



European Communities

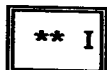
EUROPEAN PARLIAMENT

# SESSION DOCUMENTS

English Edition

26 March 1991

A3-0080/91



## REPORT

of the Committee on the Environment, Public Health and Consumer Protection

on the Commission proposal for a Council directive on sweeteners for use in foodstuffs  
(COM(90)381 final - C3-320/90 - SYN 296)

Rapporteur : Mrs Caroline Jackson

DOC\_EN\RR\106980

PE 145.368/fin.  
Or. EN

A Series: Reports - B Series: Motions for Resolutions, Oral Questions - C Series: Documents received from other Institutions (e.g. Consultations)



= Consultation procedure requiring a single reading



= Cooperation procedure (second reading) which requires the votes of a majority of the current Members of Parliament for rejection or amendment



= Cooperation procedure (first reading)



= Parliamentary assent which requires the votes of a majority of the current Members of Parliament

C O N T E N T S

	<u>Page</u>
Procedural page.....	3
A. Amendments to the Commission proposal.....	4
LEGISLATIVE RESOLUTION.....	16
B. EXPLANATORY STATEMENT.....	17
Opinion of the Committee on Economic and Monetary Affairs and Industrial Policy .....	21

By letter of 5 October 1990, the Council consulted the European Parliament, pursuant to Article 100 A of the EEC Treaty, on the Commission proposal for a Council directive on sweeteners for use in foodstuffs.

At the sitting of 12 October 1990 the President of Parliament announced that he had referred this proposal to the Committee on Environment, Public Health, and Consumer Protection as the committee responsible and to the Committee on Economic Monetary Affairs and Industrial Policy for its opinion

At its meetings of 17 October 1990 the Committee on Environment, Public Health, and Consumer Protection appointed Mrs Caroline Jackson rapporteur.

At its meetings of 18 December 1990, 1 February and 21 March 1991 it considered the Commission proposal and draft report.

At the latter meeting it adopted the draft legislative resolution by 24 votes to one with one abstention.

The following took part in the vote:

Mr Collins (Chairman), Mrs Schleicher (1st Vice-Chairman), Sir James Scott-Hopkins (2nd Vice-Chairman), Mrs Jackson (Rapporteur), Mrs Bjornvig, Mrs Braun-Moser (for Mr Alber), Mrs Ceci, Mr Chanterie, Mrs Diez di Rivera, Messrs Di Rupo, Florenz, Mrs Green, Mr Guidolin, Mrs Jensen, Mrs Kuhn, Messrs Lannoye (for Mr Amendola) Monnier-Besombes, Muntingh, Mr Nordmann (for Mr Bertens), Partsch, Pimenta, Mrs Roth-Behrendt, Messrs L Smith, Vernier, Vertemati, Vohrer

The opinion of the Committee on Economic Monetary Affairs and Industrial Policy is attached.

The report was tabled on 26 March 1991.

The deadline for tabling amendments will appear on the draft agenda for the part-session at which the report is to be considered.

A  
Commission proposal for a Council directive  
on sweeteners for use in foodstuffs

Commission text<sup>1</sup>

Amendments

(Amendment n° 1)

Recital 2

whereas the prime consideration for any rules on sweeteners and their conditions of use should be the need to protect the consumer;

whereas the prime consideration for any rules on sweeteners and their conditions of use should be the need to protect and inform the consumer

(Amendment n° 2)

Recital 6

Whereas the use of sweeteners to replace sugar is justified for the production of energy-reduced or sugar-free food and in some cases where the replacement of sugar extends the shelf life,

Whereas the use of sweeteners to replace sugar is justified for the production of energy-reduced food, non-cariogenic foodstuffs or food without the addition of sugar, for the extension of shelf life through the replacement of sugar, for the widening of consumer choice and for the production of diabetic and dietetic products,

(Amendment n° 3)

Recital 6(a)(new)

whereas 'sugars' is defined in Council Directive 90/496/EEC (1) to mean all monosaccharides and disaccharides present in food, excluding polyols

1) OJ L 276, 6.10.1990

(Amendment n° 4)

Recital 6(b)(new)

whereas it is necessary to lay down an approved method of analysis for checking and comparing use levels of sweeteners,

<sup>1</sup> For full text see OJ No. C 242, 27.9.1990, p. 4

(Amendment n° 5)  
Recital 6(c) (new)

whereas 'sugar free' means food additives containing no monosaccharides, disaccharides or honey,

(Amendment n° 6)  
Recital 6(d) (new)

whereas the labelling and advertising of products containing sweeteners must not give the impression that their use may have a slimming effect,

(Amendment n° 7)  
Article 1, paragraph 3 A (new)

Table-top sweeteners are considered as additives sold to the final consumer and will be subject to particular labelling provisions as set out in directive 89/107 and in Article 2 of this directive.

