EUROPEAN PARLIAMENT

1999 *2004*

Session document

FINAL
A5-0049/2003

20 February 2003

***I
REPORT

on the proposal for a Directive of the European Parliament and of the Council amending Directive 94/35/EC on sweeteners for use in foodstuffs
(COM(2002) 375 – C5-0341/2002 – 2002/0152(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Anne Ferreira

CODE1AM

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

Page

PROCEDURAL PAGE

By letter of 11 July 2002 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 95 of the EC Treaty, a proposal for a Directive of the European Parliament and of the Council amending Directive 94/35/EC on sweeteners for use in foodstuffs (COM(2002) 375 – 2002/0152 (COD)).

At the sitting of 2 September 2002 the President of Parliament announced that he had referred the proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and to the Committee on Industry, External Trade, Research and Energy for its opinion (C5-0341/2002).

The Committee on the Environment, Public Health and Consumer Policy appointed Anne Ferreira rapporteur at its meeting of 2 October 2002.

It considered the Commission proposal and the draft report at its meetings of 28 November 2002, 21 January 2003 and 19 February 2003.

At the last meeting it adopted the draft legislative resolution by 30 votes to 11, with 2 abstentions.

The following were present for the vote: Caroline F. Jackson (chairman), Alexander de Roo, Mauro Nobilia and Guido Sacconi (vice-chairmen), Anne Ferreira (rapporteur), María del Pilar Ayuso González, Emmanouil Bakopoulos (for Pernille Frahm), Hans Blokland, David Robert Bowe, John Bowis, Hiltrud Breyer, Philip Bushill-Matthews (for Martin Callanan), Dorette Corbey, Chris Davies, Avril Doyle, Jim Fitzsimons, Karl-Heinz Florenz, Cristina García-Orcoyen Tormo, Laura González Álvarez, Robert Goodwill, Françoise Grossetête, Jutta D. Haug (for Torben Lund), Bernd Lange, Paul A.A.J.G. Lannoye (for Patricia McKenna), Peter Liese, Giorgio Lisi (for Raffaele Costa), Minerva Melpomeni Malliori, Erik Meijer (for Mihail Papayannakis), Emilia Franziska Müller, Riitta Myller, Ria G.H.C. Oomen-Ruijten, Béatrice Patrie, Marit Paulsen, Fernando Pérez Royo (for Rosemarie Müller), Dagmar Roth-Behrendt, Yvonne Sandberg-Fries, Karin Scheele, Inger Schörling, Jonas Sjöstedt, Renate Sommer (for Marialiese Flemming), María Sornosa Martínez, Catherine Stihler, Kathleen Van Brempt, Peder Wachtmeister and Phillip Whitehead.

The Committee on Industry, External Trade, Research and Energy decided on 12 November 2002 not to deliver an opinion.

The report was tabled on 20 February 2003.

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the proposal for a Directive of the European Parliament and of the Council amending Directive 94/35/EC on sweeteners for use in foodstuffs (COM(2002) 375 – C5-0341/2002 – 2002/0152(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission's proposal and amended proposal to the European Parliament and the Council (COM(2002) 375)[1],

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the proposal was submitted to Parliament by the Commission (C5-0341/2002),

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy (A5-0049/2003),

1. Approves the Commission proposal as amended;

2. Asks for the matter to be referred to it again, should the Commission intend to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission	Amendments by Parliament
Amendment 1 Recital 3	
(3) The Scientific Committee on Food ***has now established a new*** 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, leads*** to a reduction of the maximum usable doses of cyclamic acid and its sodium and calcium salts.	(3) The ***opinion of the*** Scientific Committee on Food ***concerning the*** Acceptable Daily Intake (ADI) for cyclamic acid and its sodium and calcium salts ***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.

[1] OJ C not yet published.

Justification

See justification to the amendment to the Annex, point 3(a).

Amendment 2
Recital 5

(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.	***Deleted***

Justification

See justification to the amendment to Article 1(1).

Amendment 3
ARTICLE 1, PARAGRAPH 1
Article 4 (Directive 94/35/EC)

(1) Article 4 is replaced by the following:	***Deleted***
"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."

