WELSH STATUTORY INSTRUMENTS

2005 No. 1311 (W.93)

FOOD, WALES

The Miscellaneous Food Additives (Amendment) (No.2) (Wales) Regulations 2005

 Made
 10 May 2005

 Coming into force
 20 May 2005

The National Assembly for Wales, in exercise of the powers conferred by sections 16(1)(a), 17, 26(1) and (3) and 48(1) of, and paragraph 1 of Schedule 1 to, the Food Safety Act 1990(1) and now vested in it(2) and having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency, and after consultation 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(3) makes the following Regulations:

Title, commencement and application

1. The title of these Regulations is the Miscellaneous Food Additives (Amendment) (No.2) (Wales) Regulations 2005, they come into force on 20 May 2005 and apply in relation to Wales.

Amendment of the Miscellaneous Food Additives Regulations 1995

- **2.** The Miscellaneous Food Additives Regulations 1995(4) shall be amended in accordance with regulations 3 to 14 below.
 - 3. In paragraph (1) of regulation 2 (interpretation)
 - (a) after the definition of "colour", there shall be inserted the following definition —

^{(1) 1990} c. 16; section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990.

⁽²⁾ Functions formerly exercisable by the "Secretary of State" 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 Food Standards Act 1999 (1999 c. 28).

⁽³⁾ OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (OJ No. L245, 29.9.2003, p.4). By virtue of regulation 5 of the Food Safety Act 1990 (Amendment) Regulations 2004 (S.I. 2004/2990), with effect from 7 December 2004 the consultation requirement contained in section 48(4) of the 1990 Act is disapplied in any case in which consultation is required by Article 9 of Regulation (EC) No. 178/2002.

⁽⁴⁾ S.I. 1995/3187, amended by S.I. 1997/1413, S.I. 1999/1136, S.I. 2001/1440 (W.102), S.I. 2001/1787 (W.128), SI. 2001/2679 (W.220), S.I. 2001/3909 (W.321), S.I. 2002/329 (W.42), S.I. 2002/330 (W.43), S.I. 2003/3037 (W.285), S.I. 2003/3041 (W.286), S.I. 2003/3044 (W.288), S.I. 2003/3047 (W.290), S.I. 2003/3053 (W.291), S.I. 2004/553 (W.56), S.I. 2004/554 (W.57) and S.I. 2005/259 (W.25).

""Directive 88/388 EC" means Council Directive 88/388/EEC(5) on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production;";

- (b) in the definition of "Directive 95/2/EC" for the words "and European Parliament and Council Directive 2001/5/EC" there shall be substituted the following words—
 ", European Parliament and Council Directive 2001/5/EC(6) and European Parliament and Council Directive 2003/114/EC(7);";
- (c) after the definition of flavour enhancer, there shall be inserted the following definition—

 ""flavouring" bears the same meaning as in Article 1.2 of Directive 88/388/

 EEC(8);";
- (d) for the definition of "stabiliser", there shall be substituted the following definition
 - ""stabiliser" means any substance which makes it possible to maintain the physico- chemical state of a foodstuff; including any substance which enables the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff, substances which stabilise, retain or intensify an existing colour of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food;".
- **4.** In paragraph (1) of regulation 4 (use of miscellaneous additives in or on compound foods), after the words "that compound food contains, as an ingredient, a food", there shall be inserted the following words —

"or a flavouring".

5. After regulation 4 the following regulation shall be inserted —

"Use of permitted miscellaneous additives in flavourings

- **4A.**—(1) Where
 - (a) a permitted miscellaneous additive is used in a flavouring; and
 - (b) that flavouring is an ingredient of a compound food; and
 - (c) the permitted miscellaneous additive performs a technological purpose in the final food;

the permitted miscellaneous additive shall be regarded for the purposes of these Regulations as an additive of the final food.

- (2) No person shall use any permitted miscellaneous additive in or on any flavouring where $\,$
 - (a) the level of such additives used exceeds the minimum necessary to guarantee the safety and quality of the flavouring and to facilitate its storage;
 - (b) the presence of such additives is a hazard to human health, or misleading to the consumer.".
- **6.** In regulation 11 (transitional provision and exemptions), after paragraph (1E), there shall be inserted the following paragraph —

⁽⁵⁾ OJ No. L184, 15.7.1988, p.61.

⁽⁶⁾ OJ No. L55, 24.2.2001, p.59.

⁽⁷⁾ OJ No. L24, 29.1.2004, p.58.

⁽⁸⁾ OJ No. L184, 15.7.1988, p.61.

