# COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 9 January 1975

### COMMISSION REPORT TO THE COUNCIL

on the action to be taken following the requests for information on the additives, specificiations and methods of analysis contained in letters sent by the secretariat of the Joint FAO/WHO Food Standards Programme

(OL 1973/13 and CL 1974/7)

Commission Report to the Council on the action to be taken following the requests for information on additives, specifications and methods of analysis contained in letters sent by the secretariat of the Joint FAO/WHO Food Standards Programme. (CL 1973/13 and CL 1974/7).

The two letters referred to relate to requests for information on the acceptability of specifications for thickening agents, anticaking agents, antimicrobials, antioxidants, emulsifiers, methods of analysis, enzymes, starches, preservatives etc.. The FAO/WHO secretariat has requested information before the meeting of the Joint FAO/WHO Expert Committee on Food additives in June 1974, although has unofficially informed the Commission Services that replies after this date are acceptable.

The Commission proposes the following procedure:-

# 1. For additives controlled by Community legislation

The Commission will tell the FAO/WHO secretariat of the Community Directives that already exist on Colours, Preservatives, Antioxidants and Emulsifiers (etc). and will give information on the specification contained therein for those substances under discussion by the FAO/WHO. To this end the Commission proposes to send to Codex the letter, the draft of which is to be found annexed to this document.

# 2. Additives not yet controlled by Community legislation

The Commission proposes that Member States write individually to the effect that it is impossible to give comprehensive study to all the additives, their specifications and the methods of analysis, included in the latter and accompanying documents within the timescale proposed, and that the Member States of the EEC will collectively consider over a longer period the acceptability of the limits laid down in the FAO/WHO specification in relation to the programme of work undertaken by the Community.

Subject: Criteria of purity for food additives to be considered at the 18th Session of the Joint FAO/WHO Expert Committee on Food Additives and at the 10th Session of the Codex Committee on Food Additives.

In reply to your circular letters CL 1973/12 and CL 1974/7, I can inform you that the European Economic Community has adopted Directives on colours, preservatives, antioxidents and emulsifiers (etc.), which may be used in food within the Community.

So called "general" purity criteria have been established for all additives. "Specific" purity criteria have been drawn up for individual substances, some of which are the subject of your request for observations.

The two types of specification are referred to in Annex I and reproduced in Annex II.

The Community would be pleased to see the data considered during your future work programme.

Yours faithfully,

Summary of the European Economic Community's provisions as they affect the Criteria of purity for food additives to be considered at the 18th Session of the Joint FAO/WHO Expert Committee on Food Additives and at the 10th Session of the Codex Committee on Food Additives

Summary of the European Economic Community's provisions as the Year the Criteria of purity for food additives to be considered at the 18th Session of the Joint FAO/WHO Expert Committee on Food Additives and at the 10th Session of the Codex Committee on Food Additives

FAO/WHO Ref.	FAO/WHO Classification	Additive	EEC No.	Reference
WHO Series 2 FAO Series 50	Enzymes	As a class		Not considered
	Other substan- ces	Caramel	E150	Council Directive 23.10.62 (OJ No 115, 11.11.62) Council Directive 25.10.65 (OJ No 178, 26.10.65)
(Also WS/ E5497	at de la section de	Cellulose (microcryst)	E460	Council Directive 18.6.74
(Also WS/ E5468	••••• 2 • • • • • • • • • • • • • • • •	Sedium stearcyl lac- tylate	E481	) (OJ L189, 12.7.74) ) General provisions; ) specific criteria of
(Also WS/ E5468		Calcium stearoyl lactylate	E482	purity under consideration
(Also WS/ E5198		Hexamethylenetet- ramine	E239	Council Directive 5.11.63 (OJ No 12, 27.1.64) General provisions; specific criteria of purity under consideration.
(Also WS/ E5497		Starches (chemical treated)	-	<b></b>
WS/E5497	Thickening	Agar	E406	<b>)</b>
	agents, Stabilisers	Alginic acid	<b>E</b> 400	}
	-	Ammonium alginate	E403	
		Arabic gum	E414	[ ]
		Calcium alginate	E 404	Council Directive 18.6.74
-,		Carob bean gum	E410	) (OJ No L189, 12.7.74) ) General provisions;
		Carrageenan	E 407	specific criteria of purity
		Furcellaran	<b>E 40</b> 8	\ \ under consideration.
	•	Guar gum	E412	<b> </b>
	· ·	Hydroxypropyl cell- ulose	E 463	}
	•	Hydroxypropyl methyl cellulose	E 464	}
	*	Karaya gum		-

