

PARTIAL REGULATORY IMPACT ASSESSMENT

TITLE OF PROPOSAL

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

2. 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.

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. There are no changes as regards the use of the other parabens.

- 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.

3. CONSULTATION

1.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

(a) 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. A summary of the comments can be found on the FSA website.

(b)

4. 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.

5. COSTS AND BENEFITS

(i) 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.

Any additional information on benefits would be welcome

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 three areas where costs may occur: technical development and trial work (one off); reformulated curing mixes (ongoing) and packaging changes. 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. 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.

We would welcome information from consultees on specific costs to individual companies arising from the new 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. **We would be grateful for your views on whether this is correct. If you believe that there will be additional administrative costs to business as a result of The Miscellaneous Food Additives Regulations 2007 we would be grateful if you would let us know what these are and how they will be incurred.**

6. 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 would encourage any further comments from small companies on any likely costs arising from the new legislation

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

7. COMPETITION ASSESSMENT

Overall, we do not believe that the new legislation will have a substantially negative impact on competition in the market, **but we invite comments from producers on this conclusion**

8. 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.

12. 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 currently 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. However, we are seeking further evidence to support this conclusion from the consultation.

13. DECLARATION

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

Signed by the responsible Minister.....

Date.....

Contact Point

Name: Glynis Griffiths
Division: Novel Foods, Additives and Supplements Division
Address: Room 515c, Aviation House, 125 Kingsway, London, WC2B 6NH
Telephone: 020 7276 8556
Email: glynis.griffiths@foodstandards.gsi.gov.uk

STATUTORY INSTRUMENTS

2007 No. 0000

FOOD, ENGLAND

**The Miscellaneous Food Additives and the Sweeteners in Food
(Amendment) (England) Regulations 2007**

<i>Made</i>	- - - -	***
<i>Laid before Parliament</i>		***
<i>Coming into force</i>	- -	***

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a), 17(1), 26(1) and (3) and 48(1) of, and paragraph 1 of Schedule 1 to, the Food Safety Act 1990(a) and now vested in her(b).

In accordance with section 48(4A) of that Act, she has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Title, commencement and application

1. These Regulations may be cited as the Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007, come into force on [—] 2007 and apply in relation to England only.

(a) 1990 c. 16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990.
(b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999 (c. 28) and paragraphs 12 and 21 of that Schedule amend respectively sections 17(1) and 48 of the 1990 Act. Section 48 was also amended by S.I. 2004/2990. Functions of “the Ministers” so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act and those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (c. 46) as read with section 40(2) of the 1999 Act. Regulation 13(4) of S.I. 2000/656 expressly authorises the Secretary of State to amend or revoke existing Regulations made or having effect as if made by the Minister of Agriculture, Fisheries and Food (whether with others or not) under the Food Safety Act 1990.
(c) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3).

Amendments to the Miscellaneous Food Additives Regulations 1995

2. The Miscellaneous Food Additives Regulations 1995(a) (“the Additives Regulations”) are amended in accordance with regulations 3 to 13 below.

3. In paragraph (1) of regulation 2 (interpretation) —

- (a) In the definition of “carrier” and “carrier solvent”, after “miscellaneous additive,” insert “flavouring.”;
- (b) in the definition of “Directive 95/2/EC” for the words “and European Parliament and Council Directive 2003/114/EC” substitute “, European Parliament and Council Directive 2003/114/EC(b) and European Parliament and Council Directive 2006/52/EC(c);”;
- (c) after the definition of “food additive” insert the following definition —

“‘food supplement’ means a foodstuff the purpose of which is to supplement the normal diet and which is a concentrated source of vitamins or minerals or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop-dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;”.

4. In regulation 11 (transitional provision and exemptions), after paragraph (1F), insert the following paragraph —

“(1G) In any proceedings for an offence under these Regulations in respect of any food additive or food, it shall be a defence to prove that —

- (a) the food additive or food concerned was put on the market or labelled before 15th August 2008; and
- (b) the matter constituting the offence would not have constituted an offence under these Regulations if the amendments made by regulation 5(a), 6(a), 6(b) and (d) or 8 of the Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007 had not been made when the food additive or food was placed on the market or labelled.”.

