2004 No.548

FOOD

The Sweeteners in Food Amendment (Scotland) Regulations 2004

Made - - - - 21st December 2004

Laid before the Scottish Parliament 22nd December 2004

Coming into force - - 29th January 2005

The Scottish Ministers, in exercise of the powers conferred by sections 16(1)(a) and (e), 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 Sweeteners in Food Amendment (Scotland) Regulations 2004 and come into force on 29th January 2005.
 - (2) These Regulations extend to Scotland only.

Amendments to the Sweeteners in Food Regulations 1995

- **2.** The Sweeteners in Food Regulations 1995(c) are amended in accordance with regulations 3 to 7.
 - **3.**—(1) In regulation 2(1) (interpretation)–
 - (a) at the end of the definition of "Directive 94/35/EC"(d), insert—

"and by Directive 2003/115/EC of the European Parliament and of the Council(e)";

⁽a) 1990 c.16; section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990; section 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 48(4) is disapplied in respect of these regulations by virtue of section 48(4C), inserted by S.I. 2004/2990; section 17(1) was amended by the 1999 Act, section 40(1) and Schedule 5, paragraphs 8 and 12; and section 26(3) was amended by the 1999 Act, section 40(1) and Schedule 6. 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 Scotlish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).

⁽b) Section 48(4A) was inserted by the 1999 Act, section 40(1) and Schedule 5, paragraph 21.

⁽c) S.I. 1995/3123 as relevantly amended by S.I. 1996/1477, 1997/814, 1999/982 and S.S.I. 2001/212, 2002/61, 2003/274 and 2004/6.

 $^{(\}boldsymbol{d})$ The definition of "Directive 94/35/EC" was amended by S.I. 1997/814.

⁽e) O.J. No. L 24, 29.1.04, p.65.

- (b) in the definition of "Directive 95/31/EC", for "Directive 2000/51 and Directive 2001/52/EC;"(a), substitute—
 - "Directive 2000/51/EC, Directive 2001/52/EC and Directive 2004/46/EC(b);"; and
- (c) for the definition of "permitted sweetener", substitute-
 - ""permitted sweetener" means any sweetener specified in Column 2 of Schedule 1 which satisfies the specific purity criteria for that sweetener specified in the Annex to Directive 95/31/EC".
- (2) In regulation 2(3)(c)(ii), before "saccharin" in the second place where it occurs, insert "the".
- **4.** In regulation 3 (sale and use of sweeteners)–
 - (a) at the end of paragraph (3), insert—
 - "as read with the notes to that Schedule"; and
 - (b) omit paragraph (5)(c).
- 5. In regulation 4(b)(iii) (sale of table-top sweeteners), after "aspartame", insert—
 - "or salt of aspartame-acesulfame".
- 6. In regulation 11 (transitional provision and exemption), after paragraph (1A)(d), insert-
 - "(1B) In any proceedings for an offence under these Regulations which allege a contravention of regulations 3, 4 or 5, it shall be a defence to prove that—
 - (a) the act was committed before 29th January 2006;
 - (b) the act was that of-
 - (i) selling a sweetener or food;
 - (ii) using a sweetener in or on food,
 - which in either case was placed on the market before 29th July 2005; and
 - (c) the matter constituting the offence would not have constituted an offence under these Regulations if the amendments made by regulations 3(1)(a) or (c) or (2), or 4 to 7 of the Sweeteners in Food Amendment (Scotland) Regulations 2004 had not been in force when the act was committed.".
- 7. In Schedule 1 (permitted sweeteners and the foods in or on which they may be used)(e)—
 - (a) in the entries in Column 3 relating to "E951 Aspartame", after the entry ""Snacks": certain flavours of ready to eat, pre-packed, dry, savoury starch products and coated nuts", insert the entry "Essoblaten" and in the corresponding place for that new entry in Column 4, insert "1000 mg/kg";
 - (b) in the entries relating to "E952 Cyclamic Acid and its Na and Ca salts"—
 - (i) in the entry in Column 4 relating to "Water-based flavoured drinks, energy-reduced or with no added sugar", for "400 mg/l", substitute "250 mg/l";
 - (ii) in the entry in Column 4 relating to "Milk- and milk-derivative-based or fruit juice-based drinks, energy-reduced or with no added sugar", for "400 mg/l", substitute "250 mg/l";
 - (iii) omit the entries listed in Columns 3 and 4 under the heading "Confectionery"; and
 - (iv) omit the entry in Columns 3 and 4 under the heading "Miscellaneous" relating to "Edible ices, energy-reduced or with no added sugar";
 - (c) omit the entries in Columns 2 to 4 relating to Sucralose listed at the end of the Table;

⁽a) The references to Directive 2000/51 and Directive 2001/52/EC were substituted by S.S.I. 2002/61.

