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REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD
ON
EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS

(Opinion expressed 30 November 1978)

TERMS OF REFERENCE

To review certain aspects of the Directive on Emulsifiers, Stabilizers, Thickeners and Gelling Agents for use in Foodstuffs[1], in particular the acceptability, from the point of view of safety in use, of substances listed in Annex II of the Directive.

BACKGROUND

When the Directive was agreed by the Council of Ministers in June 1974 a number of issues were left for future determination. Some substances, used only in a few Member States, were separately listed in Annex II* of the Directive. Article 3 of the Directive permits Member States to authorise the use of these substances in food for a period of "five years from the notification" of the Directive. This period comes to an end in June 1979, and therefore the Commission is currently considering whether it would be appropriate to include these substances in Annex I* (substances which may be authorised in the whole Community). In the case of some substances in Annex I namely E 408, E 450(c), E 460, E 480**, E 481 and E 482, the Council requested the Commission to reexamine their acceptability during the same period. The Commission has asked the Committee for its advice.

The basic Directive also requires that purity criteria for all substances be drawn up and the Committee notes with approval that such criteria have already been established for substances appearing in Annex I[2].

During preliminary discussions of the Commission's proposals between the Commission Services and experts from Member States, questions were raised about the toxicological acceptability of some of the purity criteria and the Committee was asked for its advice on a number of points relating to:

- the identity of E 407/E 408
- the protein content of E 412
- the identity of E 440
- the maximum molecular weight for E 466
- the acceptability of the classification of E 472

The opinions of the Committee on these questions were submitted to the Commission early in 1977 and are reproduced in extenso in this Report (Annexes 3 to 6).

The Commission has also asked the opinion of the Committee on the use of E 413 following requests by European Parliament and Economic and Social Committee members.

CURRENT REVIEW

The Commission Services requested Member States to supply up-to-date information (toxicological, technological and usage) on the substances under discussion. These date, in the main, were supplied as summaries. The Commission Services were also able to provide data, submitted to them by the industries concerned, on a number of substances.

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[1] 74/329/EEC of 18 June 1974, OJ L 189 of 12.7.1974, p. 1

[2] 78/663/EEC of 25 July 1978, OJ L 223 of 14.8.1978, p. 7

* For easy reference to names of the substances, Annexes I and II are reproduced in Annexes 1 and 2 to this Report

** E 480 has since been deleted from the Directive

The Committee decided that it would be unnecessarily cumbersome to request that all data, previously submitted to national governments, be made available to each member. However, the Committee felt unable simply to rely on summaries of data submitted to other bodies. It was agreed therefore that designated members of the Committee should examine details of different submissions in full, but that the resulting assessment could be presented in summary form to the main Committee unless there was a particular reason to depart from this procedure. References to all the data examined in this way are given for each substance under the appropriate heading in Annexes 3 to 7.

The Community Directive does not in general refer to the foodstuffs in which particular emulsifiers, stabilizers, thickeners and gelling agents may be used. Nevertheless, Article 4 of the Directive requires that the Council "shall determine as soon as possible the foodstuffs to which these substances may be added and the conditions under which they may be added". The Committee recommends that steps be taken to implement these requirements, and draws attention to the fact that any misuse of the additives discussed in this Report may lead to excessive retention of water with a reduction in the nutritional value of the food on a weight for weight basis.

The Committee therefore confined its attention mainly to establishing whether, from the point of view of safety, individual emulsifiers, stabilizer, thickeners and gelling agents were acceptable. Nevertheless it seemed desirable to indicate in the report some technological applications of which the Committee was informed although not all of these apply necessarily in the Community context. The Committee wishes to reiterate the point made in its Opinion on Fine Bakers' Wares, Rusks, Pastries and Biscuits 1) that the setting of maximum levels of use of an additive in various foods is not a purely arithmetical exercise. The desired technological results must be achieved in a way that ensures that the ADI is unlikely to be exceeded. The Committee requests that it be kept informed by the Commission of proposals for the assignment of maximum levels of use for any food additive and be invited to comment from the point of view of safety in use.

ASSESSMENT OF TOXICOLOGICAL ACCEPTABILITY

The general criteria used in the present review for the evaluation of emulsifiers, stabilizers, thickeners and gelling agnets are comparable to those employed in the assessment of the safety of colouring matters, and are summarised in paragraph 10 of the Committee's first report on such substances 2). The Committee noted that in many instances compounds proposed for use as emulsifiers, stabilizers, thickeners and gelling agents were esters which during their metabolism hydrolysed into components for which global ADIs had been established by JECFA at various times. It wished to draw attention to these evaluations of JECFA and to the need for taking these into consideration when assigning levels of use.

CLASSIFICATION OF EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS

The classification used during the present review was similar to the one used for colouring matters (see paragraph 11 of the Committee's 1st report on colouring matters).

I. Substances for which an ADI could be established and which are therefore toxicologically acceptable for use in foods within these limits

As a working principle, before a food aditive can be accepted for use in food, it is necessary to provide adequate toxicological data. Based on these data an ADI can be established using results obtained with the most sensitive animal species and using the most sensitive criterion.

II. Substances for which a temporary ADI could be established and which are toxicologically acceptable for use in food within these limits for a period of 3 years or 5 years depending on the types of information required

Not later than one year before the end of the appropriate period, the Committee expects to be provided with a report on the tests indicated in Annex 7 as necessary.

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1) Reports of the Scientific Committee for Food, 5th Series, May 1978
2) Reports of the Scientific Committee for Food, 1st Series, December 1975

Exceptionally the Committee would be prepared to consider recommending an extension of the period of validity of the temporary ADI, provided it was satisfied that substantial progress had been made with the tests required.

III. Substances for which an ADI could not be established but which are nevertheless considered acceptable or temporarily acceptable for use in food

The Committee was unable to establish formal ADIs on the basis of the available toxicological information. However, some of these substances occur naturally and are consumed as part of the diet in some parts of the world. Others are used at very low levels in food, or are used only in products of low consumption. Most of the substances are known to hydrolyse into components to which the body is already exposed, or which are of known toxicity.

IV. Substances for which an ADI could not be established and which are not toxicologically acceptable for use in food

Where a substance has been included in this category, the Committee believes that its use should be phased out. However, the Committee would be willing to reconsider its advice should adequate additional information become available.

Unless other requirements are stipulated with respect to particular substances the Committee believes that there is no objection to a gradual phase out over a period of 1 year or so.

Detailed comments on individual substances are given in Annex 7.

SUMMARY OF CONCLUSIONS

1. Substances for which an ADI could be established and which are therefore toxicologically acceptable for use in food within these limits

Carrageenan (E 407/E 408)	: ADI 0–75 mg/kg bw*
Pectin (E 440)(E 440a)	: ADI not specified
Sodium and potassium polyphosphates (E 450c)	: Acceptable total dietary phosphorus load** 0–70 mg/kg bw
Microcrystalline cellulose (E 460)/powdered cellulose	: ADI not specified
Polyglycerol esters of mono- and di-glyceride of fatty acids (E 475)	: ADI 0–25 mg/kg bw
Sodium stearoyl-2-lactylate (E 481) Calcium stearoyl-2-lactylate (E 482)	) ADI 0–20 mg/kg bw singly or in) combination
Partial polyglycerol esters of poly-condensed fatty acids of castor oil	: ADI 0–7.5 mg/kg bw
Sorbitan monopalmitate Sorbitan monostearate Sorbitan tristearate	) ADI 0–25 mg/kg bw singly or in) combination
Sorbitan monolaurate Sorbitan mono-oleate	) ADI 0–5 mg/kg bw singly or in) combination
Guar gum (E 412)	: ADI not specified

* bw = body weight

** This estimate applies to the sum of added phosphate and food phosphate. Acceptable daily intake levels of phosphate depend on the amount of calcium in the diet. The levels stated apply to diets that are nutritionally adequate with respect to calcium. However, if the calcium intake were high, proportionally higher amounts of phosphate would be acceptable, and the reverse relation would also apply.

