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**Scientific Committee on Food**

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**Opinion  
of the  
Scientific Committee on Food  
on  
a survey on dietary intake of the food contact material  
di-2-(ethylhexyl) adipate (DEHA)**

(expressed on 19 October 2000)

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**Opinion of the Scientific Committee on Food  
on a survey on dietary intake of the food contact material di-2-(ethylhexyl) adipate  
(DEHA)**

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**Terms of reference**

To evaluate, from the scientific point of view, the survey into the dietary intake of di-2-(ethylhexyl)adipate (DEHA, PM/REF No. 31920) in three EU Member States (1) and, in particular, to determine:

- a) whether the survey was designed and conducted correctly or not. If not, to explain deficiencies;
- b) whether the results of the survey mentioned above confirm the previous SCF-WG statement of the 66<sup>th</sup> meeting of the SCF's Working Group Food Contact Materials (FCM) of May 1996
- c) whether other conclusions can be extracted from the documentation submitted

**Background**

In 1994, the SCF was requested to re-evaluate the hazards to human health arising from the migration into food of DEHA present in food contact materials. In its opinion expressed on 16.12.1994 (2), the Committee concluded that the very small intakes of DEHA from its uses in food contact materials would not pose any carcinogenic hazard for man. It established a TDI of 0.3 mg/kg bw, based on a NOEL of 30 mg/kg bw for foetotoxicity in a teratogenicity study in rats. Based on this TDI, the Commission, taking into account the usual food consumption factor of 1, could propose a Directive establishing a Specific Migration Limit (SML), of 18 mg/kg food.

There has been uncertainty about the exposure of the general population apparent from the results of published intake estimates. In 1996, the European Plasticised PVC Film Manufacturers' Association (EPFMA) submitted the results of a new dietary intake study of DEHA in the UK (2) which calculated intakes from measurements of urinary ethylhexanoic acid (EHA) levels which had just become analytically determinable. EHA is a metabolite of DEHA and was therefore used as urinary biomarker for exposure to DEHA. The survey covered 112 individuals. Its result was the establishment of a median value of 2.7 mg/day for the intake of DEHA, a figure about three times lower than the 8.2 mg/day, indirectly estimated from the 1990 survey by MAFF in the UK (3).

When the SCF's WG FCM reviewed the EPFMA study in 1996, it agreed that this limited survey, carried out in the UK, was scientifically reasonable, although it would have been more informative had intake figures also been provided at the same time. The survey did not reveal any incidences of high DEHA intake and indicated that exposure was generally below the limitation recommended by the SCF of 0.3 mg/kg b.w.

EPFMA extended the intake study in 1998 to three other EU member states in order to obtain a broader overview of "real life" DEHA ingestion. This new study (1) has been submitted to the Commission services together with a request to obtain an increased SML of 60 mg/kg food instead of the proposed 18 mg/kg food, based on the argument that the new survey revealed estimated median intakes of DEHA of only 1.04 mg/day in France, 0.80 mg/day in Germany and 0.86 mg/day in The Netherlands.

## **Discussion**

The Committee noted that:

- one of the main assumptions of the study was the existence of a relationship between urinary EHA measurements and consumption of DEHA-containing cling film-wrapped food commodities although no food consumption survey was in fact carried out. Indeed 3 subjects with the highest urinary EHA excretion declared not to have consumed any cling-film wrapped food thus making the calculation of a correlation impossible;
- the absence of information on the representativity of the panel of subjects, on the criteria for their selection and on possible bias in the experimental protocol;
- the impossibility of determining the homogeneity of the survey sample;
- the smallness of the number of subjects, this number being insufficient to be representative of the general population;
- urinary EHA could also derive from metabolism of DEHP and possibly other components of the packaged foodstuffs;
- urinary EHA is not an exact measure of DEHA intake because of the individual variability in the extent of transformation of DEHA to EHA and further metabolism of EHA.

## **Conclusions**

Despite the severe limitations of the new survey on DEHA intakes in 3 Member States of the EU, the Committee considered that the new data were reassuring. The data showed that, on average, DEHA intakes were below the TDI established by the SCF. Although these new surveys did not permit the discovery of any population groups likely to approach or exceed the suggested SCF's TDI, they confirmed the usefulness of using a defined urinary biomarker as indicator for estimating exposure to compounds present in food as an alternative to intake estimates from dietary records, provided that food is the only source of the investigated compound. Because of the deficiencies and uncertainties of the new data, the Committee was unable to recommend that this new survey be used to reassess the Specific Migration Limit (SML) of DEHA. The Committee did not review the TDI of DEHA of 0.3 mg/Kg bw and therefore this TDI remains valid.

## **References**

1. Report No CTLR/R/1372 (1998). Survey into the dietary intake of di-2-(ethylhexyl) adipate in Member States of the European Community. Submitted by the European Plasticised PVC Film Manufacturers' Association (EPFMA). (CS/PM/3174/31920)
2. Scientific Committee for Food. Reports of the SCF, 30th series, 1997.

3. An assessment of the dietary uptake of DEHA in a limited population study. *Fd. Chem.* 32 (1994)
4. Ministry of Agriculture, Forestry and Fisheries (MAFF), (1990). Survey of Plasticiser Levels in Food Contact Materials and in Foods. Food Surveillance Paper No. 30, HMSO.