(Amendment n° 8)  
Article 1, paragraph 4 (new)

4. This directive applies to sugar-free and energy-reduced food. A foodstuff is considered to be energy-reduced if its calorific value has been reduced by 33 per cent by comparison with a reference foodstuff of the same weight.

(Amendment n° 9)  
Article 2, paragraph 4(a) (new)

A special label will show:

(a) in the case of table-top sweeteners:

- (i) a recommended dosage, prominently displayed, indicating its sugar equivalence;
- (ii) the presence of a substance indicated in the annex.

(b) in the case of the polyols (sorbitol, mannitol, isomalt, maltitol, lactitol and xylitol) a warning about the laxative properties of these substances;

c) in the case of aspartame, a warning about the presence of a source of phenylalanine.

(d) for all sweeteners, the following warnings:

- 'not to be taken by pregnant women or children under the age of three years'

- 'this product will only help you to lose weight as part of a diet supervised by a physician or dietitian'.

**(Amendment n° 10)  
Article 3(a) (new)**

By way of derogation from Article 3 paragraph 2(a) and (b) of Directive 89/107/EEC, where it is proposed, following the opinion of the Scientific Committee for Food, to add a new substance to the list of approved sweeteners in the Annex, to create a new category of food in which sweeteners may be used or to adjust the existing list of permitted sweeteners, this shall be done according to the procedure laid down in Article 6. The Commission will report to the European Parliament every year on the modification agreed under this procedure.

Commission text

Amendments

(Amendment n° 11)  
Article 6

Where the procedure laid down in this Article is to be followed, the matter shall be referred to the Standing Committee on Foodstuffs /hereinafter referred to as the 'Committee') by the chairman on his own initiative or at the request of the representative of a Member State.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Where the procedure laid down in this Article is to be followed, the matter shall be referred to the Standing Committee on Foodstuffs (hereinafter referred to as the 'Committee') by the chairman on his own initiative or at the request of the representative of a Member State. The Committee shall maintain a public register of declarations of interest by its members.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee, meeting in public, shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes. The minutes shall be made available to the public.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Commission text

Amendments

(Amendment n° 12)

Article 7

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than April 30, 1992 in order to :

- allow trade in and use of products conforming to this Directive no later than April 30, 1992,
- prohibit trade in and use of products not conforming to this Directive no later than April 30, 1993.

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than January 1, 1992 in order to:

- allow trade in and use of products conforming to this Directive no later than January 1, 1992,
- prohibit trade in and use of products not conforming to this Directive no later than January 1, 1993, or after expiry of the shelf date on the packaging.

(Amendment n° 13)

Article 7(a) (new)

The Member States shall, within 3 years of the adoption of this directive, establish systems of consumer surveys in order to monitor sweetener consumption.

The Commission will report to the European Parliament within 5 years of the adoption of the directive on the changes which have taken place in the sweeteners market, on the levels of use, and whether there is a need further to restrict the conditions of use to ensure against use in excess of Acceptable Daily Intake. On the basis of information from the Member States the Commission may make recommendations to modify this directive.



Commission text

Amendments

(Amendment n° 14)  
Article 7(b) (new)

No later than 30 June 1992 the Commission shall submit to Parliament and to the Council proposals for a programme of scientific research into sweeteners. The purpose of this programme shall be to establish, in conjunction with studies of the real level of consumption as laid down in Article 7a, the medium and long-term effects on human health of each sweetener and thus achieve a better understanding of the permissible daily doses. Finally, it should step up the study of the effects on human health of ingesting a combination of several different artificial sweeteners.

(Amendment n° 15)  
Annex, column 3 foodstuffs

Replace the words sugar free with the words no added sugar throughout column 3

(Amendment n° 16)  
Annex, introductory note

Note: sugar free = without any added mono- and disaccharides.

Note: sugar free = without any added mono-, olio- and disaccharide or sweeteners.

Energy-reduced = the energy removed is equivalent to at least 33 per cent of the energy supplied by similar products of the same weight or the energy that would have been supplied by such foodstuffs had the calorific value not been reduced.

In foods presented for diabetics, sugar-free means: without added mono- and disaccharides except fructose.

Commission text

Amendments

(Amendment n° 17)  
Annex, EEC n° 966, name: Lactitol

E 966  
Lactitol

Delete

(Amendment n° 18)  
Annex, EEC n° 950, name: Acesulfame K

Add a new category as follows:

(3)	(4)
<u>chewing gum</u> <u>(except sugar-</u> <u>free chewing gum</u>	<u>4 500 mg/kg</u>

(Amendment n° 19)  
Annex, EEC n° 950, name: Acesulfame K

Add a new category as follows:

(3)	(4)
<u>Energy reduced</u> <u>chewing gum</u>	<u>4 500 mg/kg</u>

(Amendment n° 20)  
Annex, EEC n° E950, name: Acesulfame K

Add a new category as follows:

(3)	(4)
<u>snack foods</u>	<u>350 mg/kg</u>

Commission text

Amendments

(Amendment n° 21)

Annex, EEC n° E950, name: Acesulfame K

Add a new category as follows:

(3)	(4)
<u>Low-alcohol beers (with an alcohol contents of less than 2.5% volume and alcohol-free beers)</u>	<u>350 mg/L</u>

(Amendment n° 22)

Annex, EEC n° E950, name: Acesulfame K

Add a new category as follows:

(3)	(4)
<u>Vitamins and dietary prepara- tions</u>	<u>2 000 mg/kg</u>

(Amendment n° 23)

Annex, EEC n° E951, name: Aspartame

Add a new category as follows:

(3)	(4)
<u>chewing gum (except sugar- free chewing gum</u>	<u>4 200 mg/kg</u>

(Amendment n° 24)

Annex, EEC n° E951, name: Aspartame

Add a new category as follows:

(3)	(4)
<u>energy reduced chewing gum</u>	<u>4 200 mg/kg</u>

Commission text

Amendments

(Amendment n° 25)  
Annex, EEC n° E951, name: Aspartame

Add a new category as follows:

(3)	(4)
<u>Low-alcohol beers (with an alcohol contents of less than 2.5% volume and alcohol-free beers)</u>	<u>200 mg/L</u>

(Amendment n° 26)  
Annex, EEC n° E951, name: Aspartame

Add a new category as follows:

(3)	(4)
<u>snack foods</u>	<u>500 mg/kg</u>

(Amendment n° 27)  
Annex, EEC n° E 951, name: Aspartame

Add a new category as follows:

(3)	(4)
<u>Vitamins and dietary prepara- tions</u>	<u>5 500 mg/kg</u>

(Amendment n° 28)  
Annex, EEC n° E952, name: Cyclamic acid and its salts

E952  
Cyclamic acid and its salts

Delete

Commission text

Amendments

(Amendment n° 29)

Annex, EEC n° E954, name: Saccharin and its Na, K and Ca salts

Add new category as follows:

(3)	(4)
<u>chewing gum</u> <u>(except sugar-</u> <u>free chewing gum)</u>	<u>2 000 mg/kg</u>

(Amendment n° 30)

Annex, EEC, n° 954, name: Saccharin and its Na, K and Ca salts

Add a new category as follows:

(3)	(4)
<u>energy reduced</u> <u>chewing gum</u>	<u>2 000 mg/kg</u>

(Amendment n° 31)

Annex, EEC n° 954, name: Saccharin and its Na, K and Ca salts

Add a new category as follows:

(3)	(4)
<u>Low-alcohol</u> <u>beers (with an</u> <u>alcohol contents</u> <u>of less than</u> <u>2.5% volume and</u> <u>alcohol-free</u> <u>beers)</u>	<u>80 mg/L</u>

(Amendment n° 32)

Annex, EEC n° 954, name: Saccharin and its Na, K and Ca salts

Add a new category as follows:

(3)	(4)
<u>snack foods</u>	<u>100 mg/kg</u>

Commission text

Amendments

(Amendment n° 33)

Annex, EEC n° 954, name: Saccharin and its Na, K and Ca salts

Add a new category as follows:

(3)	(4)
<u>Vitamins and dietary preparations</u>	<u>1 200 mg/kg</u>

(Amendment n° 34)

Annex, EEC n° E957, name: Thaumatin

Add a new category as follows:

(3)	(4)
<u>chewing gum (except sugar-free chewing gum)</u>	<u>200 mg/kg</u>

(Amendment n° 35)

Annex, EEC n° E957, name: Thaumatin

Add a new category as follows:

(3)	(4)
<u>energy reduced chewing gum</u>	<u>200 mg/kg</u>

(Amendment n° 36)

Annex, EEC n° 957, name: Thaumatin

Add a new category as follows:

(3)	(4)
<u>Low-alcohol beers (with an alcohol contents of less than 2.5% volume and alcohol-free beers)</u>	<u>20 mg/L</u>

Commission text

Amendments

(Amendment n° 37)  
Annex, EEC n° 957, name: Thaumatin

Add a new category as follows:

(3)	(4)
<u>Vitamins and dietary prepara- tions</u>	<u>400 mg/kg</u>

(Amendment n° 28)  
Annex, EEC, n° E959, name: Neohesperidine

E959  
Neohesperidine

Delete

### **LEGISLATIVE RESOLUTION**

(Cooperation procedure : first lecture)  
embodying the opinion of the European Parliament  
on the Commission proposal for a Council directive on  
sweeteners for use in foodstuffs

The European Parliament,

- having regard to the Commission proposal to the Council (COM(90)381 final-SYN 296) <sup>(1)</sup>
  - having been consulted by the Council pursuant to Article 100A of the EEC Treaty (C3-320/90),
  - having regard to the report of the Committee on Environment, Public Health and Consumer Protection and the opinion of the Committee on Economic Monetary Affairs and Industrial Policy (A3-0080/91),
1. Approves the Commission proposal in accordance with the vote thereon;
  2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149 of the EEC Treaty;
  3. Asks to be consulted again should the Council intend to make substantial modifications to the Commission proposal;
  4. Calls on the Council to incorporate Parliament's amendments in the common position that it adopts in accordance with Article 149 of the EEC Treaty;
  5. Instructs its President to forward this opinion to the Council and Commission.