⁽b) O.J. No. L 114, 21.4.04, p.15.

⁽c) Paragraph (5) was inserted by S.S.I. 2003/274.

⁽d) Paragraph (1A) was inserted by S.I. 1997/814.

⁽e) Schedule 1 was replaced by S.I. 1997/814 and amended by S.S.I. 2002/61.

(d) after the entries relating to "E954 Saccharin and its Na, K and Ca salts", insert-

٠	E955	Sucralose	Non-alcoholic drinks	
			 Water-based flavoured drinks, energy-reduced or with no added sugar 	300 mg/l
			 Milk- and milk- derivative-based or fruit- juice-based drinks, energy- reduced or with no added sugar 	300 mg/l
			Desserts and similar products	
			 Water-based flavoured desserts, energy-reduced or with no added sugar 	400 mg/kg
			 Milk- and milk-derivative- based preparations, energy- reduced or with no added sugar 	400 mg/kg
			 Fruit- and vegetable-based desserts, energy-reduced or with no added sugar 	400 mg/kg
			 Egg-based desserts, energy- reduced or with no added sugar 	400 mg/kg
			 Cereal-based desserts, energy-reduced or with no added sugar 	400 mg/kg
			 Breakfast cereals with a fibre content of more than 15% and containing at least 20% bran, energy reduced or with no added sugar 	400 mg/kg
			 Fat-based desserts, energy- reduced or with no added sugar 	400 mg/kg

Confe	ctionery	
	onfectionery with no added	1000 mg/kg
co re	ocoa- or dried-fruit-based onfectionery, energy- educed or with no added agar	800 mg/kg
en	tarch-based confectionery, nergy-reduced or with no dded sugar	1000 mg/kg
	ornets and wafers, for ice ream, with no added sugar	800 mg/kg
m	reath-freshening icro-sweets with no added igar	2400 mg/kg
fre	trongly flavoured eshening throat pastilles ith no added sugar	1000 mg/kg
	hewing gum with no added	3000 mg/kg
	nergy-reduced tablet form onfectionery	200 mg/kg
Miscel	llaneous	
re dr	Snacks": certain flavours of eady to eat, pre-packed, ry, savoury starch products and coated nuts	200 mg/kg
- Es	ssoblaten	800 mg/kg
fa en	ocoa-, milk-, dried-fruit- or tt-based sandwich spreads, nergy-reduced or with no dded sugar	400 mg/kg
– Ci	ider and Perry	50 mg/l
m dr	rinks consisting of a nixture of a non-alcoholic rink and beer, cider, perry, pirits or wine	250 mg/l
	pirit drinks containing less an 15% alcohol by volume	250 mg/l

	Alcohol free been on with an	250 mg/l
_	Alcohol-free beer or with an alcohol content not exceeding 1.2% vol	250 mg/l
_	"Bière de table/Tafelbier/Table beer" (original wort content less than 6%) except for "Obergäriges Einfachbier"	250 mg/l
_	Beers with a minimum acidity of 30 milli- equivalents expressed as NaOH	250 mg/l
_	Brown beer of the "oud bruin" type	250 mg/l
_	Energy-reduced beer	10 mg/l
_	Edible ices, energy-reduced or with no added sugar	320 mg/l
_	Canned or bottled fruit, energy-reduced or with no added sugar	400 mg/kg
_	Energy-reduced jams, jellies and marmalades	400 mg/kg
_	Energy-reduced fruit and vegetable preparations	400 mg/kg
_	Sweet-sour preserves of fruit and vegetables	180mg/kg
_	Feinkostsalat	140 mg/kg
_	Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs	120 mg/kg
_	Energy-reduced soups	45 mg/l
_	Sauces	450 mg/kg
_	Mustard	140 mg/kg
_	Fine bakery products for special nutritional uses	700 mg/kg

		-
_	Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 1996/8/EC	320 mg/kg
_	Dietary foods for special medical purposes as defined in Directive 1999/21/EC	400 mg/kg
_	Food supplements as defined in Directive 2002/46/EC supplied in a liquid form	240 mg/l
_	Food supplements as defined in Directive 2002/46/EC supplied in a solid form	800 mg/kg
_	Food supplements as defined in Directive 2002/46/EC, based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form	2400 mg/kg

