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Assessing and reporting uncertainties in dietary exposure analysis – Part II: Application of the uncertainty template to a practical example of exposure assessment

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ABSTRACT

A previous publication described methods for assessing and reporting uncertainty in dietary exposure assessments. This follow-up publication uses a case study to develop proposals for representing and communicating uncertainty to risk managers. The food ingredient aspartame is used as the case study in a simple deterministic model (the EFSA FAIM template) and with more sophisticated probabilistic exposure assessment software (FACET). Parameter and model uncertainties are identified for each modelling approach and tabulated. The relative importance of each source of uncertainty is then evaluated using a semi-quantitative scale and the results expressed using two different forms of graphical summary. The value of this approach in expressing uncertainties in a manner that is relevant to the exposure assessment and useful to risk managers is then discussed. It was observed that the majority of uncertainties are often associated with data sources rather than the model itself. However, differences in modelling methods can have the greatest impact on uncertainties overall, particularly when the underlying data are the same. It was concluded that improved methods for communicating uncertainties for risk management is the research area where the greatest amount of effort is suggested to be placed in future.

1. Introduction

In a recent paper, Kettler et al. (2015) identified, mapped and described uncertainties related to different methods used in assessing consumer exposure to different components of their diet. This work was accompanied by methods for presenting and reporting uncertainties in a transparent and easy to understand manner. The authors attempted to map the different sources and types of uncertainties for a better understanding of uncertainty analysis in general, and to ultimately generate a more realistic comprehension of dietary exposure to a range of compounds relevant for human health. Amongst the key conclusions in the study was the fact that the same uncertainties are often common to screening techniques based on point estimates (deterministic

Abbreviations: ADI, Acceptable Daily Intake; ANS, The EFSA Panel on Food Additives and Nutrient Sources Added to Food; EFSA, European Food Safety Authority; EC, European Commission; EU, European Union; FAIM, Food Additives Intake Model; FAO, Food and Agriculture Organization of the United Nations; JRC, Joint Research Centre; MPL, Maximum Permitted Level; P95, 95th percentile of distribution; t-TDI, temporary Tolerable Daily Intake; WHO, World Health Organization.

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methods) as well as probabilistic exposure assessment methods, as the underlying data are often the same, and that uncertainty tables are a valuable tool for presenting and describing uncertainties in a structured manner.

The objective of this publication is to apply the approach to uncertainty analysis as described in Kettler et al. (2015) in a practical example using an exposure assessment of a food ingredient, namely the food additive aspartame. The analysis was carried out with a focus on parameter and model uncertainties found in specific deterministic and probabilistic models, which are commonly used for assessing dietary exposure in Europe. This is with a view to demonstrating how to describe and present uncertainties in a tiered approach, as well as how to assess the combined impact of multiple uncertainties in a qualitative manner using graphical tools to facilitate better risk communication as part of the overall risk assessment.

To achieve a qualitative and semi-quantitative estimation of the uncertainties associated with an exposure assessment for aspartame, two different models were applied; a deterministic screening method and a more refined probabilistic model. Where possible, inputs were treated consistently across both methods in order to clearly identify differences due to model uncertainties. In particular, alternative models were derived from the same underlying data.

Firstly, the Food Additive Intake Model (FAIM) that was developed by the European Food Safety Authority (EFSA) for the rough estimation of the exposure to a food additive in comparison with a set Acceptable Daily Intake (ADI) was used as an example of a lower tier assessment (EFSA, 2012a). Secondly, the Flavourings, Additives and food Contact materials Exposure Tool (FACET) software was used for a more refined calculation of exposure to aspartame using probabilistic modelling (Hearty, 2011; Mistura et al., 2013; Vin et al., 2013). Both model calculations use the same underlying food consumption and chemical concentration data, but these are treated very differently in the two approaches.

