

REGULATORY APPRAISAL

FOOD, WALES

THE MISCELLANEOUS FOOD ADDITIVES (AMENDMENT) (NO. 2) (WALES) REGULATIONS 2005

Background

1. The Miscellaneous Food Additives Regulations 1995 (as amended) implement the provisions of EC Directive 95/2/EC on food additives, other than colours and sweeteners. EC Directive 95/2/EC sets out a list of authorised miscellaneous additives, the foods in which they may be used and their conditions of use.
2. Additives used in other additives (for example, to preserve another additive) are also subject to controls set out in Directive 95/2/EC. Prior to the adoption of Directive 2003/114/EC, however, different laws applied in individual Member States to the use of additives in flavourings, with no specific controls existing in the UK. Although any substance added to food is required to meet the general requirements of the Food Safety Act 1990. Under the new Regulations, additives used in flavourings are, in most cases, controlled by way of a maximum limit in the flavouring, given that the carryover levels of most additives into food via flavourings is very low, and with no technological function in the final food. (Most flavoured foods contain less than 1% of the flavouring). However, in cases where a transferred additive has a technological function in the food, the relevant maximum use level is that which applies to the final food.
3. Additives are used for several functions in flavourings e.g. for storage or dilution. Additives which are already restricted for use in foods, in particular preservatives and anti-oxidants, as well as carrier solvents, will also be restricted when used in flavourings under the new legislation, although many generally permitted additives will continue to be allowed in flavourings on an unrestricted basis. In many cases the new rules are in line with current UK practice in this area, but in others UK manufacturers of flavouring preparations will be required to reduce the use of certain additives to meet the new legislation and to stop using others altogether.

Purpose and intended effect of the measure

4. The Regulations implement, in Wales, European Parliament and Council Directive 2003/114/EC of 22 December 2003, amending Directive 95/2/EC on food additives, other than colours and sweeteners, for the fifth time. The key provisions are as follows:
 - the authorisation of one new food additive, hydrogenated poly-1-decene (E 907) for use as a glazing agent for sugar confectionery and dried fruits, and a number of new food uses for currently permitted food additives;
 - the clarification or extension of certain food categories in which food additives may be used, and the introduction of alternative names - cellulose gum and enzymatically hydrolysed cellulose gum respectively bulking agents and emulsifiers used in a wide range of foods- for E 466 (carboxy methyl cellulose and E 469 (enzymatically hydrolysed carboxy methyl cellulose);

- the deletion of one food entry (cider and perry – a cider made from pears) from the foods permitted to contain phosphates (E 338 - 452), and the transfer of controls on certain preservatives used on fruit - biphenyl, orthophenyl phenol and sodium orthophenyl phenol (E 230-232) - to legislation on plant protection products, once suitable labelling provisions have been included;
- the introduction of numerical maximum limits for uses of carnauba wax a glazing agent used in chocolate products in particular (E 903) following recent advice from the Scientific Committee on Food. This was previously permitted to be used at quantum satis level (i.e. in line with good manufacturing practice);
- the extension of the scope of the existing food additive category of stabilisers to cover binding agents;
- the introduction of harmonised controls on additives needed for the storage and use of flavourings. At present, different laws apply in individual Member States to these substances, with no specific controls existing in the UK, although any substance added to food must meet the general requirements of the Food Safety Act 1990. Under the new Regulations additives used in flavourings are, in most cases, controlled by way of a maximum limit in the flavouring. Their use in flavourings is very low, with no technological function in the final food. (Most flavoured foods contain less than 1% of flavouring). However, in cases where a transferred additive has a technological function in the food, the relevant maximum use level is that which applies to the final food; and
- Additives E407a (processed eucheama seaweed), in addition to E407 (carrageenan) and E440 (pectins), may now be standardised with sugars, provided that this is stated wherever the number and designation of the additive is stated (which includes when labelled in ingredients lists).

