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Estimation of exposure to food packaging materials. 3. Development of consumption factors and food type distribution factors from data collected on Irish Children.

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Abstract

There are many initiatives in Europe to try to refine the exposure assessment for food packaging migrants. In the USA, the Food and Drug Administration (FDA) use food consumption and food type distribution factors to aid the exposure assessment process and generate more realistic estimates of exposure. The present study developed food consumption factors and food type distribution factors for Irish children aged 5-12 years from data collected as part of a National Children's Food Survey (NCFS) completed in Ireland in 2003-04, combined with data from the 2003-05 Irish Food Packaging Database and from literature data on surface area to weight ratios for food packaging. Consumption factors are defined as the fraction of a person's diet likely to contact a specific food contact material while food type distribution factors reflect the fraction of all food contacting each material that is aqueous, acidic, alcoholic or fatty. In this study, it was found that "total plastics" had the highest consumption factor of 0.83, while "total paper & board" had a factor of 0.13 and "total metal & alloys" had a factor of 0.06. Although it is tentative to compare the FDA factors with the factors derived in the current study, as the FDA data is for the total US population, the consumption factor for "total plastics" in the present study (0.83) was similar to that used by the FDA (0.79). However, a large difference existed for the consumption factor for "total metal & alloys" in the Irish data (0.06) and the FDA data (0.2). In terms of the type of materials used for foods, glass was used mainly for acidic foods (0.67) while plastic was uniformly used for all food types. The food contact area for plastic packaging for all foods consumed by children was 10.67 dm²/child/day, which is slightly lower than the proposed value for the average European consumer of 12.4 dm²/person/day (ILSI 1997). However this should be expected, as children do not

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3 consume as much food as adults. When scenario exposure estimates were made, it
4 was found that when using EU assumptions, estimates were much larger than when
5 using consumption factors and food type distribution factors in the exposure
6 assessment, even when conservative assumptions were employed for the consumption
7 factor. This study highlighted the potential use of consumption factors and food type
8 distribution factors in the refinement of the exposure assessment process and how
9 these factors can be calculated using data collected as part of a national food survey.
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16 17 18 **Introduction**

19 Over the past number of years the refinement of exposure assessments for food
20 packaging migratory compounds has been under discussion among regulators and the
21 food packaging industry. One of the main issues is that the current method in the EU
22 is viewed as being overly conservative and does not give any indication of the true or
23 real exposure to a food packaging migrant. To refine the exposure assessment,
24 progress has been made in relation to the use of probabilistic exposure assessment
25 modeling to estimate exposure to a food packaging migrant (Holmes et al. 2005). This
26 methodology accounts for variability and uncertainty in the exposure assessment and
27 provides a more realistic exposure based on available data and on expert opinion.
28 Probabilistic modeling is also used for the exposure assessment of other food
29 chemicals. However, it is only undertaken when there is a need for a highly refined
30 estimate of exposure. The general approach to exposure assessments is a step-wise
31 approach, which begins with crude screening methods based on worst case
32 assumptions and then proceeds to more refined methods, if results from crude
33 methods dictate the need to do so (Nutriscan 1994, Gibney & Lambe 1996, European
34 Commission 1998, Kroes et al. 2002).
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50 If the principles of this tiered approach for other food chemicals are borne in mind
51 when examining exposure to food packaging migrants, there is a need for another tier
52 between the current conservative method used by the EU and the highly refined
53 probabilistic exposure assessment for food packaging migrants. An approach similar
54 to the one currently used in the US by the Food and Drug Administration (FDA) to
55 calculate intakes of food packaging migrants could be viewed as being more realistic
56 than the current EU method but less refined than probabilistic exposure modeling.
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3 This approach is a deterministic as a single value is chosen for each parameter in the
4 exposure algorithm yielding a single estimate of exposure.
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9 The US FDA estimates probable exposure to food contact substances (FCS) by
10 combining migrant levels in food, often from migration studies, with information on
11 the uses of food-contact articles that may contain the FCS (i.e. on the fraction of a
12 person's diet likely to contact food-contact articles containing the FCS) (FDA 2002).
13 Both the concentration in the daily diet (i.e. dietary concentration) and the estimated
14 daily intake (EDI) from the FCS and the cumulative EDI (CEDI) from all regulated
15 uses and effective food contact notifications is used by the FDA in the safety
16 evaluation of a FCS. The approach is designed to deal with the majority of FCSs
17 intended for single use. In this calculation, a number of factors are combined to
18 estimate potential exposure. "Consumption factors" describe the fraction of the daily
19 diet expected to be in contact with specific packaging materials. To account for the
20 variable nature of food contacting each food contact article, the FDA has calculated
21 "food-type distribution factors" for each packaging material to reflect the fraction of
22 all food contacting each material that is aqueous, acidic, alcoholic or fatty. This
23 information is then combined with migrant levels in food and a total food intake of
24 3kg per person per day (total solids and liquids) to calculate exposure to a food
25 migratory compound.
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40 If an approach similar to that of US FDA for estimating exposure to food packaging
41 migrants was adopted in the EU, it could be viewed as the next tier in the exposure
42 assessment of migrants. However the FDA approach has not been adopted in Europe
43 for a number of reasons. A major factor is that the EU and US differ in their approach
44 to regulating chemicals for use in food contact materials. In the US, a petition is
45 submitted to the FDA for approval of, for example, a unique FCS, such as an
46 antioxidant, for use in a polymer in contact with a specific food type. Therefore
47 approval for this FCS is for use in that particular polymer, which in turn is used for a
48 specific food. If this FCS is then used in a different polymer or this polymer is used
49 for a different food group, this new use would then need separate approval. In the EU,
50 once a chemical is permitted for use in plastics it can be used in any plastic for any
51 food type provided that it complies at all times with safety criteria. Therefore, for
52 chemicals with a wide range of end applications, the current EU exposure assessment
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3 method may not overestimate intakes by a large margin. In the US, the FDA has
4 collected the data to compute the consumption factors and food-type distribution
5 factors. However, no such data have been collected in the EU. The EU and US also
6 differ in relation to the use of exposure assessment data. In the US, toxicology data
7 requirements are tiered to correspond to the potential dietary exposure to the
8 substance in question (Heckman 2005). However in the EU, migration data
9 determines the toxicology requirements and exposure assessments are used mostly to
10 demonstrate adherence with the tolerable daily intake (TDI).
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19 The argument regarding which system (FDA exposure data or EU migration data) is
20 superior for regulatory clearance of a substance has been discussed comprehensively
21 (Heckman 2005) and is not the topic of the current study. Instead, the aim of the
22 present study was to create consumption factors and food type distribution factors
23 similar to those used by the FDA from data collected as part of an Irish national food
24 consumption survey. These factors, which are for Irish children aged 5-12 years, were
25 derived using data on food consumption, packaging usage and surface area to weight
26 ratios. These factors were calculated to highlight how similar factors could be created
27 for other countries if food consumption surveys collected information on packaging
28 used for foods.
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38 **Methodology**

