

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food related to

exposure of adults to

epoxidised soybean oil used in food contact materials

Question No EFSA-Q-2005-219

Adopted on 16 March 2006 by written procedure

SUMMARY

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) has been asked to evaluate the results of the new surveys available on the migration of epoxidised soybean oil (ESBO) into foodstuffs such as sauces, condiments and products in oil packaged in glass jar with metal lids lined with polyvinyl chloride (PVC) containing ESBO. The evaluation is requested in relation to the exposure of adults to ESBO.

ESBO is used as a plasticiser and stabiliser for plastics such as PVC. It is used in particular in sealing gaskets of metal lids for glass jars, where it can be present at up to 40% of the weight of the gasket. There is thus a potential for migration into the food both during processing and storage. ESBO is also used as a stabiliser in plasticised PVC cling films for wrapping foods.

For the estimation of the potential exposure of adults to ESBO the Panel made several conservative assumptions, for example on the extent of packaging used, migration levels and food consumption. This was done to provide a first screen in comparison to the Tolerable Daily Intake (TDI).

Based on average concentration levels of ESBO in foods packaged in glass jars with PVC-lined lids, the potential high dietary exposure of adults was estimated to be 0.25 mg/kg bw/day. Based on the 90th percentile of the concentration values measured, the potential dietary exposure of adults was estimated to be 0.64 mg/kg bw/day. In both scenarios daily consumption values at the 95th percentile were used for largely consumed foods and a weekly consumption was assumed for minor food categories. Potential dietary exposure of adults to ESBO from foods packaged in cling films was estimated to not exceed 0.2 mg/kg bw/day.

Using conservative scenarios of exposure, the Panel noted that the potential dietary exposure of adults to ESBO from foods packaged in glass jars and in cling films is below the TDI of 1 mg/kg bw. The Panel considered therefore that further refinement of the exposure estimates was not necessary.

KEY WORDS

Epoxidised soybean oil, ESBO, CAS No. 008013-07-8, PVC, jars, sauces, condiments, gaskets, films.

BACKGROUND

In May 2004, EFSA issued an opinion on the risk of dietary exposure to ESBO and ESBO derivatives with particular attention to infants regarding the consumption of commercial baby foods packed in glass jars sealed with metal lids lined with PVC gaskets (EFSA, AFC, 2004). At the time, regarding adults the quantity of available data on target foods was very limited, but it was expected that the contribution from foods in jars and bottles to the total diet of adults was likely to be smaller than in the diet of infants.

Recent surveys in Denmark, Germany, Austria and Switzerland have shown in some cases high levels of ESBO in fatty food such as, fatty sauces and especially pesto sauce, and vegetables, cheese or fish in oil. Because of the high migration figures, an estimation of the exposure of adults to ESBO was therefore necessary in order to find out if the TDI of 1 mg/kg body weight set by the Scientific Committee on Food (SCF, 1999) was exceeded.

TERMS OF REFERENCE

In accordance with Article 29(1)a of Regulation (EC) No 178/2002, the Commission asks the European Food Safety Authority (EFSA) to update its previous opinion on ESBO for use in food contact materials as concerns the exposure of adults in the light of new data that have become available.

INTRODUCTION

ESBO is used up to 40% in PVC gaskets of metal lids of glass jars and in PVC cling film up to 10%. Each application is considered in turn and emphasis is placed on the migration from gaskets because of the new survey data. The overall exposure from these applications is compared to the TDI of 1 mg/kg bw for ESBO set by the SCF (SCF, 1999).

ASSESSMENT

EXPOSURE ESTIMATES FROM FOODS PACKAGED IN GLASS JARS

Levels of ESBO in foods packaged in glass jars

The data came from surveys in four different countries (Austria, Germany, Denmark, Switzerland). A total of 222 samples of mostly fatty foods were tested because ESBO is more likely to migrate into these foodstuffs. The foodstuffs included fatty sauces such as mayonnaise, and condiments (béarnaise, tartar, mustard, horseradish etc), vegetable sauces (pesto, tomato, basil, olive paste etc), vegetables preserved in oil (olives, artichokes, eggplants, garlic, sun-dried tomatoes, paprika, mushrooms, cactus leaves, capers, beans, pickles etc), cheese preserved in oil (feta, goat etc), and fish preserved in oil (sardines, tuna, mussels, seafood, herring, shrimps etc). Non fatty foods were not included because ESBO is barely soluble in foods with no fat and therefore it is not expected to migrate into such foods.

Due to the very limited amount of data on processed meat and desserts, these categories were not considered any further in the evaluation.

The results of analysis for the different categories of foods tested are summarised in table 1 as the percentage of the different sample types tested, falling within the concentration ranges indicated.