Xanthan gum	: ADI 0–10 mg/kg bw
Extract of Quillaia	: ADI 0–5 mg spray dried extract/kg bw
Propane-1,2-diol esters of fatty acids (E 477) *	: ADI 0–25 mg/kg bw
Ammonium phosphatides	: ADI 0–30 mg/kg bw
Fatty acid esters of mono- and diglycerides of fatty acids (E 472 a–d, f)	: ADI not specified
(E 472 e)	: ADI 0–50 mg/kg bw

2. Substances for which a temporary ADI could be established and which are toxicologically acceptable for use in food within these limits for a period of 3 years or 5 years depending on the types of information required

Amidated pectin (E 440b)	: temporary ADI 0–25 mg/kg bw
Polysorbates (20, 40, 60, 65 and 80)	: temporary ADI 0–25 mg/kg bw
Polyoxyethylene (40) stearate	: temporary ADI 0–25 mg/kg bw
Dioctyl sodium sulphosuccinate	: temporary ADI 0–0.1 mg/kg bw

3. Substances for which an ADI could not be established but which are nevertheless considered temporarily acceptable for use in food

Tragacanth (E 413)(temporary)

Propoane-1,2-diol esters of fatty acids (E 477) ** (temporary)

Polyoxyethylene (8) stearate (temporary)

Oxidatively thermally polymerised soya bean oil interacted with mono- and di-glycerides (temporary)

Lactylated fatty acid esters of glycerol and propane-1,2-diol (temporary)

4. Substances for which an ADI could not be established and which are not toxicologically acceptable for use in food

Karaya gum

Ghatti gum

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* with a total content of dimer and trimer of propane-1,2-diol of 0.5% or less

** with a total content of dimer and trimer of propane-1,2-diol between 0.5% and 4%.

ANNEX 1

EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS WHICH MAY BE USED IN FOODSTUFFS

EEC No.	Designation	Conditions of use
E 322	Lecithins	
E 339	Sodium orthophosphates	
E 340	Potassium orthophosphates	
E 341	Calcium orthophosphates	
E 400	Alginic acid	
E 401	Sodium alginate	
E 402	Potassium alginate	
E 403	Ammonium alginate	
E 404	Calcium alginate	
E 405	Propane-1,2-diol alginate	
E 406	Agar	
E 407	Carrageenan	
E 410	Locust bean gum	
E 412	Guar gum	
→ E 413	Tragacanth	
E 414	Acacia or gum arabic	
E 420	(i) sorbitol (ii) sorbitol syrup	
E 421	Mannitol	
E 422	Glycerol	
E 440 (a)	Pectin	
E 440 (b)	Amidated pectin	
E 450 (a)	(i) diSodium dihydrogen diphosphate (ii) triSodium diphosphate (iii) tetraSodium diphosphate (iv) tetraPotassium diphosphate	
E 450 (b)	(i) pentaSodium triphosphate (ii) pentaPotassium triphosphate	
E 450 (c)	(i) sodium polyphosphates (ii) potassium polyphosphates	
E 460	Microcrystalline cellulose	
E 461	Methylcellulose	
E 463	Hydroxypropylcellulose	
E 464	Hydroxypropylmethylcellulose	
E 465	Ethylmethylcellulose	
E 466	Carboxylmethylcellulose	
E 470	Sodium, potassium and calcium salts of fatty acids	Exclusively in the manufacture of 'Dutch' type rusks up to a level singly or in combination of not more than 1.5% of flour used

EEC No.	Designation	Conditions of use
E 471	Mono- and diglycerides of fatty acids	
E 472 (a)	Acetic acid esters of mono- and diglycerides of fatty acids	
E 472 (b)	Lactic acid esters of mono- and diglycerides of fatty acids	
E 472 (c)	Citric acid esters of mono- and diglycerides of fatty acids	
E 472 (d)	Tartaric acid esters of mono- and diglycerides of fatty acids	
E 472 (e)	Mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids	
E 472 (f)	Mixed acetic and tartaric acid esters 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	Polyglycerol esters of fatty acids	
E 477	Propane-1,2-diol esters of fatty acids	
E 481	Sodium stearoyl-2-lactylate	These substances may not be used in bread unless permitted under national law
E 482	Calcium stearoyl-2-lactylate	
E 483	Stearyl tartrate	

ANNEX 2

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 oxidized 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)

ANNEX 3

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON CARRAGEENAN (E 407) AND FURCELLARAN (E 408)

(Opinion expressed January, 1977)

TERMS OF REFERENCES

The Committee was asked to give its opinion on whether carrageenan and furcellaran can be included within a single specification of purity and, if so, whether substances complying with this specification can be recommended for acceptance on a Community basis beyond June 1979.

CONCLUSIONS

The Committee accepts that on the basis of the current information on source materials, production methods, chemical nature and toxicological information, a single combined specification for carrageenan and furcellaran for food use of high molecular weight is justified.

BACKGROUND

The Directive on the approximation of the laws of Member States relating to emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs (74/329/EEC of 18 June 1974) permits the use of carrageenan and furcellaran on a Community basis. However, within 5 years of the notification of the Directive (i.e. by June 1979) the Council, on the basis of a proposal from the Commission, must decide whether to delete, retain or otherwise change the status of furcellaran. (Article 2.2.)

The Commission, in accord with Article 7 of the Directive, is preparing specific criteria of purity for carrageenan and for furcellaran. The producers of carrageenan and furcellaran have stated that formerly these stabilisers were obtained from separate algae sources, but that currently they are both obtained from a wide but similar range of red algae. The producers have therefore suggested that a single combined specification for carrageenan/furcellaran would now be more appropriate.

SOURCE MATERIALS FOR CARRAGEENAN AND FURCELLARAN

The Committee was informed that the source materials for both carrageenan and furcellaran are red algae of the Order Gigartinaes from the Class Rhodophyceae (1). Carrageenan was formerly obtained principally from algae of the Family Gigartinaceae, in particular, Chondrus crispus. However, the increasing scarcity of such algae has led to the use of red algae from other Families of the same Order – including Furcellariaceae. Furcellaran was originally obtained solely from the species Furcellaria fastigiata of the Order Furcellariaceae. The Committee was informed that this species is no longer available in sufficient quantities, so that the source material for furcellaran is often a mixture of Furcellaria fastigiata with Chondrus crispus and other similar red algae. Thus, there has been a considerable extension of the number of Families of red algae used in the production of carrageenan, one of the Families, Furcellariaceae, being that from which furcellaran is obtained; whilst furcellaran is currently obtained from mixtures of Furcellaria fastigiata and other red algae that are also used in the production of carrageenan.

PRODUCTION METHODS

The Committee was informed that carrageenan is obtained by extracting the red algae with hot water, filtering the extract and then precipitating the carrageenan with an alcohol (normally propan-2-ol but sometimes ethanol or methanol). Furcellaran can be obtained in similar fashion, though it is more usual to precipitate the furcellaran by addition of potassium chloride (1). The Committee noted that degraded carrageenan, prepared by the partial hydrolysis of Eucheumaspinosum, is not used for food purposes but is sold for medical use as an anti-peptic agent (2).

CHEMICAL NATURE OF CARRAGEENAN/FURCELLARAN

The product as obtained primarily from Chondrus crispus, consists chiefly of the calcium, potassium, sodium and magnesium salts of polysaccharide sulphate esters, the dominant hexose units of which are galactose and 3,6-anhydrogalactose. The sulphate content, as SO_4 on a dry-weight basis is between 18 and 40% (3)(4).

However, the product obtained primarily from Furcellaria fastigiata, consists chiefly of the potassium salts of polysaccharide sulphate esters, the dominant hexose units again being galactose and 3,6-anhydrogalactose. The sulphate content, as SO_4 on a dry-weight basis, ranges from 14 to 18 per cent (4).

The Committee was told that when alcohols are used for precipitation it is difficult to reduce the level of residual solvent to below 1 per cent.

TOXICOLOGICAL EVALUATION AND CRITERIA OF PURITY

The Committee noted that in 1970 JECFA published separate specifications for carrageenan and furcellaran (4), the two substances were considered together for the purposes of toxicological evaluation (5). In 1973, JECFA reviewed the toxicology of the two substances together (2) and in 1974 decided to put forward tentatively a single combined specification (6).

