

**Explanatory Memorandum
The Miscellaneous Food Additives and the Sweeteners in Food
(Amendment) (Wales) Regulations 2008**

**This Explanatory Memorandum has been prepared by the Food Standards Agency
Wales and is laid before the National Assembly for Wales.**

1. Description

1.1 This Statutory Instrument updates in Wales the rules relating to the use of miscellaneous additives and sweeteners in foods. The Miscellaneous Food Additives Regulations 1995 and the Sweeteners in Food Regulations 1995 (both as amended) implement all existing European legislation relating to miscellaneous additives and sweeteners. These Regulations amend both of the 1995 Regulations.

2. Matters of special interest to the Subordinate Legislation Committee

2.1 None.

3. Legislative Background

3.1 Welsh Ministers have the required powers under section 16(1)(a) and 17(2) and 48 (1) of the Food Safety Act 1990, and Standing Order 24. The provisions of the Act were transferred from the National Assembly for Wales to Welsh Ministers under the provisions of the Government of Wales Act 2006. The Regulations are subject to the negative resolution procedure.

3.2 The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007 are being made to implement the provisions of European Parliament and Council Directive 2006/52/EC (as corrected) which itself amends European Parliament and Council Directives 95/2/EC and 94/35/EC. A Transposition Note showing how the key elements of Directive 2006/52/EC are being implemented is attached at Annex A.

3.3 Council Directive 2006/52/EC of 5 July 2006 was published in the Official Journal of the European Communities (L204/10) on 26 July 2006 and amends Directives 95/2/EC and 94/35/EC for the sixth and third times respectively. The Directive sets out lists of authorised miscellaneous additives and sweeteners, the foodstuffs in which they may be used and their conditions of use. A Corrigendum to Directive 2006/52/EC was published on 17th March 2007 (OJ No. L78, p32).

4. Purpose and intended effect of the legislation

4.1 Council Directives 95/2/EC and 94/35/EC form part of the Single Market initiative on the use of additives and sweeteners in the European Union and ensure consumer protection measures are in place in relation to miscellaneous additives and sweeteners. Directives 95/2/EC and 94/35/EC were amended on this occasion to incorporate recent technical and scientific developments in relation to miscellaneous additives and sweeteners.

4.2 The key aspects are:

- A reduction in, and other changes to, the authorised levels for nitrites and nitrates in meat and other food products, which takes account of the opinion of the European Food Safety Authority (EFSA), published on 26 November 2003 and aims to keep levels of nitrosamines as low as possible whilst maintaining the microbiological safety of food products. EFSA is the authority which was set up in 2000 to advise the European Commission on food safety issues. Derogations have been included to meet the needs of producers of traditional meat products, such as Wiltshire cured ham, bacon and similar products to be produced based on residual amounts (Regulation 8 and Schedule 1).
- The withdrawal of two preservatives E 216 (propyl p-hydroxybenzoate) and E 217 (sodium propyl p-hydroxybenzoate) following an EFSA evaluation of E 214 – 219 parahydroxybenzoates (parabens) which concluded that an Acceptable Daily Intake level could not be established for E 216 and E 217. (Regulation 6)
- The withdrawal of the authorisation for gelling agents for use in jelly mini-cups, which are a single, pre-packed sweet or confectionery and which are considered a choking risk because of their consistency, shape and form. This makes permanent an earlier Commission decision suspending the marketing in the EU of jelly mini-cups containing certain food additives derived from seaweed and/or certain gums. (Regulation 5).
- The authorisation of seven new food additives: erythritol, 4-Hexylresorcinol, soybean hemicellulose, starch aluminium octenyl succinate, ethyl cellulose pullulan and tertiary butyl hydroquinone and one new sweetener: erythritol following positive evaluations by the Scientific Committee on Food (SCF) and the European Food Safety Authority. As well as requiring authorisation under Directive 95/2/EC as a flavour enhancer, erythritol can also be used as a sweetener and therefore requires authorisation under Directive 94/35/EC for such uses. Although the SCF opinion noted that laxative effects from erythritol occur at higher intake levels than seen for other polyols, it was nevertheless agreed during Brussels discussions that erythritol should not be exempt from the labelling rule regarding laxative effects in table-top sweeteners containing polyols. (Regulations 5, 9, 10, and 14 and Schedule 2)
- A number of additional uses of already permitted food additives. (Regulations 6, 7, 10, 11, 12 and 13).

