

2005 No.214

FOOD

**The Miscellaneous Food Additives Amendment (Scotland)
Regulations 2005**

<i>Made</i> - - - -	<i>12th April 2005</i>
<i>Laid before the Scottish Parliament</i>	<i>13th April 2005</i>
<i>Coming into force</i> - -	<i>5th May 2005</i>

The Scottish Ministers, 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 of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A)(b) of that Act to relevant advice given by the Food Standards Agency, hereby make the following Regulations:

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Miscellaneous Food Additives Amendment (Scotland) Regulations 2005 and shall come into force on 5th May 2005.

(2) These Regulations extend to Scotland only.

Amendment to the Miscellaneous Food Additives Regulations 1995

2. The Miscellaneous Food Additives Regulations 1995(c) are amended in accordance with regulations 3 to 14 below.

(a) 1990 c.16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990; sections 16(1) and 48(1) were amended by the Food Standards Act 1999 (c.28) (“the 1999 Act”), section 40(1) and Schedule 5, paragraph 8; section 17(1) was amended by the 1999 Act, section 40(1) and Schedule 5, paragraphs 8 and 12; section 26(3) was amended by the 1999 Act, section 40(4) and Schedule 6; section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C), inserted by S.I. 2004/2990; section 53(2) was amended by the 1999 Act, section 40(4) and Schedule 6, and by S.I. 2004/2990; amendments made by Schedule 5 to the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998. Insofar as not so transferred, those functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

(b) Section 48(4A) was inserted by the Food Standards Act 1999 (c.28) Act, Schedule 5, paragraph 21.

(c) S.I. 1995/3187, as relevantly amended by S.I. 1997/1413 and 1999/1136 and S.S.I. 2001/38, 103 and 450, 2003/132, 291, 293, 311 and 599, and 2004/6 and 413.

3. In regulation 2(1) (interpretation)–

(a) after the definition of “colour”, insert–

““Directive 88/388/EEC” means Council Directive 88/388/EEC(a) on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production as corrected by corrigenda published on 14th December 1988(b) and 10th April 1996(c) and as amended by Commission Directive 91/71/EEC(d) and Regulation (EC) No. 1882/2003 of the European Parliament and of the Council(e);”;

(b) in the definition of “Directive 95/2/EC(f)” for “and European Parliament and Council Directive 2001/5/EC”, substitute–

“, European Parliament and Council Directive 2001/5/EC(g) and European Parliament and Council Directive 2003/114/EC(h);”;

(c) after the definition of “flavour enhancer”, insert–

““flavouring” has the same meaning as in Article 1.2 of Directive 88/388/EEC(i);”;

(d) for the definition of “stabiliser”, substitute–

““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 regulation 4(1) (use of miscellaneous additives in or on compound foods), after “food” in the third place that it occurs, insert “or a flavouring”.

5. After regulation 4, insert–

“Use of permitted miscellaneous additives in flavourings

4A.—(1) Where–

- (a) a permitted miscellaneous additive is used in a flavouring,
- (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, or
- (b) the presence of such additives is a hazard to human health, or misleading to the consumer.”.

(a) O.J. No. L 184, 15.7.88, p.61.

(b) O.J. No. L 345, 14.12.88, p.29.

(c) O.J. No. L 89, 10.4.96, p.46.

(d) O.J. No. L 42, 15.2.91, p.25.

(e) O.J. No. L 284, 31.10.03, p.1.

(f) O.J. No. L 61, 18.3.95, p.1, as corrected by corrigendum to 95.2.EC (O.J. No. L 248, 14.10.95, p.60).

(g) O.J. No. L 55, 24.2.01, p.59.

(h) O.J. No. L 24, 29.1.04, p.58.

(i) O.J. No. L. 184, 15.7.88, p.61.

6. In regulation 11 (transitional provision and exemptions), after paragraph (1E), insert–

“(1F) In any proceedings for an offence under these Regulations in respect of any food additive, 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 27th 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, 9(a), 10, 11(a) to (c), (e) to (i), (k) and (l) of the Miscellaneous Food Additives Amendment (Scotland) 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, substitute–

“(1) The substances E 407, E 407a and E 440 may be standardised with sugars, on condition that this is stated in addition to the number and designation.”;

(b) in the entry relating to E 170, in the second column, for “Calcium carbonates (i) Calcium carbonate (ii) Calcium hydrogen carbonate”, substitute “Calcium carbonate”;

(c) in the entry relating to E 466, in the second column, insert at the end–
“Cellulose gum”;

(d) in the entry relating to E 469, in the second column, insert 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 of the second table, for “Partially baked, pre-packed bakery wares intended for retail sale”, substitute–

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

(b) at the end of the second table insert–

(i) “

Crayfish tails, cooked, and pre-packed marinated cooked molluscs	2000						
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”;and

(ii) “

Flavourings				1500			
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”.

