

**2007 No. 1778**

**FOOD, ENGLAND**

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

<i>Made</i>	- - - -	<i>20th June 2007</i>
<i>Laid before Parliament</i>		<i>27th June 2007</i>
<i>Coming into force</i>	- -	<i>25th July 2007</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 25th July 2007 and apply in relation to England only.

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(a) 1990 c. 16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and 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 paragraph 8 of Schedule 5 to the 1999 Act. 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 thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

(c) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended as at the date this instrument was made 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 expression “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) in the definition of “Directive 96/77/EC”, for the expression “and Commission Directive 2004/45/EC” substitute “, Commission Directive 2004/45/EC and Commission Directive 2006/129/EC**(d)**,”; and
- (d) 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
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(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. This Directive was corrected by a Corrigendum published on the 17<sup>th</sup> March 2007 (OJ No L78, 13.3.2007, p.32).

(d) OJ No. L346, 9.12.2006, p.15.

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;
- (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*
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- (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 —

“ <i>Salsicha fresca</i>	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 —

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

“Libamáj, egészben és tömbben	250 mg/kg”
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(b) after the entry relating to E 967 insert the following —

E 968	Erythritol	Food in general (except drinks and those foods referred to in Article 2(3) of Directive 95/2/EC	<i>quantum satis</i>
		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
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- (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 and 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 foods 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 “*foie gras, foie gras entier, blocs de foie gras*”, in the first column add the expression “*Libamáj, libamáj egészben, 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 proteins, peptides and amino acids	120 mg/kg"
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#### **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) —

(a) in the definition of "Directive 94/35/EC", for the expression "and by Directive 2003/115/EC" substitute " and by European Parliament and Council Directives 2003/115/EC(b) and 2006/52/EC(c).";

(b) in the definition of "Directive 95/31/EC", for the expression "and by Directive 2004/46/EC" substitute "and by Directives 2004/46/EC and 2006/128/EC(d).".

(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

20th June 2007

*Caroline Flint*  
Minister of State  
Department of Health

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(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.

(d) OJ No. L346, 9.12.2006, p.6.

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 NaNO<sub>2</sub>)</i>	<i>Maximum residual level (expressed as NaNO<sub>2</sub>)</i>
E 249	Potassium nitrite <sup>(x)</sup>	Meat Products	mg/kg 150	mg/kg
E 250	Sodium nitrite <sup>(x)</sup>	Sterilised meat products (Fo > 3,00) <sup>(y)</sup>	100	
		Traditional immersion cured meat products <sup>(1)</sup> : <i>Wiltshire bacon</i> <sup>(1.1)</sup> ; <i>Entremeada, entrecosto, chispe, orelheira e cabeça (salgados)</i> <i>Toucinho fumado</i> <sup>(1.2)</sup> ; and similar products		175
		<i>Wiltshire ham</i> <sup>(1.1)</sup> ; and similar products		100
		<i>Rohschinken, nassgepökelt</i> <sup>(1.6)</sup> ; and similar products		50
		<i>Cured tongue</i> <sup>(1.3)</sup>		50
		Traditional dry cured meat products <sup>(2)</sup> : <i>Dry cured bacon</i> <sup>(2.1)</sup> ; and similar products		175
		<i>Dry cured ham</i> <sup>(2.1)</sup> ; <i>Jamón curado, paleta curada, lomo embuchado y cecina</i> <sup>(2.2)</sup> ; <i>Presunto, presunto da pà and paio do lombo</i> <sup>(2.3)</sup> ; and similar products		100
		<i>Rohschinken, trockengepökelt</i> <sup>(2.5)</sup> ; and similar products		50
		Other traditionally cured meat products <sup>(3)</sup> ;  <i>Vysočina</i> <i>Selský salám</i> <i>Turistický trvanlivý salám</i>	180	