4.3 The main impact of the new legislation falls on producers of meat products. The British Meat Processors' Association have confirmed that their members' interests have been adequately represented, and their main concerns on the need to protect the integrity of traditionally cured products effectively taken account of during Brussels negotiations. However, they highlight concerns about the impact that the reduction of nitrites/nitrates will have on the shelf life of meat products, which could lead to reduced stocking and sales through retail outlets. Due to the fact that the direct impact will be different for individual products they have been unable to provide costs. Manufacturers will not be required to withdraw products not complying with the provisions of the Directive until August 2008, which will help to reduce the negative impact of any reformulation costs.

Therefore no significant financial impact on business is likely. All companies operating in the EU will be required to meet the restrictions set out in the new Directives – this is not just an issue for the UK.

5. Implementation

5.1 It is intended that these Regulations be made on 22 January to come into force on 15 February 2008. Parallel legislation has been introduced in England, the Regulations originally came into force on 25 July 2007 but were corrected due to a drafting error and will now come into force by February 2008. In Northern Ireland the parallel Regulations come into force from February 2008, and came in on the 1 October 2007 in Scotland.

6. Consultation

6.1 The new measures do not impact directly on the work of other Government Departments, but DEFRA was kept informed on the aspects of the proposal relating to nitrite/nitrate levels in meat products since these directly affected producers of traditional bacon and ham in the UK. The Small Business Service was also included in the consultation but did not offer any comments.

6.2 Approximately 450 stakeholders from industry, enforcement and consumer groups were consulted on the Commission's formal proposal. During the initial consultation on the Commission's original proposal, no specific costs were identified by stakeholders. However, it became clear during subsequent discussions with the British Meat Processors Association (BMPA), that the proposal would not meet the needs of all manufacturers of traditional UK meat products. Following complex negotiations during the UK Presidency, however, agreement was obtained from Member States on the use of nitrites and nitrates in meat products that took account of advice from the European Food Safety Authority to reduce levels of these additives, whilst recognising their use in certain traditional products in Member States. Throughout negotiations in Brussels, stakeholders (in particular meat product manufacturers and importers of grapes and lychees) were updated on events.

6.3 In Wales, interested parties were consulted on the draft Regulations and accompanying Regulatory Impact Assessment (RIA) between January and April 2007. Only one comment was received in Wales. The Welsh Consumer Council made no substantive comments. Food Standards Agency colleagues in England, Scotland and Northern Ireland have carried out their own parallel consultation exercises. No comments were received in Scotland and Northern Ireland. In England five comments were received in response to the consultation on the initial proposal, most of which expressed concern about the implications of the amendments to the entries on nitrites/nitrates in meat products. Nine responses were received in England on the consultation on the draft implementing regulations, most of which were broadly supportive of the new legislation. Although the BMPA welcomed the derogation for traditional UK meat product, they identified further costs relating to the likelihood of a reduced shelf life of non-traditional products, due to lower permitted levels of nitrites and nitrates although no precise figures were given. Also, LACORS pointed out that there may be some additional resource requirements for local authorities due to the need for additional sampling, although this is not expected to be significant. Summaries of the comments can be found on the FSA website.