9. In Schedule 2, Part C (other preservatives)–

(a) omit the entries relating to E 230;

(b) for the entries relating to E 1105, substitute–

“ E 1105	Lysozyme)	Ripened cheese	<i>quantum satis</i>
)	Wine in accordance with	<i>Pro memoria</i>
)	Regulation (EC) No	
)	1493/1999(a) and its	
)	implementing	
)	Regulation (EC) No	
)	1622/2000(b)	

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

(a) for the entry relating to E 310, E 311, E 312, E 320 and E 321, substitute–

“ E 310 E 311 E 312 E 320 E321	Propyl gallate	} Fats and oils for the } professional } manufacture of } heat-treated foods } Frying oil and } frying fat, } excluding olive } pomace oil } Lard; fish oil; beef, } poultry and sheep } fat } } } } } } } } } }	} 200 ⁽¹⁾ (gallates } and BHA, } individually or in } combination) } } 100 ⁽¹⁾ (BHT) } } both expressed on } fat } Note: } ⁽¹⁾ When } combinations of } gallates, BHA } and BHT are } used, the } individual levels } must be reduced } proportionally.
	Octyl gallate		
	Dodecyl gallate		
	Butylated hydroxyanisole (BHA)		
	Butylated hydroxytoluene (BHT)		
	} 200 (gallates and } BHA, } individually or in } combination) } } expressed on fat } } } } } } } } }		
	} 25 (gallates and } BHA, } individually or in } combination)		

(a) O.J. No. L 179, 14.7.99, p.1.
(b) O.J. No. L 194, 31.7.00, p.1.

	} Chewing gum } Dietary } supplements }	} 400 (gallates, } BHT and BHA, } individually or in } combination)
	} Essential oils } (E 310, E 311, E } 312 and E 320 } only)	} 1000 mg/kg } (gallates and } BHA, } individually or in } combination) E 310, E 311, E 312 and E 320 only
	} Flavourings other } than essential oils } (E 310, E 311, E } 312 and E 320 } only)	} 100 mg/kg } (gallates, } individually or in } combination) or } 200 mg/kg (BHA) E 310, E 311, E 312 and E 320 only

”; and

(b) in the entry relating to E 315 and E 316, in the third column, for “Semi-preserved and preserved meat products”, substitute—

“Cured meat products and preserved meat products”.

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

(a) in the entry relating to E 338, E 339, E 340, E 341, E 343, E 450, E 451 and E 452—

(i) in the third column, insert at the end the entry “Flavourings” and in the fourth column insert the corresponding entry “40 g/kg”;

(ii) in the third column, omit the entry “cider and perry” and, where it occurs in the corresponding entry in the fourth column, omit “2 g/l”;

(b) in the entry relating to E 416, in the third column, insert at the end the entry “Flavourings” and in the fourth column insert the corresponding entry “50 g/kg”;

(c) for the entry relating to E 432, E 433, E 434, E 435 and E 436, substitute—

“	E 432	Polyoxyethylene sorbitan monolaurate (polysorbate 20)	Fine bakery wares	3 g/kg
			Fat emulsions for baking purposes	10 g/kg
	E 433	Polyoxyethylene sorbitan monooleate (polysorbate 80)	Milk and cream analogues	5 g/kg
			Edible ices	1 g/kg
	E 434	Polyoxyethylene sorbitan monopalmitate (polysorbate 40)	Desserts	3 g/kg
			Sugar confectionery	1 g/kg
			Emulsified sauces	5 g/kg
			Soups	1 g/kg
	E 435	Polyoxyethylene sorbitan monostearate (polysorbate 60)	Chewing gum	5 g/kg
			Dietary food supplements	<i>quantum satis</i>
E 436	Polyoxyethylene sorbitan tristearate (polysorbitan 65)	Dietetic foods intended for special medical purposes – Dietetic formulae for weight control intended to replace total daily food intake or an individual meal	1 g/kg	
		Flavourings, except liquid smoke	10 g/kg	
		flavourings and flavourings based on spice oleoresins ⁽¹⁾		
		Foodstuffs containing liquid smoke	1 g/kg	
		flavourings and flavourings based on spice oleoresins ⁽¹⁾		
		Note: ⁽¹⁾ 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.		

