
STATUTORY INSTRUMENTS

2004 No. 3348

FOOD, ENGLAND

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

Made - - - - *14th December 2004*
Laid before Parliament *21st December 2004*
Coming into force - - *29th January 2005*

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⁽¹⁾ and now vested in him⁽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 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) (England) Regulations 2004;
- (b) shall come into force on 29th January 2005; and

(1) 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.

(2) 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.

(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 7th December 2004 the consultation requirement contained in section 48(4) of the 1990 Act is disappplied in any case in which consultation is required by Article 9 of Regulation (EC) No. 178/2002.

- (c) shall apply in relation to England only.

Amendments to the Sweeteners in Food Regulations 1995

2. The Sweeteners in Food Regulations 1995(4) 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(5)

- (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(6)

- (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,

(4) 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.

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

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

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.”.

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	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,	400 mg/kg

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- energy-reduced or with no added sugar
- 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
- Confectionery**
- Confectionery with no added sugar 1000 mg/kg
 - Cocoa or dried-fruit based confectionery, energy-reduced or with no added sugar 800 mg/kg
 - Starch-based confectionery, energy-reduced or with no added sugar 1000 mg/kg
 - Cornets and wafers, for ice cream, with no added sugar 800 mg/kg

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

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

– Chewing gum with no added sugar 3000 mg/kg

– Energy-reduced tablet form confectionery 200 mg/kg

Miscellaneous

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

– *Essoblaten* 800 mg/kg

– Cocoa, milk, dried fruit or fat-based sandwich spreads, energy-reduced or with no added sugar 400 mg/kg

– Cider and Perry 50 mg/l

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

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

– Alcohol-free beer or with an alcohol content not exceeding 1.2% vol 250 mg/l

– Biere de table/ Tafelbier/Table beer (original wort content less than 6% except for “Obergariges Einfachbier”) 250 mg/l

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– 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/kg
– 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
– <i>Feinkostsalat</i>	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”

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

“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, 350 mg/kg ^(a)

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energy-reduced or
with no added sugar

– 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^(a)

– 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,
500 mg/kg^(b)

dry, savoury starch products and coated nuts	
– <i>Essoblaten</i>	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/l ^(a)
– “Biere de table/ Tafelbier/Table beer” (original wort content less than 6%) except for “Obergariges 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 “ <i>oud bruin</i> ” 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)

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– 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)
– <i>Feinkostsalat</i>	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 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
chewable form

- (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”(7);
- (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”(8);
- (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”(9);
- (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 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.”.

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

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

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

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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)*);

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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(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.