] "

(e) after the entries relating to E959 Neohesperidine DC, insert-

"	E962	Salt of	Non-alcoholic drinks	
		aspartame- acesulfame	 Water-based flavoured drinks, energy-reduced or with no added sugar 	350 mg/I ^(a)
			 Milk- and milk-derivative- based or fruit-juice-based drinks, energy-reduced or with no added sugar 	350 mg/I ^(a)
			Desserts and similar products	
			 Water-based flavoured desserts, energy-reduced or with no added sugar 	350 mg/kg ^(a)
			 Milk- and milk-derivative- based preparations, energy- reduced or with no added sugar 	350 mg/kg ^(a)
			 Fruit- and vegetable-based desserts, energy-reduced or with no added sugar 	350 mg/kg ^(a)

 Egg-based desserts, energy- reduced or with no added sugar 	350 mg/kg ^(a)
 Cereal-based desserts, energy-reduced or with no added sugar 	350 mg/kg ^(a)
 Breakfast cereals with a fibre content of more than 15% and containing at least 20% bran, energy-reduced or with no added sugar 	1000 mg/kg ^(b)
 Fat-based desserts, energy- reduced or with no added sugar 	350 mg/kg ^(a)
Confectionery	
 Confectionery with no added sugar 	500 mg/kg ^(a)
 Cocoa- or dried-fruit-based confectionery, energy- reduced or with no added sugar 	500 mg/kg ^(a)
 Starch-based confectionery, energy-reduced or with no added sugar 	1000 mg/kg ^(a)
 Breath-freshening micro- sweets with no added sugar 	2500 mg/kg ^(a)
 Chewing gum with no added sugar 	2000 mg/kg ^(a)
Miscellaneous	
 "Snacks": certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts 	500 mg/kg ^(b)
– Essoblaten	1000 mg/kg ^(b)
 Cocoa-, milk-, dried-fruit or fat-based sandwich spreads, energy-reduced or with no added sugar 	1000 mg/kg ^(b)
Cider and perry	350 mg/l ^(a)

_	Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine	350 mg/l ^(a)
_	Spirit drinks containing less than 15% alcohol by volume	350 mg/l ^(a)
_	Alcohol-free beer or with an alcohol content not exceeding 1.2% vol	350 mg/I ^(a)
_	"Bière de table/Tafelbier/Table beer" (original wort content less than 6%) except for "Obergäriges Einfachbier"	350 mg/l ^(a)
_	Beers with a minimum acidity of 30 milliequivalents expressed as NaOH	350 mg/l ^(a)
_	Brown beers of the "oud bruin" type	350 mg/l ^(a)
_	Energy-reduced beer	25 mg/l ^(b)
_	Edible ices, energy-reduced or with no added sugar	800 mg/kg ^(b)
_	Canned or bottled fruit, energy-reduced or with no added sugar	350 mg/kg ^(a)
_	Energy-reduced jams, jellies and marmalades	1000 mg/kg ^(b)
_	Energy-reduced fruit and vegetable preparations	350 mg/kg ^(a)
_	Sweet-sour preserves of fruit and vegetables	200 mg/kg ^(a)
_	Feinkostsalat	350 mg/kg ^(b)
_	Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs	200 mg/kg ^(a)
_	Energy-reduced soups	110 mg/l ^(b)
_	Sauces	350 mg/kg ^(b)

_	Mustard	350 mg/kg ^(b)
-	Fine bakery products for special nutritional uses	1000 mg/kg ^(a)
-	Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 1996/8/EC	450 mg/kg ^(a)
-	Dietary foods for special medical purposes as defined in Directive 1999/21/EC	450 mg/kg ^(a)
-	Food supplements as defined in Directive 2002/46/EC supplied in a liquid form	350 mg/l ^(a)
-	Food supplements as defined in Directive 2002/46/EC supplied in a solid form	500 mg/kg ^(a)
_	Food supplements as defined in Directive 2002/46/EC, based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form	2000 mg/kg ^(a)

(f) for "Complete formulae for weight control intended to replace total daily food intake or an individual meal", in each place where it appears, substitute—

"Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 96/8/EC(a)";

(g) for "Complete formulae and nutritional supplements for use under medical supervision", in each place where it appears, substitute—

"Dietary foods for special medical purposes as defined in Directive 1999/21/EC(b)";