5. In Schedule 1 (miscellaneous additives generally permitted for use in foods not referred to in Schedule 6, 7 or 8) —

(a) as Note (5) add the following —

“(5) The substances E400, E401, E402, E403, E404, E406, E407, E407a, E410, E412, E413, E414, E415, E417, E418 and E440 may not be used in jelly cups, defined for the purpose of these Regulations as jelly confectionery of a firm consistency, contained in semi-rigid mini-cups or mini-capsules, intended to be ingested in a single bite by exerting pressure on the mini-cup or mini-capsule so as to project the confectionery into the mouth.”
;

(b) after the entry relating to E461 insert the following —

E 462	Ethyl cellulose
-------	-----------------

6. In Schedule 2 (conditionally permitted preservatives and antioxidants) part A (sorbates, benzoates and p-hydroxybenzoates) —

- (a) omit the entries for E 216 Propyl p-hydroxybenzoate and E 217 Sodium propyl p-hydroxybenzoate in the first table;

(a) S.I. 1995/3187, amended in relation to England by S.I. 1997/1413, S.I. 1999/1136, S.I. 2000/3323, S.I. 2001/60, S.I. 2001/2294, S.I. 2001/3442, S.I. 2001/3775, S.I. 2002/379, S.I. 2003/1008, S.I. 2003/1563, S.I. 2003/1564, S.I. 2003/1596, S.I. 2003/1659, S.I. 2003/2243, S.I. 2003/3120, S.I. 2003/3295, S.I. 2004/2601 and S.I. 2005/1099.
(b) OJ No. L24, 29.1.2004, p.58.
(c) OJ No. L204, 26.7.2006, p.10.

- (b) omit the entries for “Shrimps, cooked” and “Crayfish tails, cooked and pre-packed Marinated cooked molluscs” in the second table;
- (c) in the first column (entitled “Food”) of the second table, for the words “Dietetic foods intended for special medical purposes” substitute “Dietary foods for special medical purposes as defined in Directive 1999/21/EC(a)”;
- (d) add the following entries to the second table at the end:

“Crustaceans and molluscs, cooked		1000		2000		
Food supplements supplied in liquid form				2000		”

7. In Schedule 2 Part B (sulphur dioxide and sulphites), in the second table —

- (a) for the entries relating to crustaceans and cephalopods substitute the following —

“Crustaceans and cephalopods: fresh, frozen and deep frozen crustaceans, <i>Panaeidae</i> , <i>Solenoceridae</i> , <i>Aristaeidae</i> family: — ≤ 80 units — > 80 units but ≤ 120 units — > 120 units cooked cooked crustaceans, <i>Panaeidae</i> , <i>Solenoceridae</i> , <i>Aristaeidae</i> family: — ≤ 80 units — > 80 units but ≤ 120 units — > 120 units * In edible parts”	150* 150* 200* 300* 50* 135* 180* 270*
--	---

- (b) for the expression “Starches (excluding starches for weaning foods, follow-on formulae and infant formulae)” substitute “Starches (excluding starches in infant formulae, follow-on formulae and processed cereal-based foods and baby foods)”;
- (c) at the end of the table add the following entries —

“Salsicha fresca	450
Table grapes	10
Fresh lychees	10 (measured on edible parts)”

8. In Schedule 2 Part C (other preservatives) the table relating to E 249, E 250, E 251 and E 252 is replaced by the table set out in Schedule 1 to these Regulations.

9. In Schedule 2 Part D (other antioxidants) the table is replaced by the table set out in Schedule 2 to these Regulations.

10. In Schedule 3 (other permitted miscellaneous additives)—

- (a) in the entry relating to E385 in the third and fourth columns (entitled respectively “Food” and “Maximum level”) add the following entries —

“Libamáj, egézben és tömbben	250 mg/kg
------------------------------	-----------

- (b) after the entry relating to E 967 insert the following —

E 968	Erythritol	Food in general	<i>quantum satis</i>
-------	------------	-----------------	----------------------

(a) OJ No. L91, 7.4.1999, p.29.

