Food and Chemical Toxicology 82 (2015) 79–95

Contents lists available at ScienceDirect

Food and Chemical Toxicology

journal homepage: www.elsevier.com/locate/foodchemtox

Review

Assessing and reporting uncertainties in dietary exposure analysis Mapping of uncertainties in a tiered approach

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ARTICLE INFO

Article history:
Received 15 September 2014
Accepted 2 April 2015
Available online 15 April 2015

Keywords:
Dietary exposure assessments
Uncertainty analysis
Tiered approach
Deterministic models
Point estimates
Probabilistic models

ABSTRACT

Uncertainty analysis is an important component of dietary exposure assessments in order to understand correctly the strength and limits of its results. Often, standard screening procedures are applied in a first step which results in conservative estimates. If through those screening procedures a potential exceedance of health-based guidance values is indicated, within the tiered approach more refined models are applied. However, the sources and types of uncertainties in deterministic and probabilistic models can vary or differ.

A key objective of this work has been the mapping of different sources and types of uncertainties to better understand how to best use uncertainty analysis to generate more realistic comprehension of dietary exposure. In dietary exposure assessments, uncertainties can be introduced by knowledge gaps about the exposure scenario, parameter and the model itself. With this mapping, general and model-independent uncertainties have been identified and described, as well as those which can be introduced and influenced by the specific model during the tiered approach.

This analysis identifies that there are general uncertainties common to point estimates (screening or deterministic methods) and probabilistic exposure assessment methods. To provide further clarity, general sources of uncertainty affecting many dietary exposure assessments should be separated from model-specific uncertainties.

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1. Introduction

Dietary exposure assessments are an important part of any risk and benefit analysis for foods including their ingredients and components (e.g. nutrients, food additives, flavourings, novel foods) as well as substances that are present unintentionally (e.g. pesticide residues and contaminants) (EFSA, 2010a). Therefore, a clear understanding of the strengths and limitations of any dietary exposure assessment is important for informed risk management decisions in order to achieve a high level of consumer protection while supporting sustained innovation. The question is not whether we know everything but how can a decision be best made with what we know. Understanding the uncertainties involved in this analysis to further

Abbreviations: ADI, acceptable daily intake; APET, Added Portions Exposure Technique; EFCOVAL, European Food Consumption Validation; EFSA, European Food Safety Authority; EPIC, European Prospective Investigation into Cancer and Nutrition; EU, European Union; FAIM, Food Additives Intake Model; FAO, Food and Agriculture Organization of the United Nations; LOD, level of detection; LOQ, level of quantification; MCRA, Monte Carlo Risk Assessment; MPL, maximum permitted level; MSDI, Maximized Survey Derived Intake; NEVO, Dutch Food Composition Database (*Nederlands Voedingsstoffenbestand*); OIM, observed individual means; PRIMo, Pesticide Residue Intake Model; PPR, Panel on Plant Protection Products and their Residues; SCOOP, Scientific Co-operation on Questions Relating to Food; TDS, Total Diet Study; US EPA, United States Environmental Protection Agency; WHO, World Health Organization.

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http://dx.doi.org/10.1016/j.fct.2015.04.007
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improve dietary risk assessments is important in providing a realistic and clear picture for all stakeholders, including food industry, policy makers, and finally consumers.

The fundamental concept of a dietary risk assessment is the comparison between health-based guidance values for a food constituent and the exposure of the population to the food constituent. Sources of uncertainties can be found for both the toxicological and the exposure elements. However, this publication focuses on uncertainty analysis related to dietary exposure assessments.

Actually, why should the assessment and reporting of uncertainties be considered in dietary exposure analysis? To support a well-informed decision making process based on transparency, trust and credibility, it is a critical part to demonstrate that uncertainties have been taken into account, to recognise when more or better information is needed and to translate uncertainties into information to be considered in the risk management process. The 2009 *EFSA Scientific Committee Guidance on Transparency* (EFSA, 2009a) highlights that "each scientific output should describe the types of uncertainties encountered … and indicate their relative importance and influence on the assessment outcome".

A systematic examination of all potential sources and types of uncertainties should be included in any dietary exposure assessment to maximise the likelihood that important uncertainties are recognised and evaluated (Codex Alimentarius Commission, 2003; EFSA, 2011; World Health Organization/International Program on Chemical Safety, 2008). However, many of those assessments follow standard screening procedures that are intended to produce conservative[1] estimates of exposure and do not always provide a detailed analysis of uncertainty. If those screening methods indicate exceedance in relation to health-based guidance values, more refined assessments are necessary. However, the sources and types of uncertainties can differ or vary between deterministic and probabilistic models.