Risk assessment

5. Levels of additives used in flavourings by UK manufacturers are generally low, and it is considered that intakes of additives from such uses would, in most cases, not significantly affect an individual's overall intake level. The new EU provisions will ensure that additives used in flavourings will be subject to the same strict controls as additives used in other food ingredients, i.e. they will only be permitted where they have been evaluated for safety, where the technological use has been justified, and where no intake concerns have been identified. If the Directive were not implemented in the UK, consumers would not be offered the increased protection brought about by the reduction in the number and levels of additives used in flavourings.
6. In addition, the rules in the UK would be out of line with those in the rest of the European Community. This would place the UK food and flavourings industry at a competitive disadvantage, and would create significant difficulties for UK manufacturers exporting to the rest of the European Community. Directive 2003/114 is required to be implemented in all Member States by 26 July 2005. Failure by the UK to bring into effect implementing legislation may lead to infraction proceedings from the Commission.

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 implemented.

Benefits

8. Implementing the Directive, including the new harmonised controls on additives in flavourings, would fulfil the UK's obligations under the EC Treaty.

Social

9. Implementation of the Regulation will provide increased protection for consumers from possible uses of additives in excess of recommended intake levels, permit manufacturers and consumers to benefit from the newly permitted food additive and uses of food additives, and allow UK manufacturers to operate freely and competitively within the single market.

Environmental

10. There would appear to be no identifiable environmental benefits or disadvantages arising from the implementation of the provisions in Directive 2003/114/EC.

Economical

11. With the exception of the new controls on additives used in flavourings, which several flavourings manufacturers have claimed will lead to additional costs, industry have generally welcomed the provisions in Directive 2003/114/EC. Food manufacturers will be able to benefit from the additional permitted uses of existing additives. Confectionery manufacturers and dried fruit producers will benefit most from the newly permitted additive, hydrogenated poly-1-decene, which is to be permitted for use only as a glazing agent for sugar confectionery and dried fruit. Industry have indicated that it can accept the proposed decreases in levels of carnauba wax (E903) used for glazing purposes. Three alternative waxes can be used at *quantum satis* level (i.e. in line with good manufacturing practice).

Financial Implications for Wales

12. Enforcement of this legislation is the responsibility of Local Authority Public Protection Departments in Wales. The public consultation exercise in Wales invited comments on any additional costs envisaged in implementing the Directive. No comments were forthcoming from the Local Authorities Co-ordinators of regulatory services (LACORS), the co-ordinating body for local authority trading standards departments in England and Wales, or the Welsh Local Government Association. No additional costs to local authorities or the Assembly have been identified. A cost to the industry is discussed below.
13. The flavourings industry in England have indicated that some re-formulation of existing flavouring preparations will be required, in particular those containing benzyl alcohol, propylene glycol and Isopropyl Alcohol (IPA) as carrier solvents, which are required to disperse flavourings in soft drinks. IPA is not currently a permitted additive within the EU. Under Directive 2003/114, benzyl alcohol is not permitted in flavourings used in soft drinks. Propylene glycol is

permitted, but at levels not high enough to disperse flavourings in drinks such as blackcurrant cordials and high juice squashes, due to their high sugar content. These drinks tend to be popular in the UK only. Ethyl alcohol, the principle alternative to propylene glycol in soft drinks, was until recently considered to be unacceptable to the Muslim population. However, a recent ruling by the UK Muslim Law Council would appear to indicate that its use as a carrier in these products is now acceptable under Muslim dietary laws.

14. The British Soft Drinks Association has commented that, whilst some flavourings used in soft drinks may need to be reformulated, it has not identified the new rules on additives in flavourings as a major issue. However, a number of flavourings companies have, via their trade organisation the British Essence Manufacturers' Association, claimed the necessary reformulation of flavouring preparations is likely to result in some extra costs. This will involve modification and consumer acceptance of new preparations, including reviewing of flavour development, re-writing of specifications, product application, sensory analysis and final customer presentation. New staff may need to be employed to carry out this work. Businesses which buy flavouring preparations from 3rd countries, in particular the USA, containing non-permitted additives such as Isopropyl Alcohol – a solvent used in foods, will need to find alternative suppliers.
15. Manufacturers will not be required to withdraw products not complying with the provisions of the Directive until 27 January 2006, which will help to reduce the negative impact of any reformulation costs. Moreover, it is normal industry practice to routinely reformulate flavouring products to improve consumer acceptability, cost effectiveness etc. Therefore, no significant financial impact on business is likely.

