

**EXPLANATORY MEMORANDUM TO
THE MISCELLANEOUS FOOD ADDITIVES AND THE SWEETENERS IN FOOD
(AMENDMENT) (ENGLAND) REGULATIONS 2007**

2007 No.1778

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

- 2 **Description**

This Statutory Instrument updates in England 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.

- 3 **Matters of special interest to the Joint Committee on Statutory Instruments**

None.

- 4 **Legislative Background**

General

- 4.1 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.

EU Legislation

- 4.2 A Transposition Note showing how the key elements of Directive 2006/52/EC are being implemented is attached
- 4.3 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 Directives 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).
- 4.4 An Explanatory Memorandum on this dossier cleared scrutiny in the House of Commons on 10 November 2004 and 3 October 2005.

5. Extent

The Regulations apply to England only. Parallel Regulations are being made in Scotland, Wales and Northern Ireland.

6 European Convention on Human Rights

As this instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7 Policy Background

7.1 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.

7.2 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.

7.3 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), and aims to keep levels of nitrosamines as low as possible whilst maintaining the microbiological safety of food products. Derogations have been included to meet the needs of producers of traditional meat products, such as Wiltshire bacon (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 and form. (Regulation 5)
- The authorisation of seven new food additives and one new sweetener following positive evaluations by the Scientific Committee on Food and the European Food Safety Authority. (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).

7.4 Public consultations were carried out on the Commission's initial draft proposal and on the draft implementing Regulations, details of which are included in the Regulatory Impact Assessment at Annex A. The level of public interest was low for

this consultation exercise as shown by the limited number of responses received (nine responses to the consultation on the draft amending Regulations). Most of the responses were broadly supportive of the new legislation, although some further costs were identified by the British Meat Processors' Association, and resource requirements for local authorities were identified, though the latter are not thought to be significant. We consider these costs to be proportionate and unavoidable, and will be working with BMPA to monitor the situation. In addition, resource requirements for local authorities were identified, though the latter are not thought to be significant. The summary of responses can be found at <http://www.food.gov.uk/multimedia/pdfs/consultationresponse/additiveresponseeng07.pdf>

8 **Impact**

- 8.1 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.
- 8.2 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.
- 8.3 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.
- 8.4 A Regulatory Impact Assessment is attached at Annex A. Copies can be obtained from Benedict Duncan¹. There are no identifiable costs to the public or the Exchequer.

9 **Contact Point**

Helen Chapman at the Food Standards Agency (Tel: 0207 276 8000 or E-mail: Helen.chapman@foodstandards.gsi.gov.uk) will act as the contact point for any queries regarding the instrument.

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FINAL REGULATORY IMPACT ASSESSMENT

TITLE OF PROPOSAL

THE MISCELLANEOUS FOOD ADDITIVES AND THE SWEETENERS IN FOOD (AMENDMENT) (ENGLAND) REGULATIONS 2007

1. PURPOSE AND INTENDED EFFECT

(i) Objective

The proposed Regulations will implement European Parliament and Council Directive 2006/52/EC, which amends Directive 95/2/EC on food additives other than colours and sweeteners for the sixth time and Directive 94/35/EC on sweeteners for use in foodstuffs for the third time. They also implement the provisions of two European Commission Directives setting out new and amended purity criteria (specifications) for certain miscellaneous additives and sweeteners but as these Directives incur no financial costs they have not been included within the scope of this Regulatory Impact Assessment.

The key objectives of the Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007 are as follows:

- A reduction in 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. In addition, in line with EFSA's recommendations, controls on the level of nitrites and nitrates in non-heat treated or heat treated meat products, in cheese and in fish, will be based on added rather than residual amounts. However, during Brussels discussions on the Commission's original proposal, Member States recognised that a degree of compromise was required in order to achieve the objective of further controls on the use of nitrates and nitrites in most meat products, whilst allowing the continued production of certain traditional products. These compromises, which include provisions which will permit traditional UK meat products such as Wiltshire cured ham, bacon and similar products to be produced based on residual amounts, were brokered by the UK Presidency, and are contained within the new legislation.
- 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.
- 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.

- The authorisation of seven new food additives – erythritol, 4-Hexylresorcinol, soybean hemicellulose and starch aluminium octenyl succinate (following positive evaluations by the Scientific Committee on Food), and ethyl cellulose, pullulan and tertiary butyl hydroquinone (TBHQ) (following positive evaluations by the European Food Safety Authority).
- A number of additional uses of already permitted food additives – sodium hydrogen carbonate in sour milk cheese, sorbates and benzoates in crustaceans, silicon dioxide as a carrier in certain colours, sulphites in cooked crustaceans, grapes and lychees and additives in traditional Hungarian products.
- The authorisation of a new sweetener, erythritol, following a positive evaluation by the Scientific Committee on Food. 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.

