



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 9.10.2003
COM(2003) 583 final

2002/0274 (COD)

Amended Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 95/2/EC on food additives other than colours and sweeteners

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

EXPLANATORY MEMORANDUM

1. PROCEDURE

On 29 November 2002, the Commission adopted a proposal for a Directive of the European Parliament and Council amending Directive 95/2/EC on food additives other than colours and sweeteners^A. The proposal was sent to the European Parliament and the Council on the same day. The European Economic and Social Committee issued its opinion supporting the Commission proposal on 14 May 2003.

On 25 June 2003, Coreper agreed unanimously on a revised text.

On 3 July 2003, the European Parliament voted in favour of amendments in line with the revised text resulting from Coreper.

As there is agreement between the European Parliament and the Council, it is the intention of the Council to adopt the proposal as an A point during the Italian presidency.

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The Commission proposed to amend Directive 95/2/EC as follows:

- To authorise a new food additive
- To withdraw the authorisation for the use of some food additives
- To extend the authorisations for use of some already authorised food additives
- To clarify the scope of the functional class “stabilisers”
- To harmonise the use of food additives in flavourings at Community level.

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

The Commission can accept all the amendments adopted by the European Parliament.

4. CONCLUSION

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

^A COM(2002) 662 final - 2002/0274 (COD)

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DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 95/2/EC on food additives other than colours and sweeteners

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the **European** Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty³,

Whereas:

- (1) Food additives may be approved for use in foodstuffs only if they comply with Annex II to 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 consumption⁴.
- (2) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners⁵ lays down a list of food additives that may be used in the Community and the conditions for their use.
- (3) There have been technical developments in the field of food additives since the adoption of Directive 95/2/EC. That Directive should be adapted to take account of those developments.
- (4) Council 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 production⁶ provides for the adoption of a list of additives necessary for the storage and use of flavourings, and the adoption of any special conditions for the use of such additives that may be necessary for the protection of public health and to ensure fair trade.

¹ **COM(2002) 662 final - 2002/0274 (COD)** OJ C , , p. .

² **NAT/173 – CESE 581/2003** OJ C , , p. .

³ [...]

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

⁵ OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2001/5/EC (OJ L 55, 24.2.2001, p. 59).

⁶ OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 47, 15.2.1991, p. 25).

- (5) It is desirable to incorporate into Directive 95/2/EC those measures on additives necessary for the storage and use of flavourings, in order to contribute to transparency and consistency of Community legislation, and to facilitate compliance with Community legislation on food additives by food manufacturers, especially by small and medium size enterprises. In addition, according to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁷, flavourings fall within the definition of 'food'.
- (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 **be guaranteed correct, adequate and non-misleading information** ~~not be misled~~ on the use of additives.
- (7) The presence of an additive in a foodstuff, due to the use of a flavouring, is generally low and the additive does not have a technological function in the foodstuff. However, if under certain circumstances the additive does have a technological function in the compound foodstuff, it should be considered as an additive of the compound foodstuff and not as an additive of the flavouring, and the relevant rules relating to the additive in the particular foodstuff should 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 foodstuffs⁸.
- (8) Food manufacturers should be informed about the concentrations of all additives in flavourings in order to enable them to comply with Community legislation. This is in accordance with Directive 88/388/EEC, which requires quantitative labelling of each component subject to a quantitative limitation in a foodstuff. **A quantitative limitation is expressed either numerically or by the "quantum satis" principle.**
- (9) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring market unity and a high level of consumer protection to lay down rules on the use of additives in flavourings. This Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.
- (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/EC⁹, hydrogenated poly-1-decene, which was authorised at national level under Directive 89/107/EEC, should be approved at Community level.
- (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

⁷ OJ L 31, 1.2.2002, p. 1.

⁸ OJ L 109, 6.5.2000, p. 29. Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p.19).