”;

- (d) in the entry relating to E 444, in the third column insert at the end the entry “Flavoured cloudy spirit drinks containing less than 15% alcohol by volume” and in the fourth column insert the corresponding entry “300 mg/l”;

(e) for the entry relating to E 459, substitute–

“ E 459	Beta-cyclodextrine	Foods in tablet and coated tablet form	<i>quantum satis</i>
		Encapsulated flavourings in - flavoured teas and flavoured powdered instant drinks - flavoured snacks	500 mg/l 1 g/kg in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer

(f) for the entry relating to E 551, E 552, E 553a, E 553b, E 554, E 555, E 556 and E 559, substitute–

“ E 551 E 552 E 553a E 553b E 554 E 555 E 556 E 559	Silicon dioxide	} Dried powdered foods (including sugars) } Salt and its substitutes } Dietary food supplements } Foods in tablet and coated tablet form } Sliced or grated hard, semi-hard and processed cheese } Sliced or grated cheese analogues and processed cheese analogues } Seasonings } Confectionery excluding chocolate (surface treatment only) } Tin-greasing products	10 g/kg
	Calcium silicate		10 g/kg
	(i) Magnesium silicate		<i>quantum satis</i>
	(ii) Magnesium trisilicate ⁽¹⁾		<i>quantum satis</i>
	Talc ⁽¹⁾		10 g/kg
	Sodium aluminium silicate		10 g/kg
	Potassium aluminium silicate		10 g/kg
	Calcium aluminium silicate		30 g/kg
	Aluminium silicate (Kaolin)		<i>quantum satis</i>
			30 g/kg Individually or in combination

Notes: (1) Asbestos free (2) E 553b only (3) E 551 only	Chewing gum	} <i>quantum</i> } <i>satis</i> ⁽²⁾
	Rice	
Sausages (surface treatment only)		
	Flavourings	50 g/kg ⁽³⁾

- (g) in the entry relating to E 900, in the third column, insert at the end the entry “Flavourings” and in the fourth column insert the corresponding entry “10 mg/kg”;
- (h) in the entry relating to E 901 to E 904, omit “E 903” and “Carnauba wax” where they appear in the first and second columns respectively;
- (i) after the entry relating to E 901 to E 904, insert–

“ E 903	Carnauba wax	As glazing agents only:	
		- confectionery (including chocolate)	500 mg/kg 1200 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 relating to E 905, insert–

“ E 907	Hydrogenated poly-1-decene	As glazing agent for	
		- sugar confectionery	2 g/kg
		- dried fruits	2 g/kg

- (k) omit the entries relating to E 1505 and E 1518;
- (l) at the end of the table, insert–

E 1505	Triethyl citrate	Flavourings	3 g/kg from all sources in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer; individually or in combination. In the case of beverages, the maximum level of E 1520 shall be 1 g/l
E 1517	Glyceryl diacetate (diacetin)		
E 1518	Glyceryl triacetate (triacetin)		
E 1520	Propan-1,2-diol (propylene glycol)		
E 1519	Benzyl alcohol	Flavourings for - liqueurs, aromatised wines, aromatised wine-based drinks and aromatised wine-products cocktails - confectionery including chocolate and fine bakery wares	100 mg/l 250 mg/kg from all sources in foodstuffs as consumed or as reconstituted according to the instruction of the manufacturer

12. In Schedule 4 (permitted carriers and carrier solvents)–

- (a) in the entry for E 468, in the second column, insert at the end the entry “Cross-linked cellulose gum”;
- (b) at the end of the table, insert–

E 555	Potassium aluminium silicate	In E 171 titanium dioxide and E 172 iron oxides and hydroxides (max 90% relative to the pigment)
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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(a), in the second column, insert at the end the entry “E 472c Citric acid esters of mono- and diglycerides of fatty acids” and in the third column, insert the corresponding entry “*quantum satis*”;
- (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(b), the entry relating to ripened cheese and the entry relating to sliced and grated ripened cheese, in the second column, in each case for “E 170 Calcium carbonates”, substitute “E 170 Calcium carbonate”;
- (c) in the entry relating to frozen and deep-frozen unprocessed fruit and vegetables; pre-packed, refrigerated unprocessed fruit and vegetables ready for consumption and pre-packed, unprocessed and peeled potatoes, in the second column, insert at the beginning the entry “E 296 Malic acid” and in the third column, insert the corresponding entry “*quantum satis* (only for peeled potatoes)”;

(a) O.J. No. L 197, 3.8.00, p.19.

