



COMMISSION OF THE EUROPEAN COMMUNITIES

REPORTS
OF THE SCIENTIFIC COMMITTEE
FOR FOOD

Second series

1976

COMMISSION OF THE EUROPEAN COMMUNITIES

**REPORTS
OF THE SCIENTIFIC COMMITTEE
FOR FOOD**

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(1) O.J. No. C 114 of 27.9.1974, p. 22

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON AMARANTH

Opinion expressed 27 February 1976

Terms of Reference

1. The Scientific Committee for Food has been asked by the Commission whether in the light of the recent reports on amaranth received from the U.S.A. the opinion of the Committee, as expressed in its report of June 1975 remains the same.

Discussion and Conclusions

2. The Committee's Report on the Revision of the Directive on colours of 27 June 1975 included in para 7 the statement :

"Not all the Members agreed on the need for colours in food. However, the Committee accepted that the existence of a Community Directive, and of national legislation in Member States and in many other countries on colouring matters in foodstuffs, and the fact that the Commission had requested the advice of the Committee indicated that many authorities regard the use of colours as justified. It is therefore necessary for the Committee to formulate advice on their safety".

3. The Committee has reviewed all the data with regard to amaranth and reaffirms its opinion given in June 1975. This was that a temporary ADI be allocated of 0-0.75 mg/kg body weight. It also requested by 31 December 1978 the results of adequate further long term and reproduction studies.
4. The situation would be reviewed earlier if new data become available.

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD
ON SOME CHEMICALLY MODIFIED STARCHES

Opinion expressed 27 February 1976

Terms of Reference

The Scientific Committee for Food has been requested to give an opinion on the safety of certain chemically modified starches, under consideration for inclusion in a proposed Community Directive on the manufacture and trade in starches intended for food use.

Conclusions

1. The Committee considers that starches listed in Group A of the Appendix to this Report may be used without special restrictions.
2. Chemically modified starches listed in Group B of the Appendix to this Report may be used temporarily until 31 December 1980 but that the numbers and amounts used should be limited in infant foods. For these latter foods every effort should be made to work within a maximum of 3.5 %.
If technologically necessary for the manufacture of certain products the Committee could accept a maximum of 5 %.
3. The use of chemically modified starches listed in Group C of the Appendix to this Report should not be allowed in infant foods. The majority of the Members of the Committee considers that these modified starches are acceptable for use in food, other than that prepared for infants, on a temporary basis until 31 December 1980 subject to a limit for total chlorohydrins of 1 mg/kg in the relevant specifications. By 31 December 1980 the results of long-term studies on these residues and by-products must be made available.

Discussion

1. The chemically modified starches listed in the Appendix have been requested for inclusion in a proposed Council Directive on the manufacture and trade of starches intended for food use, and the Scientific Committee for Food was asked to give an opinion of these chemically modified starches.
2. The Committee considers that starches listed in Group A of the Appendix to this Report may be used without special restrictions.
3. Within this group the Committee has included starches modified enzymatically providing the enzyme used is acceptable from the point of view of safety in use. The Committee has not yet been asked to consider generally the enzymes used in the production of food. In the meantime, in the absence of any definitive Community provisions, the Committee believes that as an interim measure amylolytic enzymes from sources approved by the FAO/WHO Joint Expert Committee on Food Additives would be acceptable.

