

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(79) 184 final

Brussels, 10 April 1979

Proposal for a
COUNCIL DIRECTIVE

amending for the second time Directive 74/329/EEC on the
approximation of the laws of the Member States relating to
emulsifiers, stabilizers, thickeners and gelling agents
for use in foodstuffs

(submitted to the Council by the Commission)

COM(79) 184 final

EXPLANATORY NOTE

1. The Council Directive 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)¹ (as modified by Council Directive 78/612/EEC)² requires that within five years of notification of the Directive, the Commission should examine the status of two groups of substances:

(a) Substances permitted for use in the Community by virtue of Article 2.2 of Directive 74/329/EEC

Council decisions have been taken on all these substances except E 460 (microcrystalline cellulose). The Commission has now completed its examination on this substance and proposes that E 460 should be subdivided into microcrystalline cellulose and powdered cellulose. The Scientific Committee for Food has advised that from the point of view of public health this proposal is acceptable³.

(b) Substances not permitted for use in the Community as a whole but which may be permitted by individual Member States by virtue of Article 3 of Directive 74/329/EEC

The Commission asked the Scientific Committee for Food whether the substances in this group, and which are listed in Annex II of the basic Directive, could be safely added to Annex I, (i.e. substances which may be authorised throughout the Community).

2. The present proposal implements the Committee's advice³ by:

(a) authorizing certain for a further limited period until 31 December 1984 (see the Annex to the attached proposal for Directive)

(b) including certain in Annex I of the basic Directive (see Article 3.2 of the attached proposal for Directive). The proposal recommends that Quillaia extract (E 441) should be authorized in soft drinks (and beverages containing soft drinks), as the Scientific Committee for Food saw no objection on health grounds to this use. However as the Commission is preparing proposals for Community measures on the

description and composition of soft drinks the present proposal requires that E 441 should be permitted only where national law allows its use. It is envisaged that a more complete description of the "conditions of use" will be possible only when the Community measures on soft drinks are accepted.

The Scientific Committee for Food advised that Karaya gum should be subjected to a number of preliminary toxicological studies which should be presented within one year so that a decision could be taken by the Committee as to whether it could accept a further temporary approval of the substance for a longer period to allow more extensive toxicological testing to be completed. The Commission has been informed that the preliminary toxicological studies are expected to be undertaken and that the results of such studies would be available within one year.

The proposal therefore recommends that Karaya gum should be maintained in Annex II but that the situation be reviewed before 31 December 1980.

(c) deleting the reference to Ghatti gum from Annex II. It is proposed that foodstuffs containing ghatti gum can be marketed until the 30 June 1980 (Article 5).

3. The Commission has also received a number of requests for a reexamination of Tragacanth (E 413). The Scientific Committee for Food has advised³ that the substance should be subjected to extensive toxicological testing within four years but that in the meantime its use is acceptable. The present proposal recommends that the situation be reviewed at the end of 1982 so that the Scientific Committee for Food can be informed of the progress of the studies and to allow the Commission to take appropriate action at an early stage.

¹OJ No L 189, 12.7.1974, p. 1

²OJ No L 197 of 22.7.1978, p. 22

³Scientific Committee for Food (Seventh Series)

Proposal for a Council Directive amending for the second time
Directive 74/329/EEC on the approximation of the laws of the Member States
relating to emulsifiers, stabilizers, thickeners and gelling agents for
use in foodstuffs

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 Commission¹;

Having regard to the opinion of the European Parliament²;

Having regard to the opinion of the Economic and Social Committee³;

Whereas Directive 74/329/EEC⁴, as last amended by Directive 78/612/EEC⁵,
lays down a single list of emulsifiers, stabilizers, thickeners and gelling
agents which may be authorized for use in foodstuffs by the Member
States;

Whereas having regard to the most recent scientific and technical knowledge
the reference to microcrystalline cellulose (E 460) in Annex I to Directive
78/612/EEC must be reworded; and whereas the use of tragacanth (E 413)
should be reevaluated after an enquiry by the Commission;

Whereas Annex II to Directive 74/329/EEC indicates the designations of the substances
which may be temporarily authorized by Member States for use in foodstuffs;

Whereas Article 3, (1) of Directive 74/329/EEC authorizes this
derogation for a period of five years from the date of notification of the Directive;

Whereas having regard to the most recent scientific and technical knowledge
the said Annex II must be revised; whereas, therefore, for certain substances
period of temporary authorization must be prolonged to permit the
completion of certain toxicological investigations necessary in the light

1 OJ No

2 OJ No

3 OJ No

4 OJ No L 189, 12.7.1974, p. 1

5 OJ No L 197, 22.7.1978, p. 22

of present-day requirements regarding the safety of their use in foodstuffs;

Whereas for certain substances the scientific and technical knowledge is satisfactory, thus allowing their transfer to Annex I to the above mentioned Directive; and whereas ghatti gum must no longer be used after a temporary period to allow the sale of foodstuffs containing this substance which are already on the market;

HAS ADOPTED THIS DIRECTIVE

Article 1

Directive 74/329/EEC is hereby amended as follows:

1. Paragraphs 2 and 3 of Article 2 are replaced by the following:

" 2. However, as regards the substances referred to in Annex I under E 413 and E 440 by the Council, acting in accordance with the procedure provided for in Article 100 of the Treaty, may decide, by 31 December 1982 and after an enquiry by the Commission, to delete them from the Annex or otherwise change their status."

2. Article 3 (1) is replaced by the following:

"By way of derogation from Article 2(1), Member States may authorize until 31 December 1984 the use in foodstuffs of the substances listed in Annex II, and until 30 June 1980 the marketing of foodstuffs containing ghatti gum. However as regards Karaya gum the Council, acting in accordance with the procedure provided for in Article 100 of the Treaty, may decide, before 31 December 1980 and after an enquiry by the Commission, to delete it from the Annex or otherwise change its status."

3. Annex I is amended as follows:

(a) The indent relating to E 460 microcrystalline cellulose is replaced by the following:

EEC No	Designation	Conditions of use
E 460	i) Microcrystalline cellulose ii) Powdered cellulose	

(b) The following is inserted:

EEC No	Designation	Conditions of use
E 415	Xanthan gum	Exclusively in soft drinks and in beverages where soft drinks are an ingredient, and at a level of not more than 200 mg/kg where this use is permitted under national law
E 441	Quillaia extract	
E 442	Ammonium phosphatides	
E 476	Polyglycerol poly- ricinoleate	
E 491	Sorbitan monostearate	
E 492	Sorbitan tristearate	
E 493	Sorbitan monolaurate	
E 494	Sorbitan monooleate	
E 495	Sorbitan monopalmitate	

4. Annex II is replaced by the Annex to this Directive.

Article 2

Member States shall, within one year of 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 two years after notification of this Directive.

Article 3

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

The President

ANNEX

"ANNEX II

Designation

Karaya gum (synonym: sterculia gum)

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 monooleate (synonym: polysorbate 80)

Polyoxyethylene (8) stearate

Polyoxyethylene (40) stearate

Oxidatively thermally polymerised soya bean oil interacted with mono- and
and di-glycerides of fatty acids

Lactylated fatty acid esters of glycerol and propylene glycol

Diethyl sodium sulphosuccinate"