

2004 No. 3348

FOOD, ENGLAND

**The Sweeteners in Food (Amendment) (England)
Regulations 2004**

<i>Made</i>	- - - -	<i>14th December 2004</i>
<i>Laid before Parliament</i>		<i>21st December 2004</i>
<i>Coming into force</i>		<i>29th January 2005</i>

The Secretary of State, in exercise of the powers conferred upon him 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 now vested in him(b) 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(c), makes the following Regulations:

Title, commencement and application

1. These Regulations —

- (a) may be cited as the Sweeteners in Food (Amendment) (England) Regulations 2004;
- (b) shall come into force on 29th January 2005; and
- (c) shall apply in relation to England only.

(a) 1990 c. 16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990; section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c. 40), Schedule 6 to the Food Standards Act 1999 (1999 c. 28) and S.I. 2004/2990.

(b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable, in relation to England, by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c.28). Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act. Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act. Section 17(1) was amended by paragraph 12(a), and section 48 by paragraph 21, of Schedule 5 to the 1999 Act. Section 48 was also amended by S.I. 2004/2990. Regulation 13(4) of S.I. 2000/656 expressly authorises the Secretary of State to amend existing Regulations made by the Minister of Agriculture, Fisheries and Food (whether with others or not) under the Food Safety Act 1990.

(c) 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 7th 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.

Amendments to the Sweeteners in Food Regulations 1995

2. The Sweeteners in Food Regulations 1995(a) shall be amended insofar as they apply in relation to England in accordance with regulations 3 to 7.

3.—(1) In regulation 2 (interpretation) paragraph (1) —

(a) in the definition of “Directive 94/35/EC” after the words “Directive 96/83/EC of the European Parliament and Council” there shall be inserted —

“and by Directive 2003/115/EC(b)”;

(b) in the definition of “Directive 95/31/EC” after the words “Directive 2001/52/EC” there shall be inserted —

“and by Directive 2004/46/EC(c)”;

(c) for the definition of “permitted sweetener” there shall be substituted 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”

shall be omitted; and

(b) in sub-paragraph (c)(ii) after the words “as the case may be” where those words first appear in that sub-paragraph, there shall be inserted 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) there shall be added at the end the words “as read with the notes to that Schedule”; and

(b) paragraph (5) shall be omitted.

5. In regulation 4 (sale of table–top sweeteners) in paragraph (b)(iii), after the words “where it contains aspartame” there shall be inserted the following words —

“or salt of aspartame–acesulfame”.

6. In regulation 11 (transitional provision and exemption) after paragraph (1A) there shall be inserted the following paragraph —

“(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) (England) Regulations 2004 had not been made when the act was committed.”.

(a) S.I. 1995/3123, amended by S.I. 1996/1477, S.I. 1997/814, S.I. 1999/982, S.I. 2001/2294, S.I. 2002/379 and S.I. 2003/1182.

(b) OJ No. L24, 29.1.2004, p.65.

(c) OJ No. L114, 21.4.2004, p.15.

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” there shall be inserted in Column 3 the following entry —

“*Essoblaten*”

and in the corresponding place in Column 4 there shall be inserted the following entry —

“1000mg/kg”;

- (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 there shall be substituted the following entry —

“250 mg/l”,

- (ii) in the entry under that 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 there shall be substituted the following entry —

“250 mg/l”,

- (iii) the entries listed in Columns 3 and 4 under the heading “Confectionery” shall be 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” shall be omitted;

- (c) after the entries relating to “E954 Saccharin and its Na, K and Ca salts”, the following entries shall be inserted —