Justification

The Commission justifies this proposed amendment by the fact that the two other sectoral directives relating to additives incorporate the new provision and by the need for a swift response to be made to any developments in the sector, so that it can be determined whether or not a new substance constitutes a sweetener. It should be pointed out that, once the Scientific Committee on Food decided to authorise the two new sweeteners, the Commission took nearly two years to submit its proposed revision of Directive 94/35/EC.

The Commission has also announced that, in the course of 2003, it will propose a revision of Framework Directive 89/107/EEC on food additives. Hence the rapporteur prefers to allow the scope of the Commission's powers in the area to be determined by means of this general legislative revision procedure. Furthermore, the rapporteur notes that Parliament has very little way of finding out about comitology decisions.

Amendment 4
ARTICLE 1 a (new)

Article 1a

The Commission shall present a report to the European Parliament and the Council regarding a re-evaluation of the authorisation granted in respect of the sweetener aspartame, including a historical evaluation of the FDA approval processes.

The report shall also include legislative proposals for improving the labelling of products containing aspartame, especially for the protection of vulnerable persons such as pregnant women, infants and young children.

The Commission shall also re-examine the restrictions on the use of the traditional sweetener Stevia, taking into account all available data.

Justification

The use of aspartame increases the exposure to its metabolites methanol/formaldehyde and phenylalanine, and is reported to provoke i.a. headaches, nausea and allergic reactions, especially in the case of vulnerable persons. Its widespread use should therefore be re-evaluated by the Commission and the relevant scientific committees, taking into account all available data and respecting the precautionary principle.

A historical evaluation is required as there seems to be evidence that original studies did not prove the safety of aspartame. Nevertheless further approvals are mainly based on the FDA assessment.

Amendment 5
ARTICLE 1 b (new)

Article 1b

Within three years, the Commission and the European Food Safety Authority shall review the conditions for the use of salt of aspartame-acesulfame and sucralose given in this Directive and shall propose the necessary amendments, focusing, as regards maximum content, on the effects on children's health.

Justification

A revision clause is necessary: to date, there is no clear outline of a host of additives on children's health. Sensibly enough, the new limit values to be laid down must be based on the most vulnerable and most sensitive group of consumers. The effects of additives on children's health must therefore be the decisive factor in making the appraisal.

Children and young people consume large quantities of non-basic foodstuffs such as various types of sweets, soft drinks, confectionery and snacks. The maximum levels of additives laid down are based on the assumption that only small quantities of these products are consumed in addition.

Amendment 6
ARTICLE 2, first paragraph

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

Directive by […] at the latest. ***They*** shall forthwith inform the Commission thereof.	Directive by […] at the latest. ***The purpose of those laws, regulations and administrative provisions shall be to:*** - ***authorise, by … [12 months after entry into force] at the latest, the marketing and the use of products which comply with this directive;*** - ***ban, by … [12 months after entry into force] at the latest, the marketing and the use of products which do not comply with this Directive.*** ***Member States*** shall forthwith inform the Commission thereof.

Justification

The Member States must be allowed time to transpose this legislative revision. However, the transition must be made relatively quickly in order to enable technological developments to be taken into account, and also the ban on the use of certain sweeteners in the composition of certain foodstuffs. Hence a 12-month deadline for implementing the directive seems reasonable and justified.

Amendment 7
ANNEX, point 1

The category 'fine bakery products for special nutritional uses' shall be renamed 'fine bakery products, energy-reduced or with no added sugar';	***Deleted***

Justification

The rapporteur takes the view that the consumption of products containing sweeteners should be indicated for a given product type; this chiefly concerns health problems. The rapporteur therefore proposes that the Commission's amendment be deleted so as to retain the old wording, which she thinks is more appropriate.

