Regulations. Therefore, it was decided that the existing five amendments to the original 1998 Regulations and this sixth amendment would present too unwieldy a set of Regulations to the businesses that have to abide by them and to others who have to work with them, such as enforcement authorities, enforcement laboratories, the Courts and those professionals that act as consultants.
3. Harmonised European rules on food contact plastics are laid down by Commission Directive 2002/72/EC. These rules are routinely amended as technical and scientific knowledge enables experts within the European Food Safety Authority (EFSA) to evaluate or re-evaluate any risk for public health arising from migration of chemicals from food contact materials into food. The latest of these amendments is contained in Commission Directive 2005/79/EC.
4. For certain substances, the restrictions already established at Community level have been amended on the basis of new information becoming available. In particular, for Epoxidised Soybean Oil (ESBO), a specific limit of migration from food contact plastics into food has been established for its use in PVC gaskets used to seal the lids of glass food jars. This Specific Migration Limit (SML) is 60 milligrams of ESBO per kilogram of food or food simulant. Along with the restrictions in the 2005 EC Directive for other substances, materials and articles compliant with this limit may be traded and used from 19 November 2006. The manufacture and import of non-compliant materials and articles is prohibited from 19 November 2007.

This allows time for the manufacturers of these materials and articles to change the constituents of their products where necessary, without risking the safety of foodstuffs and their ability to comply with the law.

5. However, for PVC gaskets containing epoxidised soybean oil (ESBO) used to seal the lids of glass food jars containing infant and follow-on formulae, or containing processed cereal-based foods and baby foods for infants and young children, the Specified Maximum Limit (SML) for ESBO has been set at half the limit for other applications. The limit in these cases is 30 milligrams per kilogram of food or simulant. Additionally, the EC Directive requires that the ESBO-containing gaskets used in these applications be compliant with this migration limit by 19 November 2006. This lower migration limit takes account of the fact that babies and infants can consume proportionately higher amounts of food from this source than adults, given their much smaller body weight. Goods manufactured using ESBO and which are compliant with the rules in place before this change takes effect on 19 November 2006, may continue to be placed on the market providing they are marked with the date of filling or a code representing that date.
6. These proposals fulfil the Government's policies of meeting its EU obligations; of keeping food safe by reducing the risks to consumers from chemical contamination; of meeting the Lisbon agenda to improve the competitiveness of businesses in Europe by providing harmonised rules within which business compete; and of simplifying the laws in Wales.
7. The Food Standards Agency believes that the adoption of these proposals provides essential powers to enforce the modernised regulatory framework that removes trade barriers and allows for technological innovation. Consumer protection will continue in an area of food control where inadequate controls would have serious long-term implications for the prevention of human cancers, gene mutations and reproductive defects arising from the ingestion of amounts of substances known to carry, or are seriously suspected of carrying, an unacceptable risk to consumer health, particularly among more vulnerable people.

Purpose and intended effect of the measure

8. The purpose of these proposals is to meet several policy objectives. The Food Standards Agency are seeking to protect human health from consumption of food containing harmful levels of chemicals migrating from materials and articles with which the food has intentionally been placed in contact. Such materials and articles will commonly be food packaging, adhesives and coatings used in the packaging and articles used in the handling and storage of the food. We are also seeking to prevent these chemicals from changing the nature and quality of the food. Furthermore, these proposals will implement Commission Directive 2005/79/EC relating to plastic materials and articles intended to come into contact with food in its entirety. This will routinely update restrictions on the use of certain substances in the manufacture of food contact plastics and provide for particular restrictions on the use of epoxidised soybean oil (ESBO) in the

manufacture of sealing gaskets used in the lids of glass food jars. We are seeking to provide a harmonised set of rules across the European Union with which businesses have to comply to replace and prevent further, purely national rules within EU Member States. The proposals, therefore, come about from the UK supported adoption in the EU of a European Regulation that achieves these objectives throughout the European Union. Finally, as part of our regulatory simplification programme, we are seeking to consolidate The Plastic Materials and Articles in Contact with Food Regulations 1998 and five amending Regulations into one set of Regulations. This will make it easier for businesses and others that have to refer to the Regulations to understand their provisions.

9. These proposals will have the effect of providing for enforcement by the enforcement authorities in Wales of Commission Regulation (EC) No. 1895/2005, on the restrictions of use of certain epoxy derivatives in materials and articles intended to come into contact with food. They will also put in place offences that may be prosecuted before the Courts where alleged breaches of the European Regulations arise, defences against those alleged breaches under particular circumstances and penalties to apply upon conviction for an offence under them. They will also revoke existing national provisions in our Regulations for Wales that govern these substances.

