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food - science and techniques

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(Fifteenth series)

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Reports of the Scientific Committee for Food concerning

- Emulsifiers, Stabilizers, Thickeners and Gelling Agents 1
  (Opionion expressed 8 July 1983)

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

(Opinion expressed 8 July 1983)

TERMS OF REFERENCE

1. To review the data on the safety of emulsifiers, stabilizers, thickeners and gelling agents made available since the report of the Committee adopted 30 November 1978[1].

BACKGROUND

2. When the Council Directive on emulsifiers, stabilizers, thickeners and gelling agents[2] was agreed in 1974 a number of issues were left unresolved. A period of five years was left for further investigation and during this period the Committee was asked to advise on the substances concerned. In the discussion leading up to the Committee's 1978 review, a number of other matters were drawn to the attention of the Committee. Details are given in the 1978 report.

3. The Committee's advice was examined by the Commission and the Member States' government departments concerned, and as a result of this examination the Council decided to prolong the temporary approval of the substances for which the Committee had requested further information to give sufficient time for interested parties to obtain the required data[3,4].

4. The present report concerns the information made available to the Committee up to mid 1983. The data submitted to the Committee, including key references, are summarized in Annex II.

Substances concerned in the present review

5. The Committee was asked to examine the following substances:

polyoxyethylene (8) stearate	(paragraph 7)
polyoxyethylene (40) stearate	(paragraph 7)
lactylated fatty acid esters of glycerol and propylene glycol	(paragraph 7)
dioctyl sodium sulphosuccinate	(paragraph 7)
gum tragacanth	(paragraph 8)
karaya gum	(paragraph 9)
oxidatively thermally polymerised soya bean oil interacted with mono- and di-glycerides of fatty acids	(paragraph 10)
amidated pectin	(paragraph 11)
polysorbates 20, 40, 60, 65, 80	(paragraph 12)

A summary of decisions taken on the substances evaluated is contained in Annex I. The Committee has used the same classification as in its 1978 Report (see Annex I). Specifications were made available to the Committee.

6. The Committee was informed that the use of propane-1,2-diol esters of fatty acids (E 477) with a content of dimer and trimer of propane-1,2-diol of more than 0.5% was being phased out and that as a consequence the information requested by the Committee would not be forthcoming.

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[1] Reports of the Scientific Committee for Food, Seventh Series (1978).

[2] OJ L 189, 12.7.1974 p. 1.

[3] OJ L 197, 22.7.1978 p. 22.

[4] OJ L 155, 23.6.1980 p. 23

The Committee is aware of work being carried out on carrageenan (E 407), suggesting that degraded carrageenan might be formed from food quality undegraded carrageenan under certain food processing conditions. The Committee wishes to keep this situation under review.

7. No new data has been presented on the following:

polyoxyethylene (8) stearate
polyoxyethylene (40) stearate
lactylated fatty acid esters of glycerol and propylene glycol
dioctyl sodium sulphosuccinate

The Committee has concluded that these substances be reclassified in category 4.

8. In 1978, for gum tragacanth (E 413) the Committee required the results of a long term study in order to establish an ADI[1]. In the meantime many data have been accumulated.

The gum is digested by intestinal organisms and some degradation products may be absorbed. The claims for biochemical effects on liver and heart were not confirmed in extensive electron microscopy examinations, and no enzyme induction was found. Teratogenicity and reproduction studies are known to have been carried out but details are not available to the Committee. No 90-day or long-term study exists. Mutagenicity tests were negative. The gum has sensitizing potential equivalent to eggalbumin. Large doses cause no reactions in man when taken for 3 weeks. The temporary acceptance should be extended until the results of the 90-day, reproduction, and teratology studies can be examined. A lifespan study may not be needed if the results of these studies are satisfactory.

The Committee concluded that gum tragacanth could be temporarily maintained in category 3 until the end of 1985.

9. Data on karaya gum have also become available. These new data have demonstrated that karaya gum is practically undigested and not degraded by intestinal bacteria and is probably not absorbed to any great extent by man. The only toxic effects are those due to bulk. There is no evidence of genotoxicity or teratogenicity. The available 90-day study in rats gives a no-effect level of 5%.

The Committee requires submission of the results of a short-term study in a non-rodent species including an estimation of urinary rhamnose at intervals during the study. It would be desirable to supplement the available human studies by urinary rhamnose estimation. Long-term and reproduction studies will not be needed if the results of these experiments are satisfactory. The results should be available by the end of 1985.

In the meantime karaya gum is temporarily acceptable and can be classified in category 2. A temporary ADI of 0-12.5 mg/kg bw was established.

10. Long term, and other studies are under way in Denmark on oxidatively thermally polymerised soya bean oil interacted with mono- and di-glycerides of fatty acids (specified in the Directive as thermally oxidized soya bean oil interacted with mono- and di-glycerides of fatty acids) and will be available for evaluation before the end of 1985. Interim reports show no untoward findings. The Committee agreed that the compound for which a specification is available was temporarily acceptable and could be maintained in category 3.

11. Data on amidated pectin (E 440b) have been presented to the Committee fulfilling the requirements of the Committee. The Committee has concluded that these data adequately complete the data base necessary to regard amidated and non-amidated pectin as toxicologically equivalent. Therefore, the Committee established a group ADI "not specified" for pectins (amidated and non-amidated).

