WELSH STATUTORY INSTRUMENTS

2005 No. 1156 (W.73)

FOOD, WALES

The Sweeteners in Food (Amendment) (Wales) Regulations 2005

 Made
 12 April 2005

 Coming into force
 30 April 2005

The National Assembly for Wales, 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 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 both 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. These Regulations
 - (a) may be cited as the Sweeteners in Food (Amendment) (Wales) Regulations 2005;
 - (b) come into force on 30 April 2005; and
 - (c) apply in relation to Wales only.

Amendments to the Sweeteners in Food Regulations 1995

- **2.** The Sweeteners in Food Regulations 1995(**4**) are amended in so far as they apply in relation to Wales in accordance with regulations 3 to 7.
 - **3.**—(1) In regulation 2 (interpretation) paragraph (1) —

⁽**1**) 1990 c. 16

⁽²⁾ Functions of the Secretary of State under the Food Safety Act 1990, 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).

⁽³⁾ OJ No. L31, 1.2.2001, 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. 1995/3123, amended by S.I. 1996/1477, S.I. 1997/814, S.I. 1999/982, S.I. 2001/2679 (W.220), S.I. 2002/330 (W.43) and S.I. 2003/1713 (W.181).

- (a) in the definition of "Directive 94/35/EC" after the words "Directive 96/83/EC of the European Parliament and Council" insert "and by Directive 2003/115/EC(5)
- (b) in the definition of "Directive 95/31/EC" after the words "Directive 2001/52/EC" insert—
 "and by Directive 2004/46/EC(6)
- (c) for the definition of "permitted sweetener" substitute the following definition —

""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 paragraph (3)
 - (a) in sub-paragraph (c)(i) the words
 - "and salt of aspartame-acesulfame"
 - (b) in sub-paragraph (c)(ii) after the words "as the case may be" where those words first appear in that sub-paragraph, insert the following words
 - "the maximum amount of free imide contained in the".
- **4.** In regulation 3 (sale and use of sweeteners)
 - (a) in paragraph (3) add at the end the words "as read with the notes to that Schedule"; and
 - (b) paragraph (5) is omitted.
- **5.** In regulation 4 (sale of table-top sweeteners) in paragraph (b)(iii), after the words "where it contains aspartame" insert the following words —

"or salt of aspartame-acesulfame".

- **6.** In regulation 11 (transitional provision and exemption) after paragraph (1A) insert the following paragraph
 - "(1B) In any proceedings for an offence under these Regulations which allege a contravention of regulations 3, 4 or 5 it is 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)(c) or (2), or 4 to 7 of the Sweeteners in Food (Amendment) (Wales) Regulations 2005 had not been made when the act was committed."
- 7. In Schedule 1 (permitted sweeteners and the foods in or on which they may be used)
 - (a) in the entries in Column 3 relating to "E951 Aspartame" after the words ""snacks": certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts" insert the following entry —

"Essoblaten"

and in the corresponding place in Column 4 insert the following entry—"1000mg/kg";

⁽⁵⁾ OJ No. L24, 29.1.2004, p.65.

⁽⁶⁾ OJ No. L114, 21.4.2004, p.15.

- (b) in the entries relating to "E952 Cyclamic Acid and its Na and Ca salts"—
 - (i) in the entry under the heading "non-alcoholic drinks" relating to "Water-based flavoured drinks, energy-reduced or with no added sugar", for the entry "400 mg/l" in Column 4 substitute the following entry —

"250 mg/l",

(ii) in the entry under the heading relating to "Milk and milk-derivative based or fruit juice-based energy-reduced or with no added sugar", for the entry "400 mg/l" in Column 4 substitute the following entry —

"250 mg/l",

- (iii) the entries listed in Columns 3 and 4 under the heading "Confectionery" are omitted, and
- (iv) the entry in Columns 3 and 4 under the heading "Miscellaneous" relating to "Edible ices, energy-reduced or with no added sugar" is omitted;
- (c) after the entries relating to "E954 Saccharin and its Na, K and Ca salts", the following entries are inserted —

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-	400 mg/kg

reduced or with no added sugar

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

— Breakfast cereals with a fibre content of more than 15% and containing at least 20% bran, energy-reduced or with no added sugar

— Fat-based 400 mg/kg desserts, 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 2400 mg/kg freshening microsweets with no added sugar

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

— Chewing gum 3000 mg/kg with no added sugar

— Energy- 200 mg/kg reduced tablet form confectionery

Miscellaneous

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

— Essoblaten 800 mg/kg

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

— Cider and Perry 50 mg/l

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

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

exceeding 1.2% vol

— Alcohol-free 250 mg/l beer or with an alcohol content not

— Biere de table/ 250 mg/l Tafelbier/Table beer (original wort content less than 6% except for "Obergariges Einfachbier"

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

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

— Energy-reduced 10 mg/l beer

— Edible ices, 320 mg/kg energy-reduced or with no added sugar

— Canned or 400 mg/kgbottled fruit, energyreduced or with no added sugar — Energy-reduced 400 mg/kgjams, jellies and marmalades - Energy-reduced 400 mg/kgfruit and vegetable preparations - Sweet-sour 180 mg/kgpreserves of fruit and vegetables — Feinkostsalat 140 mg/kg — Sweet-sour 120 mg/kg 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 320 mg/kg for use in energyrestricted diets for weight reduction as referred to in Directive 1996/8/EC — Dietary foods 400 mg/kg for special medical purposes as defined in Directive 1999/21/EC 240 mg/l — Food supplements as defined in Directive 2002/46/EC supplied in a liquid form — Food 800 mg/kgsupplements as

defined in Directive 2002/46/EC supplied in a solid form

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

(d) after the entries relating to E959 Neohesperidine DC, the following entries are inserted —

