Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Evaluation of the EU exposure model for migration from food contact materials (FCM)

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

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SUMMARY

The Norwegian Food Safety Authority (Mattilsynet) requested on 10 November 2006 the Norwegian Scientific Committee for Food Safety (VKM), the Scientific Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics (Scientific Panel 4), to evaluate critical points in the present European Union (EU) exposure model used in setting specific migration limit (SML) values from the acceptable daily intake (ADI) or tolerable daily intake (TDI) values for substances migrating from food contact materials (FCM). In this model, it is assumed that a consumer has a body weight of 60 kg. This 60 kg of body weight is used to derive the SML from an ADI or TDI into food. It is also assumed that every EU citizen consumes up to 1 kg of packaged food each day over a lifetime, this food is always packaged in the same material containing the substance in question, the plastic always releases the substance at the maximum concentration permitted, e.g. the SML, and 1 kg food is in contact with 6 dm^2 of packaging material. Other sources of exposure are usually not taken into account.

In this opinion, Norwegian and Danish data on body weight and food consumption were used to evaluate this EU exposure model for FCM, in addition to information found in the published literature. These data were used to compare the different assumptions in the model with real data to see whether the model is sufficiently protective for human health or whether it should/could be improved. In the terms of reference, a list of questions regarding this model was requested to be answered. The answers to these questions are summarised below.

Regarding the question on whether there is a need to revise the standard adult body weight of 60 kg used in the model, the available Norwegian and Danish data on present average body weight in the adult populations showed that in general there is no need to revise this value, although some women have a slightly lower body weight than 60 kg. However, children have a body weight below 60 kg, which might lead to underestimation of their exposure.

For children, a general correction factor for reduction of numerical restriction values (e.g. SML) for migration from FCM will not be applicable, since children have a higher consumption than adults of some foods, and a lower consumption of other foods. Instead, risk assessment of FCM for foods for infants and young children should be addressed on a case by case basis. In order to provide the same level of protection and ensure that numerical restriction on exposure is not exceeded, it should be considered to reduce the SML values for substances used to make food contact materials and articles intended specifically for the foodstuffs for infants (e.g. SML/10) and young children (e.g. SML/4-5).

In the current EU exposure model for FCM, it is assumed that a person consumes 3 kg of food (liquid and non-liquid in total), but only 1 kg is packaged. Based on the Norwegian and Danish data, there is a need to revise this assumption especially for liquid food. The total consumption of food (liquid and non-liquid) is higher than the standard 1 kg/person/day in all age groups, and therefore, this assumption may underestimate the exposure on a per kg body weight basis if all the consumed food is packaged. When the food consumption data were divided in liquid and non-liquid food, both Danish and Norwegian data showed a much higher intake of liquid food than of non-liquid food. The intake of packaged liquid foods was more than one litre (approximately equivalent to 1 kg for the different liquid food types) per day for adults and often also for children. The proportion of packaged food is mostly unknown, especially for non-liquid food, but will probably often be more than one third of the total food consumption of the assumed 3 kg, since more and more of standard food in EU is packaged.

Therefore, the current assumption used in the EU that 1 kg of packaged foods (liquid and non-liquid in total) is consumed per person per day cannot be viewed as sufficiently protective.

Based on published studies on food contact area to food mass ratio, the current official conversion factor for migration from surface area of FCM to food (6 dm^2/kg) is too low, both for various age groups of children and for adults, and may therefore lead to underestimation of exposure. Available data should be used to revise the 6 dm^2/kg value in the exposure model. A realistic surface area should be used for the packaged food in question. Irrespective of the conversion factor used, it is the amount of the migrant present in food that is of importance.

The introduction of a fat (consumption) reduction factor (FRF) is generally acceptable, since the fat consumption is below 200 g/person/day both for average and high consumer adults. It is also concluded based on the available data that the use of a FRF for fatty foods would be protective also for children. However, the introduction of the FRF may give rise to an underestimation of exposure. This could be the case if the food contact area to food mass ratio is much higher than the standard 6 dm^2/kg, e.g. sliced fatty food packaged between several layers of plastic material. Even though the fat consumption is below 200 g/person/day the migration may exceed the limits.

The use of a reduction factor for aqueous foods does not seem to be justified, since the amount of consumed liquid foods is more than 1 kg per day. On the basis of consumption data, it might be more relevant to introduce an extra safety factor of 2 (e.g. SML/2) for FCM used for liquids. For acidic foodstuffs (as defined in Council Directive 85/572/EEC), no conclusions on the use of reduction factors can be drawn because of lack of data. For alcoholic beverages, we do not see any arguments for introduction of a reduction factor.

Although limited, available published data has shown that repackaging of foods several times from the producer to the consumer may give rise to up to five times higher concentration in the final food. Therefore, repeated repackaging of food should be taken into consideration also in the legislation.

In most cases, the food simulants in use today are adequate. However, studies have shown that in some situations they are not adequate and representative of the foods themselves, and may in some instances lead to underestimation of exposure. New and better simulants are under development, and some of these will be introduced in the new plastic legislation, the Plastics Implementation Measure (PIM) regulation. Analysis of migration into food itself and/or mathematical modelling can be used in addition to or instead of migration studies with simulants.

It is not feasible to fix one specific value for allocating exposure from FCM to the TDI. Exposure from other sources should be taken into account in the risk assessments of FCM if such data are available on a case by case basis.

At present, it is not possible to fix maximum values for exposure to non-intentionally added substances (NIAS) migrating from FCM into food. However, some work has been initiated by industry in this area in order to develop exposure models and set limits for NIAS. The Threshold of Toxicological Concern (TTC) principle may be used in some circumstances and is currently discussed in the European Food Safety Authority (EFSA).

Based on the answers to all the questions in this opinion, it can be concluded that the EU exposure model for FCM is not sufficiently protective in all instances, especially not for FCM specifically made for infants and young children where there could be a need for an extra safety factor. Norwegian and Danish data show that an additional safety factor of 10 (e.g. SML/10) used for FCM for infant formula and other foods for babies, and an additional factor of 4-5 (e.g. SML/4-5) for FCM used for food for young children would in general be sufficient to protect children in these age groups at the same level (same margin of safety) as adults. The data show that also for liquid food there might be a problem, and an extra safety factor of 2 (e.g. SML/2) could be used for FCM for liquid food.

However, the model seems to be sufficiently protective for the average consumer in general taking into account that it is assumed that 1 kg packaged food is consumed each day throughout the whole life-time, and that this 1 kg of food is packaged in the same FCM which always contain the substance in question (i.e. monomer or additive). In the model, it is also assumed that the FCM releases the substance at the highest level permitted (e.g. at the SML), which is an overestimation in many instances.

If further refinement of the model is planned in order to make it less conservative, it should be kept in mind that the model is not sufficiently protective in all instances, as shown in this opinion. Especially, the consumption of packaged food is higher than assumed. The higher food consumption may lead to an underestimation of the real exposure, in particular among infants and young children. A better estimate of the consumption of packaged food is therefore desirable. In addition, there is a tendency for more and more food to be packaged, in smaller and smaller pack sizes, in order to give the customers food packaged in single portions, thereby increasing the FCM surface area to food mass ratio.

In conclusion, even if certain assumptions in the model are not consistent with real data, the exposure model may in general be regarded as sufficiently protective. However, it is important to the consumer’s health that the model is not being made gradually less protective, by changing single assumptions or introducing new correction factors. The model should be maintained sufficiently protective as a whole.

The VKM Panel 4 suggests that special attention is given to improving this model with regards to FCM for infants and young children, FCM for liquid foods, the proportion of packaged foods, and the FCM surface area to food mass ratio.

SAMMENDRAG

Mattilsynet bad 10. november 2006 Vitenskapskomiteen for mattrygghet (VKM) om å gjøre en vurdering av kritiske punkter i den nåværende eksponeringsmodellen i den europeiske union (EU) som brukes for å fastsette verdier for spesifikk migrasjonsgrense (SMG) fra det akseptable eller tolererbare inntaket (ADI/TDI) for stoffer som migrerer fra matkontaktmaterialer. Saken har blitt vurdert av Faggruppe for tilsetningsstoffer, aroma, matemballasje og kosmetikk (Faggruppe 4). I denne eksponeringsmodellen er det antatt at en gjennomsnittsforbruker veier 60 kg. Kroppsvekten på 60 kg benyttes til å utlede en SMG-verdi for et stoffs migrasjon fra matkontaktmaterialer til næringsmidler basert på ADI eller TDI for stoffet. Videre er det antatt at enhver person innenfor EU spiser opp til 1 kg emballert mat hver dag gjennom hele livet, at denne maten alltid er pakket inn i det samme matkontaktmaterialet og at dette inneholder det aktuelle migrerende stoffet (migranten), at plastmaterialet alltid frigir migranten i den maksimalt tillatte konsentrasjonen (f.eks. tilsvarende SMG), og at 1 kg mat er i kontakt med 6 dm^2 av pakkematerialet. Andre eksponeringskilder enn emballasje tas vanligvis ikke med i betraktning i disse risikovurderingene.

VKM har i denne uttalelsen benyttet seg av norske og danske data på matinntak og kroppsvekt i ulike aldersgrupper i befolkningen for å vurdere EUs eksponeringsmodell for stoffer som migrerer fra matkontaktmaterialer. I tillegg er det innhentet relevant informasjon fra publisert vitenskapelig litteratur. Disse dataene ble brukt til å vurdere flere ulike antagelser som EUs eksponeringsmodell er basert på for å se om modellen gir tilstrekkelig beskyttelse mot helserisiko hos mennesker, eller om modellen bør/kan forbedres. I oppdragsteksten fra Mattilsynet er VKM bedt om å svare på en liste med spørsmål som angår eksponeringsmodellen. Svarene på disse spørsmålene er oppsummert nedenfor.

Når det gjelder spørsmålet om det synes nødvendig å revidere den standard kroppsvekten på 60 kg for voksne personer som benyttes i eksponeringsmodellen, viser tilgjengelig norske og danske data for gjennomsnittlig kroppsvekt hos voksne at det generelt ikke er behov for endringer av denne verdien, selv om noen kvinner veier mindre enn 60 kg. Barn har derimot en kroppsvekt godt under 60 kg, og dette kan føre til at eksponeringen hos barn blir underestimert.

En generell omregningsfaktor brukt for barn på numeriske grenseverdier for migrasjon fra matkontaktmaterialer (f.eks. SMG) vil ikke være egnet, ettersom barn kan ha et høyere inntak av visse næringsmidler enn voksne, og et lavere inntak av andre næringsmidler. Risikoen fra matkontaktmaterialer brukt til næringsmidler produsert spesielt for spedbarn og små barn bør derfor heller vurderes fra sak til sak. For å sikre et likt beskyttelsesnivå og samtidig sørge for at numeriske grenseverdier for eksponering ikke overskrides, bør det vurderes å redusere SMG-verdiene for stoffer som benyttes til å lage matkontaktmaterialer og artikler spesielt utviklet for næringsmidler rettet mot spedbarn (f.eks. SMG/10) og små barn (f.eks. SMG/4-5).

I den gjeldende eksponeringsmodellen for matkontaktmaterialer er det antatt at en person inntar 3 kg næringsmidler (både i flytende form og som fast føde), hvorav bare 1 kg er emballert. De norske og danske inntaksdataene viser at denne antagelsen bør revideres, spesielt når det gjelder næringsmidler i flytende form. Det totale inntaket av næringsmidler (både i flytende form og som fast føde) er høyere enn den antatte standardverdien på 1 kg/person/dag i alle aldersgrupper, noe som tilsier at en slik antagelse kan føre til at

eksponeringen per kg kroppsvekt underestimeres hvis alle næringsmidler som inntas er emballert. Når kostholdsdataene deles opp i næringsmidler i flytende form og i fast føde, viser både de danske og norske dataene et mye høyere inntak av næringsmidler i flytende form enn av fast føde. Inntaket av emballerte drikkevarer var mer enn en liter (tilnærmet det samme som 1 kg for ulike typer væsker) per dag for voksne, og dette var ofte tilfelle også for barn. Det er uvisst hvor stor andel av næringsmidlene som er emballert, spesielt når det gjelder fast føde, men andelen vil trolig ofte utgjøre mer enn en tredjedel av det totale inntaket av næringsmidler som er antatt å være 3 kg, ettersom stadig flere vanlige matvarer i EU-området nå selges innpakket. Den gjeldende antagelsen i EUs eksponeringsmodell om at hver person inntar 1 kg emballerte næringsmidler (både i flytende form og som fast føde) per dag kan derfor ikke anses å gi tilstrekkelig beskyttelse.

Resultater fra publiserte vitenskapelige studier om forholdet mellom overflatearealet av et matkontaktmateriale og matvarens masse viser at den gjeldende omregningsfaktoren for migrasjon per flateenhet av matkontaktmaterialet til maten (6 dm^2/kg) er for lav, både for ulike aldersgrupper av barn og for voksne. Dette kan medføre at eksponeringen underestimeres. Tilgjengelige data bør benyttes til å revidere denne verdien på 6 dm^2/kg i eksponeringsmodellen. Videre bør det tas utgangspunkt i et realistisk overflateareal for det aktuelle emballerte næringsmidlet i risikovurderingene. Uavhengig av hvilken omregningsfaktor som benyttes, er det den faktiske mengden av migranten som gjenfinnes i næringsmidlet som er av betydning.

Introduksjonen av en fettreduksjonsfaktor er generelt sett akseptabel ettersom inntaket av fett er lavere enn 200 g/person/dag for voksne, både hos forbrukere med et gjennomsnittlig og et høyt inntak. Basert på tilgjengelige data kan det også konkluderes med at bruken av en fettreduksjonsfaktor for fettholdige næringsmidler vil være beskyttende også for barn. Det er imidlertid verdt å bemerke at introduksjonen av en fettreduksjonsfaktor kan lede til at eksponeringen underestimeres i visse tilfeller. Dette kan inntreffe hvis forholdet mellom arealet av matkontaktmaterialet og matens masse er mye høyere enn standardverdien på 6 dm^2/kg, noe som f.eks. kan være tilfelle for oppskårede skiver av fet mat som skinke pakket lagvis med plast. Selv om inntaket av fett er lavere enn 200 g/person/dag kan migrasjonen da tenkes å overskride grenseverdiene.

Det synes ikke å være noen god grunn til å benytte en reduksjonsfaktor for vandige næringsmidler, ettersom inntaket av drikkevarer er høyere enn 1 kg per dag. Med bakgrunn i inntaksdataene kan det være mer relevant å introdusere en ekstra sikkerhetsfaktor på 2 (f.eks. SMG/2) for emballasje for drikkevarer. For sure næringsmidler (som definert i EU-direktiv 85/572/EEC), er det ikke mulig å trekke noen konklusjoner om bruken av reduksjonsfaktorer på grunn av manglende data. For alkoholholdige drikkevarer anses det ikke å være noen argumenter for å introdusere en reduksjonsfaktor.

Tilgjengelige publiserte vitenskapelige data, selv om de er noe begrenset, har vist at gjentatt emballering av næringsmidler gjennom flere produksjonsledd til forbruker kan medføre opp til fem ganger høyere konsentrasjon av en migrant i sluttproduktet. Gjentatt emballering av næringsmidler bør derfor tas hensyn til, også i regelverket.