- "(1F) In any proceedings for an offence under these Regulations in respect of any food additives, food or flavouring, it shall be a defence to prove
 - (a) the food additive, food or flavouring concerned was put on the market or labelled before 27 January 2006; and
 - (b) the matter constituting the offence would not have constituted an offence under these Regulations if the amendments made by regulations 3 to 6, 7(b), 8(a), 8(b) (ii), 9(a), 10, 11(a) to (c), (e) to (i) and (k) to (l) of the Miscellaneous Food Additives (Amendment) (No.2) (Wales) Regulations 2005 had not been made when the food additive, food or flavouring was placed on the market or labelled.".
- 7. In Schedule 1 (miscellaneous additives generally permitted for use in foods not referred to in Schedule 6,7 or 8)—
 - (a) for Note 1, there shall be substituted the following note
 - "(1) The substances E407, E407a and E440 may be standardised with sugars, on condition that this is stated in addition to the number and designation.";
 - (b) in the entry relating to E170, in the second column, for the words "Calcium carbonates (i) calcium carbonate (ii) calcium hydrogen carbonate", there shall be substituted the following words —

"Calcium carbonate";

(c) in the entry relating to E466, in the second column, the following words shall be added at the end—

"Cellulose gum";

(d) in the entry relating to E469, in the second column, the following words shall be added at the end —

"Enzymatically hydrolysed cellulose gum".

- **8.** In Schedule 2 (conditionally permitted preservatives and antioxidants) part A (sorbates, benzoates and p-hydroxybenzoates)
 - (a) in the first column (entitled "Food") of the second table, for the words "Partially baked, pre-packed bakery wares intended for retail sale", there shall be substituted the following words —

"Partially baked, pre-packed bakery wares intended for retail sale and energy-reduced bread intended for retail sale";

(b) the following entries shall be added to the second table at the end:

"Craythsh 2000 tails, cooked and pre-packed Marinated cooked molluscs

1500"

- 9. In Schedule 2 Part C (other preservatives)
 - (a) the entry relating to E230 shall be omitted;
 - (b) in the entry relating to E1105, in the third and fourth columns (entitled respectively "Food" and "Maximum level") there shall be added the following entry —

"Wine in accordance with Regulation (EC) Pro memoria" No. 1493/1999(9) and its implementing Regulation (EC) No. 1622/2000(10)

10. In Schedule 2 Part D (other antioxidants) —

(a) in the entry relating to E310, E311, E312 and E320, in the third and fourth columns (entitled respectively "Food" and "Maximum level (mg/kg)") the following entries shall be added —

"Essential oils	1000 mg/kg (gallates and BHA, individually or in combination) E310-E320 only
Flavourings other than essential oils	100 mg/kg (gallates, individually or in combination) or 200 mg/kg (BHA)E310—E320 only"

(b) in the entry relating to E315 and E316, for the words "semi-preserved and preserved meat product", there shall be substituted the following words —

"Cured meat products and preserved meat products".

- 11. In Schedule 3 (other permitted miscellaneous additives)—
 - (a) in the entry relating to E338, E339, E340, E341, E343, E450, E451 and E452
 - (i) in the third and fourth columns (entitled respectively "Food" and "Maximum level") the following words shall be added—

"Flavourings	40g/kg"
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- (ii) in the third column, the words "cider and perry" and in the corresponding entry in the fourth column, the words "2g/l" shall be omitted;
- (b) in the entry relating to E416, in the third and fourth columns, the following words shall be added —

(c) in the entry relating to E432, E433, E434, E435 and E436, in the third and fourth columns, the following words shall be added —

"Flavourings, except liquid smoke	10g/kg
flavourings and flavourings based on spice	
oleoresins	
Foodstuffs containing liquid smoke flavourings and flavourings based on spice oleoresins	1g/kg"

⁽⁹⁾ Council Regulation (EC) No. 1493/1999 of 17 May 1999 on the common organisation of the market in wine, OJ No. L179, 14.7.1999, p.1.

⁽¹⁰⁾ Commission Regulation (EC) No. 1622/2000 of 24 July 2000 laying down certain detailed rules for implementing Regulation (EC) No. 1493/1999 on the common organisation of the market in wine and establishing a Community code of oenological practices and processes, OJ No. L194, 31.7.2000, p.1.

