# Dietary Exposure Assessment: General Approaches and Considerations

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**Dietary Exposure Assessment Tools for Prioritizing Food Safety Concerns**

**November 18-19, 2008**

# 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

$$\text{Dietary exposure} = \sum (C_f)_i \, (L)_i$$

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

# Tiered Approach to Estimating Exposure

- 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

# Tiered Approach, cont.

- 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’

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*Refer to summary tables*

## 1. POINT ESTIMATES OF DIETARY EXPOSURE

***From less to more precise methods***

| Type of exposure estimate | Data Used in Exposure Calculation | | | | |
|---|---|---|---|---|---|
| | **Consumption data** | **Value used** | **Populations represented** | **Concentration data** | **Value used** |
| Chronic | Model diet for veterinary drugs | Physiological limits of consumption | Total only | Measured levels from controlled studies | Median |
| Chronic | •Food production stats<br>•GEMS/Food Regional or Cluster Diets | Mean (per capita) | Total only | - ML<br>- MRL<br>- STMR (pesticides)<br>- Monitoring levels | Mean/median |
| Chronic | Food purchases or expenditures | Mean | Household or individual | Measured levels | Mean/median |
| Chronic | TDS simulated diets | Mean (all individuals)* | Total + subgroups | TDS measured levels | Mean/median |
| Chronic | Individual consumption data | Mean (all individuals)* | Total + subgroups | Measured levels | Mean/median |
| Acute | Individual consumption data | Upper %ile (eaters only) | Total + subgroups | Measured levels | Mean/median |
| Acute | GEMS/Food Large Portion Database | 97.5$^{th}$ %ile (eaters only) | Total + M/F 6 yrs and under | - STMR/HR (pesticides)<br>- Other measured levels | Median/high<br>Mean/median |

* All individuals = eaters + non-eaters

## 2. PROBABILISTIC ESTIMATES OF DIETARY EXPOSURE

| Type of exposure estimate | Data Used in Exposure Calculation | | | |
|---|---|---|---|---|
| | Consumption data | Value | Concentration data | Value |
| Chronic and/or acute | National consumption data - individual | Point estimate | Measured levels | Distribution |
| | | Distribution | | Point estimate |
| | | Distribution | | Distribution |
| Usual (chronic) | National consumption data + FFQ – individual | Mean (all individuals) | Measured levels | Mean/median |

# 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