7. Regulatory Impact Assessment

7.1 A Regulatory Impact Assessment is included in this Explanatory Memorandum.

Regulatory Impact Assessment

8. Options

8.1 Option 1: Do nothing. Commission Regulations are directly applicable in Member States from the date that they take effect and the UK agreed to the measures after consultation during the negotiating stages. The UK has a legal obligation to ensure that provisions are in place providing for their enforcement. The Miscellaneous Food additives & Sweeteners in Food (Amendment) (Wales) Regulations 2008 have been developed for this purpose. To do nothing would risk incurring infraction proceedings on the UK from the EC. To follow this option will also hamper enforcement authorities to carry out their duties in protecting public safety.

8.2 Option 2: Implement fully the provisions of Directive 2006/52 /EC domestic law. Corresponding legislation has been introduced separately in Scotland, England and Northern Ireland.

9. Sectors and groups affected.

9.1 The purpose of The Miscellaneous Food Additives and the Sweeteners in Food (Wales) (Amendment) (Wales) Regulations 2008 is to give effect to EC measures which aim to provide an increased level of food safety for consumers. The new legislation will affect manufactures of food additives and sectors of the food industry which use additives in their manufacture, although any costs arising from the new legislation are likely to impact primarily upon meat product manufacturers. The enforcement authorities and consumers will also be affected but to a much lesser extent. The FSA does not consider that the new legislation has any impact on race equality and on sustainability.

10. Benefits

10.1 **Option 1:** Under this option, the current rules would continue, with which industry and enforcement bodies are familiar. No changes in product formulation would be necessary. There would be no direct cost to industry.

10.2 **Option 2:** The following benefits are:

- The new provisions on nitrites and nitrates will enable the majority of the requirements of the UK meat product industry to be met, whilst protecting the health and safety of consumers who will in particular be protected from the reduction in levels of nitrosamines.
- The withdrawal of E 216 and E 217, and of the authorisation for gelling agents for use in jelly mini-cups, will also provide additional consumer protection.
- This option will also permit manufacturers to benefit from the newly permitted food additives and uses of food additives. In particular, fat and oil

manufacturers, and manufacturers of processed foods using fats and oils, will be able to use the newly permitted antioxidant TBHQ in addition to, or in place of, BHA and gallates. Consumers, as well as manufacturers, will particularly benefit from the permitted use of erythritol, which has a lesser laxative effect than other sweeteners, and the permitted use of 4-hexyresorcinol in place of sulphites to prevent melanosis (blackspot) in crustaceans. Provisions in the legislation permitting the continued use of low levels of sulphur dioxide in imported grapes and lychees will benefit the UK fresh produce industry and will ensure that these popular products continue to be available to UK consumers.

- Finally, Option 2 will enable Welsh and other UK manufacturers to operate freely and competitively within the single market.

11. Costs

11.1 **Option 1.** There would be no direct costs to industry, but manufacturers and consumers would not be able to benefit from the new additives and uses of new additives permitted by the legislation. In addition, this option would leave UK rules out of step with the rest of the Community. Most importantly, failure to implement the Directive would leave the UK open to infraction proceedings from the Commission under Article 226 of the EC Treaty; other Member States could initiate proceedings under Article 227. This is not a viable option therefore.

11.2 **Option 2.** Any costs arising from the new legislation are likely to impact primarily upon meat product manufacturers. Following negotiations, exemptions were agreed to allow traditionally produced specialist meat products to remain on the market in Member States, including, for example, Wiltshire ham in the UK, which we believe will meet the needs of UK producers of these products. However, manufacturers of non-traditional meat products will have to comply with the reduced levels of nitrites/nitrates specified in the legislation, which may result in costs. There are four areas where costs may occur: technical development and trial work (one off); reformulated curing mixes (ongoing); packaging changes and . decreased shelf life of certain meat products for which lower levels of nitrites/nitrates will be permitted. Of these, it is estimated that the first will cost a business with, on average, 10 product formulations, approximately £25,000 with a rough estimate for the whole UK industry of £1.0 million. Ongoing costs of reformulated mixes are considered to be minimal, and packaging changes will be left to coincide with the regular, usually annual designs and there will not therefore be a cost attributable to the legislative change. Costs arising from decreased shelf life are considered to be unquantifiable because of the variability between individual products. Any costs will, moreover, be offset by the lengthy implementation period permitted in the Directive – manufacturers have until 15 August 2008 to comply with the legislation.