---

<sup>1</sup> OJ n° 242, 27.09.1990, p. 4



EXPLANATORY STATEMENTBACKGROUND INFORMATION

The sweeteners directive will form part of the Commission's proposals for the harmonisation of all food additive legislation in the Community by the end of 1992. It forms the first proposal in what will become a comprehensive directive specifying all the permitted additives within the meaning of the framework directive on food additives authorized for use in foodstuffs intended for human consumption (89/107/EEC). This allows the Council, under Article 100A, to adopt a list of all permitted additives, the foodstuffs to which these substances may be added, the conditions under which they may be used and limits (where appropriate) on the purposes for which they may be used.

Aims of the directive

The main aim of the sweeteners directive is to ensure that there are no remaining barriers to trade in foodstuffs resulting from different national rules on the sweeteners which are permitted in food, the levels at which they may be used and the specific foodstuffs to which particular substances may be added. All Member States allow the use of sweeteners, but detailed provisions vary from a ban on the use of intense sweeteners in some to no regulation at all in others. Where limits have been placed on the amount of sweetener which may be used, those limits can differ by a factor of 10 between different Member States.

The Commission aims to protect the health and safety of consumers by proposing limits on the levels which may safely be used in food, in accordance with the acceptable daily intakes recommended by the Scientific Committee for Food.

AREAS OF CONTROVERSY

The most important areas of debate on this directive concern, first, the determination of which sweeteners should be permitted and in what quantity and, secondly, how the directive can be amended once it has been adopted. Lesser concerns are the position of table-top sweeteners; certain labelling requirements; and the omission of certain categories of food, probably by inadvertence.

SAFETY

The safety of permitted additives is of paramount concern to the Parliament

The additives framework directive states (Annex II) that food additives can only be approved if it can be demonstrated that there is a reasonable technological need for them, that they do not present a hazard to the health of the consumer, and that they do not mislead the consumer. Additives may only be considered for use where there is evidence that the proposed use of the additive would have demonstrable advantages to the consumer. Thus the "need" for the additive must be demonstrated, and such additives must serve one or more of the following purposes, where they cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to health:

- to preserve the nutritional quality of food;
- to serve the needs of groups of consumers with special dietary needs;
- to enhance the keeping quality or stability of food, provided that this does not deceive the consumer;
- to provide aids in manufacture, preparation, treatment etc, of food, provided that this does not serve to disguise faulty raw materials or undesirable practices.

The basic additives directive, therefore, already provides a framework of safety precautions within which the sweeteners directive takes its place.

The Scientific Committee for Food must be consulted on the safety of all additives before they can be included in the Commission proposals. This has been done for the sweeteners in this directive and the result is that in some countries, following the adoption of the directive, sweeteners will be permitted where they have not been before.

Doubts have sometimes been expressed about the degree of confidence that can be placed in the Scientific Committee for Food. It is composed of experts from the Member States, nominated by national governments. Some wish to replace the experts there with other experts of their own choosing; some would turn to other international committees. Of such alternatives, the only real candidate is the WHO/FAO Joint Expert Committee on Food Additives (JECFA). But unlike the SCF, which meets frequently, JECFA meets annually, and introducing a JECFA as another filter in the Community's affairs would slow the legislative process up very considerably. JECFA does evaluate the safety of additives internationally, and recommends maximum acceptable daily intakes (ADIs) on the basis of toxicological information. But JECFA's views represent the balance of international opinion. The Community may well want to differ from, or improve on, that consensus (which includes such stalwart defenders of the consumer as the USSR).

It seems to the rapporteur that the SCF is the most appropriate body that the Community can call on for the work the Community needs to have done.

#### The permitted list and levels of use

The proposed levels of use are the result of compromises between the maximum levels requested by industry to allow for current needs and future developments, and the levels which legislators have been willing to accept, taking into account need and the safety considerations which are the task of the SCF. There has been little consumer consultation, but the evidence is that the Commission was sceptical about industry's claims for the levels of use it needed, and has reduced these considerably. One of the problems for the Parliament about the levels of use proposed is that there is little data available about consumption patterns in the Community. This is the reason why an amendment is being proposed which would establish a system of consumer surveys.

