Annex 1. Epoxidized soy bean oil (ESBO, CAS n° 8013-07-8)

ESBO (epoxidized soybean oil, CAS n° 8013-07-8) is considered together with ETP (fatty acids, tall-oil, epoxidized, 2-ethylhexyl esters, CAS n° 61789-01-3), EODA (9-octadecanoic acid (Z)-, epoxidized, ester w/propylene glycol, CAS n° 68609-92-7) and ELSO (or ELO, epoxidized linseed oil, CAS n° 8016-11-3) in the epoxidized oils and derivatives (EOD) category. Epoxidized oils and derivatives are epoxidized fatty acid esters. The oils from which these products are derived are naturally occurring long chain fatty acid sources, and there is considerable overlap in the composition of the fatty acid portion of these products. They are primarily the C18 acids: oleic, linoleic, and linolenic acid. ETP is a monoester with 2-ethylhexanol. EODA is a diester with propylene glycol. ESBO and ELSO are triesters with glycerol (triglycerides). These substances are used as plasticizers in polyvinyl chloride (PVC) for a wide range of applications including food contact materials. They are considered a category for purposes of environmental and health hazard screening assessments because of the similar metabolism (uptake results in rapid metabolism by esterases) in microbial, aquatic and mammalian systems (OECD, 2006).

Commission Regulation (EU) n° 10/2011 specifies a specific migration limit (SML) of 60 mg/kg for ESBO. In the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Commission Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Commission Directive 2006/125/EC, the SML is lowered to 30 mg/kg.

1.1. <u>Hazard identification</u>

Epoxidized soy bean oil (ESBO) is a modified oil resulting from an epoxidation reaction of soybean oil. Soybean oil consists of a mixture of triglycerides with an average composition in predominant fatty acids of about 11% palmitic (16:0), 4% stearic (18:0), 23% oleic (18:1), 55% linoleic (18:2), and 8% linolenic (18:3) acid (EFSA, 2004). ESBO is usually fully epoxidized and consists of triglycerides with ~ 53% diepoxy linoleic acid (18:2 2E), 25% epoxy oleic acid (18:1 E), 7% triepoxy linolenic acid (18:3 3E) as well as non-modified palmitic (16:0) and stearic acid (18:0). ESBO is used as additive for PVC, where it serves as plasticizer and as stabilisator by acting as a scavenger for hydrogen chloride liberated from PVC during heat treatment for manufacturing. PVC containing ESBO is used, e.g., as plastisols for the gaskets in lids for glass jars, PVC cling films and organosol can coatings (Fankhauser-Noti *et al*., 2006; EFSA, 2004).

1.1.1. Reaction products

ESBO has been found to generate chlorohydrins and chlorinated cyclic derivatives during processing. The formation of reaction products such as chlorohydrins from ESBO in PVC is related to the release of HCl from the PVC at high temperature and the reaction of HCl with an epoxy group of ESBO. Cyclic compounds can be formed from ESBO due to a specific reactivity of α-diepoxides leading to formation of 5 or 6 membered rings, most likely facilitated by acid catalysis. Besides chlorohydrins and cyclic compounds identified and accounting for about half the lost epoxides in PVC, it is relatively unknown to what extent other ESBO reaction products could be formed (EFSA, 2004).
Due to lack of adequate analytical and toxicological data on ESBO derivatives, no advice can yet be given on the health significance of such derivatives in foods. Experimental data on fatty acid model systems indicated that heating at 200°C for 15 minutes gives 5-15% conversion of ESBO into chloro-derivatives. These chloro-derivatives are expected to migrate at the same rate as the non-reacted ESBO itself, since the derivatised epoxy fatty acids are attached to the same glycerol moiety as the underivatised ones (Suman *et al.*, 2010; EFSA, 2004; Biedermann-Brem *et al.*, 2003; Fantoni & Simoneau, 2003).

1.1.2. Epoxidised fatty acids in food

In order to investigate the relevance of the FCM ESBO for human exposure to epoxidized fatty acids in the light of the oxidized fatty acids anyway ingested with our food, Fankhauser-Noti *et al*. (2006)

determined the epoxidized fatty acids of ESBO in those foods of our normal diet which are expected to contain the highest concentrations, i.e., oxidized edible oils (including degraded frying oils), fried foods, bakery ware and roasted meat. The contribution of epoxy oleic acid from ESBO to our diet turned out to be negligible. If this acid were the toxic component in ESBO, the toxicological assessment would primarily be a warning regarding oxidized fats and oils. The contribution of diepoxy linoleic acid from ESBO might be similar to the exposure from oxidized fats and oils of our diet, whereas the intake of triepoxy linolenic acid from ESBO exceeds that from normal food by around two orders of magnitude.

