Issues and Challenges in Dietary Exposures in the Context of Risk Ranking

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Dietary Exposure Assessment Tools for Prioritizing Food Safety Concerns
JFSAN Workshop
November 18-19, 2008
TOPICS

• Risk ranking general concept
• Screening level v. refined risk ranking
• Exposure considerations
  – Data and uncertainty
  – Decision confidence
• Operational Risk Management
  – Communicating risk and uncertainty
RISK RANKING GENERAL ATTRIBUTES

- Simple and easy to use
- Transparent
- Available data
- Flexible (to augment when new data become available)
- Applicable to various classes of chemicals
- Reproducible
- Comparable
RISK RANKING GENERAL ATTRIBUTES

• Complete
  – Purpose and application
  – Health criteria and endpoints
  – Exposure criteria
  – Data selection and handling of missing data
  – Rationale/method for weights/scores
    • Potency and severity
    • Exposure
  – Algorithm to combine
CONTINUUM OF RISK RANK SYSTEMS

- Screening Level
- Refined system
- Something in between
- Think of it as a “tiered” process
SCREENING LEVEL RISK RANKING SYSTEMS

- Many EPA chemical ranking systems
- Simple, worst case, point estimates
- Readily available data
- Goal: avoid false negatives
- Reduce the number of chemicals one needs to worry about
- Non-resource intensive approach
CHEMICAL EXPOSURE VARIABLES

- Environmental degradation or transformation
- Mobility and partitioning
- Estimated dose, occurrence, concentration, amount release
- Receptors (size or types)
DIETARY EXPOSURE POTENTIAL MODEL (EPDM)

- Screening level exposure based ranking model
- Correlates extant food information to extant food residue data
- Aggregation of data:
  - 11 food groups (820 core foods represent 6700 foods reported as consumed by the US population)
  - Residue data mapped to core foods
- Not a refined risk assessment model
  - Research priority setting
PATHOGENS

• Stepwise and interactive evaluation of food safety by an expert system (Van Gerwen et al 2000)
  – Screening level system
  – systematically prioritizes high hazard pathogens by relying on set of knowledge rules, e.g.
    • Presence or absence, and survival or inactivation of pathogens.
    • Rules concerning growth opportunities and toxin production, e.g. ability to grow is based on the use of the minimum and maximum growth temperature, pH, and water activity.
PATHOGENS

• Ross and Sumner (2002) spreadsheet software
  – Simplification of farm to fork pathway
  – Screen food borne risks and identify those requiring more rigorous assessment

...\food_ranking\literature_review\RATool.xls
PATHOGENS

• Draft Risk Assessment of the Relative Risk to Public Health from *L. monocytogenes* in categories of RTE foods (FDA/FSIS, 2001)
  – “highly refined”
  – Resource intensive

• IFT/FDA risk ranking tool
  – “highly refined”
  – Data need
  – Expert judgment and transparency

• Broad regulatory impact: regulatory priorities, resource re-allocation, research agenda
TIERED APPROACH TO ESTIMATING EXPOSURE

- Screening level
  - Utilizes available information to the maximum extent possible
  - Begins with simple but conservative estimates that ensure overestimate of exposure
- Refined level
  - Uses progressively more refined data and exposure methods to obtain more realistic estimates
  - Relies on resource-intensive (e.g., probabilistic) approaches only when necessary
EXPOSURE BASED RANKING

• Limited scenarios
  – Single contaminant in multiple foods (LM in various RTE meats)
  – Family of contaminants (HPV chemicals, prioritize within a family based on exposure potential)
  – Chemical groups based on QSAR – ranking based on exposure within group.

• Hazard information is implicitly inherent in these scenarios
EXPOSURE SCENARIOS

- Exposure variables/criteria of interest
  - Consumption, Concentration/level
  - Duration of exposure
  - Scope of exposure - local v. widespread

- Data and uncertainty
  - High, medium, low
## Exposure Uncertainty

<table>
<thead>
<tr>
<th>Exposure Data</th>
<th>Uncertainty</th>
<th>Short term exposure</th>
<th>Long term exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consumption Data</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific food intakes from national surveys (NHANES, CSFII)</td>
<td>L</td>
<td>M</td>
<td></td>
</tr>
<tr>
<td>TDS Foods (intakes of 280 food groups based on CSFII) or other aggregate food groups (aggregate intakes based on data from national food consumption surveys)</td>
<td>M</td>
<td>H</td>
<td></td>
</tr>
<tr>
<td><strong>Level/Concentration Data</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimates based on processing parameters or physico-chemical properties</td>
<td>H</td>
<td>H</td>
<td></td>
</tr>
<tr>
<td>Use level, application rate/ amount</td>
<td>H</td>
<td>H</td>
<td></td>
</tr>
<tr>
<td>Measured levels (contaminants, metabolites, by-products, etc...)</td>
<td>L to H*</td>
<td>L to H*</td>
<td></td>
</tr>
</tbody>
</table>
## Exposure Uncertainty

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<th>Level/Concentration Data</th>
<th>Short-term Exposure</th>
<th>Long-term Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Combined Uncertainty</td>
<td>Assessment Tier</td>
</tr>
<tr>
<td>Specific food intake from national survey (NHANES, CSFII)</td>
<td>Estimates based on processing parameters or physico-chemical parameters</td>
<td>M</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Use level, application rate/amount</td>
<td>M</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Measured levels (contaminants, breakdown products, by-products, etc...)</td>
<td>M to L</td>
<td>2 to 3</td>
</tr>
<tr>
<td>TDS Foods (intakes of 280 food groups based on CSFII) or Other aggregate food groups (intakes based on other National food consumption surveys)</td>
<td>Estimates based on processing parameters or physico-chemical parameters</td>
<td>H</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Use level, application rate/amount</td>
<td>H</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Measured levels (contaminants, metabolites, by-products, etc...)</td>
<td>M to L</td>
<td>2 to 3</td>
</tr>
</tbody>
</table>
### Operational Risk Management

#### Risk Matrix

<table>
<thead>
<tr>
<th>Severity</th>
<th>Catastrophic</th>
<th>Critical</th>
<th>Moderate</th>
<th>Negligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability</td>
<td>Frequent A</td>
<td>Likely B</td>
<td>Occasional C</td>
<td>Seldom D</td>
</tr>
<tr>
<td></td>
<td>Extremely High</td>
<td>High</td>
<td>Medium</td>
<td>Low</td>
</tr>
</tbody>
</table>
RISK, UNCERTAINTY SCENARIOS AND DECISION CONFIDENCE

A. Risk Scenarios
High risk $H_R$
Medium risk $M_R$
Low risk $L_R$

B. Uncertainty Scenarios
High level of uncertainty $H_U$
Medium level of uncertainty $M_U$
Low level of uncertainty $L_U$

C. Decision Confidence Levels
High, Medium and Low
WORLD OF RISK RANKING

• Lumping rather than splitting
• Uncertainty is the fact of life
• Precise but not necessarily accurate
• Resource saving minded