(d) in the entry relating to E444, in the third and fourth columns, the following words shall be added —

"Flavoured cloudy spirit drinks containing 300 mg/l" less than 15% alcohol by volume

(e) in the entry relating to E459, in the third and fourth columns, the following words shall be added —

"Encapsulated flavourings in 2-flavoured teas and flavoured powdered instant drinks or as reconstituted according to the 2-flavoured snacks

500 mg/l 1g/kg in foodstuffs as consumed instructions of the manufacturer"

(f) in the entry relating to E551, in the third and fourth columns, the following words shall

"Flavourings 50g/kg E551 only"

(g) in the entry relating to E900, in the third and fourth columns, the following words shall be added —

"Flavourings 10 mg/kg"

- (h) the entry relating to E901, E902, E903 and E904, the words "E903 Carnauba wax" shall be omitted;
- (i) after the entry relating to E901, E902, E903 and E904 as amended by paragraph (h) above, the following entry shall be inserted —

"E903	Carnauba wax	As glazing agents only:	
		— confectionery (including chocolate)	1500 mg/kg 11200 mg/kg (only for chewing gum)
— small products of fine bakery wares coated with chocolate	200 mg/kg		
		— snacks	200 mg/kg
		— nuts	200 mg/kg
		— coffee beans	200 mg/kg
		dietary food supplements	200 mg/kg
		— fresh citrus fruits, melons, apples, pears, peaches and pineapples (surface treatment only)	200 mg/kg"

⁽j) after the entry for E905, the following entry shall be inserted —

	"E907	Hydrogenated poly-1-decene	As glazing age	ent for
			— sugar confectionery	2g/kg
			— dried fruits	2g/kg"
(k)	the following entries	shall be added to t	he table at the end –	_
	"E1505 Triethyl citra	ate Flavourin	ngs	3g/kg from all sources in foodstuffs as consumed or
	E1517 Glyceryl diac (diacetin)	etate		as reconstituted according to the instructions of the manufacturer; individually
	E1518 Glyceryl triac (triacetin)	cetate		or in combination. In the case of beverages, the maximum level of
	E1520 Propan-1,2-di (propylene glycol)	iol E1520 sh	all be 1g/l	
	E1519 Benzyl alcoho	ol Flavourin	ngs for	
		wines, ar wine-bas	ors, aromatised omatised ed drinks and ed wine - products	100 mg/l
			ctionery including e and fine bakery	250 mg/kg from all sources in foodstuffs as consumed or as reconstituted according to the instruction of the manufacturer"

(l) at the end of the Schedule, after the table, the following words shall be added —

"Note:

Spice oleoresins are defined as extracts of spices from which the extraction solvent has been evaporated leaving a mixture of the volatile oil and resinous material from the spice."

- 12. In Schedule 4 (permitted carriers and carrier solvents)
 - (a) in the entry for E468, in the second column (entitled "Name") the following words shall be added —

"Cross-linked cellulose gum";

(b) the following entry shall be added to the table at the end —

"E555	Potassium aluminium silicate	In E171 titanium dioxide and E172 iron oxides and
		hydroxides (max 90% relative to the pigment)"

- **13.** In Schedule 7 (foods in which a limited number of miscellaneous additives listed in Schedule 1 may be used)
 - (a) in the entry relating to cocoa and chocolate products as defined in Directive 2000/36/EC, in the second and third columns as delineated below (entitled respectively "Additive" and "Maximum level") the following entry shall be added —

"E472c	Citric acid esters of mono- and diglycerides of fatty acids	quantum satis"
	acias	

(b) in the entry relating to cocoa and chocolate products as defined in Directive 2000/36/EC, the entry relating to grape juice as defined in Directive 2001/112/EC, the entry relating to ripened cheese and the entry relating to sliced and grated ripened cheese, in the second column, for the words "E170 Calcium carbonates", there shall be substituted in each case the following words —

"E170 Calcium carbonate".

(c) in the entry relating to frozen and deep-frozen unprocessed fruit and vegetables; prepacked, refrigerated unprocessed fruit and vegetables ready for consumption and prepacked, unprocessed and peeled potatoes, in the second and third columns, the following words shall be added —

"E296	Malic acid	quantum satis (only for
		peeled potatoes)"

(d) in the entry relating to fruit compote, in the second and third columns, the following words shall be added —

"E440	Pectin	quantum satis (only for fruit compote other than apple)
E509	Calcium chloride"	

(e) in the entry relating to mozzarella and whey cheese, in the second and third columns, the following words shall be added —

"E460ii	Powdered cellulose	quantum satis (only for grated and sliced cheese)"
"UHT goat milk	E331 Sodium citrates	4g/l
Chestnuts in liquid	E410 Locust bean gum	quantum satis
	E412 Guar gum	
	E415 Xanthane gum"	

- 14. In Schedule 8 (miscellaneous additives permitted in foods for infants and young children)
 - (a) in the Notes, after note 1A there shall be inserted the following note
 - "1B. Formulae and weaning foods for infants and young children may contain E1450 starch sodium octenyl succinate resulting from the addition of vitamin preparations or polyunsaturated fatty acid preparations. The carry over of E1450 in the product ready for

- consumption is not to be more than 100 mg/kg from vitamin preparations and 1000 mg/kg from polyunsaturated fatty acid preparations.";
- (b) in Part 3 (miscellaneous additives permitted in weaning foods for infants and young children in good health), in the entry relating to E170, in the second column, for the words "Calcium carbonates" there shall be substituted the words —