#### The problem of future amendments

Under the terms of Article 5 of the basic additives directive (89/107/EEC), new sweeteners may only be added to the permitted list, or new uses allowed for permitted sweeteners, by an amendment to this directive in the form of an amending directive under Article 100A. This is a cumbersome process for what

may be minor amendments; it is also a lengthy process if a new sweetener offers advantages to the consumer over those which are already permitted. But there is no short cut via the route of an advisory committee or regulatory committee procedure.

The Parliament, therefore, has to decide whether it wishes to stay with the procedure proposed, whether it wishes to try to institute the advisory committee procedure, or whether it can, with the Commission, find some better solution.

Two amendments adopted by the Committee, creating a new Article 3(a) and amending Article 6, set out the Committee's preferred option.

This is that modifications to the directive, to add new substances to the approved list, to create new categories of food in which sweeteners may be used, or to adjust the existing list of sweeteners, should be done using the advisory committee procedure. In fact this procedure is already in the directive, in Article 5, but is only to be used for the adaption of existing Community provisions to the rules laid down in the directive.

However, the advisory committee procedure creates a dilemma for the Parliament since it does not involve any degree of parliamentary scrutiny or control. The only opportunity for the Parliament to be informed about matters dealt with by the procedure currently rests on the exchange of letters between President Delors and President Plumb, where the Commission undertook to inform the Parliament of matters dealt with under the advisory committee procedure. But this system of information has completely failed to supply the Committee on the Environment, Public Health and Consumer Protection of the Parliament with the information it would like.

Hence the Committee has proposed bringing the advisory committee procedure, as employed by the Standing Committee for Foodstuffs, into the open, which it believes to be entirely appropriate, given that the Standing Committee for Foodstuffs will, in effect, be adopting legislation for the Community.

The Committee notes that, if the Commission accepts this new procedure, then an amendment will be needed to the basic additives directive (89/107/EEC) and look forward to hearing the Commissioner's reaction on this point.

#### Lactitol, cyclamic acid and neohesperidine

The Committee decided, by varying majorities, to delete these three substances from the permitted list. The reasons for this illustrate all the problems of reconciling national preferences and scientific evidence.

Lactitol and neohesperidine, the Committee were told, are not permitted in Denmark. Danish members then led the vote to remove them from the permitted list in the directive. It emerged in the discussion that the Scientific Committee for Food, which approved the proposed list of permitted sweeteners unanimously, contains two Danish food scientists of impeccable credentials. In this confusing state of affairs, the Committee decided to err on the safe side.

Cyclamic acid and its salts falls into a different category. The Scientific Committee for Food is considering evidence from the British government's Committee on Toxicity in Chemicals in Food, Consumer Products and the

Environment on the connection between intake of cyclamates and testicular toxicity in rats. The Acceptable Daily Intake set by the British government following this evidence was so low that, in effect, it ruled out the use of cyclamates in food. The fact that the directive permits the use of cyclamates was not, therefore, supported by the unanimous endorsement of the Scientific Committee for Food at the time that the Committee voted, and the Committee decided on this basis to delete cyclamates from the permitted list.

The Committee's action on these three substances should be seen as an important reflection of its concern for consumer protection and for securing a consensus on a directive which could be adopted finally by a majority vote, against the wishes of a minority of Member States.

#### Labelling

The Committee noted the Commission's opinion that this directive does not apply to table top sweeteners, which are covered by the basic additives directive. But, nevertheless, it took the opportunity of this directive to express the view that table top sweeteners should be covered by specific provisions on labelling, as in Article 2, paragraph 4(a).

The Committee also wanted greater attention paid to the need to label sweeteners with laxative properties, and those which contain a source of phenylalanine. At the moment the requirements for such indications vary in the Member States, and the Committee opted for the highest degree of information and protection.

This concern was also true in the case of pregnant women, children and the claims associated with sweeteners in diet foods.

#### Future provisions

The Committee felt that the directive should do more than set out what is permitted. The Community needs to know what happens under the aegis of its legislation. It therefore proposes, in new Article 7(a), that the Member States should carry out consumer surveys to establish consumption patterns for sweeteners. The European Parliament will be kept informed of these surveys, which may lead to future modifications of the directive. A programme of scientific research is also called for.

#### Amendments to the Annex

The Committee created a number of new categories in the Annex, where it felt that existing products which pose no problem for human health and which are already appreciated by consumers, would otherwise be driven off the market. The Committee did not agree to amendments seeking to alter the quantities of permitted sweeteners, since it did not feel that it should get involved in such detailed matters.

The Committee attempted to deal with the question of definitions for "sugar free" and "no added sugar" which, as they stand, are potentially misleading to consumers. A definition of "energy reduced" was added, where the Committee preferred a figure of 33% energy reduction equivalent to 50%.

O P I N I O N

(Rule 120 of the Rules of Procedure)

of the Committee on Economic and Monetary Affairs and Industrial Policy  
for the Committee on Environment, Public Health and Consumer Protection  
Draftsman: Mr Gary TITLEY

At its meeting of 30 October 1990, the Committee on Economic and Monetary Affairs and Industrial Policy appointed Mr Titley draftsman.