1.2. Hazard characterization

Because of the similarity in physicochemical properties, it is assumed that epoxidized oils and derivatives are absorbed and metabolized in a manner similar to vegetable oils, rather than simply excreted (OECD, 2006).

ESBO can cause mild eye and skin irritation, and has a very low acute toxicity. There is no indication for carcinogenicity or genotoxicity. ESBO has not been shown to have reproductive or developmental toxicity (OECD, 2006; EFSA, 2004).
The EU Scientific Committee on Food specified a TDI ('tolerable daily intake) for ESBO of 1 mg/kg body weight (bw) (SCF, 1999), based on a NOAEL ('no observed adverse effect level') of 140 mg/kg bw derived from a toxicological assessment performed by the British Industrial Biological Research Association in the late 1980s.

1.3. Exposure assessment

1.3.1. ESBO levels migrating from the packaging to food

a) Belgian monitoring data

The level of ESBO was measured in various foodstuff on the Belgian market packed in glass jars with PVC-lined metal lids within the framework of the control programme 2008, 2009, 2010, 2011 and 2012 of the FASFC. A total of 170 food samples and of 130 baby food samples were analysed. The analyses were performed in the laboratory of the Scientific Institute for Public Health (IPH) and at Eurofins-Berlin using a combined gas chromatographic/mass spectrometric (GC/MS) analytical procedure (limit of quantification or LOQ = 1 mg/kg). Both laboratories were ISO 17025 accredited.
Since a statistical comparison of the ESBO levels shows overall no significant differences in function of time, data from 2008 until 2012 are pooled.[1,2] Due to the limited number of data and because concentration data are not available for all foods packed in the relevant packaging type, following broad food categories are considered for further evaluation: sauces (pesto and other sauces such as tomato sauce, mayonnaise, etc.), vegetables-in-oil (olives included), cheese-in-oil, fish-in-oil and baby food (fruit- and vegetable-based baby foods) (**table 1**).

[1] Statistical analysis was performed with SPSS 11.0 for Windows (SPSS Inc., USA). The Kolmogorov-Smirnov test was used to test normality. When data were normally distributed, means were compared using analysis of variance (one-way ANOVA) and Post Hoc Multiple Comparison tests (Tukey when variances were equal or Games-Howell when variances were unequal). Homogeneity of variances was tested using the Levene test. In case of non-normality Kruskal-Wallis test was used.
[2] Exception: mean ESBO level in sauces was significant higher in 2008 compared to the other years

Table 1. Levels of ESBO (mg/kg) analyzed in different food groups on the Belgian market (FASFC pooled data from 2008 to 2012)

	Baby food			Sauces			Vegetables-in-oil	Cheese-in-oil	Fish-in-oil
	total	*vegetables*	*fruit*	**total**	*pesto*	*other*			
n	130	*71* [c]	*17* [c]	91	*22*	*69*	53	14	12
# > LOQ	63	*47* [c]	*2* [c]	35	*15*	*20*	33	5	8
median [a]	1.2 (0.0-1.2)	*2.9* *(2.9-3.1)*	*0.5* *(0.0-0.5)*	0.5 (0.0-1.0)	*9.8* *(9.8-9.8)*	*0.5* *(0.0-1.0)*	3.7 (3.7-3.7)	0.5 (0.0-1.0)	7.8 (7.8-7.8)
average [a]	6.4 (6.1-6.7)	*8.6* *(8.4-8.8)*	*4.6* *(4.0-4.6)*	5.6 (5.3-5.9)	*14.9* *(14.8-15.1)*	*2.6* *(2.2-3.0)*	23.8 (23.6-23.9)	5.4 (5.1-5.7)	14.0 (13.8-14.2)
upper average [b]	12.7	*12.6*	*34.4*	13.7	*21.6*	*7.7*	37.8	14.2	20.7
P90 [a]	20.0 (20.0-20.0)	*24.0* *(24.0-24.0)*	*7.0* *(5.5-7.0)*	25.0 (25.0-25.0)	*31.8* *(31.8-31.8)*	*5.0* *(5.0-5.0)*	39.0 (39.0-39.0)	12.2 (12.2-12.2)	33.5 (33.5-33.5)
P95 [a]	28.0 (28.0-28.0)	*33.0* *(33.0-33.0)*	*22.0* *(22.0-22.0)*	28.5 (28.5-28.5)	*36.4* *(36.4-36.4)*	*10.1* *(10.1-10.1)*	47.8 (47.8-47.8)	20.8 (20.8-20.8)	41.5 (41.5-41.5)
P97.5 [a]	46.3 (46.3-46.3)	*47.2* *(47.2-47.2)*	*38.5* *(38.5-38.5)*	35.5 (35.5-35.5)	*42.3* *(42.3-42.3)*	*20.9* *(20.9-20.9)*	176.7 (176.7-176.7)	28.5 (28.5-28.5)	46.2 (46.2-46.2)
max [a]	55.0	*54.0*	*55.0*	49.0	*48.6*	*49.0*	450.0	36.1	50.8