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40 In this study, consumption factors and food type distribution factors similar to those
41 used by the FDA were calculated. Due to differences in the underlying data there
42 were small differences in the methodology used to calculate the FDA consumption
43 factors and those presented in this paper. The FDA used data on the types of food
44 consumed, the types of food contacting each packaging surface, the number of food
45 packaging units in each food packaging category, the distribution of container size
46 and the ratio of the weight of all food packaged to the weight of the package. All of
47 this data was obtained from market data analysis (FDA 2002). In the present study,
48 factors were calculated based on (1) food consumption data, (2) packaging use data,
49 and (3) surface area to weight ratios for the area of a packaging material contacting a
50 food. This information was obtained from a number of different sources outlined
51 below.
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(1) Food Consumption Data

The National Children's Food Consumption Survey (NCFS) was a cross-sectional study of food and nutrient intakes of a representative sample of 594 Irish children aged 5-12 years (IUNA 2005). A 7-day weighed food record was used to measure food and beverage intakes. Respondents recorded the day, time, location and meal type for each eating occasion, along with a detailed description of the food, the weight of the food and the packaging used for the food. The weight of food consumed in the NCFS was corrected, where necessary, to reflect the amount of that food that was actually packaged and not just the amount of food consumed. These correction factors were applied to dried or dehydrated foods that were reconstituted before consumption (e.g. dried soups, sauces, gravies, custards, pasta dishes etc). A complete list of these factors is available in Duffy et al. 2006a.

Each food consumed in the NCFS was assigned into one of the food types outlined in European Council Directive 85/572/EEC (i.e. aqueous, acidic, alcoholic or fatty) (European Council 1985). A food type was also created for dried and frozen foods, which are recognised in the EU as having no migration potential, this groups was referred to as the "dry" group. The FDA also uses similar food groupings to create their "food-type distribution factors" with the exception of a "dry" food type. These factors are used to reflect the fraction of all food contacting each material that is aqueous, acidic, alcoholic and fatty. Therefore, by coding each food in the NCFS into one of these food types, a food type distribution factor was calculated. As alcoholic products were not used in this sample age group, there were no foods classified as alcoholic. However, a food type distribution factor was calculated for dry food types.

(2) Packaging usage data

The packaging used for each food consumed in the NCFS was documented in the subjects' diary and the actual packaging used for the food was also collected and forwarded to the coordinating centre where it was used to develop the Irish Food Packaging Database (IFPD) (Duffy et al. 2006b). The IFPD was created to store exact information on the type of packaging used for foods (e.g. clear plastic wrapper), the contact layer of this packaging format (e.g. plastic) and the exact polymer used for the plastic contact layer if available (e.g. polyethylene). For food items with more than one material in contact with the food, this packaging format was also recorded. For

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example, glass jars with metals lids were categorised into the packaging group “glass and metal and alloys”. Other combinations of packaging materials in contact with the food included glass and plastic (e.g. chocolate spread packaged in a glass jar with a plastic lid), metal and alloys and paper (e.g. Chinese takeaway packaged in an aluminium tray with a paper lid), metal and alloys and plastic (e.g. cream cheese packaged in a plastic container with an aluminium foil lid), and plastic and paper and board (e.g. chocolate biscuits packaged in a plastic wrapper with an inner paper tray). Full details of the analyses of this database are available in Duffy et al. 2006a.