Devolution

10. These Regulations apply to Wales only. Separate but parallel Regulations apply and came into force in England, Scotland and Northern Ireland on 30 June 2006. However, these Regulations will be amended in England, Scotland and Northern Ireland and will come into force across these countries by 19 November 2006 as the Plastic Material and Articles in Contact with Food (No.2) Regulations 2006.

Risk Assessment

11. If these Regulations are not made then there will be a continued risk to human health from ingesting harmful levels of chemicals that could have migrated from the materials or articles their food was intentionally brought into contact with.

Options

Option 1 – Do Nothing

12. These proposals fulfil the Assembly's policies of meeting its EU obligations; of keeping food safe by reducing the risks to consumers from chemical contamination; of meeting the Lisbon agenda to improve the competitiveness of businesses in Europe by providing harmonised rules within which business compete; and, of simplifying the laws in Wales. In respect of this legislation, the "Do Nothing" option is not an option. The European regulation will still apply, but the obligation to put in place provisions to enable its enforcement, to provide for offences to be prosecuted, for defences for those that could have been prosecuted and to provide for penalties to be applied to those that could have been found

to be in breach of those Regulations will not have been fulfilled and the Welsh Assembly Government would inevitably be cited in infraction proceedings by the European Commission.

Option 2 - Make the Legislation

13. This option meets the Assembly's commitment to fulfil its EU obligations and contributes significantly to providing an up-to-date means of protecting consumers from ingesting harmful levels of chemicals that could have migrated from the materials or articles their food was intentionally brought into contact with. It will do this without stifling innovation and technological development that is so necessary to businesses. As the EC Regulation is already in force, we are required to provide for its enforcement in Wales, for offences to be created and for defences to apply in particular circumstances and for penalties to apply upon conviction for an offence. This ensures that the enforcement authorities can fulfil the requirements placed upon them and that the Courts can impose penalties that are in line with others elsewhere in our food law. It also provides for defences in law for those against whom offences may be alleged in Court. Simplification will allow six sets of Regulations to be consolidated into one set of Regulations and brought up to date with modern drafting practice that will make them more understandable and, therefore, easier to comply with.
14. Under EC legislation we are required to implement Directive 2005/79/EC. Enforcement authorities want the improved clarity contained in these proposals, consumers want the improved public health protection given by these proposals and businesses want the harmonisation of rules between Member States of the EU that implementation of this EC Directive across the UK provides.

Sectors and groups affected

15. Businesses that use 2,2-Bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (otherwise known as BADGE) and certain of its derivatives, in the manufacture of food contact plastics, adhesives and coatings will be affected in so far as they will have returned to them access to defences in the event of prosecution for an alleged offence, but they will also be subject to the reintroduction of the penalties provided for in the proposed Regulations if convicted of that offence.
16. Consumers of foods placed in contact with the materials and articles subject to the provisions will be assured that there are proper deterrent measures in place to dissuade manufacturers from breaching the European regulation that seeks to protect their health. Thus, they shall not be exposed to levels of substances assessed to be harmful.
17. All enforcement authorities and business that need to refer to the proposed Regulations for Wales will be able to refer to a single set of Regulations governing the enforcement of the European Regulation and the manufacture of food contact plastics using a wide range of other substances. The proposed single set of Regulations will replace the 1998

Regulations and its five amendments and prevent a sixth amendment from making those Regulations even more complex.

Benefits

18. By implementing these measures in full, the Government ensures that UK consumers benefit from increased health protection. Consumers in the UK and throughout the EU will enjoy the same degree of protection from the potential contamination of foodstuffs from substances that may migrate from food contact plastics. This increase in consumer protection is based around the prevention of the public health costs that could be associated with migration of potential genotoxic carcinogens from plastic packaging to food. Full implementation ensures that manufacturers and suppliers of the materials and articles that are the subject of these Regulations enjoy the benefits of a set of Regulations that are applied throughout the single market of the EU and that Regulations move closer to full harmonisation.
19. Consumers of foods placed in contact with the materials and articles subject to the provisions in the EC Directive will be assured that there are proper deterrent measures in place to dissuade manufacturers from breaching the EC Directive that seeks to protect their health. Thus, they shall not be exposed to levels of substances assessed to be harmful.

