Dietary Exposure Assessment: General Approaches and Considerations

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Dietary Exposure Assessment Tools for Prioritizing Food Safety Concerns
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Overview

• Available data for estimating dietary exposure:
  Contaminant concentration data
  Food consumption data

• Potential sources of uncertainty:
  Data quality
  Data characteristics/considerations when selecting data for estimating exposure

• Approaches to estimating exposure
Calculating Dietary Exposure

Dietary exposure = \( \sum (C_f)_i (L)_i \)

- \( i \) = number of different foods consumed
- \( C_f \) = concentration of substance in foods
- \( L \) = amount of food consumed
Concentration Data

Types of data used to estimate dietary exposure:

- Regulatory levels/limits
- Measured levels from:
  - Pre-market studies
  - Monitoring/surveillance programs
  - Total Diet Studies/Surveys
Regulatory Levels

• Include:
  Maximum residue limits (MRLs)
    – For pesticides, veterinary drugs
  Maximum levels (MLs)
    – For contaminants, natural toxicants

• Uncertainties when used in exposure estimates:
  Very conservative – assumes substance always present at highest levels
  Provide no information on actual concentrations in foods at point of consumption
Data from Pre-Market Studies

• Includes:
  Controlled studies (veterinary drugs)
  Supervised trials (pesticides)
  – Highest residue level from trial (HR, HR-P)
  – Supervised trial median residue levels (STMR, STMP-P)

• Uncertainty when used in exposure estimates:
  Very conservative – assumes highest use rate and number of applications, shortest withdrawal interval
Other Measured Levels

- Monitoring/surveillance programs
  Purpose is to enforce regulations, gather information
  May target specific foods

- Total Diet Studies/Surveys (TDS)
  Includes broad range of foods/beverages
  More accurate measure of contaminant concentrations:
  - Analytical methods more sensitive
  - Foods analyzed ‘as consumed’
Measured Levels: Data Quality

- Representativeness of samples:
  Random v. targeted
  Adequacy of sample size

- Sample handling, storage, preparation

- Analytical method:
  Validated method and QC procedures
  Method sensitivity (LOD/LOQ)
  What metabolites are measured (are all of toxicological concern included?)
Measured Levels: Other Considerations

• Form/portion of the foods analyzed:
  Raw v. as consumed
  Edible portion only or including inedible portions

• Analytical samples:
  Individual samples v. composites
  If composites, single foods or food groups?

• Extrapolation of data:
  From analyzed foods to other foods, food categories, crop groups
  Between countries, regions
Measured Levels: Other Considerations

- Data reported/availability: ‘raw’ data or only compiled/aggregated data
- Treatment of non-detects (ND): Assume zero, LOD/2 or LOD for NDs? The greater the proportion of NDs, the greater the uncertainty of the true distribution of concentrations
Food Consumption Data

Types of data used to estimate dietary exposure:

- Food supply data (food balance sheets or FBS)
- Model diets
- Food purchases/expenditures
- Food consumption by individuals (individual consumption data)
Food Supply Data

• Description:
  Gross estimates of annual national availability of food commodities from which daily per-capita consumption amounts are calculated

• Uncertainties when used to estimate exposure:
  Do not account for waste, food losses - over-estimates actual consumption
  Provide no information by population subgroup or region
Model Diets

**Description:**
Are designed to represent typical consumption patterns for a general population.
Are constructed from available information on food consumption.

**Examples:**
Model diets for veterinary drugs
- Based on default amounts of animal products consumed daily by 60 kg person.
Model Diets, cont.

WHO GEMS/Food Regional or Cluster Diets

- 5 Regional Diets based on grouping of FBS data by geographic region
- 13 Cluster Diets based on grouping of FBS data by consumption patterns

• Uncertainties when used to estimate exposure:
  Both types over-estimate consumption
  Provide no information about consumption by population subgroups
Food Purchases/Expenditures

• Description:
  Information collected on food purchased over period of time (days, weeks, months)
  May be at household or individual level

• Uncertainties when used to estimate exposure:
  Represents purchases rather than actual consumption - over-estimates consumption
  Household data provide no information on individuals
Individual Consumption Data

• Description:
  Detailed information on foods/beverages consumed by individuals
  Often provides other data useful in exposure estimates (demographics, body weights)

• Various validated methods used to collect data:
  Examples: diet history, dietary recall, food frequency questionnaire
Individual Consumption Data: Data Quality

• Survey design:
  Size and representativeness of the sample
  Time-frame (all seasons? all days of the week?)
  Number of days of data/individual (usually 1 to 7)

• Survey methodology:
  Self-administered or by an interviewer
  Precision in describing foods
  Accuracy in reporting consumption amounts
Individual Consumption Data: Examples

- National surveys conducted by many countries, including:
  - Australia: National Nutrition Survey (NNS)
  - France: Individual National Food Consumption Survey (INCA)
  - UK: National Diet and Nutrition Survey
  - US: CSFII, NHANES

- TDS simulated diets:
  - Model diets derived from national survey data
  - Represents average consumption by selected age/gender groups
Individual Consumption Data: Examples

- Comparing consumption data obtained using different methodologies can be a challenge.
- EFSA has sponsored projects to harmonize food consumption survey methods and data.

  has developed the “Concise European Food Consumption Database” from national survey results.

Comprises average daily consumption per person for 15 broad categories and 21 subcategories of food.

Intended to be used as a screening tool for preliminary exposure estimates.
Individual Consumption Data: Other Considerations

• Reporting of consumption:
  Degree of specificity (e.g., oranges v. citrus fruit)
  As commodities/ingredients or as consumed?

