

DIRECTIVE 2003/115/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 December 2003
amending Directive 94/35/EC on sweeteners for use in foodstuffs

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Economic and Social Committee ⁽²⁾,

After consultation of the Scientific Committee on Food, pursuant to Article 6 of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ⁽³⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽⁴⁾,

Whereas:

- (1) Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs ⁽⁵⁾ lays down a list of sweeteners that may be used in the Community and their conditions of use.
- (2) Since 1996, two new sweeteners, sucralose and the salt of aspartame and acesulfame, have been found acceptable for use in food by the Scientific Committee on Food.
- (3) The opinion of the Scientific Committee on Food on cyclamic acid and its sodium and calcium salts (which led to the establishment of a new acceptable daily intake (ADI)) and recent studies on the intake of cyclamates lead to a reduction of the maximum usable doses of cyclamic acid and its sodium and calcium salts.
- (4) The designation of certain food categories in Directive 94/35/EC should be adapted to take into account Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements ⁽⁶⁾ and of specific directives adopted for some groups of foodstuffs listed in Annex I to Council Directive 89/398/EEC ⁽⁷⁾.

- (5) The use of the food additives concerned complies with the general criteria laid down in Annex II to Directive 89/107/EEC.
- (6) Articles 53 and 54 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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 ⁽⁸⁾ establish procedures for taking emergency measures in relation to food of Community origin or imported from a third country. They allow the Commission to adopt such measures in situations where food is likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.
- (7) The measures necessary for implementation of Directive 94/35/EC should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽⁹⁾.
- (8) Directive 94/35/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 94/35/EC is hereby amended as follows:

1. Article 4 shall be replaced by the following:

'Article 4

It may be decided in accordance with the procedure laid down in Article 7:

- where there are differences of opinion as to whether sweeteners can be used in a given foodstuff under the terms of this Directive, whether that foodstuff is to be considered as belonging to one of the categories listed in the third column of the Annex, and

⁽¹⁾ OJ C 262 E of 29.10.2002, p. 429.

⁽²⁾ OJ C 85, 8.4.2003, p. 34.

⁽³⁾ OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).

⁽⁴⁾ Opinion of the European Parliament of 10 April 2003 (not yet published in the Official Journal), Council Common Position of 25 June 2003 (OJ C 277 E, 18.11.2003, p. 1) and position of the European Parliament of 22 October 2003 (not yet published in the Official Journal).

⁽⁵⁾ OJ L 237, 10.9.1994, p. 3. Directive as amended by Directive 96/83/EC (OJ L 48, 19.2.1997, p. 16).

⁽⁶⁾ OJ L 183, 12.7.2002, p. 51.

⁽⁷⁾ OJ L 186, 30.6.1989, p. 27. Directive as last amended by Directive 1999/41/EC of the European Parliament and of the Council (OJ L 172, 8.7.1999, p. 38).

⁽⁸⁾ OJ L 31, 1.2.2002, p. 1.

⁽⁹⁾ OJ L 184, 17.7.1999, p. 23.

- whether a food additive listed in the Annex and authorised at “quantum satis” is used in accordance with the criteria referred to in Article 2.;
2. a third indent shall be added to Article 5(2):
 ‘— salt of aspartame and acesulfame: “contains a source of phenylalanine”.’;
3. Article 7 shall be replaced by the following:
 ‘Article 7
 1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up pursuant to Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as “the Committee”.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.
- The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.
3. The Committee shall adopt its rules of procedure.
- (*) OJ L 31, 1.2.2002, p. 1.
 (**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).’
4. the Annex shall be amended in accordance with the Annex to this Directive.

Article 2

By 29 January 2006 at the latest, the Commission shall submit a report to the European Parliament and the Council outlining the progress made in the re-evaluations of additives under way and setting out a provisional calendar for future re-evaluations, especially those for sucralose and salt of aspartame-acesulfame. These re-evaluations shall be carried out on the basis of consumer data supplied by the Member States and shall take account of the effects of additives on vulnerable population groups.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive in order to:

- authorise trade in and use of products conforming with this Directive by 29 January 2005 at the latest,
- prohibit trade in and use of products not conforming with this Directive by 29 July 2005 at the latest; however, products placed on the market before that date which do not comply with this Directive may be marketed until 29 January 2006.

They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 22 December 2003.