Costs

20. These proposals place no new burdens on businesses, they simply provide for the enforcement of a European regulation, for defences against alleged offences and for penalties upon conviction for an offence. The Food Standards Agency does not anticipate any cost implications for businesses arising from these proposals and this view has been supported by industry.
21. There were substantive comments, in England on the Regulatory Appraisal in relation to the cost implications. The trade associations that represent the packaging industry overall fully supported the Agency's proposal to amend the food contact plastics legislation within the UK and particularly welcomed the consolidation into one single Instrument. However, they fully agreed with the Agency's assessment that any additional cost to businesses arising from the proposed Regulations would be negligible. They envisaged that some administration and financial savings would arise as a result of the simplification. However, they could be no more specific and did not specify any savings figures. The Food Standards Agency is following this up with the relevant stakeholders with the intention of estimating cost saving as part of the Agency's regulatory Simplification Plan, which is proposed for issue in 2007.
22. The Food and Drink Federation, for the food and drink industry, also fully supported the Agency's proposal to simplify the Regulations, thereby making them easier to understand and comply with by consolidating the legislation into one single instrument.

23. The Food Standards Agency does not anticipate new cost implications for enforcement authorities arising from these proposals as they simply reinstate those responsibilities that exist under current provisions in the 1998 Regulations that these proposals would revoke. Therefore, there will be no additional financial implications for enforcement authorities, the Assembly, industry, charity or voluntary sectors arising from the making of these Regulations.

Consultation with small business – the Small Firms’ Impact Test

24. In our consultation on these proposals one organisation commented that there might be some cost implications for smaller business operators in relation to costs to cover product testing, but they were unable to provide any specific amounts. The companies involved in this area are represented through their national trade bodies to those at European level. The Small Business Service and the Forum of Private Businesses (FPB) were consulted at every stage about the financial implications for small businesses arising from the proposal. Initial observations made by the FPB were that there were no financial implications. There were no further comments by the FPB.
25. The FPA represents UK plastic film producers, converters and users with a broad membership ranging from small-localised businesses to large, multi-national corporations. The FPA supported the Agency’s view that these proposals would not disproportionately affect small or medium sized firms, nor would they hinder competitiveness.
26. The FPA fully support the implementation across the UK of Commission Directive 2005/79/EC. They commented that whilst it was difficult to furnish precise cost/benefit figures in respect of the new legislation, they were confident that failure to fully implement the provisions of the Directive would present a significant burden to UK businesses. As a result of differing requirements for plastics sold within the UK, compared to those exported to other Member States, the FPA stressed that consolidation of the legislation into a single instrument will simplify commercial documentation and aid clarity and will also result in administrative savings. The FPA also stated that failure to fully implement the Directive would mean that prevailing national legislation would no longer accord with Community provisions.
27. The companies involved in this area are represented through their national trade bodies to those at European level. The Agency believes that the financial implications for small and medium sized businesses are likely to be negligible. One trade association (the Metal Packaging Manufacturers Association (MPMA) supports this view.
28. The food and drink packaging industry is highly fragmented and diverse and is served by a large number of suppliers. In 2003, a study of the UK’s packaging industry identified 13,000 packaging companies in the UK, combined they employ 250,000 people. The study also revealed that

half of all packaging companies have a turnover less than £10 million, and that 85% are small to medium size enterprises.

29. In 2001, the industry employed approximately 100,000 people in around 2,700 companies – 85% of which are described as small to micro-sized companies. The potential commercial impact of the proposals applies equally to all businesses involved, small or large. The figures are representative of the packing industry as a whole and do not reflect a particular sector or packaging type.

Competition Assessment

30. The provision for implementing Commission Directive 2005/79/EC does not place any hindrance on the competitiveness of businesses. Industry and businesses have been closely involved at European level, principally through representation by British businesses in the development of these harmonised EU rules that relate to 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 existing and new manufacturers of plastic materials and articles intended to be brought into contact with food and will not, therefore, disadvantage any particular business sector, nor company. This view was supported by the packaging industry who confirmed that these proposals would not disproportionately effect small or medium sized firms and nor would it hinder competitiveness.