		(except drinks and those foods referred to in Article 2(3) of Directive 95/2/EC	
		Frozen and deep-frozen unprocessed fish, crustaceans, molluscs and cephalopods Liqueurs	<i>quantum satis</i> <i>quantum satis</i> For purposes other than sweetening

(c) after the entry relating to E 425 insert the following —

E 426	Soybean hemicellulose	Dairy-based drinks intended for retail sale Food supplements Emulsified sauces Pre-packaged fine bakery wares intended for retail sale Pre-packaged ready-to-eat oriental noodles intended for retail sale Pre-packaged ready-to-eat rice intended for retail sale Pre-packaged processed potato and rice products (including frozen, deep-frozen, chilled and dried processed products) intended for retail sale Dehydrated, concentrated, frozen and deep-frozen egg products Jelly confectionery, except jelly mini-cups	5 g/l 1.5 g/l 30 g/l 10 g/kg 10 g/kg 10 g/kg 10 g/kg 10 g/kg 10 g/kg
-------	-----------------------	---	--

- (d) in the third column of the entry relating to E 468, for the expression “Solid dietary supplements” substitute “Food supplements supplied in solid form”;
- (e) in the third column of the entry relating to E 338 to E 452, for the expression “Dietary supplements” substitute “Food supplements”;
- (f) in the third column of the entries relating to E 405, E 416, E 432 to E 436, E 473, E 474, E 475, E 491 to E 495, E 551 to E 559 and E 901 to E 904, for the expression “Dietary food supplements” substitute “food supplements”;
- (g) in the third column of the entries relating to E 1201 and E 1202, for the expression “Dietary food supplements in tablet and coated form” substitute “Food supplements in tablet and coated form”;

- (h) in the third column of the entries relating to E 405, E 432 to E 436, E 473 and E 474, E 475, E 477, E 481 and E 482, and E 491 to E 495, for the expression “Dietetic food intended for special medical purposes” substitute “Dietary foods for special medical purposes as defined in Directive 1999/21/EC”;
- (i) in the fourth column of the entries relating to E 1505 to E 1520, after the expression “In the case of beverages,” insert the expression “with the exception of cream liqueurs,”;
- (j) at the end of the table add the following entries —

“E 1204	Pullulan	Food supplements in capsule and tablet form	<i>quantum satis</i>
		Breath-freshening micro-sweets in the form of films	<i>quantum satis</i>
E 1452	Starch Aluminium Octenyl Succinate	Encapsulated vitamin preparations in food supplements	35 g/kg in food supplement”

11. In Schedule 4 (permitted carriers and carrier solvents) —

- (a) after the entry relating to E 967, in the first column insert “E 968” and in the second column opposite insert “Erythritol”;
- (b) after the entry relating to E 461, in the first column insert “E 462” and in the second column opposite insert “Ethyl cellulose”;
- (c) in the third column of the entry related to E 551 and E 552, add the expression “For E 551: in E 171 titanium dioxide and E 172 iron oxides and hydroxides (max. 90% relative to the pigment).”.

12. In Schedule 7 (foods in which a limited number of miscellaneous additives listed in Schedule 1 may be used) —

- (a) for the entry relating to ripened cheese, substitute the following —

“Ripened cheese	E 170 calcium carbonate	<i>quantum satis</i>
	E 504 Magnesium carbonates	
	E 509 Calcium chloride	
	E 575 Glucono-delta-lactone	
	E 500ii Sodium hydrogen carbonate	<i>quantum satis</i> (only for sour milk cheese)”

- (b) in the entry relating to “*pain courant français*”, in the first column add the expression “*Friss búzankenyér, fehér és félbarna kenyerek*”;
- (c) in the entry relating to “*fois gras, foie gras entiere, blocs de foie gras*”, in the first column add the expression “*Libamáj, libamáj egézben, libamáj tömbben*”.

13. In Schedule 8 (miscellaneous additives permitted in foods for infants and young children) —

- (a) in paragraphs 1, 1A and 1B of the introductory notes, for the expression “weaning foods” substitute in each case the expression “processed cereal-based foods and baby foods”;
- (b) in Part 3 (miscellaneous additives permitted in weaning foods for infants and young children in good health) —
- (i) where it appears in the title and in the third column of the entries relating to E 170 to E 526, E 500 to E 503, E 338, E 410 to E 440, E 1404 to E 1450, and E 1451, for the expression “weaning foods” substitute “processed cereal-based foods and baby foods”; and
- (ii) after the entry relating to E 472c insert the following entry —

“E 473	Sucrose esters of fatty acids	Products containing hydrolysed	120
--------	-------------------------------	--------------------------------	-----

		proteins, peptides and amino acids	mg/kg
--	--	------------------------------------	-------

Amendments to the Sweeteners in Food Regulations 1995

14.—(1) The Sweeteners in Food Regulations 1995(a) are amended in accordance with paragraphs (2) and (3).

