Creme

Annex 8.6: Detailed Background on Dietary Exposure Assessment

PlasticsEurope

Guidance on Exposure Assessment for Repeat Use Applications

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Consumer populations are routinely exposed to a large number of chemicals on a daily basis, from a variety of sources, via the dermal, oral and inhalation routes. In order to ensure that these chemical exposures are not adversely affecting human health, appropriate risk assessments need to be carried out in order to quantify the likelihood of harm. In chemical risk assessment, risk is evaluated as being a function of hazard and exposure:

$$Risk = Fn\ (\ Hazard\ ,\ Exposure\ )$$

Hazard is the intrinsic property of a chemical and its potential to cause harm, quantified as the dose-response-relationship between a specific health effect (or toxicological endpoint) and the magnitude of dose. This dose-response relationship is used to set a Health Based Guidance Value (HBGV), typically in the form of form of a Tolerable Daily Intake (TDI) or Tolerable Weekly Intake (TWI). This is a threshold below which no adverse health risks are expected over a lifetime of exposure.

Exposure is the size or magnitude of dose of a chemical which consumers undergo in the real world, arising from their interaction with their environment in which they encounter the chemical from different sources (e.g. food, consumer products, inhaled air etc.). Risk characterisation then is the comparison of hazard and exposure and their relative magnitudes to determine the likelihood of an adverse health outcome. In the event that a human health risk cannot be ruled out, risk management measures may be warranted, whereby steps need to be taken to reduce the levels of human exposure in order to reduce risk to an acceptable level.

In the case of chemicals whereby the main source of exposure is due to their presence in food, a dietary exposure assessment is generally performed to quantify the level of exposure in human populations. This requires data on food consumption in specific populations and data on the level of chemical in the foods consumed. The levels of dietary exposure are then compared to a HBGV to assess associated human health risk.

Conceptually, dietary exposure within risk assessment is straightforward to describe. Exposure is calculated as follows:

$$\text{Exposure} = \text{Amount} \times \text{Concentration}$$

where the amount is the quantity of food consumed and the concentration is the level of chemical in the food. The exposure is then compared to a safe level of intake for the chemical such as a TDI to determine the associated risk. The question of dietary exposure becomes quite complex and challenging when it is considered that a chemical can be present at varying levels in a large variety of foods, consumed in varying quantities, in different combinations, by different consumers, in different countries/regions, and at different life stages. Therefore, exposure in a population is intrinsically variable, and this variability should be captured in a given risk assessment, if required.

Exposure assessment is, by necessity, an iterative process. It has been recommended that assessing exposure should be via a tiered approach[1,2], where the lowest tier consists of a rough estimate of exposure, the mid-tier tends to be a more quantitative estimate, such as a deterministic estimate with conservative assumptions, and the highest tiers provide more realistic estimations of population exposure, modelled using probabilistic methods and person-orientated approaches, using more detailed exposure input data, such as population distributions or even raw data sets.

Should it not be possible for unacceptably high human health risks to be ruled out at the highest tier of exposure assessment (that can be feasibly analysed), risk management measures may be warranted. As hazard is an intrinsic property of the chemical itself and therefore cannot be changed, risk management is focused upon reducing consumer exposure. This in turn enforces the concept that a detailed exposure assessment must be performed in order to correctly identify an appropriate risk management measure.

Dietary exposure assessment requires two primary inputs:

1. Data on food consumption
2. Data on chemical concentrations in food

For an exposure assessment to be representative of a given population, both of these inputs are equally required to be representative of foods consumed and representative of the levels of chemicals in those foods. Ideally, both inputs should be statistically robust and as recent as possible.

Data on food consumption is generally in the form of a dietary survey, which for EU member states is a nationally representative survey of subjects from a chosen population, detailing their entire dietary habits for one or more days. Additionally, demographic and anthropometric information such as gender, age, body weight etc. are recorded. National food consumption surveys are carried out in a number of countries on a regular or sporadic basis. These surveys are used for:

- Food safety exposure assessments – contaminants, additives, pesticides, food toxins etc.
- Assessing and monitoring health and nutritional status of a population
- Public Health Nutrition: healthy eating guidelines, lifestyle, portion sizes, diet quality, diet related diseases
- Benefits and safety – food fortification, dietary supplements

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[1] Delmaar JE, van Engelen JGM. 2006. Aggregating Human Exposure to Chemicals an Overview of Tools and Methodologies. RIVM report 630700001/2006. RIVM, Bilthoven, The Netherlands.