Table 1: Summary of data from surveys on ESBO levels in foods in glass jars

| Concentration in food (mg/kg) | Sauces and condiments (a) | | | (b) | (c) | (d) |
|-------------------------------------|---------------------------|----------------|-----------------|-------------|----------------------|------------------|
| | Fatty sauce | Pesto sauce | Tomato sauce | Fish in oil | Vegetables in oil | Cheese in oil |
| 0-5 | 50% | 0 | 41% | 39% | 15% | 25% |
| 6-30 | 43% | 13% | 38% | 0 | 18% | 17% |
| 31-60 | 7% | 17% | 12% | 17% | 11% | 25% |
| 61-100 | 0 | 10% | 3% | 11% | 16% | 8% |
| 101-200 | 0 | 40% | 6% | 11% | 23% | 25% |
| 201-300 | 0 | 13% | 0 | 6% | 10% | 0 |
| 301-400 | 0 | 3% | 0 | 17% | 7% | 0 |
| 401-500 | 0 | 0 | 0 | 0 | 0 | 0 |
| 501-600 | 0 | 0 | 0 | 0 | 0 | 0 |
| 601-700 | 0 | 3% | 0 | 0 | 0 | 0 |

The Panel noted that due to the variability of the migration values, a migration value covering 90% of the samples for each category could be used as a conservative estimate of the concentration for estimating the chronic exposure of adults to ESBO.

The migration of ESBO in fatty sauces other than pesto did not exceed 60 mg/kg, and 30 mg/kg represented the 90th percentile of the concentration level.

In the case of pesto the migration did not exceed 300 mg/kg in 90% of the cases. The same applied for vegetables in oil. For fish in oil the value covering 90% of the cases was around 350 mg/kg, and that for cheese in oil was 150 mg/kg.

Food consumption

Food consumption data for the relevant types of foodstuffs expected to be in contact with PVC-lined lids were reviewed from data in the literature. Data could be obtained for 11 countries (listed in the reference section) from the EU database Expofacts (<http://www.ktl.fi/expofacts/>).

a. Sauces and condiments

The approach taken was to consider that tomato-based sauces and mayonnaise type sauces could make up to 100% of the whole food category of sauces and condiments. The highest average consumptions were exhibited in Ireland, France and The Netherlands, with values all around 70g/day (highest value for all ages and both sexes). Only Ireland had a value for the 95th percentile, which was around 200g/day. As Ireland had both the highest mean in common with 2 other countries and showed a 95th percentile, this value was taken as reference.

Pesto sauce is not expected to be consumed on a daily basis. A conservative average value of 10g/day was taken, considering that 70 g of this sauce (the highest average daily consumption of the group “sauces and condiments”) could be consumed on a weekly basis by regular consumers.

b. Fish in oil

Details related to consumption of fish and shellfish in oil were not available in the food consumption studies provided to the Panel. An overestimation was again taken, assuming that the items considered fish in oil made up by themselves 100% of the category of processed fish.

Within the category processed fish, the most precise (over)estimation was from Italy from a category combining fish and shellfish preserved (with the highest average for consumers being 15 g/day). Data from Ireland further showed that for fish in oil the ratio between the mean and the 95th percentile could vary by a factor 2 to 4. A factor of 3, which is often used to estimate high percentiles of consumption on the basis of average consumption in consumers only, was used to estimate the 95th percentile: 45g/day (15g/day x 3).

c. Vegetables in oil

Only the category of processed vegetables was available in the food consumption studies provided to the Panel. Those usually comprise any processed food (frozen, canned, dehydrated) for any type of vegetables.

For the average male/female, both the Irish study and the Italian study showed similar values which were the highest with respect to other countries for “tinned or jarred vegetables” and the sum of the values in “fruit, preserved (including olives)” and “vegetables preserved” respectively. Both male and female average values for these two countries were around 15 g/day (for consumers), with the Irish 95th percentile being 43.5 g/day.

d. Cheese in oil

Cheese in oil is not expected to be consumed on a daily basis. A conservative average value of 7 g/day was taken, considering that 46 g (the highest average daily consumption of the group “cheese”, found in France) could be consumed on a weekly basis by regular consumers of cheese in oil.

Exposure estimates

The exposure was calculated for an average and for a 90th percentile of the concentration level of ESBO measured in foods in glass jars. For the calculation of the average concentration only those samples containing more than 5mg/kg ESBO were taken into consideration. An adult bodyweight of 60 kg was used in the calculations.

The data and the results of the calculation of the exposure are shown at the table 2 below.

Table 2: Calculations of exposure of adults to ESBO from foods in glass jars

| Foods | concentration value upper average ⁽¹⁾ (mg/kg) | concentration value for high migration ⁽²⁾ (mg/kg) | food consumption (g/day) | adults exposure - upper average migration level (mg/kg bw/day) | adults exposure - high migration level (mg/kg bw/day) |
|-----------------------|--|---|--------------------------|--|---|
| Sauces and condiments | 21 | 30 | 200 ⁽³⁾ | 0.07 | 0.10 |
| Pesto | 134 | 300 | 10 ⁽⁴⁾ | 0.02 | 0.05 |
| Fish in oil | 103 | 350 | 45 ⁽³⁾ | 0.08 | 0.26 |
| Vegetable in oil | 102 | 300 | 44 ⁽³⁾ | 0.07 | 0.22 |
| Cheese in oil | 52 | 150 | 7 ⁽⁴⁾ | 0.005 | 0.01 |
| SUM | | | | 0.25 | 0.64 |

⁽¹⁾ The upper average means that only samples containing more than 5mg/kg ESBO were taken into consideration in the calculation of the average.