Issues Of Equity and Fairness

16. The provisions of Directive 2003/114/EC apply to all businesses throughout the Community – this is not just an issue for the UK. There is no disadvantage for businesses in Wales.

Business 1

17. This business is a manufacturer of natural and other flavourings, and spice oleoresins (i.e. extracts of spices from which the extraction solvent has been evaporated leaving a mixture of the volatile oil and resinous material from the spice), with a turnover of £20 million, employing 180 people. 30% of flavourings are exported, mainly to non-EU countries i.e. the Far East, Middle East and Africa. The company uses preservative, antioxidants, antifoaming agents and emulsifiers in the manufacture of its flavourings, but considers that the major cost will arise through the need to reformulate flavourings for soft drinks in which carrier solvents are used, in particular IPA, benzyl alcohol and propylene glycol, since IPA and benzyl alcohol will no longer be permitted in these flavourings, and levels of propylene glycol will be restricted. Around 1000 flavourings would be affected, and it is estimated that to modify each one would take around 10 hours, at an overall cost of around £1 million.

Business 2

18. This business is a manufacturer of natural and other flavourings, and spice oleoresins with a turnover of £20 million, employing 80 employees. Half the products are sold to the UK market, the other half to other EU countries and

elsewhere in the world. The company has cited a number of areas where reformulation will be required, in particular for flavourings where benzyl alcohol, propylene glycol, diacetyl and triacetyl are used as carriers and are currently used at higher levels than will be permitted. This company also considers that the major cost will arise through the need to reformulate flavourings for soft drinks in which carrier solvents are used for the reasons stated in the paragraph above. However, the company was not able to quantify these costs.

Business 3

19. This business is a manufacturer of natural flavourings, ingredients and botanicals employing 30 staff and with an annual turnover of approximately £500,000 selling globally. They are not aware of any additional costs likely to arise.

Competition Assessment

20. The proposed Regulations affect a wide range of additives producers, but as the costs are likely to concentrate on flavourings producers, only they are considered in this competition assessment.

21. The market for flavourings is here defined in isolation from that for additives (e.g. colours, preservatives, etc.), as flavourings are a specialised product, regulated under separate EU legislation. With one or two exceptions, additives and flavourings are manufactured by different companies. The UK has around 50 producers of flavourings. Some of the larger ones supply aromas for non-food uses in perfumery and toiletry. A report on the Global Additives Market published by Leatherhead Food Research Association in April 2002 estimates that globally food and drink usage accounts for 45% of production of flavourings. The same report estimates that in Europe, 27% of flavourings used in food and drink are used in processed foods, 25% in soft drinks, 18% in dairy and 14% in confectionery. The overall size of the UK market (including non-food uses) is estimated by the British Essence Manufacturing Association to be around £250m.

22. There is some concentration in the market, with three firms each having a share of over 10%. We do not currently believe that any one producer has a share of over 20%, or that the three largest producers have a share of over 50%. Around half of flavourings manufacturers are Small Medium Enterprises.

23. The proposed legislation is unlikely to impose higher barriers to entry and will, of course, apply to all flavourings manufacturers in the EU and to those elsewhere exporting to the EU. It is, however, unlikely to substantially alter the market structure, for example, by changing the number or size of firms. The main impact is on existing producers who will have to reformulate some of their formulations and make appropriate changes to their labels. Such one-off reformulations can be costly and may have a disproportionate impact on smaller producers.

24. Producers are given until 27 January 2006 to comply and can use up any existing stock, which does not comply with the legislation beyond that period, provided the products were manufactured or labelled before the deadline. This means that flavourings containing additives not permitted by the legislation and manufactured before the deadline sold directly to consumers will be able to be

sold until stocks are finished. This generous implementation timetable will reduce the negative impact of the possibly large one-off reformulation costs. It is not considered that these transitional arrangements will compromise consumer's health, rather the increased level of protection (from the reduction in numbers and levels of additives used as flavourings) will be achieved over time. Overall, we do not believe that the proposed Regulation will have a substantially negative impact on competition in the market.

