Food Consumption and Packaging Usage Factors

Summary of a Workshop held in July 1996

Organised by
ILSI Europe
Packaging Material Task Force

FOOD CONSUMPTION AND PACKAGING USAGE FACTORS

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ILSI Europe Packaging Material Task Force, 83 Avenue E. Mounier, B-1200, Brussels, Belgium

ILSI Europe held a 1-day workshop in Brussels on 15 July 1996 at which experts described the US approach to indirect additive exposure assessment (T.C. Brown, Keller and Heckman Law Offices, Belgium), food consumption patterns in Europe (M.J. Gibney, University of Dublin, Ireland), the collection of European statistics for food packaging materials use (M. Palmer, Maurice Palmer Associates Ltd., UK) and the way in which available information might be used to propose the use of food consumption factors in European food packaging regulations (L. Castle, Ministry of Agriculture, Fisheries and Food, UK). This paper, produced by two rapporteurs, summarises the above presentations and draws together the conclusions of the expert group.

Key words: regulations, consumption factors, migration, safety

CONTENTS

1. INTRODUCTION

In the European Union, the safety of plastics packaging is assessed on a worst-case assumption of the maximum possible dietary intake of a component that may migrate into foods. For each substance under consideration, it is assumed that 1 kg / day of the diet for a person over a lifetime is packaged in plastic that contains that substance and that this food contains the substance at the maximum concentration permitted by the specific migration limit (SML). In contrast, in the USA, intake calculations made in the approval process use various formulae which make some allowance for the different types of foods in the diet (fatty, alcoholic, etc.) and some allowance for the relative proportion of the different types of packaging materials which come into contact with these foods. The factors employed in these calculations (food type and packaging use) are termed “food consumption factors”.

The aim of this 1-day interactive meeting of invited experts and members of the ILSI Europe Task Force on Food Packaging was to critically examine the applicability of food consumption factors in the EU. This was done by examining whether sufficient background data exist for Europe to propose an approach similar to that used in the USA and, if so, to assess the possible benefits, bearing in mind the different mechanisms of regulation in Europe and the USA.

2. OBJECTIVES

1 To understand and critically assess the US Food and Drug Administration's (FDA) approach to the assessment of exposure to indirect additives which use consumption factors and food-type distributions, and to understand how the system is updated to respond to changing patterns in diet and packaging use.

2 To examine the food consumption data for EU countries and assess whether a single data set could reasonably be used to represent the diversity of European habits. This review should assess the uncertainty associated with high consumption for groups such as children and the extent to which this will perturb any generalised European dietary consumption figures.

3. To propose plastics use factors for food packaging based on the European data provided by Maurice Palmer Associates. This proposal could be based on broad bands much as are used in the USA, and should take account of the significance (if any) of differences in the use of materials between different EU countries.

4 To draw together the options open to the EU, based on the information presented in 2 and 3 above, and to explore the advantages and disadvantages of these options.

3. THE FDA APPROACH TO INDIRECT ADDITIVE EXPOSURE ASSESSMENT

In understanding how and why food consumption factors are employed in the USA, it is important to appreciate the very different regulatory process that operates in terms of approval of polymers for food contact use. In the USA a dossier is submitted to the FDA for approval of, say, a polymer containing a unique additive for specified food uses. This dossier would contain relevant migration data on food simulants. The tolerable daily intake (TDI) would be known for the additive in question. To assess whether probable migration could lead to consumer exposure exceeding the TDI, a calculation is made using the level of migration measured in food simulants, the proportion of each food type in contact with that polymer, and the proportion of that polymer type used to package the nation's diet. The migration values on simulants are effectively adjusted to give an intake assessment which allows for the fact that not all foods are going to be packaged in the same material. Thus, a particular additive in a polymer might be approved in this way for aqueous food use only and for use only in, say, polyvinyl chloride. A proportion of the TDI would effectively be assigned to this approved use. A further dossier application for use of the same additive but for another plastic or another food type would be subsequently assessed on the basis of the remaining unassigned TDI. If the sum of all uses of that additive exceeded the TDI (existing and proposed), the new application might be rejected.

The food-type distribution factor (F_T) reflects the fraction of all food in contact with each material that is aqueous, acidic, alcoholic or fatty. These factors were derived from existing databases on food consumption (such as the US Department of Agriculture nationwide Food Consumption Survey [mean and 90th percentile] and FDA market basket surveys). F_T figures have been established for each type of packaging and for individual polymer types as subsets of “all plastics”. For example, for polyolefins the assigned values are 0.67 (aqueous), 0.01 (acidic), 0.01 (alcoholic) and 0.31 (fatty). These figures have not changed markedly with time, although the fatty food figure has been reduced to reflect the reduction in fat consumption in the US diet.