The Committee accepts that on the basis of the current information on source materials, production methods, chemical nature and toxicological information, a single combined specification for carrageenan and furcellaran is justified stating that the minimum viscosity of 1.5 per cent solution should not be less than 5 centipoises at 75°C.

The Committee gave attention to solvent residues and to the molecular weight restrictions.

The Committee recommends that the levels and kinds of residual solvent in the final product should not exceed 1 per cent for methanol, ethanol or propan-2-ol (isopropanol) singly or in combination. The Committee considers that, if practicable the use of methanol should be avoided and the product should only be obtained using ethanol or propan-2-ol.

The Committee noted the evidence summarised by JECFA (2) that degraded carrageenan has an ulcerogenic effect in some animal species (rat, guinea pig, rabbit) but not others (mouse, hamster, gerbil, ferret, pig, squirrel or monkey). On the other hand there is no evidence that patients given degraded carrageenan for the treatment of peptic ulceration and ulcerative colitis have suffered ill effects. Since then Engster and Abraham have published their work on the caecal response to different molecular weights and types of carrageenan in the female guinea pig (7). Kappa (K) and Lambda (λ) fractions were obtained by treatment of Chondrus crispus extracts with alkali and precipitation by alcohol. Iota (i) fractions were obtained from Eucheuma spinosum extracts after acid hydrolysis. Results are summarised briefly in the following table:

Fraction	Intrinsic viscosity (dl/g)	Number average molecular weight (Mn)	Response to 1% solution in drinking water (2 weeks)	Response to 2% level fed in diet (10 weeks)
K	11.95	314.000	negative	nt
K	1.451	51.500	negative	nt
K	0.117	8.500	negative	nt
λ	10.250	275.000	negative	nt
λ	2.243	74.800	negative	nt
λ	0.503	20.800	negative	nt
i	7.51	145.000	negative	negative
i	5.34	107.000	+	negative
i	4.19	88.000	+	negative
i	1.62	39.000	+ +	negative
i	0.685	21.000	+ +	negative

Fraction	Intrinsic viscosity (dl/g)	Number average molecular weight (Mn)	Response to 1% solution in drinking water (2 weeks)	Response to 2% level fed in diet (10 weeks)
i	0.285	8.700	+	negative
i	0.113	ca 5.000	negative	nt

Code:

\+ epithelial thinning, slight erosion, cellular infiltration and crypt abscesses in caecum.

\+ + as above, plus ulceration of the caecal mucosa.

nt not tested.

Pittman, Golberg and Coulston (8) give a variety of Iota, Kappa and Lambda carrageenans to guinea pigs, monkeys and rats, either in drinking water or by gavage or in the diet. Substantial amounts of carrageenan were found in the livers of guinea pigs and rats given low molecular weight i, K or λ carrageenans (below 40.000 Mn). Intermediate amounts were found in the livers of animals given carrageenans ranging in number average molecular weights (Mn) between 40.000 and 150.000. Degradation occurred on or after passage through the intestinal tract since the Mn values of carrageenans from the livers of guinea pigs tended to be about 10.000. Excretion of carrageenans in the urine was limited to values of Mn of probably 10.000 or less. The authors calculated that i-carrageenans containing only molecules of Mn above 50.000 - 85.000 Mn would not be absorbed and found in the liver.

The Committee was of the opinion that the evidence concerning possible adverse effects of degraded carrageenan in the human diet was inconclusive.* However, as a matter of prudence the level of degraded carrageenan in carrageenan for food use should be kept to a minimum. There is no reliable analytical method for detecting small amounts of degraded carrageenan in food grade carrageenan. But the Committee was informed that in practice this does not present a problem since, for food use, undegraded carrageenan is less expensive and superior from a technological view point. Degraded carrageenan is made by a separate process.

*Since submitting this report the Committee was informed about the adverse findings reported in recent studies on degraded carrageenan (9), which reinforce its opinion that food grade carrageenan should contain as low a level as possible of degraded material. In order to align this earlier report with the formal presentation in its present Report on Emulsifiers, Stabilizers, Thickeners, and Gelling Agents, the Committee wishes to record that it does not object to the endorsement of the ADI of 0-75 mg/kg bw established by JECFA.

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ANNEX 4

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON GUAR GUM (E 412)

(Opinion expressed January 1977)

TERMS OF REFERENCE

The Committee was asked to express its opinion on the implications of a recent report on research on guar gum (1) in relation to proposed specifications for this substance and its continued inclusion on the Community list of acceptable emulsifiers, stabilisers, thickeners and gelling agents.

CONCLUSIONS

The Committee concluded on toxicological grounds that the protein content of guar gum for use in human food should be as low as possible. There was some evidence that a level of 5 per cent protein in guar gum should be technologically feasible, but, meanwhile, the Committee would not object to the continued inclusion of guar gum (milled endosperm of guar seed on the Community list of acceptable emulsifiers, stabilisers, thickeners and gelling agents provided that the protein level of the gum does not exceed 7 per cent.[A] This opinion on acceptability for use in food relates solely to use at the levels required for emulsifying, stabilising or thickening purposes, normally not exceeding 2 per cent. Further consideration would need to be given to the acceptability of guar gum for dietary products (e.g. as a bulking aid in low energy preparations) when levels of use could be in excess of 2 per cent.

BACKGROUND

The Council Directive on the approximation of the laws of Member States relating to emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs (74/329/EEC of 18 June 1974) permits the use of guar gum on a Community basis. Article 7 of the Directive requires that the Council on a proposal from the Commission, shall lay down specific criteria of purity. During discussions on these criteria of purity with experts from the Member States the Commission's attention was drawn to a report by Feldheim and Stamm on animal feeding trials with guar seeds and guar seed fractions (1).

The Commission therefore requested the Committee's opinion on the implications of this report as regards both the proposed specification for guar gum and the continued acceptability of guar gum for inclusion in the Directive.

PRODUCTION TECHNOLOGY, TERMINOLOGY AND USAGE

The Committee were given details of the method of production of and terminology for the various guar seed products (2)(3). The guar seeds are crushed and the germ, endosperm and husks separated mechanically. The germ is milled to produce raw guar meal. This is usually heat treated prior to use as a protein source in animal feed. The endosperm is milled to give the product known as guar gum and the husks are discarded.

Guar meal has a protein content of about 45–50 per cent. Pure guar endosperm, separated by hand, has a protein content of about 4–5 per cent. However, commercial guar endosperm (guar gum) contains small residual amounts of germ and husk which it is claimed cannot be separated economically without substantial loss of endosperm. The Committee was informed that the maximum protein content of 7 per cent for guar gum suggested as practicable by the trade would imply that its germ content was no higher than 6 per cent. The Committee was provided with the following table showing the composition of guar seeds and their utilisable products (2):

[A] calculated on the basis of total nitrogen determination and using the factor of 6.25 to convert total nitrogen to protein.

Product	Protein Content (%)	Galactomannan Content (%)	Use
Guar seed (cyamopsis tetra gonolobus L).	28–34	30–35	Source material
Guar meal (germ)	45–50	6–10	Animal feed
Guar gum (endosperm)			
- technical grade	6– 9	65	paper, textiles mining
- food grade	7	75	thickener and stabiliser

As a thickener and stabiliser, use levels in food are generally no more than about 2 per cent.

TOXICOLOGICAL INFORMATION

In 1975 the FAO/WHO Joint Expert Committee on Food Additives (JECFA) confirmed its evaluation of "ADI not specified" for guar gum (5)* Feldheim and Stamm's report (1) appeared in 1976 and was not therefore considered by JECFA. Feldheim and Stamm summarised earlier feeding trials on cattle, poultry and rats with guar seeds or their protein-rich or carbohydrate-rich fractions. The protein-rich fractions caused toxic effects which were diminished if heated fractions were fed. Carbohydrate-rich fractions depressed growth. According to the authors this was probably due to poor utilisation of galactomannans (the main carbohydrate fraction of guar) by the animals or to a decrease in fodder consumption due to expansion of the fodder in the gut. Feldheim and Stamm cited other studies in which isolated guar protein caused swelling and inflammation of the intestines when fed to rats. Raw guar meal (the protein-rich fraction) is known to contain a trypsin inhibitor (6,7) as do many other plant seeds (e.g. soya beans). The Committee was informed that preliminary tests showed the trypsin inhibitor activity of guar meal to be about 20 per cent of the activity found in soya protein and that no trypsin inhibitor activity could be detected in guar gums with 4 to 10 per cent protein content (3).

