COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

STATEMENT ON TEREPHTHALIC AND ISOPHTHALIC ACIDS FROM CAN COATINGS

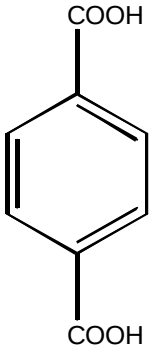
Introduction

1. The views of the Committee were sought on the health implications of the results of a survey[1] of terephthalic acid (TA) and isophthalic acid (IA) migration from can coatings into food. In particular the Committee was asked to give its views on the possibility that these compounds might have endocrine disruptor activity.

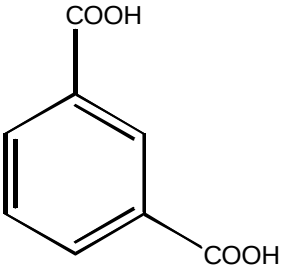
Background

2. TA and IA (see Figure) are starting materials in the manufacture of polyester resins, which are used in coatings on the internal surface of some metal cans designed to come into contact with food.

Figure



Terephthalic acid (TA)



Isophthalic acid (IA)

3. As part of the Food Standards Agency's continuing programme of surveillance on the migration of chemicals from food contact materials a two-part survey for TA and IA was carried out. In the first phase of the survey various canned foods were purchased and the cans were tested for the presence of coatings made from polyester resins. In the second phase, further samples of the products in those cans which had polyester coatings were analysed to determine whether migration of TA and IA into the can contents had occurred.[1]

Survey results

4. Twenty-eight products were identified as being in cans coated with polyester resin on all, or part, of their internal surfaces. In samples of the contents of these cans, TA was found in 3 of 28 samples at or just above the limit of quantification[*] and in 7 samples at levels between the limit of detection[†] and limit of quantification. IA was detected in 4 of 28 samples at levels between the limit of detection and limit of quantification.

5. Estimates were made of the potential intakes of TA and IA from canned foods studied in the second phase of the survey. Intakes were estimated for different age groups according to the types of foods in which these substances were found. The estimates used the analytical results for samples in which TA and/or IA were found. Intakes were calculated by summing the intakes of 97.5th percentile consumers[‡] for each food in which the given substance was detected, giving greatest weight in this summation to the two highest estimates of intake. The intake estimate was divided by bodyweight to derive contaminant exposure in milligrams per kilogram of bodyweight (mg/kg b.w.) per day, bodyweights used were: 8.8 kg for infants, 14.5 kg for toddlers (1½-4½ years old) and 60 kg for adults.

6. The potential intake of TA by infants between 6 and 12 months old who were 97.5th percentile consumers was estimated as 0.0074 mg/kg b.w. per day. For toddlers who were 97.5th percentile consumers the potential intake of TA was estimated as 0.083 mg/kg b.w. per day. For adults who were 97.5th percentile consumers the potential intake of TA was estimated as 0.0025 mg/kg b.w. per day.

7. The intake of IA by adult 97.5th percentile consumers was estimated as 0.0013 mg/kg b.w. per day. There are no estimates of intake by infants as no IA was detected in baby foods.

Toxicology of TA and IA

8. The European Commission's Scientific Committee for Food (SCF) reviewed studies of the toxicity and migration of both TA and IA.

9. In view of the availability of data from long-term studies the SCF was able, pending submission of full reports, to set a temporary Tolerable Daily Intake (TDI) for TA of 0.125 mg/kg b.w., which was based on 3-month and 2-year dietary studies in rats.[2] The major finding in the long-term study with TA was the occurrence of malignant and benign tumours of the urinary tract at high doses.[3,4] These were documented as being associated with the formation of stones in the urinary bladder which represents a potential non-genotoxic mechanism for the formation of such tumours.

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[*] Limit of quantification: the lowest level at which the amount of a substance can be stated with confidence.

[†] Limit of detection: the lowest level at which a substance can be detected with confidence.

[‡] 97.5th percentile consumers are those whose consumption of a specific food or group of foodstuffs corresponds to the 97.5th percentile point on a distribution curve for consumption of the given food or foods.

10. On the basis of the available data from migration and toxicity studies submitted by industry the SCF has also set a restriction (for migration from plastics) of 5 mg/kg food for IA.[2] This limit was based on negative genotoxicity data and a 90-day dietary study in rats, from which a No Observed Effect Level of 250 mg/kg b.w. per day was established.

11. The manufacturers of TA and IA submitted a commentary on the available reproductive and developmental toxicity data for both compounds. In this it was proposed that the weight of the evidence from these studies does not support a role for these acids in modulating the endocrine system.[5]

12. The Committee noted that the toxicity studies on TA and IA were not carried out to modern standards. It was recognised that the limited nature of the published work would not allow them to address fully the questions that they had been asked.

13. It was requested that, in the light of the urinary tumours occurring in rats fed the highest dietary concentration of TA, the view of the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment be sought on the potential *in vivo* genotoxicity of this compound.

14. It was noted that the estimated intakes of TA by infants, toddlers and adults who were 97.5th percentile consumers were below the temporary TDI established by the SCF. In addition, it was noted that the concentrations of IA found in samples of canned food in the survey were below the migration limit set by that committee.

Conclusions

i) The Committee *concluded* that the concentrations of TA and IA that had been determined in foods analysed in the survey were not of concern for public health on the basis of available information.

ii) The Committee *noted* the commentary of the manufacturers on possible endocrine disruptor activity of TA or IA. However, it was considered that the toxicity studies were inadequate to exclude this possibility. It was therefore *recommended* that appropriate studies should be carried out to determine whether TA or IA possess endocrine disruptor activity.

September 2000

COT Statement 2000/08

References

1. Food Standards Agency (2000). Chemical Migration From Can Coatings Into Food - Terephthalic and Isophthalic Acids. Food Surveillance Information Sheet number 7/00, October 2000

2. Commission of The European Communities, Directorate General III (2000) Synoptic Document: provisional lists of monomers and additives notified to the European Commission as substances which may be used in the manufacture of plastics intended to come into contact with foodstuffs. Updated to 10 January 2000.

3. Chemical Industry Institute of Toxicology (1982). A ninety day study of terephthalic acid-induced urolithiasis and reproductive performance in Wistar and CD rats (cited in reference 2 above).

4. UK document (1984). Terephthalic acid, proposed use in animal foodstuffs (cited in reference 2 above).

5. Isophthalic and terephthalic acids: Assessment of endocrine modulating potential; 6 pp. Submitted to the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment by BP Amoco Chemicals on 14 March 2000.