De næringsmiddelsimulanter som brukes per i dag gir i de fleste tilfeller tilfredsstillende resultater. Studier har imidlertid vist at de i enkelte situasjoner ikke vil være representative nok for selve næringsmidlet, og at dette enkelte ganger kan føre til at eksponeringen underestimeres. Nye og bedre simulanter er under utvikling, og noen av disse vil bli introdusert i det nye regelverket for plastmaterialer i EU. Faktiske analyser av migrasjonen av et stoff til selve næringsmiddelet og/eller matematisk modellering kan brukes i tillegg til, eller i stedet for, migrasjonsstudier med simulanter.

Det er ikke gjennomførbart å fastsette én spesifikk verdi for hvor mye av et stoffs TDI som kan utgjøres av eksponeringen for matkontaktmaterialer. Data for eksponering fra andre kilder bør tas i betraktning fra sak til sak i risikovurderinger av matkontaktmaterialer, hvis slike data er tilgjengelige.

Per i dag er det ikke mulig å fastsette maksimumsverdier for eksponering for stoffer som ikke er tilsatt med hensikt i matkontaktmaterialet og derfor ofte er ukjente ("non-intentionally added substances", NIAS), som kan migrere fra matkontaktmaterialer til næringsmidler. Industrien har imidlertid initiert et arbeid for å kunne utvikle eksponeringsmodeller og fastsette grenseverdier for migrasjon av slike ukjente stoffer. "The threshold of toxicological concern" (TTC)-prinsippet kan under visse betingelser benyttes, og dette blir for tiden diskutert i European Food Safety Authority (EFSA).

Basert på svarene på alle Mattilsynets spørsmål i denne uttalelsen, kan det konkluderes med at EUs eksponeringsmodell for matkontaktmaterialer ikke gir tilstrekkelig beskyttelse i alle tilfeller. Spesielt gjelder dette for matkontaktmaterialer til næringsmidler spesielt rettet mot spedbarn eller små barn hvor det kan være behov for å innføre en ekstra sikkerhetsfaktor. Norske og danske inntaksdata viser at en ekstra sikkerhetsfaktor på 10 (f.eks. SMG/10) for matkontaktmaterialer til barnemat og andre næringsmidler produsert spesielt for spedbarn, og en ekstra sikkerhetsfaktor på 4-5 (f.eks. SMG/4-5) for matkontaktmaterialer til næringsmidler rettet mot små barn, vil være tilstrekkelig for å gi barn i disse aldersgruppene samme grad av beskyttelse som voksne. Dataene viser at det også kan være et problem relatert til eksponering for drikkevarer, og en ekstra sikkerhetsfaktor på 2 (f.eks. SMG/2) kunne derfor benyttes for matkontaktmaterialer til denne typen næringsmidler.

Eksponeringsmodellen virker imidlertid generelt å gi tilstrekkelig beskyttelse for en gjennomsnittlig forbruker, tatt i betraktning at det antas at en person inntar 1 kg emballert næringsmiddel daglig gjennom hele livet, og at denne ene kiloen er pakket inn i det samme matkontaktmaterialet som alltid inneholder den aktuelle migranten (f.eks. plastmonomer eller tilsetningsstoff). I eksponeringsmodellen er det også antatt at matkontaktmaterialet frigir den høyeste tillatte mengden av migranten (f.eks. tilsvarende SMG), noe som i mange tilfeller vil overestimere eksponeringen.

I den grad det tas sikte på å gjennomføre ytterligere forbedringer av eksponeringsmodellen for å gjøre den mindre konservativ, bør det tas hensyn til at modellen ikke er tilstrekkelig beskyttende i alle situasjoner, slik denne uttalelsen viser. Spesielt er inntaket av emballerte næringsmidler høyere enn hva som antas i modellen, noe som kan medføre at den reelle eksponeringen underestimeres, først og fremst hos spedbarn og små barn. Det er derfor ønskelig med et bedre estimat av inntaket av emballerte næringsmidler. I tillegg er det en tendens til at stadig flere matvarer emballeres, og at de selges i stadig mindre forpakninger for å kunne tilbys kundene i enkeltporsjoner, noe som bidrar til å øke forholdet mellom overflatearealet av matkontaktmaterialet og matvarens masse.

Selv om enkelte antagelser i modellen ikke bekreftes av reelle inntaksdata, kan det konkluderes med at EUs eksponeringsmodell generelt sett kan betraktes som tilstrekkelig beskyttende. Det er imidlertid viktig for forbrukernes helse at modellen ikke gjøres gradvis mindre beskyttende gjennom å endre enkeltantagelser eller ved å introdusere nye reduksjonsfaktorer. Eksponeringsmodellen bør i sin helhet opprettholdes som tilstrekkelig beskyttende.

VKMs Faggruppe 4 anbefaler at det rettes spesiell oppmerksomhet mot å forbedre eksponeringsmodellen med hensyn til følgende forhold: matkontaktmaterialer til næringsmidler spesielt rettet mot spedbarn og små barn, matkontaktmaterialer for drikkevarer, kunnskap om hvor stor andel av inntaket som kommer fra emballerte næringsmidler, og forholdet mellom matkontaktmaterialets overflateareal og selve matvarens masse.

LIST OF ACRONYMS

ADI	-	acceptable daily intake
AFC	-	EFSA Scientific Panel on Food additives, Flavourings, Processing Aids and Materials in Contact with Food
Ah receptor	-	aryl hydrocarbon receptor
BADGE	-	bisphenol A diglycidyl ether
CAS	-	Chemical Abstracts Service
DEHA	-	di-(2-ethylhexyl)adipate
DEHP	-	bis(2-ethylhexyl)phthalate
DRF	-	simulant D reduction factor
EC	-	European Commission
EEC	-	European Economic Community
EFSA	-	European Food Safety Authority
ESBO	-	epoxidised soybean oil
EU	-	European Union
FCM	-	food contact material
FCS	-	food contact substance
FRF	-	fat (consumption) reduction factor
GIES	-	General Intake Estimation System
ILSI	-	International Life Sciences Institute
ITX	-	2-isopropyl thioxanthone
NIAS	-	non-intentionally added substances
NOAEL	-	no observed adverse effect level
PIM	-	Plastics Implementation Measure
ppb	-	parts per billion
SCF	-	Scientific Committee for Food
SD	-	standard deviation
SML	-	specific migration limit
TDI	-	tolerable daily intake
ToR	-	threshold of regulation
TRF	-	total reduction factor
TTC	-	threshold of toxicological concern
US FDA	-	The United States Food and Drug Administration
VKM	-	The Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet)
WHO	-	World Health Organization

CONTENTS

Contributors

Persons working for the Norwegian Scientific Committee for Food Safety (VKM), either as appointed members of the Committee or as *ad hoc* experts, do this by virtue of their scientific expertise, not as representatives for their employers. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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BACKGROUND

Within the European Union (EU), food contact materials (FCM) are regulated by the Framework Regulation (EC) 1935/2004 ("Rammeforordningen"), which sets general requirements for all food contact materials, legislation which cover specific groups of materials and articles listed in the Framework Regulation, and directives on individual substances or groups of substances used in manufacture of materials and articles intended for food contact (1). Of the specific materials, the regulation of plastics, in Commission Directive 2002/72/EC (2), is the most developed. The regulation of materials and articles to be used in contact with food within the EU is based on risk assessments, mainly performed by the European Food Safety Authority (EFSA). The risk that a chemical will cause adverse effects on human health is determined by two things: toxicity and exposure. Therefore, exposure assessment is a key part of risk assessment. The exposure assessment is not well defined at the European level as no common protocol or model exists. Different sectors apply different approaches. A guidance document for exposure assessment of substances migrating from food packaging materials is recently published by ILSI Europe (3). For the assessment of FCM substances by EFSA, a deterministic model is used to estimate exposure, which is assumed to be sufficiently protective to human health in most instances. In this model, it is assumed that:

- a consumer has a body weight of 60 kg
- this 60 kg of body weight is used to derive the specific migration limit (SML) from an acceptable daily intake (ADI) or tolerable daily intake (TDI) into food
- every EU citizen consumes up to 1 kg of packaged food each day over a lifetime
- this food is always packaged in the same material containing the substance in question
- the plastic always releases the substance at the maximum concentration permitted, e.g. the SML
- 1 kg food is in contact with 6 dm^2 of packaging material
- no other significant sources of exposure exist.

Consequently, when an ADI or TDI is converted into a SML value using the conventional factor of 60 (a 60 kg person consuming 1 kg packaged solid food and beverages daily). These conventions are chosen, because the positive list for FCM does normally not restrict a substance to any particular application(s). As the EU directives are drafted, any manufacturer can use the substance for any purpose in most instances, provided migration does not exceed the SML or other numerical restrictions in food (or simulants). However, in some instances a restriction to specific plastic materials is made, due to limited data on migration from other plastic materials.

In general, the average consumer should be well protected using this model. However, this approach contains some uncertainties, and during the last decade the refinement of this model for exposure assessment of compounds in FCM has been discussed between regulators and the food packaging industry. The main issue of this discussion is that the current method in EU is viewed, especially by industry, to be overly conservative (overprotective).

There are many other initiatives in Europe trying to refine the exposure assessment for food packaging migrants (4), e.g. by introducing food consumption factors (the fraction of a person's diet likely to be in contact with a specific FCM), and food type distribution factors (the fraction of all food contacting each material that is aqueous, acidic, alcoholic or fatty). In the USA, the US Food and Drug Administration (US FDA) uses food consumption and food-type distribution factors to aid the exposure assessment process and generate less conservative and maybe more realistic estimates of exposure. In addition, it is assumed by US FDA that a person consumes 3 kg of packaged food. There is another main difference between the EU model and the US FDA approach. In USA, a food contact substance (FCS) is approved for a specific polymer in contact with a specific food.

In order to make the conventional EU model more realistic (and less conservative) when considering the migration to fatty foods, a fat (consumption) reduction factor of 5 was introduced in 2002, because it was estimated that a person will normally not eat more than 200 g fat per day (5). However, the current system of conventions may also underestimate the human exposure in certain situations. Both overestimation and underestimation have to be dealt with simultaneously to obtain improved risk assessment and risk management (6).

TERMS OF REFERENCE

The Norwegian Food Safety Authority (Mattilsynet) has in a letter of 10 November 2006 asked the Norwegian Scientific Committee for Food Safety (VKM), the Scientific Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics, to evaluate critical points in the present EU exposure model used in setting SML values from the TDI values for substances migrating from FCM, in order to evaluate whether the overall model is sufficiently protective for human health. In this evaluation, the following list of questions is requested to be answered. The order of questions has been somewhat changed to obtain a clearer connection between them, and two questions about children are answered together.

1. *Is there a need to revise the standard adult body weight of 60 kg used in the model in light of data for present average body weight in the population, and maybe also the body weight for children?*
2. *Is there a need for a separate factor to account for the fact that children (in various age groups) have a higher consumption per kg body weight than adults, and if so, what should this (these) factor(s) be?*
3. *It is assumed that of a total adult consumption of 3 kg of food (liquid and non-liquid) every day, 1 kg is packaged. Is there a need to revise this standard assumption? Especially, is there a need to revise the consumption of packaged liquid food?*
4. *Is the current official conversion factor for migration from surface area of FCM to food (6 dm^2/kg) correct, based on available data? Should the concentration of a migrant in food be used in the regulations rather than the migration per packaging surface area?*
5. *Is introduction of a fat (consumption) reduction factor (FRF) acceptable? If so, are there arguments for introduction of (consumption) reduction factors also for other types of foodstuffs, e.g. aqueous, acidic and alcoholic foodstuffs? If so, which daily consumption values should be the basis for such factors?*
6. *Foodstuffs may be (re)packaged several times from the producer to the consumer, i.e. at the farm/fishing vessel, during transportation, in food industry and before final sale to the consumer. Should repeated packaging be taken into consideration also in the legislation?*
7. *Are the food simulants in use today appropriate, or can their use lead to underestimation of exposure?*
8. *What is the best proportion of TDI for a substance to be allocated for FCM compared to potential contributions from all other sources?*

9. *Will it be feasible to fix maximum values for exposure to unknown substances, i.e. non-intentionally added substances (NIAS), and if so, what should they be?*

If weaknesses associated with the present model are detected after answering the above-mentioned questions, suggestions for improvements of the model should be given.

OPINION

In the present EU exposure model for FCM, it is assumed that a consumer has a body weight of 60 kg, and this 60 kg of body weight is used to derive the SML from an ADI or TDI in food, that every EU citizen consumes up to 1 kg of packaged food each day over a lifetime, and that this food is always packaged in the same material containing the substance in question, and that the plastic FCM always releases the substance at the maximum concentration permitted (e.g. SML). Further, it is assumed that 1 kg food is in contact with 6 dm^2 of packaging material, and that no other significant sources of exposure exist.

In the following opinion, Norwegian (7-13) and Danish (14-21) data on food consumption and body weight, as well as relevant data from Ireland, England and Germany available from the literature (up to November 2008), are used to evaluate whether the present model is sufficiently protective. This is done by answering and discussing specifically the questions given in the Terms of reference. Thereafter, a general conclusion about whether the overall model can be regarded as sufficiently protective is reached based on all the questions.

1.) Is there a need to revise the standard adult body weight of 60 kg used in the model in light of data for present average body weight in the population, and maybe also the body weight for children?

The body weights of adolescents and adults in Norway and Denmark are presented in Tables 1-3 below.

Table 1. Mean body weight (in kg) of adolescents and adults in Norway (7).

Age (years)	16-19	20-29	30-39	40-49	50-59	60-69	70-79	All ages
Men	71	80	83	83	82	81	77	80
Women	60	64	65	67	68	70	70	66

Data from 1997 covering the whole of Norway shows that already from the age groups 16-19 and 20-29 years for men and women, respectively (Table 1), the mean body weight is larger than 60 kg.

Table 2. Mean body weight (in kg) of adults in Oslo (8) and Oppland (9).

Age (years)		30	40+45	59-60	75-76	All ages
Oslo	Men	83	84	84	80	83
	Women	67	69	70	67	68
Opp-land	Men	87	87	86	79	85
	Women	72	71	74	70	72

Newer data from 2000-2001 on body weight of Norwegian adults are presented in Table 2, from a study including the whole city of Oslo (8), representing urban living, and a study from the Oppland county (9), representing more rural living areas.

From the Norwegian data presented in Table 2, both for men and woman the average body weight is larger than the standard body weight of 60 kg across all age groups (30-76 years) in both studies. Men weigh 19-27 kg (32-45%) above the default value of 60 kg, and women weigh 7-14 kg (12-23%) above this value. Comparisons between Table 1 and Table 2 indicate an increase in body weight from 1997 to 2000-2001 both in men and women.

The mean body weight of adults in Norway based on references 7, 8 and 9 is 82 kg for men and 68 kg for women.

Table 3. Body weight (in kg) of adolescents and adults in Denmark (14, 15).

