



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 04.09.1996

COM(96) 303 final

96/0166 (COD)

Proposal for a

**EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE**

**amending European Parliament and Council Directive 95/2/EC**

**on food additives other than colours and sweeteners.**

**(presented by the Commission)**



## EXPLANATORY MEMORANDUM

### 1. SUBSIDIARITY IMPACT STATEMENT

#### 1. What are the objectives of the proposed measure with regard to the Community's obligations?

Directive 89/107/EEC provides for the adoption of specific directives to harmonise the use of different categories of additives in foodstuffs. The Directive 95/2/EC on food additives other than colours and sweeteners was adopted on 20 February 1995. It now needs to be adapted in the light of recent technical and scientific developments.

#### 2. Does competence for the proposed measure lie solely with the Community or is it shared with the Member States?

Competence for the proposed measure lies solely with the Community.

#### 3. To what extent is this a problem on a Community scale?

Harmonisation of the use of additives at Community level was a priority for completion of the internal market. It was also a difficult subject. The framework Directive 89/107/EEC on additives was adopted on 21 December 1988 and the three specific Directives in 1994 and 1995. Since then, the instruments relating to the use of additives have been the same in the fifteen Member States. This structure guarantees the free movement of foodstuffs, ensures a high level of consumer protection and offers the consumer greater freedom of choice between different foodstuffs.

Like the two other specific Directives, Directive 95/2/EC on food additives other than colours and sweeteners is based on the principle of the positive list. A list of authorised food additives is set out in the different Annexes to the Directive with a list of the foodstuffs in which they may be used and the conditions of use. All food additives not included in the list are prohibited.

Since the legal basis of the Directive is Article 100A of the EC Treaty, the proposal for the amendment has to follow the same procedure, implying the participation of Parliament in the decision making process.

#### 4. What is the most effective solution taking into account the means available to the Community and the Member States?

Once the period for transposing the aforementioned Directives has expired, Member States will not be able to use new additives (except for a limited period of 2 years for new food additives not included in the positive lists) or amend the rules governing use on their own initiative. Action must therefore be taken at Community level.

**5. What practical additional benefit will the proposed measure provide and what would be the cost of failure to take action?**

The Commission proposals will establish effective legislation at Community level, attuned to new developments in industry and consumer needs. If the amendment is not adopted the legislation will become ineffective, if not obsolete, and this could disrupt the proper functioning of the internal market in foodstuffs.

**6. What forms of action are open to the Community?**

A new Directive adopted by Parliament and the Council on the basis of Article 100a is needed to amend Directive 95/2/EC.

**7. Is it absolutely necessary to adopt uniform rules or would a Directive establishing general principles and leaving implementation to the Member States be sufficient?**

The Commission proposal is based on the principle of complete harmonisation at Community level, as prescribed by the framework directive on food additives. Uniform rules are needed since additives concern public health. There needs to be a large degree of transparency between the Member States in order to establish a reasonable level of safety in trade in foodstuffs within the Community.

**2. SPECIFIC REMARKS**

This amendment to Directive 95/2/EC merely allows already authorised food additives to be used in certain new categories of food which are not included in the directive. These products are effectively on the market since several years and the entering in force of the directive will effectively prohibit its marketing.

Furthermore the proposal for amendment takes into account certain foodstuffs manufactured in the new Member States not covered by the Directive and in which certain additives are used.

Some new food additives, which are currently forbidden, and which have recently been evaluated by the Scientific Committee for Food and found acceptable for human consumption, are included in this proposal.

No further changes can be made to the conditions of use laid down in the Directive until the results of the consumer surveys required by Article 7 of the Directive are available.

**Proposal for a  
European Parliament and Council Directive  
amending European Parliament and Council 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 100a thereof,

Having regard to the proposal from the Commission,<sup>1</sup>

Having regard to the opinion of the Economic and Social Committee,<sup>2</sup>

Acting in accordance with the procedure referred to in Article 189b of the Treaty,<sup>3</sup>

Having regard 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,<sup>4</sup> as last amended by Directive 94/34/EC,<sup>5</sup> and in particular Article 3(2) thereof;

Whereas since the adoption of Directive 95/2/EC<sup>6</sup> there have been technical developments in the field of food additives;

Whereas the Directive should be adapted to take account of these developments;

Whereas the Scientific Committee for Food was consulted before the adoption of provisions liable to have an effect on public health,

**HAVE ADOPTED THIS DIRECTIVE:**

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<sup>1</sup> OJ

<sup>2</sup> OJ

<sup>3</sup> OJ

<sup>4</sup> OJ N° L 40, 11.2.89, p.27.

<sup>5</sup> OJ N° L 237, 10.9.94, p.1.

<sup>6</sup> OJ N° L 61, 20.2.1995 p.1.

### *Article 1*

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

1. Article 2(3) (a) 3rd indent is replaced by :

"- non-emulsified oils and fats of animal or vegetable origin (except oils and fats for cooking and frying purposes)."

2. Article 2(3) (a) 11th indent is replaced by :

"- dry pasta excluding gluten-free pasta"

3. Article 2(3) (a) 5th indent is replaced by :

"pasteurized and sterilized (including UHT) milk (including plain, skimmed and semi-skimmed") and plain pasteurized cream"

4. The tables of the Annexes are modified in accordance with the dispositions contained in the Annex to this Directive.

### *Article 2*

Member States shall, where necessary, amend their laws, regulations and administrative provisions in order to :

- authorise trade in products conforming to this Directive, by 31 December 1997 at the latest;
- prohibit trade in products not conforming to this Directive from 30 June 1998. However, products placed on the market or labelled before that date which do not comply with the Directive may be marketed until stocks are exhausted.

They shall forthwith inform the Commission thereof.

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

### *Article 3*

This Directive shall enter into force on the seventh day following its publication in the Official Journal of the European Communities.

**Article 4**

**This Directive is addressed to the Member States.**

**Done at Brussels,**

**For the European Parliament  
The President**

**For the Council  
The President**

**ANNEX**

1. The following additives are added to Annex I:

E468	Cross linked sodium carboxymethylcellulose
E469	Enzymatically hydrolysed carboxymethylcellulose
E1103	Invertase
E1451	Acetylated oxidised starch

2. The list of additives and the maximum level permitted for "jams, jellies and marmalades as defined in Directive 79/693/EEC and other similar fruit spreads including low-calorie products" mentioned in Annex II is completed as follows:

	E471 Mono and diglycerides of fatty acids	<i>quantum satis</i>
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3. The designation of "sterilised pasteurized and UHT cream, low-calorie cream and pasteurised low-fat cream" mentioned in Annex II is modified as follows:

"Plain pasteurized cream"

4. The designation of "Frozen and deep-frozen unprocessed fruit and vegetables" mentioned in Annex II is modified as follows:

"Frozen and deep-frozen unprocessed fruit and vegetables; prepacked, refrigerated unprocessed fruit and vegetables ready for consumption "

5. The designation of "Non-emulsified oils and fats of animal or vegetable origin (except virgin oils and olive oils)" mentioned in Annex II is modified as follows:

"Non-emulsified oils and fats of animal or vegetable origin (except virgin oils, olive oils, oils and fats for cooking and frying purposes)"

6. The following table is added to Annex II:

Sliced and grated ripened cheese	E170 Calcium carbonate E504 Magnesium carbonates E509 Calcium chloride E575 Glucono-delta-lactone E460 Cellulose	<i>quantum satis</i>
Soured-cream butter	E500 Sodium carbonates	<i>quantum satis</i>

7. The list of additives and the maximum level permitted for "canned and bottled fruit and vegetables" mentioned in Annex II is completed as follows:

Canned and bottled fruit and vegetables	E296 Malic acid	<i>quantum satis</i>
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8. The list of additives and the maximum level permitted for "*Mozzarella* and whey cheese" mentioned in Annex II is completed as follows:

<i>Mozzarella</i> and whey cheese	E260 Acetic acid E507 Hydrochloric acid	<i>quantum satis</i>
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9. The list of additives and the maximum level permitted for "*Gehakt*" mentioned in Annex II is completed as follows:

<i>Gehakt</i>	E300 Ascorbic Acid E301 Sodium ascorbate E302 Calcium ascorbate	<i>quantum satis</i>
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10. The following foodstuffs and the corresponding maximum levels:

"Emulsified sauces with a fat content of 60 % or more"

"Emulsified sauces with a fat content of less than 60 %"

mentioned in Annex III part A are deleted.

11. The following foodstuffs and maximum levels mentioned in Annex III part A are added:

Foodstuff	Maximum level (mg/kg or mg/l as appropriate)				
	Sa	Ba	Sa +Ba	Sa+PHB	Sa+Ba+PHB
<i>...Mehu and Makeutettu ... Mehu</i>	500	200			
Analogues of meat, fish, crustacean, cephalopods and cheese, based on vegetable-cereal or mycoprotein	2000				
<i>Dulce de membrillo Marmalada</i>		1000			
<i>Ostkaka</i>	2000				
<i>Pasha</i>	1000				
Cheese and cheese analogues (surface treatment only)	<i>quantum satis</i>				
Cooked red beet		2000			
Emulsified sauces with a fat content less than 60 %			1500		
Emulsified sauces with a fat content of 60 % or more			1000		

12. The designation "Non-heat-treated dairy-based desserts" in Annex III part A, in the foodstuffs column is replaced by "Non-sterilised (including UHT) dairy-based desserts".

13. The following foodstuffs and maximum levels are added to Annex III part B:

Foodstuff	Maximum level (mg/kg or mg/l as appropriate) Expressed as SO <sub>2</sub>
Cooked crustaceans and cephalopods	50 mg/kg <sup>7</sup>
Marinated nuts	50 mg/kg
Dehydrated apples and pears with a moisture content of more than 12% not sold to the end consumer	1500 mg/kg
Analogues of meat, fish, crustacean, cephalopods and cheese, based on mycoprotein	200

14. The following foodstuffs and maximum levels are added to the table concerning food additives E251 and E252 mentioned in Annex III part C :

E251	Sodium nitrate	<i>Foie gras, foie gras entier,</i>		50 <sup>(4)</sup>
E252	Potassium nitrate	<i>blocs de foie gras</i>		

15. The following foodstuffs and maximum levels are added to the table concerning food additives E280, E281, E282 and E283 mentioned in Annex III part C :

E280	Propionic acid	Prepacked <i>pølsebrød,</i> <i>boller</i> and <i>flutes</i>	2000 mg/kg expressed as propionic acid
E281	Sodium propionate		
E282	Calcium propionate		
E283	Potassium propionate		

16. The designation concerning "dehydrated granulated potatoes" mentioned in table of Annex III part D in the foodstuffs column is replaced by "dehydrated potatoes"

17. The designation "instant tea powder" contained in the table of Annex IV concerning E297 Fumaric acid is replaced by "flavoured tea and herbal infusions, and their instant products"

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<sup>7</sup> in edible parts.

18. The table concerning E 338 to E452 mentioned in Annex IV is replaced by the following table :

"In the following applications the indicated maximum levels of phosphoric acid and the phosphates E 338, E 339, E 340, E 341, E343, E 450, E 451 and E 452 may be added individually or in combination (expressed as P<sub>2</sub>O<sub>5</sub>)

E 338	Phosphoric acid	Non-alcoholic flavoured drinks	700 mg/l
E 339	Sodium phosphates	Sterilised and UHT milk	1 g/l
	(i) Monosodium phosphate	Partly dehydrated milk with less than 28% solids	1 g/kg
	(ii) Disodium phosphate	Partly dehydrated milk with more than 28% solids	1.5 g/kg
	(iii) Trisodium phosphate	Dried milk and dried skimmed milk	2.5 g/kg
E 340	Potassium phosphates	Pasteurised, sterilised and UHT creams	5 g/kg
	(i) Monopotassium phosphate	Whipped cream and vegetable fat analogues	5 g/kg
	(ii) Dipotassium phosphate	Unripened cheese (except <i>MOZZARELLA</i> )	2 g/kg
	(iii) Tripotassium phosphate	Processed cheese and processed cheese analogues	20 g/kg
E 341	Calcium phosphates	Meat products	5 g/kg
	(i) Monocalcium phosphate	Sport drinks and prepared table waters	0.5 g/l
	(ii) Dicalcium phosphate	Dietary supplements	quantum satis
	(iii) Tricalcium phosphate	Salt and its substitutes	10 g/kg
E 343	Magnesium phosphates	Vegetable protein drinks	20 g/l
	(i) Monomagnesium phosphate	Beverage whiteners	30 g/kg
	(ii) Dimagnesium phosphate	Beverage whiteners for vending machines	50 g/kg
E 450	Diphosphates	Edible ices	1 g/kg
	(i) Disodium diphosphate	Desserts	3 g/kg
	(ii) Trisodium diphosphate	Dry powdered dessert mixes	7 g/kg
	(iii) Tetrasodium diphosphate	Fine bakery wares	20 g/kg
	(v) Tetrapotassium diphosphate	Flour	2.5 g/kg
	(vi) Dicalcium diphosphate	Flour, self raising	20 g/kg
	(vii) Calcium dihydrogen diphosphate	<i>SODA BREAD</i>	20 g/kg
E 451	Triphosphates	Liquid egg (white, yolk or whole egg)	10 g/kg
	(i) Pentasodium triphosphate	Sauces	5 g/kg
	(ii) Pentapotassium triphosphate	Soups and broths	3 g/kg
E452	Polyphosphates	Tea and herbal infusions	2 g/l
	(i) Sodium polyphosphate	Cider and perry	2 g/l
	(ii) Potassium polyphosphate	Chewing gum	quantum satis
	(iii) Sodium calcium polyphosphate	Dried powdered foodstuffs	10g/kg
	(iv) Calcium polyphosphates	Chocolate and malt dairy-based drinks	2 g/l
		Alcoholic drinks (excluding wine and beer)	1 g/l
		Breakfast cereals	5 g/kg
		Snacks	5 g/kg
		Surimi	1 g/kg
		Fish and crustacean paste	5 g/kg
		Toppings (syrops for pancakes, flavoured syrops for milkshakes and ice cream; similar products)	3 g/kg
		Special formulae for particular nutritional uses	5 g/kg
		Glazings for meat and vegetable products	4 g/kg
		Sugar confectionery	5 g/kg
		Icing sugar	10 g/kg
		Noodles	2 g/kg
		Batters	12 g/kg
		Fillets of unprocessed fish, frozen and deep-frozen	5 g/kg
		Frozen and deep-frozen crustacean, cephalopod and mollusc products	5 g/kg
		Processed potato products(including frozen, deep-frozen, chilled and dried processed products) and pre-fried frozen and deep-frozen potatoes	5 g/kg
		Spreadable fats excluding butter	5 g/kg
		Soured-cream butter	2 g/kg

19. The entry concerning "Minarine" in the table concerning E385 mentioned in Annex IV is modified as follows:

		Spreadable fats as defined in Annex B and C of Regulation No 2991/94 <sup>(8)</sup> having a fat content of 41 % or less	100 mg/kg
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20. The following foodstuffs and maximum levels are added to the table concerning E473 and E474 mentioned in Annex IV:

E473	Sucrose esters of fatty acids Sucroglycerides	Milk and cream analogues	5 g/kg
E474		Sterilised cream and reduced fat cream	5 g/kg
		Water based flavoured drinks	200 mg/l

21. The entry concerning "Low and very low fat spreads and dressings " in the table concerning E476 mentioned in Annex IV is modified as follows:

E476	Polyglycerol polyricinoleate	Spreadable fats as defined in Annex A, B and C of Regulation No 2991/94 having a fat content of 41 % or less	4 g/kg
		Spreadable fats with a very low fat content of less than 10 % fat	4 g/kg
		Dressings	4 g/kg

22. The following foodstuffs and maximum levels mentioned in the table concerning E551 to E559 of Annex IV are added:

		Fats and oils for frying purposes	30 g/kg
		Seasonings	30 g/kg
		Confectionery (surface treatment only)	<i>quantum satis</i>

23. The entry concerning "sliced hard cheese and sliced processed cheese" mentioned in the table concerning E551 to E559 of Annex IV is modified as follows:

		Sliced or grated hard, semi-hard and processed cheese	10g/kg
		Sliced or grated cheese analogues and processed cheese analogues	

<sup>(8)</sup>OJ. L 316 of 09.12.94 p.2

24. The following foodstuff and maximum level is added to the table concerning E405 mention in Annex IV:

E405	Propane-1,2-diol alginate	cider (excluding <i>cidre bouché</i> )	100 mg/l
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25. The following foodstuff and maximum levels is added to the table concerning E900 mention in Annex IV are added:

E900	Dimethyl polysiloxane	cider (excluding <i>cidre bouché</i> )	10 mg/l
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26. The following foodstuff and maximum level is added to the table concerning E912 and E914 mentioned in Annex IV:

E912	Montanic acid esters	Fresh melon, mango, papaya and avocado, surface treatment only	quantum satis
E914	Oxidised polyethylene wax		

27. The entries concerning "Margarine, Minarine" mentioned in the table concerning E959 of Annex IV are modified as follows:

E959	Neohesperidine DC	Spreadable fats as defined in Annex B and C of regulation No 2991/94	5 mg/kg
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28. The following foodstuff and maximum levels is added to the table concerning E999 mention in Annex IV are added:

E999	Quillaia extract	cider (excluding <i>cidre bouché</i> )	200 mg/kg calculated as anhydrous extract
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29. The following table is added to Annex IV:

E905	Microcrystalline wax	Surface treatment of - glazed rice - confectionery excluding chocolate - chewing gum - melons, papaya, mango and avocado	<i>quantum satis</i>  140 mg/kg
E1518	Triacetin	Chewing gum	<i>quantum satis</i>

30. The following entry is added to the table contained in annex V:

E1451	Acetylated oxidised starch	
E468	Cross linked sodium carboxymethylcellulose	
E469	Enzymatically hydrolysed carboxy methyl cellulose	

31. The following entry is added to the table contained in annex VI part 3:

E1451	Acetylated oxidised starch	Weaning foods	50 g/kg
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32. The following sentence is added to Annex VI part 4:

"E1450 Starch sodium octenyl succinate (E1450) may be added up 20 g/kg to infant formulae for infants for special medical purposes and for follow-on formulae for infants for special medical purposes."



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