4. The Committee gave particular attention to one feature in the long-term rat studies with starches and chemically modified starches listed in Group B. The kidneys of a number of animals fed on different types of these modified starches and also the kidneys of animals fed high levels of unmodified starches showed relatively large lesions consisting of mineral deposits beneath the epithelium of the renal papillae associated with hyperplasia of the renal pelvic epithelium. The lesions were minimal in some control animals fed on a low dosage of unmodified starch but larger lesions have been seen at high dosage levels with unmodified starches and in other non-contemporary controls, and have also been seen in rats fed a number of other substances, both natural and non-natural, of widely differing chemical compositions and in those fed a diet with a high magnesium content. Some of the animals treated with the chemically modified starches showed these lesions without a clear dose relationship but the incidence and size of the lesions in these animals were generally greater than in the controls. However, studies from one laboratory indicated that the lesions were present to a similar extent and degree in rats fed non-modified starches at the same level.
5. There is uncertainty regarding the origin of these lesions which appear to be sporadic in nature, have been reported only in certain strains of rats if fed high doses of starch whether modified or not, and may be related to the mineral content of the diet. While these findings do not appear to indicate a potential hazard to man it is important to determine their toxicological significance by suitable studies.
6. Information on the aetiology of these lesions, on the possible subcellular, biochemical and enzymatic changes associated with them, and on their occurrence in other species after prolonged ingestion of modified starches, as well as on the toxicology of the less digestible molecular fractions of the chemically modified starches, is necessary. If desired, protocols for these studies may be submitted to the Commission for appraisal by the Committee and the results should be submitted by 31 December 1980.
7. The Committee considered the fact that many food products containing modified starches have enjoyed established uses for many years without any apparent harm to health of the public. However, the Committee was of the opinion that it might be prudent to regard the chemically modified starches listed in Group B in the Appendix to this Report and affected by the above mentioned problem as temporarily acceptable until 31 December 1980. The Committee was aware of the considerations which apply to the use of infant foods containing modified starches in Group B. Because these infant foods are the major source of food for many infants during early infancy, the Committee was of the opinion that the use in infant food of only five of the modified starches listed in Group B (i.e. E 1410, E 1411, E 1413, E 1414, E 1422) and for which a technological need had been shown, should be permitted, and these subject to restriction. The Committee believes that every effort should be made to work within a maximum of 3.5 %. If technologically necessary for the manufacture of certain products, the Committee could accept a maximum of 5 %. The Committee recommends that the Commission and Member States should ensure that the technological needs are justifiable.
8. In assessing the available data, the Committee noted that certain modified starches, used widely at present and listed in Group C of the Appendix to this Report, contained residues or by-products of modifying agents on which specific toxicological information was not available. This applied particularly to the chlorohydrins. They were therefore unable to assess the safety of these residues in modified starches, specifically those modified with epichlorhydrin or propylene oxide. Therefore the Committee is of the opinion that these starches are unsuitable for use in infant food and recommends that they should not be used in infant foods for the time being until the safety aspects have been clarified.

9. Even though there was not enough evidence to assess the safety of the residues of chlorohydrins in the modified starches listed in Group C, the majority of the Members of the Committee considered that these modified starches were acceptable for use in food other than that prepared for infants, on a temporary basis until 31 December 1980, subject to a limit for total chlorohydrins of 1 mg/kg in the relevant specification.
By 31 December 1980 the results of long-term studies on these residues and byproducts must be made available. Temporary acceptance could of course be reconsidered following earlier review if interim results justify this.

Type of modifications and specifications for the purity of modified starches for human consumption examined by the Committee

GROUP A

EEC No.	Denominations	Treatment and limitation	Specifications
E 1400	White or yellow dextrins. Roasted starch	Dry starch heat treated with - 0.15 % max. <u>hydrochloric acid</u> or - 0.17 % max. <u>phosphoric acid</u> calculated on dry matter	Final pH 2.5 to 7.0
E 1401	Acid treated starches	Heat treated with - 7 % max. <u>hydrochloric acid</u> or <u>orthophosphoric acid</u> or - 2 % max. <u>sulphuric acid</u>	Final pH 4.8 to 7.0
E 1402	Alkaline treated starches	1 % max. <u>sodium</u> or <u>potassium hydroxide</u> calculated on dry matter	Final pH 5 to 7.5
E 1403	Bleached starches	Treated with - <u>peracetic acid</u> and/or <u>hydrogen peroxide</u> (up to 0.45 % by weight of starch of active oxygen) - <u>sodium hypochlorite</u> (up to 0.82 % by weight of starch of available chlorine) - <u>sodium chlorite</u> (up to 0.5 % by weight of starch) - <u>sulphur dioxide</u> (or the alternative forms permitted as a preservative in food - the general purity criteria in the directive control the level of residual sulphur dioxide) - <u>potassium permanganate</u> (up to 0.2 % by weight of starch)	<u>No carboxyl groups</u> <u>Residual Mn</u> 50 mg/kg max.
	Enzyme treated starches	See paragraph 3 of the report	