[a]: for results < LOQ a concentration of LOQ/2 is assumed (i.e. 'middle bound' scenario); lower (< LOQ = 0) and upper (< LOQ = LOQ) bound scenarios between brackets
[b]: 'upper average' calculated by omitting results < LOQ, according to EFSA, 2006
[c]: for 42 samples of baby food the type (fruit/vegetable) is not recorded; a value "< 5 mg/kg" was reported for one 'fruit' and one 'vegetable' sample, which was considered as the LOQ for these samples

b) Discussion

ESBO is found in ~50% of the baby food samples, ranging from 1 to 55 mg/kg, and six baby food samples (4.6%) exceed the SML of 30 mg/kg (4 vegetable-based, 1 fruit-based and 1 not specified) (**table 1**). With respect to the other food categories, ESBO is found in 47.6% of the samples. In 3.5% of the samples ESBO levels above 30 mg/kg are observed (4 sauce, 9 vegetable-in-oil, 1 cheese-in-oil, and 2 fish-in-oil samples). The SML of 60 mg/kg was exceeded in a garlic-in-oil sample (230 mg/kg) and in an olive sample (450 mg/kg). The high levels observed in these samples illustrate the high heterogeneity in ESBO levels that can migrate. With the exclusion of the two elevated ESBO levels observed in the vegetable-in-oil samples, pesto and tapenades have in general a higher median and mean ESBO level implying a higher potential for ESBO migrating from the lids.

ESBO levels reported for baby food are in accordance with ESBO levels reported by Hammarling *et al.* (1998), who observed levels in the range of < 1.5 to 50.8 mg/kg, with a mean of 11.9 mg/kg and a median of 7.8 mg/kg in different baby food dishes with detectable levels. By analyzing baby food that never had been in contact with the lids, it was demonstrated that the ESBO levels observed were only due to migration from the lids and not of natural origin.
Higher levels were observed in a European survey conducted by the Joint Research Centre (JRC) in 2000 and 2001 on 248 samples of baby food from 15 European Union Member states (including Belgium, 8 samples) as well as from Switzerland (Fantoni & Simoneau, 2003). ESBO was found in 95 of the 248 samples with levels ranging from 1.5 to 135.2 mg/kg. 11% of the samples had levels between 30 and 60 mg/kg ESBO and 4% exceeded the overall migration limit of 60 mg/kg. The highest concentrations were found in main dish mixed foods such as vegetables and meat or carbohydrate- and vegetable-based mixes. Results lacked any evident direct correlation between the percentage of fat and the migration level. One hypothesis is that a factor could be the state of dispersion of fat rather than the fat content itself. The concentrations of ESBO in caps were generally higher for jars used to pack food of lower fat content, which seemed to indicate the existence of various 'recipes' being used for lining for various types of foodstuffs. The average percentage of ESBO encountered in caps was 30% for pasteurized foods of low fat content such as vegetables, fruit, fresh cheese or yoghurts. For meat products, with a greater fat concentration, the percentage of ESBO found was lower. Since the migration phenomenon most likely might occur mainly during the sterilization process in which the food is heat-treated under pressure, the various processes of sterilization could give various levels of migration on similar samples (e.g. dynamic retorting or sterilization under rotation conditions having a greater impact, although sterilization times would be reduced to a certain extent).