Age (years)	Gender	N	Mean (SD)	95 percentile	10 percentile	5 percentile
15-18	**Boys**	78	70 (12)	91	56	52
	Girls	120	61 (9)	76	50	47
19-24	**Men**	127	79 (13)	107	65	63
	Women	174	66 (13)	90	52	50
25-34	**Men**	272	82 (11)	100	69	64
	Women	315	67 (12)	91	54	51
35-44	**Men**	330	84 (13)	107	69	66
	Women	359	67 (13)	90	54	50
45-54	**Men**	312	84 (12)	106	70	66
	Women	370	67 (12)	90	55	52
55-64	**Men**	242	84 (13)	107	70	65
	Women	263	70 (13)	94	55	52
65-75	**Men**	165	80 (11)	98	68	65
	Women	164	67 (12)	90	51	49

As shown in Table 3, the mean body weight of adolescents and adults in Denmark is also larger than 60 kg both for men and women from 15 to 75 years. However, a considerable fraction (10%) of girls/women in these age groups has a body weight below 60 kg.

Comments (body weight in adults)

Based on Norwegian and Danish data, assuming a 60 kg body weight for adults will in most instances overestimate exposure per unit body weight both in men and women already from adolescence, if 1 kg food is consumed per person (see also answers to Question 3). However, some women (about 10%) have a body weight slightly below 60 kg, which may give rise to a minor underestimation if 1 kg food is consumed.

Since it is likely that also children's body weight has increased, data on the body weight of children in Norway and Denmark are presented in Tables 4-6 below.

Table 4. Body weight (in kg) of children in Norway (10-13).

Age/ Gender	Mean (SD)		
	Boys	**Girls**	**Both genders**
6 months	8 (1)	8 (1)	8 (1)
2 years	13 (1)	12 (1)	13
4 years	18 (3)	18 (3)	18
8-10 years	32 (6)	32 (6)	32
12-14 year	49 (10)	50 (9)	49

Children up to the age of 12-14 years in Norway have mean body weight well below 60 kg (Table 4). Their mean body weight is roughly similar to the recommended values for body weight of children in U.S.A. (22).

Table 5. Body weight (in kg) of children (1-3 years) in Denmark (16).

Age (years)	Mean	95 percentile	5 percentile
1 year	12	15	9
2 years	14	17	12
3 years	16	19	13

Table 6. Body weight (in kg) of children (4-14 years) in Denmark (15, 17).

Age (years)	Gender	N	Mean (SD)	95 percentile	10 percentile	5 percentile
4-6	**Boys**	116	22 (4)	31	17	16
	Girls	116	22 (4)	28	18	16
7-10	**Boys**	177	33 (7)	43	25	23
	Girls	153	33 (8)	45	23	21
11-14	**Boys**	127	51 (14)	73	38	36
	Girls	119	50 (11)	68	38	34

As shown in Tables 5 and 6, the mean body weight of Danish children is, in accordance with the Norwegian data, well below 60 kg up to the age of 14 years. This is also the case if the 95 percentile is used for boys and girls up to 10 years of age.

Comments (body weight in children)

Contrary to in adults, no default value is set for body weight of children. As expected, the body weight of children both in Norway and Denmark is lower than the default value of 60 kg set for adults, and thereby may give rise to an underestimation of exposure per unit body weight if 1 kg of food is consumed.

Conclusions (body weight in adults and children)

There is no need to change the conventional assumption that an adult is weighing 60 kg, although this default value is lower than the body weight of many adults, since there is also a considerable number of adolescents and women who have a body weight slightly below 60 kg. In addition, the exposure to substances migrating from FCM also depends of the food consumption as described under Question 3. For children, the body weight is considerably lower in early life and this question will be further elaborated when dealing with the consumption per kg body weight under Question 2.

2.) Is there a need for a separate factor to account for the fact that children (in various age groups) have a higher consumption per kg body weight than adults, and if so, what should this (these) factor(s) be?

Infants and children have a higher food consumption than adults on a per kg body weight basis, and they also have different dietary habits and food preferences compared with adults. The term “infant” is taken to mean children under the age of 12 months. Unless anything else is mentioned, “young children” is taken to mean children aged between one and three years.

Using the EU exposure model, it can be calculated that an adult is assumed to eat up to 16.7 g packaged food/kg body weight/day. Compared with this default exposure model, infants and children differ in a number of significant respects:

- a higher food consumption per kg body weight
- a higher and more regular usage of certain food contact materials (e.g. baby bottles, cans, glass jars with lids and sealing rings)
- smaller pack sizes with a higher ratio of FCM area to food mass.

A higher food consumption per kg body weight

Infants and young children have higher physiological needs, and therefore consume a greater quantity of food expressed on a body weight basis than adults do. For example, in their opinion on bisphenol A from 2002 (23), the Scientific Committee for Food (SCF) summarised food consumption as described in the following modified Table 7:

Table 7. Consumption per kg body weight/day for different age groups of infants and children compared to a "conventional" 60 kg adult (adapted from reference 23).

Consumer group	Type of packaged food	Amount consumed/day	Consumption g/kg body weight/day
Infant 0-4 months 4.5 kg	**Formula**	0.7 litre	156
Infant 6-12 months 8.8 kg	**Formula**	0.7 litre	80
Infant 6-12 months 8.8 kg	**Canned food**	0.4 kg	43
Child 4-6 years 18 kg	**Canned food**	1.1 kg	58
"Conventional" 60 kg adult	**All types of packaged food**	1.0*	16.7

*It is assumed that a conventional adult has a body weight of 60 kg and consumes 1 kg **packaged** food per day. For infants and small children, it is assumed that all the food is packaged (infant formula or canned food, respectively).

It can be seen from Table 7 that at age 0-4 months an infant may consume 156 g food/kg body weight/day which is nearly 10 times the present convention for FCM of 16.7 g food/kg body weight/day.

Table 8. Consumption of milk and porridge (liquid foods) among 6 months old infants (consumers only) in Norway, in g/day (10).

Food type	Gender	N	Mean (SD)	10 percentile	50 percentile	90 percentile
Infant formula	Boys	362	609 (534)	-	-	-
	Girls	347	532 (609)	-	-	-
	Both	713	511 (341)	60	540	960
Industrial produced porridge	Boys	857	173 (185)	-	-	-
	Girls	837	148 (128)	-	-	-
	Both	1699	161 (161)	25	100	300

Table 9. Consumption of milk and porridge (liquid foods) among 6 months old infants (consumers only) in Norway, in g/kg body weight/day* (10).

Food type	Gender	N	Mean	10 percentile	50 percentile	90 percentile
Infant formula	**Boys**	362	73	-	-	-
	Girls	347	70	-	-	-
	Both	713	64	8	68	120
Industrial produced porridge	**Boys**	857	21	-	-	-
	Girls	837	19	-	-	-
	Both	1699	20	3	13	38

*Consumption per kg body weight is obtained by dividing the consumption values by the mean body weights for 6 months old infants from Table 4 in all columns. Data on 10, 50 and 90 percentiles of body weight were not available for the genders separately.

As can be seen from Tables 8 and 9, there was information available on consumption of packaged infant formula and industrial produced porridge among 6 months old infants in Norway. As is shown in Table 9, the infants in Norway may also have a mean consumption of up to 7 times higher than 16.7 g packaged food/kg body weight/day.

Consequently, if an ADI or TDI is converted into a SML value using the conventional factor of 60 (a 60 kg person consuming 1 kg packaged solid food and beverages daily), then materials and articles which comply with such a SML could yet cause the ADI/TDI to be exceeded considerably for infants and young children. Such a situation will reduce the safety margin between exposure and adverse effects.

A food consumption survey in Denmark in 1995 (18) showed that relative to their energy consumption, children consume (twice as much) more milk compared to adults, and they eat more bread and cereals, fruits and sugar than adults. On the other hand, they eat less cheese, vegetables, meat, fish and eggs.

Based on comparisons of results from comprehensive British surveys of adults aged 16-64 years (*n*=2197), infants aged 6-12 months (*n*=448) and young children aged 1.5-4.5 years (*n*=1675) (referred in 24), it was concluded that, on a body weight basis, energy requirements, protein requirements and water consumption may be up to 3, 2.5 and 5 times larger, respectively, for infant and young children than for adults. The average consumption of the main food groups, such as fruit and vegetables, bread and cereals, meat, fish and eggs, dairy products, and sugar and confectionery, was found to be about 2.5 times higher in young children than in adults.

Danish Veterinary and Food Administration have a database covering the dietary habits for about 280 children at the age of 1, 2 and 3 years, and also for adults (19). Several papers are published based on the German “DONALD” study. One of the papers is about the consumption of infant food products, and the data come from weighed diet records for 680 infants at an age of 3, 6, 9 and 12 months (25). In Figure 1, selected results from the Danish database extracts and the German study are shown.

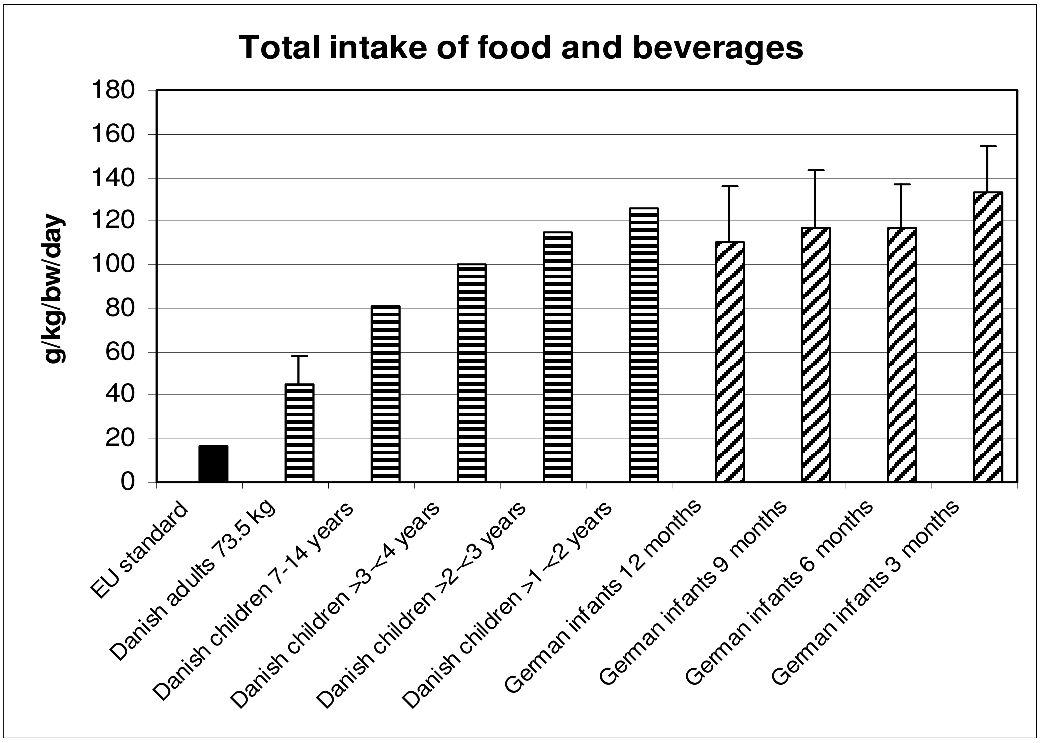

Figure 1. *The total consumption of solid and liquid foods (mean and SD, except for Danish children, where the SD was not stated). The data are taken from a Danish survey (18) and a German study (25). The filled bar represents the EU standard assumption of the consumption of 1 kg packaged food per kg body weight for a person weighing 60 kg. For Danish adults, a mean body weight of 73.5 kg was used. The columns with horizontal bars and diagonal bars represent Danish and German data, respectively, for the total consumption of food (liquid and non-liquid) per kg body weight for different age groups. This figure is modified from (26).*

As shown in Figure 1, the total consumption of all foodstuffs is different in different age groups and highest for children at the age below 2 years. Even for adults the total consumption was more than the double of the conventional EU standard of 16.7 g/kg body weight if liquid foodstuff is included, and even when a body weight of 73.5 kg is used instead of the conventional 60 kg. For solid foodstuff, the consumption mean was calculated to be 17.3 g/kg body weight for Danish adults. However, it should be stressed that in these studies it is unknown how much of the consumed food that was packaged and in which food contact materials.

In a report from England of packaged food consumption in children (27), it was found that as age increases from <1 year to 4-6 years total food consumption/kg body weight decreases. Infants aged 0-1 years, children aged 1-4 years and children aged 4-6 years consumed 137, 100 and 70 g/kg body weight/day, respectively, of total foods (packaged and unpackaged). Children aged 1-4 years were found to have the highest consumption of packaged food/kg body weight at 68 g/kg, with infants 0-1 year and children aged 4-6 years having very similar consumptions of packaged foods; 50 and 48 g/kg body weight, respectively (27).

A higher and more regular usage of certain food contact materials

A variety of packing types is used for foodstuffs intended for infants and young children. These include plastic baby bottles and other repeat-use articles, metal cans, glass jars with polymeric sealing gaskets and plastic pouches. There is a smaller variety of materials used for foodstuffs intended specifically for infants and young children compared to the variety of materials used in contact with other foodstuffs. For example, a polycarbonate baby bottle, a glass with metal lids, or a coated can, could be a very regular feature of the materials in contact with the diet of an infant or a young child.

Smaller pack sizes with a higher ratio of contact area to food mass
Not only is the use of a limited selection of materials more regular, the ratio of the contact area to food mass is often higher for the smaller portions of food consumed by infants and young children. This would have consequences should migration limits be expressed on the basis of the surface area of contact rather than in units of concentration in foods or food simulants. In the new EU regulation, the Plastics Implementation Measure (PIM) regulation (an explanatory note can be found at http://www.slv.se/upload/dokument/nyheter/2009/Explanatory_note_on_the_recast_of_the_rules_for_plastics.pdf), it is proposed only to use mg/kg food for children. See also the discussion of restrictions based on food contact area versus concentration in foods below under Question 4.

Comments on food consumption in children versus in adults
Especially infants and young children have a higher food consumption than adults when expressed on a per kg body weight basis. The food consumption of infants can be up to about 10 times larger and the food consumption by young children can be up to about 4 times larger, compared to the present conventional exposure model which assumes that a 60 kg body weight adult consumes 1 kg each day of the foodstuff in question equivalent to 16.7 g/kg body weight. This means that at any given migration level, the exposure on a per kg body weight basis might be higher for infants and young children than for adults. In order to provide the same level of protection (margin of safety) and ensure that any set ADI, TDI or other numerical restriction on exposure is not exceeded, special rules should be considered to reduce the SML values for substances used to make food contact materials and articles intended specifically for the foodstuffs of infants and young children.

If migration limits are expressed on the basis of the food contact area of the foodstuff rather than as a concentration in the foodstuff (SMLs), then special rules should also be considered to reflect the larger usage of FCM on a food contact area to body weight basis for foodstuffs intended for infants and young children. This should be taken into consideration in the new PIM regulation. See also the discussion of restrictions based on food contact area versus concentration in foods below under Question 4.

Since for some food groups, children (older than 3 years) have a higher consumption than adults, and for other food groups, a lower consumption, a separate factor to be used in general for children will not be applicable. Instead, the higher consumption of certain foods, and therefore the potential for a higher risk of adverse effects from contaminants migrating from the food packaging into these foods, or exposure from other FCM used especially for infants and young children, e.g. plates and cups, should be addressed on a case by case basis in the risk assessments.

