
STATUTORY INSTRUMENTS

2008 No. 138 (W.20)

FOOD, WALES

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

<i>Made</i>	- - - -	<i>22 January 2008</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>24 January 2008</i>
<i>Coming into force</i>	- -	<i>15 February 2008</i>

The Welsh Ministers make 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⁽¹⁾.

In accordance with section 48(4A) of that Act, the Welsh Minister have 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⁽²⁾ there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Title, commencement and application

1. The title of these Regulations is the Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (Wales) Regulations 2008, they come into force on 15 February 2008 and apply in relation to Wales.

Amendments to the Miscellaneous Food Additives Regulations 1995

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

(1) 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. Functions 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. Functions of the National Assembly for Wales are now exercisable by the Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c. 32).

(2) 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).

(3) S.I. 1995/3187, amended in relation to Wales by S.I. 1997/1413, S.I. 1999/1136, S.I. 2001/1787, SI. 2001/1440, S.I. 2002/329, S.I. 2003/945, S.I. 2005/1311 and S.I. 2005/3254.

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(4) and European Parliament and Council Directive 2006/52/EC(5);”;
- (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(6);”; 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) (Wales) Regulations 2008 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)—

(4) OJ No. L24, 29.1.2004, p.58.
(5) OJ No. L204, 26.7.2006, p.10.
(6) OJ No. L346, 9.12.2006, p.15.

- (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(7)”;
- (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	150*
crustaceans, Panaeidae, Solenoceridae, Aristaeidae family:	
— [\leq]80 units	150*
— $>$ 80 units but [\leq] 120 units	200*
— $>$ 120 units	300*
Cooked	50*
cooked crustaceans, Panaeidae, Solenoceridae, Aristaeidae family:	
— [\leq] 80 units	135*
— $>$ 80 units but [\leq] 120 units	180*
— $>$ 120 units	270*
* In edible parts”	

- (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
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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
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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	Quantum satis
		Frozen and deep-frozen unprocessed fish, crustaceans, molluscs and cephalopods	Quantum satis
		Liqueurs	Quantum satis
			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	5 g/l
		Food supplements	1.5 g/l
		Emulsified sauces	30 g/l
		Pre-packaged fine bakery wares intended for retail sale	10 g/kg
		Pre-packaged ready-to-eat oriental noodles intended for retail sale	10 g/kg
		Pre-packaged ready-to-eat rice intended for retail sale	10 g/kg

Pre-packaged processed potato and rice products (including frozen, deep-frozen, chilled and dried processed products) intended for retail sale	10 g/kg
Dehydrated, concentrated, frozen and deep-frozen egg products	10 g/kg
Jelly confectionery, except jelly mini-cups	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 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	Quantum satis
		Breath-freshening micro-sweets in the form of films	Quantum satis
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	quantum satis
	E 504 Magnesium carbonates	
	E 509 Calcium chloride	
	E 575 Glucono-delta-lactone	
	E 500ii Sodium hydrogen carbonate	quantum satis (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 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) omit the entry relating to E 473; and
- (ii) 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”.
- (c) in Part 4 (miscellaneous additives permitted in dietary foods for infants and young children for special medical purposes as defined in Directive 1999/21/EC), after the entry relating to E 472c insert the following entry—

“E 473	Sucrose esters of fatty acids	Products containing 120 mg/l” hydrolysed proteins, peptides and amino acids
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Amendments to the Sweeteners in Food Regulations 1995

14.—(1) The Sweeteners in Food Regulations 1995⁽⁸⁾ 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](#)⁽⁹⁾ and [2006/52/EC](#)⁽¹⁰⁾.”;

(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](#)⁽¹¹⁾.”.

(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”.

22 January 2008

Gwenda Thomas
Under authority of the Minister for Health and
Social Services, one of the Welsh Ministers

⁽⁸⁾ S.I. [1995/3123](#), amended in relation to Wales by S.I. [1997/814](#), S.I. [2001/2679](#), S.I. [2002/330](#), S.I. [2003/1713](#), S.I. [2005/1156](#) and S.I. [2005/3253](#).