"E962	Salt of aspartameacesulfame	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, energyreduced or with no added sugar

 $350 \text{ mg/kg}^{(a)}$

— Breakfast cereals with a fibre content of more than 15% and containing at least 20% bran, energy-reduced or with no added sugar

— Fat-based desserts, energyreduced or with no added sugar

350 mg/kg^(a)

Confectionery

— Confectionery with no added sugar500 mg/kg^(a)

— Cocoa or dried-fruit-based confectionery, 500 mg/kg^(a) energyreduced or with no added sugar

— Starch-based confectionery, energy-reduced or with 1000 no added sugarmg/kg^(a)

— Breath freshening microsweeets with no added sugar 2500 mg/kg^(a)

— 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 fat-

based sandwich

spreads, energyreduced or with no added sugar — Cider and perry $350 \text{ mg/l}^{(a)}$ — Drinks consisting 350 mg/l^(a) of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine — Spirit drinks $350 \text{ mg/l}^{(a)}$ containing less than 15% alcohol by volume — Alcohol-free 350 mg/l^(a) beer or with an alcohol content not exceeding 1.2% vol — "Biere de table/ $350 \text{ mg/l}^{(a)}$ Tafelbier/Table beer" (original wort content less than 6%) except for "Obergariges Einfachbier" — Beers with a $350 \text{ mg/l}^{(a)}$ minimum acidity of 30 milli-equivalents expressed as NaOH — Brown beers of $350 \text{ mg/l}^{(a)}$ the "oud bruin" type — Energy-reduced 25 mg/l^(b) beer — Edible ices, $800 \text{ mg/kg}^{(b)}$ energy-reduced or with no added sugar — Canned or 350 mg/kg^(a) bottled fruit, energyreduced or with no added sugar - Energy-reduced 1000 mg/kg^(b) jams, jellies and marmalades — Energy-reduced 350 mg/kg^(a) fruit and vegetable preparations

— Sweet-sour 200 mg/kg^(a) preserves of fruit and vegetables — Feinkostsalat 350 mg/kg^(b) — Sweet-sour 200 mg/kg^(a) preserves and semipreserves of fish and marinades of fish, crustaceans and molluscs - Energy-reduced $110 \ mg/l^{(b)}$ soups — Sauces 350 mg/kg^(b) — Mustard $350 \text{ mg/kg}^{(b)}$ — 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 $350 \text{ mg/l}^{(a)}$ supplements as defined in Directive 2002/46/EC supplied in a liquid form — Food $500~mg/kg^{(a)}$ supplements as defined in Directive 2002/46/EC supplied in a solid form -Food 2000 mg/kg^(a)" supplements as defined in Directive 2002/46/EC based on vitamins and/or mineral elements

and supplied in a syrup-type or chewable form

- (e) the entries relating to Sucralose listed at the end of the Table in Columns 2 to 4 are omitted;
- (f) for the words "Complete formulae for weight control intended to replace total daily food intake or an individual meal", wherever they occur, substitute the following words —

"Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 96/8/EC"(7);

(g) for the words "Complete formulae and nutritional supplements for use under medical supervision", wherever they occur, substitute the following words —

"Dietary foods for special medical purposes as defined in Directive 1999/21/EC"(8);

(h) for the words "Liquid food supplements/dietary integrators", wherever they occur, substitute the following words —

"Food supplements as defined in Directive 2002/46/EC supplied in a liquid form"(9);

(i) for the words "Solid food supplements/dietary integrators", wherever they occur, there are substituted the following words —

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

(j) for the words "Food supplements/diet integrators based on vitamins and/or mineral elements, syrup-type or chewable", wherever they occur, substitute the following words—

"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 the following notes
 - "3. The maximum usable doses in Column 4 relating to salt of aspartame-acesulfame 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 in Column 4 relating to E962 salt of aspartame-acesulfame are expressed either as^(a) acesulfame-K equivalents or^(b) aspartame equivalents."

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

12 April 2005

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

⁽⁷⁾ OJ No. L55, 6.3.1966, p.22.

⁽⁸⁾ OJ No. L91, 7.4.1999, p.29.

⁽⁹⁾ OJ No. L183, 12.7.2002, p.51.

^{(10) 1998} c. 38.

EXPLANATORY NOTE

(This note is not part of the Regulations)

- 1. These Regulations, which apply in relation to Wales only, further amend the Sweeteners in Food Regulations 1995 (S.I.1995/3123 as already amended), which extend to Great Britain, and 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 (OJ No. L24, 29.1.2004, p.65); and
 - (b) Commission Directive 2004/46/EC amending Directive 95/31/EC as regards E955 sucralose and E962 salt of aspartame-acesulfame (OJ No. L114, 21.4.2004, p.15).
 - 2. These Regulations amend the Sweeteners in Food Regulations 1995 in relation to Wales 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" (the Directive relates to specific purity criteria for sweeteners which are to be used in foodstuffs) so as to cover its amendment by Directive 2004/46/EC (regulation 3(1)(b));
 - (c) substituting a new definition for the definition of the term "permitted sweetener" to reflect the fact that sucralose and salt of aspartame-acesulfame are now permitted sweeteners (regulation 3(1)(c));
 - (d) making minor amendments to the definition of 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-K 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-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));

Status: This is the original version (as it was originally made).

- (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(k)).
- **3.** A regulatory appraisal has been prepared for these Regulations 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 referred to in paragraph 1 above are transposed into domestic law by these Regulations. Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff, CF10 1EW.