Conclusions on food consumption in children versus in adults
Infants and young children have a higher food consumption than adults when expressed on a per kg body weight basis. The food consumption of infants can be up to about 10 times higher and the food consumption by young children can be up to about 4 times higher, compared to the present conventional exposure model which assumes that a 60 kg body weight adult consumes 1 kg each day of the foodstuff in question, equivalent to 16.7 g/kg body weight. It is assumed that an additional safety factor of 10 (e.g. SML/10) used for FCM for infant

formula and other foods for babies, and an additional factor of 4-5 (e.g. SML/4-5) for FCM used for food for young children, would in general be sufficient to protect infants and young children at the same level (same margin of safety) as adults.

For some food groups, children older than 3 years have a higher consumption than adults, and for other food groups, a lower consumption. Therefore, a separate factor to be used in general for children more than 3 years old will not be applicable. Instead, risk assessment of foods for infants and young children should be addressed on a case by case basis. In addition to the higher food consumption per kg body weight of many food types in children, their food often has a larger area in contact with FCM compared with foods consumed by adults due to a smaller package size. Their foods may also be less varied than the great variety of food types in many different package materials consumed by adults. Therefore, at any given migration level, the exposure on a per kg body weight basis might be higher for infants and young children than for adults. In order to provide the same level of protection (margin of safety) and ensure that any respective ADI, TDI or other numerical restriction on exposure is not exceeded, special rules should be considered to reduce the SML values for substances used to make food contact materials and articles intended specifically for the foodstuffs of infants and young children.

3.) It is assumed that of a total adult consumption of 3 kg of food (liquid and non-liquid) every day, 1 kg is packaged. Is there a need to revise this standard assumption? Especially, is there a need to revise the consumption of packaged liquid food?

In the EU exposure model, it is assumed that the consumption of total packaged foods (liquid and non-liquid) is 1 kg, corresponding to 16.7 g/kg body weight/day, for a person weighing 60 kg. However, in this opinion, the food consumption is divided in liquid and non-liquid foods in order to pay special attention to liquid foods.

Liquid foods

Table 10. Daily consumption of liquid foods in Norway, with tap water and alcohol excluded (7, 11-13).

Gender	Age (years)	Consumption (g/person/day)		Consumption (g/kg body weight/day)*	
		Mean	95 percentile	Mean	95 percentile
Girls	**2**	783	1435	63	116
Boys	**2**	835	1598	65	124
Girls	**4**	799	1211	45	68
Boys	**4**	807	1252	45	70
Girls	**8-10**	963	1499	30	47
Boys	**8-10**	1099	1703	34	53
Girls	**12-14**	1082	1833	22	37
Boys	**12-14**	1285	2465	26	50
Women	**40-49**	1746	3203	26	48
Men	**40-49**	2065	3786	25	46

*For calculation of consumption per kg body weight in children, the mean body weight for each age group from Table 4 was used, both for mean consumption and 95 percentile consumption. For adults, the mean body weight of women and men in Norway aged 40-49 years was used (Table 1).

As can be seen from food consumption surveys in Norway (Table 10), the average consumption of liquid food alone is above 1 kg in most age groups except for 2-8 years old girls and 2-4 years old boys. For high consumers, it is above 1 kg in all age groups. Assuming all the liquid food in the surveys is packaged the exposure from FCM may be nearly two-fold higher in adults having an average consumption (mean), and more than three-fold in high consumers (95 percentile). A mean daily consumption of 1 kg is reached in boys from the age of 8-10 years and increasing upwards with age, and is already 50% higher in two-year old high consumers. On a per kg body weight basis, the youngest children (2 years old) consume about 40-70% more than children aged 4 years, the double of children aged 8-10 years, and 2.5-3 times more than children aged 12-14 and adults.

Table 11. Daily consumption of liquid foods in Denmark, with alcohol included and tap water excluded (20).

Gender	Age (years)	Consumption (g/person/day)		Consumption (g/kg body weight/day)*	
		Mean	95 percentile	Mean	95 percentile
Girls	**4-6**	944	1735	44	62
Boys	**4-6**	1067	1843	48	60
Girls	**7-10**	1299	2475	40	55
Boys	**7-10**	1411	2566	43	60
Girls	**11-14**	1347	2568	27	38
Boys	**11-14**	1549	2906	30	40
Girls	**15-18**	1590	3240	26	43
Boys	**15-18**	1964	4236	28	47
Women	**45-54**	1913	2773	29	31
Men	**45-54**	2344	3694	28	35

*For calculation of food consumption per kg body weight, the consumption data per person/day for different age and gender groups was used and divided by the body weight for the same age and gender groups (see Tables 3 and 6). The mean food consumption is divided by the mean body weight, and the 95 percentile food consumption is divided with the 95 percentile body weight, even though it might not be the heaviest people who consume the highest amount.

Table 12. Daily consumption of liquid foods as specified (g/person/day) in Denmark, with tap water excluded (20).

Liquid category	Men (Mean)	Women (Mean)
Total (from Table 11)	2344	1913
Coffee	1055	851
Tea	153	239
Beer	372	82
Wine and alcoholic drinks	139	137
Other liquids	625	604

In the consumption data in Tables 11-12, only liquid foods which are assumed to be packaged are included. These are milk, juice and soft drinks (including bottled water), mainly packaged in cardboard or plastic. Also included are wine, beer and alcoholic drinks, most of which are in glass bottles, however, a part of it is packaged in plastic-coated cardboard. Coffee and tea are also included, although they are diluted with tap water. It can be discussed whether tap water should have been excluded, since it is also in contact with FCM (e.g. water pipes, water kettles and vacuum jugs). For simplicity, only one representative age group (45-54 years) of adults is included.

From the Danish data, it is clear that the mean consumption of liquid foods alone is above 1 kg for all the age groups included in the survey, except for 4-6 years old girls, where it is very close to 1 kg. On a body weight basis, children in the age groups 4-6 and 7-10 years consume nearly the double amount of adults, and of boys and girls between the ages of 11-18 (Table 11).

In Table 12, the liquid consumption in different categories is specified. The average amount of consumed coffee and tea is about 1200 and 1000 g for men and women, respectively. For men, the amount of beer, wine and alcoholic drinks was around 500 g for average consumers, and for women, the average consumption was around 200 g. If these categories are subtracted from the total liquid consumption (tap water already subtracted), the rest of liquid foodstuff is about 600 g for both men and women. If only coffee and tea are excluded the consumption of liquid foodstuffs is around 1150 g and 850 g for men and women, respectively. The amount of soft drinks for men is 230 g and 840 g for average and high consumers, respectively, and for women the amount is 200 g and 700 g for average and high consumers, respectively. For children and young people, the total amount of consumed soft drinks is highest in the age group 15-18 years with an average consumption of 700 g for boys and 500 g for girls. For high consumers (95 percentile), the amount is 1500 g for boys and 1200 g for girls.

In young children aged 1.5-4.5 years in U.K., the average consumption of non-alcoholic beverages was about 2 times higher than in adults on a body weight basis, however, the consumption of preferred beverages such as soft drinks was more than 10 times higher for this age group (referred in 24).

Comments (liquid foods)

Data from Denmark and Norway show that the amount of consumed liquid foods alone is more than 1 kg per day for adults and for children older than 4 years (even among average consumers). For high consumers, it is higher in all age groups and more than three times higher in adults. On a per kg body weight basis the consumption is higher than the standard value of 16.7 g/kg body weight in all age groups, and up to 2.5 times larger in young children than in adults. However, not all the liquid food is packaged. Using the Danish data, which are specified in different food groups, it is estimated that for adults about 600 g (nearly 2 kg if coffee and tea are included) of the consumed liquid foods is packaged for the average consumers. Young people in the age group 15-18 years consume a large amount of soft drinks, more than 1 kg for the high consumers.

It is not unrealistic to assume that high consumers could get a substantial part of their liquids from the same type of packaging, and it is recommended to take account of this, when setting SMLs for such types of packaging. To keep the model sufficiently protective also for liquid foods, a factor of two could be introduced (e.g. SML/2) for substances used for packaging materials used for liquid foods.

Non-liquid foods

Table 13. Daily consumption of non-liquid foods in Norway (7, 11-13).

Gender	Age (years)	Consumption (g/person/day)		Consumption (g/kg body weight/day)*	
		Mean	95 percentile	Mean	95 percentile
Girls	**2**	722	1222	58	99
Boys	**2**	775	1268	60	98
Girls	**4**	668	924	38	52
Boys	**4**	693	1079	39	60
Girls	**8-10**	795	1220	25	38
Boys	**8-10**	850	1228	26	38
Girls	**12-14**	797	1297	16	26
Boys	**12-14**	896	1545	18	31
Women	**40-49**	1050	1661	16	25
Men	**40-49**	1249	2086	15	25

*For calculation of consumption per kg body weight in children, the mean body weight for each age group from Table 4 was used, both for mean consumption and 95 percentile consumption. For adults, the mean body weight of women and men in Norway aged 40-49 years was used (Table 1).

As can be seen from food consumption surveys in Norway (Table 13), assuming a total consumption of 1 kg of non-liquid foods per day is underestimating exposure nearly two-fold in adult high consumers (95 percentile). A mean daily consumption of 1 kg is reached in 2-year old girls and boys, 4-year old boys and 8-10 year-old children who are high consumers and increasing upwards with age. The mean consumption is below 1 kg in children of all age groups, and above 1 kg in adults. Due to a larger body weight than 60 kg the consumption value on a per kg body weight basis is lower than 16.7 g/kg body weight/day for adult average consumers. High consumer adults are above, and high consumer children have up to more than 6 times higher consumption than the default value.

Table 14. Daily consumption of non-liquid foods in Denmark (20).

Gender	Age (years)	Consumption (g/person/day)		Consumption (g/kg body weight/day)*	
		Mean	95 percentile	Mean	95 percentile
Girls	**4-6**	742	1540	34	55
Boys	**4-6**	794	1502	36	49
Girls	**7-10**	803	1592	25	35
Boys	**7-10**	874	1740	27	41
Girls	**11-14**	771	1650	15	24
Boys	**11-14**	911	1967	18	27
Girls	**15-18**	786	1675	13	22
Boys	**15-18**	927	2170	13	24
Women	**45-54**	920	1930	14	22
Men	**45-54**	1055	2279	13	22

*For calculation of food consumption per kg body weight, the consumption data per person/day for different age and gender groups was used and divided by the body weight for the same age and gender groups (see Tables 3 and 6). The mean food consumption is divided by the mean body weight, and the 95 percentile food consumption is divided with the 95 percentile body weight, even though it might not be the heaviest people who consume the highest amount.

The consumption of non-liquid foods per person is slightly larger for children, but slightly smaller for adults, in Denmark compared to in Norway. On a body weight basis, Danish children aged 4-6 years consume from 2.5 to 2.8 times more than adults of non-liquid foods alone, and the amount eaten is up to 3.3 times larger than the EU standard assumption of 16.7 g/kg body weight/day (Table 14). Adults, 15-18 year old boys and girls and 11-14 year old girls (mean consumption) are below the default value if only solid foods are taken into account, whereas high consumers in these age groups are above. It is assumed that all non-liquid foods are packaged.

Comments (non-liquid foods)

Food consumption data from Denmark and Norway show that for high consumers (95% percentile) the consumption of non-liquid foods alone is higher than 1 kg for all age groups except for 4 years old children in Norway, which is close to 1 kg. On a per kg body weight basis the consumption is higher than the EU standard value of 16.7 g/kg body weight for all age groups of high consumers and even for average consumers, except for adults and Danish children in the age groups 11-18 years, due to a larger body weight than the standard 60 kg.

Total foods (liquid and non-liquid foods)

Table 15. Daily consumption of liquid and non-liquid foods in Norway (7, 11-13).

Gender	Age (years)	Consumption (g/person/day)		Consumption (g/kg body weight/day)*	
		Mean	95 percentile	Mean	95 percentile
Girls	**2**	1505	2361	121	190
Boys	**2**	1611	2571	125	199
Girls	**4**	1467	2016	83	114
Boys	**4**	1500	2223	83	124
Girls	**8-10**	1757	2525	55	79
Boys	**8-10**	1949	2772	60	86
Girls	**12-14**	1880	2814	38	57
Boys	**12-14**	2181	3526	44	72
Women	**40-49**	2796	4598	42	69
Men	**40-49**	3313	5598	40	68

*For calculation of consumption per kg body weight in children, the mean body weight for each age group from Table 4 was used, both for mean consumption and 95 percentile consumption. For adults, the mean body weight of women and men in Norway aged 40-49 years was used (Table 1).

Table 16. Daily consumption of liquid and non-liquid foods in Denmark (20).

Gender	Age (years)	Consumption (g/person/day)		Consumption (g/kg body weight/day)*	
		Mean	95 percentile	Mean	95 percentile
Girls	**4-6**	1686	3369	78	120
Boys	**4-6**	1861	3345	83	109
Girls	**7-10**	2102	4068	65	90
Boys	**7-10**	2285	4306	70	100
Girls	**11-14**	2118	4218	42	62
Boys	**11-14**	2460	4873	48	67
Girls	**15-18**	2376	4916	39	65
Boys	**15-18**	2890	6406	42	70
Women	**45-54**	2833	4703	42	52

Men	**45-54**	3400	5973	40	56

*For calculation of food consumption per kg body weight, the consumption data per person/day for different age and gender groups was used and divided by the body weight for the same age and gender groups (see Tables 3 and 6). The mean food consumption is divided by the mean body weight, and the 95 percentile food consumption is divided with the 95 percentile body weight, even though it might not be the heaviest people who consume the highest amount.

Data on total food consumption (liquid and non-liquid foods) from Norway and Denmark are at the same level and clearly show that the 1 kg assumption on total consumption of food is an underestimation if all the food is packaged (Tables 15 and 16).

In a report from England of packaged food consumption in children (27), it was found a mean total food consumption of 1.4 kg for 1-4 year old children. The consumption of total foods (solids and liquids, packaged or non-packaged) was 1.5 ± 0.4 kg/person/day (mean ± SD) and 2.2 kg/person/day (95 percentile) for children aged 5-12 in an Irish study (28). Many others have also reported the same, i.e. that the consumption of total foods (packaged or unpackaged) by children far exceeds the assumption of a consumption of 1 kg per day for a person with 60 kg body weight, or 16.7 g/kg body weight (see references in 28). Also the consumption of packaged food per kg body weight may be above this level, for instance 39 g/kg body weight (mean) and 67 g/kg body weight (97.5 percentile) was found for children aged 5-12 in an Irish study (28). The total food consumption (solid foods + liquid foods) in adults reported was 2.84 kg/day in Ireland, 2.9 kg/day in the U.K. and 3 kg/day in U.S.A. (see references in 28).

Comments (total foods)

Data on total food consumption (liquid and non-liquid foods) from Norway and Denmark are at the same level and clearly show that the 1 kg assumption on total consumption of food is an underestimation if all the food is packaged. Data from the literature also show that often more than 1 kg of consumed foods is packaged.

Conclusions (total foods)

In the current EU exposure model for FCM it is assumed that a person consumes 3 kg of foods (liquid and non-liquid), but only 1 kg is packaged. Often, data on the proportion of foods which are packaged is not available. However, since more and more of standard food in EU is packaged, the proportion of packaged food will probably often be more than one third of the total food consumption. On the other hand, it is unlikely that all the solid food is packaged in the same type of packaging material, in contrast to liquid food, where polyethylene terephthalate (PET) is the dominating material.