1.3.2. Exposure to ESBO migrating from the packaging: Belgian population

a) Migration from PVC lined lids

The EFSA has published two opinions on the exposure of ESBO from food-contact materials (EFSA, 2004, 2006). The first opinion examined exposure of infants to ESBO, while the second opinion evaluated the exposure of adults to ESBO. Due to the variability of the migration value in foods from glass jars with PVC lined lids, a migration value covering 90% of the samples for each category (P90 or 90^{th} percentile) was used as a conservative estimate of the concentration for estimating the chronic exposure of adults to ESBO (EFSA, 2006). Besides the P90, calculations were also made for the trimmed average (which was calculated considering only samples containing > 5 mg/kg ESBO).
In accordance with this EFSA opinion, the exposure of the Belgian adult consumer to ESBO through food packed in glass jars was calculated based on the trimmed average and the P90 ESBO level (**table 2**). In the present study, the trimmed average was calculated by omitting the results for which the ESBO concentration was below the LOQ. Additionally, the average and P95 migration levels were considered as well. Consumption data were obtained from the Belgian Food Consumption Survey (BFCS) of 2004 (Devriese *et al.*, 2005). Given the low percentage of consumers (75.0% for sauces, 35.4% for fish-in-oil, 4.6% for vegetables-in-oil and 16.7% for cheese-in-oil), two P95 scenarios were considered: the whole population as well as 'consumers only', based on the Belgian Food Consumption Survey (BFCS) of 2004 (Devriese *et al.*, 2005).

The potential exposure of Belgian adults to ESBO from foods packed in glass jars is well below the TDI of 1 mg/kg bw (**table 2**).

The ESBO exposure of infants through baby food is presented in **table 3**. Similarly to the exposure estimation of adults the calculation is based on the average, the trimmed average, the P90 and the P95 migration level in baby food. Consumption data were taken from the EFSA opinion regarding the ESBO exposure of infants, aged 4 to 12 months (EFSA, 2004). In case of a high intake, the exposure of infants to ESBO may exceed the TDI of 1 mg/kg bw per day.
Table 4 presents the ESBO exposure of infants as well, but based on consumption values reported in a design study of market baskets of EU commercial baby food for the assessment of the exposure of an 'average' infant to food chemicals (Piccinelli *et al.*, 2010). Consumption values are in the same range as the ones considered in **table 3**, resulting equally in an exposure that can exceed the TDI.

b) Migration from PVC films

There are no Belgian survey data available for the migration of ESBO from PVC films for applications such as wrapping food and covering food for re-heating in a microwave oven. Migration levels of ESBO from PVC cling films reported by Castle *et al.* (1990) ranged from < 1 to 4 mg/kg for wrapped fresh retail meat samples (but were higher (max. 22 mg/kg) in retail cooked meat), and from < 1 to 27 mg/kg for 'take-away' sandwiches and rolls. When the film was used for microwave cooking in direct contact with food, ESBO levels from 5 to 85 mg/kg were observed, whereas when the film was employed only as a splash cover for re-heating foods, ESBO levels ranged from 0.1 to 16 mg/kg.
In the EFSA assessment migration values for ESBO in PVC films were extrapolated from studies on the plasticizer di(2-ethylhexy)adipate (DEHA) (EFSA, 2006). DEHA is often used in combination with ESBO in cling films, but usually at higher amounts. Both compounds migrate preferentially in fatty foods, but DEHA being a smaller molecule, its tendency to migrate is higher compared to ESBO. Based on biomonitoring results for the exposure of adults to DEHA, it was assumed in the EFSA opinion that the maximum exposure to ESBO from cling film will not exceed 12 mg/day (0.2 mg/kg bw/day for an adult weighing 60 kg). Considering this exposure route in addition to the exposure of adults through foods packed in glass jars (**table 2**), the TDI of ESBO will still not be exceeded.