(2) In regulation 2 (interpretation), in the definition of Directive 94/35/EC for the expression “and by Directive 2003/115/EC” substitute the expression “, and by European Parliament and Council Directives 2003/115/EC(b) and 2006/52/EC(c)”.

(3) In Schedule 1 (permitted sweeteners and the foods in or on which they may be used) —

- (a) in column 1 after “E 967” add “E 968”; and
- (b) in column 2 after “Xylitol” add “Erythritol”.

Signed by authority of the Secretary of State for Health

Caroline Flint
Minister of State
Department of Health

Nth Month 2007

(a) S.I. 1995/3123, amended in relation to England by S.I. 1996/1477, S.I. 1997.814, S.I. 1999/982, S.I. 2001/2294, S.I. 2003/379, S.I. 2003/1182 and S.I. 2004/3348.
(b) OJ No. L24, 29.1.2004, p.65.
(c) OJ No. L204, 26.7.2006, p.10.

SCHEDULE 1

Regulation 8

Entries to be substituted in Part C of Schedule 2 to the Additives Regulations

<i>EC No.</i>	<i>Name</i>	<i>Food</i>	<i>Maximum amount that may be added during manufacture (expressed as NaNO₂)</i>	<i>Maximum residual level (expressed as NaNO₂)</i>
E 249	Potassium nitrite ^(x)	Meat Products	Mg/kg 150	Mg/kg 175 100 50 175 100 50
E 250	Sodium nitrite ^(x)	Sterilised meat products (Fo > 3,00) ^(y)	100	
		Traditional immersion cured meat products ⁽¹⁾ : <i>Wiltshire bacon</i> ^(1.1) ; <i>Entremeada, entrecosto, chispe, orelheira e cabeça (salgados)</i> <i>Toucinho fumado</i> ^(1.2) ; and similar products		
		<i>Wiltshire ham</i> ^(1.1) ; and similar products		
		<i>Rohschinken, nassgepökelt</i> ^(1.6) ; and similar products		
		<i>Cured tongue</i> ^(1.3)		
		Traditional dry cured meat products ⁽²⁾ : <i>Dry cured bacon</i> ^(2.1) ; and similar products		
		<i>Dry cured ham</i> ^(2.1) ; <i>Jamón curado, paleta curada, lomo embuchado y cecina</i> ^(2.2) ; <i>Presunto, presunto da pà and paio do lombo</i> ^(2.3) ; and similar products		
		<i>Rohschinken, trockengepökelt</i> ^(2.5) ; and similar products		
		Other traditionally cured meat products ⁽³⁾ ; <i>Vysočina</i> <i>Selský salám</i> <i>Turistický trvanlivý salám</i>	180	

	<i>Kantwurst</i> ^(3.3) ;		
	<i>Rohschinken, trocken-/nassgepökelt</i> ^(3.1) ; and similar products		250
	<i>Salchichón y chorizo tradicionales de larga curación</i> ^(3.4) ; <i>Saucissons secs</i> ^(3.6) ; and similar products	250 (without added E 249 or E 250)	
	<i>Jellied veal and brisket</i> ^(3.2) ;		10
	Hard, semi-hard and semi-soft cheese	150 in the cheese milk or equivalent level if added after removal of whey and addition of water	
	Dairy-based cheese analogue		
	Pickled herring and sprat	500	

^(x) When labelled “for food use”, nitrite may be sold only in a mixture with salt or a salt substitute.

^(y) Fo-value 3 is equivalent to 3 minutes heating at 121°C (reduction of the bacterial load of one billion spores in each 1,000 cans to one spore in a thousand cans).

^(z) Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment.

⁽¹⁾ Meat products are immersed in curing solution containing nitrites and/or nitrates, salt and other components. The meat products may undergo further treatments eg. smoking.

^(1.1) Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures.

^(1.2) Immersion cured for 3 to 5 days. Product is not heat-treated and has a high water activity .

^(1.3) Immersion cured for at least 4 days and pre-cooked.

^(1.4) Meat is injected with curing solution followed by immersion curing. Curing time is 14 to 21 days followed by maturation in cold-smoke for 4 to 5 weeks.