Various studies show that the total consumption of foods (packaged or unpackaged) or of packaged food only is higher than 1 kg/day, therefore, assuming a consumption of 1 kg food or 16.7 g food/kg body weight/day for adults and children will underestimate the exposure.

Therefore, the current assumption used in the EU that 1 kg of packaged food is consumed per day by children cannot be viewed as sufficiently protective. This would also be the case for adults in some instances. For solid foods, the model may still be sufficiently protective, since not all food (liquid and solid) consumed each day is packaged in the same material. However, as mentioned above, for packaging materials used for liquid foods it may be advisable to introduce an extra safety factor of 2 (e.g. SML/2) when setting SMLs.

4.) Is the current official conversion factor for migration from surface area of FCM to food (6 dm^2/kg) correct, based on available data? Should the concentration of a migrant in food be used in the regulations rather than the migration per packaging surface area?

FCM for some food products may have a surface area to food mass ratio higher than the official and legally prescribed value of 6 dm^2/kg. This is especially pertinent for food packaged in small portions, such as foods for children. There is a current trend towards smaller portions and therefore smaller packages, because of smaller households and attempts to limit individual portion sizes. In a survey of food packaging materials in the Netherlands (29), it was found that the ratio between area of packaging material in contact with food and the mass of food varied from 6-95 dm^2/kg. For soft drinks, liquid dairy products and canned foods the ratio approached 6 dm^2/kg. For bakery products, meat, fish, fruit, vegetables, salads, (microwave) meals, nuts and sauces this ratio varied from 10-30 dm^2/kg. For herbs, this ratio was very unfavourable; 95 dm^2/kg. This project showed that for most of the food packaging materials examined, this factor was too low compared with the official and legally prescribed conversion factor for migration testing of 6 dm^2/kg.

A mean value of 20.1 dm^2/person/day (20.1 dm^2/kg food, based on a consumption of 1 kg food/person/day) was estimated for food contact area for all packaging materials used by individuals across Europe, while the mean food contact area for plastics was 12.4 dm^2/person/day (30). In a Danish enforcement campaign on migration of primary aromatic amines from flexible laminated plastics, the average food contact area found for flexible laminates was 40 dm^2/kg (31). In a study of exposure to food packaging materials in Irish children aged 5-12 years, the area of all packaging materials used was 13.4 dm^2/child/day, and the food contact area for plastics was 10.7 dm^2/child/day (32). All these values differ greatly from the food contact area of 6 dm^2/person/day (6 dm^2/kg food) currently used in EU exposure assessments.

In a survey of packaged food consumption in children in the U.K. (27), it was found that for infants (less than one year old) the mean area of packaging per kg food was less than 6 dm^2. For children aged 1-4 years, the value was 8.3 dm^2, and for children aged 4-6 years, the mean value was 9.7 dm^2. For all age groups of children, the mean surface area of packaging associated with 1 kg of food was 7.7 dm^2.

As stated above under the second question, if migration limits are expressed on the basis of the food contact area of the foodstuff rather than as a concentration in the foodstuff (SMLs), then special rules should also be considered to reflect the larger usage of FCM on a food contact area to body weight basis for foodstuffs intended for infants and young children. In the new EU regulation on FCM (the PIM regulation), which presumably will be adopted in the beginning of 2010, it is proposed that the overall migration should always be expressed as mg/dm^2. However, for children the migration from FCM should always be expressed as mg/kg food or food simulant.

Conclusions

Based on published studies on food contact area to food mass ratio, the current official conversion factor for migration from surface area of FCM to food (6 dm^2/kg) is too low, both for various age groups of children and for adults, and may therefore lead to underestimation of exposure. Available data should be used to revise the 6 dm^2/kg value in the exposure model. A realistic surface area should be used for the packaged food in question. Irrespective of the conversion factor used, it is the amount of the migrant present in food that is of importance.

5.) Is introduction of a fat (consumption) reduction factor (FRF) acceptable? If so, are there arguments for introduction of (consumption) reduction factors also for other types of foodstuffs, e.g. aqueous, acidic and alcoholic foodstuffs? If so, which daily consumption values should be the basis for such factors?

Fatty foodstuffs

The exposure model described above has been debated for many years in the EU. The industry has claimed, and has compiled documentation showing that no individual consumes 1 kg of fat each day. This discussion has led to introduction of a fat (consumption) reduction factor (33).

In an EFSA opinion (34), it was considered that, for nutritional reasons, the consumption of 200 g fat/person/day, corresponding to 3.3 g fat/kg body weight/day, is a realistic maximum. The fat (consumption) reduction factor is restricted to certain cases only:

- Only for fatty foods with more than 20% fat.
- The total reduction factor (TRF) (= FRF + simulant D (i.e. olive oil) reduction factor (DRF)) should not exceed 5.
- It will be applicable only to selected substances that may migrate into fatty foods, but that have negligible migration into non-fatty foods. (Migration (simulant A, B, C) < 10% of SML under worst case conditions of use).
- It will not be applicable to substances on SCF list 4 (substances which should not be detectable in food).

As an example, if the fatty food contains 50% of fat, only 400 grams of this fatty food can be ingested and not one kilogram, which is the theoretical value used to establish SML values from ADI/TDI values. Therefore, the migration value determined experimentally by testing the food, or food simulant, should be corrected by a reduction factor of 2.5 (=1000/400). In general, the value of the FRF will be variable from 1 to 5 according to the percentage of fat in the fatty food. In practice, that means that the migration can be up to 5 times higher compared to if FRF was not used.

Table 17. Daily consumption of fat in Norway (7, 11-13).

Gender	Age (years)	Consumption (g/person/day)		Consumption (g/kg body weight/day)*	
		Mean	95 percentile	Mean	95 percentile
Girls	**2**	52	79	4	6
Boys	**2**	57	89	4	7
Girls	**4**	55	83	3	5
Boys	**4**	56	85	3	5
Girls	**8-10**	67	108	2	3
Boys	**8-10**	75	108	2	3

Girls	**12-14**	68	119	1	2
Boys	**12-14**	79	142	2	3
Women	**40-49**	67	121	1	2
Men	**40-49**	94	174	1	2

*For calculation of consumption per kg body weight in children, the mean body weight for each age group from Table 4 was used, both for mean consumption and 95 percentile consumption. For adults, the mean body weight of women and men in Norway aged 40-49 years was used (Table 1).

As can be seen from food consumption surveys in Norway (Table 17), the average dietary consumption of fat is far below 1 kg per day, as used in the standard EU model, both for various age groups of children and for adults. The consumption was below 200 g/day (3.3 g/kg body weight/day) also for high consumers (95 percentile) among children and adults. However, the average fat consumption on a per kg body weight basis is higher for 2-year old children than for a conventional 60 kg adult, i.e. 4.3 versus 3.3 g/kg body weight/day. The high consumers aged 2-10 years also had a higher fat consumption than this value.

Table 18. Daily consumption of fat in Denmark (20).

Gender	Age (years)	Consumption (g/person/day)		Consumption (g/kg body weight/day)*	
		Mean	**95 percentile**	**Mean**	**95 percentile**
Girls	**4-6**	69	104	3	4
Boys	**4-6**	73	110	3	4
Girls	**7-10**	72	111	2	3
Boys	**7-10**	83	118	3	3
Girls	**11-14**	71	117	1	2
Boys	**11-14**	85	126	1	2
Girls	**15-18**	67	103	1	1
Boys	**15-18**	88	131	1	1
Women	**45-54**	67	107	1	1
Men	**45-54**	95	171	1	2

*For calculation of food consumption per kg body weight, the consumption data per person/day for different age and gender groups was used and divided by the body weight for the same age and gender groups (see Tables 3 and 6). The mean food consumption is divided by the mean body weight, and the 95 percentile food consumption is divided with the 95 percentile body weight, even though it might not be the heaviest people who consume the highest amount.

The fat consumption per person per day is comparable in Norway and Denmark both for average and high consumers. Also in Denmark (Table 18), the fat consumption is below 200 g/person/day both for average and high consumers. On a per kg body weight basis the value was higher than 3.3 g/kg body weight/day only for 4-6 years old children who were high consumers.

Also in the survey of Irish children aged 5-12 years (28), it was concluded that using a fat reduction factor of 5, giving a maximum fat consumption of 200 g/day, will be sufficiently protective, since the 95 percentile of fat consumption from all foods (packaged and unpackaged) was 93 g/day, and from all packaged foods 90 g/day.

At a Nordic workshop, “Food reduction/consumption factors” in Copenhagen in 2002 (6), it was discussed whether there is a need to examine the consequences of the introduction of this new reduction factor for the exposure of children. Their exposure per kilogram body weight is expected to be larger than the exposure of adults.

This question was also raised in the EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel), which adopted an opinion in 2004 on this issue (34).

In the EFSA AFC opinion, it was concluded that infants and children have a higher fat consumption than adults on a body weight basis, ranging from 6.5 to 3.8 g fat/kg body weight/day, considering the energy requirements of infants and children from 6 months to 10 years of age. While this might imply the need for a lower FRF for infants and children, in practice the FRF will not be applicable to a number of the foods they consume.

The FRF is not applicable to milk, ready-to-feed infant formula or pre-packaged baby foods, because these products contain less than 20% fat. In the case of infant formula sold as dry powder or liquid concentrate, even if the standard FRF for adults was to be applied to assess compliance of the packaged product with any SML, the large dilution with water used to make these foodstuffs ready to feed would automatically ensure that the concentration in the formulae as consumed would be far below any respective SML. Therefore, in practice, no special FRF is needed for infants in relation to consumption of milk, infant formulae or pre-packaged baby foods.

With respect to other foods, infants and children do have a higher consumption of energy on a body weight basis than adults, and the fraction of this energy that is derived from fat is also higher. It may range, for high fat diets, from 4.4 g fat/kg body weight/day for a 12-month infant down to 3.8 g fat/kg body weight/day for a 10-year-old child. These figures are not markedly different from the maximum fat consumption of 3.3 g/kg body weight/day for adults that was used as a basis for the introduction of the FRF. Consequently, the AFC Panel was of the opinion that the higher consumption of fat on a body weight basis from these other foods by infants and children, compared to that of adults, is modest, and that no special FRF is needed for infants and children for any foods.

The EFSA AFC Panel noted that, setting aside the consumption of specifically fatty foods, children have a significantly higher food consumption than adults when expressed on a per kg body weight basis. Whilst a special FRF for children does not seem to be necessary, special rules for migration into all foods specifically intended for children should be considered, which is in line with the conclusion under Question 2 in the present opinion.

Comments on fatty foodstuffs

The fat consumption per person per day was generally below 200 g/person/day both for average and high consumers. On a per kg body weight basis the value was higher than 3.3 g/kg body weight/day only for 4-6 years old children in Denmark who were high consumers, but in Norway also 2-year old children with an average consumption, and the high consumers aged 2-10 years also had a higher fat consumption than this value. Therefore, the available data from Denmark and Norway show that the introduction of a fat (consumption) reduction factor in most cases is acceptable. The use of a FRF for fatty foods would be protective for most children with an average (mean) consumption, and also for most high consumers (95 percentile) among children.

EFSA concluded that no special FRF is needed for infants and children for any foods, since the foods specifically eaten by infant and children have less than 20% fat and therefore FRF is not applicable, they will be diluted before consumption, or there is only a minor difference compared to adult fat consumption.

Aqueous and acidic foodstuffs

Aqueous foodstuffs (liquid foods) have been discussed under Question 3. Data from Denmark and Norway show that the amount of consumed liquid foods is more than 1 kg per day for adults and for children older than 4 years (even among average consumers). Therefore, the use of a reduction factor for aqueous foods does not seem to be justified. Instead it might be more relevant to introduce an extra safety factor of 2 (e.g. SML/2) for FCM used for liquids. No data is available on total consumption of acidic foods in Norway and only sparse data in Denmark. Therefore, no conclusions can be drawn about the protection of the consumers, including children, if food (consumption) reduction factors also for acidic foods were introduced in the EU legislation.

Alcoholic beverages

The daily consumption of alcoholic beverages in Norway is shown in Table 19.

Table 19. Consumption of alcoholic beverages in Norway (7).

	Consumption (g/person/day)		Consumption (g/kg body weight/day)*	
Gender/Age	**Mean**	**95 percentile**	**Mean**	**95 percentile**
Women (40-49 years)	66	256	1	4
Men (40-49 years)	153	570	2	7

*For calculation of consumption of alcoholic beverages (beer, wine, spirits) per kg body weight, the mean body weight of adult women and men in Norway aged 40-49 years was used (Table 1), both for mean consumption and 95 percentile consumption.

The daily consumption of alcoholic beverages in Denmark is shown in Table 20.

Table 20. Consumption of alcoholic beverages in Denmark (20).

	Consumption (g/person/day)		Consumption (g/kg body weight/day)*	
Gender/Age	**Mean**	**95 percentile**	**Mean**	**95 percentile**
Women (45-54 years)	137	380	2	4
Men (45-54 years)	139	404	2	4

*For calculation of consumption of alcoholic beverages (beer, wine, spirits) per kg body weight, the body weight of adult women and men in Denmark aged 45-54 years was used (Table 3). The mean alcohol consumption is divided by the mean body weight, and the 95 percentile alcohol consumption is divided with the 95 percentile body weight, even though it might not be the heaviest people who consume the highest amount.

The consumption of alcoholic beverages in the two countries is comparable. However, the consumption is lower for men and higher for women in Denmark compared to Norway (Tables 19 and 20).

The daily consumption of alcoholic beverages in Denmark and Norway is below 1 kg also for high consumers. If alcohol consumption factors should be introduced in order to get more realistic data and a less conservative model, several reservations should be made as for the introduction of fat consumption factors:

- Only for alcoholic beverages with more than a certain percentage of alcohol, e.g. 20%.

- Only applicable to substances that may migrate into alcoholic beverages, but not to aqueous or fatty food.
- Not applicable to substances on SCF list 4.

It is the opinion of the VKM Panel 4 that introduction of such a reduction factor for alcoholic beverages may not be possible or relevant.

Comments on alcoholic beverages
It should be noted that the Norwegian and Danish consumption data for liquid food, non-liquid food, total food and alcoholic beverages are for all persons, not only consumers. Especially the consumption of alcoholic beverages would have been higher if only data from consumers was used.

Conclusions on fatty, aqueous and acidic foodstuffs and alcoholic beverages
The use of a fat (consumption) reduction factor for fatty foodstuffs would be sufficiently protective for both adults and children with an average (mean) consumption, and also for high consumers (95 percentile). Therefore, the introduction of a FRF is acceptable in most cases both for adults and children.

Data from Denmark and Norway show that the amount of consumed liquid foods is more than 1 kg per day for adults and for children older than 4 years (even among average consumers). Therefore, the use of a reduction factor for aqueous foods does not seem to be justified. Instead it might be more relevant to introduce an extra safety factor of 2 (e.g. SML/2) for FCM used for liquids. No conclusions can be drawn about the protection of the consumers, including children, if food consumption factors also for acidic foods were introduced in the EU legislation, because of lack of data. If a consumption factor should be introduced also for alcoholic foodstuffs, i.e. assuming a maximum consumption of approximately 600 g alcoholic drinks per day, in order to make the model less conservative and to allow higher migration of certain substances, it should be kept in mind that the model is not always sufficiently protective as described above (under Questions 3 and 4).

