

COMMISSION OF THE EUROPEAN COMMUNITIES

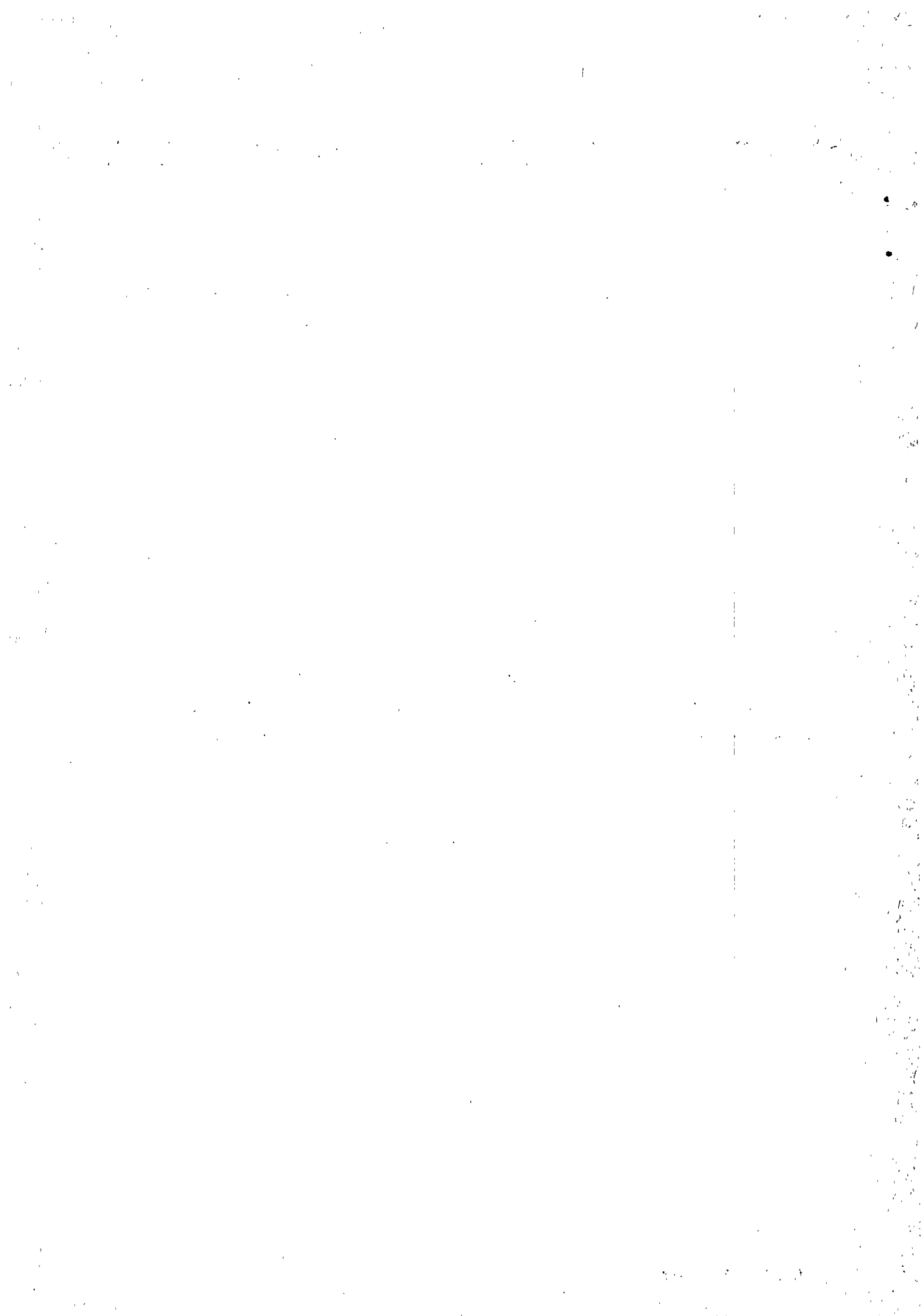
COM(75) 254 final

Brussels, 5 June 1975

PROPOSAL FOR A COUNCIL DIRECTIVE

for an amendment to Directive 64/54/EEC on the
approximation of the laws of the Member States concerning the
preservatives authorized for use in foodstuffs intended for human consumption

(submitted to the Council by the Commission)



EXPLANATORY MEMORANDUM

1. The Council Directive on Preservatives for use in foodstuffs (1) as last amended by the Directive of 22 July 1974 (2) provides for the use of methyl p-hydroxybenzoate (E218) as preservative, and sodium nitrite and sodium propionate as substances having a subsidiary preservative effect.
2. The Treaty of Accession, Annex VII (IX.2) (3) allows new Member States to use sodium derivative of methyl p-hydroxybenzoate, potassium nitrite and potassium propionate, where this use was authorized by national legislation at the time of Accession. This derogation expires on 31 December 1977. There is a great deal of chemical similarity between the sodium derivative of methyl p-hydroxybenzoate and the ester itself, between sodium and potassium nitrite and between sodium and potassium propionate. The equivalent compounds can be used as alternatives.
3. The aim of the present Directive is to allow all the Member States the facility to use these latter additives since it is clear that permission to use these substances throughout the Community has economic advantages.
4. From the toxicological point of view the assessment of the safety in use of the sodium derivative of methyl p-hydroxybenzoate is so similar to that of the ester that the Scientific Committee for Food has no objection to the inclusion of the sodium salt as well as the ester, in the Directive. Similarly, the Scientific Committee for Food has no objection, from the point of view of safety in use to the extension of the list of Preservatives to include the two potassium salts since the use of potassium nitrite or potassium propionate instead of the sodium salt creates no problems of safety in use and, indeed, in some cases may be advantageous. The advice of the Committee is attached to this note.
5. It is already provided for in the basic Directive that at a second stage the Community will act on the approximation of the laws concerning individual foodstuffs to which the preservatives listed in the Directive may be added.