At its meetings of 29 January 1991 and 28 February 1991, it considered the draft opinion.

At the last meeting it adopted the amendments annexed to this opinion as follows: No. 1-16 unanimously, No. 17, 18, 20, 23 and 24 by 12 votes to 2, with 2 abstentions, No. 19, 21, 22 and 25 by 8 votes to 5 with 1 abstention.

The following were present for the vote: Mr BEUMER, chairman; Mr TITLEY rapporteur; Mr BEAZLEY, Mr BOFILL, Mr COX, Mr CRAVINHO, Mr DESSYLAS (for Mr FERREIRA RIBEIRO), Mr DONNELLY, Mr HERMAN, Mr METTEN, Mrs READ, Mr ROUMELIOTIS, Mr SISO CRUELLAS, Mr SPECIALE, Mrs TONGUE and Mr WETTIG.

## Introduction

The proposal under question seeks to implement Article 3, paragraphs 1 and 2 of Council Directive 89/107/EEC.<sup>1</sup> In fact, the latter is a 'framework regulation' intended as a vehicle for future Commission proposals in the field of food additives and their use in foodstuffs.

The need for this kind of a Council directive derives from two facts. First, there are wide divergencies between Member States regarding the authorization of additives and their use in different foodstuffs; some additives are permitted in some countries and some prohibited in others or vice-versa. Such a situation has given rise to a large number of technical barriers to trade and has provided a hidden weapon for national protectionism.

Second, food additives have proved to be products of high technological content that have increased European firm's productivity; they reduce costly inputs, mainly energy-based, and have promoted safety and health in specific cases such as the diabetics.

## Content of the proposal

The overall objective is to create a unified food additives law in the context of the completion of the internal market. It should be added that only certain, specific areas within the vast range of food additives have been subject to Community regulation; there are sectors that have been escaped (such as sweeteners) or regulated only in part.

It should also be said that food additives and by-products or combination of such additives are both numerous (roughly 450) and complex not only as regards their composition but also their technological function. Additives are introduced at various stages of manufacture, packaging, transport and storage of foodstuffs and that further complicates their overall value.

This is why one has to rely on the Scientific Committee for Food - set up by Council Decision 74/234/EEC<sup>2</sup> - for its evaluations. This in fact means that food additives are subjected to an evaluation by this Committee. For all food additives and their derivatives, appropriate toxicological testing and evaluation are carried out by the producer concerned but assessed by the scientific committee. If the Scientific Committee does not approve of an additive, authorization is not granted. The sweeteners contained in the Annex of the proposal have been cleared by the Scientific Committee and maximum levels for acceptable daily intakes have been proposed.

The maximum levels indicated in the Annex have been proposed by the Commission after consultation with manufacturers involved and representatives from Member States. Hence the proposed maxima are supposed in principle to take account of the approved ADI, the need for harmonization of maximum levels approved in Member States and the list of food additives and their use by

---

<sup>1</sup> see 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 on foodstuffs intended for human consumption (OJ L 40 11.2.89, pp. 27-32).

<sup>2</sup> OJ L 136, 20.5.74, p. 1

world organisations. However this information is not available in the explanatory memorandum of the proposal in question.

A related aspect of food additives is the principal criteria employed by the Scientific Committee for Food for its authorization of sweeteners or their by-products becoming a component of food production. In the framework directive in Annex II, three general criteria are stated: a) a reasonable technological need, b) no hazard to the health of the consumer and c) the consumer is not misled. For the proposal under discussion these three criteria are supposed to be met by the following recital: "... the use of sweeteners to replace sugar is justified for the production of energy-reduced or sugar-free food and in some cases where the replacement of sugar extends the shelf life."

#### Future needs

A production area like that of food additives is characterized by heavy investment in research and development; new inventions are protected by patents but the afforded protection is limited in duration. Such a situation raises three questions. The first has to do with the monopolistic exploitation of an invention protected by a patent, the second, with varying durations of a patent in Member States and in the rest of the world, that create unfair conditions of competition by 'free riders' once the legal protection is over and the third has to do with the economic incentives for research and development that would result in new inventions.

The case of 'sucralose' should be seen in such a context. One spoon of sucralose is equivalent to 600 teaspoons of sugar. Sucralose is calorie free and is claimed to have no effect on the body nor the teeth. If that is the case then it is suitable for diabetics.

Sucralose, however, is not included in the list of sweeteners. The scientific committee has requested additional information on the toxicological tests but the two principal companies involved in the invention of sucralose have not yet supplied the requested data. If sucralose is approved by the scientific committee and thus included in the list of the proposal, it is likely that the whole list of the Annex would have to change.