6.) Foodstuffs may be (re)packaged several times from the producer to the consumer, i.e. at the farm/fishing vessel, during transportation, in food industry and before final sale to the consumer. Should repeated packaging be taken into consideration also in the legislation?

There are examples of increased exposure through repackaging of food. For instance, it was shown that when applying realistic practises from buying meat to the final food preparation, the concentration of the plasticizer di-(2-ethylhexyl)adipate (DEHA) increased from 20 to 100 mg/kg after repeated repackaging (35). In addition, the food may be repackaged one or several times at home by the consumers.

Conclusion
There are good reasons to take the possibility of repeated packaging of food into consideration. However, at present this seems not to be achievable due to lack of adequate data.

7.) Are the food simulants in use today appropriate, or can their use lead to underestimation of exposure?

For the measurement of migration of chemical substances into foodstuff the EU directive provides two options:

1. to carry out the migration tests with foodstuffs themselves or
2. to carry out the migration tests using food simulants.

Directives 97/48/EC (36) and 85/572/EEC (37) provide the following four simulants:

- distilled water or water of equivalent quality (simulant A) for aqueous foodstuffs
- 3% acetic acid (w/v) in aqueous solution (simulant B) for acetic foodstuffs
- 10% ethanol (v/v) in aqueous solution (simulant C) for alcoholic foodstuffs
- rectified olive oil (simulant D) for fatty foodstuffs

For compliance testing in the industry predictive diffusion modelling or "more severe" testing with solvents will often be the first choice.

According to Council Directive 85/572/EEC (37), no migration testing is required for dry foodstuffs, such as cereals, pasta, cereal flour and meal, powdered eggs, dried milk, herbs and spices, coffee, solid sugar and salt, fresh or dried fruits and vegetables, or for frozen foods. Instead, testing showing compliance with regulations must be performed on the food itself, which is more technically difficult and costly. However, since it has been demonstrated that low levels of organic and inorganic contaminants may migrate into dry foods from paper and board (38, 39), dry foods should not automatically be exempted from being tested for migration by simulants. Polyphenylene oxide (i.e. Tenax®) was found to be a suitable food simulant for migration of organic substances into dry foods and dry fatty foods, such as pastry and pizza base (38), but not the optimal simulant for inorganic contaminants (39), since it is a chromatography support developed for collection and analysis of volatile organic substances. In the draft PIM regulation on plastics, new simulants are proposed, among these Tenax is proposed for some dry foodstuffs (40).

In the Food Migrosure project (41), supported by the European Commission (EC) under the Fifth Framework Programme, experiments and mathematical modelling were performed that clearly showed that distilled water was not the appropriate simulant for milk, since at least lipophilic substances had a high solubility in the fat phase of the milk (42). Council Directive 85/572/EEC (37) was recently amended in Commission Directive 2007/19/EC (5) in a way that milk and certain milk products are now classified as fatty food, for which 50% ethanol in water is the appropriate simulant. This was based on studies having shown that distilled water may not be the most appropriate simulant for milk, since migration of styrene into milk was increasing with increasing fat content of the milk, and increasing with increasing percentage of ethanol (43).

It was also found in the Food Migrosure project that clouded drinks, such as fruit juice with pulp, behave differently from drinks without pulp. In the Draft Community Guidelines on migration testing of plastic materials and articles (PIM guidelines), it is proposed to use 20% ethanol for such drinks (40).

In general, the aqueous, acidic and alcoholic food simulants (distilled water, 15% ethanol (v/v) in aqueous solution and 3 % acetic acid (w/v) in aqueous solution, respectively) may not be representative of the real situation in foods, because of poor solubility, and therefore underestimate exposure (44). In the PIM guidelines, it is proposed to exclude distilled water as a food stimulant and to use 10% ethanol instead. For alcoholic beverages 20% ethanol should be used (40).

The extractive power of olive oil (= simulant D) is generally higher than any solid or semi-solid fatty foods. Therefore, the simulant D reduction factors (numbers between 1 and 5 with which the measured migration to the food simulant shall be divided) are tabulated for all types of fatty foodstuffs (37). If the material or article is intended to come into contact with more than one foodstuff or group(s) or foodstuffs having different reduction factors, various reduction factors shall be applied. If one or more results of such calculation, after consideration of the analytical tolerance, exceed the restriction, then the material is not suitable for that (those) group(s) of foodstuff(s).

Although olive oil is normally regarded as a “worst case” food simulant, it is not always the case. If this simulant is used to measure migration from Teflon-coated plastic backs used for preparation of e.g. popcorn in a microwave oven there is a great underestimation of the migration into the food. In this case, butter was a better simulant (45).

Research is also going on to establish in which instances of specific migration the olive oil simulant is inappropriate and which simulant would be a good replacement (44). The Food Migrosure project also showed that in many cases compliance shown with the food simulant testing could be contradicted by the migration determined in the food itself. For some types of food, testing in one simulant may be adequate. For other types of food, testing in more than one simulant (polar and non-polar) may be necessary, or testing may possibly be done in one simulant and mathematical modelling used to estimate the migration in the other simulants in the future. Migration into food will always prevail over migration into simulants (37, 46).

Conclusions

Research has shown that for some food types, the simulants in use today are not adequate and representative of the food itself. In some instances, this may lead to underestimation of exposure. Further research is necessary to find the best possible simulant for all food types. Some of the simulants will be changed in the near future. For instance, based on the results from the Food Migrosure project, it is proposed in the new PIM regulation to use 10% ethanol instead of water, to use 20% ethanol for alcoholic beverages and cloudy juice, 50% ethanol for milk, and to introduce Tenax for dry foodstuffs (40).

For the food types for which it is now known that the current simulants are not representative of the food, analysis of migration into food should be used. Mathematical modelling may also be used in addition to or instead of migration studies with simulants in the future (47), and is now implemented in the regulation, i.e. Directive 2002/72/EC (2).

8.) What is the best proportion of TDI for a substance to be allocated for FCM compared to potential contributions from all other sources?

The contribution to the total exposure that come from FCM will vary for each chemical substance, and be dependent also on the FCM in question and the type of food packaged in the FCM, as well as contact time and temperature. For some substances, the exposure is mainly from FCM and for other substances other sources are more important. Therefore, it will not be appropriate to fix one default value for contribution to TDI from FCM compared to contribution from other sources.

As mentioned in the Background chapter, the exposure model used in EU will normally not take into consideration exposure from other sources. However, in a few instances where the exposure from other sources is known to be high, and/or the exposure from FCM is estimated to be close to the TDI, only a proportion of the TDI has been allocated to FCM. In the following, a few examples are given:

In the EFSA opinion on bis(2-ethylhexyl)phthalate (DEHP), the AFC panel concluded that exposure to DEHP from food consumption is in the range of the TDI (48). There are, however, a number of other sources which contribute to the overall human exposure to DEHP. The AFC panel recommends that improved estimates of exposure to DEHP from all sources along with their relative importance should be provided in order to decide what proportion of the TDI can be allocated to FCM alone. In 2005, a TDI of 0.05 mg/kg body weight was set by EFSA's AFC panel. The specific migration limit set by the EU commission is 1.5 mg/kg food, which is 50% of the value which could be calculated from the conventional practice (TDI x 60 kg). DEHP is not permitted for use in single-use applications such as cap seals or gaskets in order to eliminate the exposure of infants and young children.

For silver and fluoride in FCM, the exposure from drinking water was taken into consideration. For silver, the human no observed adverse effect level (NOAEL) is considered to be 0.39 mg/person/day on the basis of epidemiological and pharmacokinetic knowledge (49). On the basis of a daily consumption of 2 l of drinking water, it is estimated that a concentration up to 0.1 mg/l of silver (used to maintain the bacteriological quality of drinking water) can be tolerated without risk to human health. This concentration is equal to a daily silver intake of 0.2 mg/person/day and gives a total dose over 70 years of half the human NOAEL. Therefore, a restriction of 0.05 mg/kg of food was allocated to FCM, covering 25 % of the remaining, or 12.5 % of the total, human NOAEL.

In Council Directive 98/83/EC (50), the upper limit for fluoride in water for human consumption is 1.5 mg/l based on the increasing risk of dental fluorosis, and progressively higher concentrations lead to increasing risks of skeletal fluorosis (51). Taking these data into account, the EFSA AFC Panel considered that a concentration of fluoride in foods, migrating from FCM, not exceeding the 10% of the restriction in drinking water poses no risk to human health (52).

Conclusions

Exposure from other sources should be taken into account in the risk assessments of FCM if such data are available. This is especially important if the exposure is high and close to the TDI, especially from other sources than FCM, such as drinking water, air or consumer products and cosmetics. It is not feasible to fix one value for allocating exposure from FCM to the TDI. There will have to be case by case evaluations.

9.) Will it be feasible to fix maximum values for exposure to unknown substances, i.e. non-intentionally added substances (NIAS), and if so, what should they be?

In some instances, compounds migrating into food are not only the intentionally added substances (e.g. monomers and additives). Reaction products and degradation products can also migrate in small amounts, e.g. chlorinated degradation products of epoxidised soybean oil (ESBO). Sometimes they can migrate in even higher amounts than the substance itself, e.g. bisphenol A diglycidyl ether (BADGE) degradation products from internally coated food cans. Sometimes chemical analysis of these migrating substances gives rise to a "forest of peaks" of unknown degradation products, and it will be very time and cost consuming, if not impossible, to evaluate all these substances. Therefore, other approaches are needed. The Matrix project was initiated by the plastic industry in 2005 with the objective to develop a tool to calculate consumer exposure to migrants from plastic FCM and a tool for risk assessment of NIAS in (plastic) FCM based on exposure (see (53) for a presentation of this project held in Copenhagen 1 October 2009).

Other examples of NIAS in food are set-offs from printing inks. High concentrations of 2-isopropyl thioxanthone (ITX) and 3-methyl-benzopenone from printing inks have been found in food, and gave rise to Rapid Alerts in the EU member states. Such situations should be avoided and show a need for a better regulation of printing inks. Due to these rapid alerts, public debate and pressure from regulators, member states and food industry using printing inks, the European Printing Ink association, EuPIA, has issued a guideline on Food Packaging Inks. A preliminary draft of this guideline (54) was presented in Copenhagen 1 October 2009 (55).

In addition, unknown substances from recycled material like paper and board may migrate into food. For recycled materials, a "functional barrier" can be used. A functional barrier" means a barrier consisting of one or more layers of FCM which ensures that the recycled material or article complies with Article 3 of Regulation (EC) No 1935/2004 (the framework regulation (1)), i.e. it does not transfer its constituents to food in amounts which could endanger human health or bring about unacceptable changes in the composition of the food or of its organoleptic properties. The migration of the substances referred to above into food shall not exceed 10 µg/kg food (10 ppb), corresponding to 10 µg/person/day and the substances shall not belong to either of the following categories:

(a) substances classified as proved or suspected carcinogenic, mutagenic or toxic to reproduction in Annex I to Council Directive 67/548/EEC (56),
(b) substances classified under the self-responsibility criteria as carcinogenic, mutagenic or toxic to reproduction according to the rules of Annex VI to Directive 67/548/EEC (56).

The analytical detection limit of 10 µg/kg for some compounds on EFSA list 4 for FCM (potential genotoxic and carcinogenic compounds) has been used as a Threshold of Regulation (ToR) value for unknown substances behind a functional barrier. From a toxicological point of view this ToR value appears too high. For compounds which are both genotoxic and carcinogenic, it is not possible to establish a safe limit. However, as discussed below, if the Threshold of Toxicological Concern (TTC) principle is used, a TTC value of 0.15 µg/person/day, which would represent a negligible risk, has been proposed for genotoxic and carcinogenic substances (57). This value is 67 times lower than the "ToR" used for NIAS migrating from FCM. Although it is requested that NIAS behind a functional barrier should not belong to certain toxicological "classes", it might be difficult to classify unknown substances.

Unfortunately, 10 µg/kg seems to be considered by industry as a threshold below which there is no safety concern, and it is proposed in a draft guideline for printing inks that no testing should be required for printing ink substances migrating to food in levels lower than 10 µg/kg (54). This value is also used in the Matrix project, mentioned above, as a level of interest, and defined as a level below which no safety concern exists for NIAS. Again, this value may be regarded as too high from a toxicological point of view.

Another possibility is to relate the detected migrating levels of NIAS to the ToR used by the US FDA for indirect food additives, including FCM. The US FDA considers an intake level of 0.5 µg/kg food simulant, i.e. 1.5 µg/person/day, safe for humans, including for carcinogenic compounds (58). If conditions for exemption according to the ToR policy are met, toxicological testing and premarket safety evaluation are not necessary. However, basic information such as chemical name, Chemical Abstracts Service (CAS) number, existing toxicological data etc., must be provided. As a further development of this policy, an ILSI Europe Expert Group has suggested a lower threshold value of 0.15 µg/person/day for genotoxic substances, while the 1.5 µg/person/day value is valid only for non-genotoxic substances, which are further subdivided into three different classes depending on their chemical structure indicating potential for toxicity, and having a separate threshold value. Therefore, at least some basic knowledge of chemical structure is needed to be able to use this TTC principle for NIAS (57).

The Scientific Committee of EFSA has established a working group on the TTC principle: "Exploring options for providing preliminary advice about possible human health risk based on the concept of Threshold of Toxicological concern". In this working group, the TTC principle for FCM will also be considered. It is expected that an opinion will be finalised in autumn 2010.

In addition, it has been proposed (59) to use a battery of *in vitro* tests with different toxicological end points (e.g. cytotoxicity, mutagenicity, estrogenic activity and Ah receptor activity) as screening test for potential toxic migrants from FCM which were not intentionally added, such as reaction and degradation products, or compounds in recycled material for food contact. This approach has been used in combination with chemical analysis for the detection of toxic compounds, and was proposed for the detection of "unknown" substances in the migrate. The Biosafepaper project, a joint EU Commission/Paper Industry shared cost project within the EU Fifth Framework Programme, employed a battery of *in vitro* cytotoxicity and genotoxicity tests for use in risk assessment of paper and board intended to come into contact with food as part of a decision tree approach (60). Such methods may possibly also be used for screening and detecting unexpected and unknown substances. However, such methods need to be further evaluated and approved, before they can be used for regulatory purposes.

Conclusions

At present, it is not possible to fix maximum values for exposure to NIAS migrating from FCM into food. However, some work has been initiated by industry in this area in order to develop exposure models and set limits for NIAS. The TTC principle may be used in some circumstances and is currently discussed in EFSA.

ANSWERS TO THE QUESTIONS RAISED IN THE TERMS OF REFERENCE

In this opinion, Norwegian and Danish data on body weight and food consumption were used to evaluate the current EU exposure model for FCM, in addition to information found in the published literature. These data were used to compare the different assumptions in the model with real data to see whether the model is sufficiently protective for human health or whether it should/could be improved.

In the following, answers to he questions asked in the terms of reference are given in order to evaluate the different assumptions which are the basis for this exposure model.

1.) Is there a need to revise the standard adult body weight of 60 kg used in the model in light of data for present average body weight in the population, and maybe also the body weight for children?

In general, there is no need to revise the standard body weight of 60 kg for adults, although some women have a slightly lower body weight than 60 kg. However, children have a body weight below 60 kg, which might lead to underestimation of their exposure.

2.) Is there a need for a separate factor to account for the fact that children (in various age groups) have a higher consumption per kg body weight than adults, and if so, what should this (these) factor(s) be?

For children, a general correction factor for reduction of numerical restriction values (e.g. SML) for migration from FCM will not be applicable, since children have a higher consumption than adults of some foods, and a lower consumption of other foods. Instead, risk assessment of FCM for foods for infants and young children should be addressed on a case by case basis. In order to provide the same level of protection and ensure that numerical restriction on exposure is not exceeded, it should be considered to reduce the SML values for substances used to make food contact materials and articles intended specifically for the foodstuffs for infants (e.g. SML/10) and young children. (e.g. SML/4-5).

3.) It is assumed that of a total adult consumption of 3 kg of food (liquid and non-liquid) every day, 1 kg is packaged. Is there a need to revise this standard assumption? Especially, is there a need to revise the consumption of packaged liquid food?

In the current EU exposure model for FCM, it is assumed that a person consumes 3 kg of food (liquid and non-liquid in total), but only 1 kg is packaged. Based on the Norwegian and Danish data, there is a need to revise this assumption especially for liquid food.

The total consumption of food (liquid and non-liquid) is higher than the standard 1 kg/person/day in all age groups, and therefore, this assumption may underestimate the exposure on a per kg body weight basis if all the consumed food is packaged. When the food consumption data were divided in liquid and non-liquid food, both Danish and Norwegian data showed a much higher intake of liquid food than of non-liquid food. The intake of packaged liquid foods was more than one litre (approximately equivalent to 1 kg for the different liquid food types) per day for adults and often also for children. The proportion of packaged food is mostly unknown, especially for non-liquid food, but will probably often be more than one third of the total food consumption of the assumed 3 kg, since more and more of standard food in EU is packaged. Therefore, the current assumption used in the EU that 1 kg of packaged foods (liquid and non-liquid in total) is consumed per person per day cannot be viewed as sufficiently protective.

4.) Is the current official conversion factor for migration from surface area of FCM to food (6 dm^2/kg) correct, based on available data? Should the concentration of a migrant in food be used in the regulations rather than the migration per packaging surface area?

Based on published studies on food contact area to food mass ratio, the current official conversion factor for migration from surface area of FCM to food (6 dm^2/kg) is too low, both for various age groups of children and for adults, and may therefore lead to underestimation of exposure. Available data should be used to revise the 6 dm^2/kg value in the exposure model. A realistic surface area should be used for the packaged food in question. Irrespective of the conversion factor used, it is the amount of the migrant present in food that is of importance.

5.) Is introduction of a fat (consumption) reduction factor (FRF) acceptable? If so, are there arguments for introduction of (consumption) reduction factors also for other types of foodstuffs, e.g. aqueous, acidic and alcoholic foodstuffs? If so, which daily consumption values should be the basis for such factors?

The introduction of a FRF is generally acceptable, since the fat consumption is below 200 g/person/day both for average and high consumer adults. It is also concluded based on the available data that the use of a FRF for fatty foods would be protective also for children. However, the introduction of the FRF may give rise to an underestimation of exposure. This could be the case if the food contact area to food mass ratio is much higher than the standard 6 dm^2/kg, e.g. sliced fatty food packaged between several layers of plastic material. Even though the fat consumption is below 200 g/person/day the migration may exceed the limits.

The use of a reduction factor for aqueous foods does not seem to be justified, since the amount of consumed liquid foods is more than 1 kg per day. On the basis of consumption data, it might be more relevant to introduce an extra safety factor of 2 (e.g. SML/2) for FCM used for liquids. For acidic foodstuffs (as defined in Council Directive 85/572/EEC), no conclusions on the use of reduction factors can be drawn because of lack of data. For alcoholic beverages, we do not see any arguments for introduction of a reduction factor.

6.) Foodstuffs may be (re)packaged several times from the producer to the consumer, i.e. at the farm/fishing vessel, during transportation, in food industry and before final sale to the consumer. Should repeated packaging be taken into consideration also in the legislation?

Although limited, available published data has shown that repackaging of foods several times from the producer to the consumer may give rise to up to five times higher concentration in the final food. Therefore, repeated repackaging of food should be taken into consideration also in the legislation.

7.) Are the food simulants in use today appropriate, or can their use lead to underestimation of exposure?

In most cases, the food simulants in use today are adequate. However, studies have shown that in some situations they are not adequate and representative of the foods themselves, and may in some instances lead to underestimation of exposure. New and better simulants are under development, and some of these will be introduced in the new plastic legislation, the Plastics Implementation Measure (PIM) regulation. Analysis of migration into food itself and/or mathematical modelling can be used in addition to or instead of migration studies with simulants.

8.) What is the best proportion of TDI for a substance to be allocated for FCM compared to potential contributions from all other sources?

It is not feasible to fix one specific value for allocating exposure from FCM to the TDI. Exposure from other sources should be taken into account in the risk assessments of FCM if such data are available on a case by case basis.

9.) Will it be feasible to fix maximum values for exposure to unknown substances, i.e. non-intentionally added substances (NIAS), and if so, what should they be?

At present, it is not possible to fix maximum values for exposure to NIAS migrating from FCM into food. However, some work has been initiated by industry in this area in order to develop exposure models and set limits for NIAS. The TTC principle may be used in some circumstances and is currently discussed in EFSA.

CONCLUSIONS

Based on the answers to all the questions in this opinion, it can be concluded that the EU exposure model for FCM is not sufficiently protective in all instances, especially not for FCM specifically made for infants and young children where there could be a need for an extra safety factor. Norwegian and Danish data show that an additional safety factor of 10 (e.g. SML/10) used for FCM for infant formula and other foods for babies, and an additional factor of 4-5 (e.g. SML/4-5) for FCM used for food for young children would in general be sufficient to protect children in these age groups at the same level (same margin of safety) as adults. The data show that also for liquid food there might be a problem, and an extra safety factor of 2 (e.g. SML/2) could be used for FCM for liquid food.

However, the model seems to be sufficiently protective for the average consumer in general taking into account that it is assumed that 1 kg packaged food is consumed each day throughout the whole life-time, and that this 1 kg of food is packaged in the same FCM which always contain the substance in question (i.e. monomer or additive). In the model it, is also assumed that the FCM releases the substance at the highest level permitted (e.g. at the SML), which is an overestimation in many instances.

If further refinement of the model is planned in order to make it less conservative, it should be kept in mind that the model is not sufficiently protective in all instances, as shown in this opinion. Especially, the consumption of packaged food is higher than assumed. The higher food consumption may lead to an underestimation of the real exposure, in particular among infants and young children. A better estimate of the consumption of packaged food is therefore desirable. In addition, there is a tendency for more and more food to be packaged, in smaller and smaller pack sizes, in order to give the customers food packaged in single portions, thereby increasing the FCM surface area to food mass ratio.

Even if certain assumptions in the model are not consistent with real data, the exposure model may in general be regarded as sufficiently protective. However, it is important to the consumer’s health that the model is not being made gradually less protective, by changing single assumptions or introducing new correction factors. The model should be maintained sufficiently protective as a whole.

RECOMMENDATIONS

The VKM Panel 4 suggests that special attention is given to improving this model with regards to FCM for infants and young children, FCM for liquid foods, the proportion of packaged foods, and FCM surface area to food mass ratio.

References

1. European Commission. Food Contact materials – EU Legislation. Available from: URL: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm
2. The Commission of the European Communities. Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs. Available from: URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:091:0017:0036:EN:PDF
3. ILSI Europe (2007) Guidance for exposure assessment of substances migrating from food packaging materials. Report of an ILSI Europe Expert Group. Reviewed at a Workshop held in Brussels in March 2007. ISBN: 9789078637097. Available from: URL: http://www.ilsi.org/europe/publications/o2007gui_exp.pdf.
4. de Fátima Pocas M, Hogg T. Exposure assessment of chemicals from packaging materials in foods: a review. Trends Food Sci Tech 2007;18:219-30.
5. The Commission of the European Communities. Commission Directive 2007/19/EC of 2 April 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs. Available from: URL: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_097/l_09720070412en00500069.pdf.
6. Fabech B, Binderup M-L, Jørgensen T, Højslev Petersen J, Hallikainen A, Ólafsson G, Sveinsdóttir SM, Bergsten C, Fjeldal P, Skjevrak I, Ionescu C, Svensson K (2003) Food reduction/consumption factors. An acceptable new element in the exposure assessment of substances (migrants) from food contact materials? Views from a Nordic workshop, November 2002. Available from: URL: http://www.norden.org/da/publikationer/publikationer/2003-401/at_download/publicationfile.
7. Johansson L, Solvoll K. Norkost 1997. Landsomfattende kostholdsundersøkelse blant menn og kvinner i alderen 16-79 år. Rapport nr. 2/1999, IS-0168, Statens råd for ernæring og fysisk aktivitet. (In Norwegian.) Available from: URL: http://www.shdir.no/vp/multimedia/archive/00003/IS-0168_3745a.pdf.
8. The Oslo Health Study (Helseundersøkelsen i Oslo, Hubro) 2000-2001. Available from: URL: http://www.fhi.no/eway/default.aspx?pid=238&trg=MainLeft_5895&MainArea_5811=5895:0:15,4225:1:0:0:::0:0&MainLeft_5895=5825:28244::1:5830:3:::0:0.
9. Helseundersøkelsen i Oppland 2000-2001. (In Norwegian). Available from: URL: http://www.fhi.no/eway/default.aspx?pid=233&trg=MainArea_5661&MainArea_5661=5631:0:15,3854:1:0:0:::0:0&MainLeft_5631=5757:28230::1:5641:1:::0:0.
10. Øverby NC, Kristiansen AL, Frost Andersen L, Lande B. Spedkost - 6 måneder. Landsomfattende kostholdsundersøkelse blant 6 måneder gamle barn. Rapport IS-1535, Oslo 2008, Helsedirektoratet, Mattilsynet og Universitetet i Oslo. (In Norwegian). Available from: URL: http://www.helsedirektoratet.no/vp/multimedia/archive/00054/IS-1535_54649a.pdf.
11. Lande B, Frost Andersen L. Kosthold blant 2-åringer. Landsomfattende kostholdsundersøkelse - Småbarnskost. Rapport IS-1299, Oslo 2005, Sosial- og helsedirektoratet. (In Norwegian). Available from: URL: http://www.shdir.no/vp/multimedia/archive/00006/IS-1299_6113a.pdf.
12. Pollestad ML, Øverby NC, Frost Andersen L. Kosthold blant 4-åringer. Landsomfattende kostholdsundersøkelse. Ungkost 2000. Rapport IS-1067, Oslo 2002, Sosial- og

helsedirektoratet. (In Norwegian). Available from: URL: http://www.shdir.no/vp/multimedia/archive/00002/IS-1067_2008a.pdf.

13. Øverby NC, Frost Andersen L. Ungkost-2000. Landsomfattende kostholdsundersøkelse blant elever i 4.- og 8. klasse i Norge. Rapport IS-1019, Oslo 2002, Sosial- og helsedirektoratet. (In Norwegian). Available from: URL: http://www.shdir.no/vp/multimedia/archive/00003/IS-1019_Ungkost_3756a.pdf.
14. Fagt S (2009). Unpublished results on body weight of adolescents and adults from the 2000-2002 survey of dietary habits in Denmark (ref. 21). National Food Institute. Technical University of Denmark.
15. Matthiessen J, Groth MV, Fagt S, Biltoft-Jensen A, Stockmarr A, Andersen JS, Trolle E. Prevalence and trends in overweight and obesity among children and adolescents in Denmark. Scand J Public Health 2008;36:153-60.
16. Fagt S (2009). Unpublished results on body weight of 1-3 year old children from the 1995 survey of dietary habit in Denmark (ref. 18). National Food Institute. Technical University of Denmark.
17. Fagt S (2009). Unpublished results on body weight of 4-14 year old children from the 2000-2002 survey of dietary habits in Denmark (ref. 21). National Food Institute. Technical University of Denmark.
18. Andersen NL, Fagt S, Groth MV, Hartkopp HB, Møller A, Ovesen L, Warming DL. Danskernes kostvaner 1995. Hovedresultater. Levnedsmiddelstyrelsen, Søborg, 1996. (In Danish with an English summary).
19. Fagt S (2009). Unpublished results from the 1995 survey of dietary habit in Denmark (ref. 18). National Food Institute. Technical University of Denmark.
20. Fagt S (2009). Unpublished results from the 2000-2002 survey of dietary habits in Denmark (ref. 21). National Food Institute. Technical University of Denmark.
21. Lyhne N, Christensen T, Groth MV, Fagt S, Biltoft-Jensen A, Hartkopp HB, Hinsch HJ, Matthiessen J, Møller A, Saxholt E, Trolle E (2005). Danskernes kostvaner 2000-2002. Hovedresultater (Dietary habits in Denmark 2000-2002. Main results). DFVF Publikation nr. 11. National Food Institute, Technical University of Denmark.
22. Environmental Protection Agency (2008). Child-Specific Exposure Factors Handbook, Table 8-1. Recommended values for body weight, EPA/600/R-06/096F, September 2008. Available from: URL: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=199243.
23. European Commission. Opinion of the Scientific Committee on Food on Bisphenol A. (Expressed on 17 April 2002). SCF/CS/PM/3936 Final, 3 May 2002. Available from: URL: http://ec.europa.eu/food/fs/sc/scf/out128_en.pdf.
24. International Life Sciences Institute (ILSI) Europe. Applicability of the acceptable daily intake (ADI) to infants and children. Consensus report of a workshop held in January 1997. ISBN 1-57881-018-3. 1998. Available from: URL: http://www.ilsi.org/Europe/Publications/R1997App_ADI.pdf.
25. Kersting M, Alexy U, Sichert-Hellert W, Manz F, Schöch G. Measured consumption of commercial infant food products in German infants: Results from the DONALD study. J Pediatr Gastr Nutr 1998; 27:547-52.
26. Petersen JH (2003). Proposal for a new paragraph in the food contact plastics legislation concerning an exposure based consumption factor applicable to migration limits for substances migrating from food contact materials for infants and young children. Letter to Luigi Rossi, Food Contact Materials Task Force, DG-SANCO. Note of 7. February 2003, File no 2002-20-222-00041, Danish Veterinary and Food Administration, Søborg, Denmark. National Food Institute. Technical University of Denmark.
27. Foster E, Adamson A (2006). Packaged food intake in children. FSA Project A03051, Final report to Food Standards Agency, June 2006. Available from: URL:

http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/contactmaterials/a03prog/a03projlist/a03051/.

28. Duffy E, Hearty AP, Flynn A, McCarthy S, Gibney MJ. Estimation of exposure to food-packaging materials. 2: Patterns of intakes of packaged foods in Irish children aged 5-12 years. Food Addit Contam 2006;23:715-25.
29. Bouma K, Stavenga K, Draaijer A. Domestic use of food packaging materials in the Netherlands. Report NDFCM010/01, August 2003. Available from: URL: http://www.vwa.nl/cdlpub/servlet/CDLServlet?p_file_id=10411.
30. International Life Sciences Institute (ILSI) Europe. Food consumption and packaging usage factors. Summary of a workshop held in July 1996. 1997. Available from: URL: http://www.ilsi.org/Europe/Publications/R1997Food_Con.pdf.
31. Trier XT, Petersen JH. Migration of primary aromatic amines from flexible laminated plastics. Fødevarerapport 2002:12. (In Danish with English summary).
32. Duffy E, Hearty AP, McCarthy S, Gibney MJ. Estimation of exposure to food packaging materials. 3: Development of consumption factors and food-type distribution factors from data collected on Irish children. Food Addit Contam 2007;24;63-74.
33. Scientific Committee on Food (SCF). Opinion of the Scientific Committee on Food on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials (expressed on 4 December 2002). CS/PM/3998 Final, 12 December 2002. Available from: URL: http://ec.europa.eu/food/fs/sc/scf/out149_en.pdf.
34. European Food Safety Authority (EFSA). 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 introduction of a Fat (consumption) Reduction Factor for infants and children. Question No EFSA-Q-2003-070. Adopted on 5 October 2004. EFSA J 2004;103:1-8. Available from: URL: http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/afc_opinion22_ej103_fatreducinfchild_en1.pdf?ssbinary=true
35. Petersen JH, Naamansen ET. DEHA-plasticized PVC for retail packaging of fresh meat. Z Lebensm Unters F A 1998;206:156-60.
36. The Commission of the European Communities. Commission Directive 97/48/EC of 29 July 1997 amending for the second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs. Available from: URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997L0048:EN:NOT.
37. The Council of the European Communities. Council Directive of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (85/572/EEC). Available from: URL: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/leg_files/85-572_en.pdf.
38. Summerfield W, Cooper I. Investigation of migration from paper and board into food – development of methods for rapid testing. Food Addit Contam 2001;18:77-88.
39. Parry SJ, Aston DSJ. Migration of inorganic contaminants into dry food from packaging made from recycled paper and board. Food Addit Contam 2004;21:506-11.
40. EU Commission. Draft community guidelines on migration testing of plastic materials and articles. EMB/1138. Available from: URL: http://www.slv.se/upload/dokument/nyheter/2009/Community_Guidelines_on_migration_testing_of_plastic.pdf.

41. The Food Migrosure Project. Modelling migration from plastics into foodstuffs as a novel and cost efficient tool for estimation of consumer exposure from food contact material. Available from: URL: http://www.foodmigrosure.com/.
42. Franz R. Migration modelling from food-contact plastics into foodstuffs as a new tool for consumer exposure estimation. Food Addit Contam 2005;22:920-37.
43. Tawfik MS, Huyghebaert A (1998) Polystyrene cups and containers: styrene migration. Food Addit Contam 1998;15:592-9.
44. Gilbert J, Rossi L. European priorities for research to support legislation in the area of food contact materials and articles. Food Addit Contam 2000;17:83-127.
45. Begley TH, Hsu W, Noonan G, Diachenko G. Migration of fluorochemical paper additives from food-contact paper into foods and food simulants. Food Addit Contam 2008;25:384-90.
46. Grob K, Pfenninger S, Pohl W, Laso M, Imhof D, Rieger K. European legal limits for migration from food packaging materials: 1. Food should prevail over simulants; 2. More realistic conversion from concentrations to limits per surface area. PVC cling films in contact with cheese as an example. Food Control 2007;18:201-10.
47. Begley T, Castle L, Feigenbaum A, Franz R, Hinrichs K, Lickly T, Mercea P, Milana M, O'Brien A, Rebre S, Rijk R, Piringer O. Evaluation of migration models that might be used in support of regulations for food-contact plastics. Food Addit Contam 2005;22:73-90.
48. EFSA (2005). 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 Bis(2-ethylhexyl)phthalate (DEHP) for use in food contact materials. Question Nº EFSA-Q-2003-191. Adopted on 23 June 2005 by written procedure. EFSA J 2005;243:1-20. Available from: URL: http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/afc_op_ej243_dehp_en2.pdf?ssbinary=true.
49. EFSA (2005). 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 a 7th list of substances for food contact materials. The EFSA Journal (2005)201, 1-28. Available from URL: http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/afc_op_ej201_fcm2.pdf?ssbinary=true.
50. The Council of the European Union. Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. Available from: URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0083:EN:NOT.
51. WHO (2008). Guidelines for drinking-water quality, third edition, incorporating the first and second addenda. Available from: URL: http://www.who.int/water_sanitation_health/dwq/fulltext.pdf.
52. EFSA (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 a 5th list of substances for food contact materials. EFSA J 2004;109:1-26. Available from URL: http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/afc_opinion20_ej109_list5_en1.pdf?ssbinary=true
53. Eisert R. The Exposure Matrix Project. Assessment of NIAS based on exposure data. (Data from Germany only.) Temadag om emballage, Copenhagen, 1 October 2009. Available from: URL: http://www.plast.dk/billeder/fakta/PlasticsEuropeexposurematrixprojectOct2009.pdf.

54. European Printing Ink Association (EuPIA). EuPIA Guideline on Printing Inks applied to the non-food Contact Surface of Food Packaging Materials and Articles - 17 April 2008 (update 21 September 2009). Available from: URL: http://www.eupia.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=10008E&eas:dat_im=05048E.
55. Langhammer J-P. How can the packaging chain work together for compliance with the GMP directive and other legislation in regard to printing inks? Temadag om emballage, Copenhagen, 1 October 2009. Available from: URL: http://www.plast.dk/billeder/fakta/PresentationJPLanghammerEuPIAcooperationinPackagingChain.pdf.
56. The Council of the European Economic Community. Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Available from: URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31967L0548:EN:NOT.
57. Kroes R, Renwick AG, Cheeseman M, Kleiner J, Mangelsdorf I, Piersma A, Schilter B, Schlatter J, van Schothorst F, Vos JG, Würtzen G. Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet. Food Chem Toxicol 2004;42:65–83.
58. The Norwegian Scientific Committee for Food Safety. Present and suggested use of the Threshold of Toxicological Concern (TTC) principle in areas of risk assessment relevant for the Norwegian Scientific Committee for Food Safety (VKM). A document providing background information for discussions within VKM. 05/902-4 final. 24 May 2006. Available from: URL: http://www.vkm.no/dav/14974abeca.pdf.
59. Binderup M-L, Pedersen GA, Vinggaard AM, Rasmussen ES, Rosenquist H, Cederberg T. Toxicity testing and chemical analyses of recycled fibre-based paper for food contact. Food Addit Contam 2002;19(Suppl 1):13-28.
60. The European Commission/Paper Industry. Biosafepaper. Application of bioassays for safety assessment of paper and board for food contact. Available from: URL: http://www.uku.fi/biosafepaper/.

APPENDIX

Norwegian food consumption and body weight data

The Norwegian food consumption data are taken from various studies, briefly described in the following. For more details, please see the respective reports.

Johansson L, Solvoll K. Norkost 1997. Landsomfattende kostholdsundersøkelse blant menn og kvinner i alderen 16-79 år (In Norwegian). Rapport nr. 2/1999, IS-0168, Statens råd for ernæring og fysisk aktivitet. (7) This cross-sectional, country-representative survey is comprised of a random sample of 2672 individuals (1291 men and 1381 women) aged 16–79 years drawn from the central population register (Statistics Norway). Dietary intake was obtained using a quantitative food frequency questionnaire with response categories for 180 typical foods and dishes in the Norwegian diet, as eaten during the previous year. The frequency choices were per day, per week or per month depending on food type. The amounts of food consumed were given in household measures (cups, spoons, slices etc.). The food frequency questionnaires were sent by mail and collected by home visits, or filled out during telephone interviews. Information on variables such as body weight, height, physical activity, smoking and intentions to eat healthily was also obtained. Information about socio-demographic variables was obtained from Statistics Norway. The food consumption data was presented as mean per person per day, and in some cases SD was given.

Øverby NC, Kristiansen AL, Frost Andersen L, Lande B. Spedkost - 6 måneder. Landsomfattende kostholdsundersøkelse blant 6 måneder gamle barn (In Norwegian). Rapport IS-1535, Oslo 2008, Helsedirektoratet, Mattilsynet og Universitetet i Oslo. (10) This cross-sectional, country-representative survey is comprised of 3000 children in Norway drawn from the central population register (Statistics Norway), and includes all children born in Norway during a three-week period from April 17 - May 8, 2006, of mothers born in Norway, Sweden or Denmark. In total, 1986 children participated; 993 boys and 987 girls, as well as 6 children for whom gender were not specified. Dietary intake was obtained using a food frequency questionnaire. Information on mother's age, the parents' education, number of children born by the mothers, time of birth relative to expected birth date, mother's family situation and work situation, mother's smoking and allergy/asthma in the family, was also obtained. Various questions about breast-feeding were also included. The children's length and body weight were recorded by health personnel at the ordinary six-month control. Intake data was presented as mean and SD, as well as percentiles for some food types.

Lande B, Frost Andersen L. Kosthold blant 2-åringer. Landsomfattende kostholdsundersøkelse - Småbarnskost (In Norwegian). Rapport IS-1299, Oslo 2005, Sosial- og helsedirektoratet. (11) This cross-sectional, country-representative survey is comprised of 3000 2-year old children in Norway drawn from the central population register (Statistics Norway), and includes all children born in Norway during a three-week period from March 8-27, 1997, of mothers born in Norway or other Scandinavian countries. In total, 1720 children participated in the survey, 868 were boys and 852 were girls. Dietary intake of 135 food types was obtained using a semi-quantitative food frequency questionnaire describing the food consumption as close to two years of age as possible, and should be representative for the child's normal diet during the last 14-day period. Photos were used to identify amount of food eaten, or given in household measures (cups, spoons, slices etc.). Information on avoiding consumption of potentially allergenic food types, the parents' education, number of children born by the mothers, time of birth relative to expected birth date, mother's family situation and work situation, and allergy/asthma in the family, was also obtained. Various questions about breast-feeding were also included. The children's length and body weight were recorded by health personnel at the ordinary two-year control. Intake data was presented as mean and SD, as well as percentiles for some food types.

Pollestad ML, Øverby NC, Frost Andersen L. Kosthold blant 4-åringer. Landsomfattende kostholdsundersøkelse. Ungkost 2000 (In Norwegian). Rapport IS-1067, Oslo 2002, Sosial- og helsedirektoratet. (12) This cross-sectional, country-representative survey is comprised of 9 urban municipalities and 18 rural municipalities in Norway drawn from the central population register (Statistics Norway). Of the 391 4-year old children participating in the survey august – desember 2001 by registering their food consumption using a 4-day pre-coded food diary, the parents of 332 children also answered a short questionnaire about height, body weight, where the child spent most of its daytime, the parents' education, time spent by the child with TV, video, PC etc., as well as meal patterns and frequency of some food types. The amounts of food consumed were given in household measures (cups, spoons, slices etc.). Portion sizes were estimated from photos of different portion sizes. Intake of energy, nutrients and food types was presented as mean and SD.

Øverby NC, Frost Andersen L. Ungkost-2000. Landsomfattende kostholdsundersøkelse blant elever i 4.- og 8. klasse i Norge (In Norwegian). Rapport IS-1019, Oslo 2002, Sosial- og helsedirektoratet. (13) This cross-sectional, country-representative survey is comprised of a random sample of 105 schools in 53 municipalities in Norway, where one school with 4th grade (9-year old) pupils and one school with 8th grade (13-years old) pupils were invited to participate. Data from 1824 pupils are included in the analyses, 815 9-year old pupils (411 girls and 404 boys) and 1009 13-year old pupils (517 girls and 492 boys). Dietary intake was obtained using a 4-day pre-coded food diary. The amounts of food consumed were given in household measures (cups, spoons, slices etc.). Portion sizes were estimated from photos of different portion sizes. Information on variables such as height, body weight, physical activity, smoking (only for 13-year-olds), intentions to eat healthily, frequency of some food types, as well as parents' education was obtained with a separate questionnaire. Intake of energy, nutrients and food types was presented as mean and SD.

Adult body weight data from Norway was also obtained from the following studies:

The Oslo Health Study (Helseundersøkelsen i Oslo, Hubro) 2000-2001. (8) The Oslo Health Study (HUBRO) was conducted in the city of Oslo from May 2000 to September 2001. The study consisted of an adult part where more than 18 000 individuals participated (46 % of all invited). An invitation was sent to all men and women born in 1924, 1925, 1940, 1941, 1955, 1960 and 1970. The participants completed questionnaires in a health examination. The data generated from this health study have been used to build a health profile (in Norwegian), a comprehensive overview of the health status of Oslo residents.

Helseundersøkelsen i Oppland 2000-2001 (In Norwegian). (9) In 2000 and 2001, Statens helseundersøkelser, which today is part of the Norwegian Institute of Public Health, performed a health study in the Norwegian counties Hedmark and Oppland (OPPHED). An invitation was sent to all men and women born in 1925, 1940, 1955, 1960, 1970 and 1985, more than 25 000 men and women. The participants completed questionnaires in a health examination. The data generated from this health study have been used to build a comprehensive overview of the health status of people living in the counties Hedmark and Oppland.

Danish food consumption and body weight data

The Danish data is retrieved from two nationwide dietary surveys, described below. Some of the data shown in this report has not been published.

The Danish National Survey of Dietary Habits 1995. (15, 16, 18, 19) The food consumption data is provided from this survey, which is a cross-sectional survey comprising a sample stratified by age and sex of 3098 individuals aged 1–75 years from the central population register. Dietary intake was obtained using a 7-day pre-coded food diary with response categories for the most commonly eaten foods and dishes in the Danish diet supplemented with open-ended alternatives. The amounts of food consumed were given in household measures (cups, spoons, slices etc.) or estimated from photos of different portion sizes showing four different portions. Trained interviewers from PLS Consult gave instructions on how to complete the food diary and how to estimate portion sizes. The interviewers also conducted in-person interviews in order to obtain information on variables such as social background, leisure-time physical activity, height, body weight and intentions to eat healthily. The mean food consumption was calculated for each individual based on Danish Food Composition Tables, 4. edition, 1996, National Food Administration, Søborg, Denmark.

The Danish National Survey of Dietary Habits and Physical Activity 2000-2002. (14, 15, 17, 20, 21) The food consumption data is provided from this survey, which is a cross sectional survey comprising a random sample of 4120 individuals aged 4–75 years from the central population register. Dietary intake was obtained using a 7-day pre-coded food diary with response categories for the most commonly eaten foods and dishes in the Danish diet supplemented with open-ended alternatives. The amounts of food consumed were given in household measures (cups, spoons, slices etc.) or estimated from photos of different portion sizes showing four to six different portions. Trained interviewers from the Danish National Institute of Social Research gave instructions on how to complete the food diary and how to estimate portion sizes. The interviewers also conducted in-person interviews in order to obtain information on variables such as social background, leisure-time physical activity, height, body weight and intentions to eat healthily. The mean food consumption was calculated for each individual using the General Intake Estimation System (GIES) version 0.995a (Danish Institute for Food and Veterinary Research, Søborg, Denmark).