c) Discussion

In the EFSA 2006 opinion, the potential dietary exposure of adults to ESBO from glass jars was estimated to be 0.25 and 0.64 mg/kg bw per day based on the trimmed average and the high or P90 migration value respectively (EFSA, 2006). The trimmed average and high exposures estimated in the present study are much lower, namely 0.08 and 0.11 mg/kg bw per day respectively. Even when only consumers of the concerned food products are considered, the exposure remains below the EFSA estimates (**table 2**). This is not only due to lower migration values observed in the present study, but also to lower food consumption levels.
With respect to the exposure of infants to ESBO, exposure values between 0.43 and 2.65 mg/kg bw per day were obtained in an EFSA assessment (EFSA, 2004). Based on the same consumption values, the exposure of infants in the present study appears to be lower, namely between 0.18 and 1.16 mg/kg bw per day (**table 3**). In an assessment of the Norwegian Scientific Committee for Food Safety, similar exposure estimates are reported, with a mean and worst case (P90 consumption and max. ESBO level) intake of 0.2 and 1.6 mg/kg bw per day for 12-month infants (bw = 10 kg) and of 0.2 and 2.0 mg/kg bw per day for 6-month infants (bw = 8 kg) (VKM, 2005).

The exposure of children aged 5-12 years to ESBO was estimated by Duffy & Gibney (2007) using the Irish National Children's Food Survey (NCFS) and the Irish Food Packaging Database (IFPD), and P90 migration values of ESBO in foods derived from literature. The mean and P95 intake of ESBO for Irish children was 0.023 and 0.077 mg/kg bw per day respectively. The food group that contributed most to ESBO intake was tomato sauces packed in glass jars with PVC-lined metal lids (46.8%).

Table 2. Exposure of adults to ESBO (mg/kg bw per day)[a] through in glass jars packed food (deterministic approach, based on average, upper average and P90 ESBO levels from the FASFC control data (2008 - 2012) and the P95 consumption level taken from the BFCS (Devriese *et al.*, 2005))

		Exposure population					**Exposure consumers only**			
	median	**average**	**upper average** [b]	**P90**	**P95**	**median**	**average**	**upper average** [b]	**P90**	**P95**
Sauces total	0.001 (0.000-0.002)	0.009 (0.008-0.009)	0.022	0.040 (0.040-0.040)	0.045 (0.045-0.045)	0.001 (0.000-0.002)	0.010 (0.010-0.011)	0.025	0.046 (0.046-0.046)	0.052 (0.052-0.052)
Pesto	*0.000 (0.000-0.000)*	*0.000 (0.000-0.000)*	*0.000*	*0.000 (0.000-0.000)*	*0.000 (0.000-0.000)*	*0.005 (0.005-0.005)*	*0.008 (0.008-0.008)*	*0.012*	*0.017 (0.017-0.017)*	*0.020 (0.020-0.020)*
other	*0.001 (0.000-0.002)*	*0.004 (0.004-0.005)*	*0.012*	*0.008 (0.008-0.008)*	*0.016 (0.016-0.016)*	*0.001 (0.000-0.002)*	*0.005 (0.004-0.005)*	*0.014*	*0.009 (0.009-0.009)*	*0.019 (0.019-0.019)*
Vegetables-in-oil	0.005 (0.005-0.005)	0.030 (0.030-0.031)	0.048	0.050 (0.050-0.050)	0.061 (0.061-0.061)	0.007 (0.007-0.007)	0.045 (0.045-0.046)	0.072	0.074 (0.074-0.074)	0.091 (0.091-0.091)
Cheese-in-oil	0.000 (0.000-0.000)	0.000 (0.000-0.000)	0.000	0.000 (0.000-0.000)	0.000 (0.000-0.000)	0.000 (0.000-0.001)	0.004 (0.004-0.005)	0.012	0.010 (0.010-0.010)	0.017 (0.017-0.017)
Fish-in-oil	0.004 (0.004-0.004)	0.008 (0.008-0.008)	0.012	0.019 (0.019-0.019)	0.023 (0.023-0.023)	0.009 (0.009-0.009)	0.016 (0.016-0.016)	0.024	0.038 (0.038-0.038)	0.047 (0.047-0.047)
SUM	**0.010 (0.009-0.011)**	**0.047 (0.046-0.048)**	**0.082**	**0.109 (0.109-0.109)**	**0.129 (0.130-0.130)**	**0.017 (0.016-0.019)**	**0.075 (0.075-0.078)**	**0.133**	**0.168 (0.168-0.168)**	**0.207 (0.207-0.207)**

[a]: for results < LOQ a concentration of LOQ/2 is assumed (i.e. 'middle bound' scenario); lower (< LOQ = 0) and upper (< LOQ = LOQ) bound scenarios between brackets
[b]: average calculated by omitting results < LOQ, according to EFSA, 2006

