



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16.5.2003
COM(2003) 277 final

2002/0152 (COD)

Amended proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 94/35/EC on sweeteners for use in foodstuffs

(presented by the Commission pursuant to Article 250 (2)
of the EC Treaty)

EXPLANATORY MEMORANDUM

1. PROCEDURE

On 11 July 2002, the Commission adopted a proposal for a European Parliament and Council Directive amending Directive 94/35/EC on sweeteners for use in foodstuffs¹. The proposal was sent to the European Parliament and Council on the same day. The Economic and Social Committee issued its opinion supporting the Commission proposal on 11 December 2002.

On 10 April 2003, the European Parliament has in first reading given a favourable opinion on the proposal. The Parliament adopted 8 amendments, 2 of which were accepted by the Commission.

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The Commission proposal aims at adapting Directive 94/35/EC on sweeteners for use in foodstuffs to recent technical and scientific developments. To this end it foresees:

- To authorise two new sweeteners, sucralose and the salt of aspartame and acesulfame, after favourable opinions by the Scientific Committee on Food.
- To reduce the intake of an already authorised sweetener, cyclamate, following an opinion of the SCF lowering the ADI (Acceptable Daily Intake) for this substance. Since soft drinks contribute to a large extent to the intake of sweeteners, and there are indications that the ADI could be exceeded, the Commission proposed a reduction of the maximum permitted use dose of cyclamates in soft drinks from 400 to 350 mg/l.
- To confer on the Commission the power to decide whether a substance should be considered as a sweetener according to the Directive.
- To clarify the meaning of the food category ‘fine bakery wares for special nutritional uses’ that is not interpreted in a homogeneous manner by Member States.

3. COMMISSION OPINION ON THE AMENDMENTS ADOPTED BY THE EUROPEAN PARLIAMENT

In total, the European Parliament adopted 8 amendments to the Commission proposal. Out of these 8 amendments, 2 can be accepted by the Commission without changes: Amendment 1 concerning the recital number 3 on cyclamates and amendment 6 concerning article 2 on the transposition of the Directive. The Commission refuses amendments 2, 3, 4, 5, 12rev and 13 (merged) and 9.

¹ COM(2002) 375 final, 11 July 2002.

The Commission had agreed to an amendment of the Parliament tabled for the Plenary requesting to reduce the maximum permitted dose of cyclamates for soft drinks to 250 mg/l and to extend this reduction to milk and juice based drinks. This amendment fell when amendment 9 requesting a value of 100 mg/l for these food categories was adopted by Parliament. In line with its position expressed in the Plenary, the Commission now proposes to reduce the dose of cyclamates to 250 mg/l in soft drinks and to extend this reduction to milk and juice based drinks.

4. CONCLUSION

Having regard to Article 250 paragraph 2 of the EC Treaty, the Commission modifies its proposal as follows.

Amended proposal for a

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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 Commission²,

Having regard to the opinion of the European Economic and Social Committee³,

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 authorized for use in foodstuffs intended for human consumption⁴,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁵,

Whereas:

- (1) European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs⁶ 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 ~~has now established a new~~ **concerning the** Acceptable Daily Intake (ADI) for cyclamic acid and its sodium and calcium salts. ~~The opinion of the Scientific Committee on Food, in conjunction with a rigorous interpretation of intake estimations,~~ **and recent studies on the intake of cyclamate** lead to a reduction of the maximum usable doses of cyclamic acid and its sodium and calcium salts.

² OJ C ..., ..., p. ...

³ OJ C ..., ..., p. ...

⁴ OJ L 40, 11.2.1989, p. 27. Directive as amended by European Parliament and Council Directive 94/34/EC (OJ L 237, 10.9.1994, p. 1).

⁵ OJ C ..., ..., p. ...

⁶ OJ L 237, 10.9.1994, p. 3. Directive as amended by European Parliament and Council Directive 96/83/EC (OJ L 48, 19.2.1997, p. 16).

- (4) The food additives concerned comply with the general criteria laid down in Annex II to Directive 89/107/EEC.
- (5) It is desirable that when a decision is taken on whether a particular substance is a sweetener, the consultation of the Standing Committee on the Food Chain and Animal Health procedure is followed.
- (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 safety⁷ 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 provisions of Directive 94/35/EC should be adapted to take account of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁸.
- (8) Directive 94/35/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 94/35/EC is amended as follows:

- (1) Article 4 is replaced by the following:

”Article 4

 1. It may be decided in accordance with the procedure referred to in Article 7(2) whether a substance is a sweetener within the meaning of Article 1(2).
 2. Where there are differences of opinion as to whether sweeteners can be used in a given foodstuff under the terms of this Directive, it may be decided in accordance with the procedure referred to in Article 7 (2) whether that foodstuff is to be considered as belonging to one of the categories listed in the third column of the Annex.”
- (2) Article 7 is replaced by the following:

”Article 7

 1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002 (hereinafter referred to as “the Committee”).

⁷ OJ L 31, 1.2.2002, p. 1.

⁸ OJ L 184, 17.7.1999, p. 23.

2. Where reference is made to this paragraph, 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 three months.
 3. The Committee shall adopt its rules of procedure.”
- (3) The Annex is amended in accordance with the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [...] at the latest. **The purpose of those laws, regulations and administrative provisions shall be to:**

- **authorise, by ... * at the latest, the marketing and the use of products which comply with this Directive;**
- **ban, by ... * at the latest, the marketing and the use of products which do not comply with this Directive**

They **Member States** shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or 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 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

* **Twelve months from the date of entry into force of this Directive**

ANNEX

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

- (1) The category ‘fine bakery products for special nutritional uses’ shall be renamed ‘fine bakery products, energy-reduced or with no added sugar’;
- (2) For E 951 aspartame the following category is added:

‘- Cornets and wafers, for ice cream, with no added sugar	1000 mg/kg’
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- (3) For E 952 cyclamic acid and its sodium and calcium salts:
 - (a) for the category ‘water-based flavoured drinks, energy-reduced or with no added sugar’ **and ‘milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar’** the maximum usable dose of ‘400 mg/l’ is replaced by ‘~~350~~ **250** mg/l’;
 - (b) the following categories and maximum usable doses are 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	1500 mg/kg
- Breath-freshening micro-sweets, with no added sugar	2500 mg/kg
- Edible ices, energy-reduced or with no added sugar	250 mg/kg’

- (4) The following tables are added:

‘EC-No	Name	Foodstuff	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 - 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 - Fat-based desserts, energy-reduced or with no added sugar - ‘Snacks’: certain flavours of ready to eat, pre-packed, dry, savoury starch products and coated nuts <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 - Cornets and wafers, for ice cream, with no added sugar - <i>Eßoblaten</i> - Cocoa-, milk-, dried-fruit- or fat-based sandwich spreads, 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 - Breath-freshening micro-sweets, energy reduced or with no added sugar - Strongly flavoured freshening throat pastilles with no added sugar - Chewing gum 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>200 mg/kg</p> <p>1000 mg/kg</p> <p>800 mg/kg</p> <p>1000 mg/kg</p> <p>800 mg/kg</p> <p>800 mg/kg</p> <p>400 mg/kg</p> <p>400 mg/kg</p> <p>2400 mg/kg</p> <p>1000 mg/kg</p> <p>3000 mg/kg</p>

- Energy-reduced tablet form of 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
- 'Bière de table/Tafelbier/Table beer' (original wort content less than 6%) except for 'Obergäriges Einfachbier'	250 mg/l
- Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH	250 mg/l
- Brown beers 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	180 mg/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, energy-reduced or with no added sugar	700 mg/kg
- Complete formulae for weight control intended to replace total daily food intake or an individual meal	320 mg/kg
- Complete formulae and nutritional supplements for use under medical supervision	400 mg/kg
- Liquid food supplements/dietary integrators	240 mg/kg
- Solid food supplements/dietary integrators	800 mg/kg
Food supplements/diet integrators based on vitamins and/or mineral elements, syrup-type or chewable	2400 mg/kg

