Food and Nutrition Sciences, **2013, 4, 315-320**
http://dx.doi.org/10.4236/fns.2013.43042 Published Online March 2013 (http://www.scirp.org/journal/fns)

GUIDEA—Guidance for Dietary Intake and Exposure Assessment—A New Resource for Exposure Assessment Professionals

John Howlett[1], Neil Buck[2], Matthew Buck[3], Jeanne H. M. de Vries[4], Veronika Ehrlich[5], Melody Hove[4], Astrid G. Kruizinga[6], Pratima R. Jasti[7*], Benjamin Smith[8], David Tennant[9]

[1]West Hill, Wembley Park, UK; [2]DSM, Basel, Switzerland; [3]RatwareUK, Skelmersdale, UK; [4]Wageningen University, Wageningen, The Netherlands; [5]Nestec LTD., Lausanne, Switzerland; [6]TNO, Zeist, The Netherlands; [7]ILSI Europe A.I.S.B.L., Brussels, Belgium; [8]Firmenich S.A., Geneva, Switzerland; [9]Food Chemical Risk Analysis, Brighton, UK.
Email: [*]publications@ilsieurope.be

Received December 13th, 2012; revised January 13th, 2013; accepted January 21st, 2013

ABSTRACT

Exposure assessment is a key component of any risk-benefit assessment, yet it is clear that there is a lack of reliable methodology in this area for assessing consumer exposures to both food constituents and nonfood products. The International Life Sciences Institute (ILSI) Europe Food Intake Methodology Task Force has in the past explored methods to assess the intake of nutrients/additives and exposure to contaminants/residues from food. In December 2008, a workshop was held to discuss the differences between different types of exposure assessments as well as the difficulties involved in the practical application of the methods available. It was noted that although no two assessments are the same in terms of data required and its availability, or the assumptions made, there is also wide and perhaps unnecessary variation between the approaches taken by different assessors. As a result, the ILSI Europe Food Intake Methodology Task Force initiated an activity aimed at producing a practical guide for conducting intake/exposure assessments in the form of an interactive web-based application. During the course of this work it became clear that the best form in which to present the guide would be a web-based MediaWiki-type system. A website was developed and launched in October 2012, at which time global experts and practitioners in dietary exposure assessment were invited to register to use the site and help keep the knowledge contained within it, relevant and up-to-date. It is hoped that the guide will be an important reference source for a wide group of stakeholders, providing concise guidance on the planning, conduct, reporting and interpretation of exposure assessments and contributing to greater harmonisation of the dietary intake/exposure methodologies used.

Keywords: Exposure Assessment; Intake Assessment; Risk Assessment; Online Resource

1. Introduction

Dietary exposure and intake assessments are required for a number of reasons ranging from the notification of a new food substance on the market through to understanding nutrient intake. All such assessments, however, are done for two main reasons: safety/risk assessment and/or health-benefit assessment. Usually, the term exposure assessment is used in relation to chemicals other than nutrients and most often the interest is in the high consumers. The term intake assessment is usually used in relation to nutrients, where the interest is in both the high and low consumers. In this paper, the term exposure assessment is generally used and relates to both nutrients and other chemicals. Exposure assessment can be defined as the qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant [1]. It is a key component of any risk-benefit analysis of the presence of chemicals in the diet. Risk analysis provides a scientific basis for the setting of regulatory limits pertaining to undesirable substances (including intentionally added substances) and contaminants in food where high levels have a potential to cause harm, and also to nutrients where low levels of intake have a potential to impact adversely on public health. Its outcome can be used, for example, by risk managers to establish science-based levels of exposure that will not compromise consumer health and safety. Whatever the level at which hazardous or beneficial agents may occur in the food chain, it is the level of exposure to them that determines

[*]Corresponding author.

whether or not adverse effects will be experienced by consumers and it is for this reason that exposure assessment is of key importance to any risk-benefit analysis.

