

DIRECTIVE 2003/114/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 December 2003
amending Directive 95/2/EC on food additives other than colours and sweeteners

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 Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

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 consumption ⁽³⁾.
- (2) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ⁽⁴⁾ 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 production ⁽⁵⁾ 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.

(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-sized 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 safety ⁽⁶⁾, 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 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 foodstuffs ⁽⁷⁾.

(8) In accordance with Directive 88/388/EEC, food manufacturers should be informed about the concentrations of all additives in flavourings in order to enable them to comply with Community legislation. That Directive also 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.

⁽¹⁾ OJ C 208, 3.9.2003, p. 30.

⁽²⁾ Opinion of the European Parliament of 3 July 2003 (not yet published in the Official Journal), and Decision of the Council of 1 December 2003.

⁽³⁾ OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).

⁽⁴⁾ OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2003/52/EC (OJ L 178, 17.7.2003, p. 23).

⁽⁵⁾ OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

⁽⁶⁾ OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

⁽⁷⁾ OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

- (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 does not go beyond 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 by Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety ⁽¹⁾, hydrogenated poly-1-decene, which was authorised at national level under Directive 89/107/EEC, should be authorised 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 of 15 July 1991 concerning the placing of plant protection products on the market ⁽²⁾. 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 to place on the market 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 of intake and toxicity.
- (13) Directive 95/2/EC should therefore be amended accordingly.
- (14) Council Directive 67/427/EEC of 27 June 1967 on the use of certain preservatives for the surface treatment of citrus fruit and on the control measures to be used for the qualitative and quantitative analysis of preservatives in and on citrus fruit ⁽³⁾ 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 Directive 67/427/EEC.
- (15) The Scientific Committee on Food has been consulted on the adoption of provisions that may have an effect upon public health, pursuant to Article 6 of Directive 89/107/EEC,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 95/2/EC is hereby amended as follows:

1. Article 1(3)(v) shall be 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. Article 3 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. The presence of a food additive is permissible:

- (a) in a compound foodstuff other than one mentioned in Article 2(3), to the extent to which 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 to which 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;'

(b) the following paragraph shall be added:

'3. The level of additives 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 consumers or present a hazard to their health. If the presence of an additive in a foodstuff, as a consequence of adding flavourings, has a technological function in the foodstuff, it shall be considered as an additive of the foodstuff and not as an additive of the flavouring;'

3. the Annexes shall be amended as set out in the Annex to this Directive.

Article 2

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

⁽¹⁾ OJ L 237, 28.8.1997, p. 18. Decision as amended by Decision 2000/443/EC (OJ L 179, 18.7.2000, p. 13).

⁽²⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽³⁾ OJ 148, 11.7.1967, p. 1.

2. Before 27 January 2006, 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).

Article 3

Directive 67/427/EEC shall be repealed.

Article 4

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive in order to:

- authorise trade in and use of products conforming with this Directive by 27 July 2005 at the latest,
- prohibit trade in and use of products not conforming with this Directive by 27 January 2006 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.

They shall forthwith inform the Commission thereof.

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

Article 5

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 22 December 2003.

For the European Parliament

The President

P. COX

For the Council

The President

A. MATTEOLI

ANNEX

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

1. in Annex I:

(a) Note 2 shall be 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 entire entry for E 170 shall be replaced by 'E 170 Calcium carbonate';
- in the entry for E 466, the name 'Cellulose gum' shall be added,
- in the entry for E 469, the name 'Enzymatically hydrolysed cellulose gum' shall be added;

2. in Annex II:

(a) the name 'E 170 Calcium carbonates' shall be replaced throughout by 'E 170 Calcium carbonate';

(b) the following shall be 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'	quantum satis'
--	--	----------------

(c) the following shall be 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'	quantum satis (only for peeled potatoes)'
--	--------------------	---

(d) the following shall be added to the list of additives and the maximum level for 'Fruit compote':

	'E 440 Pectin E 509 Calcium chloride'	quantum satis (only for fruit compote other than apple)'
--	--	--

(e) the following shall be inserted in the list of additives and the maximum level for 'Mozzarella and whey cheese':

	'E 460ii Powdered cellulose'	quantum satis (only for grated and sliced cheese)'
--	------------------------------	--

(f) the following rows shall be 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	quantum satis'

3. in Annex III:

A. part A shall be amended as follows:

(a) the designation 'Partially baked, pre-packed bakery wares intended for retail sale' shall be 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 shall be added:

'Crayfish tails, cooked, and prepacked marinated cooked molluscs'	2 000					
Flavourings				1 500'		

B. part C shall be amended as follows:

(a) the following rows shall be 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 (*)		

(*) The deletion of E 231 orthophenyl phenol and E 232 sodium orthophenyl phenol shall enter into force as soon as requirements for the labelling of foodstuffs treated with these substances become applicable by virtue of Community legislation on maximum residue limits for pesticides.'

(b) the following foodstuff shall be added to E 1105:

		'Wine in accordance with Regulation (EC) No 1493/1999 (*) and its implementing Regulation (EC) No 1622/2000 (**)	Pro memoria
--	--	--	-------------

(*) Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine (OJ L 179, 14.7.1999, p.1). Regulation as last amended by Commission Regulation (EC) No 1795/2003 (OJ L 262, 14.10.2003, p. 1).

(**) Commission Regulation (EC) No 1622/2000 of 24 July 2000 laying down certain detailed rules for implementing Regulation (EC) No 1493/1999 on the common organisation of the market in wine and establishing a Community code of oenological practices and processes (OJ L 194, 31.7.2000, p.1). Regulation as last amended by Regulation (EC) No 1410/2003 (OJ L 201, 8.8.2003, p. 9).'

C. part D shall be amended as follows:

(a) the following foodstuffs and maximum levels shall be added at the end of this part:

E 310	Propyl gallate	Essential oils	1 000 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' shall be replaced by the following: 'Cured meat products and preserved meat products';

4. in Annex IV:

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

		'Flavourings	40 g/kg'
--	--	--------------	----------

(b) the following foodstuff and maximum level concerning E 338 to E 452 shall be deleted:

		'Cider and perry	2 g/l'
--	--	------------------	--------

(c) the following foodstuff and maximum level shall be added to E 416:

		'Flavourings	50 g/kg'
--	--	--------------	----------

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

		'Flavourings, except liquid smoke flavourings and flavourings based on spice oleoresins (*)	10 g/kg
		Foodstuffs containing liquid smoke flavourings and flavourings based on spice oleoresins	1 g/kg

(*) 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 foodstuff and maximum level concerning E 444 shall be added:

		'Flavoured cloudy spirit drinks containing less than 15 % alcohol by volume	300 mg/l'
--	--	---	-----------

(f) the following entry concerning E 551 shall be inserted after the list of foodstuffs and maximum levels for E 535 to E 538:

'E 551	Silicon dioxide	Flavourings	50 g/kg'
--------	-----------------	-------------	----------

(g) the following foodstuff and maximum level shall be added to E 900:

		'Flavourings	10 mg/kg'
--	--	--------------	-----------

(h) in the list of foodstuffs and maximum levels for E 901 to E 904, the entry: 'E 903 Carnauba wax' shall be deleted and the following entry concerning E 903 shall be added after the entry 'E 904 shellac':

'E 903	Carnauba wax	As glazing agents only:	
		— confectionery (including chocolate)	500 mg/kg
			1 200 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 only)	200 mg/kg'

(i) the following foodstuffs and maximum levels shall be added to E 459:

		'Encapsulated flavourings in	
		— flavoured teas and flavoured powdered instant drinks	500 mg/l
		— flavoured snacks	1 g/kg in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer'

(j) the following rows shall be added at the end of the Annex:

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

5. in Annex V:

(a) the following row shall be added at the end of the Annex:

'E 555	Potassium aluminium silicate	In E 171 titanium dioxide and E 172 iron oxides and hydroxides (max 90 % relative to the pigment)
--------	------------------------------	---

(b) for E 468, the name 'Cross-linked cellulose gum' shall be added;

6. in Annex VI:

(a) in the introductory note, the following subparagraph shall be 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 1 000 mg/kg from polyunsaturated fatty acid preparations.'

(b) in part 4

— the title shall be replaced by the following:

'FOOD ADDITIVES PERMITTED IN DIETARY FOODS FOR INFANTS AND YOUNG CHILDREN FOR SPECIAL MEDICAL PURPOSES AS DEFINED IN 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).'

— the following shall be 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'
---------	---	--	---------------------