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REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON THE USE OF CERTAIN EMULSIFIERS IN CHOCOLATE AND RELATED PRODUCTS

(Opinion expressed 7 February 1979)

TERMS OF REFERENCE

To advise on the comparison of the ADIs established by the Committee in its Report on emulsifiers, stabilizers, thickeners and gelling agents (Reports of the Scientific Committee for Food, 7th Series) for certain emulsifiers used in chocolate and related products, with the estimated intakes calculated from the usage data given for these emulsifiers in the Committee's report, and various assumptions concerning the consumption of chocolate.

BACKGROUND

The Committee was provided with a table comparing the ADIs established by the Committee for certain emulsifiers with the intakes of these emulsifiers, which would arise from the usage data given in the Committee's report, and three estimated levels of chocolate consumption presented to the Committee. The emulsifiers in question are those on which a decision has to be taken before 20th June 1979 on their use in chocolate and related products. (See Table below).

Table

Substance	ADI (in mg)	ADI x 60 kg (in g)	Intake (g) of emulsifiers that might arise from the consumption of		
			25 g chocolate	50 g chocolate	100 g chocolate
Polyglycerol polyricinoleate (Partial polyglycerol esters of polycondensed fatty acids of castor oil	7.5	0.45	0.075 0.1	0.15 0.2	0.3 0.4
- sorbitan monostearate - sorbitan tristearate	25 (overall ADI)	1.5	0.1 0.25	0.2 0.5	0.4 1.0
Polyoxyethylene (20) sorbitan monostearate	25 (temporary ADI)	1.5	0.1 0.25	0.2 0.5	0.4 1.0
Ammonium salts of phosphatidic acids (ammonium phosphatides)	30	1.8	0.1 0.125	0.2 0.25	0.4 0.5

DISCUSSION

Acceptable daily intakes (ADIs) are defined as the amounts of a substance which may be ingested daily by an individual over its lifetime without causing any obvious harm to health. A safety factor is normally employed in establishing an ADI from animal data. This factor includes contributions specifically designed to cover age differences between exposed individuals and the known variability with age in susceptibility to potential adverse effects of an ingested foreign substance.

There are a few special situations in which critical groups may display excessive susceptibility to specific toxic effects of a foreign substance to which they are exposed. Examples are the effects of lead or nitrites on young children or additives in infant foods. In these few special situations it may be prudent to use safety factors, higher

than those normally employed, in establishing ADIs for these critical groups. In the opinion of the Committee no special situation of this kind exists in relation to emulsifiers used in chocolate and chocolate confectionery.

The Committee stresses that information on the intake of an additive from all foodstuffs is necessary before it is possible to compare the total intake of that additive with the ADI.

It recalls that in its Report on Emulsifiers, Stabilizers, Thickeners and Gelling Agents the Committee stated that the usage levels mentioned were not necessarily complete. Therefore the Committee suggests that accurate and up-to-date data on the levels of use and probable human intake of the emulsifiers listed in the table from chocolate, chocolate confectionery and other food commodities be obtained for various age groups in preference to mean estimates, so that probable intakes can be compared with ADIs.

REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON CERTAIN COLOURING MATTERS FOR USE IN FOOD

(Opinion expressed 23 March 1979)

TERMS OF REFERENCE

To review the situation in respect of colouring matters in particular those which the Committee classed as temporarily acceptable in 1975.

BACKGROUND

The Committee established in its first report, issued in June 1975[1], temporary acceptable daily intakes (ADIs) for 13 colouring matters in food, but requested the provision of additional toxicological information within specific periods. The position relative to these colours was to be reviewed by the 31 December 1978. The Committee also agreed the temporary acceptance of the continued use under specified conditions of Lithol Rubine BK and Cochineal/Carminic Acid until the end of 1980. Since 1975 the Committee has given additional advice on Annatto, Brown FK, Brilliant Black PN, Cochineal/Carminic Acid, Caramels and Tartrazine.

CURRENT REVIEW

The Committee has examined all available reports on completed studies, the information on ongoing studies and the time schedules for their completion, submitted to the Commission by the Member States and by the food industry. The Committee acknowledges the valuable contribution made by the coordinated efforts of the food industry[2] in providing the requested information. It recognizes that such a coordinated effort avoids unnecessary duplication of work, minimizes the demand on limited research facilities, and conserves scarce animal and manpower resources. The Committee understands and accepts the reasons for the delay in initiating the large number of studies required in such a comprehensive exercise.