Conducting an exposure assessment requires the integration of many different types of information and draws on a large number of guidelines currently available in the field of dietary exposure assessment. Dietary exposure assessments combine data on concentrations of a chemical substance present in food with data on the quantity of those foods consumed. It is often the case that direct data are not available on the occurrence, concentration and/or consumption patterns of a particular constituent of a food; and therefore reference data need to be used (such as pre-existing food consumption databases). To be able to combine these different types of data in a meaningful way it is necessary to consider standardisation of associated metadata, in particular, those relating to the description of the foods and the characteristics of the populations who consume them. A number of different methods exist to combine or integrate food consumption estimates with chemical concentration data, ranging from quick worst-case estimations to refined methods aimed at assessing actual exposure. The selection of the method usually depends on a number of factors, including the purpose of the assessment (target chemical substance, population group, degree of accuracy required, etc.) and, above all, the availability of information [2,3].

While guidance on the conduct of exposure assessment is often available, it comes from a variety of sources and there is no single source which covers all aspects of the methods, principles and approaches to conducting and reporting dietary intake/exposure assessments on the complete range of components of the diet. This short communication aims at introducing ILSI Europe's web-based resource, GUIDEA (Guidance for Dietary Intake and Exposure Assessment), which could be used as a source of reference by a number of different stakeholders and thus may fill this gap of consolidating dietary exposure/intake information.

2. ILSI Europe GUIDEA

During 2009, the ILSI Europe Food Intake Methodology Task Force initiated an activity aimed at producing a practical guide which identifies best practice for conducting intake/exposure assessments for different goals/scenarios across a wide range of chemicals in the diet. The ILSI Europe activity has resulted in an interactive, web-based system, GUIDEA (Guidance for Dietary Intake Exposure Assessment), constructed on the Media Wiki platform. This platform was chosen for GUIDEA because it is accessible to a wide audience and can be maintained as a "living" and interactive system with the potential for continuing growth and development over time through the contributions of users who are experts in the field. It also has the potential to be further developed into a teaching tool for remote, interactive use by students. As each intake assessment is unique, the system is designed to help the user find the information they need in a flexible way. It is intended that the guide will be an important reference source for stakeholders (exposure and risk assessors, experts and students in the respective fields), providing concise guidance on the planning, conduct, reporting and interpretation of exposure assessments, and will also be capable of development into materials for future training courses. By condensing information on the topic of dietary exposure assessments into a single place it is hoped that GUIDEA will contribute to greater harmonisation.

The Principles on Which GUIDEA Is Constructed

The assessment of dietary exposure relies on two key inputs: knowledge of the concentration of a component/chemical in foods; and knowledge of the consumption of those foods by individuals. Broad general guidance is available for regulatory purposes from various sources for the assessment of exposure, however these allow for differences in the conduct and reporting of assessments. Differences arise from:

- Differences in the paradigm of the assessor, for example "protectionist" versus "realist".
- Varying interpretations of the exposure scenario under consideration which may result in different assumptions being used in the calculation methodology.
- Different approaches to investigate and manage source data uncertainty.
- Differences in the determination of the level of accuracy required, and therefore the calculation methodology.

It is the recognition of the importance of exposure assessment in combination with the inherent difficulties, which has led to the production in recent years of numerous expert publications [3,4]. Furthermore, there exists a body of assessments from regulatory submissions, authority opinions and other sources from which to draw an insight into current practices. There is also a large body of knowledge on practices used by nutritionists and epidemiologists to assess the nutritional intake of populations. These practices may share some of the same difficulties inherent to exposure assessment, but may also help in formulating best practice.

Application of a tiered approach is generally recommended [2] but there is little guidance available on which tier to use in an assessment. International guidelines [5] propose that an assessment should begin with a highly conservative tier and compare the result with the hazard

characterisation level; if the assessment output compares unfavourably with the hazard characterisation, the assessment of intake/exposure should then progress to an assessment with less conservatism. This guidance is based on the purely practical consideration that more conservative assessments are invariably less resource-intensive to conduct. Although this approach has merit, it is clear that no useful purpose is served by conducting an assessment with greater conservatism than is required for the purpose of the assessment, especially when the available data would permit a more refined assessment. Therefore, identifying the appropriate method(s) for an assessment relies on balancing the degree of conservatism that is acceptable for the purpose of the assessment, and an understanding of what type of calculation the available data will support.