FAO/WHO Ref.	FAO/WHO Classification	Additive	EEC No.	Reference
		Methylcellulose	E461	)
		Methylethylcell- ulose	E 465	}
		Pectin	E 440	}
	:	Potassium alginate	E 402	Council Directive 18.
		Propylene glycol alginate	E 405	(OJ No L189, 12.7.74) General provisions;
		Sodium alginate	E 401	) specific criteria of under consideration
		Sodium carboxymethyl cellulose	E 466	}
		Tragacanth	E 413	}
WS/E5101	Anticaking	As a class	_	Not considered
	Agents	Calcium carbonate	E170	Council Directive 23.10 (OJ No 115, 11.11.62)
		Calcium phosphate, tribasic	E341	Council Directive 13.7. (OJ No L 157, 18.7.70) General provisions;
				specific criteria of pu under consideration
		Salts of myristic, palmite and stearic acid, with bases acc- epted for food use	Ex- E470	Council Directive 18 (OJ No L189, 12.7.74 General provisions;
		Tetrasodium disphos- phate	E450	specific criteria of under consideration
		Monosodium L-Cluta- mate	E214	}
WS/E5198	Antimicro-	Benzoic acid	E210	) Council Directive 5.1
	bials, Preservatives	Calcium acetate	E263	) (OJ No 12, 27.1.64) amended
		Calcium propionate	E282	Council Directive 26.
		Calcium sorbate	E203	) (OJ No 22, 9.2.65)
		'Ethyl-p-hydroxyben- zoate	E214	)
. 20		Cupric sulfate	_	
		Diethyl pyrocarbonate	_	_
		Formic acid	E236	) Council Directive 5.1
		Wethyl-p-hydroxyben- zoate	E218	) (OJ No 12, 27.1.64) a ) amended
				General provisions; specific criteria of
j			<b>f</b>	under consideration

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FAC/I	MHO	FAO/WHO Classification	Additive	EEC No.	Reference -
<del></del>			Hydrogen peroxide	-	
			DL lactic acid	E270	, .
	,		Potassium benzoate	E212	· ·
			Potassium metabis— ulfite	E224	}
	,		Potassium nitrate	E252	<b>                                     </b>
			Potassium sorbate	E202	<b> </b>
			Propionie acid	E280	}
			Propyl-p-hydroxyben- zoate	E216	Council Directive 5.11.63
			Sodium benzoate	E211	) (OJ No 12, 27.1.64) as ) amended Council Directive
			Sodium diacetate	E262	) 26.1.65
			Sodium hydrogen sulfite	E222	) (OJ No 22, 9.2.65) ) General provisions; ) specific criteria of purity
•			Sodium metabisulfite	E223	) under consideration
			Sodium nitrate	E251	<b> </b>
			Sodium nitrite	E250	<b> </b>
			Sodium propionate	E281	}
			Sodium sulphite	E221	<b>[</b>
			Sorbic acid	E200	}
			Sulfur dioxide	E220	<b>\</b>
ws/eg	469	Antioxidants	- Tocopherol	E307	)
•		Synergists	Ascorbic scid	E300	
			Ascorbyl palmitate	E304	
			Butylated hydroxy- anisol	E320	}
			Butylated hydroxy- toluene	E321	Council Directive 13.7.70
			Citric acid	E330	) (OJ No L 157, 18.7.70) ) General provisions;
		<b>Y</b>	Dodecyl gallate	E312	) specific criteria of purit
			Mixed tocopherols	Ex-	under consideration
			0-1-2	E306	1: 2
	-		Octyl gallate	E311	[ ]
			Phosphoric acid	E338	[1 <del>]</del>
Į.		1 1000 800	Sodium ascorbate	E301	1-3
er g			Tartaric acid	E334	

FAO/WHO Ref.	FAO/WHO Classification	Additive	EEC No.	Reference
		Sodium polyphosphate	<b>E4</b> 50	Council Directive 18.6.74 (OJ No General provisions; specific criteria of purity under consideration
		Calcium disodium ethy- lenediaminetetraacetate	<b></b>	) Subject to national legismonth lation see Council Direction 13.7.70 (OJ No L157,18.7.78)
;		Propyl gallate	-	) No Community specification
		Other substances on list		Not permitted in the Community
ws/e5468	Emulsifiers	Acetic and fatty acid esters of glycerol	Ex- E472	}
		Citric and fatty acid esters of glycerol	E472	) Council Directive 18.6.74 ) (OJ No L189, 12.7.74) ) General provisions;
		Diacetyl tartaric and fatty acid esters of glycerol	E472	specific criteria of purity under consideration
		Lactic and fatty acid esters of glycerol	E472	}
		Lecithin	E32 <b>2</b>	Council Directive 13.7.70 (OJ No L157, 18.7.70) General provisions; specific criteria of purity under consideration
		Mono and diglycerides	E471	<b>)</b>
		Polyglycerol esters of fatty acids	E475	Council Directive 18.6.74 (OJ No L189, 12.7.74)
		Propylene glycol esters of fatty acids	E477	<pre>General provisions; specific criteria of purity under consideration</pre>
		Sucrose esters of fatty acids	E473	) ander consideration
		Cholic acid Desoxycholic acid	-	) Not permitted - but see Article / 10/ of Council Directive
		Thermally oxidised soy bean oil		) (OJ No L189, 12.7.74)
		Other substances on list	1 5	Subject to nationallegislation See Annex II of Council Directive (OJ No L189, 12.7.74)
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1. Extract from Council Directive of 23 October 1962 on the approximation of the laws of the Member States concerning the colouring matters authorised for use in foodstuffs intended for human consumption (OJ 115 of 11.11.1962).