No adverse results have been reported so far from the toxicological studies in progress. The Committee has been asked to advise on the appropriate moment for terminating life span studies in rodents now in progress. It proposes that these studies be carried out for a minimum of two years in rats and 80 weeks in mice. They should be continued beyond these times until survival has dropped to 20% in the test groups.

The Committee's views have been sought on the furnishing of routine six-monthly interim reports. This appears to the Committee to be unnecessary unless some unexpected or adverse result requires evaluation. However, the Committee wishes to receive final reports of any completed study within a reasonable time, in order to be able to advise whether any further clarification is needed.

The Committee notes that the presently anticipated completion dates for the ongoing studies fall broadly into two groups, one at the end of 1980, the other at the end of 1981. The Committee will review the results as soon as practicable after each of these periods.

Another issue of current concern is that of hypersensitivity to food colours and other food additives. Indeed opposition has been expressed within the Committee to the addition to food of any colour alleged to cause hypersensitivity reactions. The Committee is reviewing this topic and will report its conclusions separately in due course.

CONCLUSIONS

1. The Committee has established the following ADIs:

   Annatto: 0–2.5 mg/kg b.w. calculated as extract, equivalent to 0–0.065 mg/kg b.w. carotenoids expressed as bixin

   Brilliant Blue FCF: 0–12.5 mg/kg b.w.

2. The Committee has withdrawn the temporary ADI established for Yellow 2G.

3. The Committee has retained all the other temporary ADIs established in its first report.

4. The Committee has confirmed the temporary acceptance until the end of 1980 of Lithol Rubine BK for the external colouring of cheese rind.

5. The Committee considers the teratogenicity and embryotoxicity studies on Cochineal/ Carminic Acid to be acceptable subject to the provision of a satisfactory specification of the colouring matter tested. It confirms that the use of this colour in certain alcoholic beverages is temporarily acceptable until the end of 1980.

6. The Committee is reviewing the topic of hypersensitivity to food additives and will report its conclusions separately in due course.

[illegible] The corresponding ADI for the carotenoids of Annatto is 0-0.065 mg/kg b.w. carotenoids expressed as bixin.

Amaranth

The Committee has been informed that the long-term study requested in its first report is in progress. The design of this study appears to be satisfactory. The Committee has received the data on the completed reproduction study[3]. The Committee has also been informed that a study on the metabolism of this colour is being performed in Canada. Although this study was not a requirement of the Committee it would be pleased to see the full details when these become available.

Azorubine

The Committee has reviewed a multigeneration and a one-year study in rats published in Toxicology[4]. The metabolic and long-term studies are under way. The design of the long-term study appears to be satisfactory.

Brilliant Black PN

The Committee had advised earlier, that metabolic studies carried out on material labelled in the Cleve's acid moiety would be acceptable. The metabolic study has now been submitted. The reproduction/embryotoxicity/teratogenicity studies are under way.

Brilliant Blue FCF

The Committee has been provided with an adequate metabolic study in 3 species which shows virtual absence of intestinal absorption. It is very likely that the same would be true for man. No metabolism by intestinal bacteria was noted. Because all the required information has now been supplied the Committee has established an ADI of 0-12.5 mg/kg b.w.

Brown FK

The Committee has been provided with an adequate teratology study in the rat and has been informed, that the reproduction study requested is in progress. It has also been supplied with information allowing the withdrawal of the Committee's request for information on the nitrite content of the diet used. The Committee has received the specification of the colouring matter being tested in the new studies. It has been informed that the long-term study in another strain of rat requested in 1975 is in progress.

Caramels (ammonia processes)

The Committee accepts the suggestion that classification of caramels into burnt sugar, ammonium sulphite, ammonia and caustic-caramels might facilitate evaluation of caramels. It wishes to have information on the uses of these different categories of caramel in foodstuffs and of the various intakes by different population groups. The Committee will require satisfactory specifications for these different types of caramel.

The Committee has received the results of long-term and reproduction/teratology studies on ammonia caramel and ammonia sulphite caramel as well as long-term studies on 4-methylimidazole.