[1] Acceptable daily intake.

12. The toxicological evidence on the five polyoxyethylene (20) sorbitan esters of fatty acids (synonyms: polysorbates 20, 40, 60, 65, 80) permitted by the Emulsifiers, Stabilizers, Thickeners and Gelling Agents Directive was assessed by the Committee, in 1978, which established a temporary ADI. A metabolic study and a 90-day study in a rodent species was required in order to fully assess this group of compounds.

The Committee has now been provided with the results of an adequate 90-day study in rats using polyoxyethylene (20) sorbitan monostearate (polysorbate 60) as a representative of the polysorbates under consideration, and a review of the existing metabolic data on polysorbates.

The review of the metabolic data showed that the evidence was consistent with intestinal hydrolysis of the ester linkage and metabolism of the fatty acid by the normal pathways. For these reasons the Committee has accepted this review in lieu of the study required in 1978.

The Committee established a group ADI of 0-10 mg/kg bw for polysorbates.

SUMMARY OF THE EVALUATIONS OF THE COMMITTEE FOR EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS EXAMINED DURING THE CURRENT REVIEW

1. SUBSTANCES FOR WHICH AN ADI COULD BE ESTABLISHED AND WHICH ARE THEREFORE TOXICOLOGICALLY ACCEPTABLE FOR USE IN FOOD WITHIN THESE LIMITS

   Pectin/Amidated pectin: Group ADI not specified

   Polysorbates (20, 40, 60, 65 and 80): Group ADI 0-10 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

   Karaya gum: temporary ADI 0-12.5 mg/kg bw

3. SUBSTANCES FOR WHICH AN ADI COULD NOT BE ESTABLISHED BUT WHICH ARE NEVERTHELESS CONSIDERED TEMPORARILY ACCEPTABLE FOR USE IN FOOD

   Gum tragacanth

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

4. SUBSTANCES FOR WHICH AN ADI COULD NOT BE ESTABLISHED AND WHICH ARE NOT TOXICOLOGICALLY ACCEPTABLE FOR USE IN FOOD

   Polyoxyethylene (8) stearate

   Polyoxyethylene (40) stearate

   Lactylated fatty acid esters of glycerol and propylene glycol

   Dioctyl sodium sulphosuccinate

ASSESSMENT OF INDIVIDUAL EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS

Gum Tragacanth (E 413)

In its earlier review the Committee noted the observed effects of this and similar thickening agents on cardiac function. Since then a number of additional studies have become available, including digestibility studies by various enteric and other micro-organisms, acute toxicity and digestibility studies in a number of species, tolerance and allergenic studies in man, and several studies in rats to reexamine the microsomal effects on liver and heart of various periods of dietary exposure to different doses of gum tragacanth.

The microbiological investigations showed the gum to be digested by intestinal organisms thus permitting absorption of the degradation products. The digestibility of the diet in rats and quail was not affected by the addition of the gum but was reduced in the case of chickens. Human tolerance was good apart from the induction of intestinal hurry. No increase in specific antibody formation or allergenicity to orally ingested gum tragacanth was found in man although the gum has a sensitizing potential equivalent to eggalbumin.

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Karaya Gum

Since the last review the results of a considerable number of studies have become available covering digestibility by intestinal micro-organisms and some mammalian species, acute toxicity, short-term studies in several species, mutagenicity studies and some long-term feeding experiments. Studies on sensitization in man and the mouse have also been evaluated by the Committee.

Karaya gum is practically undigested by mammals. The observed adverse effects in the short and long-term investigations were largely the effect of bulk in the gastrointestinal tract. The *in vivo* mutagenicity studies produced no evidence of genotoxicity. No increase in specific antibody formation or allergenicity to orally ingested karaya gum was found in man although the gum has a sensitizing potential equivalent to eggalbumin.

The Committee requires the submission of the results of a short-term study in a non-rodent species including an estimation of urinary rhamnose at intervals during the study. It would be desirable to supplement the available human studies by urinary rhamnose estimations. Long-term, reproduction and teratology studies may not be needed, if the results of the above mentioned experiments are satisfactory.

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

Since the last review a summary of the interim results of a long term study in the rat has shown the absence of any untoward findings.

REFERENCES

Unpublished information submitted by the Danish National Food Institute (1983).

Amidated Pectin (E 440b)

Since the last review a number of further studies on teratogenicity in rats, multi-generation reproduction in rats and a long-term study in rats have become available for evaluation. No adverse effects were noted in the teratological and multi-generation reproduction study when amidated pectin was fed up to 5% in the diet. The long-term study showed the absence of any dose-response relationship in the incidence of hyperkeratosis of the forestomach, a lesion noted in an earlier long-term feeding study.

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*Audited independently to verify the accuracy of the reporting of the data.

Polysorbates 20, 40, 60, 65, 80

Since the previous review a further 90-day study on polysorbate 60 as a representative of the five polysorbates under consideration established a no-effect level of 2% in the diet and a review of metabolic data on polysorbates showed that most of the material was excreted in the faeces, a small fraction being excreted in the urine and the fatty acids being metabolised by the normal pathways.

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