Estimating exposure to sweeteners in the diet

John Howlett

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Risk Analysis
Risk Analysis

Hazard Identification

↓

Hazard Characterisation

↓

Exposure Assessment

↓

Risk Characterisation

↓

Risk Assessment

Risk Communication

Risk Management

Risk Characterisation
Risk Analysis

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

* Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy.

* Codex Alimentarius: Working Principles for Risk Analysis for Food Safety for Application by Governments
Exposure

Estimation of exposure to dietary components requires information about:

- the levels and patterns of use in foods and drinks (occurrence)
- the quantities of those foods and drinks consumed and by whom.

These two types of information are combined to generate an estimate of exposure:

\[
\text{Exposure} = \text{occurrence} \times \text{amount of food consumed}
\]
A stepwise approach to exposure assessment

* Dietary Exposure Assessment of Chemicals in Food: Report of a Joint FAO/WHO Consultation, Anapolis, Maryland, 2005
Sources of occurrence data

Disappearance data
– total production figures; amounts entering the national food chain

Where and how used
– categories listed in food standards legislation and advisory texts (eg Codex General Standard for Food Additives)
– food industry usage surveys
– food labelling surveys

Use levels
– maximum permitted levels in food standards legislation and advisory texts (eg GSFA)
– industry usage survey levels*
– analytical data*

* Variability in data – range, ‘typical’, maximum?
hypothetical versus actual levels of use

Measured concentrations of sweeteners in non-alcoholic beverages in Belgium *

<table>
<thead>
<tr>
<th>Sweetener</th>
<th>Concentration (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspartame</td>
<td>600</td>
</tr>
<tr>
<td>Sucralose</td>
<td>300</td>
</tr>
<tr>
<td>Saccharin</td>
<td>80</td>
</tr>
<tr>
<td>Cyclamate</td>
<td>250</td>
</tr>
<tr>
<td>Acesulfame-K</td>
<td>350</td>
</tr>
</tbody>
</table>

Maximum permitted levels of sweeteners in Belgium (mg/litre)

Sources of food consumption data

**Data elements required:**
- description of the food
- frequency of consumption
- amount consumed
- proportion of the population consuming
- demographic/biometric data on the population consuming

**Disappearance data:**
- the amount of food entering the national food chain

**Food consumption surveys:**
- Household Budget Survey
- Diary-based record
- 24-hour recall
- Food Frequency Questionnaire
- Diet History
# Dietary assessment methods on the individual level

<table>
<thead>
<tr>
<th>Method</th>
<th>Principle</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary Record OR Food Diary</td>
<td>All foods consumed on a day are recorded, portion sizes are estimated or weighed; <strong>Duration</strong>: 1 up to 7 days</td>
<td>* Information on detailed food intake</td>
<td>* No record of change in eating habits</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>* High burden on participant</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>* Expensive</td>
</tr>
<tr>
<td>24-hour Recall</td>
<td>Interview with participant on consumption during the past 24 hours</td>
<td>* No literacy of participant needed</td>
<td>* Trained interviewer needed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* Low burden on participant</td>
<td>* Depends strongly on the memory of the participant</td>
</tr>
<tr>
<td>Food Frequency Questionnaire</td>
<td>Questionnaire on habitual consumption during longer periods in the past (month - year)</td>
<td>* Information of food consumption over a longer period of time</td>
<td>* Limited number of foods (closed food list)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* No influence of eating behaviour</td>
<td>* Depends strongly on memory of respondent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>* No specific quantification of amounts consumed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>* No correlations between consumption of foods</td>
</tr>
<tr>
<td>Diet History</td>
<td>Questionnaire to estimate usual consumption, including certain characteristics of foods consumed</td>
<td>* Information of consumption over a longer period of time</td>
<td>* Depends strongly on memory of respondent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* Information on the whole diet is obtained</td>
<td>* Consumption cannot be precisely quantified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* No influence of eating behaviour</td>
<td>* Consumption is often misreported</td>
</tr>
</tbody>
</table>
Duration of survey can influence results