[2] Meek M, Boobis A, Crofton K, Heinemeyer G, Van Raaij M, Vickers C. 2011. Risk assessment of combined exposure to multiple chemicals: a WHO/IPCS framework. Regul Toxicol Pharmacol 60(2) Supplement 1, Risk Assessment of Combined Exposure to Multiple Chemicals: A WHO/IPCS framework - WHO Supplement, 1 July 2011, Pages S1-S14.

- Industry – inform consumer intakes, new product development

Methodologies to gather this data vary widely by country and therefore data from different countries are not directly comparable to each other's.

As food intake and chemical concentrations vary across a population of consumers, as a result dietary exposure is a statistical distribution, i.e. there are a number of different levels of exposure in the population. This statistical distribution is described or summarised using statistics, in particular the mean statistic is used to characterise the average exposure and the 95th percentile used to characterise the upper or high level of exposure in the population (a percentile is a point in a distribution below which a certain percentage of values lie).

Dietary exposure can be estimated using different techniques. An overview of the different techniques used at EFSA to calculate dietary exposure was issued in a scientific report in 2011[3], ranging from worst-case estimations (i.e. an overestimation of exposure) to refined methods aiming at assessing actual exposure. One of the key recommendations of the report is that probabilistic methods, i.e. those that explicitly take exposure into account, be explored in greater depth.

Every dietary exposure assessment (indeed every scientific assessment), is affected by different uncertainties to some degree. In the case of refined exposure assessments, it is recommended that an evaluation of uncertainty be included with the outcome of the exposure assessment [4] . As with exposure assessments, it is recommended that uncertainty analysis follow a tiered approach, moving from qualitative, to deterministic analysis, to probabilistic analysis. This is with a view to understanding to what extent uncertainties (in data, methodology, or both) impact the final results and conclusions.

In the context of dietary exposure, risk management focuses on the two primary inputs for dietary exposure, food consumption and chemical exposure. To reduce dietary exposure to a given chemical, either consumption of foods containing the chemical should be reduced, the level of chemical occurrence should be reduced, or both.

Risk management measures should be justified and an evaluation of the effect of the management measure given. In particular, it should be quantified that an appreciable reduction in risk will arise from the proposed management strategy whenever possible; otherwise it is of questionable benefit whether the measure is in fact appropriate. A recent publication established a framework to determine the effectiveness of dietary exposure mitigation for chemical contaminants [5], outlining that in addition to an evaluation of the

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[3] EFSA, 2011. Overview of the procedures currently used at EFSA for the assessment of dietary exposure to different chemical substances. EFSA Journal, 9(12), pp.2490–2523.

[4] EFSA, 2006. Guidance of the Scientific Committee on a request from EFSA related to Uncertainties in Dietary Exposure Assessment. The EFSA Journal, 438(July), pp.1–54.

[5] Van der Fels-Klerx, H.J. et al., 2014. A framework to determine the effectiveness of dietary exposure mitigation to chemical contaminants. Food and Chemical Toxicology, 74, pp.360–371. Available at: http://dx.doi.org/10.1016/j.fct.2014.10.027.

effectiveness of a given control measure, secondary consequences should also be considered, along with any emerging issues and overall uncertainties impacting the risk assessment.

Below is a provisional outline of how these principles of exposure assessment can be used to model consumer exposure to repeat use applications through the consumption of food that has been in contact with a material of interest:

1) Choose a suitable food consumption survey. This choice may be based on factors such as the availability of variable which categorises eating events into those prepared at home and those prepared elsewhere.

2) For the utensil/appliance of interest, identify the foods likely to come into contact with it.

3) Further refine step 2) by identifying the eating events of those foods that can be mapped to the utensil/appliance based on a variable in the survey which distinguishes meals prepared at home from those not prepared at home (subject to the availability of such a variable in the survey data).

4) For the utensil/appliance, a probability will be assigned that it contains a material of interest (e.g. polypropylene) and/or a particular functional additive/oligomer/NIAS. These probabilities can be obtained from expert judgement or existing databases on market shares/product use.

5) When simulated, step 4) above will yield a yes/no outcome, representing whether an exposure will occur or not when a given food is consumed. If a substance of interest is present, a migration value will be assigned from e.g. migration tests relating to the appliance/utensil or other realistic value.

6) Where more than one eating event in an individual's food diary yields a substance migration from the above methodology, the individual's exposure will be the summation of values from the distinct eating events involving the pilot utensil/appliance.

7) The exposure results should be outputted as *mg of substance per kilogram body weight*.