GROUP B

EEC No.	Denominations	Treatment and limitation	Specifications
E 1404	Oxidized starches	5.5 % max. <u>Sodium hypochlorite</u> calculated as chlorine, based on dry matter	<u>sodium chloride</u> - 0.5 % max. <u>carboxyl groups</u> - 1 % max.
E 1410	Monostarch phosphate	Esterified by <u>orthophosphoric acid</u> or by <u>sodium or potassium orthophosphate</u> and/or <u>sodium tripolyphosphate</u>	<u>residual phosphate</u> (calculated as phosphorus) - 0.4 % max. for cereal starches - 0.5 % max. for potato starches
E 1411	Distarch phosphate	Esterified by <u>sodium trimetaphosphate</u>	<u>residual phosphate</u> (calculated as phosphorus) - 0.04 % max. for cereal starches - 0.14 % max. for potato starches
E 1412	Distarch phosphate	Esterified by 0.1 % max. <u>phosphorus oxychloride</u>	<u>residual phosphate</u> (calculated as phosphorus) - 0.04 % for cereal starches - 0.14 % for potato starches
E 1413	Phosphated Distarch phosphate	Combination of the treatments under E 1410 and E 1411	<u>residual phosphate</u> (calculated as phosphorus) - 0.4 % for cereal starches - 0.5 % for potato starches
E 1414	Acetylated Distarch phosphate	Esterification by <u>sodium trimetaphosphate</u> or by 0.1 % max. <u>phosphorus oxychloride</u> combined with an esterification by 10 % max. <u>acetic anhydride</u> or by 7.5 % max. <u>vinyl acetate</u>	<u>acetyl groups</u> - 2.5 % max. <u>residual phosphate</u> (calculated as phosphorus) - 0.04 % max. for cereal starches - 0.14 % max. for potato starches

GROUP B (cont.)

EEC No.	Denominations	Treatment and limitation	Specifications
E 1420	Starch acetate	Esterified by 10 % max. <u>acetic anhydride</u> calculated on dry matter	<u>acetyl groups</u> - 2.5 % max.
E 1421	Starch acetate	Esterified by 7.5 % max. <u>vinyl acetate</u> calculated on dry matter	<u>acetyl groups</u> - 2.5 % max.
E 1422	Acetylated distarch adipate	Esterification by 0.12 % max. <u>adipic anhydride</u> combined with 10 % max. <u>acetic anhydride</u>	<u>acetyl groups</u> - 2.5 % max.

GROUP C

EEC No.	Denominations	Treatment and limitation	Specifications
E 1423	Acetylated distarch glycerol	Etherification by 0.3 % max. <u>epichlorhydrin</u> combined with an esterification by 10 % max. <u>acetic anhydride</u>	<u>acetyl groups</u> - 2.5 % max. <u>epichlorhydrin</u> , and/or <u>glycerol monochlorhydrin</u> and <u>dichlorhydrin</u> - 1 mg/kg max. (total)
E 1430	Distarch glycerol	Etherified by 0.3 % max. <u>epichlorhydrin</u> calculated on dry matter	<u>epichlorhydrin</u> and/or <u>glycerol monochlorhydrin</u> and <u>dichlorhydrin</u> - 1 mg/kg max. (total)
E 1440	Hydroxypropyl starch	Etherified by 25 % max. <u>propylene oxide</u>	<u>propylene chlorhydrin</u> - 1 mg/kg max.
E 1441	Hydroxypropyl distarch glycerol	Etherification by 10 % max. <u>propylene oxide</u> combined with an etherification by 0.1 % max. <u>epichlorhydrin</u>	<u>epichlorhydrin</u> and/or <u>glycerol monochlorhydrin</u> and <u>dichlorhydrin</u> - 1 mg/kg max. (total) <u>propylene chlorhydrin</u> - 1 mg/kg max.
E 1442	Hydroxypropyl distarch phosphate	Etherification by 10 % max. <u>propylene oxide</u> combined with an esterification by 0.1 % max. <u>phosphorus oxychloride</u> or by <u>sodium trimetaphosphate</u>	<u>residual phosphate</u> (calculated as phosphorus) - 0.04 % max. for cereal starches - 0.14 % max. for potato starches <u>propylene chlorhydrin</u> - 1 mg/kg max.

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON RESEARCH NECESSARY
ON LONG CHAIN FATTY ACIDS AND OILS AND FATS USED IN FOOD

Opinion expressed 2 April 1976

Terms of Reference

Following the advice of the Committee in its Report on Rapeseed oil (16/11/1974) the Commission has asked the Committee to amplify its recommendation that further research be undertaken on long-chain fatty acids and more generally on oils and fats used in food.

