SCOTTISH STATUTORY INSTRUMENTS

2004 No. 548

FOOD

The Sweeteners in Food Amendment (Scotland) Regulations 2004

Made - - - - 21st December 2004
Laid before the Scottish 22nd December
Parliament - - - - 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(1), and of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A)(2) 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(3) 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"(4), insert-

^{(1) 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 Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c. 46).

⁽²⁾ Section 48(4A) was inserted by the 1999 Act, section 40(1) and Schedule 5, paragraph 21.

⁽³⁾ 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

⁽⁴⁾ The definition of "Directive 94/35/EC" was amended by S.I. 1997/814.

"and by Directive 2003/115/EC of the European Parliament and of the Council(5)

(b) in the definition of "Directive 95/31/EC", for "Directive 2000/51 and Directive 2001/52/EC;"(6), substitute—

"Directive 2000/51/EC, Directive 2001/52/EC and Directive 2004/46/EC(7);"; 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)(8).
- **5.** In regulation 4(b)(iii) (sale of table-top sweeteners), after "aspartame", insert—"or salt of aspartame account a
- 6. In regulation 11 (transitional provision and exemption), after paragraph (1A)(9), 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)(10)—
 - (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";

⁽⁵⁾ O.J. No. L 24, 29.1.04, p.65.

⁽⁶⁾ The references to Directive 2000/51 and Directive 2001/52/EC were substituted by S.S.I. 2002/61.

⁽⁷⁾ O.J. No. L 114, 21.4.04, p.15.

⁽⁸⁾ Paragraph (5) was inserted by S.S.I. 2003/274.

⁽⁹⁾ Paragraph (1A) was inserted by S.I. 1997/814.

⁽¹⁰⁾ Schedule 1 was replaced by S.I. 1997/814 and amended by S.S.I. 2002/61.

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

'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,	400 mg/kg

energy reduced or with no added sugar

 Fat-based desserts, 400 mg/kg energy-reduced or with no added sugar

Confectionery

- Confectionery 1000 mg/kg with no added sugar

- Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar

- Starch-based 1000 mg/kg confectionery, energy-reduced or with no added sugar

- Cornets and 800 mg/kg wafers, for ice cream, with no added sugar

Breath-freshening 2400 mg/kg micro sweets with no added sugar

 Strongly flavoured 1000 mg/kg freshening throat pastilles with no added sugar

- Chewing gum 3000 mg/kg with no added sugar

Energy-reduced 200 mg/kg tablet form confectionery

Miscellaneous

- "Snacks": certain 200 mg/kg flavours of ready to eat, pre-packed, dry, savoury starch products and coated nuts

- Essoblaten
- Cocoa-, milk-,
dried-fruit- or fat-based sandwich
spreads, energy-

reduced or with no added sugar

- Cider and Perry 50 mg/l

- Drinks consisting 250 mg/l of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine

- Spirit drinks containing less than 15% alcohol by volume 250 mg/l

- Alcohol-free 250 beer or with an alcohol content not exceeding 1.2% vol

250 mg/l

- "Bière de table/ 250 mg/l Tafelbier/Table beer" (original wort content less than 6%) except for "Obergäriges Einfachbier"

- Beers with a 250 mg/l minimum acidity of 30 milli-equivalents expressed as NaOH

- Brown beer of the 250 mg/l "oud bruin" type

Energy-reduced 10 mg/l beer

– Edible ices, 320 mg/l energy-reduced or with no added sugar

Canned or bottled 400 mg/kg fruit, energy-reduced or with no added sugar

Energy-reduced 400 mg/kg jams, jellies and marmalades

Energy-reduced fruit and vegetable preparations

400 mg/kg

- Sweet-sour 180mg/kg preserves of fruit

and vegetables

- Feinkostsalat 140 mg/kg

- Sweet-sour preserves and semipreserves of fish and marinades of fish, crustaceans and molluscs

- Energy-reduced 45 mg/l

soups

- Sauces 450 mg/kg

- Mustard 140 mg/kg

Fine bakery 700 mg/kg
 products for special nutritional uses

Foods intended for use in energy-restricted diets for weight reduction as referred to in

Dietary foods for special medical purposes as defined in Directive
 1999/21/EC
 400 mg/kg
 400 mg/kg

Directive 1996/8/EC

Food supplements 240 mg/l
as defined in
Directive 2002/46/
EC supplied in a liquid form

Food supplements 800 mg/kg as defined in
 Directive 2002/46/
 EC supplied in a solid form

- Food supplements 2400 mg/kg"; as defined in Directive 2002/46/ EC, based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form

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

'E962	Salt of aspartame- acesulfame	Non-alcoholic drinks	
		 Water-based flavoured drinks, energy-reduced or with no added sugar 	350 mg/l ^(a)
		 Milk- and milk- derivative-based or fruit-juice-based drinks, energy- reduced or with no added sugar 	350 mg/l ^(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, 350 mg/kg^(a) energy-reduced or with no added sugar

Confectionery

- Confectionery 500 mg/kg^(a) with no added sugar

- Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar

- Starch-based confectionery, energy-reduced or with no added sugar

- Breath-freshening $\,$ 2500 mg/kg $^{\!(a)}$ micro-sweets with no added sugar

- Chewing gum 2000 mg/kg^(a) with no added sugar

Miscellaneous

- "Snacks": certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts

- Essoblaten 1000 mg/kg^(b)

- Cocoa-, milk-, dried-fruit or fatbased sandwich spreads, energyreduced or with no added sugar

- Cider and perry 350 mg/l^(a)

– Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine

– Spirit drinks containing less than 15% alcohol by volume

 Alcohol-free beer or with an alcohol content not exceeding 1.2% vol 	350 mg/l ^(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 milli-equivalents expressed as NaOH 	350 mg/l ^(a)
- Brown beers of the "oud bruin" type	$350 \text{ mg/l}^{(a)}$
Energy-reduced beer	25 mg/l ^(b)
Edible ices,energy-reduced orwith 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 1000 mg/kg^(a) products for special nutritional uses Foods intended 450 mg/kg^(a) for use in energyrestricted diets for weight reduction as referred to in Directive 1996/8/EC - Dietary foods 450 mg/kg^(a) for special medical purposes as defined in Directive 1999/21/EC - Food supplements $350 \text{ mg/l}^{(a)}$ as defined in Directive 2002/46/ EC supplied in a liquid form Food supplements $500 \text{ mg/kg}^{(a)}$ as defined in Directive 2002/46/ EC supplied in a solid form Food supplements 2000 mg/kg^(a)"; as defined in Directive 2002/46/ EC, based on vitamins and/or mineral elements and supplied in a syrup-type or

- (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(11)

chewable form

- (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(12)
- (h) for "Liquid food supplements/dietary integrators", in each place where it appears, substitute—

⁽¹¹⁾ O.J. No. L 55, 6.3.96, p.22.

⁽¹²⁾ O.J. No. L 91, 7.4.99, p.29.

- "Food supplements as defined in Directive 2002/46/EC(13) 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-
 - "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.".

St Andrew's House, Edinburgh 21st December 2004

RHONA BRANKIN
Authorised to sign by the Scottish Ministers

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 accountained to be contained in Schedule 1 applied also to Salt of aspartameacesulfame in such foods (regulation 4(b));
- (g) extending to Salt of aspartame and accordiant 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));

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- (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.