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13 June 2003

**\*\*\*I**

## **REPORT**

on the proposal for a European Parliament and Council directive amending  
Directive 95/2/EC on food additives other than colours and sweeteners  
(COM(2002) 662 – C5-0577/2002 – 2002/0274(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: María del Pilar Ayuso González

***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.

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## PROCEDURAL PAGE

By letter of 29 November 2002 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 95 of the EC Treaty, the proposal for a European Parliament and Council directive amending Directive 95/2/EC on food additives other than colours and sweeteners (COM(2002) 662 – 2002/0274 (COD)).

At the sitting of 4 December 2002 the President of Parliament announced that he had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Industry, External Trade, Research and Energy for its opinion (C5-0577/2002).

The Committee on the Environment, Public Health and Consumer Policy appointed María del Pilar Ayuso González rapporteur at its meeting of 9 December 2002.

The committee considered the Commission proposal and draft report at its meetings of 30 April and 11 June 2003.

At the latter meeting it adopted the draft legislative resolution by 37 votes to 18, with no abstentions.

The following were present for the vote: Caroline F. Jackson, chairman; Alexander de Roo, Mauro Nobilia and Guido Sacconi, vice-chairmen; María del Pilar Ayuso González, rapporteur; Jean-Louis Bernié, Hans Blokland, David Robert Bowe, John Bowis, Hiltrud Breyer, Dorette Corbey, Chris Davies, Avril Doyle, Anne Ferreira, Marialiese Flemming, Karl-Heinz Florenz, Pernille Frahm, Cristina García-Orcóyen Tormo, Laura González Álvarez, Robert Goodwill, Françoise Grossetête, Cristina Gutiérrez Cortines, Jutta D. Haug (for Béatrice Patrie), Marie Anne Isler Béguin, Hedwig Keppelhoff-Wiechert (for Martin Callanan), Christa Klauß, Hans Kronberger, Bernd Lange, Paul A.A.J.G. Lannoye (for Patricia McKenna), Peter Liese, Giorgio Lisi (for Raffaele Costa), Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Jorge Moreira da Silva, Emilia Franziska Müller, Rosemarie Müller, Riitta Myller, Giuseppe Nisticò, Ria G.H.C. Oomen-Ruijten, Marit Paulsen, Frédérique Ries, Dagmar Roth-Behrendt, Yvonne Sandberg-Fries, Karin Scheele, Ursula Schleicher (for Horst Schnellhardt), Inger Schörling, Jonas Sjöstedt, María Sornosa Martínez, Catherine Stihler, Astrid Thors, Antonios Trakatellis, Kathleen Van Brempt, Peder Wachtmeister, Phillip Whitehead.

The Committee on Industry, External Trade, Research and Energy decided on 23 January 2003 not to deliver an opinion.

The report was tabled on 13 June 2003.

## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a European Parliament and Council directive amending Directive 95/2/EC on food additives other than colours and sweeteners (COM(2002) 662 – C5-0577/2002 – 2002/0274(COD))

(Codecision procedure: first reading)

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2002) 662<sup>1</sup>),
  - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0577/2002),
  - 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 (A5-0216/2003),
1. Approves the Commission proposal as amended;
  2. Calls on the Commission to refer the matter to Parliament again if it intends 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

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### Amendment 1 RECITAL 4A (new)

***(4a) Before 31 December 2006, the Commission should carry out an overall review and evaluation of the use of food additives, including colours and sweeteners. Future authorisations should be based on the following criteria, inter alia:***

***- additives should be technologically necessary,***

***- a high level of protection for human health, and***

***- the use and labelling of additives must not***

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<sup>1</sup> Not yet published in OJ.

*mislead consumers.*

*Authorisations for the use of additives which cannot fully meet these three criteria should be withdrawn.*

#### *Justification*

*Changes to the rules governing additives have hitherto meant that many new additives have been authorised and existing ones authorised for extended use. Authorisations have been withdrawn only when the additives concerned were no longer in use anyway.*

#### Amendment 2 RECITAL 6

(6) While the use of additives which are necessary to ensure the safety and quality of flavourings and to facilitate their storage and use should be authorised, the levels of additives present in such flavourings should be the minimum required to achieve the intended purpose. In addition, consumers ***should not be misled*** on the use of additives.

