



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18.10.1995  
COM(95) 482 final

95/0251 (COD)

Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

**amending European Parliament and Council Directive 94/35/EC**

**on sweeteners for use in foodstuffs**

(presented by the Commission)



## EXPLANATORY MEMORANDUM

### 1. SUBSIDIARITY IMPACT STATEMENT

#### 1. What are the objectives of the proposed measure with regard to the Community's obligations?

Directive 89/107/EEC provides for the adoption of specific directives to harmonize the use of different categories of additives in foodstuffs. The Directive on sweeteners was adopted on 21 June 1994. It now needs to be adapted in the light of recent technical and scientific developments.

#### 2. Does competence for the proposed measure lie solely with the Community or is it shared with the Member States?

Competence for the proposed measure lies solely with the Community.

#### 3. To what extent is this a problem on a Community scale?

Harmonization of the use of additives at Community level was a priority for completion of the internal market. It was also a tricky subject. The framework Directive 89/107/EEC on additives was adopted on 21 December 1988 and the three specific Directives in 1994. Since then, the instruments relating to the use of additives have been the same in the fifteen Member States. This structure guarantees the free movement of foodstuffs, ensures a high level of consumer protection and offers the consumer greater freedom of choice between different foodstuffs.

Like the two other specific Directives, Directive 94/35/EC on sweeteners for use in foodstuffs is based on the principle of the positive list. A list of authorized sweeteners is set out in the Annex to the Directive with a list of the foodstuffs in which they may be used and the conditions of use. All sweeteners not included in the list are prohibited.

Since the legal basis of the Directive is Article 100A of the EC Treaty, the proposal for amendment has to follow the same procedure, implying the participation of Parliament in the decision-making process.

#### 4. What is the most effective solution taking into account the means available to the Community and the Member States?

Once the period for transposing the aforementioned Directives has expired, Member States will not be able to use new additives or amend the rules governing use on their own initiative. Action must therefore be taken at Community level.

**5. What practical additional benefit will the proposed measure provide and what would be the cost of failure to take action?**

The Commission proposals will establish effective legislation at Community level, attuned to new developments in industry and consumer needs. If the amendment is not adopted the legislation will become ineffective, if not obsolete, and this could disrupt the proper functioning of the internal market in foodstuffs.

**6. What forms of action are open to the Community?**

A new Directive adopted by Parliament and the Council on the basis of Article 100a is needed to amend Directive 94/35/EC.

**7. Is it absolutely necessary to adopt uniform rules or would a Directive establishing general principles and leaving implementation to the Member States be sufficient?**

The Commission proposal is based on the principle of complete harmonization at Community level. Uniform rules are needed since additives concern public health. There needs to be a large degree of transparency between the Member States in order to establish a reasonable level of safety in trade in foodstuffs within the Community.

**2. SPECIFIC REMARKS**

This amendment to Directive 94/35/EC merely allows already authorized sweeteners to be used in certain new categories of food in which they cannot currently be used.

No changes can be made to the conditions of use laid down in the Directive until the results of the consumer surveys required by Article 8 of the Directive are available.

New sweeteners will not be accepted as they have yet to be dealt with in a report by the Scientific Committee for Food and have not been proved harmless.

The proposal also adds technical Articles (definition of "*quantum satis*", introduction of the carryover clause) to bring Directive 94/35/EC into line with the other additives Directives.

Lastly, the proposed amendment reformulates a category of foodstuffs authorized to contain sweeteners which had caused controversy on account of its relatively imprecise wording; "Vitamins and dietary preparations" thus becomes "Food supplements/diet integrators (e.g. vitamins, trace elements), syrup-type or chewable."

**Proposal for a  
European Parliament and Council Directive  
amending European Parliament and Council 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 100a thereof,

Having regard to the **proposal from the Commission,**<sup>1</sup>

Having regard to the **opinion of the Economic and Social Committee,**<sup>2</sup>

Acting in accordance with the procedure referred to in Article 189b of the Treaty,<sup>3</sup>

Having regard to 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 consumption,<sup>4</sup> as last amended by Directive 94/34/EC,<sup>5</sup> and in particular Article 3(2) thereof,

Whereas since the adoption of Directive 94/35/EC there have been many technical developments in the field of sweeteners;

Whereas the Directive should be adapted to take account of these developments;

Whereas the Scientific Committee for Food set up by Commission Decision 74/234/EEC<sup>6</sup> was consulted before the adoption of provisions liable to have an effect on public health;

**HAVE ADOPTED THIS DIRECTIVE:**

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1 OJ  
2 OJ  
3 OJ  
4 OJ L 40, 11.2.89, p.27.  
5 OJ L 237, 10.9.94, p.1.  
6 OJ L 136, 20.5.74, p.1.

## *Article 1*

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

1. The following paragraph 5 is added to Article 2: "5. In the Annex to this Directive "*quantum satis*" means that no maximum level is specified. Nonetheless, sweeteners shall be used in accordance with good manufacturing practice, the dose used shall not exceed the amount required to achieve the intended purpose and the consumer must not be misled."
2. The following Article 2a is added:

### *Article 2a*

The presence of a sweetener in a foodstuff is permissible:

- in compound foodstuffs other than those mentioned in Article 2(3), provided that the sweetener is permitted in one of the ingredients of the compound foodstuff

or

  - if the foodstuff is intended for use solely in the preparation of a compound foodstuff which conforms to the provisions of this Directive."
3. The category "Vitamins and dietary preparations" in the Annex is renamed "Food supplements/diet integrators (e.g. vitamins, trace elements), syrup-type or chewable".
  4. The table in the Annex is completed in accordance with the table in the Annex to this Directive.