^(1.5) Immersion cured for 4 to 5 days at 5 to 7°C, matured for typically 24 to 40 hours at 22°C, possibly smoked for 24 hrs at 20 to 25°C and stored for 3 to 6 weeks at 12 to 14°C.

^(1.6) Curing time depending on the shape and weight of meat pieces for approximately 2 days/kg followed by stabilisation/maturation.

⁽²⁾ Dry curing process involves dry application of curing mixture containing nitrites and/or nitrates, salt and other components to the surface of the meat followed by a period of stabilisation/maturation. The meat products may undergo further treatments eg. smoking.

^(2.1) Dry curing followed by maturation for at least 4 days.

^(2.2) Dry curing with a stabilisation period of at least 10 days and a maturation period of more than 45 days.

^(2.3) Dry cured for 10 to 15 days followed by a 30 to 45 day stabilisation period and a maturation period of at least 2 months.

^(2.4) Dry cured for 3 days + 1 day/kg followed by a one week post-salting period and an ageing/ripening period of 45 days to 18 months.

^(2.5) Curing time depending on the shape and weight of meat pieces for approximately 10 to 14 days followed by stabilisation/maturation.

⁽³⁾ Immersion and dry cured processes used in combination or where nitrite and/or nitrate is included in a compound product or where the curing solution is injected into the product prior to cooking. The products may undergo further treatments eg. smoking.

- (3.1) Dry curing and immersion curing used in combination (without injection of curing solution). Curing time depending on the shape and weight of meat pieces for approximately 14 to 35 days followed by stabilisation/maturation.
- (3.2) Injection of curing solution followed, after a minimum of 2 days, by cooking in boiling water for up to 3 hours.
- (3.3) Product has a minimum 4-week maturation period and a water/protein ratio of less than 1:7.
- (3.4) Maturation period of at least 30 days.
- (3.5) Dried product cooked to 70°C followed by 8 to 12 day drying and smoking process. Fermented product subject to 14 to 30 day three-stage fermentation process followed by smoking.
- (3.6) Raw fermented dried sausage without added nitrites. Product is fermented at temperatures in the range of 18 to 22°C or lower (10 to 12°C) and then has a minimum aging/ripening period of 3 weeks. Product has a water/protein ratio of less than 1:7.

SCHEDULE 2

Regulation 9

Entries to be substituted in Part D of Schedule 2 to the Additives Regulations

<i>EC No.</i>	<i>Name</i>	<i>Food</i>	<i>Maximum level (mg/kg)</i>
E 310	Propyl gallate	Fats and oils for the professional manufacture of heat-treated foods	200* (gallates, TBHQ and BHA, individually or in combination)
E 311	Octyl gallate	Frying oil and frying fat, excluding olive pomace oil	100* (BHT), both expressed on fat
E 312	Dodecyl gallate		
E 319	Tertiary-butyl hydroquinone (TBHQ)	Lard; fish oil; beef, poultry and sheep fat	
E 320	Butylated hydroxyanisole (BHA)	Cake mixes; cereal-based snack foods; milk powder for vending machines	200 (gallates, TBHQ and BHA, individually or in combination) expressed on fat
E 321	Butyolated hydroxytoluene (BHT)	Dehydrated soups and broths; sauces; dehydrated meat; processed nuts; pre-cooked cereals Seasonings and condiments Dehydrated potatoes Chewing gum; food supplements Essential oils Flavourings other than essential oils	200 (gallates and BHA, individually or in combination) expressed on fat 25 (gallates, TBHQ and BHA, individually or in combination) 400 (gallates, TBHQ, BHT and BHA, individually or in combination) 1,000 (gallates, TBHQ and BHA, individually or in combination) 100*(gallates, individually or in combination) 200*(TBHQ and BHA, individually or in combination)
E 315	Erythorbic acid	Cured meat products and preserved meat products	500 expressed as erythorbic acid
E 316	Sodium erythorbate	Preserved and semi-preserved fish products; Frozen and deep-frozen fish with red skin	1,500 expressed as erythorbic acid
E 586	4-Hexylresorcinol	Fresh, frozen and deep-frozen crustaceans	2 as residues in crustacean meat

* When combinations of gallates, TBHQ, BHA and BHT are used, the individual levels must be reduced proportionally

EXPLANATORY NOTE

(This note is not part of the Regulations)