EC-No	Name	Foodstuffs	Maximum usable dose ⁹		
E 962	Salt of aspartame-acesulfame		Salt of aspartame-acesulfame	Aspartame equivalent	Acesulfame-K equivalent
		Non-alcoholic drinks			
		- Water-based flavoured drinks, energy-reduced or with no added sugar	796 mg/l	512 mg/l	350 mg/l
		- Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	796 mg/l	512 mg/l	350 mg/l
		Desserts and similar products			
		- Water-based flavoured desserts, energy-reduced or with no added sugar	796 mg/kg	512 mg/kg	350 mg/kg
		- Milk- and milk-derivative-based preparations, energy-reduced or with no added sugar	796 mg/kg	512 mg/kg	350 mg/kg
		- Fruit- and vegetable-based desserts, energy-reduced or with no added sugar	796 mg/kg	512 mg/kg	350 mg/kg
		- Egg-based desserts, energy-reduced or with no added sugar	796 mg/kg	512 mg/kg	350 mg/kg
		- Cereal-based desserts, energy-reduced or with no added sugar	796 mg/kg	512 mg/kg	350 mg/kg
		- Fat-based desserts, energy-reduced or with no added sugar	796 mg/kg	512 mg/kg	350 mg/kg
		- ‘Snacks’: certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts	777 mg/kg	500 mg/kg	342 mg/kg
		Confectionery			
		- Confectionery with no added sugar	1137 mg/kg	731 mg/kg	500 mg/kg
		- Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar	1137 mg/kg	731 mg/kg	500 mg/kg
		- Starch-based confectionery, energy-reduced or with no added sugar	2273 mg/kg	1462 mg/kg	1000 mg/kg

⁹ Maximum usable doses for the salt of aspartame-acesulfame are derived from the maximum usable doses for its constituent parts aspartame (E 951) and acesulfame-K (E950). The maximum usable doses for aspartame (E 951) and acesulfame-K (E950) shall not be exceeded by their use in combination with the salt of aspartame-acesulfame.

- Cornets and wafers, for ice cream, with no added sugar	1554 mg/kg	1000 mg/kg	684 mg/kg
- Cocoa-, milk-, dried-fruit or fat-based sandwich spreads, energy-reduced or with no added sugar	1554 mg/kg	1000 mg/kg	684 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	1554 mg/kg	1000 mg/kg	684 mg/kg
- Breath-freshening micro-sweets, energy reduced or with no added sugar	5683 mg/kg	3656 mg/kg	2500 mg/kg
- Chewing gum with no added sugar	4546 mg/kg	2925 mg/kg	2000 mg/kg
- Cider and perry	796 mg/l	512 mg/l	350 mg/l
- Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine	796 mg/l	512 mg/l	350 mg/l
- Spirit drinks containing less than 15% alcohol by volume	796 mg/l	512 mg/l	350 mg/l
- Alcohol-free beer or with an alcohol content not exceeding 1,2 % vol	796 mg/l	512 mg/l	350 mg/l
- ‘Bière de table/Tafelbier/Table beer’ (original wort content less than 6%) except for ‘Obergäriges Einfachbier’	796 mg/l	512 mg/l	350 mg/l
- Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH	796 mg/l	512 mg/l	350 mg/l
- Brown beers of the ‘oud bruin’ type	796 mg/l	512 mg/l	350 mg/l
- Energy-reduced beer	39 mg/l	25 mg/l	17 mg/l
- Edible ices, energy-reduced or with no added sugar	1243 mg/kg	800 mg/kg	547 mg/kg
- Canned or bottled fruit, energy-reduced or with no added sugar	796 mg/kg	512 mg/kg	350 mg/kg
- Energy-reduced jams, jellies and marmalades	1554 mg/kg	1000 mg/kg	684 mg/kg
- Energy-reduced fruit and vegetable preparations	796 mg/kg	512 mg/kg	350 mg/kg
- Sweet-sour preserves of fruit and vegetables	455 mg/kg	292 mg/kg	200 mg/kg
- <i>Feinkostsalat</i>	544 mg/kg	350 mg/kg	239 mg/kg

	- Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs	455 mg/kg	292 mg/kg	200 mg/kg
	- Energy-reduced soups	171 mg/l	110 mg/l	75 mg/l
	- Sauces	544 mg/kg	350 mg/kg	239 mg/kg
	- Mustard	544 mg/kg	350 mg/kg	239 mg/kg
	- Fine bakery products, energy-reduced or with no added sugar	2273 mg/kg	1462 mg/kg	1000 mg/kg
	- Complete formulae for weight control intended to replace total daily food intake or an individual meal	1023 mg/kg	658 mg/kg	450 mg/kg
	- Complete formulae and nutritional supplements for use under medical supervision	1023 mg/kg	658 mg/kg	450 mg/kg
	- Liquid food supplements/dietary integrators	796 mg/kg	512 mg/kg	350 mg/kg
	- Solid food supplements/dietary integrators	1137 mg/kg	731 mg/kg	500 mg/kg
	Food supplements/diet integrators based on vitamins and/or mineral elements, syrup-type or chewable	4546 mg/kg	2925 mg/kg	2000 mg/kg'