Opinion of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety

Date: 8 March 2005

Risk assessment of health hazards from epoxidised soybean oil (ESBO) migrated from lids used on glass containers of baby food

Summary

The Norwegian Food Safety Authority [*Mattilsynet*] asked The Norwegian Scientific Committee for Food Safety [*Vitenskapskomiteen for mattrygghet* (VKM)] to issue an opinion on the risk for infants linked to intake of epoxidised soybean oil (ESBO, CAS no. 8013-07-8), based on values of ESBO found in baby foods on the Norwegian market in a survey conducted by the Norwegian Food Safety Authority in 2004. The case was evaluated by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics. The panel was also asked to give an opinion on the proposal of a specific migration limit (SML) for substances in food contact materials intended specifically for infants and young children, that should be 1/10, or even 1/20, of the regular SML.

ESBO is used as a plasticiser and stabiliser in polyvinyl chloride (PVC) gaskets of metal lids used to seal jars and bottles of baby foods. The levels of ESBO determined in baby foods on the Norwegian market were 3-58 mg/kg. The EC Scientific Committee for Food (SCF) has established a tolerable daily intake (TDI) of 1 mg/kg bw/day for ESBO. The exposure assessments show that for 6-12 months infants the estimated mean intake of ESBO from baby foods on the Norwegian market was 4-5 fold below the TDI, but could in a worst case result in infants having an intake exceeding the TDI by up to 2-fold. It is generally considered that occasional excursions of intake above the TDI do not represent serious health risks. Moreover, ESBO is not found to be either carcinogenic, genotoxic or to have reproductive or developmental toxicity. However, intake exceeding the TDI is undesirable because it could reduce on a regular basis the safety margin between exposure and adverse effects.

The calculations with ESBO also show that for some chemical substances with a low TDI value migrating in amounts at or below the total migration limit of 60 mg/kg foodstuffs, the TDI value may still be exceeded for infants, because of their high food intake relative to body weight. Therefore, a specific migration limit (SML) lower than necessary to protect adults may be warranted for substances in food contact materials intended specifically for infants.

Terms of reference

In its letter of 8 October 2004 the Norwegian Food Safety Authority asked the Norwegian Scientific Committee for Food Safety to issue an opinion on the risk for infants linked to intake of epoxidised soybean oil (ESBO, CAS no. 8013-07-8), based on values of ESBO found in baby foods on the Norwegian market in a survey conducted by the Norwegian Food Safety Authority in 2004 (1). The case was evaluated by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics. The panel was also asked to give an opinion on the proposal of a specific migration limit (SML) for substances in food contact materials intended specifically for infants and young children, that should be 1/10, or even 1/20, of the regular SML (2).

Background

ESBO is used as a plasticiser and stabiliser in polyvinyl chloride (PVC) gaskets of metal lids used to seal jars and bottles, where it can be employed at up to 40% of the formula weight of the gasket. The gasket forms an airtight seal preventing microbiological and other contamination. This type of lids is commonly used for glass jars containing baby foods. This evaluation was conducted in the context of the amounts of ESBO determined in a survey of baby foods on the Norwegian market, which were found to be 3-58 mg/kg (1). ESBO is listed on the positive list for plastics (Directive 2002/72/EC) (3) and in the Synoptic document (4), without a specific migration limit (SML). The EC Scientific Committee for Food (SCF) established a tolerable daily intake (TDI) of 1 mg/kg bw/day for ESBO (5), resulting in a SML similar to the overall migration limit of 60 mg/kg food.

Toxicology

A risk assessment of ESBO in baby foods was performed by EFSA in 2004 (6). The toxicological data summarized in this opinion were based on a report made by The British Industrial Biological Research Association (BIBRA) from 1997 (7), and the evaluation published by SCF in 1999 (5), and are as follows:

Irritation and sensitization
ESBO samples with different specifications (oxygen content and iodine number) show mild skin and eye irritating properties in rabbits, and do not induce sensitization in guinea pigs.

Acute toxicity
ESBO has very low acute toxicity in rats (LD50 >5 g/kg bw).

Chronic toxicity
Repeated exposure studies show slight changes in uterus, liver and kidney weights, and no alteration of blood parameters, in rats fed with diets containing up to 5% ESBO (approximately 2.5 g/kg bw/day) for 2 years. The no observed adverse effect level (NOAEL) was approximately 140 mg/kg bw/day and the lowest observed adverse effect level (LOAEL) was approximately 1400 mg/kg bw/day. This figure was used by the UK Committee on Toxicity to derive, using an uncertainty factor of 100, a TDI of 1 mg/kg bw (8). The same TDI was adopted by the SCF in 1995-96.