Discussion and conclusions

1. Since publication of the Committee's Report many communications have appeared in the literature which relate to these subjects. The Committee was hampered in its assessment of this information for the purpose of delineating the most useful directions for research by the fact that some of the results were conflicting, others were difficult to interpret because of lack of knowledge of the precise composition of the materials investigated. The studies were performed with a variety of animal species and under experimental conditions which did not allow comparison of the results.
2. The Committee therefore proposes that before it recommends specific lines of extensive and costly research, a critical review of the whole area should be commissioned. It would wish to be consulted before this recommendation is implemented. This review should be undertaken as soon as possible and would deal in particular, with the compositional aspects of the various fats and oils used experimentally, and those normally used for incorporation in food, e.g. rapeseed oil, other vegetable oils, marine oils.
3. If possible, information should also be obtained on the occurrence of individual long-chain saturated and unsaturated fatty acids (C_{20} upwards) in items of the normal diet as well as on the total intake from all dietary sources.
4. The review should also cover the biological effects of oils and fats and should be extended to include those fatty acids with a chain length of C_{20} and upwards.
5. Meanwhile the Committee recommends that some specific short term research should be carried out to elucidate some of the problems. This should be done using the individual long-chain fatty acids or their triglycerides and should include investigation of the absorption, distribution and excretion following oral administration and the kinetics of distribution. The possibility of using isotopically labelled material should be envisaged.
6. Further short-term research should be concerned with correlating the biological effects observed with blood and tissue levels, of the individual long-chain fatty acids or their triglycerides administered orally. These investigations should be performed in several animal species and attention should be paid to the possible biological effects of the fats and oils used as vehicles in these experiments and to the influence of the major components of the animal diets. The Committee considers it useful to include in these investigations electron microscopy, histochemistry and studies on the effects at the cellular and subcellular level. Particular attention should be paid to the establishment of a no-effect level and the reversibility of any adverse effects observed.
7. The Committee recognises that most of the available information is derived from animal studies and that there are inherent difficulties with studies on man. Nevertheless the Committee considers that useful information might also be obtained from further epidemiological studies, investigations of blood and tissue levels of individual long-chain fatty acids as well as from studies on human tissue culture or human mitochondrial preparations.

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD
ON THIABENDAZOLE

Opinion expressed 2 April 1976

Terms of Reference

To give an opinion on the following subjects:

- acceptability from the point of view of health and hygiene, of the use of thiabendazole for the protection of citrus fruit against moulds,
- the possibility of raising the maximum residue of thiabendazole in citrus fruit to 10 mg/kg of whole fruit as requested by the users, instead of 6 mg/kg now accepted on a provisional basis by the Community Directive on Preservatives authorized for use in foodstuffs intended for human consumption.

Conclusions

1. The Committee recommends that before 31 December 1978 information be presented to the Commission to allow the Committee to assess the total human intake of thiabendazole from all sources, including the intake resulting from the use of thiabendazole as a pesticide and in veterinary medicine.
2. In the meantime the Committee does not object to the extension to 31 December 1978 of the existing provisions for thiabendazole in citrus fruit and bananas in the Community Directive on Preservatives.

Discussion

1. The Committee notes that thiabendazole is used not only to protect the surface of citrus fruit but is also permitted by the same Community Directive for use on bananas at a maximum level of 3 mg/kg of whole fruit. In addition the Committee is aware that thiabendazole is used as a pre-harvest pesticide not only for citrus fruit but also for a variety of other agricultural products. There may also be residues in meat as a result of its use in veterinary medicine. The Committee was informed that it also has applications in human medicine.
2. The Committee believes that, in general, it is not desirable to use in agriculture products which have a use either in human or in veterinary medicine.
3. The Committee does not have information on the total human intake of thiabendazole from all sources. It therefore requests that such information be made available to the Commission before 31 December 1978. Meanwhile it recommends that there should be no new food uses of thiabendazole or any raising of the levels of existing uses.
4. In the meantime the Committee does not object to the extension to 31 December 1978 of the existing provisions for thiabendazole in citrus fruit and bananas in the Community Directive on Preservatives.

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON PROPYL GALLATE

Opinion expressed 2 July 1976

Terms of reference

The Scientific Committee for Food has been requested to give an opinion on whether propyl gallate could, from the point of view of safety-in-use, be added to the Community list of antioxidants for use in food.