Similar inventions may exist in other areas but the case of sucralose demonstrates the need for a speedy and flexible approach to sweeteners. Under the procedure provided for in Article 6 by this proposal any new additive, although approved by the standing committee for foodstuffs, cannot be included in the list unless a new proposal containing the appropriate amendment is adopted. Two options might have to be considered:

- a) either to include in the Annex additives approved 'in principle' pending the approval of the Scientific Committee;
- b) or to amend Article 6 of the proposal in such a way that responsibility for future amendments to the approved list lies with the Standing Committee for Food.

#### Amendments

The proposed amendments by the draftsman are intended to improve the proposal by marrying the industrial aspects of food additives with health considerations inherent in sweeteners which affect the degree of competition.

Amendments No. 1 and 2 are definitional but necessary because they link the present proposal with existing legislation.

Amendment No. 3 is important in the sense that it introduces a third criterion that of the technological need and increased consumer benefit. Consequently, Amendments No. 12, 13, and 14 follow the logic of the third criterion.

Amendment No. 4 takes account of the procedure provided for by Article 6A.

Amendment No. 5 is the result of the third criterion of technological need.

Amendment No. 6 takes account of the comments made on the way the maximum levels are set by the Commission and for which the scientific committee for food should be involved.

Amendment No. 7 is intended to set conditions concerned with warnings on utilization and conditions for harmonization of manufacturing practices.

Amendments No. 8 and 9 link the procedure with the one provided for by Article 6. Amendment No. 9 proposes a solution to the two options referred to in the section on new inventions, research and development and marketing in the field of sweeteners. It does not prejudice the procedure stated in Article 6. It states clearly under what conditions a new sweetener could be deemed approved. It also draws on academic research which shows that under a fair regulatory system, innovations in food additives and their by-products have been encouraged.

Amendment No. 10 simply extends to 3 years the period of circulation of products produced before the entry into force of this Directive.

Amendments No. 11, 15 and 16 are intended to correct the maximum levels following the Acceptable Daily Intakes approved by the Scientific Committee.

Amendments No. 12, 13, 14, 17, 18, 19, 20, 22, 23, 24 and 25 follow the logic of amendment No. 3 and add low alcohol beers as well as chewing gum (except sugar free chewing gum) to the Annex.

Commission text

Amendments

(Amendment No. 1)  
New recital 6A

Whereas 'sugars' is defined in Council Directive 90/496/EEC (1) to mean all monosaccharides and disaccharides present in food, excluding polyols

(1) OJ L 276, 6.10.1990



(Amendment No. 2)  
New recital 6B

Whereas 'sugar free' means food additives containing no monosaccharides, disaccharides or honey.

(Amendment No. 3)  
New Recital 6C

Whereas the use of sweeteners to replace sugar in part is justified on meeting a technological need, and results in a greater benefit to the consumer,

(Amendment No. 4)  
Article 2 (1)

- |                                                                   |                                                                                                                          |
|-------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 1. Only sweeteners listed in the Annex may be used in foodstuffs. | 1. Only sweeteners listed in the Annex <u>or approved under the procedure of Article 6A</u> , may be used in foodstuffs. |
|-------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|

(Amendment No. 5)  
Article 2 (2)

- |                                                                                                                |                                                                                                                                                                   |
|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2. Sweeteners may only be used in those foodstuffs listed in the Annex under the conditions specified therein. | 2. Sweeteners may only be used in those foodstuffs listed in the Annex, <u>as amended in conformity with recital 6C</u> , under the conditions specified therein. |
|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|

(Amendment No. 6)  
Article 2 (4)

- |                                                                                                                                               |                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4. Maximum levels indicated in the Annex refer to the ready-for-consumption foodstuffs prepared according to the manufacturer's instructions. | 4. Maximum levels indicated in the Annex, <u>after approval by the Scientific Committee for Food</u> , refer to the ready-for-consumption foodstuffs prepared according to the manufacturer's instructions. |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

(Amendment No. 7)  
Article 2A (new)

Without prejudice to Council Directive 90/496/EEC, food additives approved in the Annex should contain the following information on the labelling:

- a) amount of sweeteners contained in the product,
- b) acceptable daily intake, and maximum amount of daily consumption,
- c) where appropriate, the 'best before' date,
- d) manufacturer's advice on proper use by consumer and, in particular, by pregnant women.

(Amendment No. 8)  
Article 4

Where necessary, it may be decided by the procedure laid down in Article 6 of this Directive, whether a particular foodstuff belongs to a category of foods mentioned in Article 2(3) and foodstuffs listed in the Annex.

Where necessary, it may be decided by the procedure laid down in Articles 6 and 6A of this Directive, whether a particular foodstuff belongs to a category of foods mentioned in Article 2(3) and foodstuffs listed in the Annex.

(Amendment No. 9)  
Article 6 A (new)

1. Without prejudice to Article 6, food additives, not yet included in the Annex pending its revision pursuant to paragraph 4 of Annex II of Council Directive 89/107/EEC, may be deemed 'approved' provided that:

- a) the general criteria stated in Annex II of Council Directive 89/107/EEC are met,
- b) the Scientific Committee for food has authorized its use, the maximum levels and acceptable daily intake, and
- c) the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has already approved its use.

2. The Commission shall submit a proposal to the Council and the Parliament in order to take account of developments under paragraph 1.

(Amendment No. 10)  
Article 7

Member States shall bring into force the law, regulations and administrative provisions necessary to comply with this Directive not later than April 30, 1992, into order to:

- allow trade in and use of products conforming to this Directive no later than April 30, 1992,
- prohibit trade in and use of products not conforming to this Directive no later than April 30, 1993

Member States shall bring into force the law, regulations and administrative provisions necessary to comply with this Directive not later than April 30, 1992, into order to:

- allow trade in and use of products conforming to this Directive no later than April 30, 1992,
- prohibit trade in and use of products manufactured no later than April 30, 1993 not conforming to this Directive no later than April, 30, 1996

(Amendment No. 11)  
Annex

EEC No.: E 950  
Name: Acesulfame K  
Foodstuffs: Sugar free chewing gum  
Maximum level: 2000 mg/kg

EEC No.: E 950  
Name: Acesulfame K  
Foodstuffs: Sugar free chewing gum  
Maximum level: 6000 mg/kg

(Amendment No. 12)  
Annex (new)

EEC No.: E 950  
Name: Acesulfame K  
Foodstuffs: Chewing gum (except sugar free chewing gum)  
Maximum level: 4500 mg/kg

(Amendment No. 13)  
Annex (new)

EEC No.: E 951  
Name: Aspartame  
Foodstuffs: Chewing gum (except sugar free chewing gum)  
Maximum level: 4,200 mg/kg

(Amendment No. 14)  
Annex (new)

EEC No.: E 952  
Name: Cyclamic Acid and its NA and CA salts  
Foodstuffs: Chewing gum (except sugar free chewing gum)  
Maximum level: 2000 mg/kg

(Amendment No. 15)  
Annex

EEC No.: E 954  
Name: Saccharin and its NA, K and CA salts  
Foodstuffs: Sugar free chewing gum  
Maximum level: 1200 mg/kg

EEC No.: E 954  
Name: Saccharin and its NA, K and CA salts  
Foodstuffs: Sugar free chewing gum  
Maximum level: 2000 mg/kg

(Amendment No. 16)  
Annex

EEC No.: E 957  
Name: Thaumatin  
Foodstuffs: Sugar free chewing gum  
Maximum level: 50 mg/kg

EEC No.: E 957  
Name: Thaumatin  
Foodstuffs: Sugar free chewing gum  
Maximum level: 200 mg/kg

(Amendment No. 17)  
Annex (new)

Add a new category as follows:

EEC No.: E 950  
Name: Acesulfame K  
Foodstuffs: Low alcohol beers and alcohol-free beers  
Maximum level: 350 mg/l

(Amendment No. 18)  
Annex (new)

Add a new category as follows:

EEC No.: E 951  
Name: Aspartame  
Foodstuffs: Low alcohol beers and alcohol-free beers  
Maximum level: 600 mg/l

(Amendment No. 19)  
Annex (new)

Add a new category as follows:

EEC No.: E 954  
Name: Saccharin and its Na, K and Ca salts  
Foodstuffs: Chewing gum (except sugar free chewing gum)  
Maximum level: 2000 mg/Kg

(Amendment No. 20)  
Annex (new)

Add a new category as follows:

EEC No.: E 954  
Name: Saccharin and its Na, K and Ca salts  
Foodstuffs: Low alcohol beers and alcohol-free beers  
Maximum level: 80 mg/l

(Amendment No. 21)  
Annex

EEC No.: E 957  
Name: Thaumatin  
Foodstuffs: Sugar free chewing gum  
Maximum level: 50 mg/kg

EEC No.: E 957  
Name: Thaumatin  
Foodstuffs: Sugar free chewing gum  
Maximum level: 200 mg/kg

(Amendment No. 22)  
Annex (new)

Add a new category as follows:

EEC No.: E 957  
Name: Thaumatin  
Foodstuffs: Chewing gum (except sugar free chewing gum)  
Maximum level: 200 mg/kg

(Amendment No. 23)

Annex (new)

Add a new category as follows:

EEC No.: E 957

Name: Thaumatin

Foodstuffs: Low alcohol beers and  
alcohol-free beers

Maximum level: 20 mg/l

(Amendment No. 24)

Annex (new)

Add a new category as follows:

EEC No.: E 959

Name: Neohesperidine DC

Foodstuffs: Low alcohol beers and  
alcohol-free beers

Maximum level: 10 mg/l

(Amendment No. 25)

Annex (new)

Add a new category as follows:

EEC No.: E 959

Name: Neohesperidin DC

Foodstuffs: Chewing gum (except sugar  
free chewing gum)

Maximum level: 400 mg/kg