(3) *Surface area to weight ratios*

Before calculating consumption factors and food type distribution factors, the amount of each food consumed was corrected to take into account the amount of contact it had with a specific packaging material. Due to resource constraints, the surface area of the packaging in contact with the food was not calculated in this study. However literature from previous studies was used to assign surface area to weight ratios to the food packaging formats. These ratios and their sources are documented in Table 1. As some foods had more than one type of material in contact with its’ surface (e.g. plastic wrapper and paper tray), food surface area to weight ratios were used for the total packaging in contact with the food. Surface area to weight ratios were not available for all foods and hence a conservative surface area to weight ratio of 12 dm²/kg was used in the absence of more specific data. The factor of 12 dm²/kg was used as recent studies have shown that the currently used default in the EU of 6 dm²/kg is not accurate and underestimates the surface area to weight ratio of food in contact with packaging for many foods (Bouma et al. 2003; Grob et al. *in press*). Closures with large mass-to-surface areas were not accounted for in this study, instead only the fact that package type actually contained that type of closure was documented i.e. glass jars with metal lids were classified as “glass and metal and alloys”. Therefore liners (for plastic lids) or sealing gaskets (for metal lids) were not accounted for in the derivation of the packaging factors.

[Insert Table 1 about here]

Consumption Factors

Information from the consumption database, packaging database and surface area to weight ratios were merged to create an information source, which included all the relevant details to enable the development of consumption factors. Similar to the FDA approach, the consumption factors developed in the present study represent the ratio of the amount of a specific contact material used to the amount of all contact materials used. In the food consumption survey, there were 2.5% (n=1808) of eating events where no information was recorded on the packaging status of the food consumed (i.e. whether it was packaged or not). These unknown entries were not included in the analysis. As some plastic contact layers had their polymers identified, consumption factors were also calculated for the main polymer types identified in the study. To represent the plastic contact materials that did not have their specific polymer identified, a consumption factor for “unidentified polymers” was created.

By combining the three datasets (food consumption, packaging use and surface area to weight ratio factors) consumption factors (c_m) were calculated for each contact material m . These factors were separately calculated for each specific material in contact with the food (e.g. plastic) and when these materials were used in combination with other materials in contact with the food (e.g. plastic and paper). The following equation was used:

$$c_m = \frac{\sum_f a_{fm} s_{fm}}{\sum_m \left(\sum_f a_{fm} s_{fm} \right)}$$

where a_{fm} is the amount consumed of food f packaged in food contact material m . s_{fm} is the surface area to weight ratio for food f packaged in material m .

The product $a_{fm} s_{fm}$ is summed over all foods f , so that the numerator gives the total amount of contact material m used.

The denominator is equal to the numerator summed over all contact materials m .

Hence it corresponds to the total amount of all contact materials used.

Therefore c_m is the ratio of the amount of contact material m used to the amount of all contact materials used.

Food type distributions factors

Food type distributions factors, d_{mt} , correspond to the fraction of all packaging material m that is used with food of type t . The four types of food are: aqueous, acidic, fatty and dry (no alcoholic foods were consumed in this study). The distribution factors were calculated separately for each specific material in contact with the food and when these materials were used in combination with other materials. The following equation was used:

$$d_{mt} = \frac{\sum_f a_{fnt} s_{fnt}}{\sum_t \left(\sum_f a_{fnt} s_{fnt} \right)}$$

where a_{fnt} is the amount consumed of food f , where food f is packaged in food contact material m , and is of type t (where t is either aqueous, acidic, fatty or dry). s_{fnt} is the surface area to weight ratio for that food f (packaged in contact material m and of type t). The product $a_{fnt} s_{fnt}$ is summed over all foods f , so that the numerator gives the total amount of contact material m used with food of type t .

The denominator is equal to the numerator summed over all food types t . Hence it corresponds to the total amount of contact material m used with food of any type.

Therefore d_{mt} is the fraction of packaging material m that is used with food of type t .

Exposure calculations

In the FDA document entitled "Guidance for Industry" an example of how to apply food consumption factors and food type distribution factors to estimate exposure to a proposed new antioxidant in polyolefins is provided (FDA 2002). A similar example of such an exposure assessment was completed using data from this study for the addition of a new antioxidant to polyethylene. Four deterministic exposure scenarios were completed for this antioxidant. In the first scenario, some of the EU assumptions

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3 for calculating the intake of a chemical migrant (i.e. that 1 kg of packaged food is
4 consumed per day and that the chemical migrates at the maximum permitted level i.e.
5 at the specific migration limit of 15mg/kg in this scenario) and a body weight of 30kg
6 for children were used to calculate exposure to the antioxidant. In the next scenario no
7 migration data were available and hence the SML value of 15mg/kg was used again
8 but the consumption factor for polyethylene (Table 2) was used. This was in addition
9 to children's consumption of packaged food and the mean body weight of children, as
10 derived in the current study. The next two scenarios used consumption factors, food
11 type distribution factors and real migration data in addition to data on children's
12 consumption of packaged food and the mean body weight of children. In the first of
13 these two scenarios, the consumption factor used was a conservative consumption
14 factor, as it was the sum of the consumption factor for "polyethylene" and
15 "unidentified polymers" as some of the unidentified polymers could have been
16 polyethylene and therefore by using the consumption factor for unidentified polymers
17 (in addition to the consumption factor for polyethylene) it was assumed that all of
18 these unidentified polymers were polyethylene. In the other of these exposure
19 scenarios, the consumption factor for polyethylene only was used. Full details of these
20 calculations are described in the appendix.
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37 *Food contact area*