12. Competition Assessment

12.1 The Food Standards Agency does not believe that the new legislation will have an impact on competition in the market.

13. Consultation

Within Government

13.1 The new measures do not impact directly on the work of other Government Departments, but DEFRA was kept informed on the aspects of the proposal relating to nitrite/nitrate levels in meat products since these directly affected producers of traditional bacon and ham in the UK. The Small Business Service was also included in the consultation but did not offer any comments.

Public consultation

13.2 Approximately 450 stakeholders from industry, enforcement and consumer groups were consulted on the Commission's formal proposal. During the initial consultation on the Commission's original proposal, no specific costs were identified by stakeholders. However, it became clear during subsequent discussions with the British Meat Processors Association (BMPA), that the proposal would not meet the needs of all manufacturers of traditional UK meat products. Following complex negotiations during the UK Presidency, however, agreement was obtained from Member States on the use of nitrites and nitrates in meat products that took account of advice from the European Food Safety Authority to reduce levels of these additives, whilst recognising their use in certain traditional products in Member States. Throughout negotiations in Brussels, stakeholders (in particular meat product manufacturers and importers of grapes and lychees) were updated on events.

13.3 In Wales, interested parties were consulted on the draft Regulations and accompanying Regulatory Impact Assessment (RIA) between January and April 2007. Only one comment was received in Wales. The Welsh Consumer Council made no substantive comments. Food Standards Agency colleagues in England, Scotland and Northern Ireland have carried out their own parallel consultation exercises. No comments were received in Scotland and Northern Ireland. In England five comments were received in response to the consultation on the initial proposal, most of which expressed concern about the implications of the amendments to the entries on nitrites/nitrates in meat products. Nine responses were received in England on the consultation on the draft implementing regulations, most of which were broadly supportive of the new legislation. Although the BMPA welcomed the derogation for traditional UK meat product, they identified further costs relating to the likelihood of a reduced shelf life of non-traditional products, due to lower permitted levels of nitrites and nitrates although no precise figures were given. Also, LACORS pointed out that there may be some additional resource requirements for local authorities due to the need

14. Implementation and review

14.1 Enforcement of the Wales Regulations will continue to be the responsibility of Local Authority Trading Standards or Environmental Health Departments. The maximum penalty on conviction for an offence under the Regulations is a fine not exceeding level 5 on the standard scale (currently £5,000). Member States are obliged under the provisions of Directives 95/2/EC and 94/35/EC to monitor and review the consumption and use of food additives and to report their findings to the European Commission. The Local Authorities Co-ordinators of Regulatory Services (LACORS), the Association of Port Health Authorities (APHA) and the Association of Public Analysts are consulted specifically through

established Agency liaison mechanisms such as interested parties letters during the development of the EU proposals.

14.2 The Agency continually consults with enforcement, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation. As part of this process, the Agency meets regularly with representatives from the Association of Public Analysts (the APA Liaison meetings) to help inform this review.

14.3 The Agency will contact stakeholders when the new Regulations come into force, and will amend our guidance notes on food additives legislation to reflect the provisions of the new Regulations. The Agency will be monitoring the increased costs identified by the BMPA.

15. Summary

15.1 Summary Costs and Benefits Table

	Costs	Benefits
Option 1	No direct costs, but would not permit manufacturers and consumers to benefit from the newly permitted additive and new additive uses. Would not deliver improved consumer protection measures of the new Directive. Would leave UK at risk of infraction proceedings.	
Option 2	Likely to result in additional costs to non-traditional meat product manufacturers due to the need to reformulate products to meet reduced levels of nitrites/nitrates, with a rough estimate of £1.0 million for the whole meat product industry.	Would deliver full benefits to manufacturers wishing to use the new additives and new additive uses. Would offer consumers increased health and safety protection and the continued availability of traditional bacon and ham and imports of grapes and lychees. Also alternatives to sulphites in crustaceans and a sweetener with a less laxative effect than currently permitted ones.

