COMMISSION OF THE EUROPEAN COMMUNITIES

COM(81) 708 final.
Brussels, 24 November 1981

Proposal for a
Council Directive
amending Directive 78/663/EEC laying down specific criteria of purity for emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs

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(submitted to the Council by the Commission)

EXPLANATORY NOTE

The modifications in the present amendment to the Directive on specific purity criteria* for emulsifiers, stabilisers, thickeners and gelling agents, with the exception of small modifications to the purity criteria for alginic acid (E 400) and alginates (E 401 - E 404), are the result of previous Council decisions included in the basic Directive on emulsifiers (74/329/EEC) or on purity criteria for emulsifiers (78663/EEC) that mandate the Commission to make proposals on these specific topics.

1. Alginic acid and alginates (E 400 - E 404)

   It has become apparent that the method for 'insoluble matter in dilute NaOH' is inapplicable. The figure was to some extent superfluous given other specific criteria in the specification and the Commission has decided that the reference should be deleted. It has also been put to the Commission that a more realistic figure for 'acid insoluble ash' for the product in international trade would be a maximum of 2%.

2. Xanthan gum (E 415); Powdered cellulose (E 460(ii))

   The addition of these substances to the permitted list of emulsifiers, stabilisers, thickeners and gelling agents imposes the requirement to determine specific criteria of purity. The number for micro-crystalline cellulose becomes E 460 (i) as a consequence of the addition to the list of powdered cellulose (E 460 (ii)).

3. Sucroglycerides (E 474)

   Technological advances have led to the use of cyclohexane and isobutanol for the production of sucroglycerides. These solvents are provided for in the proposed revision to supplement those already included in the text.

4. Propane-1,2-diol esters of fatty acids (E 477)

   When the Scientific Committee for Food (SCF) evaluated this material in 1978 the product containing 0.5% dimer and trimer was considered acceptable. The Committee recommended that as the product with 4% dimer and trimer was only temporarily acceptable its authorisation should be reviewed on the basis of further toxicological investigations the results of which should be available "within two years" (of the date of publication of the report - 30. November 1978). The Council Directive appertaining to this matter (78/663/EEC) required that the Commission review the situation so that any necessary amendments could be made before 31 December 1981.

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*compositional parameters which define the purity of the substance

The Commission has now been informed that no extra toxicology is being carried out but that at present a reduction of 0.5% will put some manufacturers in difficulty. The Commission has also been informed that development work has been undertaken to bring down the level from 4% to the level of 0.5% considered acceptable by the SCF. The present proposal assumes that this work can be completed within three years and allows Member States, who so require, to authorize the product with the high level of dimer and trimer in the intervening period.

5. Ammonium phosphatides polyglycerol polyricinoleate, sorbitan monostearate, sorbitan tristearate, sorbitan monolaurate, sorbitan monooleate and sorbitan monopalmitate

This group of substances was included in Article 2(a) of the Council Directive 74/329/EEC under the following conditions:

i) the substances may be authorized in foodstuffs by individual Member States. No obligation is placed on Member States to authorize them;

ii) no limit in time is provided for this derogation;

iii) the Council may, in accordance with the procedure laid down in Article 100 of the Treaty, include in Annex I the substances to which this paragraph refers at the same time stipulating the conditions for their use in foodstuffs, provided that in accordance with usual procedure their purity criteria are established.

The "usual procedure" for the establishment of purity criteria is that the Council adopts criteria on the basis of a Commission proposal. The present proposal applies this procedure.

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the proposal from the Commission[1],

Whereas Council Directive 78/663/EEC[2] provides that, as regards substances E 474 and E 477, the Council may, acting unanimously on a proposal from the Commission, decide on any necessary amendments by 31 December 1981;

Whereas the criteria of purity for substances E 400, E 401, E 402, E 403 and E 404 should be modified to take account of scientific developments, particularly of methods of analysis;

Whereas Council Directive 74/329/EEC of 18 June 1974 on the approcimation of the laws of the Member States relating to emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs[3], as last amended by Directive 80/597/EEC[4] specifies that the Council may include in Annex I of the Directive ammonium phosphatides, polyglycerol polyricinoleate, sorbitan monostearate, sorbitan tristearate, sorbitan monolaurate, sorbitan monooleate and sorbitan monopalmitate only when inter alia their purity criteria are established; whereas Directive 80/597/EEC also amended Annex I of Directive 74/329/EEC to permit Xanthan gum (E 415) and powdered cellulose (E 460 (ii)) and whereas therefore purity criteria for these materials should be prescribed and the nomenclature of E 460 modified accordingly;