• Extrapolation of consumption estimates
  From one population subgroup to another (e.g., from adults to children)
  From one country to another

• Using default rather than actual body weights when estimating consumption:
  60 kg for adults (55 kg for Asian adults)
  15 kg for children
Estimates of Usual and High Consumption

• Two dietary exposure scenarios require special attention:
  Long-term or ‘usual’ consumption patterns are needed for estimating chronic/lifetime exposure
  Upper percentiles of consumption (high consumers) are needed for estimating acute exposures
‘Usual’ Food Consumption

• Most individual consumption surveys are short-term (1 to 7 days), which are likely to
  over-estimate long-term consumption
  underestimate consumption of infrequently consumed foods (e.g., fish) as well as the proportion of individuals who consume them

• Statistical models are being developed to estimate ‘usual’ consumption
  Combine consumption amounts from short-term survey with food frequency data
High Consumers

- Estimating acute dietary exposures requires estimates of individual consumption for eaters only at the upper percentiles.

- In lieu of individual consumption data:
  Multiply average consumption by factor of 2 or 3
  Use GEMS/Food Large Portion Database
  - Based on highest national reported 97.5th %ile consumption (eaters only) on commodity basis for the general population and children 6 years and younger.
Approaches to Estimating Dietary Exposure

• The specific approach taken and the data used depends on:
  Type of substance/contaminant
  Toxicity profile (acute v. chronic effects)
  Whether some subgroups are more sensitive, at greater risk
  Geographic scope of the situation (local, national, international)
  Availability of data (concentration/consumption)
  Purpose of the exposure estimate
The “best” or “most realistic” estimate of exposure may not always be most appropriate or necessary.

A **tiered (or stepwise) approach** is recommended:

- Utilizes available information to the maximum extent possible
- Begins with simple but conservative estimates that ensure overestimate of exposure
- Uses progressively more refined data and exposure methods to obtain more realistic estimates
- Relies on resource-intensive (i.e., probabilistic) approaches only when necessary
• Begins with **screening methods** using crude estimates of consumption
  Model diets for veterinary drugs
  Food production/supply data
  GEMS/Food Regional or Cluster Diets

• Progresses to **more refined methods using point estimates** based on
  Food expenditure/purchase data
  Individual consumption data
  TDS simulated diets
  GEMS/Food Large Portion Database
Tiered Approach, cont.

• Proceeds to **probabilistic estimates** for highest-tier assessments using
  
  Full distributions of concentration and/or consumption data

  Statistical models to estimate ‘usual exposure’

  ________________________________

  Refer to summary tables
## 1. POINT ESTIMATES OF DIETARY EXPOSURE
*From less to more precise methods*

<table>
<thead>
<tr>
<th>Type of exposure estimate</th>
<th>Data Used in Exposure Calculation</th>
<th>Value used</th>
<th>Value used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic</td>
<td>Model diet for veterinary drugs</td>
<td>Physiological limits of consumption</td>
<td>Total only</td>
</tr>
<tr>
<td>Chronic</td>
<td>Food production stats</td>
<td>Mean (per capita)</td>
<td>Total only</td>
</tr>
<tr>
<td></td>
<td>GEMS/Food Regional or Cluster Diets</td>
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</tr>
<tr>
<td>Chronic</td>
<td>Food purchases or expenditures</td>
<td>Mean</td>
<td>Household or individual</td>
</tr>
<tr>
<td>Chronic</td>
<td>TDS simulated diets</td>
<td>Mean (all individuals)*</td>
<td>Total + subgroups</td>
</tr>
<tr>
<td>Chronic</td>
<td>Individual consumption data</td>
<td>Mean (all individuals)*</td>
<td>Total + subgroups</td>
</tr>
<tr>
<td>Acute</td>
<td>Individual consumption data</td>
<td>Upper %ile (eaters only)</td>
<td>Total + subgroups</td>
</tr>
<tr>
<td>Acute</td>
<td>GEMS/Food Large Portion Database</td>
<td>97.5th %ile (eaters only)</td>
<td>Total + M/F 6 yrs and under</td>
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</tbody>
</table>

* All individuals = eaters + non-eaters
## 2. PROBABILISTIC ESTIMATES OF DIETARY EXPOSURE

<table>
<thead>
<tr>
<th>Type of exposure estimate</th>
<th>Data Used in Exposure Calculation</th>
<th>Value</th>
<th>Concentration data</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic and/or acute</td>
<td>National consumption data - individual</td>
<td>Point estimate</td>
<td>Measured levels</td>
<td>Distribution</td>
</tr>
<tr>
<td></td>
<td>National consumption data - individual</td>
<td>Distribution</td>
<td></td>
<td>Point estimate</td>
</tr>
<tr>
<td></td>
<td>National consumption data - individual</td>
<td>Distribution</td>
<td>Measured levels</td>
<td>Distribution</td>
</tr>
<tr>
<td>Usual (chronic)</td>
<td>National consumption data + FFQ – individual</td>
<td>Mean (all individuals)</td>
<td>Measured levels</td>
<td>Mean/median</td>
</tr>
</tbody>
</table>
Sources of Uncertainties in Dietary Exposure Estimates

- Inherent uncertainties of the underlying concentration and consumption data
- The extent to which both data sets reflect the situation being assessed
  - Specific food(s)
  - Time period
  - Geographic scope
  - Populations of concern
- The approach used to estimate exposure
Summary

• Many data sets/tools available for estimating dietary exposure

• Understanding uncertainties of underlying data will help to understand uncertainty in the exposure estimate

• Step-wise approach recommended for estimating exposure
  Simple estimates can identify hazards of little or no concern
  Most complex, probabilistic estimates are needed only in selected cases