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#### **COUNCIL DIRECTIVE**

of 13 July 1970

on the approximation of the laws of the Member States concerning the antioxidants authorised for use in foodstuffs intended for human consumption

(70/357/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 227 (2) 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 all laws relating to the antioxidants which may be used in foodstuffs intended for human consumption must give priority to the protection of public health, the protection of the consumer against falsification and, so far as health protection allows, economic and technological needs must also be taken into consideration;

Whereas differences between national laws concerning these substances hinder the free movement of foodstuffs intended for human consumption and may create conditions of unfair competition, thereby directly affecting the establishment or functioning of the common market;

Whereas the approximation of those laws is necessary for the free movement of foodstuffs intended for human consumption;

Whereas such approximation must involve, as a first stage, the establishment of a single list of the substances in question whose use is authorised for the protection of foodstuffs intended for human consumption against deterioration caused by oxidation and the laying down of the criteria of purity which those substances must satisfy;

Whereas, in order to take the economic and technological needs of certain Member States into account, 'a period should be set during which such Member States may, in respect of certain of those substances, maintain their existing laws;

Whereas it is desirable that for all cases where the Council empowers the Commission to implement rules relating to foodstuffs, provision should be made for a procedure establishing close co-operation between the Member States and the Commission within the Standing Committee for Foodstuffs set up by Council Decision of 13 November 1961<sup>1</sup>;

Whereas, during a second stage, the Council must decide on the approximation of the laws concerning individual foodstuffs intended for human consumption to which the antioxidants listed in the Annex to this Directive may be added, and on the conditions governing the addition of such antioxidants, account being taken of the relevant scientific information;

Whereas the approximation of the national laws provided for in this Directive does not prejudice the application of the provisions of Articles 31 and 32 of the Treaty;

HAS ADOPTED THIS DIRECTIVE:

### Article 1

Member States shall not authorise the use, for the protection of foodstuffs intended for human consumption (hereinafter called 'foodstuffs') against deterioration caused by oxidation, such as fat deterioration and colour changes in foodstuffs caused

<sup>&</sup>lt;sup>1</sup> OJ No L 291, 19.12.1969, p. 9.

by autoxidation, of any substances other than those listed in Parts I to III of the Annex to this Directive which may, if necessary, be dissolved in or diluted with the substances listed in Part IV of the Annex.

#### Article 2

By way of derogation from Article 1, Member States may, for a period of three years following notification of this Directive, maintain the provisions of their national laws authorising the use in foodstuffs of synthetic beta-tocopherol, calcium disodium ethylene diamine tetra-acetate, propyl gallate and L-ascorbic acid esters of the unbranched fatty acids C14 and C18.

Before expiry of the period set in paragraph 1 the Council may, under Article 100 of the Treaty, act on a proposal for a Directive authorising the inclusion in the Annex to this Directive of the substances referred to in paragraph 1.

The decision to include those substances in the Annex to this Directive may be taken only if, after scientific investigation, they are proved harmless to human health and if their use is necessary for economic reasons.

## Article 3

- 1. Where the use in foodstuffs of one of the substances listed in the Annex, or the level of one or more of the components referred to in Article 4 contained in such substances, might endanger human health, a Member State may, for a maximum period of one year, suspend the authorisation to use that substance or reduce the maximum authorised level of one or more of the components in question. It shall inform the Commission thereof forthwith and the Commission shall consult the Member States.
- 2. The Council, acting unanimously on a proposal from the Commission, shall decide without delay whether the list in the Annex should be amended, and, if so, adopt by directive the necessary amendments. The Council, acting by a qualified majority, on a proposal from the Commission, may also, if necessary, extend for a maximum of one year the period set in the first sentence of paragraph 1.

### Article 4

The Member States shall take all measures necessary to ensure that the substances listed in the Annex and intended for use in foodstuffs satisfy:

- (a) the following general criteria of purity:
  - they must contain not more than 3 milligrams per kilogramme of arsenic and not more than 10 milligrams per kilogramme of lead;
  - they must contain not more than 50 milligrams per kilogramme of copper and zinc taken together, of which the zinc content must not be higher than 25 milligrams per kilogramme, always subject however to any exceptions implicit in the specific criteria referred to in subparagraph (b);
  - they must not contain any measurable trace of toxicologically dangerous elements, in particular other heavy metals, always subject however to any exceptions implicit in the specific criteria referred to in subparagraph (b);
- (b) the specific criteria of purity laid down in accordance with Article 5 (1).

## Article 5

- 1. The Council shall, acting unanimously on a proposal from the Commission, lay down by directive the specific criteria of purity for the substances listed in Parts I to III or IV (4) to (7) of the Annex to this Directive.
- 2. The procedure laid down in Article 6 shall be used to determine:
- the methods of analysis needed to verify that the general and specific criteria of purity referred to in Article 4 are satisfied;
- the procedure for taking samples and the methods for the qualitative and quantitative analysis of antioxidants in and on foodstuffs.

## Article 6

- 1. Where the procedure laid down in this Article is to be followed, matters shall be referred by the Chairman either on his own initiative or at the request of the representative of a Member State, to the Standing Committee for Foodstuffs (hereinafter called the 'Committee') set up by Council Decision of 13 November 1969.
- 2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its Opinion on the draft within a time limit set by the Chairman according to the urgency of the matter. Opinions shall be delivered by a majority of 12 votes, the votes of the Member States being weighted as provided in Article 148 (2) of the Treaty. The Chairman shall not vote.

- (a) The Commission shall adopt the measures envisaged where they are in accordance with the Opinion of the Committee.
- (b) Where the measures envisaged are not in accordance with the Opinion of the Committee, or if no Opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.
- (c) If within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

### Article 7

The provisions of Article 5 shall apply for eighteen months from the date on which a matter was first referred to the Committee, either under Article 6 (1) or under any other corresponding provision.