The purpose of the ILSI Europe-GUIDEA activity was to draw together all of the above by formulating practical guidance that provides a standardised view and highlights how to address shortcomings of current approaches. Using GUIDEA, one should be able to obtain answers to the following key questions:

- What type of assessment is appropriate for which purpose?
- How should assessments be conducted?
- How should assessments be reported?

3. The ILSI EUROPE-GUIDEA Project

The website demonstrates the use of GUIDEA as a concise guide in exposure assessments by presenting a few examples for specific substance groups/scenarios to highlight some current practices. The website will be available at http://www.ilsi-guidea.org. It is based on the structure as shown in **Figure 1**.

3.1. About ILSI GUIDEA

This section provides information on the background of GUIDEA, set-up process, project planning and objectives of GUIDEA.

3.2. Dietary Exposure Assessment

This section covers aspects with the aim of providing guidance to the user on the data sources, calculation methods (deterministic, probabilistic etc.), substance groups (types of exposure assessment available/used in different scenarios), selection of tier and the reporting template to be used. GUIDEA helps in identifying the purpose of the assessment such as, for example, to estimate the intake of an established nutrient or exposure to a new contaminant. This characterisation of the purpose of the assessment provides information on the perspective, whether the

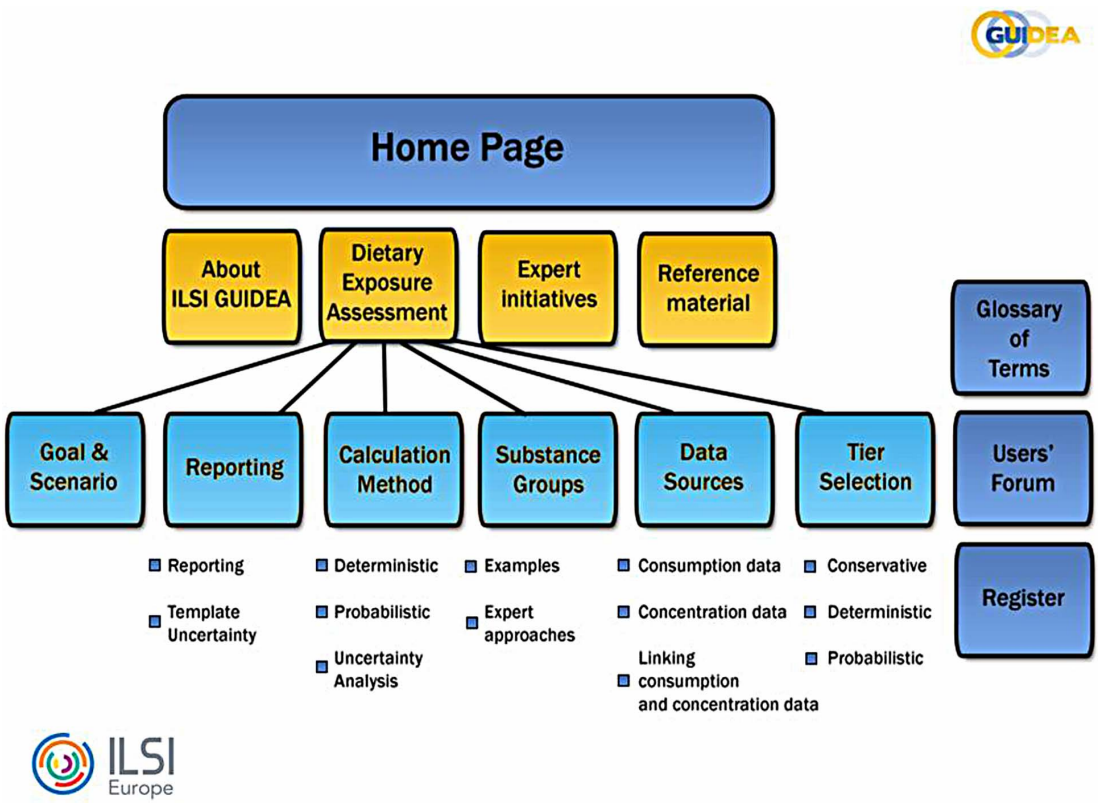

Figure 1. GUIDEA site map.

assessment would rely on retro- or prospective data. This gives an insight into the main areas of assumption required. The subsection on "Substance groups" describes the current practices used in dietary intake and/or exposure estimates under the following sub-headings:

- Information from regulatory bodies, directives or guidance documents (currently the focus of GUIDEA is on European regulatory aspects but it is intended to widen the scope to international regulatory aspects specific to each region);
- Goals to assess exposure assessment;
- Selection and description of examples and finally;
- Discussion and conclusion regarding current practice.