(6) While the use of additives which are necessary to ensure the safety and quality of flavourings and to facilitate their storage and use should be authorised, the levels of additives present in such flavourings should be the minimum required to achieve the intended purpose. In addition, consumers ***shall be guaranteed correct, adequate and non-misleading information*** on the use of additives.

#### *Justification*

*Self-explanatory.*

#### Amendment 3 RECITAL 10

(10) In accordance with a request from a Member State and the opinion of the Scientific Committee on Food, established under Commission Decision 97/579/EC , hydrogenated poly-1-decene, which was authorised at national level under Directive 89/107/EEC, should be approved at Community level.

(10) In accordance with a request from a Member State and the opinion of the Scientific Committee on Food, established under Commission Decision 97/579/EC , hydrogenated poly-1-decene, which was authorised at national level under Directive 89/107/EEC, should be approved at Community level, ***but the conditions of use and the approval must be reviewed within***

***two years of the entry into force of this Directive.***

*Justification*

*In line with the approaches in other related legislation the use of hydrogenated poly-1-decene must be revised especially with respect to children. Hydrogenated poly-1-decene is among other things used as a glazing agent in products like candy.*

Amendment 4  
RECITAL 11

(11) Biphenyl (E 230), orthophenyl phenol (E 231) and sodium orthophenyl phenol (E 232) are listed as preservatives in and on citrus fruits in Directive 95/2/EC. However, they fall under the definition of plant protection products in Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. Therefore, they should no longer come within the scope of Directive 95/2/EC.

(11) Biphenyl (E 230), orthophenyl phenol (E 231) and sodium orthophenyl phenol (E 232) are listed as preservatives in and on citrus fruits in Directive 95/2/EC. However, they fall under the definition of plant protection products in Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. Therefore, they should no longer come within the scope of Directive 95/2/EC. ***The Member States and the Commission should take all possible steps to ensure that there is no legal vacuum with regard to these substances. Authorisation for these substances as plant protection products should be dealt with as swiftly as possible. Member States and the Commission shall ensure that the labelling requirements for these substances are maintained when they are marketed as plant protection products.***

*Justification*

*Self-explanatory. The industry has already applied for the corresponding authorisations. The procedure should be as swift as possible. The labelling of these substances, which are applied after harvesting the fruits, should remain compulsory.*

Amendment 5  
RECITAL 11 A (new)

***(11a) The maximum levels for nitrites and nitrates (E 249, E 250, E 251 and E 252) shall be revised after consultation of the European Food Safety Agency.***

*Justification*

*In its ruling of 20 March 2003, the European Court of Justice has underlined the fact that the Commission did not take account of the 1995 opinion of the Scientific Committee for Food which called into question the maximum amounts of nitrites set under Directive 95/2/EC. These maximum levels have to be adapted as soon as possible.*

Amendment 6  
ARTICLE 1, POINT 1  
Article 1, paragraph 3, point (v) (Directive 95/2/EC)

***(1) In Article 1(3), point (v) is replaced by the following:*** ***Deleted***

***“(v) ‘stabilisers’ are substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilisers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff, substances which stabilise, retain or intensify an existing colour of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food.”***

*Justification*

*The change in the definition of stabilisers may give rise to various problems. Firstly, widening the definition in this way would include certain enzymes, such as transglutaminase or pectinases. Enzymes are explicitly excluded from the scope of Directive 95/2/EC (Article 1(1)).*

*Secondly, some of these substances are used to create links between proteins (such as small pieces of meat) which improve the appearance of re-constituted food (for example, a denser fillet). This would amount to a violation of the third condition laid down in Directive 89/107/EEC for the authorisation of food additives: that they do not mislead the consumer.*

Amendment 7  
ARTICLE 1, POINT 2A (NEW)  
Article 3, paragraph 1 a (new) (Directive 95/2/EC)