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2 OJ L 223, 14.8.1978, p. 7

3 OJ L 189, 12.7.1974, p. 1

4 OJ L 155, 23.6.1980, p. 23

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 78/663/EEC is hereby amended as follows:

1. Article 2 is replaced by the following:

"Article 2

As regards the substance referred to in the Annex under E 477, Member States may, until 31 December 1984, authorize for use in foodstuffs a product containing not more than 4é dimer and trimer of propane-1,2-diol.".

2. The Annex is amended as follows:

(a) Under E 400, E 401, E 402, E 403 and E 404, the entries relating to Insoluble matter in dilute NaOH are deleted, and the entries relating to cid-insoluble ash are amended to "Not more than 2%".

(b) The following is inserted between E 414 and E 420 (i)

"E 415 - Xanthan gum

Chemical description:	Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with Xanthomonas campestris, purified by recovery with ethanol or isopropanol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid, and is prepared as the sodium, potassium or calcium salt. Its solutions are neutral.
Description:	Cream coloured powder
Content:	Xanthan gum yields, on a volatile matter-free basis, not less than 4.2% and not more than 5.0% of carbon dioxide.
Volatile matter:	Not more than 15% determined by drying at 105°C for 2 1/2 hours.
Ash:	Not more than 16% on a volatile matter-free basis determined at 600°C after drying at 105°C for 4 hours.

Pyruvic acid: Not less than 1.5%

Nitrogen: Not more than 1.5%

Isopropanol: Not more than 750 mg/kg

Microbiological criteria: Viable cells of Xanthomonas campestris shall be absent."

(c) The number "E 460" becomes "E 460 (i)".

(d) The following is inserted between E 460 (i) and E 461

"E 460 (ii) - Powdered Cellulose

Chemical description: Powdered cellulose is purified mechanically disintegrated cellulose prepared by processing alpha-cellulose obtained directly from fibrous plant material. It has a molecular weight of 1.6×10^5 or greater.

Description: A white, odourless powder.

Content: Not less than 92% $(C_{12}H_{20}O_{10})_n$

Volatile matter: Not more than 7% determined by drying at 105°C for 3 hours.

pH: Shake about 5 g with 40 ml of carbon dioxide-free water for 20 minutes and centrifuge. The pH of the supernatant liquid is between 5.0 and 7.5.

Sulphated ash: Not more than 0.3% determined at 800 $\pm$ 25°C.

Water soluble substances: Not more than 1%.

Diethyl ether extractable matter: Not more than 0.15%.

Chloride: Not more than 500 mg/kg expressed as Cl.

Sulphate: Not more than 500 mg/kg expressed as SO_4."

(e) Under E 474

- the last sentence in the entry relating tom Chemical description is replaced by the following:

"No organic solvents shall be used in their preparation other than cyclohexane, dimethylformamide, ethyl acetate, isobutanol and isopropanol."

- a new entry is added as follows:

"Total Cyclohexane and Isobutanol content: Not more than 10 mg/kg singly or in combination."

(f) Under E 477 the entry relating to Dimer and trimer of propane-1,2-diol is amended to "Not more than 0.5%".

(g) The following substances are added:

"Ammonium Phosphatides

Chemical description:	Ammonium phosphatides consist essentially of a mixture of the ammonium salts of phosphatidic acids derived from partially hardened rapeseed oil, or other edible oils, together with unreacted partially hardened oil.
Description:	An unctuous semi-solid (at 25°C).
Matter insoluble in light petroleum (40°C-60°C)	Total: Not more than 2.5 per centum. Inorganic matter: Not more than 0.2 per centum.
pH of an aqueous extract of melted ammonium phosphatides:	Not less than 6.0 and not more than 8.0
Phosphorus:	Not less than 3.0% and not more than 3.4%.
Ammonium nitrogen:	Not less than 1.2% and not more than 1.5%.
Unreacted oil:	Not more than 42%.
Arsenic:	Not more than 5 mg/kg.