# ex Article 8

The Member States shall take all measures necessary:

- to ensure that the colouring matters listed in Annex I, where these are used to colour foodstuffs, satisfy the criteria, both general and specific, laid down in Annex III;
- to ensure that the products listed in Article 6, where these are used to dilute or dissolve the colouring matters listed in Annex I, satisfy the general criteria of purity laid down in Annex III, Section A (I) and (2) (b).

# ex Annex III

# A. General Criteria of Purity

Unless otherwise provided in the specific criteria in Section B the colouring matters referred to in Annex I are required to satisfy the following criteria of purity:

- 1. Inorganic impurities
- (a) They should contain not more than 5 mg/kg of arsenic and not more than 20 mg/kg of lead;
- (b) They should contain not more than 100 mg/kg of the following substances, taken separately: antimony, copper, chromium, zinc, barium sulphate; and not more than 200 mg/kg of these products taken together;
- (c) They should not contain cadmium, mercury, selenium, tellurium, thallium, uranium or chromates, or soluble combinatations of barium in detectable quantities.
- 2. Organic impurities
- (a) They should not contain 2-naphthylamine, benzidine, amino-4-diphenyl (or xenylamine) or their derivatives;
- (b) They should not contain polycyclic aromatic hydrocarbons;

- (c) Synthetic organic colouring matters should contain not more than 0.0% of free aromatic amines;
- (d) Synthetic organic colouring matters should contain not more than 0.5% of intermediate synthetic products other than free aromatic amines;
- (e) Synthetic organic colouring matter should contain not more than 4% of accessory colouring matters (isomers, homologues etc.);
- (f) Sulphonated organic colouring matters should contain not more than 0.2% of substances extractable by diethyl ether.
- B. Specific Criteria of Purity E 150 Caramel

## ex Annex I

- (i) Products obtained exclusively by heating sucrose or other edible sugars or amorphous brown products, soluble in water, obtained by the controlled action of heat on edible sugars in the presence of one or more of the following chemical compounds:
  - acetic, citric, phosphoric, sulphuric and sulphurous acids and sulphur dioxide;
  - ammonium, sodium and potassium hydroxides and ammonium gas;
  - ammonium, sodium and potassium carbonates, phosphates, sulphates and sulphites.

#### ex Annex III

- (ii) Ammonia-nitrogen : not more than 0.5% determined according to the Tillmans-Mildner method.
  - Sulphur dioxide : not more than 0.1% determined according to the Monier-Williams E.W. Method.
  - pH : not less than 1.8.
  - Phosphates : not more than 0.5% expressed as P205.
- 2. (a) Extract from Council Directive of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorised for use in foodstuffs intended for human consumption.

  (OJ 12 of 27.1.1964).

# Article 7

Member States shall take all measures necessary to ensure that the preservatives 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 mg/kg of arsenic and not more than 10 mg/kg of lead;
  - they must contain not more than 50 mg/kg of copper and sinc taken together, of which the zinc content must not be higher than 25 mg/kg nor must they 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 where appropriate and in accordance with Article 8 (1).
- 2. (b) Council Directive of 26 January 1965 laying down specific criteria of purity for preservatives authorised for use in foodstuffs intended for human consumption. (OJ 22 of 9.2.1965 as modified by OJ 126 of 12.7.1965 and OJ 148 of 11.7.1967).

#### ex Article 4

3. 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. (OJ L 157 of 18.7.1970).

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 ......
- 4. Council Directive 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.

# 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:
  - (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 copperhand zinc taken together of which the zinc content must in no case exceed 25 mg/kg ....
- 2. Member States shall also ensure that the substances listed in Annex I under:
  - E 471 Mono- and diglycerides of fatty acids
  - E 472(b) Lactic acid esters of mono- and diglycerides of fatty acids
  - E 473 Sucrose-esters of fatty acids
  - E 474 Sucroglycerides
  - E 475 Polyglycol esters of fatty acids, and
  - E 477 Propylene glycol esters of fatty acids.

do not in addition contain more than 6% of sodium, potassium and oalcium salts of fatty acids (E 470).