Variation in apparent consumption of carbonated beverages by schoolchildren aged 4-18 years according to duration of survey*

*Tennant D.R., data from UK NDNS 1997
methods of calculation

- crude
  - screening models
  - deterministic
  - probabilistic
  - direct models
  - conservative
  - refined
  - point estimates
  - distributional

GUIDEA (http://www.ils-gidea.org)
Simple screening

Based on disappearance ("poundage") data:

\[
\text{Exposure} = \frac{\text{total production or sales in country}}{\text{total population}}
\]

- Useful indicator of \textit{per capita} average, mg/day.
- Problems accounting for low bodyweight individuals (children)
- Problems accounting for high level exposure
“Budget method”

Predicts a maximum use level that would not cause intakes to exceed ADI.

Assumes that:
• energy demands per unit body weight per day are constant (50 kcal/kg bw/day)
• 50 kcal is associated with 25g of food
• only a limited proportion of the diet (25%) can contain additives.

Reduces down to:
- Maximum level in foods (mg/kg) = ADI (mg/kg bw) × 160
- Maximum level in beverages (mg/l) = ADI (mg/kg bw) × 40

For additives used in a wide range of foods:
- Maximum level (mg/kg) = ADI (mg/kg bw) × 80

If the additive is permitted in solid foods and beverages then the ADI must be divided between foods and drinks and the convention is to split it 50:50.
Deterministic modelling

• Spreadsheet-based
• Uses data-derived fixed values to represent both food consumption and additive use levels
• Gives rise to point estimates (‘mean’, ‘typical’, ‘high level’, ‘maximum’ intakes etc)

Limitations:
• Difficult to estimate total high level intake from all foods
• Problems with bodyweight correction
Simple distributional modelling

- Uses raw data from a food consumption survey to estimate food consumption for each individual.

- Uses fixed values for use levels and calculates the intake for each individual.

- Provides mean and percentiles for the consuming population.
Refined probabilistic modelling – Mont Carlo simulation

- Requires comprehensive food consumption data (food diaries)
- Takes account of variability in food consumption and usage data
- Can take uncertainty and variability into account in 2-dimensional model
- Provides a more realistic representation of exposure across the population
- Statistically complex and may require many iterations – high resource demand

1. Random sample from usage distribution
2. Random sample from consumption distribution
3. Add to intake distribution
4. Repeat many 000’s of times to achieve stability
Some sources of additional information

FAO/WHO Environmental Health Criteria 240

IPCS
International Programme on Chemical Safety

Environmental Health Criteria 240
Principles and Methods for the Risk Assessment of Chemicals in Food

Chapter 6
Dietary Exposure Assessment of Chemicals in Food

www.ils expo sure.org
FAO/WHO Environmental Health Criteria 240
Uncertainty

“... Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis ...”

“... Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner ...”

“... The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment ...”
Aspartame intake (mean and high percentile of highest consumer group)

as reported by EFSA 36th Advisory Forum, May 2010

- a Italy    Arcella et al, 2004
- b Korea    Chung et al, 2005
- c Canada   Devitt et al, 2004
- d UK       Food Standards Agency, 2003
- e Australia/NZ FSANZ, 2004
- f Sweden   Illback et al, 2003
- g Denmark  Leth et al, 2007
- h Portugal Lino et al, 2008
- i USA      Magnuson et al, 2007
- j Norway   Norwegian SCFS, 2007
- k Netherlands van Rooij-van den Bos et al, 2004
- l EU       EFSA, 2013
- m Japan    Ministry of Heath & Welfare, 2000
- n Italy    Leclercq et al, 1999
- o France   Garnier-Sagne et al, 2001
- p Belgium  Huvaere et al 2012
Intakes of some intense sweeteners expressed as %ADI

(highest values reported per study, Renwick A.G., 2006, Food Additives and Contaminants 23(4), 327-338)