***(2a) The following paragraph 1a is inserted in Article 3:***

***"1a. The level of additives present in flavourings shall be limited to the minimum necessary to guarantee the safety and quality of flavourings and to facilitate their storage. Furthermore, the presence of additives in flavourings must not mislead the consumer."***

*Justification*

*The situation could arise where an additive without a limited ADI could be used in flavourings according to the 'quantum satis' principle. In the case of certain foods, additives listed in Annex I may not be added but flavourings can be added. The use of additives in flavourings might therefore represent a path by which non-authorized additives could enter foods without needing to be labelled.*

*The general principle set out in the new paragraph 1(b) on the incorporation of additives in flavourings therefore needs to be clarified substantially.*

Amendment 8  
ARTICLE 1, POINT 2B (NEW)  
Article 3, paragraph 1 b (new) (Directive 95/2/EC)

***(2b) The following paragraph 1b is inserted in Article 3:***

***"1b. If the presence of an additive in a foodstuff, as a consequence of using a flavouring, exceptionally does have a technological function in the compound foodstuff, it shall be considered as an additive of the compound foodstuff and not as an additive of the flavouring. Consequently, the relevant rules relating to the additive in the particular foodstuff shall apply, including the labelling rules laid down in Directive 2000/13/EC of the***

***European Parliament and of the Council  
of 20 March 2000 on the approximation  
of the laws of the Member States relating  
to the labelling, presentation and  
advertising of foodstuffs and Directive  
88/388/EEC of 22 June 1988 on the  
approximation of the laws of the Member  
States relating to flavourings for use in  
foodstuffs and to source materials for  
their production."***

*Justification*

*The situation could arise where an additive without a limited ADI could be used in flavourings according to the 'quantum satis' principle. In the case of certain foods, additives listed in Annex I may not be added but flavourings can be added. The use of additives in flavourings might therefore represent a path by which non-authorised additives could enter foods without needing to be labelled.*

*The general principle set out in the new paragraph 1(b) on the incorporation of additives in flavourings therefore needs to be clarified substantially.*

Amendment 9  
ARTICLE 1, POINT 3 A (new)

***(3a) Within two years of the entry into force  
of this Directive, the Commission shall  
submit a proposal to the European  
Parliament and the Council which limits  
the total number of food additives  
authorised.***

*Justification*

*The ever increasing number of food additives leads to a cumulation of a large number of small risks for food safety, which are not easily evaluable, and which might create synergy effects between different substances. The total number of authorised food additives should therefore be limited, so that the industry, when applying for a new authorisation, has to make a proposal for withdrawing an additive of little use.*

Amendment 10  
ANNEX, POINT 6 (D)  
Annex IV (Directive 95/2/EC)

Text proposed by the Commission

(d) the following foodstuffs and maximum levels concerning E 432 to E 436 are added:

		'Flavourings, except liquid smoke flavourings and flavourings based on spice oleoresins	10 g/kg
		Liquid smoke flavourings and flavourings based on spice oleoresins	75 g/kg

Amendment by Parliament

(d) the following foodstuffs and maximum levels concerning E 432 to E 436 are added:

		'Flavourings, except liquid smoke flavourings and flavourings based on spice oleoresins	10 g/kg
		<b><i>Foods containing liquid smoke flavourings and flavourings based on spice oleoresins</i></b>	<b><i>1 g/kg as consumed or as reconstituted according to the instructions of the manufacturer</i></b>

*Justification*

*This specifies a 1g/kg limit to the amount of E432 to E436 polysorbates in the final foodstuff where liquid smoke flavourings and flavourings based on spice oleoresins are used, rather than specifying a limit to the amount of these additives in the flavouring itself, as a better way of controlling the amount of these polysorbates in foodstuffs; 1g/kg is the lowest level already authorised in certain foods by Directive 95/2/EC; and by setting the level of additive in the foodstuff, the additive has to be labelled on final food products.*

Amendment 11  
ARTICLE 1, POINT 3 A (new)

***(3a) Within two years of entry into force of this Directive, the Commission and the European Food Safety Authority shall review the conditions for the use of hydrogenated poly-1-decene focusing, as***

***regards maximum content, on the effects  
on children's health.***

*Justification*

*In line with the approaches in other related legislation the use of hydrogenated poly-1-decen must be revised especially with respect to children. Hydrogenated poly-1-decene is among other things used as a glazing agent in products like candy.*

Amendment 12

ARTICLE 1, POINT 3 A (new), PARAGRAPH 1 (new)

***Within two years of entry into force of this  
Directive, the Commission and the  
European Food Safety Authority shall  
review the conditions for use of  
polysorbates E 432-436, as regards  
maximum content, on the effects on public  
health.***

*Justification*

*Polysorbates are used as preservatives in cakes, cheeses and wines, for example. Extended use may be assumed to cause damage to health; it is therefore important that their use is subject to review.*

Amendment 13  
ARTICLE 1, POINT 3 A (new), PARAGRAPH 2 (new)

***Before 1 July 2004, the Commission and the European Food Safety Authority shall review the conditions for the use of Parabens E 214-219 and Succinate D- $\alpha$ -tocopheryl acid succinate (TAS) in line with the statements of the Scientific Committee on Food of 4 April 2003.***

*Justification*

*Parabens are used as a preservative in surface treatment of dried meat products, cereal- or potato-based snacks and coated nuts etc. and can cause cell proliferation in the forestomach and developmental toxicity.*

*Succinate D- $\alpha$ -tocopheryl acid succinate (TAS) is a substance that might be used as a source of vitamin E for products of particular nutritional needs, consequently having antioxidant properties.*

*The Scientific Committee on Food has in two different statements of 4 April 2003 expressed concern about the further use of parabens and succinates.*

Amendment 14  
ARTICLE 1, POINT 3 A (new), PARAGRAPH 3 (new)

***Before 1 July 2004, the Commission and the European Food Safety Authority shall review the conditions for the use of nitrite and nitrate E 249-252.***

*Justification*

*Nitrites and nitrates are used in food and have a preservative effect but may also cause cancer. The use of these substances should therefore be restricted as far as possible. The Court of Justice ruled on 20 March 2003 in case C-3/00 that a Member State could, in accordance with Article 95(4) of the EC Treaty, introduce more restrictive environmental protection measures than the EU in relation to nitrites and nitrates. The Court stresses that Directive 95/2 establishes a much higher ceiling for nitrite and nitrate additives than the Scientific Committee's earlier recommendation. The Court finds it necessary to reduce the quantity of nitrite and nitrate additives in food to the minimum required to achieve the preservative effect and to protect against health risks.*

Amendment 15  
ANNEX, POINT 5(B)  
Annex III, part D (Directive 95/2/EC)

(b) in the list of foodstuffs concerning E 315 and E 316, the designation ‘Semi-preserved and preserved meat products’ is replaced by the following: ‘Cured meat products and **canned** meat products’

(b) in the list of foodstuffs concerning E 315 and E 316, the designation ‘Semi-preserved and preserved meat products’ is replaced by the following: ‘Cured meat products and **preserved** meat products’

*Justification*

*The new wording helps to avoid confusion.*

Amendment 16

ANNEX, POINT 6 (A)  
Annex IV (Directive 95/2/EC)

Text proposed by the Commission

(a) the following foodstuff and maximum level concerning E338 to E452 are added:

		'Flavourings	<b>50 g/kg'</b>
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Amendment by Parliament

(a) the following foodstuff and maximum level concerning E338 to E452 are added:

		'Flavourings	<b>40 g/kg'</b>
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*Justification*

*Without reducing the level so much as to make it difficult for manufacturers to gain any technological function from these phosphates, this amendment reduces the maximum level for E338 to E452 phosphates in flavourings to ensure that even if the flavouring comprised 1% of the foodstuff (the usual level is about 0.1%), the amount of phosphates in the foodstuff would be safely below the 500mg/kg limit for phosphates in foodstuffs.*

Amendment 17

ANNEX, POINT 6 (D A) (new)  
Annex IV (Directive 95/2/EC)

