II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 18 June 1974

on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs

(74/329/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 [1];

Having regard to the Opinion of the Economic and Social Committee [2];

Whereas differences between national laws relating to emulsifiers, stabilizers, thickeners and gelling agents hinder the free movement of foodstuffs 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;

Whereas all laws relating to the emulsifiers, stabilizers, thickeners and gelling agents which may be used in foodstuffs must give priority to the protection of public health, but 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 such approximation must, as a first stage, involve the establishment of a single list of emulsifiers, stabilizers, thickeners and gelling agents which may be authorized by the Member States for the treatment of foodstuffs and the laying down of the general criteria of purity which those agents must satisfy;

Whereas, particularly in the case of substances E 408, E 450 (c), E 460, E 475, E 480, E 481 and E 482, advances in research may provide new data; whereas it may therefore be necessary to re-examine the case of these substances within a certain period of time;

Whereas, during a second stage, the Council must decide on the conditions for the use of each of the said agents;

Whereas, to take the economic and technological needs of certain Member States into account, a period should be set during which such Member States may authorize the use of certain agents in foodstuffs;

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[1] OJ No C 139, 28. 10. 1969, p. 45.
[2] OJ No C 144, 8. 11. 1969, p. 8.

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 cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs set up by Council Decision No 69/414/EEC of 13 November 1969 [1];

Whereas this Directive does not affect the possible use of the substances to which it refers for purposes other than those specified in Article 1 and in particular as bulking aids used at high levels in certain low-calorie foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

For the purposes of this Directive:

— emulsifiers and stabilizers mean those substances which, when added to a foodstuff, make it possible to form or maintain a uniform dispersion of two or more immiscible substances;

— thickeners mean those substances which, when added to a foodstuff, increase its viscosity;

— gelling agents mean those substances which, when added to a foodstuff, give it the consistency of a gel.

Article 2

1. Member States shall authorize the use as emulsifiers, stabilizers, thickeners and gelling agents in foodstuffs intended for human consumption, of only those substances listed in Annex I and where appropriate, only under the conditions specified therein.

2. However, within five years of the notification of this Directive and on the basis of a study by the Commission, the Council may, acting in accordance with the procedure laid down in Article 100 of the Treaty, delete or otherwise change the status of the substances listed in Annex I under E 408, E 450 (c), E 460, E 475, E 480, E 481 and E 482.

Article 3

1. Notwithstanding Article 2 (1) and for a period of five years from the notification of this Directive, Member States may authorize the use in foodstuffs of the substances listed in Annex II.

2. Where a Member State exercises the option under paragraph 1 other than by merely retaining the legislation in force at the time of notification of this Directive, it shall forthwith inform the other Member States and the Commission of the measures taken and shall furnish evidence which in its view justifies such measures.

3. Before the end of the period provided for in paragraph 1, the Council may, in accordance with the procedure laid down in Article 100 of the Treaty, include in Annex I the substances to which paragraph 1 refers.

In the case referred to in paragraph 2, the Council may, in accordance with the procedure laid down in Article 100 of the Treaty, decide on any other appropriate measure.

Article 4

The Council, in accordance with the procedure laid down in Article 100 of the Treaty, shall determine as soon as possible the foodstuffs to which the substances listed in Annex I may be added and the conditions under which they may be added.

Article 5

1. Where the use in foodstuffs of any substance listed in Annex I or the level of one or more of the components referred to in Article 6 contained in such substances might endanger human health, a Member State may, for a maximum period of one year, suspend the authorization to use that substance or reduce the maximum authorized level of one or more of the components in question. It shall forthwith inform the Commission thereof, which shall consult the Member States.

2. The Council, acting unanimously on a proposal from the Commission, shall decide without delay whether the list in Annex I should be amended and, if appropriate, adopt the necessary amendments by means of a directive. 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 referred to in paragraph 1.

Article 6

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

[1] OJ No L 291, 19. 11. 1969, p. 9.

(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); however, the limit fixed for copper shall not apply to pectins;

(b) the specific criteria of purity determined in accordance with Article 7 (1); these criteria shall also specify the maximum copper content of pectins.

2. Member States shall also ensure that the substances listed in Annex I under E 471, E 472 (b), E 473, E 474, E 475 and E 477 do not in addition contain more than 6 % of the substances listed in Annex I, under E 470, expressed as sodium oleate.

Article 7

1. The Council, acting unanimously on a proposal from the Commission, shall lay down by means of a Directive the specific criteria of purity for the substances listed in Annex I.

2. The following shall be determined in accordance with the procedure laid down in Article 10:

— the methods of analysis necessary for the control of the general and specific criteria of purity referred to in Article 6 (1) and the limit specified in Article 6 (2),

— the procedure for taking of samples and the methods for qualitative and quantitative analysis of emulsifiers, stabilizers, thickeners and gelling agents in and on foodstuffs.

Article 8

1. Member States shall take all necessary measures to ensure that the substances listed in Annex I and intended for use in foodstuffs for the purposes listed in Article 1 may be marketed 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 law of the Member State where he is resident; a person importing a product from a third country shall be regarded as the manufacturer:

(b) the number and name of the substance as given in Annex I;

(c) the statement 'for foodstuffs (restricted use)';

(d) in the case of substances listed in Annex I when mixed with each other or with other additives, and where relevant, with substances in which such other additives can be dissolved or diluted:

— the name of each component or, where appropriate, its number as given in Annex I;

— the percentage of each component where this requirement is laid down in provisions relating to other categories of additives.

2. In the case of mixtures described in paragraph 1 (d) Member States may also make obligatory an indication of the percentage of those substances enumerated in Annex I for which their national legislation provides a quantitative limitation in foodstuffs, except when the same limit applies singly or in combination to all of the compenonts in the mixture.