Consultation

With Stakeholders

31. The Food Standards Agency Wales fully consulted all stakeholders on the proposed Regulations. Informal and formal consultations have been carried out on the benefits and costs of the legislation to public health and businesses including enforcement authorities. Formal consultation on these regulatory proposals involved not just those organisations with an interest in food contact plastics but those manufacturers that use the substance 2,2-Bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl)ether (BADGE) and certain derivatives, in the manufacture of food contact plastics, adhesives and coatings. It also involved those businesses manufacturing Poly Vinyl Carbonate (PVC) gaskets containing epoxidised soybean oil (ESBO). However, the consultation exercise on a UK basis confirmed that the measures proposed have no specific extra requirements that lay any new financial burdens. Stakeholders from sector specific organisations, such as those representing industry sectors, to those with wider interest in food contact plastics, enforcement authorities, consumer organisations and the Small Business Service were also consulted.
32. A two stage formal 12-week public consultation exercise was conducted in Wales. Over sixty-four stakeholders including consumer groups, industry, enforcement authorities and other government departments were consulted on the draft Regulations. A list of the bodies consulted in

Wales is attached at Annex A. The consultation period from 17 February 2006 to 8 May 2006 and 2 June 2006 to 25 August 2006, respectively produced no responses within Wales. Similar consultation exercises were conducted in Scotland between 19 December 2005 to 14 March 2006, and 13 March 2006 to 5 June 2006. Only one substantive response was received in Scotland, which supported the legislation. In Northern Ireland, consultations were conducted between 16 February 2006 and 11 May 2006 and 8 March 2006 to 9 June 2006. The exercise in Northern Ireland produced no substantive comments.

33. In England, 132 interested parties were consulted on the draft Regulations in a two stage consultation exercise. The first stage consultation conducted from 2 February 2006 to 5 May 2006 produced 8 responses; four from the packaging industry, two from the trade associations that represent the food and drink industry, one from LACORS (the local authority co-ordinating body) and one from the Laboratory of the Government Chemist (LGC), none of which made any substantive comments. In the second stage consultation exercise in England, conducted from March 2006 to June 2006, 3 responses were received. These responses were from the Flexible Packaging Association (FPA), which is one of the trade associations representing the packaging industry, the Food and Drink Federation (FDF), representing the food and drink industry and one from the British Soft Drinks Association (BSDA), representing the soft drinks sector. The FPA fully supported the Agency's proposal to amend the food contact plastics legislation in England, and particularly welcomed the deletion of the detailed technical lists of authorised monomers and other starting substances and additives from the proposed text of the Statutory Instrument. The BSDA also welcomed the proposal to update the substance lists. The FDF noted that in the context of the partial Regulatory Impact Assessment in England and the partial Regulatory Appraisal in Wales, the FSA had interpreted the requirements of Commission Directive 2005/79/EC as requiring full compliance with the reduced Specified Maximum Limit for epoxidised soybean oil (ESBO) containing gaskets used for baby food by 19 November 2006. In this respect, FDF requested and received the legal reasoning underpinning this interpretation.
34. No comments were received from the Small Business Service in response to these formal consultations, but during earlier inter-departmental consultation they had indicated some financial implications for small businesses that they were not able to be more specific about, but which were not considered major. Consultation comments on drafting detail have been acted upon where necessary. The Regulations have not been amended as a result of the consultation exercise with the exception of some minor drafting amendments.

With Subject Committee

35. These Regulations were originally notified to the Health & Social Services Committee via the list of forthcoming legislation, on 23 November 2005 (HSS (2)–12-05 (p.1b) FSA 26 (05)), but have been incorporated into the entry now known as FSA 10 (06). They have remained on the list ever since. These Regulations were not identified for detailed scrutiny. These Regulations deal with food safety issues. They have not been notified to the Environment, Planning and Countryside or the Local Government and Public Services subject Committees as they relate to public health issues, have no financial implications for local authorities, and are not, therefore, considered cross-cutting.

Enforcement, Sanctions, Monitoring and Review

36. Businesses that use the substance referred to in the EC Directive in the manufacture of food contact plastics and PVC gaskets will be affected in so far as they will have returned to them access to defences in the event of prosecution for an alleged offence, but they will also be subject to the reintroduction of the penalties provided for in the proposed Regulations if convicted of that offence.

37. The enforcement of The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2006 is returned to the responsibility of local authorities and port health authorities, following removal of the responsibility by revocation of the 1998 Regulations that these proposed Regulations replace. Enforcement by these bodies is common practice in UK food law. The responsibility for enforcement of restrictions on the use of the chemical compound substances BADGE¹, BFDGE² (Bis(4-hydroxyphenyl)methane bis (2,3-epoxypropyl)ethers) and NOGE³ (Novolac glycidyl ethers) that are now contained in Regulation (EC) No. 1895/2005 is also returned to these bodies following revocation of the 1998 Regulations. The Food Standards Agency also has an enforcement role with regard to the EC Regulation in respect of declarations of compliance.

38. A person found guilty of an offence under these and other Regulations dealing with materials and articles in contact with food is liable on conviction on indictment to a fine or imprisonment for a term not exceeding two years or both; on summary conviction to a fine not exceeding the statutory maximum of £5,000 or to a term of imprisonment not exceeding 6 months or to both. These penalties are in line with The Food Safety Act 1990.

39. The Food Standards Agency also has an enforcement role with regard to the EC Regulation 1935/2004 in respect of declarations of compliance. Article 5 of the Regulation requires that appropriate documentation be

¹ 2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (otherwise known as 'BADGE')

² Bis(4-hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (otherwise known as 'BFDGE')

³ Novolac glycidyl ethers (known as 'NOGE')

made available to competent authorities (local authorities) on demand to show that their products comply with the legislation.

Implementation and delivery plan

40. Guidance for businesses has been developed and will be sent to stakeholders informing them about the changes in these proposals. The guidance will also be published on the Agency's website. Information about the new legislation will also be disseminated in an explanatory note, which covers current issues on food contact materials and any future ones. This note is updated periodically and is designed to provide a general introduction to European Union (EU) harmonised legislation and its implementation in the United Kingdom.

Post-implementation review

41. Member States are obliged under the provisions of the European Regulation to ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with the Regulation and ensure compliance with the Directive. The Food Standards Agency shall, therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations and work with enforcement authorities where problems or suspected infringements of the Regulations arise. As part of the process, the Agency meets regularly with representatives from enforcement organisations (Enforcement Liaison Group) and Public Analysts (the APA Liaison meetings) to help inform this review. The Agency shall also continue routine discussions with industry to ensure that no unforeseen difficulties arise from these Regulations.

Summary

42. The proposals here provide for the effective enforcement of Commission Regulation 1895/2005, on the restrictions of use of certain epoxy derivatives (chemical composites) in materials and articles intended to come into contact with food and implement Commission Directive 2005/79/EC relating to plastic materials and articles intended to come into contact with food in its entirety. This will routinely update restrictions on the use of certain substances in the manufacture of food contact plastics and provide for particular restrictions on the use of epoxidised soybean oil (ESBO) in the manufacture of sealing gaskets used in the lids of glass food jars.
43. The Food Standards Agency believes that the advantages of full implementation of the proposals that are the subject of this Regulatory Appraisal will benefit industry, enforcement authorities and consumers. The measures proposed are important in providing the means for improved enforcement, 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 that apply across the European Union, and simplified rules in one set of Regulations for Wales.

Annex A

INTERESTED PARTIES IN WALES

International Federation for Home Economics
RUDDOCK & SHERRATT Public Analysts Laboratories
Good Food Distributors
MERIDIAN FOODS
Co-operative Group (CWS) Ltd
Kwik Save Group Ltd
Wales Young Farmers' Club
Peters Food Service Ltd
G C Hahn & Co Ltd
Executive Food and Drink, British Retail Consortium (BRC)
Food Business, ADAS Wales
The Association of Public Analysts
Bar & Restaurant Foods Ltd
Carmarthen Water Ltd
Cerist Natural Mineral Water Co
Clark's Original Pies
Crystal Falls
Decantae Mineral Water
Dee Dairy Services
Health & Social Services Committee Members
Farmer's Union of Wales
Gower Spring Water Co
Halo Foods Ltd
Iceland Frozen Foods PLC
British Institute for Allergy & Environmental Therapy
LACORS Local Authorities Co-ordinators or Regulatory Services
Montgomery Spring Water Co
National Farmers Union (Wales)
Prince's Gate Spring Water
Rachel's Dairy
Radnor Hills Natural Mineral Water Co
Shoda Sauces Europe
Ty Nant Spring Water
Welsh Consumer Council
Chartered Institute of Environmental Health in Wales
Welsh Food Microbiological Forum, Caerphilly County Borough Council
Woodward Food Service
RHM Frozen Foods Limited
Welsh Food Advisory Committee Members
Brookfield Foods Limited
Welsh Local Government Association
Gelpak Ltd
Environmental Data Services Ltd
Eurofins Scientific Ltd, The Public Analyst's Laboratory
Minton, Treharne & Davies Ltd
Pembrokeshire Spring Water Co

Brecon Support Group for Sufferers of Food/Environmental Intolerances
Severn Trent Laboratories
Project Manager, WDA Food Directorate
Food & Agriculture Standards, Rhondda Cynon Taff CBC