Since not only the qualification of uncertainties is of relevance but also the quantification and description is of importance for risk management decisions, this publication intends to assess the use of uncertainty tables to better describe the various uncertainties in exposure assessments. Finally, it also attempts to introduce a new and innovative way to express uncertainties in a graphical way.

2. Case study: uncertainties in the exposure assessment of aspartame

Assessments of dietary exposure to food additives may serve a variety of purposes. When a new additive is developed and an application for authorisation is prepared, it is necessary to test the technologically desirable use levels against the potential ADI to ensure consumer safety. For a new food additive, there is no history of use. Although the applicants may have a good idea of which foods the additive might be used in, and at what levels, they are usually only able to specify maximum use levels across a range of foods. EFSA and their 'Food Additives and Nutrient Sources added to food' (ANS) Panel will use a similar approach when they are asked to evaluate an application for a new additive by the European Commission (EC, see for example EFSA, 2013, 2014a). Any method for dietary exposure assessment in this context would therefore only need to accommodate maximum values for each food category. For food additives that have a long history of use, the situation is very different. Food manufacturers using the food additive will have developed patterns of use according to the need in individual food products that employ the minimum concentration necessary to achieve the desired technological effect. This level can vary widely within a category of food because of different technological needs, e.g. physical and chemical characteristics of foods such as fat content, pH, water content, turbidity, density, etc. and presence of other competing or complimentary food additives.

2.1. Introduction to FAIM and FACET exposure models

The FAIM (EFSA, 2012a) and FACET (Hearty, 2011; Mistura et al., 2013) exposure models were both developed to estimate dietary exposures to food additives. Although these models are based on different modelling principles, they incorporate some of the same food consumption data for European consumers and so provide an opportunity to investigate differences in quantitative outputs when the same additive concentration input data are available. This in turn may allow a greater understanding of the qualitative and quantitative impacts of uncertainties associated with those models and with the presentation of input parameters.

The FAIM model is deterministic in nature and incorporates fixed values for population average and consumers' P95 (95th percentile) as a measure of high level food consumption data for each of 66 categories of food taken from an earlier version of the EFSA Comprehensive European Food Consumption Database (EFSA, 2011a). Food consumption data are combined with the Maximum Permitted Level (MPL) or actual usage levels for each food category and total intake is estimated for each population group by adding the P95 for intake from the food group with the highest exposure, and taking the average intake from all other foods. This is reported in the model as 'high level' exposure and typically is the exposure considered not of safety concern if below the ADI.

The FACET project was a pan-European research project under FP7 with the primary goal to develop a food chemical surveillance system for the protection of consumer health in the EU (Hearty, 2011). The project involved harmonising databases on food consumption and chemical occurrence, linking 15 dietary surveys from 8 EU Member States to databases on chemical occurrence for flavourings, additives, and food packaging migrants using probabilistic modelling. All databases and probabilistic exposure models were integrated into a desktop software application, available for download from the European Commission's Joint Research Centre website (JRC, 2014).

The FACET tool can operate as a full probabilistic model where distributions of additive usage data can be combined with individual food consumption data to provide distributional estimates of population intakes. In reality, distributional data about levels of additives in foods are seldom available and so it is often necessary to use single values to represent food additive concentrations (although within the FACET project distributions of some use level data were derived from ranges of values submitted by industry to FoodDrinkEurope). Nevertheless, within the FACET system the potential intake of every individual in each survey from all dietary sources can be calculated and the result represented as a distribution of total intakes.

In addition to being able to compare the results of deterministic and probabilistic models, different types of additive usage data can be introduced to obtain a better understanding of their impact on overall exposure and related uncertainties. The EFSA ANS Panel has introduced a refinement to their exposure assessment approach in some of their recent opinions (see for example the re-evaluation of Indigo Carmine (E132) in EFSA (2014a)). This introduces new scenarios in addition to using just the MPL or upper level of actual usage data as provided in the FAIM model. The new approach takes account of the potential for brand loyalty in two additional scenarios: