

# COMMISSION OF THE EUROPEAN COMMUNITIES

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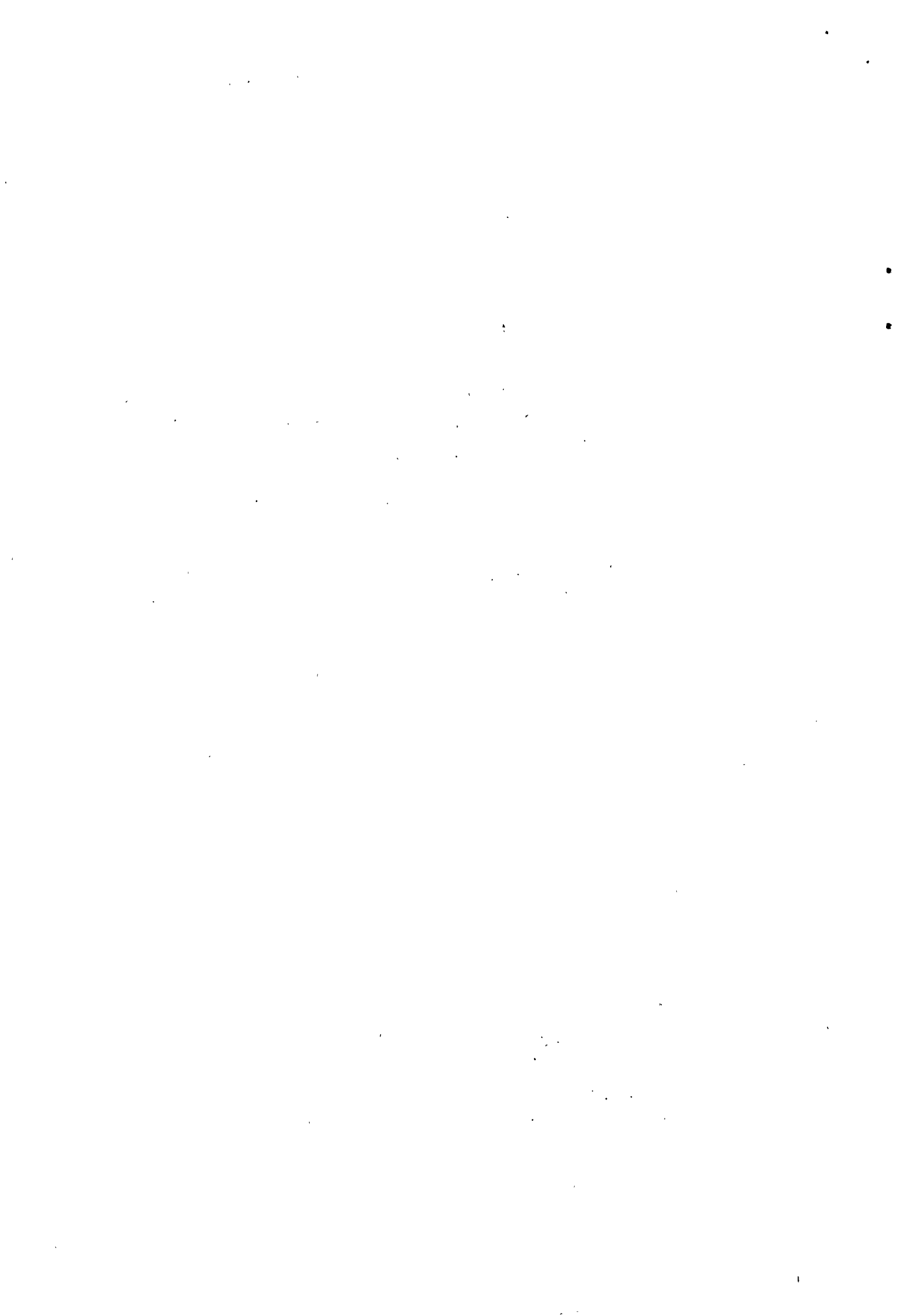
## PROPOSAL FOR A COUNCIL DIRECTIVE (EEC)

amending for the second time Council Directive No 65/66/EEC  
on the approximation of the laws of the Member States  
laying down specific criteria of purity for preservatives  
authorized for use in foodstuffs intended for human consumption

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(submitted to the Council by the Commission)





EXPLANATORY NOTE

1. Council Directive N° 64/54/EEC of 5 November 1963 (1) established a single list of preservatives in the Community authorized for use in foodstuffs intended for human consumption. The Directive also provides for the laying down of criteria of purity with which these preservatives must comply.
2. These criteria of purity were developed and included in Council Directive N° 65/66/EEC of 26 January 1965 (2), modified by Council Directive N° 67/428/EEC of 27 June 1973 (3). It is inevitable that any modification to the list of preservatives referred to in paragraph 1 is likely to produce a consequential amendment to this Directive.
3. The present proposal for Directive relates to additives which have already been added to the list of preservatives by modifications to the basic Directive of 5 November 1963, namely :
  - calcium sulphite (E 226), added by the Council Directive N° 71/160/EEC of 30 March 1974(3)
  - methyl parahydroxybenzoate (E218) and calcium bisulphite (E227), added by the agreement reached at the entry of the three new Member States into the Community (Annex 1, chapter XI.2 of the Act of Accession) (4)
  - thiabendazole (E233), added by the Council Directive N°74/394/EEC of 22 July 1974 (5)
  - formic acid (E236) and its sodium (E237) and calcium (E238) salts and hexamethylenetetramine (E239), added by the Council Directive N° 74/62/EEC of 12 December 1973 (6).

The aim of this proposal for Directive is the completion of the Directive of 26 January 1965 by the addition of the criteria of purity for the above mentioned substances.

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- (1) OJ N° 12 of 27.1.1964 p.161/64
  - (2) OJ N° 22 of 9.2.1965 p.373/65
  - (3) OJ N° 148 of 11/7/1967 p. 10
  - (4) OJ N° L 87 of 17/4/1971 p. 12
  - (5) OJ N° L 73 of 27/3/1972 p. 121
  - (6) OJ N° L 208 of 30/7/1974 p. 25
  - (7) OJ N° L 38 of 11/2/1974 p. 29

Proposal for a Council Directive amending for the second time Council Directive N° 65/66/EEC on the approximation of the laws of the Member States laying down specific criteria of purity for the preservatives authorized for use in foodstuffs intended for human consumption.

THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic Community;

Having regard to the Council Directive N° 64/54/EEC (1) of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption, as last amended by Council Directive N° 74/394/EEC(2) of 22 July 1974 and in particular Article 8 thereof;

Having regard to the proposal from the Commission;

(3) amended by Council Directive N° 67/428/EEC (4)  
Whereas the Council Directive N° 65/66/EEC laid down specific criteria of purity for the preservatives listed in the Annex to the Council Directive N° 64/54/EEC; whereas that Annex was supplemented by the Council Directive N° 71/160/EEC (4) of 30 March 1971 which added calcium sulphite; by the Act of Accession (5) of Denmark, Ireland and the United Kingdom which added methyl p-hydroxybenzoate and calcium bisulphite; by the Council Directive N° 74/62/EEC of 12 December 1973 (6) which added formic acid, sodium formate, calcium formate and hexamethylenetetramine; and by Council Directive N° 74/394/EEC of 22 July 1974 (7) which added thiabendazole to the list of authorized preservatives;

Whereas it is necessary to lay down specific criteria of purity for the eight preservatives mentioned above;

HAS ADOPTED THIS DIRECTIVE

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(1) OJ N° 12, 27.1.1964, p.161/64

(2) OJ N° L 208, 30.7.1974, p.25

(3) OJ N° 22, 9.2.1965, p.373/65

(4) OJ N° 148 of 11/7/1967 p. 10

(5) OJ N° L 87 of 17/4/1971

(6) OJ N° L 73 of 27.3.1972 p. 121

(7) OJ N° L 38 of 11.2.1974 p. 29

(8) OJ N° L 208 of 30.7.1974 p. 25

Article 1

The Annex to the Council Directive N° 65/66/EEC shall be amended as follows :

1. The following specification should be inserted between N°s E 217 and E 220

E 218 Methyl p-hydroxybenzoate (methyl ester of parahydroxybenzoic acid)

Appearance :	White, almost odourless crystalline powder
Melting range :	125° - 128° C
Content :	Not less than 99.0% calculated as $C_8H_8O_3$ after drying for 2 hours at 80°C
Sulphated ash :	Not more than 0.05 %
Free acidity :	Not more than 0.7% expressed as p-hydroxybenzoic acid
Salicylic acid :	Not more than 0.1 %
Loss on drying :	Not more than 0.5% after drying for 2 hours at 80°C

2. The following specifications should be inserted between N°s E 225 and E 230

E 226 Calcium sulphite

Appearance :	White crystals or crystalline powder
Content :	Not less than 95% of $CaSO_3 \cdot 2H_2O$ and not less than 39% of $SO_2$
Sulphate :	Not more than 0.1%
Chloride :	Not more than 0.05%
Iron :	Not more than 0.005 %
Selenium :	Not more than 10 mg per kg of the sulphur dioxide content

E 227 Calcium bisulphite (calcium hydrogen sulphite)

Appearance :	Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide
Content :	6 to 8% (w/v) of sulphur dioxide and 2.5 to 3.5 % (w/v) of calcium oxide corresponding to 10-14% (w/v) of calcium bisulphite $[Ca(HSO_3)_2]$
Iron :	Not more than 30 mg per kg
Selenium :	Not more than 10 mg per kg of the sulphur dioxide content

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3. The following specifications should be inserted between N° E232 and E 250.

E 233 2 - (4-thiazolyl) benzimidazole (thiabendazole)

Appearance : white or almost white odourless powder  
 Melting range : 296 - 303° C  
 Content : 98 to 101 %  $C_{10}H_7N_3S$  calculated on the anhydrous product  
 Sulphated ash : Not more than 0.2 %  
 Moisture : Not more than 0.5 % (Karl - Fischer)  
 UV Absorption : E 1 % at  $302 \pm 2$  nm = about 1230  
 (0.0005 % w/v in E 1 % at  $258 \pm 2$  nm = about 200  
 0.1NHCl) E 1 % at  $243 \pm 2$  nm = about 620

Ratio of absorption at 241 - 245 nm = 0.47-0.53  
absorption at 300 - 304 nm

Ratio of absorption at 256 - 260 nm = 0.14-0.18  
absorption at 300 - 304 nm

Selenium = 30 mg/kg

E 236 Formic acid

Appearance : Clear colourless highly corrosive liquid with a characteristic pungent odour  
 Content : Contains not less than 98.0% of  $CH_2O_2$ .  
 Acetic acid : Not more than 0.5%  
 Sulphate : Not more than 40 mg/kg  
 Sulphite : Dilute 25 ml of formic acid with 25 ml of water.  
 Add 0.1 ml of 0.1 N iodine solution. The solution should retain a distinct yellow colour.  
 Chloride : Not more than 50 mg/kg  
 Specific gravity : 1.216 - 1.220 (20°/20°)  
 Non volatile matter: Not more than 0.05%  
 Aldehydes : A slightly alkaline 5% solution, on heating must not give off a sharp or burnt smell  
 Formaldehyde : Not more than 0.1% of the formic acid content, estimated with chromotropic acid  
 Oxalic acid : Not more than 0.5% of the formic acid content estimated as calcium oxalate

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E 237 Sodium formate (sodium salt of formic acid)

Appearance : White crystalline powder  
Content : Not less than 98% Na CHO<sub>2</sub> after drying for 2 hours at 105° C  
Volatile matter : Not more than 2% determined by drying for 2 hours at 105° C  
Degree of acidity or alkalinity : Neutralisation of 1 gram of sodium formate in the presence of phenolphthalein must not require more than 0.5 ml of 0.1 N HCl or 0.1 N NaOH  
Aldehydes : A 5% solution on heating must not give off a sharp or burnt smell  
Formaldehyde : Not more than 0.1% of the content of sodium formate estimated with chromotropic acid  
Oxalic acid : Not more than 0.5 % of the content of sodium formate estimated as calcium oxalate

E 238 Calcium formate (calcium salt of formic acid)

Appearance : White crystalline powder  
Content : Not less than 98% CaC<sub>2</sub>H<sub>2</sub>O<sub>4</sub> after drying for 2 hours at 105° C  
Volatile matter : Not more than 2% determined by drying for 2 hours at 105° C  
Water-insoluble matter: Not more than 0.5%  
Degree of acidity or alkalinity : Neutralisation of 1 gram of calcium formate in the presence of phenolphthalein must not require more than 0.5 ml of 0.1 N HCl or 0.1 N NaOH  
Aldehydes: A 5% solution on heating must not give off a sharp or burnt smell.  
Formaldehyde : Not more than 0.1% of the content of calcium formate estimated with chromotropic acid  
Oxalic acid : Not more than 0.3% of the content of calcium formate estimated as calcium oxalate

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E 239 Hexamethylenetetramine

Appearance :	Colourless or white crystalline powder
Content :	Not less than 99% $C_6H_{12}N_4$
Loss on drying :	Not more than 0.5% after drying at 105° C in vacuum over phosphorus pentoxide for two hours.
Sublimation point :	Sublimes at about 260° C without melting
Sulphated Ash:	not more than 0.05 %
Sulphate :	Not more than 0.005 %
Chloride :	Not more than 0.005 %

Article 2

Member States shall, within one year from the notification of this Directive, amend their laws in accordance with the preceding provisions and shall forthwith inform the Commission thereof. The laws thus amended shall be implemented at the latest two years after notification of this Directive.

Article 3

This Directive is addressed to the Member States.

For the Council  
The President