## *Article 2*

Member States shall, where necessary, amend their laws, regulations and administrative provisions in order to:

- authorize trade in products conforming to this Directive, by 31 December 1995 at the latest;
- prohibit trade in products not conforming to this Directive from 30 June 1996. However, products placed on the market or labelled before that date which do not comply with the Directive may be marketed until stocks are exhausted.

They shall forthwith inform the Commission thereof.

5

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

Article 3

This Directive shall enter into force on the seventh day following its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament  
The President

For the Council  
The President

## Annex

*Note*

1. For the substance E952, cyclamic acid and its Na and Ca salts, maximum usable doses are expressed in free acid.
2. or the substance E954, saccharine and its Na and Ca salts, maximum usable doses are expressed in free imide.

EC No	Name	Foodstuffs	Maximum usable dose
E 950	Acesulfame K	<ul style="list-style-type: none"> <li>- high-fibre breakfast cereals, energy-reduced or with no added sugar</li> <li>- energy-reduced soups</li> <li>- small breath-freshening sweets, with no added sugar</li> <li>- reduced-energy fruit wines</li> <li>- carbohydrate-free beer</li> <li>- drinks consisting of a mixture of a non-alcoholic drink with beer, cider, perry, spirits or wine</li> <li>- biscuits for ice-cream, with no added sugar</li> <li>- prepared salads</li> <li>- Essoblaten</li> </ul>	<ul style="list-style-type: none"> <li>1200 mg/kg</li> <li>110 mg/l</li> <li>2500 mg/kg</li> <li>350 mg/l</li> <li>25 mg/l</li> <li>350 mg/l</li> <li>2000 mg/kg</li> <li>350 mg/kg</li> <li>2000 mg/kg</li> </ul>
E 951	Aspartame	<ul style="list-style-type: none"> <li>- high-fibre breakfast cereals, energy-reduced or with no added sugar</li> <li>- energy-reduced soups</li> <li>- small breath-freshening sweets, with no added sugar</li> <li>- reduced-energy fruit wines</li> <li>- carbohydrate-free beer</li> <li>- drinks consisting of a mixture of a non-alcoholic drink with beer, cider, perry, spirits or wine</li> <li>- prepared salads</li> </ul>	<ul style="list-style-type: none"> <li>1000 mg/kg</li> <li>110 mg/l</li> <li>6000 mg/kg</li> <li>600 mg/l</li> <li>25 mg/l</li> <li>600 mg/l</li> <li>350 mg/kg</li> </ul>



E 952	Cyclamic acid and its Na and Ca salts	<ul style="list-style-type: none"> <li>- high-fibre breakfast cereals, energy-reduced or with no added sugar</li> <li>- energy-reduced soups</li> <li>- small breath-freshening sweets, with no added sugar</li> <li>- energy-reduced fruit wines</li> <li>- food supplements/diet integrators (e.g. vitamins, trace elements), syrup-type or chewable</li> <li>- drinks consisting of a mixture of a non-alcoholic drink with beer, cider, perry, spirits or wine</li> </ul>	<p>250 mg/kg</p> <p>400 mg/l</p> <p>4000 mg/l</p> <p>400 mg/l</p> <p>2000 mg/kg</p> <p>400 mg/l</p>
E 954	Saccharine and its Na, K and Ca salts	<ul style="list-style-type: none"> <li>- high-fibre breakfast cereals, energy-reduced or with no added sugar</li> <li>- energy-reduced soups</li> <li>- small breath-freshening sweets, with no added sugar</li> <li>- reduced-energy fruit wines</li> <li>- drinks consisting of a mixture of a non-alcoholic drink with beer, cider, perry, spirits or wine</li> <li>- biscuits for ice-cream, with no added sugar</li> <li>- prepared salads</li> </ul>	<p>100 mg/kg</p> <p>110 mg/l</p> <p>3000 mg/kg</p> <p>80 mg/l</p> <p>80 mg/l</p> <p>800 mg/kg</p> <p>160 mg/kg</p>
E 957	Thaumatococcus	<ul style="list-style-type: none"> <li>- edible ices, energy-reduced or with no added sugar</li> </ul>	50 mg/kg

E 959	Neohesperidine DC	<ul style="list-style-type: none"> <li>- high-fibre breakfast cereals, energy-reduced or with no added sugar</li> <li>- energy-reduced soups</li> <li>- small breath-freshening sweets, with no added sugar</li> <li>- food supplements/diet integrators (e.g. vitamins, trace elements), syrup-type or chewable</li> <li>- energy-reduced fruit wines</li> <li>- drinks consisting of a mixture of a non-alcoholic drink with beer, cider, perry, spirits or wine</li> <li>- prepared salads</li> </ul>	<p>50 mg/kg</p> <p>50 mg/l</p> <p>400 mg/kg</p> <p>400 mg/kg</p> <p>10 mg/l</p> <p>30 mg/l</p> <p>50 mg/kg</p>
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