***(da) The following foodstuff and maximum level concerning E 444 is added:***

		<b><i>"Cloudy spirituous beverages containing less than 15% alcohol by volume"</i></b>	<b><i>300 mg/l"</i></b>
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#### *Justification*

*The inclusion of this new use of E 444 responds to a request from the industry which came too late to be included in the amendment to the Directive. E 444 is a stabiliser used to prevent flavouring oils in aqueous solutions from rising to the surface of the drink and oxidising on contact with the air. The technological justification provided is a reasonable one.*

*Additive E 444 is currently approved for non-alcoholic flavoured cloudy drinks at a maximum level of 300 mg/l. The report on dietary food additive intake in the European Union (COM(2001) 542 final) states that theoretical food consumption data did not exceed the maximum permitted use levels, and consequently the additive does not present a hazard.*

#### Amendment 18 ANNEX, POINT 6(E) Annex IV (Directive 95/2/EC)

***(e) in the list of foodstuffs concerning E 541, the designation 'Fine bakery wares (scones and sponge wares only)' is replaced by the following: 'Fine bakery wares'*** ***Deleted***

#### *Justification*

*According to the Commission report COM(2001) 542 final, the provisional tolerable weekly intake for additive E 541 is 7 mg/kg, and national data on the average consumption of foodstuffs indicate that the maximum authorised usage levels are being exceeded. Taking the above document as a reference (60 kg being the reference body weight for an adult), the weekly amount would stand at:*

*7 mg/kg x 60 kg = 420 mg per week.*

*Bearing in mind that the maximum level for E 541 is 1 g/kg, we can conclude that it is not advisable to extend the uses for this additive.*

## EXPLANATORY STATEMENT

Scientific and technological progress enables us to: (1) enjoy higher-quality food products thanks – among other things – to the use of small quantities of food additives, and (2) prevent their inappropriate use.

Directive 89/107/EEC<sup>1</sup> represents the general framework for the regulation of additives used in food products intended for human consumption. That directive lays down the various categories of additives and constitutes the 'horizontal' legislative framework for regulating these substances.

Directives 94/35/EC<sup>2</sup>, 94/36/EC<sup>3</sup> and 95/2/EC provide 'vertical' regulation for each of these categories of food additives. Directive 95/2/EC, which the Commission is now proposing to amend, regulates all food additives other than colours and sweeteners.

Unlike sweeteners and colours, the bulk of the additives regulated by Directive 95/2/EC are obtained from natural raw materials. These are substances which are needed to improve the preservation of food, prevent oxidation, control pH levels, regulate mixtures and dispersions, enhance flavours or improve appearance, to list only some examples.

The image of food additives among consumers has deteriorated in recent years. This situation has not brought about a shift in the consumption of certain food products for the simple reason that these are products of primary consumption, i.e. they cannot easily be substituted. The combined impact of food crises, lack of knowledge and media pressure has undermined consumer confidence in food.

Furthermore, such developments undoubtedly exert pressure on the work of legislators. In these circumstances, we are faced with a paradoxical situation in which the legislator, 'for political reasons', sometimes departs from scientific opinion, which is in most cases unanimous.

We are living in an age when food safety is very sound. Production methods are being further improved, checks on food and risk assessment are increasingly frequent, labelling and packaging requirements are more stringent, quality food has become fashionable, and we also have a new European Food Safety Authority, which is still in the process of being formed.

In the case of food additives, the risk can be considered non-existent. The Scientific Committee for Food (SCF) carries out regular new evaluations of additives wherever there are reasonable doubts regarding their usefulness and safety. Under Annex II to Directive 89/107/EEC, approved food additives must meet three conditions:

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<sup>1</sup> Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption; OJ L 40, 11.2.1989, p. 27. Directive amended by Directive 94/34/EC of the European Parliament and of the Council; OJ L 237, 10.9.1994, p. 1.

<sup>2</sup> European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs; OJ L 237, 10.9.1994, p. 3.

<sup>3</sup> European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs; OJ L 237, 10.9.1994, p. 13.