Amendment 8
ANNEX, point 3(a)

(3) For E 952 cyclamic acid and its sodium and calcium salts:	(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'*** the maximum usable dose of '400 mg/l' is replaced by '***350*** mg/l';	(a) for ***the following categories*** the maximum usable dose of '400 mg/l' is replaced by '***250*** mg/l'***:***
	- 'water-based flavoured drinks, energy-reduced or with no added sugar';
	- 'drinks based on milk and products derived therefrom or on fruit juice, energy-reduced or with no added sugar';

Justification

Recent research on cyclamate intake (in particular a study carried out in Denmark) has shown that the acceptable daily intake (ADI) could be exceeded when certain products were consumed by children, in particular drinks containing cyclamates. It would appear that a child weighing 15 kg (i.e. aged about three) exceeds the ADI by consuming just a single glass of a drink containing cyclamates.

The Commission is not proposing any reduction in the limit other than for water-based drinks and it is leaving the maximum authorised dose for milk-based drinks unchanged. Reducing the limit for only one of the two categories of drink is unacceptable, since children may consume either type of drink indiscriminately in the course of the day and therefore very quickly exceed the ADI.

Moreover, further studies are being carried out by the Member State, the initial conclusions of which apparently indicate that fresh data have come to light which justify a further reduction in the limits.

EXPLANATORY STATEMENT

Directive 94/35/EC is derived from Framework Directive 89/107/EEC on food additives. It concerns sweeteners authorised for use in foodstuffs and it contains an Annex listing authorised sweeteners and the products in which they may be used.

The directive is being revised for the second time since it was adopted in 1994 and it is proposed that two new sweeteners (sucralose and salt of aspartame-acesulfame) be incorporated into it. These two new sweeteners were authorised by the Scientific Committee on Food during the year 2000.

Those sweeteners are already in use in other countries (in particular the USA, Canada, Japan and Australia) and it is on the basis of the data available in those countries that the Scientific Committee has taken its decision. Data on actual consumption within the European Union must be gathered as soon as products containing those sweeteners start to appear on the market, so that existing information can be reassessed within the customary time-limits, in accordance with the monitoring system which is already in place (Article 8 of Directive 94/35/EC).

The proposed legislative revision also concerns a third sweetener – cyclamic acid – which has recently been re-evaluated in the light of new information relating to that substance, derived in particular from research carried out in Denmark. On the basis of the conclusions drawn from that re-evaluation the Scientific Committee on Food has laid down a permanent acceptable daily intake (ADI) to replace a temporary one which had been in force for a number of years. The research carried out showed that a child weighing 15 kg or less could very rapidly reach the ADI limit and thus potentially damage his or her health. The Commission is therefore proposing to reduce the limits for cyclamates contained in certain products: water-based drinks and a number of other confectionery products. Other research currently under way in a number of Member States appears to confirm these findings.

Hence the rapporteur regards it as preferable to propose a greater reduction in the limit indicated by the Commission and, in particular, to extend that reduction to the second category of drinks containing cyclamic acid, i.e. milk-based and fruit-juice-based drinks, since such beverages can, on account of their very nature, be more readily served to small children.

Although we may welcome the fact that regular research makes it possible to improve legislative texts on the basis of the outcome of such research, questions may nonetheless be raised regarding the suitability of the risk assessment upon which authorisations for such products and the rules governing the placing thereof on the market are based.

In another paragraph of its proposal the Commission suggests that it should be granted responsibility for deciding whether or not a substance comes into the category of sweeteners, without following the procedure for securing Parliament's approval. The Commission gives no reasons for this amendment to the directive, despite the fact that the use of a sweetener must be accompanied by the maximum useable dose, which is determined by Parliament and the Council.

The rapporteur cannot accept this proposal, even though such highly technical matters create a

great deal of work for Parliament. Indeed, Parliament's legislative powers must be exercised, since scientific appraisal may be subject to dispute and be placed under pressure.

In conclusion, the rapporteur is well aware that sweeteners may ease the lives of certain people whose state of health requires them to follow a special diet and that the diversity of such products, their better taste and the fact that they contain fewer calories constitute benefits in the eyes of consumers.

However, the existence of such products must not be allowed to disguise the extremely serious public-health problem of obesity. It also raises the issue of health and nutrition education as a means of preventing certain diseases which may be linked to the consumption of given foodstuffs.

Lawmakers must always be mindful of the need for consumers to be provided with accurate information by means of labelling laws and the introduction of the new codes E 955 and E 962 must be accompanied by a consumer information campaign.