⁽⁹⁾ OJ No. L24, 29.1.2004, p.65.

⁽¹⁰⁾ OJ No. L204, 26.7.2006, p.10.

⁽¹¹⁾ OJ No. L346, 9.12.2006, p.6.

<i>EC No.</i>	<i>Name</i>	<i>Food</i>	<i>Maximum amount that may be added during manufacture (expressed as NaNO₂)</i> mg/kg	<i>Maximum residual level (expressed as NaNO₂)</i> mg/kg
		Traditional dry cured meat products ⁽²⁾ ;		
		<i>Dry cured bacon⁽²⁻¹⁾; and similar products</i>		175
		<i>Dry cured ham⁽²⁻¹⁾;</i>		100
		<i>Jamón curado, paleta curada, lomo embuchado y cecina⁽²⁻²⁾; Presunto, presunto da pà and paio do lombo⁽²⁻³⁾; and similar products</i>		
		<i>Rohschinken, trockengepökelt⁽²⁻⁵⁾; and similar products</i>		50
		Other traditionally cured meat products ⁽³⁾ ;		
		<i>Vysoèina</i>	180	
		<i>Selský salám</i>		
		<i>Turistický trvanlivý salám</i>		
		<i>Polièan</i>		
		<i>Herkules</i>		
		<i>Lovecký salám</i>		

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<i>EC No.</i>	<i>Name</i>	<i>Food</i>	<i>Maximum amount that may be added during manufacture (expressed as NaNO₂)</i> mg/kg	<i>Maximum residual level (expressed as NaNO₂)</i> mg/kg
		<i>Dunajská klobása</i> <i>Paprikás</i> ^(3.5) ; and similar products		
		<i>Rohschinken, trocken-/nassgepökelt</i> ^(3.1) ; and similar products		50
		<i>Jellied veal and brisket</i> ^(3.2)		
E 251	Potassium nitrate ^(z)	Non-heat-treated meat products	150	
E 252	Sodium nitrate ^(z)	Traditional immersion cured meat products ⁽¹⁾ ;		
		<i>Kylmäsavustettu poronliha/ Kallrökt renkött</i> ^(1.4) ;	300	
		<i>Wiltshire bacon and Wiltshire ham</i> ^(1.1)		250
		<i>Entremeada, entrecosto, chispe, orelheira a cabeça (salgados),</i>		
		<i>Toucinho fumado</i> ^(1.2) ;		
		<i>Rohschinken, nassgepökelt</i> ^(1.6) ;		

<i>EC No.</i>	<i>Name</i>	<i>Food</i>	<i>Maximum amount that may be added during manufacture (expressed as NaNO₂)</i> mg/kg	<i>Maximum residual level (expressed as NaNO₂)</i> mg/kg
		and similar products		
		<i>Bacon, Filet de bacon⁽¹⁻⁵⁾; and similar products</i>		250 without added E 249 or E 250
		<i>Cured tongue⁽¹⁻³⁾</i>		10
		Traditional dry cured meat products ⁽²⁾ ; <i>Dry cured bacon and Dry cured ham⁽²⁻¹⁾;</i> <i>Jamón curado ,paleta curada, lomo embuchado y cecina⁽²⁻²⁾;</i>		250
		<i>Presunto, presunto da pá and paio do lombo⁽²⁻³⁾;</i> <i>Rohschinken, trockengepökelt⁽²⁻⁵⁾; and similar products</i>		
		<i>Jambon sec, jambon sel sec et autres pièces maturées séchées similaires⁽²⁻⁴⁾</i>		250 without added E 249 or E 250

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)

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

<i>EC No</i>	<i>Name</i>	<i>Food</i>	<i>Maximum level (mg/kg)</i>
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 Wales and amend the Miscellaneous Food Additives Regulations 1995 (*SI 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 (*SI 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 labeled before 15th 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 to, removing certain substances from and adding others to the conditionally permitted preservatives and anti-oxidants to the tables 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) replace 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) replace 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 copies are available from the Food Standards Agency, 11th Floor, Southgate House, Wood, Street, Cardiff, CF10 1EW.