“E955	Sucralose	<p>Non-alcoholic drinks</p> <ul style="list-style-type: none"> – Water-based flavoured drinks, energy-reduced or with no added sugar – Milk and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar <p>Desserts and similar products</p> <ul style="list-style-type: none"> – Water-based flavoured desserts, energy-reduced or with no added sugar – Milk and milk-derivative-based preparations, energy-reduced or with no added sugar – Fruit and vegetable-based desserts, energy-reduced or with no added sugar – Egg-based desserts, energy-reduced or with no added sugar – Cereal-based 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 desserts, energy-reduced or with no added sugar <p>Confectionery</p> <ul style="list-style-type: none"> – Confectionery 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 	<p>300 mg/l</p> <p>300 mg/l</p> <p>400 mg/kg</p> <p>400 mg/kg</p> <p>400 mg/kg</p> <p>400 mg/kg</p> <p>400 mg/kg</p> <p>400 mg/kg</p> <p>400 mg/kg</p> <p>1000 mg/kg</p> <p>800 mg/kg</p> <p>1000 mg/kg</p>
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	<ul style="list-style-type: none"> – Cornets and wafers, for ice cream, with no added sugar – Breath freshening micro-sweets with no added sugar – Strongly flavoured freshening throat pastilles with no added sugar – Chewing gum with no added sugar – Energy-reduced tablet form confectionery 	<ul style="list-style-type: none"> 800 mg/kg 2400 mg/kg 1000 mg/kg 3000 mg/kg 200 mg/kg
	<p>Miscellaneous</p> <ul style="list-style-type: none"> – “Snacks”: certain flavours of ready to eat, pre-packed, dry, savoury starch products and coated nuts – <i>Essoblaten</i> – Cocoa, milk, dried fruit or fat-based sandwich spreads, energy-reduced or with no added sugar – Cider and Perry – Drinks consisting of a mixture of 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 – Biere de table/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 – Brown beer of the ‘oud bruin’ type – Energy-reduced beer – Edible ices, energy-reduced or with no added sugar – Canned or bottled fruit, energy-reduced or with no added sugar – Energy-reduced jams, jellies and marmalades – Energy-reduced fruit and vegetable preparations – Sweet-sour preserves of fruit and vegetables – <i>Feinkostsalat</i> – Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs – Energy-reduced soups – Sauces – Mustard – Fine bakery products for special nutritional uses – Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 1996/8/EC – Dietary foods for special medical purposes as defined in Directive 1999/21/EC – Food supplements as defined in Directive 2002/46/EC supplied in a liquid form – Food supplements as defined in Directive 2002/46/EC supplied in a solid form – 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 	<ul style="list-style-type: none"> 200 mg/kg 800 mg/kg 400 mg/kg 50 mg/l 250 mg/l 250 mg/l 250 mg/l 250 mg/l 250 mg/l 250 mg/l 250 mg/l 250 mg/l 10 mg/l 320 mg/kg 400 mg/kg 400 mg/kg 180mg/kg 140 mg/kg 120 mg/kg 45 mg/l 450 mg/kg 140 mg/kg 700 mg/kg 320 mg/kg 400 mg/kg 240 mg/l 800 mg/kg 2400 mg/kg”

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

“E962	Salt of aspartame–acesulfame	Non–alcoholic drinks	
		<ul style="list-style-type: none"> – Water–based flavoured drinks, energy–reduced or with no added sugar – Milk and milk–derivative–based or fruit–juice based drinks, energy–reduced or with no added sugar <p>Desserts and similar products</p> <ul style="list-style-type: none"> – Water–based flavoured desserts, energy–reduced or with no added sugar – Milk and milk–derivative–based preparations, energy–reduced or with no added sugar – Fruit and vegetable–based desserts, energy–reduced or with no added sugar – Egg–based desserts, energy–reduced or with no added sugar – Cereal–based 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 desserts, energy–reduced or with no added sugar <p>Confectionery</p> <ul style="list-style-type: none"> – Confectionery 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 micro–sweets with no added sugar – Chewing gum with no added sugar <p>Miscellaneous</p> <p>“Snacks”: certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts</p> <ul style="list-style-type: none"> – <i>Essoblaten</i> – Cocoa, milk, dried–fruit or fat–based sandwich spreads, energy–reduced or with no added sugar – Cider and perry – 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 – ‘Biere de table/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 – Brown beers of the ‘oud bruin’ type – Energy–reduced beer’– – Edible ices, energy–reduced or with no added sugar – Canned or bottled fruit, energy–reduced or with no added sugar – Energy–reduced jams, jellies and marmalades 	<p>350 mg/l^(a)</p> <p>350 mg/l^(a)</p> <p>350 mg/kg^(a)</p> <p>350 mg/kg^(a)</p> <p>350 mg/kg^(a)</p> <p>350 mg/kg^(a)</p> <p>350 mg/kg^(a)</p> <p>1000 mg/kg^(b)</p> <p>350 mg/kg^(a)</p> <p>500 mg/kg^(a)</p> <p>500 mg/kg^(a)</p> <p>1000 mg/kg^(a)</p> <p>2500 mg/kg^(a)</p> <p>2000 mg/kg^(a)</p> <p>500 mg/kg^(b)</p> <p>1000 mg/kg^(b)</p> <p>1000 mg/kg^(b)</p> <p>350 mg/l^(a)</p> <p>350 mg/l^(a)</p> <p>350 mg/l^(a)</p> <p>350 mg/l^(a)</p> <p>350 mg/l^(a)</p> <p>350 mg/l^(a)</p> <p>350 mg/l^(a)</p> <p>350 mg/l^(a)</p> <p>350 mg/l^(a)</p> <p>25 mg/l^(b)</p> <p>800 mg/kg^(b)</p> <p>350 mg/kg^(a)</p> <p>1000 mg/kg^(b)</p>