⁹ OJ L 237, 28.8.1997, p. 18. Decision as amended by Decision 2000/443/EC (OJ L 179, 18.7.2000, p. 13).

of 15 July 1991 concerning the placing of plant protection products on the market¹⁰. 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.**

(12) On 4 April 2003, the Scientific Committee on Food stated that the temporary acceptable daily intake for E 214 to E 219 p-hydroxybenzoic acid alkyl esters and their sodium salts should be withdrawn if no further data are submitted in respect to intake and toxicity.

(13) Directive 95/2/EC should therefore be amended accordingly.

(14) Council Directive 67/427/EEC¹¹ lays down the control measures on preservatives in and on citrus fruits. Since those preservatives are no longer authorised for use in citrus fruits by Directive 95/2/EC, it is necessary to repeal that Directive.

(15) The Scientific Committee on Food has been consulted on the adoption of provisions liable to have an effect on public health, pursuant to Article 6 of Directive 89/107/EEC,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 95/2/EC is amended as follows:

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

“(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.”

(2) The following paragraphs are inserted after Article 2 (8):

“9. For E 231 orthophenyl phenol and E 232 sodium orthophenyl phenol, point (4)(a) of the Annex shall enter into force as soon as requirements for the labelling of food treated with these substance(s) become applicable by virtue of Community legislation on maximum residue limits for pesticides.

10. Before 1 July 2004, the Commission and the European Food Safety Authority shall review the conditions for the use of the additives E 214 to E 219.

¹⁰ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2002/64/EC (L 189, 18.7.2002, p. 27).

¹¹ OJ L 148, 11.7.1967, p. 1.

11. Within 2 years after entry into force of this Directive, the Commission shall submit to the European Parliament and the Council a report on the progress of the re-evaluation of additives. This re-evaluation shall in particular focus on E 432 to E 436 (polysorbates) as well as E 251 and E 252 (nitrates) and E 249 and E 250 (nitrites)."

(3)(2) Article 3(1) is replaced by the following:

“1. The presence of a food additive in a foodstuff is permissible:

- (a) in a compound foodstuff other than one mentioned in Article 2 (3) to the extent that the food additive is permitted in one of the ingredients of the compound foodstuff;
- (b) in a foodstuff where a flavouring has been added to the extent that the food additive is permitted in the flavouring in compliance with this Directive and has been carried over to the foodstuff via the flavouring, provided the food additive has no technological function in the final foodstuff; or
- (c) if the foodstuff is destined to be used solely in the preparation of a compound foodstuff and to an extent such that the compound foodstuff conforms to the provisions of this Directive.”

(4) **The following paragraph is inserted after Article 3 (2):**

“3. As regards additives in flavourings, the level of additives 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 and shall not present a hazard to the health of consumers. If the presence of an additive in a food, as a consequence of adding flavourings, has a technological function in the food, it shall be considered as an additive of the food and not as an additive of the flavouring.”

(5)(3) The Annexes are amended as set out in the Annex to this Directive.

Article 2

Directive 67/427/EEC is repealed.

Article 3

Member States shall ~~bring into force~~**adopt and publish, before [...],** the laws, regulations and administrative provisions necessary to comply with this Directive **in order to:.** ~~They shall forthwith inform the Commission thereof.~~

~~They shall apply those provisions in such a way that:~~

- **authorise trade in and use of products conforming with this Directive by [18 months after entry into force] at the latest,**

~~(a) — trade in and use of products which comply with this Directive are permitted from [18 months after entry into force];~~

– prohibit trade in and use of products not conforming with this Directive by [24 months after entry into force] at the latest; however, products placed on the market or labelled before that date which do not comply with this Directive may be marketed until stocks are exhausted.

~~(b) — trade in and use of products which do not comply with this Directive are prohibited from [24 months after entry into force].~~

~~However, products put on the market or labelled before the date specified in point (b) and which do not comply with this Directive may be marketed until stocks of such products are exhausted.~~

They shall inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX

The Annexes to Directive 95/2/EC are amended as follows:

(1) In Annex I:

(a) Note 2 is replaced by the following:

‘2. The substances listed under numbers E 407, E 407a and E 440 may be standardised with sugars, on condition that this is stated in addition to the number and designation.’