(1) OJ No 12, 27.1.1964, p. 161/64.
(2) OJ No L208, 30.7.74, p. 25.
(3) CJ Special Edition (L73) 27.3.1972.

However, it is not the intention of the present proposal to enter into this field, but merely to amend in a limited manner the existing provisions.

6. The amendment to Article 7 of the Directive brings the wording in line with that recently agreed in similar circumstances during the elaboration of the Directive on Emulsifiers, Stabilisers, Thickeners and Gelling Agents. This is an interim modification which will be open to change when measures are taken concerning contaminants in food.
7. Similar modifications will shortly be included in the corresponding paragraphs of the Directives on Colours and Antioxidants in Food on the occasion of the next amendments of these Directives.

Proposal for a Council Directive for an 11th amendment to Directive 64/54/EEC on the approximation of the laws of the Member States concerning 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 and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Parliament,

Having regard to the Opinion of the Economic and Social Committee,

Whereas the Council Directive 64/54/EEC of 5 November 1963 (1) on the approximation of the laws of Member States concerning the preservatives authorized for use in food intended for human consumption, as last amended by the Council Directive 74/394/EEC of 22 July 1974 (2) provides for the use of the preservative methyl p-hydroxybenzoate (E218) but not its sodium derivative;

Whereas the aforementioned Directive also authorizes the use of sodium nitrite (E250) and sodium propionate (E281) as substances having a subsidiary preservative effect but not potassium nitrite and potassium propionate;

Whereas the usefulness of the sodium derivative of methyl p-hydroxybenzoate, potassium nitrite and potassium propionate has been demonstrated on a technological plane at Community level to replace partially or wholly the use of methyl p-hydroxybenzoate, sodium nitrite and sodium propionate respectively;

Whereas the addition of these substances to the list of permitted preservatives creates no hazards to health, having regard to the toxicological examinations carried out on this subject;

Whereas it is convenient at the same time to modify the provisions in the Directive concerning the presence of toxicologically dangerous elements as an interim measure until the Community legislation on these contaminants to food is completed and to bring this Directive in conformity with the Council Directive 74/329/EEC of 18 June 1974 on the approximation of the laws of the Member States relating to Emulsifiers, Stabilisers, Thickeners and Gelling Agents for use in foodstuffs;

.../...

(1) OJ No. 12 of 27.1.1964, p.161/64.

(2) OJ No. L 208 of 30.7.1974, p.25.

(3) OJ No. L 189 of 12.7.1974, p. 1.

HAS ADOPTED THIS DIRECTIVE,

Article 1

Article 1 of the Directive 64/54/EEC is amended as follows:

Article 7, paragraph (a) is replaced by:

" (a) the following general criteria of purity

- they shall not contain a toxicologically dangerous amount of any element, in particular heavy metals;
- they shall not contain more than 3 mg/kg of arsenic or more than 10 mg/kg of lead;
- they shall not contain more than 50 mg/kg of copper and zinc taken together of which the zinc content must in no case exceed 25 mg/kg subject to any exception deriving from the specific criteria of purity referred to in (b) ".

Article 2

Part I of the Annex of the Directive 64/54/EEC is modified as follows:

EEC Number	Name	Conditions of use
E219	Sodium derivative of methyl p-hydroxybenzoate	

Article 3

Part II of the Annex of the Directive 64/54/EEC is modified as follows:

EEC Number	Name	Conditions of use
E249	potassium nitrite	Solely in a mixture with sodium chloride
E283	potassium propionate (potassium salt of propionic acid)	

Article 4

Member States shall bring into force not later than 12 months after notification of this Directive, the laws, regulations or administrative provisions, necessary to comply with this directive and shall forthwith inform the Commission.

Article 5

The Directive is addressed to Member States.

Done at Brussels,

For the Council,

The Chairman.

OPINION OF THE SCIENTIFIC COMMITTEE FOR FOOD

on

Sodium methyl parahydroxybenzoate,
potassium nitrite and potassium propionate

Opinion expressed 15 November 1974

TERMS OF REFERENCE

To give an opinion on whether the sodium derivative of methyl parahydroxybenzoate, potassium nitrite and potassium propionate could from the point of view of safety in use be added to the Community list of Preservatives for use in food.

CONCLUSIONS

1. The sodium derivative of methyl parahydroxybenzoate could be added to the Community list of preservatives for use in food.
2. Potassium propionate could be added to the Community list of preservatives for use in food.
3. Potassium nitrite could be added to the Community list of preservatives for use in food under the same conditions as for the sodium salt.
4. The Committee draws the attention of the Commission to the need for a review of
 - a) the use of nitrite and nitrate;
 - b) the balance in human nutrition of mineral ions, in particular, of sodium and potassium.