Enforcement and Sanctions

25. Enforcement of the Welsh Regulations will continue to be the responsibility of Local Authority Trading Standards or Environmental Health Departments. The penalty on conviction for an offence under the regulations is a fine not exceeding level 5 on the standard scale (currently £5,000).

Monitoring and Review

26. Member States are obliged under the provisions of Directive 95/2/EC to monitor and review the consumption and use of food additives and to report their findings to the European Commission.

Consultation

With Stakeholders

27. The Food Standards Agency Wales carried out a consultation from 15 October 2004 to 14 January 2005. Stakeholders included all Assembly Members, consumer and industry representative bodies (a full list of consultees is attached at Annex A). They were invited to comment on the draft Regulations and any costs associated with the implementation of these Regulations. No comments were received. Parallel consultations, which also commenced in October 2004 were carried out in England, Scotland and Northern Ireland. No responses were received. A summary of the responses received in England follows:-

Summary – Consultation on the Commission's formal proposal to amend Directive 95/2/EC

28. Five responses were received on this consultation. Two of the respondents had no comments to make. One respondent had concerns over a new provision in the proposal that would have prevented early transposition of the Directive by Member States, i.e. prior to the 18 month deadline for implementation. In the past the UK has been able to implement amendments to EU food additives legislation as soon as practicable after adoption in order that consumers and industry can benefit from newly approved additives and new uses of permitted additives. This point was raised at Working Group meetings and the Commission eventually amended the provision to the UK's satisfaction. Two respondents requested additional uses for existing additives, neither of which was supported by other Member States during Working Group meetings. One respondent expressed concern that the extended definition of "stabilisers" to cover substances which increase the binding capacity of a food would include, and thereby prohibit, products such as the enzyme preparation transglutaminase. Transglutaminase, which is not listed as a permitted additive, is used to bind pieces of meat together. As a processing aid it currently falls outside the scope of food additives legislation. The Commission confirmed during EU Working Group meetings that enzymes acting as processing aids would continue to fall outside the scope of food additives legislation

29. In addition, stakeholders were regularly consulted as the proposal progressed during Brussels discussions. No adverse comments were received from flavourings manufacturers on the initial proposal. However, amendments supported by the majority of Member States during negotiations resulted in additional restrictions on the use of certain additives in flavourings, in particular carrier solvents, which were of concern to the UK flavourings industry

Summary – Consultation on the Draft Miscellaneous Food Additives (Amendment) (England) Regulations 2005.

30. Eight responses were received in response to this consultation. Overall, the responses demonstrated that there was no disproportionate impact on businesses (including small businesses) as a result of the new Regulations coming into force. None of the responses indicated that any changes were required to the draft Regulatory Impact Assessment. Six of the respondents did not comment on the draft Regulations. One respondent expressed concern at the level of propylene glycol as a carrier for flavourings, which would appear to be insufficient to achieve the desired technical function. Another welcomed the introduction of the alternative name cellulose gum for E 466.

31. No policy changes to the draft Regulations were identified as a consequence of the public consultation.

With Subject Committee

32. There has been no prior scrutiny of the proposed Regulations by the Health and Social Services Committee. However, these Regulations have been notified to the Committee via the list of forthcoming legislation, put to the Committee on 3 March 2004 (HSS(2)-04-04 (p.4b), item no. FS 05(04)) and in successive meetings. The Regulations have not been identified for detailed scrutiny.

Consultation with Small Businesses (The Small Firms Impact Test)

33. The Federation of Small Businesses stakeholders were included in the consultation on the draft Regulations but did not respond.

Summary and Recommendations

34. The Food Standards Agency believes that the Miscellaneous Food Additives (Amendment) (No. 2) (Wales) Regulations 2005 will deliver the full public health protection benefits of the Directive. It will also fulfil the UK's community obligations by providing for the Directive's enforcement. Support for the adoption of these proposals is recommended.

Contact Point

Helen George
Food Standards Agency Wales
11th Floor, Southgate House
Wood Street, Cardiff CF10 1EW
Telephone: 029 2067 8906
Fax: 029 2067 8918
E-mail: Helen.george@foodstandards.gsi.gov.uk

ANNEX A

Contact	Company Name
Judyth Jenkins, Nutrition & Dietetics Services Manager	All Wales Dietetic Advisory Committee
Colin Hunt	Biotrace Limited
Charles Phillips, Head of Public Protection Svcs	Conwy County Borough Council
Rhian Connick	National Federation of Womens Institutes - Wales
David Jackson	Peters Food Service Ltd
Mr T B Dickens	Tillery Valley Foods Ltd
Mr Norman Biggs	Welsh Food Laboratories
Mr Robert Kennard	Graig Farm Organics
Brian Davies, Principal EHO	Ceredigion County Council
Mr Bryan Thomas, Director of Environmental Services	Ceredigion County Council
Kim Pugh, Environmental Health Manager	Monmouthshire County Council
A Jenkins, Director of Consumer Services	Neath Port Talbot County Borough Council
CJ Taylor, Head of Public Protection	Powys County Council
Mrs Reena Owen, Director of Environment	City and County of Swansea
Mr David Roberts	Senior Assistant Trading Standards Officer, Ceredigion County Council
Kate Thompson, Operations manager, Regulatory Services	Vale of Glamorgan Council
Steve Delahaye, Secretary	Society of Directors of Public Protection Wales - Trading Standards Group
Mike Stoddart, Ass Director of Public Protection	Bridgend CBC
Ms Susan Perkins	LACORS (Welsh Officer)
Viv Sugar, Chair	Welsh Consumer Council
Mr Arwyn Owen, Director of Policy	Farmers' Union of Wales
Mr Sandy Blair	Welsh Local Government Association
Diane McCrea	
Paul Lenartowicz - Vice President	The Association of Public Analysts
Jean Sullivan	Welsh Food Alliance
Katherine Gallimore, Centre for Nutrition & Dietetics	UWIC
R Andrew Young	Rhondda Cynon Taff County Borough Council
Paul Gandy	Rhondda Cynon Taff County Borough Council
David Dier, Head of Public Health	Merthyr Tydfil County Borough Council
Ceri J Baillie	Clark's Original Pies
Cate Barrow - Food Business Development Manager	ADAS Wales
R A Ennion	Ruddock & Sherratt
Rod Denley-Jones, Head of Environmental Protection	Torfaen County Borough Council

Julie Barratt, Director	Chartered Institute of Environmental Health in Wales
Peter Lee, Technical Manager	Iceland Frozen Foods
Alan Lowe, Director of Public Protection	Flintshire County Council
The Secretary	G C Hahn & Co Ltd
Mr M Howard	Brookfield Foods Limited
Elizabeth Williams	Halo Foods Ltd
Mr K F Powell	Good Food Distributors
Sheila Dooley, Public Protection Department	Denbighshire County Council
Mr Paul Handby, Development Co-ordinator	Chartered Institute of Environmental Health in Wales
Ffion Roberts, Public Protection Manager	Gwynedd County Council
Emyr Searell Jones	Gwynedd County Council
Wendy Cave	Co-operative Group (CWS) Ltd
Bob Mitchard - Director of Environmental Services	Caerphilly County Borough Council
Norman Gatehouse, Chief Environmental Health Offic	Caerphilly County Borough Council
David Hughes, Chief Public Protection Officer	Blaenau Gwent County Borough Council
AD Fretter, Director of the Environment	Torfaen County Borough Council
Mr S J Whitehouse, Env Management Dept	Torfaen County Borough Council
Stephen Davison	Newport County Borough Council
Mr J Frow	Rhondda Cynon Taff County Borough Council, Trading Standards Dept
Mr Lester Lewis	Society of Directors of Public Protection
Gary Sumner, Acting Head of Public Protection and regulatory Services	Denbighshire County Council
Kevin P Jones, Panel Chairman	Society of Directors of Public Protection - North Wales
Mr Derek Mitchell, Quality Manager	Red Star Bio Products
Dr David Lindsay	Department of Food Science & Technology, CEBAS-CSIC, Spain
Mrs Mary James	National Farmers Union (Wales)
The Secretary	British Institute for Allergy and Environmental Therapy
Mrs Brenda Davies	Meridian Foods
Philip Walton, Director of Environmental Services	Wrexham County Borough Council

Annex B

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 2003/114/EC AMENDING DIRECTIVE 95/2/EC ON FOOD ADDITIVES OTHER THAN COLOURS AND SWEETENERS

<i>Articles</i>	<i>Objectives</i>	<i>Implementation</i>	<i>Responsibility</i>
<i>Article 1.1</i>	<i>amends Directive 95/2/EC by:</i> <ul style="list-style-type: none"><i>Amending the definition of “stabilisers” to include substances used as binding agents.</i>	<i>Regulation 3 (d) of the Miscellaneous Food Additives (Amendment) (England) Regulations 2005 which will come into force on 28 February 2005</i>	<i>The National Assembly for Wales Minister for Health and Social Services on the advice of the Food Standards Agency is responsible for the measures taken to implement the Directive in Wales</i>

<p><i>Article 1.2 (a)</i></p>	<p><i>Amends Directive 95/2/EC by:</i></p> <p><i>Replacing Article 3 of Directive 95/2/EC, with a numbered version containing the same provisions plus one extra provision to permit a miscellaneous additive used in a flavouring to be carried over into the final food in which a flavouring is used, provided that there is no technological function performed in the final food by the miscellaneous additive</i></p>	<p><i>Regulation 5 of the above Regulations. This inserts a new regulation 4A (1) into the Miscellaneous Food Additives Regulations 1995, providing that where there is a technological function in the final food, any such additive is to be regarded as an additive of the final food rather than an additive of the flavouring.</i></p> <p><i>Regulation 4(1) of the 1995 Regulations already makes provision to allow the carry over of an additive into a final food (via its use in any ingredient) where there is no technological function in the final food. Regulation 4(2) already makes provision to allow use of an additive in an ingredient where the additive would be permitted in the final food.</i></p>	<p><i>As above.</i></p>
<p><i>Article 1.2 (b)</i></p>	<p><i>Limiting the level of additives in flavourings to the minimum necessary to guarantee safety and quality of the flavourings and to facilitate their storage, and ensuring that the presence of such additives is not a hazard to human health or misleading to the consumer.</i></p>	<ul style="list-style-type: none"> • <i>Regulation 5 of the above Regulations inserts a new regulation 4A (2) into the Miscellaneous Food Additives Regulations 1995</i> 	<p><i>As above</i></p>
<p><i>Article 1.3</i></p>	<p><i>Requires the Annexes in Directive 95/2/EC to be amended in Accordance with the Annex to Directive 2003/114/EC</i></p>	<p><i>Regulations 7 – 14.</i></p>	
<p><i>Article 2</i></p>	<p><i>Requires the Commission and the</i></p>	<p><i>No implementation</i></p>	<p><i>As above</i></p>

	<p><i>European Food Safety Authority to review the conditions of use of the additives E 214 – E 219 before July 2004.</i></p> <p><i>Requires the Commission to submit to the European Parliament and the Council a report on the progress of the re-evaluation of additives before 27 January 2006</i></p>	<i>required.</i>	
<i>Article 3</i>	<i>Repeals Directive 67/427/EC.</i>	<i>Regulation 9 (a)</i>	<i>As above.</i>
<i>Article 4</i>	<p><i>Requires member States to –</i></p> <ul style="list-style-type: none"> <i>• authorise trade in and use of products conforming with this Directive by 27 July 2005 at the latest</i> <i>• prohibit trade in and use of products not conforming with this Directive by 27 January 2006 at the latest; save that products placed on the market before that date which do not comply with this Directive may be marketed until this date.</i> 	<i>Regulations 1(b) and 6 of the above mentioned Regulations.</i>	<i>As above.</i>