Consumption factors (CF) represent the ratio of the weight of all food in contact with a specific packaging material to the weight of all packaged food. CF figures were derived from industry data on polymer use, commercial data (Market Research Corp. of America) and from research commissioned from Arthur D Little Inc. Factors were derived for various types of packaging, for example, glass (0.1), coated metal (0.17), uncoated metal (0.03), polymer-coated paper (0.2), uncoated paper (0.1) and polymers (0.4). These figures changed little between 1981 and 1995; for example, direct food contact with polymers changed only from 0.41 to 0.40. In 1995 the total percentage of the diet assessed as being in contact with polymers was 77%. The polymer figures were broken down into types and CFs assigned accordingly. For example, the CF for polyolefins is 0.328. A cross-check of these factors with The Society of the Plastics Industry data came up with a figure of 0.353 for polyolefins. Because this figure did not deduct scrap or polymer for non-food uses, the agreement with the value of 0.328 is considered excellent. An updating of these figures in 1995 indicated the need for some change; for example, the figure for polyesters was revised upward from 0.043 to 0.10 to reflect increased use of polyethylene terephthalate (PET) bottles.

To assess the dietary concentration of any component, the migration value in the appropriate simulant is multiplied by the appropriate F_T and subsequently by the appropriate CF for the food contact material. For example, for a polyolefin which will be in contact with aqueous, acidic, alcoholic and fatty foods, the migration values in each of the four simulants is multiplied by 0.67, 0.01. 0.01 and 0.31 respectively, and the sum of these migration values is taken as the estimated migration into food assuming the entire diet is packaged in polyolefins. To correct for the fact that the average proportion of the diet packaged in polyolefins is only 32.8%, the migration value for food is multiplied by 0.328 to give the estimated concentration in the diet. This value is then multiplied by 3 to give the intake per day on the assumption of a total consumption of 3 kg of solid food and beverage per person per day.

Although food CFs were primarily intended for use in assessing exposure to indirect additives, CFs are now also applied to the assessment of possible migration of contaminants in the case of plastics packaging recovery. The calculation in this instance is applied to the

threshold-of-regulation value of 0.5 ppb in the diet; for example, in the case of polyester beverage bottles, the tolerable migration level would be increased to reflect the fact that PET has a 10% market share of food contact use polymers.

4. FOOD CONSUMPTION PATTERNS IN EUROPE

In the EU a Scientific Cooperation (SCOOP) project involving 14 countries was recently completed which assessed the capabilities of existing food consumption databases in Europe and which identified constraints on change and recommended where improvement might be made. A series of practical database searches had been used to compare the extent of detail in different databases and to see how real-case estimates of food chemical exposure might differ depending on the database employed. The level of codification of information in the various European databases was found to vary from as few as 100 codes for Portugal to as many as 30,000 for France. Because the data were in many instances collected with different purposes in mind and in different ways, the advantages and disadvantages of the different data-bases are not directly correlated to the number of codes.

The methodology used for data collection significantly influences outcome. Whether the study considers a 1-day, 5-day or 14-day period will influence the results. For example, most people eat bread every day, whereas some consumers eat biscuits every day, some only every other day and others less frequently. The longer the data collection period, the more consumers will be captured who eat certain items infrequently. This helps explain the variations in intake results in different EU studies. In Belgium, studies are undertaken over 1 day, in the Netherlands over 2–3 days and in many other countries over 7 days. As one calculates *per capita* consumption, the intake as measured in grams/person/day falls as the number of days over which data are collected increase. A research programme is being undertaken to extrapolate short-term statistics to the more useful longer time frames.

One of the SCOOP tasks was to explore the merits of a presumptive European diet based on existing national databases. This would require a worst-case analysis, because of true variations in diet; for example, yoghurt consumption differs significantly among EU countries. The main question is, Is there a presumptive diet, and will it perform the desired function? An example of the problem is illustrated by Irish and UK high consumers. Although one might assume that food consumption is similar in both countries, milk intake for Ireland is double that in the UK at the 97.5th percentile, bread intake is almost double, but rice consumption in the UK is higher. When considered across Europe, the problem becomes considerably worse. The simplicity of a presumptive diet is attractive, but it would have to be accepted that it would be crude. Furthermore, different presumptive diets would be required to consider, say, food additives, food contact plastics or environmental contaminants. Can one apply a presumptive diet to both sexes, all ages, all countries and all persons, with their different health status? If one argues that these refinements are necessary then it is getting away from the whole concept of crude data – by definition a presumptive diet is crude and needs to pass the test that these refinements are unimportant.