(h) for "Liquid food supplements/dietary integrators", in each place where it appears, substitute-

"Food supplements as defined in Directive 2002/46/EC(c) supplied in a liquid form";

(i) for "Solid food supplements/dietary integrators", in each place where it appears, substitute-

"Food supplements as defined in Directive 2002/46/EC supplied in a solid form";

(j) for "Food supplements/diet integrators based on vitamins and/or mineral elements, syruptype or chewable", in each place where it appears, substitute—

"Food supplements as defined in Directive 2002/46/EC, based on vitamins and/or mineral elements and supplied in a syrup—type or chewable form"; and

(k) after notes 1 and 2 add-

⁽a) O.J. No. L 55, 6.3.96, p.22.

⁽**b**) O.J. No. L 91, 7.4.99, p.29.

⁽c) O.J. No. L 183, 12.7.02, p.51.

- **"3.** The maximum usable doses for the salt of aspartame–acesulfame (E962) are derived from the maximum usable doses for its constituent parts, aspartame (E951) and acesulfame-K (E950). The maximum usable doses for both aspartame (E951) and acesulfame-K (E950) are not to be exceeded by use of the salt of aspartame–acesulfame, either alone or in combination with E950 or E951.
- **4.** The maximum usable doses for the salt of aspartame–acesulfame (E962) are expressed either as ^(a) acesulfame–K equivalents or ^(b) aspartame equivalents.".

RHONA BRANKIN
Authorised to sign by the Scottish Ministers

St Andrew's House, Edinburgh 21st December 2004

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Scotland only, amend the Sweeteners in Food Regulations 1995 (S.I. 1995/3123 as amended; "the principal Regulations") to implement—

- (a) Directive 2003/115/EC of the European Parliament and of the Council amending Directive 94/35/EC on sweeteners for use in foodstuffs (O.J. No. L 24, 29.1.2004, p.65); and
- (b) Commission Directive 2004/46/EC amending Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs, as regards E955 Sucralose and E962 Salt of aspartame-acesulfame (O.J. No. L 114, 21.4.2004, p.15).

These Regulations amend the principal Regulations by-

- (a) bringing up to date the definition of "Directive 94/35/EC" so as to cover the amendment of that Directive by Directive 2003/115/EC (regulation 3(1)(a));
- (b) bringing up to date the definition of "Directive 95/31/EC" so as to cover its amendment by Directive 2004/46/EC (regulation 3(1)(b));
- (c) substituting a new definition for the term "permitted sweetener" to reflect the fact that Sucralose and the Salt of aspartame–acesulfame are now permitted sweeteners (regulation 3(1)(c));
- (d) making minor amendments to the term "maximum usable dose" as applied to those sweeteners which under the Regulations are permitted to be used in specified foodstuffs (regulation 3(2));
- (e) making explicit the fact that Schedule 1 (permitted sweeteners and the foods in or on which they may be used) is to be read in conjunction with the notes thereto (regulation 4(a));
- (f) deleting the provision which laid down that the controls on the use in specified foods of aspartame and acesulfame to be contained in Schedule 1 applied also to Salt of aspartame–acesulfame in such foods (regulation 4(b));
- (g) extending to Salt of aspartame and acesulfame the existing requirement that table top sweeteners containing aspartame be marked or labelled as specified in the Regulations (regulation 5);
- (h) including transitional provisions (regulation 6);
- (i) adding a further category of food to the categories in which the permitted sweetener E951 Aspartame may lawfully be used and specifying the maximum usable dose applicable to such use (regulation 7(a));
- (j) as regards the permitted sweetener E952 Cyclamic Acid and its Na and Ca salts, reducing the maximum usable dose of that sweetener applicable in relation to specified foods, and making it unlawful to use that sweetener in specified items of confectionery and in certain edible ices (regulation 7(b));
- (k) inserting into Schedule 1 new entries relating to the permitted sweeteners E955 Sucralose and to E962 Salt of aspartame–acesulfame (regulation 7(c) and (d) respectively);
- (l) omitting the entries relating to Sucralose previously contained in Schedule 1 (regulation 7(e));
- (m) in accordance with Directive 2003/115/EC, substituting new descriptions for the descriptions of certain food categories specified in Column 3 of Schedule 1 (regulation 7(f) to (j)); and
- (n) adding to Schedule 1 further footnotes relating to the permitted sweetener Salt of aspartame–acesulfame (regulation 7(h)).

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

£3.00

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