Table 3. Exposure of infants (4-12 months) to ESBO (mg/kg bw per day)[a] through in glass jars packed baby food (deterministic approach, based on average, upper average and P90 ESBO levels from the FASFC control data (2008 - 2012) and consumption data used in the EFSA opinion (2004))

Consumption (g/kg bw/day)	**Exposure 2008-2012** (mg/kg bw/day)				
	median	**average**	**upper average** [b]	**P90**	**P95**
53 [c]	0.06 (0.00-0.06)	0.34 (0.33-0.36)	0.67	1.06 (1.06-1.48)	1.48 (1.48-2.46)
43 [d]	0.05 (0.00-0.05)	0.28 (0.26-0.29)	0.54	0.86 (0.86-1.20)	1.20 (1.20-1.99)
28 [e]	0.03 (0.00-0.03)	0.18 (0.17-0.19)	0.35	0.56 (0.56-0.78)	0.78 (0.78-1.30)

[a]: for results < LOQ a concentration of LOQ/2 is assumed (i.e. 'middle bound' scenario); lower (< LOQ = 0) and upper (< LOQ = LOQ) bound scenarios between brackets; [b]: average calculated by omitting results < LOQ, according to EFSA, 2006; [c]: P95 consumers Donald study (Germany); [d]: P97.5 for "consumers", MAFF study (UK); [e]: average 4-6 months, Afssa (Anses) study (France)

Table 4. Exposure of infants (5-9 months) to ESBO (mg/kg bw per day)[a] through in glass jars packed baby food (deterministic approach, based on FASFC control data (2008 - 2012) and theoretical 'average' consumption data of Piccinelli *et al.*, 2010)

months	**consumption** (g/kg bw/day)	**Exposure 2008-2012** (mg/kg bw/day)				
		median	**average**	**upper average** [b]	**P90**	**P95**
5	25.0	0.03 (0.00-0.03)	0.16 (0.15-0.17)	0.32	0.50 (0.50-0.70)	0.70 (0.70-1.16)
6	46.1	0.05 (0.00-0.05)	0.30 (0.28-0.31)	0.58	0.92 (0.92-1.29)	1.29 (1.29-2.13)
7	61.4	0.07 (0.00-0.07)	0.40 (0.38-0.41)	0.78	1.23 (1.23-1.72)	1.72 (1.72-2.84)
8	58.4	0.07 (0.00-0.07)	0.38 (0.36-0.39)	0.74	1.17 (1.17-1.64)	1.64 (1.64-2.71)
9	61.1	0.07 (0.00-0.07)	0.39 (0.37-0.41)	0.77	1.22 (1.22-1.71)	1.71 (1.71-2.83)

[a]: for results < LOQ a concentration of LOQ/2 is assumed (i.e. 'middle bound' scenario); lower (< LOQ = 0) and upper (< LOQ = LOQ) bound scenarios between brackets; [b]: average calculated by omitting results < LOQ, according to EFSA, 2006

1.4. Risk Evaluation

The exposure of Belgian adults to ESBO migrating into food packed in glass jars and bottles with metal lids sealed with PVC gaskets is below the TDI of 1 mg/kg bw. The assessment is a worst case scenario, assuming that ESBO is present in all food of the considered food categories and assuming a frequent or high consumption. Considering additionally the EFSA assumption that the potential exposure of adults to ESBO from foods packed in cling films probably does not exceed 0.2 mg/kg bw/day (EFSA, 2006), the exposure remains below the TDI. Therefore, further refinement of the exposure assessment does not seem to be necessary.

Contrary to adults, the potential exposure of infants aged 6-12 months may in some scenarios exceed the TDI of 1 mg/kg bw per day (high consumption, other exposure routes such as migration from cling films, etc.). Additionally, a TDI is generally established for adults although it is also applied to children. On the other hand, results do not immediately imply adverse health effects. There is an inbuilt uncertainty factor of more than 100 in the derivation of the TDI and the numerical value of the TDI is more than 1000-fold lower than the causing effect in rats (EFSA, 2004). Moreover, ESBO is not found to be carcinogenic, genotoxic or to have reproductive or developmental toxicity. Additionally, it is remarked that beyond the first year of age, the contribution of baby foods in jars and bottles to the total diet decreases significantly (EFSA, 2004). An intake exceeding the TDI is however, undesirable because it indicates a reduction of the margin between exposure and adverse effects, which needs to be followed up. At the SML of 30 mg/kg for ESBO in baby food, the TDI will be exceeded when an infant with an average body weight of 8 kg eats 2 portions of baby food of 135 g each day.