(b) O.J. No. L 10, 12.1.02, p.58.

- (d) in the entry relating to fruit compote, in the second column, insert at the end the entries “E 440 Pectin” and “E 509 calcium chloride” and in the third column, insert as the corresponding entry to both those entries “*quantum satis* (only for fruit compote other than apple)”;
- (e) in the entry relating to mozzarella and whey cheese, in the second column, insert at the end the entry “E 460ii Powdered cellulose” and in the third column, insert the corresponding entry “*quantum satis* (only for grated and sliced cheese)”;
- (f) at the end of the table, insert–

“ UHT goat milk	E 331	Sodium citrates	4 g/l
Chestnuts in liquid	E 410	Locust bean gum	<i>quantum satis</i>
	E 412	Guar gum	
	E 415	Xanthane gum	

”.

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

- (a) in the Notes, after note 1A, insert–

“**1B.** Formulae and weaning foods for infants and young children may contain E 1450 starch sodium octenyl succinate resulting from the addition of vitamin preparations or polyunsaturated fatty acid preparations. The carry over of E 1450 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 E 170, in the second column, for “Calcium carbonates”, substitute “Calcium carbonate”;
- (c) in Part 4, for the title, substitute–
 “Miscellaneous Additives Permitted in Dietary Foods for Infants and Young Children for Special Medical Purposes as Defined in Directive 1999/21/EC(a)”;
- (d) in Part 4, at the end of the table, insert–

“ E 472c	Citric acid esters of mono- and diglycerides of fatty acids	7.5 g/l sold as powder	From birth onwards
		9 g/l sold as liquid	

”.

RHONA BRANKIN
 Authorised to sign by the Scottish Ministers

St Andrew’s House,
 Edinburgh
 12th April 2005

(a) O.J. No. L 91 7.4.99, p.29.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Scotland only, amend the Miscellaneous Food Additives Regulations 1995 (S.I. No. 1995/3187) and implement Directive 2003/114/EC of the European Parliament and of the Council amending Directive 95/2/EC on food additives other than colours and sweeteners (O.J. No. L 24, 29.1.2004, p.58).

These Regulations amend the Miscellaneous Food Additives Regulations 1995 in relation to Scotland 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 “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
- (e) (regulation 4);
- (f) 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);
- (g) prohibiting the use of additives in flavourings 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);
- (h) making transitional provision to allow the marketing of additives, flavourings or foods marketed or labelled before 27th January 2006, which are legal under existing rules (regulation 6);
- (i) allowing 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));
- (j) substituting “calcium carbonate” as the name for E170 (regulations 7(b), 13(b) and 14(b));
- (k) adding to the acceptable names for E446, E468 and E469 (regulations 7(c) and (d) and 12(a));
- (l) adding a new additive, E907, for use as a glazing agent in sugar confectionery and dried fruit (regulation 11(j));
- (m) substituting new definitions of food categories in which permitted miscellaneous additives may be used (regulations 8(a) and 10(b));
- (n) extending food categories in which permitted miscellaneous additives can be used (regulations 8(b(i)), 9(b), 11(d), 13(a) and (c)-(e), 14(d));
- (o) adding one new carrier solvent (E555) to the permitted list in Schedule 4 for use in certain specified colours (regulation 12(b));
- (p) introducing numerical limits for the use of E903 (carnauba wax) (regulation 11(i));
- (q) introducing new provisions for the restricted use of additives in flavourings (regulations 10(a), 11(a)(i)-(c) and (e)-(g) and (k)).
- (r) deleting one additive (E230) from the permitted list in Schedule 2 Part C (regulation 9(a));
- (s) deleting one food category (cider and perry) from the foods permitted to contain phosphates (regulation 11(a) (ii));
- (t) providing a definition of spice oleoresins in Schedule 3 (regulation 11(l));

- (u) clarifying the extent to which E1450 may be carried over into formulae and weaning foods for infants (regulation 14(a)); and
- (v) 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 (O.J. No. L 91, 7.4.1999, p.29) (regulation 14(c)).

A full Regulatory Impact Assessment which includes an assessment the effect which these Regulations will have on the costs of business has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency (Scotland), St Magnus House, 25 Guild Street, Aberdeen, AB11 6NJ./

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