## Article 8

- 1. Member States shall take all measures necessary to ensure that the substances listed in Parts I to III of the Annex and intended for use in foodstuffs for the purposes mentioned in Article 1 are placed on the market only if their packagings or containers bear the following information:
- (a) the name and address of the manufacturer, or of a seller responsible within the meaning of the laws of the Member State in which he is resident; a person importing a product from a third country shall be treated as the manufacturer;
- (b) the number and name of the substance as they are given in the Annex to this Directive;
- (c) the words 'for foodstuffs (restricted use)';
- (d) in the case of a mixture composed of substances listed in the Annex or including other substances:
  - the name of each component or, where appropriate, its number as given in the Annex to this Directive;
  - percentages of the components, where there is one or more of the substances listed in Parts I to III or IV (7) of the Annex to this Directive, or where this requirement is laid down in provisions relating to other categories of additives.
- 2. If the information required under paragraph 1 appears on the packagings or containers and if the information required under paragraph 1 (b) and (c) is given in two of the official languages of the Community, one of Germanic and the other of Latin

origin Member States shall not prohibit the introduction into their territory of substances listed in the Annex solely on the grounds that they consider the labelling inadequate.

#### Article 9

This Directive shall not affect national laws specifying the foodstuffs to which the substances listed in Parts I to III of the Annex to this Directive may be added and the conditions governing the addition of such substances. However, such laws must not have the effect of totally excluding the use in foodstuffs of any of the substances listed in the Annex to this Directive.

### Article 10

- 1. This Directive shall also apply to substances listed in the Annex to this Directive and intended for use in foodstuffs and to foodstuffs imported into the Community.
  - 2. This Directive shall not apply to substances listed in the Annex to this Directive or to foodstuffs intended for exportation from the Community.

### Article 11

- 1. The Member States shall, within a period of one year following notification of this Directive, amend their laws in accordance with the above provisions and shall forthwith inform the Commission thereof. The laws thus amended shall apply not later than two years after that notification.
- 2. Where the first paragraph of Article 2 is applicable, the periods set in the above paragraph shall run from the date of expiry of the period referred to in that paragraph.

# Article 12

This Directive shall also apply in the French overseas departments.

# Article 13

This Directive is addressed to the Member States.

Done at Brussels, 13 July 1970.

For the Council
The President
J. ERTL

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## ANNEX

# PART I

# Antioxidants

| EEC No  | Name  |
|---------|---|
| E 300   | L-Ascorbic acid                                       |
| E 301   | Sodium L-ascorbate (sodium salt of L-ascorbic acid)   |
| E 302   | Calcium L-ascorbate (calcium salt of L-ascorbic acid) |
| E 303   | 5, 6-diacetyl-L-ascorbic acid (ascorbyl diacetate)    |
| E 304   | 6-palmityl-L-ascorbic acid (ascorbyl palmitate)       |
| E 306   | Tocopherol-rich extracts of natural origin            |
| E 307   | Synthetic Alpha-tocopherol                            |
| E 308   | Synthetic Gamma-tocopherol                            |
| E 309   | Synthetic Delta-tocopherol                            |
| E 311   | Octyl gallate   |
| E 312   | Dodacyl gallate                                       |
| E 320 . | Butylated hydroxyanisole (BHA)                        |
| E 321   | Butylated hydroxytolnene (BHT)                        |

Part II

Substances having an antioxidant effect and also other functions

| EEC No  | Name  |
|---------|---|
| E 220   | Sulphur dioxide   |
| E 221   | Sodium sulphite   |
| E 222   | Sodium bisulphite (acid sodium sulphite)                                  |
| E 223   | Sodium metasulphite (sodium pyrosulphite or sodium disulphite)            |
| E 224 · | Potassium metabisulphite (potassium pyrosulphite or potassium disulphite) |
| E 226   | Calcium sulphite  |
| E 322   | Lecithins   |

Part III

Substances capable of increasing the antioxidant effect of other substances

| EEC No  | Name  |
|---------|---|
| E 270   | Lactic acid   |
| E 325   | Sodium lactate (sodium salt of lactic acid)                                       |
| E 326   | Potassium lactate (potassium salt of lactic acid)                                 |
| E 327   | Calcium lactate (calcium salt of lactic acid)                                     |
| E 330   | Citric acid   |
| E 331   | Sodium citrates (sodium salts of citric acid)                                     |
| E 332   | Potassium citrates (potassium salts of citric acid)                               |
| E 333   | Calcium citrates (calcium salts of citric acid)                                   |
| E 334   | Tartaric acid   |
| E 335   | Sodium tartrates (sodium salts of tartaric acid)                                  |
| E 336   | Potassium tartrates (potassium salts of tartaric acid)                            |
| E 337   | Sodium potassium tartrate   |
| E 338   | Orthophosphoric acid  |
| E 339   | Sodium orthophosphates (sodium salts of orthophosphoric acid)                     |
| E 340   | Potassium orthophosphates (potassium salts of orthophosphoric acid)               |
| E 341   | Calcium orthophosphates (calcium salts of orthophosphoric acid)                   |
| E 372 c | Citric acid ester of mono and di-glycerides of food fatty acids (citroglycerides) |

Part IV

# Substances in which the substances listed in Parts I to III may be dissolved or diluted

| Name  |  |  |
|---|--|--|
| 1. Drinking water, demineralised water, distilled water |  |  |
| 2. Edible oils  |  |  |
| 3. Edible fats  |  |  |
| 4. Ethyl alcohol  |  |  |
| 5. Glycerol   |  |  |
| 6. Sorbitol   |  |  |
| 7. Propylene glycol (1, 2-Propanediol)                  |  |  |