Polyglycerol Polyricinoleate

Chemical description:	Polyglycerol polyricinoleate is essentially a complex mixture of ethers and partial esters of polyglycerol with linearly interesterified (polycondensed) fatty acids derived from castor oil. The poly-condensed castor oil fatty acids are prepared by condensation in the absence of oxygen and have an average of about 5 fatty acid residues per molecule.

Description:	Polyglycerol polyricinoleate is a highly viscous liquid (at 25°C).
Polyglycerols:	The polyglycerol moiety is predominantly di, tri and tetra-glycerol and may contain not more than 10% of polyglycerols equal to or higher than heptaglycerol.
Refractive index; n_D 65°C:	Not less than 1.4630 and not more than 1.4665.
Hydroxyl value:	Not less than 80 and not more than 100 mg KOH/g.
Iodine value:	Not less than 72 and not more than 103 (Wijs).
Acid value:	Not more than 6 mg KOH/g.

Sorbitan Monostearate

Chemical description:	Sorbitan monostearate consists of approximately 95% of a mixture of partial esters of sorbitol and its mono and di-anhydrides with predominantly stearic and palmitic acids.
Description:	Light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour and bland taste.
Content:	See chemical description.
Water:	Not more than 2% (Karl Fisher).
Acid value:	Not less than 5 and not more than 10 mg KOH/g.
Hydroxyl value:	Not less than 235 and not more than 260 mg KOH/g.
Saponification value:	Not less than 147 and not more than 157 mg KOH/g.
Sulphated ash:	Not more than 0.5% (800 $\pm$ 25°C).

Sorbitan Tristearate

Chemical description:	Sorbitan tristearate consists of approximately 95% of a mixture of partial esters of sorbitol and its mono and di-anhydrides with predominantly stearic and palmitic acids.
Description:	Light cream to tan-coloured beads or flakes, or a hard, waxy solid with a slight characteristic odour and bland taste.
Content:	See chemical description.
Water:	Not more than 2% (Karl Fisher).
Acid value:	Not less than 12 and not more than 15 mg KOH/g
Hydroxyl value:	Not less than 66 and not more than 80 mg KOH/g.
Saponification value:	Not less than 176 and not more than 188 mg KOH/g.
Sulphated ash:	Not more than 0.5% (800 $\pm$ 25°C).

Sorbitan Monolaurate

Chemical description:	Sorbitan monolaurate consists of approximately 95% of a mixture of partial esters of sorbitol and its mono and di-anhydrides with predominantly lauric acid.
Description:	Amber coloured viscous liquid with characteristic odour.
Content:	See chemical description.
Water:	Not more than 2% (Karl Fisher).
Acid value:	Not less than 4.0 and not more than 8 mg KOH/g.
Hydroxyl value:	Not less than 330 and not more than 358 mg KOH/g.
Saponification value:	Not less than 158 and not more than 170 mg KOH/g.
Sulphated ash:	Not more than 0.5% (800 $\pm$ 25°C).

Sorbitan Monooleate

Chemical description:	Sorbitan monooleate consists of approximately 95% of a mixture of partial esters of sorbitol and its mono and di-anhydrides with predominantly oleic acid.
Description:	Amber coloured viscous liquid with odour characteristic of fatty acids.
Content:	See chemical description.
Water:	Not more than 2% (Karl Fisher).
Acid value:	Not less than 5.0 and not more than 8.0 mg KOH/g.
Hydroxyl value:	Not less than 193 and not more than 210 mg KOH/ .
Saponification value:	Not less than 145 and not more than 160 mg KOH/g.
Sulphated ash:	Not more than 0.5% (800 $\pm$ 25°C)

Sorbitan Monopalmitate

Chemical description:	Sorbitan monopalmitate consists of approximately 95% of a mixture of partial esters of sorbitol and its mono and di-anhydries with predominantly palmitic acid.
Description:	Light cream or tan-coloured beads or flakes or a hard, waxy solid with a characteristic odour and bland taste.
Content:	See chemical description.
Water:	Not more than 2% (Karl Fisher).
Acid value:	Not less than 4.0 and not more than 7.5 mg KOH/g.
Hydroxyl value:	Not less than 270 and not more than 305 mg KOH/g.
Saponification value:	Not less than 140 and not more than 150 mg KOH/g.
Sulphated ash:	Not more than 0.5% (800 $\pm$ 25°C)."

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1983. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at

For the Council