15.2 **Option 2 is favoured by FSA Wales.** This option will deliver the full public health protection benefits of the Directive, and in the long term will be of greater benefit financially to industry than option 1. It will also fulfil the UK's community obligations by providing for the Directive's enforcement.

ANNEX A

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 2006/52/EC AMENDING DIRECTIVES 95/2/EC ON FOOD ADDITIVES OTHER THAN COLOURS AND SWEETENERS AND DIRECTIVE 94/35/EC ON SWEETENERS FOR USE IN FOODSTUFFS, AS CORRECTED BY A CORRIGENDUM DATED 17.3.2007.

<i>Articles</i>	<i>Objectives</i>	<i>Implementation</i>	<i>Responsibility</i>
<i>Article 1.1</i>	<p><i>Amends Directive 95/2/EC by:</i></p> <ul style="list-style-type: none"> <i>Amending the definition of “carriers” to include carriers used with flavourings</i> 	<i>Regulation 3 (a) of the Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (Wales) Regulations 2008 “The Regulations”.</i>	<i>The 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>
<i>Article 1.2</i>	<i>Updates the terminology for “weaning foods” to take account of Council Directive 89/398/EEC, as last amended by Regulation (EC) No 1882/2003</i>	<i>Regulation 13 (a) and (b) of the Regulations</i>	<i>As above</i>
<i>Article 1.3 as read with Annexes I & II</i>	<i>Annex I specifies amendments to the Annexes to Directive 95/2/EC to be amended, and Annex II details amendments to the Annex to Directive 94/35/EC, in particular:</i>		
<i>Annex I para. 1</i>	<i>Bans use of certain additives in jellycups, and adds one substance to the list of generally permitted miscellaneous additives</i>	<i>Regulation 5 of the Regulations</i>	<i>As above</i>
<i>Annex I para. 2</i>	<i>Amends provisions relating to foods for which a limited number of additives may be used</i>	<i>Regulation 12 of the Regulations</i>	<i>As above</i>

<i>Annex I para.3</i>	<i>Makes various amendments to the Community lists of conditionally permitted preservatives and anti-oxidants</i>	<i>Regulations 6, 7, 8 and 9 and Schedules 1 and 2 to the Regulations</i>	<i>As above</i>
<i>Annex I para. 4</i>	<i>Makes various amendments to the Community list of other permitted additives</i>	<i>Regulation 10 of the Regulations</i>	<i>As above</i>
<i>Annex I para. 5</i>	<i>Amends the Community list of permitted carriers and solvents</i>	<i>Regulation 11 of the Regulations</i>	<i>As above</i>
<i>Annex I para. 6</i>	<i>Amends the Community list of additives permitted in foods for infants and young children</i>	<i>Regulation 13 of the Regulations</i>	<i>As above</i>
<i>Annex II</i>	<i>Amends the Community list of permitted sweeteners and the foods in which they may be used</i>	<i>Regulation 14 of the Regulations</i>	<i>As above</i>
<i>Article 2</i>	<i>Requires the Annex in Directive 94/35/EC to be amended in accordance with Annex II to Directive 2006/52/EC</i>	<i>Regulation 14 of the Regulations.</i>	<i>As above</i>
<i>Article 3</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 15 February 2008 at the latest</i> <i>• prohibit trade in and use of products not conforming with this Directive by 15 August 2008 at the latest; save that products placed on the market before that date which do not comply with this Directive may be marketed</i> 	<i>Regulations 1 and 4 of the Regulations.</i>	<i>As above.</i>

	<i>until this date.</i>		
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