As a test case, it is possible to estimate the proportion of fatty food in the diet from existing databases. Using data from the British Nutrition Survey of 120 foods, a crude analysis suggested that from a total estimated food and beverage intake of 2,464 g/person/day, about 24% of the food could be considered fatty. This estimate is encouragingly close to the FDA F_T value of 0.31 (31%) for fatty foods but also confirms that this factor should be based on 2.5 kg/person/day (compared with the FDA value of 3 kg) rather than the present EU conventional 1 kg/person/day.

There is great heterogeneity of food consumption data available, and this will never change. However, the SCOOP project shows that it is possible to work within this heterogeneity. A presumptive diet can be described while questions remain about the shortcomings of this approach. For food packaging requirements the data are probably available in sufficient detail, but much work is needed to extract it.

5. COLLECTION OF EUROPEAN STATISTICS FOR FOOD PACKAGING MATERIALS USE

The collection of statistics on food packaging materials use is an iterative process whereby data obtained from different complementary sources are processed to generate an overview. Where appropriate, figures are progressively refined and tested to ensure internal consistency. Maurice Palmer Associates (MPA) has undertaken a series of projects relating to the UK market, the Italian market for comparison, and then in less depth the EU market for all 15 member states. Data collection is based on shelf audits along with discussions with food manufacturers, packaging converters, raw material suppliers and trade associations. A high percentage of the figures are verified with the packaging industry on an ongoing basis. Considerable research is needed to integrate these pieces of information and to refine them into a suitable and usable format.

Packaging statistics are segmented into food type, package size, packaging material and contact coating. For each of these the numbers of units of consumption, surface area, weight of packaging and coating thicknesses have been estimated. These data are presented on spreadsheets from which the consumption of food per individual package can be calculated.

MPA gathered the most in-depth statistics for the UK and for Italy. The generation of comparison data for all 15 EU member states was based on a number of assumptions:

- Unless consumption figures were available, it was assumed that Ireland and the UK were similar and that Spain and Portugal were similar.
- Unless there was information to the contrary, it was assumed that the production and consumption of products in each country were similar.
- In some market sectors such as bread and confectionery, it was assumed that 10% of the packaging produced was not in contact with food – e.g. over-wrapping etc.
- Packaging for in-store packaging of products was excluded.
- No account was taken of out-of-home eating such as "take-away" food products.

The degree of confidence in the data produced was estimated to vary from a low of about 60% for Ireland, Finland and Sweden to a high of 90% for the UK market. It was believed that, with further work in those countries where the uncertainty levels were high, it would be possible to refine and improve the data.

MPA concluded that databases for food packaging materials for all 15 EU member states had a considerable amount of detailed information. These databases probably contain far more detail than would be needed to derive food consumption factors, although the information could if necessary be refined on a country-by-country market share or packaging-type basis. The next step should be to decide which information is required and the format to use in drawing that information from the databases.

6. PROPOSED FOOD CONSUMPTION FACTORS FOR THE EU

MPA is further processing some of the data with a view to examining whether it would be possible to combine some of the information for a "European" diet or whether this might be precluded by the degree of variation between countries. From the available data, assuming an EU population of 350 million (excluding Finland, Sweden and Austria), the food contact area for all packaging can be derived as an average of 20.1 dm^2 / person / day and for plastics (62% of all packaging by area) as 12.4 dm^2 / person / day. These figures are higher than the EU convention based on an intake of 1 kg / person / day with a contact area of 6 dm^2 / person / day. However, using the more realistic 3 kg intake figure as used in the USA, one arrives at 18 dm^2 / person / day, which is reasonably close to the 20.1 dm^2 derived from the MPA database. Increasingly with modern packaging, for example, in the case of a bag of potato crisps (chips), the ratio of surface

area to weight is significantly higher than assumed by the standard EU 1-dm cube. The total use of plastics for the EU member states ranges from a high of 17–19 dm^2/person/day for the Benelux countries and Ireland to a low of 9–9.5 dm^2/person/day for Spain and Greece. The use of an average of 12.4 dm^2/person/day would seem reasonable, provided the variation in the use of different materials is not too dissimilar.

The MPA database shows that the use of polyethylene in the Benelux countries and Ireland is around 9–10.4 dm^2/person/day and for Spain, Portugal and Greece 4–4.6 dm^2/person/day. PVC and PS/ABS appear to be relatively minor use materials (that is, below 1 dm^2/person/day), although PVC and PS/ABS were used more in France. It was concluded that in general the MPA data seemed to be reconcilable with expectations and that a considerable amount of data could be drawn on for further analysis.

However, further analysis should consider the impact of the following:

- Processing the data in terms of estimating the average for the EU and comparing the results with the average for each member state, both on the basis of food weight and food type consumed and on the basis of pack surface area by polymer type.

- Processing the data in terms of the average for the whole population and comparing the results with the average for the population of consumers.

- Processing the data in terms of the average user, the high user (<97.5th percentile) and the extreme user (>97.5th percentile).

7. SIGNIFICANCE OF INTRODUCING FOOD CONSUMPTION FACTORS IN THE EU

Food CFs might be applied in a number of ways within the EU context, and these can be considered separately:

- Overall migration. This provides blanket protection in terms of the quality of plastics materials, and the limit of 60 mg/kg (10 mg/dm^2), which should not be exceeded, is not affected by consideration of food CFs.

- Specific migration – monomers with an established TDI. Packaging use factors could be applicable in this circumstance provided that the monomer is uniquely used for discrete identified plastics. Thus, in the case of terephthalic acid with a specific migration limit (SML) of 7.5 mg/kg and a unique use for PET, the migration limit could be effectively raised to allow for the market share (or weighted to reflect high consumer consumption) of PET used in packaging materials, without compromising the TDI of 0.125 mg/kg body weight.

- Specific migration – monomers with "not detectable" restrictions. In circumstances where the SML should be "not detectable" but has been fixed numerically by the performance of analytical methodology, irrespective of food CFs, the desire is still to keep monomer levels at minimum technically achievable levels. Food CFs cannot be applied in these circumstances.

- Specific migration – monomers with an established TDI but group restrictions and/or multiple applications. In some circumstances, such as mono- and diethyleneglycols, where components have use as monomers (in PET) and as additives (in regenerated cellulose film), application of food CFs would need to consider this multiple application. No mechanisms or resources within the Commission of the EU now do this.

- Specific migration – additives with an established TDI. If the use of the additive were restricted to one or two polymer types, the food CFs probably could be applied with respect to effectively raising the SML. The only problem would arise in the future if anyone wished to use the same additive for a new polymer application. In the USA this new application would need to go through the approval process (which could be denied if the TDI were to be exceeded). In Europe unrestricted use of the additive is approved subject only to the SML limitation being met, although polymer-application-specific approval may be given in the future.

- Dossier submissions for approval of additives. In petitions to use a new additive, the application of food CFs to the submitted migration data could have the benefit of pushing the additive in question from one grouping to another thus relaxing the toxicology tests required. Again, as for the migration of additives with an established TDI, there would be problems in so doing if a subsequent user intended to employ the same additive but in a different plastic.

- Threshold of regulation. The use of food CFs could have the advantage of reducing the burden of demonstrating the absence of unauthorised substances by raising the analytical threshold while maintaining the exposure threshold. Two situations were envisaged. The first involved adventitious contaminants which by definition would be sporadic in incidence, varied in nature and not common to two or more polymers or recycling processes. An example would be consumer misuse of chemicals in a reused bottle. It would seem that there are good arguments for the application of food CFs in this circumstance. The second situation could be described as systemic contaminants which are constant in identity and occurrence, might be generic to two or more polymer recycling processes and could be cumulative. Examples might be catalyst residues or thermal degradation products, and these would need to be considered on a case-by-case basis in establishing any impact of related approvals. In both cases food CFs could be applied only if a numerical value is established for the threshold.

8. CONCLUSIONS

It was concluded that further discussion should be concentrated on the following points:

1. The US system of food consumption factors does not have direct applicability to the EU because of differences in the regulatory process, but the principle could have some application in some circumstances.

2. Sufficient detailed information exists in European food consumption databases to extract information equivalent to that used in the USA to derive consumption factors. The appropriate questions need to be asked, and there would be some cost in extracting the information in an appropriate and usable form.

3. Sufficient detailed information exists in the Maurice Palmer Associates' databases to extract appropriate plastics use factors for Europe. Although some differences are evident in the overall use of plastics packaging and in the use of different types of plastics within Europe, these differences on preliminary examination did not seem sufficiently great to rule out the derivation of European average figures.

4. The areas where food consumption factors might find application in the EU context were identified as monomers and additives with defined numerical tolerable daily intakes and specified single polymer use, dossier applications for approval for single polymer use, and applications to the threshold of no regulatory concern for recycling. A problem of implementation which needs to be addressed concerns the possibility of new uses of monomers / additives beyond the original specified single use.

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