Finally, attention should be drawn to possible reaction products formed from ESBO that have the potential to migrate into food, but for which toxicological information is lacking.

References

Biedermann-Brem S., Biedermann M. & Grob, K. 2003. Reaction of epoxidized soya bean oil (ESBO) with hydrogen chloride formed in PVC: Investigation on model systems. *Mitt. Lebensm. Hyg.* 95, 261-280.

Castle L., Mayo A. & Gilbert J. 1990 Migration of epoxidised soya bean oil into foods from retail packaging materials and from plasticised PVC film used in the home. *Food Additives & Contaminants* 7(1), 29-36.

Commission Regulation (EU) n° 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0010:EN:NOT

Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. http://eur-lex.europa.eu/Result.do?T1=V3&T2=2006&T3=141&RechType=RECH_naturel&Submit=Search

Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children. http://eur-lex.europa.eu/Result.do?T1=V3&T2=2006&T3=125&RechType=RECH_naturel&Submit=Search

Devriese, S., De Backer, G., De Henauw, S., Huybrechts, I., Kornitzer, K., Leveque, A., *et al*. 2005. The Belgian food consumption survey: aims, design and methods. *Arch. Public Health*, 63, 1-16.

Duffy E. & Gibney M.J. 2007. Use of a food-consumption database with packaging information to estimate exposure to food-packaging migrants: expoxidized soybean oil and styrene monomer. *Food Additives and Contaminants* 24(2), 216-225.

EFSA – European Food Safety Authority. 2006. 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). *The EFSA Journal* 332, 1-9. http://www.efsa.europa.eu/en/efsajournal/doc/332.pdf

EFSA – European Food Safety Authority. 2004. Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to the use of epoxidised soybean oil in food contact materials (Question N° EFSA-Q-2003-073). *The EFSA Journal* 64, 1-17. http://www.efsa.europa.eu/fr/scdocs/doc/64.pdf

Fankhauser-Noti A., Fiselier K., Biedermann-Brem S. & Grob K. 2006. Assessment of epoxidized soy bean oil (ESBO) migrating into foods: Comparison with ESBO-like epoxy fatty acids in our normal diet. *Food and Chemical Toxicology* 44, 1279–1286.

Fantoni L. & Simoneau C. 2003. European survey of contamination of homogenized baby food by epoxidized soybean oil migration from plasticized PVC gaskets. *Food Additives and Contaminants* 20(11), 1087-1096.

Hammarling L., Gustavsson H., Svensson K., Karlsson S. & Oskarsson A.1998; Migration of epoxidized soya bean oil from plasticized pvc gaskets into baby food. *Food Additives and Contaminants* 15(2), 203-208.

OECD - Organisation for Economic Co-Operation and Development. 2006. Epoxidized oils and derivatives. SIDS - Screening Information Data Set http://www.inchem.org/documents/sids/sids/Epoxidized-oils.pdf

Piccinelli R., Pandelova M., Le Donne C., Ferrari M., Schramm K.-W. & Leclercq C. 2010. Design and preparation of market baskets of European Union commercial baby foods for the assessment of infant exposure to food chemicals and to their effects. *Food Additives & Contaminants: Part A* 27(10), 1337- 1351.

SCF - Scientific Committee on Food. 1999. Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastic materials intended to come into contact with foodstuffs until 21 March 1997. Reports of the Scientific Committee for Food (42nd series). European Commission, Luxembourg. http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_42.pdf

Suman M., De Dominics E. & Commissati I. 2010. Trace detection of the chlorohydrins of epoxidised soybean oil in foodstuffs by UPLC-ESI-MS/MS. *J. Mass Spectrom.* 45(9), 996-1002.

VKM – Vitenskapskomiteen for Mattrygghet (Norwegian Scientific Committee for Food Safety). 2005. Risk assessment of health hazards from epoxidised soybean oil (ESBO) migrated from lids used on glass containers of baby food, 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. 8 March 2005. http://www.vkm.no/dav/4c8fc50ab4.pdf