GUIDEA - A new tool for exposure assessment

6th Asia Conference on Food and Nutrition Safety
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Executive & Scientific Director, ILSI Europe
Rapid changes vs. Consumer choices and concerns

- Globalisation
- Rapid pace of changes in science and technology, legislation
- Current socio-economic and socio demographic realities

Consumer concerns
- Intensified farm practices – use of pesticides
- Industrialisation of food production
- Use of additives and preservatives for improved taste, shelf-life
- New technologies

Spontaneous responses to problems and risks associated with food

- Chemical products, pesticides, toxic substances (19%)
- Food poisoning, Bacteria (e.g. salmonella, listeria) (12%)
- Diet-related diseases (high cholesterol, cardiovascular problems, diabetes, ... ) (10%)
- Obesity, overweight (9%)
- Lack of freshness, expiry dates (9%)
- Food additives, colouring, preservatives (9%)
- GMOs - genetically modified organisms (8%)
- Diet too high in fat, sugar or calories/ Unbalanced diet (7%)
- We do not know what we are eating/ traceability of the products, origin of products (7%)
- Food is not natural/ industrial/ artificial (6%)

## Food Intake Methodology Task Force

### 2012 Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Company/Institution</th>
<th>Country</th>
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<tbody>
<tr>
<td>Dr. Benjamin Smith</td>
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<td>Dr. Neil Buck</td>
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<td>Dr. Susanne Kettler</td>
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<td>BE</td>
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<td>Dr. Laurent Le Bellego</td>
<td>Danone</td>
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<td>Dr. Regina Oberdörfer</td>
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<td>Mr. Frederic Timmermans</td>
<td>ILSI Europe</td>
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Food Intake Methodology Task Force

Created: 1995 under the name ‘Food Chemical Intake’

Why?
Aimed at establishing recommendations for the estimation of human intake through the diet of food chemicals, additives and contaminants.

How?
By publishing literature reviews on dietary intake assessments in peer-reviewed journals
By facilitating discussions with experts in the field through workshops and symposia

Recent development in 2007
Scope of task force was redefined to develop and evaluate methodologies to accurately quantify food intake and the exposure to food constituents; renamed as ‘Food Intake Methodology’
Latest achievements

• GUIDEA workshop & launch of the website:
  – Workshop in November 2011, Geneva to prototype the preliminary version of the website (50 participants)
  – Website was launched in October 2012, Brussels

• Publications in Food Additives & contaminants journal:
  – Uncertainty Analysis of the Use of a Retailer Fidelity Card Scheme in the Assessment of Food Additive Intake (2011)
  – Use of Retailer Fidelity Card Schemes in the Assessment of Food Additive Intake: Sunset Yellow A case Study (2010)
Codex Alimentarius RA Framework

Risk Assessment
- Hazard Identification
- Hazard Characterisation
- Exposure Assessment
- Risk Characterisation

Risk Management
- Risk Evaluation
- Option Assessment
- Option Implementation
- Monitoring & Review

Risk Communication
Interactive exchange of information and opinions concerning risks

Source: FAO/WHO Codex Alimentarius
## Steps in Exposure Assessment

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<th>Step 1</th>
<th>Which type of exposure assessment?</th>
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<td></td>
<td>Describing the problem</td>
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<td></td>
<td>- Scenario leading to human exposure</td>
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<td>- Sources of uncertainty &amp; variability</td>
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<td>Identifying the solution</td>
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<td>- Acceptable degree of over-estimation</td>
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<td>- The purpose of the assessment</td>
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<th>Step 2</th>
<th>How to conduct the assessment?</th>
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<td>Occurrence and Concentration</td>
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<td></td>
<td>- Matching required –vs- available data</td>
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<td></td>
<td>Consumption</td>
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<td>- Matching required –vs- available data</td>
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<td></td>
<td>Calculation</td>
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<td>- Reflection of the scenario?</td>
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<td>- Mathematical procedure</td>
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<th>Step 3</th>
<th>Reporting the assessment</th>
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<td>Describing the process</td>
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<td></td>
<td>- Problem &amp; solution identification</td>
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<td>- Data identification</td>
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<td>- Calculation method</td>
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<td>Describing the result</td>
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<td></td>
<td>- Accuracy and reliability</td>
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<tr>
<td>Method</td>
<td>Principle</td>
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<tr>
<td>Dietary record or Food Diary</td>
<td>All foods consumed on one day are recorded, portion sizes are estimated or weighed; Duration: 1 up to 7 days</td>
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<td>24-hour recall</td>
<td>Interview with participant on consumption during the past 24 hours</td>
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<td>Food Frequency Questionnaire</td>
<td>Questionnaire on habitual consumption during longer periods in the past (month-year)</td>
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<td>Diet History</td>
<td>Questionnaire to estimate usual consumption, including certain characteristics of foods consumed</td>
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Guidance for Dietary Intake Exposure Assessment (GUIDEA)