Conclusions

1. An ADI was established for gallate esters of 0 - 0.2 mg/kg body weight as the sum of intakes of propyl gallate, dodecyl gallate and octyl gallate.
2. Propyl gallate is toxicologically acceptable for use in food within this limit and can, from the point of view of safety-in-use, be added to the Community list of antioxidants for use in food.

Background

1. The present Directive on the approximation of the laws of the Member States concerning the antioxidants authorised for use in foodstuffs intended for human consumption (70/357/EEC of 13/7/1970) (1) provides for the use at Community level of octyl gallate (E 311) and dodecyl gallate (E 312) but not propyl gallate.
2. In the case of the latter the Treaty of Accession (2) and a modification to the Directive (74/412/EEC of 1/8/1974) (3) permit Member States, until 31 December 1977, to maintain the provisions of their national laws authorising the use of this substance.
3. The Commission is considering whether or not it should propose to the Council that propyl gallate should be included in the Directive and has asked the Scientific Committee for Food for its opinion.

Discussion

1. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered at its 6th (4) and 8th (5) meetings the following toxicity data on propyl gallate :
 - a) biochemical aspects :

evidence indicating that propyl gallate is hydrolysed in the body and most of the gallic acid is converted into 4-O-methylgallic acid. Furthermore, free gallic acid or a conjugated derivative of 4-O-methylgallic acid is excreted in the urine.
 - b) acute toxicity :

studies on rats and mice, administration by oral and intraperitoneal routes.
 - c) short term studies :

studies on rats (10 - 16 months at 1.2 % and 2.3 % in the diet ; 6 weeks at up to 0.5 % in a diet containing 20 % lard (x) ; 13 weeks at 0.02 % in a diet containing 30 % fat followed by partial starvation (x)), guinea pigs and dogs (14 months at 0.0117 %) and pigs (13 weeks at 0.2 %).

(x) Data not available at 6th meeting.

d) long term studies :

study on rats and mice (2 years at 1 and 5 % in the diet), study on rats (2 years at 0.00117, 0.0117, 0.117, 1.17 and 2.34 % in the diet), study on rats (2 years at 0.035, 0.2 and 0.5 % in the diet) including a reproduction study.

The JECFA estimated that the unconditional ADI for man was 0 - 0.2 mg/kg body weight for total propyl, octyl and dodecyl gallates.

In 1972 the JECFA reviewed octyl gallate because new data were presented on this substance, including long term and reproduction studies and dermatological studies. The dermatological studies indicated that individuals might become sensitive to gallate esters and that gallates in general might give contact dermatitis (6).

In 1973 the JECFA again reviewed the data on all three gallates. It established a temporary ADI of total gallates for man of 0 - 0.2 mg/kg body weight. (7)

2. The Committee recognized that the reluctance of the "Scientific Commission of the EEC" to accept propyl gallate as an antioxidant for use in food intended for human consumption, had been predominantly caused by a Russian "starvation diet" study (8). In this study rats were fed propyl gallate in the diet for 13 weeks and then placed on a partial starvation diet until they died. The survival time of the animals which had received the propyl gallate was considerably reduced and the reduction in their total body protein was greater. Den Tonkelaar, Verschuuren, Kroes and Van Esch subsequently repeated this experiment and also tested alpha-tocopherol in the same way (9). They were unable to confirm the results of the Russian author. They found no difference in survival times or in protein and fat utilization between the test groups and the controls. Since it has not proved possible to repeat the findings of the Russian studies, the Committee considered that undue importance should not be attached to them.
3. More recently Dacre in a long-term feeding study established a no-effect level for propyl gallate of 1 % in the diet of mice (10) ; and the Committee also noted that propyl gallate had been shown to inhibit the formation of nitrosamines in nitrite tested bacon (11).
4. The Committee agreed that from the available long-term studies on rats and mice it was possible to establish a lowest "no-effect level" of 50 mg per kg body weight. There were adequate long-term studies available on propyl gallate, however, there were still some questions about the effect of gallates on reproduction which had not been satisfactorily resolved. In view of these doubts, the Committee has applied a safety-factor of 250 which gives an ADI of 0 - 0.2 mg per kg body weight as the sum of propyl, octyl and dodecyl gallates.
5. The Committee continued to be concerned about the problem of allergic reactions. Various allergic reactions have been reported in man following the ingestion of gallates, particularly octyl gallate, by sensitized individuals (12). The Committee recommended that there should be appropriate and clear labelling.

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