For the European Parliament
The President
 P. COX

For the Council
The President
 A. MATTEOLI

ANNEX

The Annex to Directive 94/35/EC is hereby amended as follows:

1. in the third column of the tables the following categories of foodstuffs shall be renamed:
 - (a) instead of 'Complete formulae for weight control intended to replace total daily food intake or an individual meal' to read 'Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 96/8/EC (*)';
 - (b) instead of 'Complete formulae and nutritional supplements for use under medical supervision' to read 'Dietary foods for special medical purposes as defined in Directive 1999/21/EC (**);
 - (c) instead of 'Liquid food supplements/dietary integrators' to read 'Food supplements as defined in Directive 2002/46/EC (***) supplied in a liquid form';
 - (d) instead of 'Solid food supplements/dietary integrators' to read 'Food supplements as defined in Directive 2002/46/EC supplied in a solid form';
 - (e) instead of 'Food supplements/dietary integrators based on vitamins and/or mineral elements, syrup-type or chewable' to read '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';

2. the following footnotes shall be added after the tables:

(*) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).

(**) Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).

(***) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).'

3. for E 951 'Aspartame' the following category shall be added under 'Confectionery':

'— Essoblatten	1 000 mg/kg'
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4. for E 952 cyclamic acid and its sodium and calcium salts:

- (a) for the following categories of foodstuffs, the maximum usable dose of '400 mg/l' shall be replaced by '250 mg/l':

- 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;

- (b) the following categories of foodstuffs and maximum usable doses shall be deleted:

'— Confectionery with no added sugar	500 mg/kg
— Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar	500 mg/kg
— Starch-based confectionery, energy-reduced or with no added sugar	500 mg/kg
— Chewing gum with no added sugar	1 500 mg/kg
— Breath-freshening micro-sweets, with no added sugar	2 500 mg/kg
— Edible ices, energy-reduced or with no added sugar	250 mg/kg'

5. the following tables shall be added:

EC No	Name	Foodstuffs	Maximum usable dose
E 955	Sucralose	<p>Non-alcoholic drinks</p> <ul style="list-style-type: none"> — 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 <p>Desserts and similar products</p> <ul style="list-style-type: none"> — 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 — Fat-based desserts, energy-reduced or with no added sugar 400 mg/kg — "Snacks": certain flavours of ready to eat, pre-packed, dry, savoury starch products and coated nuts 200 mg/kg <p>Confectionery</p> <ul style="list-style-type: none"> — Confectionery with no added sugar 1 000 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 1 000 mg/kg — Cornets and wafers, for ice cream, with no added sugar 800 mg/kg — <i>Essoblaten</i> 800 mg/kg — Cocoa-, milk-, dried-fruit- or fat-based sandwich spreads, 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 — Breath-freshening micro-sweets with no added sugar 2 400 mg/kg — Strongly flavoured freshening throat pastilles with no added sugar 1 000 mg/kg — Chewing gum with no added sugar 3 000 mg/kg — Energy-reduced tablet form confectionery 200 mg/kg — Cider and Perry 50 mg/l — Drinks consisting of a mixture of a 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 	

EC No	Name	Foodstuffs	Maximum usable dose
		<ul style="list-style-type: none"> — 'Bière de table/Tafelbier/Table beer' (original wort content less than 6 %) except for 'Obergäriges 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 — 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"> 250 mg/l 250 mg/l 250 mg/l 10 mg/l 320 mg/kg 400 mg/kg 400 mg/kg 400 mg/kg 180 mg/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 2 400 mg/kg
E 962	Salt of aspartame-acesulfame1 (*)	<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 	<ul style="list-style-type: none"> 350 mg/l (a) 350 mg/l (a) 350 mg/kg (a) 350 mg/kg (a) 350 mg/kg (a)

EC No	Name	Foodstuffs	Maximum usable dose
		— 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)
		— Fat-based desserts, energy-reduced or with no added sugar	350 mg/kg (a)
		— 'Snacks': certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts	500 mg/kg (b)
		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	1 000 mg/kg (a)
		— <i>Essoblaten</i>	1 000 mg/kg (b)
		— Cocoa-, milk-, dried-fruit or fat-based sandwich spreads, energy-reduced or with no added sugar	1 000 mg/kg (b)
		— Breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy-reduced or with no added sugar	1 000 mg/kg (b)
		— Breath-freshening micro-sweets with no added sugar	2 500 mg/kg (a)
		— Chewing gum with no added sugar	2 000 mg/kg (a)
		— 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)
		— '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 ' <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)
		— Energy-reduced jams, jellies and marmalades	1 000 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)

EC No	Name	Foodstuffs	Maximum usable dose
		— 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	1 000 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	2 000 mg/kg (a)

(*) Maximum usable doses for the 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. Limits in this column are expressed either as (a) acesulfame-K equivalents or (b) espartame equivalents.'