*In order to align this earlier report with the formal presentation of its present Report on Emulsifiers, Stabilizers, Thickeners, and Gelling Agents, the Committee wishes to record that it does not object to the endorsement of the ADI "not specified" established by JECFA.

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ANNEX 5

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON ESTERS OF MONO- AND DI-GLYCERIDES OF FOOD FATTY ACIDS (E 472)

(Opinion expressed January 1977)

TERMS OF REFERENCE

To give an opinion on the adequacy of the current designation for E 472 at Annex I of the Council Directive on the approximation of the laws of Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (74/329/EEC of 18 June 1974), and whether the mixed acetic/tartaric esters are acceptable for use in food from the point of view of the health of the consumer.

CONCLUSIONS

1. The Directive should be reworded so as to permit only specific mono- and di-glycerides whether produced from one or more than one of the specified organic acids.

2. The Committee is prepared to accept the specific inclusion of the mixed acetic/tartaric acid esters on the Community list of emulsifiers (etc.).

BACKGROUND

The Directive permits the use in foodstuffs, on a Community basis, of certain esters of mono- and di-glycerides of food fatty acids. These are :

(a) Acetic acid esters;

(b) Lactic acid esters;

(c) Citric acid esters;

(d) Tartaric acid esters;

(e) Mono and diacetyltartaric acid esters.

This wording has been interpreted in different ways in various Member States and this has led to different applications of the Directive in national legislation.

One interpretation is that these mono- and di-glycerides may only be esterified with one of the five listed acids at a time.

A second interpretation is that mono- and di-glycerdies may be esterified with one or any combination of the five acids listed above.

The first interpretation is complicated by the fact that lactate, citrate, tartrate and diacetyltartrate all have more than one functional group which can take part in ester linkages - even though only one of the five acids is used for esterification. The same complication arises for the second interpretation but, in this case, the number of possible end-products can be even greater when more than one of the five acids is used for esterification.

OPINION ON THE CURRENT DESIGNATION FOR E 472

The Committee rejects the second interpretation and recommends that the Directive be re-worded so as to permit only specific mono- and di-glyceride esters whether produced from one or more than one of the listed acids. This means that esters produced from one of the acids (a) - (e) above are considered acceptable.*

Other products made from more than one of the listed acide will have to be considered individually on their merits. The Committee has only been asked to consider the mixed acetic/tartaric acid esters.

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*In order to align this earlier report with the formal presentation of its present Report on Emulsifiers, Stabilizers, Thickeners and Gelling Agents, the Committee wishes to record that it does not objet to the endorsement of the ADIs established by JECFA.

OPINION ON THE MIXED ACETIC/TARTARIC ACID ESTERS

The Committee was provided with the results of two long-term feeding studies using commercial formulations based on the mixed acetic/tartaric esters, and with the composition of these formulations. Mosinger (1) administered one formulation for 24 months to 15 male and 15 female Wistar rats at 5 g/kg body weight per day. The author reported normal growth rates, no carcinogenic effect and no effects on reproduction and progeny over 2 generations. Lang, Kieckebush and Griem (2) investigated another formulation reporting the LD_{50} for male mice as greater than 20 g per kg body weight. Groups of 20 male and 20 female rats were fed the substance in doses of 100 mg/kg body weight and 400 mg/kg body weight over a period of 26 months. The authors reported no adverse effects in the rats with regard to growth, food consumption, food efficiency, state of health, reproduction (two matings), survival and gross and histo-pathology of the organs.

The toxicological data submitted, which relates to the same esters in two different formulations, indicates that from the point of view of safety in use these esters are comparable to substances already permitted by the Directive.

The Committee is therefore prepared to accept the specific inclusion of the mixed acetic/tartaric acid esters on the Community list of emulsifiers, stabilisers, thickeners and gelling agents for use in human food.*

REFERENCES

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2. Lang K., Kieckebush W. and Griem W.
   Long-term feeding tests with baking aid T 500 S (unpublished report 1970).
   Physiologish-Chemisches Institut der Universitat, Mainz.

3. Toxicological evaluation of some food colours, thickening agents, and certain other substances
   FAO Nutrition Meetings Report Series No. 55A
   WHO Food Additives Series No. 8
   FA/OWHO Rome/Geneva 1975

*In order to align this earlier report with the formal presentation of its present Report on Emulsifiers, Stabilizers, Thickeners and Gelling Agents, the Committee wishes to record that it does not object to the endorsement of the ADI established by JECFA (3).

ANNEX 6

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON PECTINS (E 440)

(Opinion expressed February 1977)

TERMS OF REFERENCE

The Committee was asked to express an opinion on whether amidated pectin could be classified with "pectins" from the point of view of specifications and toxicology.

CONCLUSIONS

1. The Committee agreed that pectin and amidated pectin should be specified separately on the basis of present technological and toxicological evidence.

2. The Committee was prepared to accept a temporary ADI of 0–25 mg/kg body weight for amidated pectin provided that the results of further toxicological studies be received by 1982. The Committee thought, that for it to be fully informed, these studies should include adequate reproduction, embryotoxicity and teratology studies in rats and an adequate long-term study in a rodent species preferably the rat.

3. The Committee endorsed the ADI "not specified" established by JECFA for non-amidated pectins.

BACKGROUND

The Council Directive on the approximation of the laws of Member States relating to emulsifers, stabilisers, thickeners and gelling agents for use in foodstuffs (74/329/EEC of 18 June 1974) authorises the use of "E 440 Pectins" (Annex I). Article 7 of the Directive requires that the Council, acting unanimously on a proposal from the Commission, shall lay down specific criteria of purity for "Pectins". During discussions on these specifications, the Commission found that experts of certain Member States were reluctant to accept amidated pectin as falling within the designation "E 440 Pectins", partly for toxicological reasons and partly on the grounds that amidated pectin cannot be regarded as a "natural" pectin.

TECHNOLOGICAL INFORMATION (1)(2)(3)

Pectins are complex acidic polysaccharides which occur in varying amounts in plant cell walls and which have the ability to form gels with sugars plus acids. They are obtained by the extraction of plant materials (usually citrus fruits, apple pomace or sugar beet) with hot water or dilute acids and are concentrated by evaporation and sold as such, or dried, or recovered from extracts by precipitation with alcohol or salts of polyvalent metals, usually aluminium and then dried.

Pectins have for many years been used to improve the consistency of jellies, jams and marmalades prepared from fruits containing insufficient endogenous levels of pectins.

Pectins consist chiefly of the partial methyl esters of polygalacturonic acid and their calcium, potassium, sodium and ammonium salts. Normally pectins contain 7 to 12 per cent methoxyl content by weight, implying that some 45 to 75 per cent of the carboxyl groups in the pectin are esterified. For gel formation with such pectins, sugar must be present in amounts of 50 per cent by weight or more and the pH must be below 3.5.

A major development has been the production of low-methoxyl pectins by partially de-methylating normal pectins with acid, alkali or enzyme treatments. Methoxyl contents range from 2 to 7 per cent by weight. Low-methoxyl pectins require little or no sugar for gel formation and satisfactory gels can be prepared within a wide range of pH e.g. 2.5 to 6.5. They are however sensitive to high levels of calcium ions.

For amidated pectin partial de-methylation is achieved by the use of ammonia in alcoholic solution. Amidated pectin contains about 5 per cent of amide groups, which implies that about 20 per cent of the carboxyl groups have been amidated. Amidated pectins do not

however precipitate in the presence of high levels of calcium and can therefore be used in the production of milk-based products.

The Committee was informed that about 20 per cent of the pectin used commercially is of the low-methoxyl type (either amidated or non-amidated). The level of use is said to be about 0.3% for jams and jellies and up to 1% for other uses such as milk gels, fruit gels, ice cream, yogourt. The Committee was also informed that about 85-95% of all pectin is used in the production of jellies and jams.

TOXICOLOGICAL INFORMATION

The FAO/WHO Joint Expert Committee on Food Additives (JECFA) evaluated pectin in 1973 (4) and amidated pectin in 1975 (5). Though the evaluations differ - a temporary ADI of 0-25 mg/kg body weight for amidated pectin and an ADI "not specified" (ADI "not limited" in 1973)[*] for non-amidated pectins - JECFA have included both types within a single specification entitled "Pectin". (6)

In addition to the JECFA review, the Committee was provided with copies of the unpublished reports of Til, Seinen and de Groot (7), of Palmer, Jones and Abul Haj (8) and of Mosinger (9). The Committee was also provided with preliminary reports of long-term, teratology and reproduction studies on rats with pectin and amidated pectin now in progress in France (10).

The Committee noted that in the studies by Til, Seinen and de Groot there was slight evidence that amidated pectin might be more toxic to rats than ordinary pectins, in giving a slight degree of hyperkeratosis of the fore-stomach and increased leucocyte counts in femals at dietary levels above 5 per cent, and more pronounced increases in caecum weights (7). Palmer, Jones and Abul Haj found no significant differences between rats fed pectin or amidated pectin for 2 years at dietary levels of 10 per cent (8). Mosinger administered amidated pectin in single doses of 100 mg/kg body weight daily to rats (approximately 0.2% in diet). There appeared to be no adverse effects at this low dietary level in comparison with available data from historical controls - no contemporary controls were used in the experiment (9). The results of these experiments were therefore difficult to interpret in a safety evaluation. The Committee was informed that no adverse effects had been noted in the study now in progress (10). The Committee agreed that neither of the completed long-term studies was adequate either in terms of number of animals used, levels fed or design of the experiments. The Committee was prepared to accept a temporary ADI of 0-25 mg/kg body weight for amidated pectin provided that the results of further toxicological studies be received by 1982. The Committee thought, that for it to be fully informed, these studies should include adequate reproduction, embryotoxicity and teratology studies in rats and an adequate long-term study in a rodent species preferably the rat. The Committee endorsed the ADI "not specified" established by JECFA for non-amidated pectins.

[*] This term was previously used by the JECFA Report of 1974.

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ANNEX 7

Tragacanth (E 413)

Description

Tragacanth is considered to contain two primary constituents, bassorin and tragacanthin. The lesser component, tragacanthin, is water soluble and contains 3 molecules of a uronic acid and 1 molecule of arabinose, with a side-chain of 2 molecules of arabinose. The larger component, bassorin, which swells but is insoluble in water, has been shown to contain polymethoxylated acids that yield tragacanthin upon demethoxylation.

A description and criteria of purity are specified in the EEC Directive 78/663/EEC.

Technological Application

Tragacanth has found application as a stabilizer in low pH salad dressings, as a thickener and binder in confectionery, and as a stabilizer in ice-cream and essential oil emulsions.

Toxicological Evaluation

The Committee examined the available data which included preliminary metabolic studies, short term studies in both the mouse and chicken, mutagenicity studies (host mediated assay, cytogenetic studies and dominant lethal studies), teratogenicity studies in rats, mice, hamsters and rabbits and studies on allergic response. The mutagenicity and teratogenicity studies were all negative and showed no adverse findings. Nevertheless, because of the absence of conventional 90 day and/or long term studies it was not possible to establish an ADI. For that purpose a long term study is required.

Bachmann and Zbinden (1978) carried out a special study to elucidate the mechanism of action of tragacanth and a few other thickening agents (e.g. gum arabic) on cardiac function. The authors studied dose levels ranging from 20 to 80 mg/kg body weight daily for a period of 4 weeks on the biochemical functions of heart and liver mitochondria. The uncoupling effect noted soon after administration disappeared during the second half of the experiment. In the liver this uncoupling effect was moderate and progressive. The relevance of these findings to human health should be studied more extensively before these findings can be used in any evaluation of safety.

The Committee agreed to accept Tragacanth on a temporary basis for 5 years and expects to receive the data requested within 4 years.

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Sodium and Potassium Polyphosphates (E 450c)

Description

A description and criteria of purity are specified in the EEC Directive 78/663/EEC.

Technological Application

Sodium and potassium polyphosphates are used at levels of 0.25–0.5% in various meat poultry and fish products. They are claimed to contribute to colour, tenderness, juiciness and flavour, and to decrease cooking shrinkage. In sausages and similar meat products their use is claimed to increase the stability of the fat emulsion and to reduce the separation of fat during cooking. It is also claimed that polyphosphates afford some measure of microbial protection, particularly against Gram positive bacteria.

Polyphosphates are used also in the processing of milk products, particularly in the manufacture of processed cheese. At a level of about 3% in cheese processing they aid pH control, sequester calcium ions and act as emulsifiers. They are also used at levels from 0.02%–1% for milk gelling preparations (such as instant puddings), for the stabilization of HTST sterlized milk concentrate and texture stabilization of alginate-based ice-creams. Sodium polyphosphate also finds application in coffee whiteners to stabilize the milk proteins when the whitener is added to hot liquids.

They are also used at varying levels in fruit and vegetable processing, where they act predominantly as sequestrants of trace amounts of heavy metals (e.g. iron, copper), to enhance colour stability and decrease oxidative spoilage.

Toxicological Evaluation

The Committee had no objection to their present use, as long as they complied with the existing specification. It endorsed the acceptable total dietary phosphorus load, established by JECFA, of 0–70 mg/kg bw. This estimate applies to the sum of added phosphate and food phosphate. Acceptable daily intake levels of phosphate depend on the amount of calcium in the diet. The levels stated apply to diets that are nutritionally adequate with respect to calcium. However, if the calcium intake were high, proportionately higher intakes of phosphate would be acceptable, and the reverse relation would also apply.

References

1. Toxicological Monographs Arising from the Fourteenth Meeting of the Joint FAO/WHO Expert Committee on Food Additives, WHO/Food Add/70.39, FAO Nutrition Meetings Rep.Ser., No. 48A, (1970), p. 66.

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Microcrystalline Cellulose (E 460) – Powdered Cellulose

Description

A definition and criteria of purity are specified in the EEC Directive 78/663/EEC for microcrystalline cellulose.

Technological Application

Microcrystalline/powdered cellulose is claimed to be particularly effective in affording stability and melting resistance to low solid products. Typical use levels in food are 5% in salad dressings, 1.5% in whipped topping, 1.5% in synthetic cream, and 0.5%–1.5% in ice-cream.

Toxicological Evaluation

The Committee agreed to endorse the ADI "not specified" established by JECFA but wished to be informed of any further work elucidating the problem of persorption. If any new findings became available the Committee would re-assess the scientific evidence. The Committee concluded that powdered cellulose could be considered toxicologically similar to microcrystalline cellulose and similarly acceptable for use in food, provided the specifications of these substances were comparable in all major respects.

References

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Carboxymethylcellulose (E 466)

Description

A description and criteria of purity are specified in the EEC Directive 78/663/EEC.

Technological Application

Carboxymethylcellulose is used as a stabilizer for frozen confectionery (e.g. ice-cream, sherbets, etc.) to prevent ice crystal growth. It prevents syneresis in icings, meringues, jellies, pie fillings and in puddings. In cakes and other baked goods it finds application as a moisture retainer.

Toxicological Evaluation

The Committee was of the opinion, that there were no toxicological reasons for specifying a limit to the molecular weight. The Committee endorsed the ADI established by JECFA.

References

1. Toxicological Evaluation of some Food Additives, including Anticaking Agents, Antimicrobials, Antioxidants, Emulsifiers and Thickening Agents, WHO Food Additives Series, (1974), No. 5.