(b) in the list of additives, **the entry for E 170 is replaced by “E 170 Calcium carbonate”**. ~~the following is deleted: “(ii) Calcium hydrogen carbonate”~~

(c) in the list of additives, for E 466 the name “Cellulose gum” is added and for E 469 the name “Enzymatically hydrolysed cellulose gum” is added.

(2) In Annex II:

(a) the following is added to the list of additives and the maximum levels concerning ‘Cocoa and chocolate products as defined in Directive **2000/36/EC**’:

	‘E 472c Citric acid esters of mono- and diglycerides of fatty acids	<i>Quantum satis</i> ’
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(b) the following is inserted in the list of additives and the maximum level for ‘Frozen and deep-frozen unprocessed fruit and vegetables; prepacked, refrigerated unprocessed fruit and vegetables ready for consumption and prepacked, unprocessed and peeled potatoes’:

	‘ E 296 Malic acid	<i>Quantum satis</i> (only for peeled potatoes)’
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(c) the following is added to the list of additives and the maximum level for ‘Fruit compote’:

	‘ E 440 Pectin E 509 Calcium chloride	<i>quantum satis</i> (only for fruit compote other than apple)’
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(d) the following is inserted in the list of additives and the maximum level for ‘*Mozzarella* and whey cheese’:

	‘ E 460ii Powdered cellulose	<i>quantum satis</i> (only for grated <u>and sliced cheese <i>Mozzarella</i></u>)’
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(e) the following rows are added at the end of the Annex:

‘UHT goat milk	E 331 Sodium citrates	4 g/l
Chestnuts in liquid	E 410 Locust bean gum E 412 Guar gum E 415 Xanthane gum	<i>Quantum satis</i> ’

(f) the entries “ E 170 Calcium carbonates” shall be read “E 170 Calcium carbonate”.

(3) In Part A of Annex III:

(a) the designation ‘Partially baked, pre-packed bakery wares intended for retail sale’ is replaced by the following: ‘Partially baked, pre-packed bakery wares **intended for retail sale** and energy-reduced bread **intended for retail sale**’

(b) at the end of this Part, the following rows are added:

<u>‘Crayfish tails, cooked, and pre-packed marinated cooked molluscs</u>	<u>2000</u>					
‘Flavourings				1500’		
<u>Dairy or fat based spreads with added foodstuffs</u>	<u>1500’</u>					

(4) In Part C of Annex III:

(a) the following rows are deleted:

‘E 230	Biphenyl, diphenyl	Surface treatment of citrus fruit	70 mg/kg
E 231	Orthophenyl phenol	Surface treatment of citrus fruit	12 mg/kg individually or in combination expressed as orthophenyl phenol’
E 232	Sodium orthophenyl phenol		

(b) the following foodstuff is added to E 1105:

'E 1105	Lysozyme	Wine in accordance with Regulation (EC) No 1493/1999 ¹² and its implementing Regulation (EC) No 1622/2000 ¹³	<i>Pro memoria</i>
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(5) In Part D of Annex III:

(a) the following foodstuffs and maximum levels are added to E 310, E 311, E 312 and E 320:

'E 310	Propyl gallate	Essential oils	1000 mg/kg (gallates and BHA, individually or in combination)
E 311	Octyl gallate		
E 312	Dodecyl gallate		
E 320	Butylated hydroxyanisole (BHA)	Flavourings other than essential oils	100 mg/kg (gallates, individually or in combination) or 200 mg/kg (BHA)

(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 canned** meat products'

(6) In Annex IV:

(a) the following foodstuff and maximum level concerning E 338 to E 452 are added:

		'Flavourings	40 50 g/kg'
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(b) the following foodstuff and maximum level concerning E 338 to E 452 are deleted:

		'Cider and perry	2 g/l'
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(c) the following foodstuff and maximum level are added to E 416:

'E 416	Karaya gum	Flavourings	50 g/kg'
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(d) the following foodstuffs and maximum levels concerning E 432 to E 436 are added:

		'Flavourings, except liquid smoke flavourings and flavourings based	10 g / kg
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¹² OJ L 179, 14.4.1999, p.1.