38 Another method previously used in the EU to estimate potential exposure to food
39 packaging was to calculate the food contact area exposure of individuals to packaging
40 i.e. $\text{dm}^2/\text{person}/\text{day}$ (ILSI 1997). The food contact area for all packaging was
41 calculated and again this was a combination of data on food consumption, packaging
42 usage and surface area to weight ratios. The amount of food packaging area used for
43 all foods consumed was initially calculated for each day for each child. This was then
44 averaged over the seven days the children completed the survey to get the average
45 daily food contact area used by each child in the survey. These values were then
46 averaged to get the mean food contact area for packaging used by all children as well
47 as the upper percentiles. The food contact area used for plastics was also calculated in
48 addition to the mean and upper percentiles of food intake and body weight.
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Results

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4 As some of the food packaging formats (9.5%, n=350) had more than one material in
5 contact with the food (i.e. glass jar and metal lid), results for the consumption factor
6 and food type distribution factor for a specific material were calculated when the
7 material was the sole contact layer and also when it was used in combination with
8 another material that was also a food contact layer.
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14 A consumption factor was calculated for the materials in contact with foods. Table 2
15 lists the consumption factors for each contact layer. “Total plastics” had the highest
16 packaging factor of 0.83, while “total paper & board” had a factor of 0.132 and “total
17 metal & alloys” had a factor of 0.061. Although the exact polymer used for all plastic
18 contact layers was not identified, a consumption factor was calculated for the main
19 polymers identified in the study with polyethylene having the highest factor at 0.332.
20 Equivalent FDA factors are also provided in Table 2 to allow comparison between the
21 data sets. The packaging factor for “total plastics” was quite similar in the Irish data
22 (0.83) and the FDA data (0.791). However, a large difference existed for the
23 consumption factor for “total metal & alloys” in the Irish data (0.061) and the FDA
24 data (0.2).
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39 The food-type distribution factors, which represent the fraction of the different types
40 of food in contact with each contact material, are recorded in Table 3. “Total glass”
41 was used mainly for acidic foods (0.670) and “total metals & alloys” were also
42 predominately used for acidic foods (0.551). “Paper & board” was primarily used for
43 dry foodstuffs (0.775). There was no specific food type packaged in plastic as it was
44 used uniformly for all food types in this study (i.e. aqueous, acidic, fatty and dry).
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51 [Insert Table 3 about here]
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55 The results of the exposure scenarios for the new hypothetical antioxidant for use in
56 polyethylene are presented in Table 4. In the first scenario, which used some of the
57 EU assumptions, an exposure of 15mg/day or 0.5mg/kg body weight/day was
58 calculated. The next scenario, which used consumption factors and the SML, resulted
59 in an exposure of 5.95mg/day or 0.18mg/kg body weight/day. For the scenario that
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3 used the conservative consumption factor, the estimated exposure was 0.39mg/day or
4 0.12mg/kg body weight/day, while when the consumption factor for polyethylene
5 only was used the exposure estimate was 0.22mg/day or 0.01mg/kg body weight/day.
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8 [Insert Table 4 about here]
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12 The mean food contact area used for all packaged foods was 13.44 dm²/child/day.
13 This corresponded to an intake of packaged food of 1195g/child/day (Table 5). The
14 upper percentiles of food contact area used for all foods were 19.58 dm²/child/day
15 (95th percentile) and 20.73 dm²/ child /day (97.5th percentile). When the food contact
16 area for plastic packaging only was calculated, the mean value was 10.67
17 dm²/child/day with upper percentiles of 15.86dm²/child/day (95th percentile) and
18 17.58dm²/child/day (97.5th percentile).
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26 [Insert Table 5 about here]
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32 Discussion

33 The tiered approach to food chemical intake has won general acceptance
34 internationally (Douglass & Tennant 1997) and is used for food additives, pesticides
35 and other food chemicals and contaminants. This methodology prevents unwarranted
36 data collection and ensures that resources for the collection of data are put to the best
37 use (Gibney & Lambe 1996). The factors derived in this study can be applied to
38 derive a more realistic deterministic estimate of exposure to food packaging materials
39 for Irish children. As can be seen from Table 4, when assumptions from the EU
40 exposure assessment approach for food packaging migrant were used, the exposure
41 estimate was much greater than the exposure estimates when using the consumption
42 factors and/or the food type distribution factors. In one scenario a conservative
43 consumption factor was used in the assessment as it allowed for the fact that some
44 polymers, which were not identified, could have been polyethylene. The result of this
45 scenario assessment was still much lower than the estimate obtained when using the
46 EU assumptions, even though it was conservative. Further conservatism could be built
47 into the exposure assessment if the upper percentiles of food intake were used to
48 estimate the exposure instead of the mean food intake. Therefore, even by combing
49 more realistic data, conservatism can still be ensured in the overall exposure estimate.
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5 The factors derived in this study are representative of consumption factors and food
6 type distribution factors for Irish children aged 5-12 years. Due to the fact that no
7 alcoholic products were consumed, no food type distribution factors could be derived
8 for the fraction of alcoholic products contacting each packaging material. Therefore,
9 these factors are not representative of Europe or Irish adults and differ from the FDA
10 factors as the FDA factors were derived for the entire US population and, as such
11 provide per capita exposure estimates (Komolprasert 2005, personal communication).
12 However the construction of this dataset demonstrates how consumption factors and
13 food type factors can be derived based on information collected as part of a food
14 consumption survey and form the basis to which more information from other
15 countries could be added in order to achieve more representative factors.
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26 The categories of food contact materials used by the FDA and those used in this study
27 differed to some extent. In this study, the materials types listed in Table 2 and 3 are
28 only for materials in contact with the food. For example, in the case where paper had
29 a coating of plastic and it was solely the plastic layer that was in contact with the food
30 (i.e. there was no paper in contact with the food) this material was recorded as plastic
31 in the present study whereas the FDA classified this as paper-polymer coated. Also in
32 this study, all canned foods were classified as packaged in “metal & alloys” with no
33 distinction being made between uncoated and polymer coated cans. Despite these
34 differences when comparisons were made between the factors used by the US FDA
35 and those derived from this study, there were a lot of similarities especially for plastic
36 materials, which are the materials that receive the most attention in terms of exposure
37 assessments and regulatory compliance. The factor derived in this study for “total
38 plastics” was 0.83 while when a similar figure was derived from the FDA data the
39 factor was 0.79. This highlights that in both the US and Ireland plastic packaging
40 dominates as the material that is used most commonly for foods. However, it must be
41 remembered that the FDA data is for the total population and therefore comparisons
42 between the FDA factors and the factors derived in this study are completely
43 speculative.
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A workshop organised by the ILSI Europe Packaging Material Task Force discussed food consumption and packaging usage factors to aid the refinement of the exposure