"Calcium carbonate";

(c) in Part 4 (miscellaneous additives permitted in foods for infants and young children for special medical purposes), for the title, the following words shall be substituted —

"MISCELLANEOUS ADDITIVES PERMITTED IN DIETARY FOODS FOR INFANTS AND YOUNG CHILDREN FOR SPECIAL MEDICAL PURPOSES AS DEFINED IN DIRECTIVE 1999/21/EC(11)

(d) in Part 4, the following entry shall be added to the table at the end —

"E472c	Citric acid esters of mono- and diglycerides of fatty acids	7.5g/l sold as powder	From birth onwards
		9g/l sold as liquid"	

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(12) 10 May 2005

D. Elis-Thomas
The Presiding Officer of the National Assembly

⁽¹¹⁾ Commission Directive 1999/21/EC on dietary foods for special medical purposes, OJ No. L91, 7.4.1999, p. 29.

^{(12) 1998} c. 38.

EXPLANATORY NOTE

(This note is not part of the Regulations)

- **1.** These Regulations, which apply in relation to Wales, further amend the Miscellaneous Food Additives Regulations 1995 (S.I. No. 1995/3187) as already amended and implement Directive 2003/114 of the European Parliament and of the Council amending Directive 95/2/EC on food additives other than colours and sweeteners (OJ No. L24, 29.1.2004, p.58).
- **2.** These Regulations amend the Miscellaneous Food Additives Regulations 1995 in relation to Wales by
 - (a) inserting a definition of flavouring, as the Regulations now apply to control the use of miscellaneous additives in flavourings (regulation 3 (a) and (c));
 - (b) bringing up to date the definition of "Directive 95/2/EC" to cover the amendment of that Directive by Directive 2003/114/EC (regulation 3(b));
 - (c) substituting a new definition for the term "stabiliser" to include substances which increase the binding capacity of food (regulation 3 (d));
 - (d) making an amendment to regulation 4 to ensure that a flavouring which lawfully has in or on it a permitted miscellaneous additive can be used as an ingredient in a compound food (regulation 4);
 - (e) providing that where a permitted miscellaneous additive used in a flavouring performs a technological function in the final food in which that flavouring is an ingredient, it is to be regarded as an additive of the final food (regulation 5);
 - (f) prohibiting the use of additives in quantities greater than the minimum necessary, or in circumstances where they would be a hazard to human health or misleading to the consumer (regulation 5);
 - (g) making transitional provision to allow the marketing of additives marketed or labelled before 27 January 2006, which are lawful under existing rules (regulation 6);
 - (h) permitting standardisation of E407a, in addition to E407 and E440 with sugars, provided this is stated in addition to the number and designation of the additive (regulation 7(a));
 - (i) substituting "calcium carbonate" as the name for E170 (regulations 7(b), 13(b) and 14(b));
 - (j) adding to the acceptable names for E466, E468 and E469 (regulations 7(c) and (d) and 12(a));
 - (k) permitting a new additive, E907 to be used as a glazing agent in sugar confectionery and dried fruit (regulation 11(j));
 - (l) substituting new definitions of food categories in which permitted miscellaneous additives may be used (regulations 8(a) and 10(b));
 - (m) prohibiting the use of E230 as a permitted preservative for surface treatment of citrus fruits (regulation 9(a));
 - (n) extending food categories in which permitted miscellaneous additives can be used (regulations 8(b)(i), 9(b), 11(d), 13(a) and (c)-(f), 14(d));
 - (o) prohibiting the use of phosphates in cider and perry (regulation 11(a) (ii));
 - (p) providing numerical limits to restrict the use of E903 (regulation 11(h) (i));

- (q) making provision for the restricted use of additives in flavourings (regulation 8(b)(ii), 10(a), 11(a)(i), (b)—(c), (e)—(g) and (k));
- (r) inserting a definition of spice oleoresins in Schedule 3 (regulation 11(1));
- (s) permitting a new carrier solvent, E555 to be used in certain specified colours (regulation 12(b));
- (t) clarifying the extent to which E1450 may be carried over into formulae and weaning foods for infants (regulation 14(a));
- (u) bringing up to date the title of Part 4 of Schedule 8 to take account of Commission Directive 1999/21/EC on dietary foods for special medical purposes (OJ No.L91, 7.4.1999, p.29) (regulation 14 (c)).
- **3.** A regulatory appraisal on the effect these Regulations have on business costs has been prepared pursuant to section 65 of the Government of Wales Act 1998 and placed in the library of the National Assembly for Wales, together with a transposition note setting out how the main elements of the Directives 2003/95/EC and 2003/45/EC are transposed into domestic law. Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Cardiff CF10 1EW.