Reproductive and developmental toxicity
No effect on fertility or offspring development was observed in rats treated with up to 1 g ESBO/kg bw/day by gavage before and after mating. No statistically significant increase in skeletal abnormalities was observed when treatments were given on days 6-15 of pregnancy.

Carcinogenicity
No evidence of carcinogenicity was seen in rats fed with 2.5% ESBO in the diet for two years.

Genotoxicity
No evidence of genotoxicity was obtained in the Ames/Salmonella test, in the forward mutation assay in mouse lymphoma L5178Y cells, or in a chromosomal aberration assay in human lymphocytes, all carried out with and without exogenous metabolic activation.

New toxicological data
The Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics did a data base search in order to obtain any new toxicological data on ESBO. Very little new information was found. Oral LD50 values for rats of 40 g/kg bw or 22.5 ml/kg bw were listed in the RTECS database (9). ESBO was tested in whole Wistar rat embryo culture assay, and was found not to exert any toxic effects on growth or development of the whole embryo, or to affect mid-brain or limb bud cell differentiation or cytotoxicity, indicating that ESBO has no effect on embryo growth, development and cytotoxicity during early organogenesis (10), in accordance with the *in vivo* results on developmental toxicity.

Analyses of migration

In 2004, the Norwegian Food Safety Authority conducted a survey on ESBO in commercial baby foods on the Norwegian Market (1). Three parallel samples of each type of baby food were analyzed for ESBO at the laboratory of the Official Food Control Authority of the Canton of Zürich, Switzerland. Values ranging from 3-58 mg ESBO per kg food were determined in the examined baby foods in the survey, therefore none of the samples contained ESBO in amounts exceeding the overall migration limit of 60 mg/kg food.

Exposure assessment of ESBO from baby foods

A TDI of 1 mg/kg bw for ESBO was established by SCF based on a NOAEL of 140 mg/kg bw/day for organ weight changes observed in a 2-year rat study (5,6). ESBO was found in amounts of 3-58 mg/kg baby foods in the Norwegian survey (1). In the following, intake of ESBO from baby foods has been estimated by the Norwegian Food Safety Authority (Christina Bergsten, personal communication) based on data for baby food intake determined in a Norwegian survey, SPEDKOST (11), calculated for a 12-month infant weighing 10 kg. Intake of ESBO from other potential sources than commercial baby foods in glass jars was not taken into consideration due to lack of data.

Based on data of consumption from all the study participants and using the mean values for ESBO in meat, fish and vegetable containing baby foods, respectively, an estimated **mean intake** of 0.2 mg/kg bw/day (1.8 mg ESBO/day) was found. This intake value is approximately 5-fold below the TDI of 1 mg/kg bw/day (10 mg/day).

Assuming a **worst case scenario** where an infant has a high consumption (90 percentile) of the specific baby food product in which the highest level of ESBO was found in the survey

will give an estimated intake of 1.6 mg/kg bw/day (15.6 mg ESBO/day). This intake value exceeds the TDI of 1 mg/kg bw/day (10 mg/day) with approximately 60%.

In the Norwegian survey the 6-month infants weighed 8 kg (11). Therefore, the two scenarios above will give intakes of ESBO for 6-month infants of 0.2 and 2.0 mg/kg bw/day, respectively, being approximately 4-fold below and 2-fold above the TDI of 1 mg/kg bw/day.

The estimated intake of ESBO from baby foods in Norway are therefore slightly lower than the values of estimated intake for infants aged 6-12 months calculated in the EFSA opinion, which in some cases exceeded the TDI by up to 4- or 5-fold (6).

Conclusions

The amounts of ESBO (3-58 mg/kg) found in baby foods in Norway (1) and estimated intakes of baby foods in Norway (11) were in the lower range of values found in the reported surveys from other countries (6). Very little new information about toxicological effects of ESBO was found. We therefore agree with the conclusions and recommendations given by EFSA in 2004 (6).

The exposure assessments show that for 6-12 months infants the estimated mean intake of ESBO from baby foods on the Norwegian market was 4-5 fold below the TDI of 1 mg/kg body weight, but could in a worst case result in infants having an intake exceeding the TDI by up to 2-fold. It is generally considered that occasional excursions of intake above the TDI do not represent serious health risks (12). Moreover, ESBO is not found to be either carcinogenic, genotoxic or to have reproductive or developmental toxicity. However, intake exceeding the TDI is undesirable because it could reduce on a regular basis the safety margin between exposure and adverse effects.

The calculations with ESBO also show that for some chemical substances with a low TDI value migrating in amounts at or below the total migration limit of 60 mg/kg foodstuffs, the TDI value may still be exceeded for infants, because of their high food intake relative to body weight. Therefore, a specific migration limit (SML) lower than necessary to protect adults may be warranted for substances in food contact materials intended specifically for infants.

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Acknowledgement

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