GUIDEA also contains a standard template for the reporting of an assessment. For the novice assessor, familiarization with this template before commencing work is recommended so that the desired form of the output of the task in-hand is understood at the outset.

3.3. Expert Initiatives

There is a wealth of information from the large number of exposure assessments which have been conducted over the years by experts in the field. There are various activities on-going or planned on exposure assessment nationally and internationally. This section attempts to establish links with parallel initiatives wherein the opinions of experts will be considered. Although the aim of this website is to try and centralize key information on dietary exposure it is clear that due to the scope and complexity of information available on this subject, a complete overview is necessarily not achievable.

3.4. Reference Materials

GUIDEA also considered the possibility of assembling all possible information (currently incomplete though ongoing) that is representative of current practices (guidelines, publications, recent assessments). This section comprises information on the following types of documents from the last 10 years concerning all possible aspects of exposure assessment:

- Guidance on any aspect of exposure assessment, from governmental, authority or quasi-official sources.
- Accepted models that are used nationally or internationally.
- Significant Reports or Reviews.
- Data sources for concentration and consumption.

4. ILSI Europe Workshop on GUIDEA

In November 2011, ILSI Europe held a workshop to demonstrate the GUIDEA website in its formative stage and to provide an opportunity for scrutiny by a broad group of experts the field of exposure assessment. The workshop consisted of two plenary sessions with presentations by invited speakers and break-out sessions in which participants were distributed amongst five working groups to discuss and test detailed aspects of the web-based utility. It was attended by more than 50 experts from industry, academia and governmental organisations. A preliminary version of the website was presented; scientific content was reviewed and the website was tested for its usability. The working groups reported the outcome of their discussions back to a final plenary session in which they were discussed. In overview, participants noted that many organisations were engaged in the assessment of exposure and its application to risk analysis and that successful harmonisation of methods and approaches between them had, to date, remained elusive. It was acknowledged that GUIDEA might provide a catalyst to facilitate interaction between approaches and thereby lead to greater harmonisation. There was discussion of the degree of interaction to be anticipated between users and the web-based system, with emphasis being placed on the need to encourage contributions from users both at the level of inputting content and at the level of contributing to the evolution of approaches to exposure assessment. It was agreed that one of the potential strengths of an interactive web-based system would be its ability to evolve and improve continuously over time. The necessity to integrate exposure assessment with toxicological evaluation in any risk analysis process was noted and the importance of reflecting this relationship on the website in order to set the value of exposure assessment into context was agreed.

The main conclusions of the workshop in relation to the structure and operation of the web-based utility can be summarised as follows:

- There is a need to set exposure assessment in the broader context of risk-benefit analysis;
- There is a need for an initial, clear structure to be set out so that users can readily identify their locus within the website;
- There is a need for a glossary to ensure that terminology within GUIDEA and between GUIDEA and other sources is aligned;
- The website should make use of visuals in preference to text wherever possible in order to engage the interest of users more immediately;
- There is a need to make maximal use of inter-linking and cross-linking between elements of the website;
- The website should clearly define its users, target groups and contributors/partners;
- There is a need to provide a sustainable resource for the management of the website in order to ensure its long term success;
- There is a need to define the balance between retention

of ownership of the website by ILSI Europe and an evolution to free-access by interested participants/ contributors.

The discussion and conclusions generated by the Workshop were greatly appreciated by the GUIDEA Expert Group. Specific comments on content, usability, presentation, functionality and maintenance were noted and taken into account in further development of the website with a view to its launch in final form on 30 October 2012. As an interactive and "living" system, GUIDEA is expected to continuously grow and develop further with the input of experts who join as registered users of the site.

Registration Process to GUIDEA

While read-only access will be available to all visitors to the site, first-time users who wish to participate in the website forum and to contribute to the content of the site itself will need to register. Registration will be at no cost to the user and full instructions for the registration process are provided on the website.