¹³ OJ L 194, 31.7.2000, p.1.

		on spice oleoresins* <u>Foods containing</u> Liquid smoke flavourings and flavourings based on spice oleoresins	<u>175</u> g/kg'
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* Spice oleoresins are defined as extracts of spices from which the extraction solvent has been evaporated leaving a mixture of the volatile oil and resinous material from the spice'

(e) **the following foodstuffs and maximum levels concerning E 444 are added: 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'**

		<u>'Flavoured cloudy spirit drinks containing less than 15 % alcohol by volume</u>	<u>300 mg/l</u>
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(f) the following foodstuff and maximum level concerning E 551 to E 559 are added:

		'Flavourings	50 g / kg (only E 551)'
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(g) the following foodstuff and maximum level are added to E 900:

'E 900	Dimethyl polysiloxane	Flavourings	10 mg/kg'
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(h) in the list for foodstuffs and maximum levels for E 903, the maximum levels are replaced by the following:

'E 903	Carnauba wax	As glazing agents only:	
		- confectionery (including chocolate)	500 mg/kg
		.	1200 mg/kg (only for chewing gum)
		- small products of fine bakery wares coated with chocolate	200 mg/kg
		- snacks	200 mg/kg
		- nuts	200 mg/kg
		- coffee beans	200 mg/kg
		- dietary food supplements	200 mg/kg
		- fresh citrus fruits, melons, apples, pears, peaches and pineapples (surface treatment	200 mg/kg'

		only)	
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(i) the following foodstuffs and maximum levels are added to E 459:

'E 459	Beta-cyclodextrin	Encapsulated flavourings in - flavoured teas and flavoured powdered instant drinks - flavoured snacks	500 mg/10,5 g/kg 1 g/kg in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer'
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(j) the following row is added at the end of the Annex:

'E 907	Hydrogenated poly-1-decene	As glazing agent for - sugar confectionery - dried fruits	2 g/kg 2 g/kg
E 1505 E 1517 E 1518 · E 1520	Triethyl citrate Diacetin Glyceryl triacetate (triacetin) Propan-1,2-diol (propylene glycol)	Flavourings	3 g/kg from all sources in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer; individually or in combination. <u>In the case of beverages, the maximum level of E 1520 shall be 1g/l.</u>
E 1519	Benzyl alcohol	Flavourings for – non-alcoholic flavoured drinks - liqueurs, aromatised wines, aromatised wine-based drinks and aromatised wine-products cocktails - confectionery <u>including chocolate</u> and fine bakery wares	50 mg/kg 100 mg/ kg 250 mg/kg from all sources in

			foodstuffs as consumed or as reconstituted according to instruction of the manufacturer.'
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(7) In Annex V:

(a) the following row is added:

'E 555	Potassium aluminium silicate	In E 171 titanium dioxide and E 172 iron oxides and hydroxides (max 90% relative to the pigment)'
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(b) for E 468 the name "Cross-linked cellulose gum" is added.

(8) In Annex VI:

(a) in the introductory note, the following subparagraph is inserted after the first subparagraph:

'Formulae and weaning foods for infants and young children may contain E 1450 starch sodium octenyl succinate resulting from the addition of vitamin preparations or polyunsaturated fatty acid preparations. The carry over of E 1450 in the product ready for consumption is not to be more than 100 mg/kg from vitamin preparations and 1000 mg/kg from polyunsaturated fatty acid preparations.'

(b) in Part 4, the title is replaced by the following:

'Food additives permitted in dietary foods for infants and young children for special medical purposes as defined in Commission Directive 1999/21/EC' **

** Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes, (OJ L 91, 7.4.1999, p. 29).'

(c) in Part 4, the following is added to the table:

E 472c	Citric acid esters of mono- and diglycerides of fatty acids	7,5 g/l sold as powder 9 g/l sold as liquid	From birth onwards'
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