⁽²⁾ The high migration value was taken as the 90th percentile of concentration levels found.

⁽³⁾ 95th percentile

⁽⁴⁾ Estimated based on a weekly assumption

The Panel considered that the use of conservative scenarios more than compensated for uncertainties arising from not including meat and desserts in the exposure assessment due to the lack of data.

EXPOSURE ESTIMATES FROM FOODS PACKAGED IN CLING FILMS

The other potential source of exposure to ESBO is from its use as a stabiliser in thin plasticised PVC cling films used for wrapping foods. Unfortunately, there are few survey data available for this application and these are from just one country (UK) for samples tested back in 1988 (Castle *et al.*, 1990). However, an indication of the potential exposure to ESBO from this source can be obtained from the extensive surveys that have been conducted for the plasticiser di(2-ethylhexyl)adipate (DEHA).

DEHA is frequently used in combination with ESBO in cling films. There are alternative plasticisers to DEHA but there are also alternative stabilisers to ESBO and so the two additives are used about as frequently as each other. DEHA is added to cling films in higher amounts than ESBO. Like ESBO, DEHA is practically insoluble in foods with no fat and so migrates only into fatty foods. Finally, DEHA is a much smaller molecule than ESBO and so its tendency to migrate from cling films is higher than ESBO. As a consequence of these factors, it can be concluded that consumer exposure to ESBO migration from cling films will be no greater than exposure to DEHA.

There is a large literature describing laboratory studies of DEHA migration from plasticised films and also several surveys of packaged foods have been reported. There have also been biomarker studies reported for limited population surveys in 4 European Countries (Loftus *et al.*, 1994; Woollen and Russell, 1998). These biomarker surveys monitored the concentration of the metabolite 2-ethylhexanoic acid (2-EHA) in urine of adults and back-calculated the estimated intake of DEHA from all sources. It was assumed that DEHA was the only source

of excreted 2-EHA. The biomonitoring studies are therefore considered to provide an over-estimate because there could be sources of 2-EHA in urine other than from DEHA and the metabolic conversion factor of 15:1 used for DEHA transformed into 2-EHA (Loftus et al, 1993) would magnify any such contributions.

A summary of the results of the analysis of urine samples for exposure to DEHA is shown in the table 3 below.

Table 3: Summary of the results for exposure of adults to DEHA based on the analysis of urine samples for 2-EHA

| Country and survey year | Number of subjects | Median intake mg/day | Maximum intake mg/day |
|-------------------------|--------------------|----------------------|-----------------------|
| UK (1992) | 112 | 2.7 | 8.2 |
| France (1998) | 40 | 1 | 5.3 |
| Germany (1998) | 51 | 0.8 | 7.2 |
| Netherlands (1998) | 48 | 0.9 | 12.4 |

Based on the considerations presented above, that consumer exposure to ESBO migrating from cling films will be no greater than the exposure to DEHA from these wrapping films, it can be expected that maximum exposure to ESBO from cling films will not exceed around 12 mg/person/day which amounts to 0.2 mg/kg bw/day for an adult weighing 60 kg.

CONCLUSIONS

Based on average concentration levels of ESBO in foods packaged in glass jars with PVC-lined lids the potential high dietary exposure of adults was estimated to be 0.25 mg/kg bw/day. Based on concentration levels at the 90th percentile of the concentration values measured, the potential dietary exposure of adults was estimated to be 0.64 mg/kg bw/day. In both scenarios daily consumption values at the 95th percentile were used for frequently consumed foods and a weekly consumption at average level was assumed for food categories less often consumed.

By analogy with data for DEHA, the potential dietary exposure of adults to ESBO from foods packaged in cling films will not exceed 0.2 mg/kg bw/day.

For the estimation of exposure several conservative assumptions were made in order to provide a first screen in comparison to the TDI.

Using the conservative scenarios of exposure, the Panel noted that the potential dietary exposure of adults to ESBO from foods packaged in glass jars and in cling films is below the TDI of 1mg/kg bw as set by the SCF (SCF, 1999).

The Panel considered therefore that further refinement of the exposure estimates was not necessary.

DOCUMENTATION PROVIDED TO EFSA

Letter from the European Commission, ref DG SANCO/D3/AS/md D(2005), dated 24/08/2005

With the following attachments:

Analyses results of national surveys on migration of ESBO from gaskets in metal lids into fatty food (excel file).

BfR , Übergang von Weichmachern aus Schraubdeckel-Dichtmassen in Lebensmittel, Stellungnahme Nr. 010/2005 vom 14. Februar 2005

Metal Closures Industry Assessment of Consumer Exposure to ESBO (July 2005) (word file)

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