- that a reasonable technological need can be demonstrated and the purpose cannot be achieved by other means which are economically and technologically practicable;
- that the additive does not present any hazard to the health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available;
- that they do not mislead the consumer.

Moreover, the method of calculating the acceptable daily intake (ADI) includes precautionary elements which guarantee that total consumption of an additive will always remain far below the intake which might actually pose a risk. Nowadays, there are more cases of allergies to natural foods (wheat, dairy products and eggs) than problems linked to the use of food additives.

On 1 October 2001 the Commission published a report<sup>1</sup> on monitoring the intake of food additives in the European Union. This is an excellent report in which the Commission explains all the steps taken to determine which additives may present a health risk and set priorities for the future.

It is made clear on the first page of this report that food consumption data was insufficient and that some Member States were not using the agreed methodology. The Commission was therefore obliged to use the most pessimistic working hypotheses so that it could finish the report within the time limits laid down in the legislation.

That report provides a series of definitions in relation to ADIs which the Rapporteur considers helpful in order to gain an overall understanding of the amendments to Directive 95/2/EC proposed by the Commission:

**Acceptable daily intake (ADI):** The amount of a food additive, expressed as mg/kg body weight, that can be ingested daily over a lifetime without incurring any appreciable health risk. The ADI is based on an evaluation of available toxicological data and established by identifying the No-Observed-Adverse-Effect-Level in the most sensitive experiment among a battery of studies in test animals performed with the test compound and extrapolating to man.

**ADI 'not specified':** A term used when, on the basis of the available toxicological, biochemical and clinical data, the total intake of the substance, arising from its natural occurrence and/or its present use or uses in food at the levels necessary to achieve the desired technological effect, will not represent a hazard to health. For this reason, the establishment of a numerical limit for the ADI is not considered necessary for the substance.

**Maximum usage level:** Highest level of a food additive permitted in foodstuff to achieve an intended technological effect. The levels are set in the specific directives.

**Quantum satis:** no maximum level is specified for the additive in question. However, the additive shall be used in accordance with good manufacturing practice, at a level not higher than necessary to achieve the intended purpose and provided that it does not mislead the consumer.

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<sup>1</sup> COM (2001) 542 final, 1.10.2001, on dietary food additive intake in the European Union.

Attention should also be drawn to the existence of food additives which are also utilised for the storage and use of **flavourings**. This applies to certain preservatives and anti-caking agents; using such additives improves the preservation of the flavouring or ensures that it can be evenly dispersed in the food product concerned.

The final concentration of these additives in the food product is minimal once the flavouring is incorporated in the product. Such additives therefore need to be included in the present directive for use in flavourings in order to meet the 'technological need' requirement laid down in Directive 89/107/EEC. At all events, the Rapporteur is proposing a number of amendments to guarantee that the incorporation of additives in flavourings does not pose any risk and is as transparent as possible.

### **Assessment of the Commission proposal**

The Environment Committee endorses most elements of the Commission proposal, but it believes that some parts need to be modified or added on. It also wants to ensure regular review of authorisations for food additives.

First of all, the Commission suggests to widen the definition of 'stabilisers' in order to include substances which increase the binding capacity of food. The Committee follows the recommendation of its Rapporteur to oppose this new definition as it would also cover certain enzymes despite the fact that enzymes are generally excluded from the scope of Directive 95/2/EC.

The authorisation of hydrogenated poly-1-decene (E 907) reflects fully the arguments set out in the SCF report<sup>1</sup>. The Committee insists however on the Commission and the European Food Safety authority to review the conditions of its use. Further review clauses have been inserted as regards the authorisation of polysorbates E 432-436 and Parabens E 214-219.

In accordance with a ruling of the Court of Justice on 20 March 2003 (Case C-3/00) in which the Court held that the quantity of nitrite and nitrate should be reduced to the minimum necessary, the Committee takes the stand that the review of its use is of particular priority and should therefore be carried out before 1 July 2004.

Apart from the review of specific substances, the Committee also calls upon the Commission to evaluate comprehensively the use of all food additives, including colours and sweeteners, before 31 December 2006 and to present a proposal to limit the total number of authorised food additives.

The Committee voices particular concern as regards the substances Biphenyl (E 230), orthophenyl phenol (E 231) and sodium orthophenyl phenol (E 232) whose authorisation the Commission suggests to withdraw; an amendment by the Rapporteur found approval which calls upon Member States and the Commission to take all possible steps to ensure that there is no legal vacuum with regard to these substances.

The Committee agrees with its Rapporteur that the proposal by the Commission to replace in

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<sup>1</sup> Opinion of the Scientific Committee on Food on hydrogenated poly-1-decene, SCF/CS/ADD/MsAd/199 final, 12.7.2001.

the list of foodstuffs concerning E 315 and E 316 the designation 'Semi-preserved and preserved meat products' by 'Cured meat products and canned meat products' does not entirely avoid confusion about the terms. The Committee feels that this formulation can be improved by using the term 'preserved' instead of 'canned' in order to include also preserving foodstuff in containers other than cans.

The withdrawal of authorisation for calcium hydrogen carbonate (E 170ii) and phosphates (E 338, E 339, E 340, E 341, E 343, E 450, E 451 and E 452) as additives in cider and perry is justified because there is no technological need for these additives.

The Committee wants to reduce the maximum level for E 338 to E 452 phosphates in flavourings to 40g/kg - as opposed to 50g/kg proposed by the Commission - so as to ensure that even if the flavouring comprised 1% of the foodstuff (the usual level is about 0.1%), the amount of phosphates in the foodstuff would be safely below the 500mg/kg limit for phosphates in foodstuffs.

Additives E 407a, E 466, E 469, E 472c, E 296, E 440, E 509, E 460ii, E 331, E 410, E 412, E 415, E 1105, E 551, E 903, E 459, E 1518, E 1520, E 468, E 1450 and E 472c fall within the list of additives with ADI 'not specified', which means that their use does not pose any risk. The uses for which they have been authorised are fully justified.

A comparison has been made between the theoretical food consumption data and the maximum levels of use authorised for additives E 200, E 202, E 203, phosphates (E 338, E 339, E 340, E 341, E 343, E 450, E 451 and E 452) and E 900.

A comparison has likewise been made between national data on average food consumption and the maximum use levels authorised for additives E 210, E 211, E 212, E 213, E 310, E 311, E 312, E 320, E 315, E 316 and E 416. According to the estimates given in the Commission's intake report, they do not pose any health risk.

Additives E 1505, E 1517 and E 1519 are authorised for use as carrier solvents in flavourings.

Additives E 432 to E 436 are authorised for use as emulsifiers in flavourings. Their incorporation in flavourings should be controlled by focusing on the amount in the final foodstuff rather than specifying a limit to the amount of these additives in the flavouring itself. The Committee believes that 1g/kg is an adequate limit; by setting the level of additive in the foodstuff, the additive has to be labelled on final food products.

The Committee takes the stand that E 444 should be included in the list of permitted additives in Annex IV of Directive 95/2/EC. E 444 is a stabiliser used to prevent flavouring oils in aqueous solutions from rising to the surface of the drink and oxidising on contact with the air which is currently approved for non-alcoholic flavoured cloudy drinks at a maximum level of 300 mg/l. The report on dietary food additive intake in the European Union (COM(2001) 542 final) states that theoretical food consumption data do not exceed the maximum permitted use levels, and consequently the additive is not a health hazard.

Additive E 555 is authorised for use as a carrier for certain food colours; on the other hand, the Committee believes that the use of additive E 541 should not be extended to other purposes given that the proposed limits are close to the tolerable intake.

Finally, the Committee agrees with the Rapporteur that the use of additives in flavourings must not represent a path by which non-authorised additives could enter foods without needing to be labelled. It therefore approves the insertion in Article 3 of Directive 95/2/EC of a clause stipulating that the level of additives present in flavourings shall be limited to the minimum necessary to guarantee the safety and quality of flavourings and to facilitate their storage.