5. Future Developments

5.1. Applicability of a Web-Based Tool to Training

Due to an acknowledged need for more training in the field of exposure assessment in Europe, it is anticipated that this project will fill an important gap. Furthermore, this exercise will help to better communicate the broader, more technical issues impacting exposure assessment outlined by the WHO/IPCS and EFSA. In a time when standards-based education has taken on a greater real world focus, it has become more important for educators to provide students with authentic connections to a learning environment beyond the school boundaries [6]. Furthermore, technological advancement calls for more innovative and versatile methods of instruction for students, and a web-based tool such as GUIDEA is one that also simulates the student-teacher scenario, offering a platform for interaction between students and experts on the discussion forums. In total, it is intended that GUIDEA will serve as a useful online training resource for industry and governmental scientists working in the fields of food safety, exposure/risk assessment and regulatory affairs; it will also provide a teaching resource for use by academics in the field of food safety and dietary intake/exposure, and a reference resource for students/early career scientists in food safety and exposure/intake assessment.

5.2. A Focus for Professional Interest

In addition to providing a platform for exposure assessors to learn and share information, a future stimulation and hope of the GUIDEA website may be the formation of a Scientific Society for Dietary Exposure Assessment. There is currently a lack of a professional body to reflect the interests of experts in Dietary Exposure Assessment and it is envisaged that the GUIDEA website could provide the seed for such a society, using as a founding group those experts in the field of exposure assessment who register as users. Such a professional body would have among its guiding principles the furtherance the practice of exposure assessment on the basis of sound scientific principles and the encouragement through training of those who wish or need to enter the field.

More information about the website in its present form can be found at: http://www.ilsi-guidea.org.

6. Acknowledgements

This work was commissioned by the Food Intake Methodology Task Force of the European branch of the International Life Sciences Institute (ILSI Europe). Industry members of this task force are (Ajinomoto Europe, Bayer CropScience BioScience, Coca-Cola Europe, Danone, DSM, Firmenich, Givaudan International, McNeil Nutritionals, Nestlé, PepsiCo International and Unilever). This publication was coordinated by Dr. Pratima Rao Jasti, Scientific Project Manager at ILSI Europe. For further information about ILSI Europe, please email info@ilsieurope.be or call +32 2 771 00 14. The opinions expressed herein and the con- clusions of this publication are those of the authors and do not necessarily represent the views of ILSI Europe nor those of its member companies.

REFERENCES

[1] CAC (Codex Alimentarius Commission), "Codex Alimentarius Commission Procedural Manual 20th Edition," Codex Alimentarius Commission, Geneva, 2011

[2] R. Kroes, D. Müller, J. Lambe, M. R. H. Löwik, J. Van Klaveren, J. Kleiner, R. Massey, S. Mayer, I. Urieta, P. Verger and A. Visconti, "Assessment of Intake from the Diet," *Food and Chemical Toxicology*, Vol. 40, No. 2-3, 2002, pp. 327-385. doi:10.1016/S0278-6915(01)00113-2

[3] European Food Safety Authority (EFSA), "Overview of the Procedures Currently Used at EFSA for the Assessment of Dietary Exposure to Different Chemical Substances," *EFSA Journal*, Vol. 9, No. 12(2490), 2011, p. 1-33. www.efsa.europa.eu/efsajournal doi:10.2903/j.efsa.2011.2490

[4] European Food Safety Authority (EFSA), "Opinion of the Scientific Committee on a Request from EFSA Related to Exposure Assessments," *EFSA Journal*, Vol. 3, No. 7 (249), 2005, pp. 1-26. www.efsa.europa.eu/efsajournal

[5] WHO, "Chapter 6: Dietary Exposure Assessment of Chemicals in Food," In: *Environmental Health Criteria* 240 *on Principles and Methods for the Risk Assessment of*

Chemicals in Food, World Health Organization, 2009, pp. 6-1-6-95.

[6] S. C. Cavanaugh, "The Effectiveness of Interactive Distance Education Technologies in K-12 Learning: A Meta-Analysis," *International Journal of Educational Telecommunications*, Vol. 7, No. 1, 2001, pp. 73-88.