Polyglycerol Esters of Fatty Acids (E 475)

Description

A description and criteria of purity are specified in the Directive 78/663/EEC.

Technological Application

Polyglycerol esters of fatty acids are used at a level of 0.5–3% in fats, oils, margarine and fat emulsions. They are claimed to be satisfactory for gelling oils in order to reduce the quantity of hard fats in a margarine blend. In addition they are claimed to reduce spattering during frying and the tendency for margarine to weep or show exudation on storage. This emulsifier is very important in bakery products, particularly for high ratio cake recipes where it also facilitates aeration.

Polyglycerol esters of fatty acids are also used in chocolate and chocolate coatings at a level of up to 1%. They afford improved fat plasticity, an emulsion stabilizing effect, and an improvement in the formation of mousses. Anti-fat bloom properties are also claimed.

Toxicological Evaluation

An apparent discrepancy exists between the FAO/WHO JECFA specification and that included in the EEC Directive. According to the FAO/WHO specification "no polyglycerols higher than hexaglycerols should be present" whereas the EEC specification permits the presence of not more than 10% polyglycerols equal to or higher than heptaglycerol. The possible difference in composition between the product studied toxicologically and evaluated by JECFA and the material characterised by the EEC criteria prompted the Committee to request further details. The Committee has now been informed that the emulsifier has been manufactured continuously by the same process and that progress in analytical techniques was the sole reason for the difference. On the basis of this evidence the Committee concluded that the toxicity data was obtained on material described by the EEC specification. The Committee considered the toxicological data to be acceptable and endorsed the ADI of 0–25 mg/kg bw established by JECFA.

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Propane-1,2-diol Esters of Fatty Acids (E 477)

Description

Propane-1,2-diol Esters of Fatty Acids are used in powdered and liquid cake shortenings to improve texture and volume in baked goods and to improve whippability and stability in powdered desserts and whipped toppings. In icings they improve aeration and stability.

Toxicological Evaluation

The Committee noted that the evaluation carried out on the substance by JECFA was based primarily on the biochemical evidence that the compound is hydrolysed into fatty acids and propylene glycol. The JECFA assessment appears to have been made on a product which did not contain appreciable quantities of dimer and trimer. The Committee was provided with a summary of data from a thirteen week rat feeding study on propylene glycol monostearate said to be produced by the propylene oxide route, with the implication that at least 4% dimer and trimer would be present. These data lacked information on histopathology. The Committee was unable to decide on the basis of this information, whether indeed dimer and trimer were present in appreciable quantities.

The Committee decided:

1. To endorse the ADI established by JECFA for the compound containing less than 0.5% dimer and trimer and to accept temporarily for use in food, without establishing an ADI, the compound containing more than 0.5% to 4% dimer and trimer.

2. A metabolic study on the fate of propylene glycol dimer and trimer is required.

3. If full reevaluation of the rat study shows it to be unsatisfactory another 90 day study would be required on the product containing more than 0.5% dimer and trimer. This, together with the metabolic study should be available for assessment within two years.

References

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Sodium Stearoyl-2-lactylate (E 481)

Description

A description and criteria of purity are specified in the Directive 78/663/EEC.

Technological Application

Sodium stearoyl-2-lactylate has the ability to bond with both proteins and starches and, unlike calcium stearoyl-2-lactylate, it is an effective emulsifier in water-oil systems. This substance therefore finds application as a dough conditioner/emulsifier in high-fat, yeast-leavened baked goods. Its use at a level of about 0.5% (based on flour weight) in baked goods, is considered to improve volume and keeping quality and to give a finer, more uniform crumb. It is also, at a level of about 0.5% used as an aerating agent in both diary and non-dairy whipped toppings and desserts. It has been used at a level of 0.2% in non-dairy coffee creamers where it functions both as a surfactant and complexing agent.

Toxicological Evaluation

The Committee endorsed the ADI established by JECFA.

References

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Calcium Stearoyl-2-lactylate (E 482)

Description

A description and criteria of purity are specified in the EEC Directive 78/663/EEC.

Technological Applications

Calcium stearoyl-2-lactylate is used at a level of 0.5% (based on flour weight) in yeast-leavened bakery products such as bread, buns, cakes, etc., and also in their respective ready-to-use mixes. As a component of the dough calcium stearoyl-2-lactylate acts in combination with gluten to give the dough greater tolerance to virtually all processing

variables, and thus contributes to the production of baked products of more uniform quality. The use of this substance is considered to impart many desirable characteristics to baked goods, such as more uniform overall quality, an improved volume, a finer, more uniform grain and texture, a more tender crust, and improved keeping properties. Calcium stearoyl-2-lactylate may also be used at a level of 0.5% as an egg-white whipping aid.

Toxicological Evaluation

The Committee endorsed the ADI established by JECFA.

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Karaya Gum

Description

Karaya gum is the dried exudate obtained from Sterculia urens Roxburgh and other species of Sterculia (fam. Sterculiaceae), or from Cochlospermum gossypium A.P. De Condolle, or other species of Cochlospermum Kunth (fam. Bixaceae).

It is a complex, partially acetylated polysaccharide of extremely high molecular weight (Ca 9,500,000). Hydrolytic studies have yielded L-rhamnose, D-galactose and D-galacturonic acid in an apparent molecular ratio of 4:6:5. It has an acid number varying from 13.4 to 22.7 and tends to release acetic acid e.g. on storage. The Committee was informed that the material on the market conforms with the specification in the Food Chemicals Codex, 1972, p. 423.

Technological Application

Karaya gum has uses based primarily upon its cold-water-swelling and suspending properties. It has been used at about 0.4% level as a stabilizer for ice-cream and frozen drinks on sticks and at up to 1% level as a binder in sausage meat and bologna where it provides water retention and cohesive properties, giving a final product with a smooth appearance. It has also been used as a stabilizer for whipped cream products, and is used at up to 0.8% in cheese spreads to prevent water separation and increase the ease of spreading. Karaya gum has also been used as a stabilizer in mayonnaise and French dressings where it functions by increasing the viscosity of the oil-water emulsion, thereby preventing or slowing separation .

Toxicological Evaluation

The Committee considered that this product was not acceptable for use in food on the basis of existing toxicological data. Establishment of an ADI would require at least a metabolic study, a 90 day study in a rodent species and a long term study in an appropriate species. Bearing in mind the traditional usage of this substance in food, and provided the results

of the metabolic and 90 day study become available within one year, the Committee would be prepared to reassess the present classification of this substance.

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Partial Polyglycerol Esters of Polycondensed Fatty Acids of Castor Oil

Description

The product is a highly viscous liquid, consists of a complex mixture of partial esters of polyglycerol with linearly esterified fatty acids derived from castor oil and conforms to the general formula:

OR

$$R- (OCH_2 - CH - CH_2O)_n - R$$

where R=H or a fatty acyl group derived from polycondensed ricinoleic acid and n = degree of polymerisation of glycerol.

It is prepared by the esterification of condensed castor oil fatty acids with polyglycerol. The polyglycerol is made by heating glycerol under vacuum with a catalyst whilst the condensed acids are made by heating castor oil fatty acids in an inert atmosphere and have an average of about five fatty acid residues per molecule.

The polyglycerol moiety is predominantly di, tri- and tetra-glycerol. The Committee was informed that the toxicological evaluation was carried out on material conforming to the FAO specification.

Technological Application

Polyglycerol esters of polycondensed fatty acids of castor oil are used for the production of water oil emulsions and as such are suitable for use in the baking trade as tin-greasing emulsions at a maximum level of 50 parts per million. This emulsifier is also used in chocolate couverture (up to 0.3%) or in block chocolate (up to 0.4%) and it is claimed to be more effective than lecithin in lowering the viscosity of chocolate.

Toxicological Evaluation

The Committee noted the development of hepatomegaly in the studies on rats fed a dietery level of 18% of the above compound and noted that this effect was reversible. Furthermore, histpathological studies failed to reveal any significant abnormalities in the enlarged livers. The observed hepatomegaly was not associated with hyperplasia. The Committee established an ADI of 7.5 mg/kg bw.

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Sorbitan Monopalmitate
Sorbitan Monostearate
Sorbitan Tristearate
Sorbitan Monolaurate
Sorbitan Mono-oleate

Description

The sorbitan esters of fatty acids consist of the partial esters of sorbitol and its mono- and di-anhydrides with palmitic, stearic, lauric and oleic acids. They are prepared by the simple esterification of food-grade sorbitol with the appropriate food-grade fatty acid in the presence of an acidic catalyst at temperatures in the range 225–250°C. Under these conditions internal ether formation as well as esterification takes place.

The Committee was informed that the toxicological evaluations of sorbitan monopalmitate and sorbitan tristearate were carried out on material conforming to the FAO specifications, in the case of sorbitan monostearate on material conforming to the specifications in the Food Chemicals Codex 1972, and in the case of sorbitan monolaurate and sorbitan mono-oleate on materials conforming to the specifications in the British Pharmaceutical Codex 1972.

Technological Applications

The sorbitan esters of fatty acids are generally insoluble or dispersible in water and soluble in most organic solvents. These substances function both as emulsifiers and as anti-foaming agents, they are particularly useful for the production of water-in-oil emulsions.

They are used at levels of 0.4 to 1.0% as antibloom agents in chocolate and chocolate couverture and as batter aerating agents at levels of 0.3% to 0.4% in sponges, cakes and cake mixes.

The surface active properties of the sorbitan esters may be utilised in a number of miscellaneous applications. In particular, they are used to supress foam in liquid glucose/sugar mixture or sucrose, and in the subsequent preparation of jams, preserves or boiled sweets. They are also used to prevent foaming of meat curing brines in modern high speed injectors. In each case the amount used is small and residues in the final product do not exceed 15–20 mg/kg.

In addition, the sorbitan esters are used to stabilize flavour emulsions intended for use in soft drinks; levels in the final product do not exceed 150 mg/l.

Toxicological Evaluation

Sorbitan Monopalmitate / Sorbitan Monostearate / Sorbitan Tristearate:

The Committee endorsed the global ADIs established by JECFA of 25 mg/kg bw for all three additives singly or in combination, calculated as sorbitan monolaurate.

Sorbitan Monolaurate / Sorbitan Mono-oleate:

The Committee reviewed the studies of Krantz and two new short-term studies. On this evidence, the Committee established a global ADI of 5 mg/kg bw for both additives singly or in combintation, calculated as sorbitan monolaurate.

References

Sorbitan Monopalmitate

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Sorbitan Monostearate

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Sorbitan Monolaurate

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Sorbitan Mono-oleate

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Polyoxyethylene (20) Sorbitan Monolaurate
Polyoxyethylene (20) Sorbitan Monppalmitate
Polyoxyethylene (20) Sorbitan Monostearate
Polyoxyethylene (20) Sorbitan Tristearate

Description

The polyoxyethylene sorbitan esters of fatty acids consist of the partial esters of sorbitol and its mono- and di-anhydrides with palmitic, stearic, lauric or oleic acids, condensed with ethylene oxide.

Sorbitan esters of fatty acids are prepared by the esterification of food-grade soritol with the appropriate food-grade acid. These esters are then treated with ethylene oxide in the presence of an alkaline catalyst at temperatures ranging from 130-170°C.

The Committee had available the specification in the Nutrition Meeting Report Series No. 35, (1964), of FAO for polyoxyethylene (20) sorbitan monopalmitate and the specifications in the Food Chemicals Codex 1972 for the other four polyoxyethylene sorbitan esters.

Technological Applications

Polyoxyethylene sorbitan esters of fatty acids function primarily as emulsifiers, although they have application as softeners in bread, cakes and similar products. These substances are generally soluble or dispersible in water and differ widely in their solubilities in organic solvents. They are particularly effective in producing oil-in-water emulsions.

They are used ice-creams at a level of 0.04% to improve texture and body. In chocolate and chocolate couverture they are used as antibloom agents at a level of 0.4 to 1.0%. They are also used in non-vitaminised margarines and fats for the baking and catering trades. In several applications these substances are used in conjunction with sorbitan esters of fatty acids.

Toxicological Evaluation

No studies other than those submitted to JECFA were available to the Committee on these compounds. On this basis the Committee established a temporary ADI of 25 mg/kg bw. A metabolic study and a 90 day study in a rodent species are required within two years.

The Committee noted that during the development of skin co-carcinogenicity tests, some special polysorbates were used and had been found to be weak promoters under these experimental conditions. It concluded that these observations had no relevance to the safety evaluation for food additive use of these substances.

References

Polyoxyethylene (20) Sorbitan Monolaurate

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Polyoxyethylene (20) Sorbitan Monostearate

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Polyoxyethylene (20) Sorbitan mono-oleate

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Polyoxyethylene (20) Sorbitan Tristearate

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Polyoxyethylene (8) Stearate
Polyoxyethylene (40) Stearate

Description

The products are composed of partial esters of stearic acid derived from food fats and mixed polyoxyethylene diols.

The structural formulae of the principal components are:

$HO(CH_2CH_2O)_nH$	$RCOO(CH_2CH_2O)_nH$	$RCOO(CH_2CH_2O)_nOCR$
free polyol	monoester	diester

Where RCOO is the fatty acid moiety and n has an average value of approximately 7.5 in the case of Polyoxyethylene (8) stearate and 40 in the case of Polyoxyethylene (40) stearate. The Committee was informed that the toxicological evaluations were based on materials conforming to the FAO specifications.

Technological Application

These two esters are used in bread, rusk, biscuits and other baked foods to improve shelf-life.

Toxicological Evaluation

The Committee reviewed the available data in experimental animals and established a temporary ADI of 25 mg/kg bw for Polyoxyethylene (40) stearate but the Committee requires a metabolic study and a 90 day study in a rodent species to become available within 2 years.

In the case of Polyoxyethylene (8) stearate, the Committee requires two studies to be available within 4 years. One to elucidate the mechanisms of stone formation in the urinary bladder, the other to be a conventional long term study. In the former, the Committee would expect to receive interim reports. Meanwhile, the Committee considers the use of this substance temporarily acceptable.

References

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Glyceric Esters of Fatty Acids obtained from Soya Oil Oxidized under heat

Description

The nomenclature in connection with commercially available mixtures is complicated and the following classes have been suggested to the Committee by the manufacturers:

A. Oxidatively thermally polymerised Soya Bean Oil.

B. Oxidatively thermally polymerised Soya Bean Oil interacted with mono- and di-glycerides.

C. Oxidatively thermally polymerised Soya Bean Oil interacted with triglycerides.

It was noted that in compound B a small percentage of triglycerides is present.

Technological Application

The Committee was informed that mixtures falling into class A are used primarily in tin greasing emulsions and are excluded from the scope of the Directive 74/329/EEC.

Mixtures falling into classes B and C are used as emulsifying and anti-spattering agents in particular for protein containing margarine, (e.g. those containing milk solids in the aqueous phase) at a level of use of 0.3 to 0.5% (maximum).

Toxicological Evaluation

The Committee was provided with a report of metabolic studies on mixtures of class B in the rat, guinea-pig and mouse. A specification has also been provided which limits, in particular, the temperature range for the polymerisation of the soya bean oil to between 190 and 200°C. The Committee was unable to establish an ADI but agreed that mixtures of class B could be temporarily acceptable for use in food for 5 years. This will allow time for the completion of a 90-day study in the rat and a long term study in a rodent species.

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Ghatti Gum

Description

Ghatti gum is an amorphous translucent exudate of the Anogeissus latifolia tree of the family Combretaceae. This is a large tree found in the dry deciduous forests of India and Ceylon. The gum exudate occurs in rounded tears and has a glassy fracture. Its colour varies from very light brown to dark brown with the lighter material yielding a better grade of gum.

Ghatti gum is basically the calcium salt of an acidic polysaccharide, ghattic acid. The purified acid has an equivalent weight reported to be between 1340 and 1735, however more recent studies have indicated that ghatti gum is a heterogeneous polymer. Fractionation by alcoholic precipitation or by chromatographic separation on silica gels yielded three fractions with equivalent weights of 1750, 1800 and 2040.

The Committee was provided with the specification for ghatti gum laid down in the UK Emulsifiers and Stabilizers in Food Regulations 1975, S.I. 1975 No. 1486.

Technological Applications

Ghatti gum has been utilised in foods as an effective emulsifier for oil-in-water emulsions. In addition, the gum acts as a natural buffer and small amounts of acid or alkali will not affect it. It has been used as an emulsifier and stabilizer in maple syrups containing butter for use on pancakes and waffles.

Toxicological Evaluation

The Committee considered this compound toxicologically unacceptable for use in food on the basis of existing data. The compound should be phased out, unless a definite assurance was received that within 4 years the following studies would be available for assessment:

1. Metabolic studies in 2 species.
2. 90-day studies in a rodent and non-rodent.
3. A long-term study in the rat.
4. Studies on the allergic response, if known, in animals and man.
5. Data on intake from food and other sources.

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Xanthan Gum

Description

Xanthan gum is a high molecular weight (1,000,000) linear polymer with a β-linked backbone containing D-glucose, D-mannose, and D-glucuronic acid with one D-mannose side-chain unit for every 8 sugar residues and one D-glucose side-chain for every 16 sugar residues. The polysaccharide is partially acetylated and contains between 3.0 and 3.5% pyruvic acid. The molar ratio D-glucose: D-mannose: D-glucuronic acid is 1.4: 1.0: 1.0.

Technological Applications

Xanthan gum functions as a hydrophilic colloid. Nether pH nor temperature have much effect on the viscosity of solutions of xanthan gum. It is soluble and stable in acid and alkaline solutions, and in solutions containing high concentrations of various salts. The gum is soluble in hot or cold water and is heat stable, even at very high temperatures. Solutions of xanthan gum have extreme pseudoplasticity (high viscosity under low shear but low viscosity under high shear) and high viscosity at low concentrations.

It is used at up to approximately 0.5% in a variety of foods such as sauces and salad dressings, instant puddings, milk drinks and dairy products.

Toxicological Evaluation

The Committee was informed that the toxicological evaluation was carried out on material conforming with the FAO specification. The Committee considered the available toxicological information to be adequate and endorsed the ADI established by JECFA of 10 mg/kg bw.

However, the Committee drew attention to the fact that in its opinion a specification for Xanthan gum should also prescribe that no viable micro-organisms should be present and that the nitrogen content of Xanthan gum should be controlled by stipulating, in the specification, a maximum nitrogen level.

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Extract of Quillaia

Description

Quillaia is the dried inner part of the bark of Quillaia saponaria Molina and of other species of Quillaia.

Quillaia extract is an aqueous extract of the dried inner part of the bark of Quillaia saponaria Molina and other species of Quillaia (Rosaceae) and contains three or possibly four saponins (two major, one minor, one trace) constituting about 10% of the extract. The sugars glucose, galactose, arabinose, xylose, rhamnose and two further unidentified sugars are also present. The two major saponins are quillaia sapogenin which has a triterpenoid structure and quillaic acid.

The Committee was informed that the toxicological evaluation was carried out on natural extract of quillaia bark as specified in the British Pharmacopoeia 1973.

Technological Application

Quillaia extract is used in the soft drink industry to give a good head of foam in ginger beer, shandy, cream soda and lemonade. These products may contain up to 200 ppm of the dry matter content of the extract. The spray dried aqueous extract of quillaia bark is prepared in such a manner that 100 parts by weight of bark yield approximately 15 parts of spray dried extract.

Toxicological Evaluation

The Committee considered in detail the composition of this product, its pharmacological properties, the source of the material, and the results of two long-term studies in the mouse and rat. For the spray-dried extract the Committee established an ADI of 5 mg/kg bw.

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Lactylated Fatty Acid Esters of Glycerol and Propylene Glycol

Description

A mixture of partial lactic and fatty acid esters of propylene glycol (propane-1,2-diol) and glycerol produced by the lactylation of a product obtained by reacting edible fats or oils with propane-1,2-diol. It varies in consistency from a soft solid to a hard, waxy solid. It is dispersible in hot water and is moderately soluble in hot isopropanol, benzene, chloroform and soya bean oil.

The Committee was provided with a specification for lactylated fatty acid esters of glycerol and propylene glycol from the Food Chemicals Codex 1972.

Technological Application

The lactylated fatty acid esters of glycerol and propylene glycol are used in cake shortenings to improve texture and volume in the baked goods, in powder desserts and whipped toppings to improve whippability and stability and in dessert mixes to improve consistency and stability of pudding and other similar products. The main use is in whippable fat powders, which are used to make synthetic creams, desserts and dessert mixes.

Toxicological Evaluation

The Committee was of the opinion that the specification should restrict the content of propylene glycol dimers and trimers to a maximum of 0.5%. It considered the compound temporarily acceptable for use in food, but requested a metabolic study and a 90-day study in a rodent species within 2 years.

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Dioctyl Sodium Sulphosuccinate

Description

Dioctyl sodium sulphosuccinate may be produced by esterifying maleic anhydride with 2-ethyl hexanol and treating the product with sodium hydrogen sulphite.

The Committee was informed that the toxicological evaluation was carried out on material conforming to the FAO specification, 1975.

Technological Applications

It has been claimed that dioctyl sodium sulphosuccinate (DSS) has useful properties in the food industry as a solubilizer for various hard-to-wet substances. These include fumaric acid and various natural and synthetic gums which form hydrophilic colloids. Applications of DSS to powdered materials at levels of about 0.5% by weight causes marked changes in the solubility characteristics of the materials.

It is used as a processing aid in the sugar industry. DSS is also used as a flavour and aroma modifer. When used at levels of about 10 ppm in the final food, many taste qualities are altered, e.g. citrus flavours are enhanced. At this low level the bitter taste of DSS itself is not detectable. This bitter taste is a self-limiting factor which would not normally allow quantities greater than 50 ppm DSS to be used in food and still give a palatable produce.

Toxicological Evaluation

The Committee established a temporary ADI of 0.1 mg/kg bw. The results of a long-term study in a rodent species are required within a period of 4 years.

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Ammonium Phosphatides

Description

Ammonium phosphatides consist essentially of a mixture of the ammonium salts of phosphatidic acids derived from edible fat (usually partially hardened rapeseed oil). They are similar in composition to commercial lecithins and consist of approximately 60% phospholipids and 40% unreacted triglyceride.

The Committee was informed that the material toxicologically evaluated for use in foodstuffs conforms to the manufacturer's specification and may be described as a mixture of ammonium salts of phosphatidic acids derived from rapeseed oil, with a proportion of triglycerides from the partially-hardened oil. The impurities did not exceed 0.2% water, 2.5% matter insoluble in light petroleum (b.p. 40–60°C), 0.2% inorganic matter insoluble in light petroleum (b.p. 40–60°C), 42% unreacted triglyceride, 3.0–3.4% phosphorus, 2.5 ppm arsenic, 2 ppm lead and 2 ppm copper; the pH of the mixture was between 6 and 8.

Technological Applications

Ammonium phosphatides are used principally in the manufacture of chocolate at a level of approximately 0.5%.

Toxicological Evaluation

The Committee established an ADI of 30 mg/kg bw.

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The Scientific Committee for Food was established by Commission Decision 74/234/EEC of 16 April 1974 (OJ No. L 136 of 20.5.1974 page 1) to advise it on any problem relating to the protection of the health and safety of persons arising from the consumption of food, and in particular the composition of food, processes which are liable to modify food, the use of food additives and other processing aids as well as the presence of contaminants.

The Members are independent persons, highly qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry, or other similar disciplines.

The present series relates to opinions on certain aspects of the Directive on Emulsifiers, Stabilizers, Thickeners and Gelling Agents for use in Foodstuffs (74/329/EEC of 18 June 1974, OJ L 189 of 12.7.1974, p. 1), in particular the acceptability, from the point of view of safety in use, of substances listed in Annex II of the Directive.