- (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	Butylated hydroxytoluene (BHT)	Dehydrated soups and broths; sauces; dehydrated meat; processed nuts; pre-cooked cereals	
		Seasonings and condiments	200 (gallates and BHA, individually or in combination) expressed on fat
		Dehydrated potatoes	25 (gallates, TBHQ and BHA, individually or in combination)
		Chewing gum; food supplements	400 (gallates, TBHQ, BHT and BHA, individually or in combination)
		Essential oils	1,000 (gallates, TBHQ and BHA, individually or in combination)
		Flavourings other than essential oils	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)*

1. These Regulations, which apply in relation to England only, amend the Miscellaneous Food Additives Regulations 1995 (S.I. 1995/3187 as amended) (“the Additives Regulations”) in order to provide for the implementation of —

- (a) Directive 2006/52/EC of the European Parliament and of the Council amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs (OJ No. L204, 26.7.2006, p.10), as corrected by a Corrigendum (OJ No. L78, 17.3.2007, p.32); and
- (b) Commission Directive 2006/129/EC amending and correcting Directive 96/77/EC laying down specific purity criteria on food additives other than colours or sweeteners (OJ No. L346, 9.12.2006, p.15).

2. These Regulations also amend the Sweeteners in Food Regulations 1995 (S.I. 1995/3123 as amended) in order to provide for the implementation of Directive 2006/52/EC mentioned above and of Commission Directive 2006/128/EC amending and correcting Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

3. In particular these Regulations amend the Additives Regulations by —

- (a) amending certain definitions used in the Additives Regulations, including updating references to recently amended EC legislation (*regulation 3*);
- (b) making a transitional provision to permit the marketing of food additives or food placed on the market or labelled before 15<sup>th</sup> August 2008 if such marketing would have been lawful under the Additives Regulations before they were amended by these Regulations (*regulation 4*);
- (c) specifying certain additives that may not be used in the manufacture of jelly cups (*regulation 5(a)*);
- (d) adding a new substance to the permitted additives listed in Schedule 1, which concerns miscellaneous additives generally permitted for foods not referred to in Schedules 6, 7 or 8 (*regulation 5(b)*);
- (e) altering certain limits, removing certain substances and adding others to the conditionally permitted preservatives and anti-oxidants in Part A of Schedule 2 (*regulation 6*);
- (f) amending the entries relating to crustaceans and cephalopods, amending references to foods for infants and young children and adding two new entries to Part B of Schedule 2, which deals with sulphur dioxide and sulphites (*regulation 7*);
- (g) replacing, with amendments, Part C of Schedule 2 which relates to the use of potassium nitrite and nitrate and sodium nitrite and nitrate (*regulation 8 and Schedule 1*);
- (h) replacing, with amendments, Part D of Schedule 2 which relates to the use of certain anti-oxidants (*regulation 9 and Schedule 2*);
- (i) adding certain substances and amending conditions of use for some already permitted substances in Schedule 3, which concerns other permitted miscellaneous additives, and amending certain defined expressions used in that Schedule (*regulation 10*);
- (j) adding two substances and amending the conditions of use for one already permitted in Schedule 4 which concerns permitted carriers and carrier solvents (*regulation 11*);
- (k) amending Schedule 7, concerning foods in which a limited number of additives may be used, by the addition of certain foods and the addition of one additive to those permitted in one particular food (*regulation 12*); and
- (l) amending a defined expression for a class of foods where it appears in Schedule 8, which concerns miscellaneous additives permitted in foods for infants and young children, and adding a permitted substance to that Schedule (*regulation 13*).

4. These Regulations amend the Sweeteners in Food Regulations 1995 by —

- (a) updating references to recently amended EC legislation (*regulation 14(2)*); and
- (b) adding a substance to Schedule 1, which concerns permitted sweeteners and the foods in or on which they may be used (*regulation 14(3)*).

**5.** A full regulatory impact assessment of the effect that this instrument will have on the costs of business has been prepared and placed in the library of each of the Houses of Parliament. Copies may be obtained from the Novel Foods, Additives and Supplements Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC 2B 6NH.

**£3.00**

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