	<ul style="list-style-type: none"> – Energy-reduced fruit and vegetable preparations – Sweet-sour preserves of fruit and vegetables – <i>Feinkostsalat</i> – Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs – Energy-reduced soups – Sauces – Mustard – Fine bakery products for special nutritional uses – Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 1996/8/EC – Dietary foods for special medical purposes as defined in Directive 1999/21/EC – Food supplements as defined in Directive 2002/46/EC supplied in a liquid form – Food supplements as defined in Directive 2002/46/EC supplied in a solid form – 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 	<ul style="list-style-type: none"> 350 mg/kg^(a) 200 mg/kg^(a) 350 mg/kg^(b) 200 mg/kg^(a) 110 mg/l^(b) 350 mg/kg^(b) 350 mg/kg^(b) 1000 mg/kg^(a) 450 mg/kg^(a) 450 mg/kg^(a) 350 mg/l^(a) 500 mg/kg^(a) 2000 mg/kg^{(a)''}
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- (e) the entries relating to Sucralose listed at the end of the Table in Columns 2 to 4 shall be omitted;
- (f) for the words “Complete formulae for weight control intended to replace total daily food intake or an individual meal”, wherever they occur, there shall be substituted the following words —
“Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 96/8/EC”(a);
- (g) for the words “Complete formulae and nutritional supplements for use under medical supervision”, wherever they occur, there shall be substituted the following words —
“Dietary foods for special medical purposes as defined in Directive 1999/21/EC”(b);
- (h) for the words “Liquid food supplements/dietary integrators”, wherever they occur, there shall be substituted the following words —
“Food supplements as defined in Directive 2002/46/EC supplied in a liquid form”(c);
- (i) for the words “Solid food supplements/dietary integrators”, wherever they occur, there shall be substituted the following words —
“Food supplements as defined in Directive 2002/46/EC supplied in a solid form”;
- (j) for the words “Food supplements/dietary integrators based on vitamins and/or mineral elements, syrup-type or chewable”, wherever they occur, there shall be substituted 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 there shall be added 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

(a) OJ No. L55, 6.3.1996, p.22.

(b) OJ No. L91, 7.4.1999, p.29.

(c) OJ No. L183, 12.7.2002, p.51.

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 by authority of the Secretary of State for Health

14 December 2004

Melanie Johnson
Parliamentary Under Secretary of State,
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in relation to England 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
- (a) 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 England 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 the 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)*);
- (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 impact assessment has been prepared for these Regulations and placed in the Library of each of the Houses of Parliament, 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 Novel Foods, Additives and Supplements Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.

STATUTORY INSTRUMENTS

2004 No. 3348

FOOD, ENGLAND

The Sweeteners in Food (Amendment) (England)
Regulations 2004

£3.00

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under the authority and superintendence of Carol Tullo, Controller of Her Majesty's
Stationery Office and Queen's Printer of Acts of Parliament.

E1743 12/2004 141743T 19585

ISBN 0-11-051255-3



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