The Member State shall inform the other Member States and the Commission of any measures taken in accordance with this paragraph.

3. In adopting the provisions provided for in Article 4, the Council shall also fix the rules which will apply at a later stage in the Community relating to the labelling of the composition of the mixtures described in paragraph 1 (d).

4. Member States may not prohibit the introduction into their territory and the marketing of the substances listed in Annex I for the sole reason that they consider the labelling inadequate if the information required by paragraph 1 is given on the packagings or containers and if the details listed in subparagraphs (b) and (c) of paragraph 1 are given in at least one of the official language of the Community. Each recipient State may however require the latter details to be given in its official language or languages.

Article 9

Article 2 shall not apply to:

(a) foodstuffs which have emulsifying, stabilizing, thickening or gelling properties, such as, for example, eggs, flour and starches;

(b) emulsifiers used in release agents;

(c) acids, bases and salts which, when added to a foodstuff during manufacture, change or stabilize the pH;

(d) blood plasma, modified starches, edible gelatine and hydrolyzed food proteins and their salts.

Article 10

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 on Foodstuffs, hereinafter called the 'Committee'.

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 forty-one votes, the votes of the Member States being weighted as provided in Article 148 (2) of the Treaty. The Chairman shall not vote.

3. (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 11

Article 10 shall apply for 18 months from the date on which a matter was first referred to the Committee under Article 10 (1).

Article 12

1. This Directive shall apply equally to emulsifiers, stabilizers, thickeners and gelling agents intended for use in foodstuffs and to foodstuffs imported into the Community.

2. This Directive shall apply neither to emulsifiers, stabilizers, thickeners and gelling agents, nor to foodstuffs intended for export outside the Community.

Article 13

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 14

This Directive shall also apply to the French Overseas Departments.

Article 15

This Directive is addressed to the Member States.

Done at Luxembourg, 18 June 1974.

For the Council

The President

J. ERTL

ANNEX I

Emulsifiers, stabilizers, thickeners and gelling agents which may be used in foodstuffs

Draft EEC No	Designation	Conditions of use
E 322	Lecithins	
E 339	Sodium orthophosphates (synonym: sodium salts of orthophosphoric acid)	
E 340	Potassium orthophosphates (synonym: potassium salts of orthophosphoric acid)	
E 341	Calcium orthophosphates (synonym: calcium salts of orthophosphoric acid)	
E 400	Alginic acid	
E 401	Sodium alginate	
E 402	Potassium alginate	
E 403	Ammonium alginate	
E 404	Calcium alginate	
E 405	Propylene glycol alginate	
E 406	Agar	
E 407	Carrageenan (synonym: carrageen)	
E 408	Furcelleran, furcellaran	
E 410	Locust bean gum (synonym: carob gum)	
E 411	Tamarind seed flour	
E 412	Guar gun (synonym: guar flour)	
E 413	Tragacanth	
E 414	Acacia (synonym: gum arabic)	
E 420	Sorbitol	
E 421	Mannitol	
E 422	Glycerol	
E 440	Pectins	
E 450	Sodium and potassium polyphosphates: (a) diphosphates (b) triphosphates (c) linear polyphosphates (containing not more than 8 % of cyclic compounds)	
E 460	Microcrystalline cellulose	
E 461	Methylcellulose	
E 462	Ethylcellulose	
E 463	Hydroxypropylcellulose	
E 464	Hydroxypropylmethylcellulose	
E 465	Methylethylcellulose	
E 466	Carboxymethylcellulose (synonym: sodium salt of: sodium carboxymethyl-cellulose)	

Draft EEC No	Designation	Conditions of use
E 470	Sodium, potassium and calcium salts of fatty acids	Exclusively in the manufacture of 'Dutch' type rusks up to a level of not more than 1·5 % of flour used
E 471	Mono- and diglycerides of fatty acids	
E 472	Esters: (a) acetic acid (b) lactic acid (c) citric acid (d) tartaric acid (e) diacetyltartaric acids of mono- and diglycerides of fatty acids	
E 473	Sucrose-esters of fatty acids	These substances may not be used in bread unless permitted under national law
E 474	Sucroglycerides	
E 475	Polyglycol esters of fatty acids	
E 477	Propylene glycol esters of fatty acids	These substances may not be used in bread unless permitted under national law
E 480	Stearoyl-2-lactylic acid	
E 481	Sodium stearoyl-2-lactylate	
E 482	Calcium stearoyl-2-lactylate	
E 483	Stearyl tartrate	

ANNEX II

Designation

Karaya gum (synonym: sterculia gum)

Partial polyglycerol esters of polycondensed fatty acids of castor oil

Sorbitan monopalmitate

Sorbitan monostearate

Sorbitan tristearate

Polyoxyethylene (20) sorbitan monolaurate (synonym: polysorbate 20)

Polyoxyethylene (20) sorbitan monopalmitate (synonym: polysorbate 40)

Polyoxyethylene (20) sorbitan monostearate (synonym: polysorbate 60)

Polyoxyethylene (20) sorbitan tristearate (synonym: polysorbate 65)

Polyoxyethylene (20) sorbitan mono-oleate (synonym: polysorbate 80)

Polyoxyethylene (8) stearate

Polyoxyethylene (40) stearate

Glyceric esters of fatty acids obtained from soya oil oxydized under heat

Ghatti gum

Xanthan gum

Extract of quillaia

Lactylated fatty acid esters of glycerol and propylene glycol

Sorbitan monolaurate

Sorbitan mono-oleate

Dioctyl sodium sulphosuccinate

Ammonium phosphatides (synonym: emulsifier YN)