http://www.ilsi-guidea.org
Background

Available reports:

- Develop a series of case studies (focus on exposure to various classes of substances, nutrients, contaminants, additives, allergens etc.)

- Identify different exposure methodologies used by different sectors and identify scope for harmonisation, where possible.
Scope of the activity

- Develop a practical guide to planning, conducting, reporting and interpreting exposure assessments.
- Using GUIDEA would provide a user with answers to the following questions:
  - What type of assessment is appropriate for which purpose?
  - How should assessments be conducted?
  - How should assessments be reported?
- Output of GUIDEA is in the format of an interactive, web-based format.
Guidance for Dietary Intake Exposure Assessment (GUIDE A)

OUT OF BOX THINKING
Brainstorming meeting

2008

2009

2010-11

2011

2012

Data collection and analysis
Building and populating the website

Updating and finalising the content

Workshop to review the website

Website LAUNCH
October 2012

SET UP
Defining the scope of the activity
Identification of experts
Planning of activity
Target groups

- Students
- New Employees

- Intake/Exposure Assessors
- Academics

- Risk-benefit Assessors
- Risk Managers
- Risk Regulators
- Risk Communicators

Learning
Learning and Discussion
Using the results
Needs of Students or new employee in this area

- Can I get an overview of dietary exposure assessment?

- Is there an overview of important references?

- What do all the terms mean?
Overview of dietary exposure assessment

Introduction to dietary exposure assessment

Contents

1 Risk assessment paradigm
2 Role of dietary exposure assessment
3 General principles of exposure assessment
   3.1 Step 1
   3.2 Step 2
   3.3 Step 3
4 References

Risk assessment paradigm

Risk assessment is defined by the Codex Alimentarius Commission (CAC, 2011) as a scientifically based process consisting of four key processes, namely:

1. Hazard identification
2. Hazard characterisation
3. Exposure assessment
4. Risk characterisation

Risk assessment is an important aspect of food law and, together with risk management and risk communication, is one of the three elements of the international framework. Risk assessment is the element for which the scientific basis of risk analysis is developed.
Overview of important references

Reference material

Glossary of terms > Data sources > Home Page > Introduction to dietary exposure assessment > Reference material

The ILSI Europe activity on exposure assessment has looked into aspects such as assembling all possible information (though not completely) that is representative of current practices. It is intended to collect information from the last 10 years concerning all possible aspects of exposure assessment using the following types of document:

- 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

The objective is to use the above as source material to summarise published ‘best practice’. However, it is a difficult task to draw together multiple documents that are written from different perspectives. As a suggestion, there could be two ways of approaching the task:

Identify common themes

Common themes in the documents can be identified and consolidated, for example:

- Scenario description
- Planning the assessment and appropriate models
- Sources and suitability of concentration data
- Sources and suitability of consumption data
- Capturing uncertainty

Meaning of terms

Glossary of terms

Data sources > Home Page > Introduction to dietary exposure assessment > Reference material > Glossary of terms

24-hour recall

A record of the food consumed by a participant (at home and away from home) during the previous 24 hours, obtained through interview with a trained interviewer.

Acceptable conservatism

Acute exposure

Exposure to a substance or contaminant over a short period of time (IUPAC, 2007)¹.

ADI - Acceptable daily intake

Estimate of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk. A standard body weight of 60 kg is generally used in calculation of the ADI (IUPAC, 2007)¹.

Available data

An assessment of exposure requires data on the occurrence and concentration of a chemical in food(s) and the consumption of those foods. In the tiered approach to exposure assessment, the higher the tier the greater the richness of this data (and the required

Needs of intake/exposure assessor and academic

• What are good data sources?

• What are the different calculation methods?

• What is the current practice for many substance groups?

• What are other expert initiatives?

• Can I discuss issues with other experts?
What are good data sources?

Dietary exposure assessments combine food consumption data with data on the concentration of chemicals in food. The data required for assessing dietary exposure are determined by the objective of the assessment.

This section lists a selection of data sources for consumption and concentration and aims to give information on the most appropriate types of data used.

### Contents [hide]

1. Food consumption data
   1.1 Dietary assessment methods
   1.2 Technical aspects
2. Concentration data
   2.1 Sources of concentration data
   2.2 Variability in data
3. Linking concentration and consumption data
4. Other data sources
5. Further reading

### Food consumption data

What are the different calculation methods?

Calculation methods

Reference material > Glossary of terms > Data sources > Tier > Calculation methods

The choice of methodology for use in dietary exposure analysis is generally limited by the nature of food consumption data and chemical occurrence data that are available. For example, if only summary data on food consumption, such as those published in the EFSA Comprehensive Database, are available then it is possible to perform only simple deterministic estimates.

If, on the other hand, detailed individual food consumption survey data, such as those published in the US National Health and Nutrition Examination Survey, are available then more sophisticated probabilistic methods can be applied.

Similarly, if only single point values, such as means or maximum values, are available to represent concentrations of chemicals in food groups then a probabilistic model will be unable to add any extra precision.

An intermediate model, usually described as a distributional method, exists where fixed values for concentrations are linked with food consumption data from an individual-based survey.

It is usual to begin by considering simple, conservative models and only if these produce unsatisfactory results is it necessary to proceed to a more detailed tier of modelling.

For more information see the following pages:

- Tier selection
- Deterministic
- Probabilistic
- Reporting

Current practice for many substance groups?

http://www.ilsi-guidea.org/index.php?title=Substance_groups
What are other expert initiatives?

Can I discuss issues with other experts?

Needs of Users of result

- How do I interpret the results?
- What are the uncertainties in the results?
How do I interpret the results?

What are the uncertainties in the results?

Uncertainty analysis

Expert initiatives > Home Page > Reporting > Home Page > Uncertainty analysis

Uncertainties are unavoidable in dietary exposure assessment. It is therefore necessary to identify the sources of uncertainty, evaluate them, reduce them where possible and, where not, provide an indication of their direction and magnitude. Effective risk management is impossible without an evaluation of uncertainty because it is necessary to be able to make judgements about the degree of conservatism in the exposure assessment in comparison with uncertainties in the toxicology and within the context of any known toxicological end-points.

The International Programme on Chemical Safety (IPCS) Harmonization Project Draft Guidance Document on Characterizing and Communicating Uncertainty in Exposure Assessment was released for comment in December 2006. The draft document was prepared by an international working group of experts in exposure assessment. Comments received on the draft were considered by working group at a meeting in Bradford, United Kingdom, in March 2007. The final document is now available on the IPCS website (WHO/IPCS, 2008).¹

The EFSA Scientific Committee has published guidelines to provide methods for addressing uncertainties in dietary exposure assessment (EFSA, 2006).² The Scientific Committee recommend that dietary exposure assessments should start with a systematic examination of potential sources and types of uncertainty, to maximise the likelihood that important uncertainties are recognised.

The Guidelines distinguish between sources of uncertainty such as:
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- Dr. Neil Buck (DSM, CH)
- Dr. Catherine Clapp (Unilever, UK)
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- Dr. Philippe Verger * (World Health Organization (WHO, CH)
- Dr. Pratima Rao Jasti (ILSI Europe, BE)

* Observer
Conclusion

GUIDEA is a valuable source of information on exposure assessment incorporating all relevant sources already available.

Initial feedback from the launch meeting on 30th October 2012:

- The website will be a useful resource for risk managers and other stakeholders (Mr. Wim Debeuckelaere, DG Health and Consumers).

- GUIDEA will be a key resource for regulators (Dr. Joseph Shavila, UK FSA).

- It is a useful tool for beginners in exposure assessment as it provides links to activities of other relevant stakeholder groups (Dr. Dieter Brigitta, DG Research).
www.ilsi.eu

Thank you!