In addition to emphasising the importance of uncertainty assessments and to further harmonise and standardise their identification, there is a need to develop principles and approaches that will enable uncertainties to be communicated in a clear, consistent and understandable way to all stakeholders.

In this publication the tiered approach for uncertainty analysis is explained and the existing methods are described. Uncertainties are presented that are common or specific to the different dietary exposure assessment methods. Consistencies and differences between those uncertainties are summarised and conclusions drawn.

2. Context and concepts

2.1. Tiered approach to dietary exposure assessments

Several international and regional bodies (EFSA, 2006, 2012a; Suhre, 2000; World Health Organization/International Program on Chemical Safety, 2008) recommend a tiered approach for dietary exposure assessments of substances in food with point estimates used in an initial tier (for screening assessment), followed by more refined point estimates or deterministic methods and, finally, probabilistic methods. This tiered approach starts from relative simple estimates based on conservative assumptions and default values to more complex and refined exposure assessments.

The analysis of uncertainties in dietary exposure assessments should follow the same tiered approach starting with simple subjective evaluation of uncertainty (qualitative methods) and progressing to refined deterministic or probabilistic modelling (qualitative and quantitative methods) when appropriate (EFSA, 2006). Uncertainties are usually not quantified explicitly in screening or basic deterministic assessments, meaning it is not required to do an analysis of uncertainty on every occasion, because the standard conservative assumptions are assumed to provide an appropriate protection level. In probabilistic assessments, however, it is necessary to consider the uncertainties explicitly, because some of the conservative assumptions of deterministic assessments have been replaced with distributions (EFSA, 2012a). It then becomes more important to address the question of how conservative still the more refined method is. For data or other information included in the assessment it is important to understand their nature as in practice information is never perfect and may have originally been collected for an entirely different purpose unrelated to the risk assessment.

2.2. Uncertainties in dietary exposure assessment

Uncertainty in risk assessment in the general sense is defined by WHO/IPCS (World Health Organization/International Program on Chemical Safety, 2008) as "imperfect knowledge concerning the present or future state of an organism, system, or (sub-)population under consideration". Uncertainties in risk assessment include considerations related to missing, incomplete and/or incorrect knowledge, as well as those associated with ignorance and/or lack of awareness. Uncertainties should be characterised as transparently as possible to ensure their adequate consideration in decision-making concerning the need for and nature of appropriate risk management and communication (EFSA, 2006).

Since dietary exposure assessments are an integral part of dietary risk assessments, it is relevant to well understand the results thereof, including the involved uncertainties, for their correct interpretation as well as final conclusion of the risk managers. Dietary exposure assessments are providing information about the source and quantity of exposure to a substance coming from the diet as well as the population groups exposed. For a reliable estimation of the overall risk, it is important to properly characterise and sufficiently quantify uncertainties related to the exposure analysis. Uncertainties in dietary exposure assessment can be grouped by scenario, parameter and model and can occur for example by a lack of consumption data, concentration data or other factors determining exposure (World Health Organization/International Program on Chemical Safety, 2008).

Why is it relevant to quantify uncertainties? The simple answer is because they are fundamental components of risk analysis, but the process is far from simple. Risks cannot be reliably estimated if exposures and their uncertainties are not properly characterised and sufficiently quantified (World Health Organization/International Program on Chemical Safety, 2008). Given that complete information is never available, exposure assessors must make simplified assumptions (e.g. use defaults) or rely on data that are not necessarily representative of the populations or conditions of interest, e.g. by extrapolating results that have been generated for other purposes (EFSA, 2006). The uncertainty may not always affect the risk analysis, depending on the objective. For example, an assessment of differences in mean exposure between countries may be unaffected by systematic errors or uncertainties that are common between countries. An example is shown in the publication (Crispim et al., 2012) where errors due to self-reporting bias are shown to be comparable between regions.

Looking at the historical context, early exposure assessments used single point estimates of the maximum exposure estimates for groups or individuals. These lacked transparency in the underlying assumptions with no information on population distribution of exposure and uncertainties available. Since the 1990s the interest in exposure of different individuals in a population grew gradually. For example, USEPA (United States Environmental Protection

[1] Conservative estimates are meant to be estimates of exposure at the upper end of the range assuming a consumption of foods with the relevant component at high levels and a consumption of foods with the relevant component present in all foods.

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