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3 assessment process currently used in Europe (ILSI 1997). During this review data
4 from Maurice Palmer Associates (MPA 1995) was processed to estimate the food
5 contact area for all packaging used by individuals across Europe and it was estimated
6 at a mean value of 20.1 dm²/person/day, while the mean food contact area for plastics
7 was 12.4 dm²/person/day. The figure derived in the present study for the food contact
8 area of all packaging material used by children was 13.44 dm²/child/day, while the
9 food contact area for plastics was 10.67 dm²/child/day. These value differs greatly
10 from the food contact area value of 6 dm²/person/day currently used in the EU
11 exposure assessment. The average plastics food contact area proposed for Europe of
12 12.4 dm²/person/day may seem reasonably close to the figure derived in this study of
13 10.67 dm²/child/day. However, the figure derived in the present study was for
14 children only and adult exposure to food contact material should be higher due to their
15 relatively higher food intake. During the course of the ILSI workshop, it was noted
16 that Ireland and the Benelux countries had a higher use of plastics at 17-19
17 dm²/person/day compared with other countries. This may explain why Irish children
18 have food contact exposure quite similar to the average EU adult consumer as there
19 may be an overall trend for higher food contact area exposure in Ireland compared
20 with other European countries. In light of these results, if the aim of the exposure
21 assessments is to ensure conservatism then the proposed EU average food contact area
22 use may need to be revised upwards to ensure the exposure assessment protects
23 consumers at the upper end of food packaging use and not just the average consumer.
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42 In addition to proposing food consumption factors for the EU, the ILSI workshop
43 focused on how the FDA approach could be applied in the EU for regulatory approval
44 of a substance for use in food packaging. It concluded that this method could have
45 applications for monomers and additives with defined numerical TDIs and specified
46 single polymer use, dossier applications for approval for single polymer use, and
47 applications to the threshold of no regulatory concern for recycling (ILSI 1997).
48 However even if an approach similar to the FDA was not adopted in Europe for
49 regulatory approval of a substance, these consumption and food type distribution
50 factors could be used to perform more realistic exposure assessments in cases of
51 concern regarding the presence or quantity of a migrant in foods post approval of the
52 substance. This would ultimately lead to a more time and resource efficient exposure
53 assessment as well as being more refined and realistic on which to base opinions
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3 regarding the safety of the migrant in question. However if this method of exposure
4 assessment shows that there may still be concerns (i.e. the exposure level approaches
5 or exceeds the TDI) regarding the exposure to a migrant, then more refined exposure
6 assessments could be computed using probabilistic modelling. In a recent safety
7 assessment by the Food Additives, Flavourings, Processing Aids and Materials in
8 Contact Food (AFC) scientific panel of the European Food Safety Authority (EFSA),
9 an opinion was provided on the exposure of adults to epoxidised soybean oil (ESBO)
10 used in food contact materials (EFSA 2006). After completing a conservative
11 exposure scenario, the panel noted that the potential dietary exposure of adults to
12 ESBO was below the TDI and therefore refinement of the exposure estimates was not
13 necessary. However this conservative exposure assessment still required collection of
14 multiple datasets on migration, food consumption and packaging use across Europe
15 and then the merger of all this data in order to perform an exposure assessment. Much
16 of this preliminary data collection could be eliminated with the use of consumption
17 factors and food type distribution factors, making the task of estimating exposure
18 from food contact materials more approachable.
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33 The demand for more refined exposure assessments for food packaging migrants has
34 been linked with the concept of the threshold of toxicological concern in Europe
35 (TTC). The TTC is a pragmatic risk assessment tool that is based on the principle of
36 establishing a human exposure threshold value for all chemicals, below which there is
37 a very low probability of an appreciable risk to human health (Kroes et al. 2004). This
38 concept, known as the threshold of regulation (TOR) in the US, has been used by the
39 FDA since 1995 when it was decided that due to their low potential health concern,
40 components of food contact materials present in the diet at a dietary concentration of
41 0.5 parts per billion (ppb) or less are subjected to an abbreviated regulatory review.
42 The main objective of this abbreviated regulatory review is to ascertain that the
43 dietary concentration resulting from the intended use is at or below the threshold level
44 and that there is no reason to suspect, based on test data in humans or animals or
45 chemical structure, that the substance may be a carcinogen (Cheeseman et al. 1999). It
46 is recognised by the FDA that the TOR process is a safety review process based on
47 probabilistic assessment of risk and therefore an estimation of consumer exposure is
48 fundamental to its implementation (Cheeseman, 2005). An expert group was
49 convened in Europe to review the TTC principle and they concluded that it could be
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3 applied for low concentrations in food of chemicals that lack toxicity data, provided
4 that there is a sound intake estimate (Barlow et al. 2001). Therefore without a more
5 refined or “sound” exposure assessment for migrants from food contact materials, the
6 TTC principle cannot be used in Europe for food packaging migrants. If
7 representative consumption factors and food type distribution factors were developed
8 for Europe then the TTC concept may have application for the safety assessment of
9 polymerisation production aids, impurities, reaction by products and aids to
10 polymerisation, if the regulators approved its use.
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19 **Conclusion**

20 Consumption factors and food type distribution factors may prove useful in the
21 refinement of the current EU method for estimating exposure to food packaging
22 migrants. They could be employed when a more realistic exposure assessment is
23 needed, if there is concern over the presence of a migrant in a food, or for use with the
24 TTC. Their use in exposure assessments could ultimately lead to a more uniform,
25 simple and realistic exposure assessment process. However, only the regulators and
26 the quality of data collected can determine their use for regulatory approval of a
27 substance.
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41 Development who provided support through the Food Institutional Research Measure
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Appendix: Exposure assessment of a hypothetical antioxidant in polyethylene using different methodologies

Exposure Scenario

The following hypothetical exposure scenarios are intended to illustrate the calculation of the concentration of a food packaging migrant in the daily diet using some of the EU assumptions and the more refined method of employing consumption factors and food type distribution factors. In the FDA document entitled “Guidance for Industry” an example of how to apply food consumption factors and food type distribution factors to estimate exposure to a hypothetical antioxidant in polyolefins is provided (FDA 2002). In the following exposure scenarios it shall be assumed that the new antioxidant is used in polyethylene materials only and has a specific migration limit (SML) of 15mg/kg in the European union.

1. Deterministic exposure estimate using EU assumptions.

For an adult, the EU exposure assessment methodology for food packaging migrants assumes that a 60kg person consumes 1kg of food packaged in the material of interest and that migration occurs at the maximum permitted level. There are no set guidelines on how to estimate intakes in children, therefore if we assume that children also consume 1kg of food packaged in the material of interest, which migrates at the SML, but that they have a body weight of 30 kg¹ we can estimate the intake of the antioxidant. The following parameters are used in the exposure calculation:

Food Consumption:	1kg
Body Weight:	30kg
Migration of antioxidant into the food:	15mg/kg

Estimated Daily intake (EDI)

$$= \text{Migration (mg / kg food)} \times \text{Food consumption (kg/day)}$$

$$= 15 \text{ mg antioxidant /kg food} \times 1 \text{ kg food /day}$$

$$= 15 \text{ mg / person / day}$$

Intake per kg body weight

$$= \frac{\text{Estimated daily intake (mg / person / day)}}{\text{Body weight (kg)}}$$

$$= \frac{15 \text{ mg / person / day}}{30\text{kg}}$$

$$= 0.5\text{mg/kg body weight/day}$$

¹ The assumption of 30kg body weight for children was used in this exposure scenario as the EPA use this body weight value for children in their “Notice of Filing of Pesticide Petitions” (Federal Register: November 20, 1998 (Volume 63, Number 224)).

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2. Deterministic exposure estimate using consumption factors and the SML for the migration value.

In this scenario the consumption factor (CF) for polyethylene (Table 2) was used in the exposure assessment to represent the fraction of the daily diet likely to contact polyethylene. In this scenario there were no food type distribution factors or real migration data available, therefore the SML of 15mg/kg of food was used as a conservative assumption. However, as data was available on the intake of packaged food for children from this study, in addition to real body weights, these figures were used in computing the intake of the antioxidant.

$$\begin{aligned} \text{CF}_{\text{Polyethylene}} * \text{Migration} &= 0.332 * 15 \text{ mg/kg} \\ &= 4.98 \text{ mg antioxidant / kg food} \end{aligned}$$

As the mean consumption of packaged food in this study (Table 5) was 1.195kg per day, the resulting estimated daily intake (EDI) for children in this study would be:

$$\begin{aligned} \text{EDI} &= 4.98 \text{ mg antioxidant / kg food} * 1.195 \text{ kg food/child/day} \\ &= 5.951 \text{ mg/child/day} \end{aligned}$$

The mean body weight of children in this study was 33.1kg (Table 5), therefore the intake per kg body weight for children would be:

$$\begin{aligned} &= \frac{\text{intake of a child per day (mg/child/day)}}{\text{body weight (kg)}} \\ &= \frac{5.951 \text{ mg / child / day}}{33.1\text{kg}} \\ &= 0.180 \text{ mg/ kg body weight /day} \end{aligned}$$

3. Deterministic exposure estimate using consumption factors and food type distribution factors.

In this scenario the consumption factor (CF) for polyethylene (Table 2) and the food type distribution factors (FT) (Table 3) derived in this study were used to estimate exposure to the antioxidant. Migration values used by the FDA in their “Guidance for Industry” document were used (FDA 2002) instead of assuming maximum migration at the SML. These migration values, which are for the migration of the antioxidant from low density polyethylene (LDPE), are as follows:

Food Type	Simulant	Migration
Aqueous & Acidic Foods	10% aqueous ethanol ²	0.06mg/kg
Alcoholic Foods	50% aqueous ethanol ³	0.92mg/kg
Fatty Foods	Miglyol 812	7.7mg/kg

The first step in this exposure calculation was to calculate the level of the migrant in the food:

$$\begin{aligned}
 \text{Migration (M)} &= (\text{FT}_{\text{aqueous}} + \text{FT}_{\text{acidic}})(\text{M}_{10\% \text{ aqueous ethanol}}) + (\text{FT}_{\text{fatty}}) (\text{M}_{\text{Miglyol 812}}) \\
 &= (0.437+0.232) (0.06\text{mg/kg}) + (0.067) (7.7\text{mg/kg}) \\
 &= 0.556 \text{ mg / kg}
 \end{aligned}$$

The concentration of the antioxidant in the daily diet resulting from the proposed use would be:

$$\begin{aligned}
 \text{CF}_{\text{Polyethylene}} * \text{Migration} &= 0.332 * 0.556 \text{ mg/kg} \\
 &= 0.185 \text{ mg antioxidant / kg food}
 \end{aligned}$$

As the mean consumption of packaged food in this study (Table 5) was 1.195kg per day, the resulting estimated daily intake (EDI) for children in this study would be:

$$\begin{aligned}
 \text{EDI} &= 0.185 \text{ mg antioxidant / kg food} * 1.195 \text{ kg food/child/day} \\
 &= 0.221\text{mg/child/day}
 \end{aligned}$$

² In the EU distilled water or water of equivalent quality is used as the aqueous simulant, as opposed to 10% aqueous ethanol used by the US FDA. For the purpose of this exposure scenario the migration value for 10% aqueous ethanol was used for aqueous foods and acidic foods. Therefore, the food type distribution factor (FT) for both aqueous and acidic food is summed and then multiplied by the migration value for 10% aqueous ethanol.

³ No alcoholic foods were consumed in the Irish National Children’s Food Survey therefore the migration value for alcoholic foods shall not be needed in this example.

The mean body weight of children in this study was 33.1kg (Table 5), therefore the intake per kg body weight for children would be:

$$\begin{aligned}
 &= \frac{\text{intake of a child per day (mg/child/day)}}{\text{body weight (kg)}} \\
 &= \frac{0.221 \text{ mg / child / day}}{33.1\text{kg}} \\
 &= 0.007 \text{ mg/ kg body weight /day}
 \end{aligned}$$

4. Deterministic exposure estimate using conservative consumption factors and actual food type distribution factors.

If a more conservative exposure assessment scenario of the antioxidant compared with the above example was required, then the consumption factor used in the calculation could be the sum of the “polyethylene” consumption factor (0.33) and the “unidentified polymers” consumption factor (0.248). As not all polymers were identified in the database some of those not identified could be polyethylene and hence it is conservative to assume that all the unidentified polymers could be polyethylene. For this scenario the exposure calculation would be as follows:

$$\begin{aligned}
 &= (\text{CF}_{\text{Polyethylene}} + \text{CF}_{\text{Unidentified polymers}}) * \text{Migration} \\
 &= (0.332 + 0.248) * 0.556 \text{ mg/kg} \\
 &= 0.323 \text{ mg/kg}
 \end{aligned}$$

As the mean consumption of packaged food in this study (Table 5) was 1.195kg per day, the resulting estimated daily intake (EDI) for children in this study would be:

$$\begin{aligned}
 \text{EDI} &= 0.323 \text{ mg antioxidant / kg food} * 1.195 \text{ kg food/child/day} \\
 &= 0.386\text{mg/child/day}
 \end{aligned}$$

The mean body weight of children in this study was 33.1kg (Table 5), therefore the intake per kg body weight for children would be:

$$\begin{aligned}
 &= \frac{\text{intake of a child per day (mg/child/day)}}{\text{body weight (kg)}} \\
 &= \frac{0.386 \text{ mg / child / day}}{33.1 \text{ kg}} \\
 &= 0.117 \text{ mg/ kg body weight /day}
 \end{aligned}$$

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Table 1. Surface area:weight ratios for foods consumed in the Irish National Children's Food Survey.

Food Groups	dm ² /kg	Reference
Soft drinks bottle	5.2	Bouma et al 2003
Juice	6.5	Bouma et al 2003
Milk	6.7	Bouma et al 2003
Cream Cheese	7	Bouma et al 2003
Custard	7.04	Bouma et al 2003
Margarine	7.1	Bouma et al 2003
Soup (general)	8	Bouma et al 2003
Yoghurt Drink	9	Bouma et al 2003
Convenience Meals	12	Bouma et al 2003
Icecream Container	12.1	Bouma et al 2003
Confectionary (includes chocolate & gum)	17	Bouma et al 2003
Meat (includes Quorn products)	18	Bouma et al 2003
Sauce container (plastic)	18.4	Bouma et al 2003
Yoghurt	18.4	Bouma et al 2003
Fish	19	Bouma et al 2003
Biscuits	21	Bouma et al 2003
Bread	21	Bouma et al 2003
Cakes	21	Bouma et al 2003
Fruit & Veg	21	Bouma et al 2003
Nuts	27	Bouma et al 2003
Dessert Mousse	28.02	Bouma et al 2003
Soup dried sachet	54	Bouma et al 2003
Herbs	95	Bouma et al 2003
Sauce dried sachet	96	Bouma et al 2003
Crisps	60	Assumptions
All other foods	12	Assumptions
Canned Foods		
Fruit	7.48	Dionisi et al 2002
Meat	11.06	Dionisi et al 2002
Fish	16.63	Dionisi et al 2002
Ready meals	7.25	Dionisi et al 2002
Vegetable	6.96	Dionisi et al 2002
Soup	8.36	Dionisi et al 2002
Milk/cream	9.07	Dionisi et al 2002
Other Foods	7.84	Dionisi et al 2002

Table 2: Consumption factors of packaging materials derived from the Irish National Children's Food Survey for children aged 5-12 years.

Material	Irish Consumption Factor	Equivalent FDA Consumption Factor
Glass	0.002	
Glass & metal & alloys	0.013	
Glass & plastic	0.003	
Total Glass	0.017	0.1
Metal & alloys	0.029	
Metal & alloys & paper & board	0.001	
Metal & alloys & plastic	0.018	
Metal & alloys & glass	0.013	
Total metal & alloys	0.061	0.2*
Paper & board	0.125	
Paper & board & metal & alloys	0.001	
Paper & board plastic	0.005	
Total paper & board	0.132	0.1†
Plastic	0.805	
Plastic & metal & alloys	0.018	
Plastic & paper & board	0.005	
Plastic & glass	0.003	
Total Plastic	0.830	0.791‡
Wax	0.0001	
Polymers:		
Polyethylene	0.332	0.31¶
Polypropylene	0.129	0.04
Polystyrene	0.084	0.1
Polyethylene terephthalate	0.033	0.16
PVC & PVDC	0.003	0.1
Unidentified polymers	0.248	

* Sum of coated (0.17) and uncoated (0.03) metal

† Paper uncoated only (0.1)

‡ Sum of paper polymer coated (0.2), polymer (0.4), adhesives (0.14), retort pouch (0.05), and microwave susceptor (0.001)

¶ Sum of LDPE (0.12), LLDPE (0.06) and HDPE (0.13)

Table 3: Food Type Distribution Factor derived from the Irish National Children's Food Survey for children aged 5-12 years.

Material	Aqueous	Acidic	Fatty	Dry
Glass	0.024	0.238	0.028	0.710
Glass & metal & alloys	0.034	0.852	0.066	0.047
Glass & plastic	0.081	0.047	0.647	0.225
Total Glass	0.041	0.670	0.150	0.140
Metal & alloys	0.138	0.511	0.326	0.025
Metal & alloys & paper & board	0.056	0.000	0.729	0.215
Metal & alloys & plastic	0.129	0.438	0.099	0.334
Metal & alloys & glass	0.034	0.852	0.066	0.047
Total metal & alloys	0.111	0.551	0.212	0.125
Paper & board	0.001	0.003	0.205	0.791
Paper & board & metal & alloys	0.056	0.000	0.729	0.215
Paper & board plastic	0.000	0.000	0.485	0.515
Total paper & board	0.001	0.003	0.220	0.775
Plastic	0.201	0.222	0.262	0.316
Plastic & metal & alloys	0.129	0.438	0.099	0.334
Plastic & paper & board	0.000	0.000	0.485	0.515
Plastic & glass	0.081	0.047	0.647	0.225
Total Plastic	0.198	0.224	0.261	0.317
Wax	0.000	0.000	1.000	0.000
Polymers:				
Polyethylene	0.437	0.232	0.067	0.264
Polypropylene	0.016	0.012	0.587	0.385
Polyethylene terephthlate	0.117	0.796	0.067	0.020
Polyvinylchloride	0.000	0.000	0.870	0.130

Table 4. Exposure assessment of a hypothetical antioxidant in polyethylene using different methodologies (full details of these assessment scenarios are documented in the appendix).

Exposure Method	Exposure mg/day	Exposure mg /kg body weight / day
Deterministic (EU Assumptions)*	15	0.500
Deterministic (CF and SML) †	5.951	0.180
Deterministic (Conservative CF, FT and migration data) ‡	0.386	0.117
Deterministic (CF, FT and migration data) §	0.221	0.007

* In this method some of the assumptions used by the EU to estimate exposure to a migrant were employed. It was assumed that 1kg of food packaged in the material of interest was consumed per day and that migration occurred at the maximum level i.e. at a specific migration limit (SML) of 15mg/kg. The EU method uses a 60kg body weight for adults, and as this exposure assessment was for children a body weight of 30kg was used instead.

† In this scenario the consumption factor (CF) for polyethylene was used in addition to the SML for the migration level. The intake of packaged food consumed by children and their mean body weight derived from this study were also used in the exposure assessment.

‡ This scenario used a conservative consumption factor (CF) in addition to realistic food type distribution factors (FT) and real migration data. The conservative consumption factor used in this method was conservative as it was the sum of the consumption factor for “polyethylene” and “unidentified polymers”.

§ This scenario used the consumption factors (CF) for polyethylene only and food type distribution factors (FT) derived in this study, in addition to real migration data, food consumption data of packaged foods and body weight data.

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Table 5: Food contact area, food intakes and body weights derived from the Irish National Children's Food Survey for children aged 5-12 years.

Parameter	Food contact area for all packaging (dm²/person/day)	Food contact area for plastic packaging (dm²/person/day)	Intake of packaged food (g/day)	Body Weight (Kg)
Mean	13.44	10.67	1195	33.1
Percentile 90th	17.29	14.38	1602	48.6
Percentile 95th	19.58	15.86	1735	54.3
Percentile 97.5th	20.73	17.58	1959	63.3
Percentile 99th	22.95	18.78	2202	70.1