(ii) Background

European Parliament and Council Directive 95/2/EC harmonised the use of food additives other than colours and sweeteners (referred to in UK legislation as miscellaneous food additives) throughout the EU. It has been amended on five previous occasions. European Parliament and Council Directive 94/35/EC harmonised the use of sweeteners for use in foods throughout the EU. It has been amended on two previous occasions. Both Directives set out lists of authorised substances (miscellaneous additives and sweeteners), the foods in which they may be used and their conditions of use.

Negotiations on the Commission's original proposal took place primarily under the UK Presidency of the European Union with the Agency acting as the lead Department. The Agency was successful in securing agreement from all Member States and the European Parliament at the first reading under the co-decision procedure. The co-decision procedure requires agreement to be reached by the Council of Ministers and the European Parliament before legislation can be finalised. Formal adoption of the amendments took place at a meeting of the European Council in June 2006. Member States are required to permit trade in and the use of products complying with the Directive by 15 February 2008 and to prohibit trade in and the use of products which do not comply with the Directive by 15 August 2008.

The most contentious issue in the negotiations was to seek agreement from Member States on the use of nitrites and nitrates in meat products to take account of advice from EFSA to reduce levels, whilst recognising their use in certain traditional products in Member States. Exemptions were agreed during negotiations to allow specialist meat products to remain on the market in Member States, including, for example, Wiltshire ham in the UK. No specific issues were raised by stakeholders in Scotland, Wales and NI.

(iii) Rationale for Government Intervention

If the new Directive were not to be implemented by the UK, UK consumers would not be able to benefit from the additional safeguards on additive use i.e. additional controls on the use of nitrites/nitrates and the withdrawal of E 216 and E 217. In addition, the withdrawal of the authorisation for gelling agents for use in jelly mini-cups would not be made permanent. UK industry and consumers would also not be able to benefit from the newly approved additives and new uses of additives in the Directive.

2. CONSULTATION

i) Within government

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.

ii) Public consultation

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.

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 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, L;ACORS 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 at <http://www.food.gov.uk/multimedia/pdfs/consultationresponse/additiveresponseeng07.pdf>.

3. OPTIONS

Option 1 – do nothing i.e. do not implement Directive 2006/52/EC into UK law.

Option 2 – implement fully the provisions of Directive 2006/52/EC into UK law.

4. COSTS AND BENEFITS

Sectors and groups affected

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.

Benefits

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.

Option 2 - the following benefits can be cited:

- 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 UK manufacturers to operate freely and competitively within the single market.

Costs

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.

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.

The Administrative Burdens Measurement Exercise carried out across Government in 2005 measured the administrative burden of regulations in force at May 2005. The exercise did not include The Miscellaneous Food Additives Regulations 1995 because we did not identify any information obligation¹ on business arising from them.

¹ A duty to procure or prepare information and subsequently make it available to a public authority, as well as a duty to facilitate the collection or preparation of information by others, e.g. by permitting and cooperating with an audit, visit or inspection. It includes regular requirements to read guidance on an information obligation and updated rules. A business cannot decline without coming into conflict with the law or being ineligible for continued funding, grants and other applied-for schemes.

5. SMALL FIRMS IMPACT TEST

We do not envisage that small companies are likely to be adversely affected by the new legislation, which will essentially affect larger manufacturers of non-traditional bacon and ham. Consultation on the nitrites/nitrates aspects of the proposal was carried out primarily via the BMPA, whose membership comprises around 35% of small producers. During the consultation period the BMPA consulted with approximately six small companies, of which three were not BMPA members, to ensure representation of the wider industry. Products manufactured by these businesses included cured tongue, canned meats, and immersion and dry cured ham and bacon. In addition, meetings between FSA officials with the BMPA included representatives from a number of small companies. It was clear from these discussions that there were a number of small producers of traditional meat products (e.g. immersion produced hams, tongue and brisket) who would have been adversely affected by the provisions in the Commission's original proposal i.e. the revised nitrites/nitrates provisions would have made it impossible for them to manufacture their products. Other Member States also cited similar problems with traditional products in their countries. However, during the UK Presidency, agreement was reached on derogations in the adopted Directive which would enable these popular UK meat products to continue to be produced by traditional methods. As far as we are aware, the requirements of small producers have been met, and the new legislation will result in few, if any, additional costs to small companies.

We have consulted the SBS throughout this process and they are content with our approach.

6. COMPETITION ASSESSMENT

Overall, we do not believe that the new legislation will have an impact on competition in the market.

7. ENFORCEMENT, SANCTIONS AND MONITORING

Enforcement of the England 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.

8. IMPLEMENTATION AND DELIVERY PLAN

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.

9. POST IMPLEMENTATION REVIEW

The Agency will be monitoring the increased costs identified by the BMPA.

10. SUMMARY AND RECOMMENDATION

	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.

6. **Option 2** is favoured by the Agency. 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.

11. DECLARATION

'I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs'

Signed by the responsible Minister.....*Caroline Flint*.....

Date...20th June 2007.....

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