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

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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

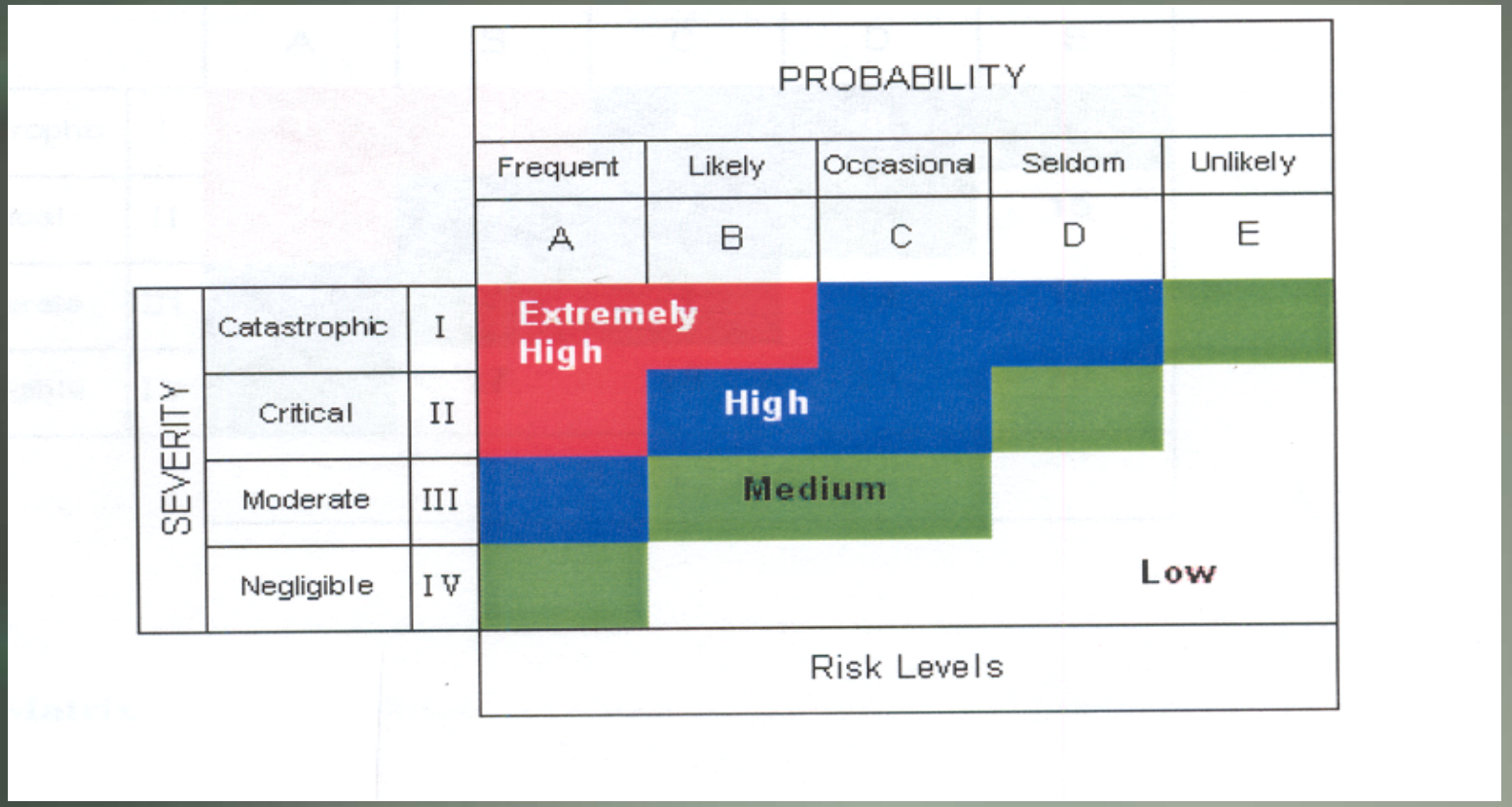
EXPOSURE UNCERTAINTY

Exposure Data	Uncertainty	
	Short term exposure	Long term exposure
Consumption Data		
Specific food intakes from national surveys (NHANES, CSFII)	L	M
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)	M	H
Level/Concentration Data		
Estimates based on processing parameters or physico-chemical properties	H	H
Use level, application rate/ amount	H	H
Measured levels (contaminants, metabolites, by-products, etc...)	L to H*	L to H*

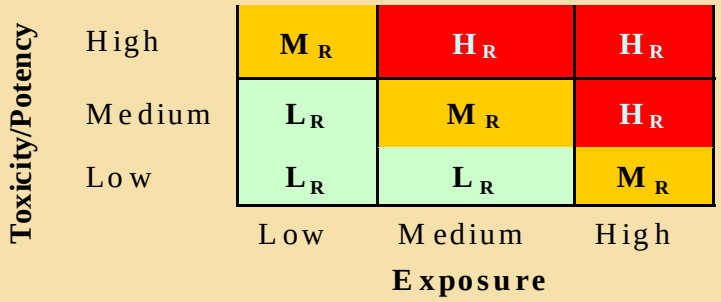
EXPOSURE UNCERTAINTY

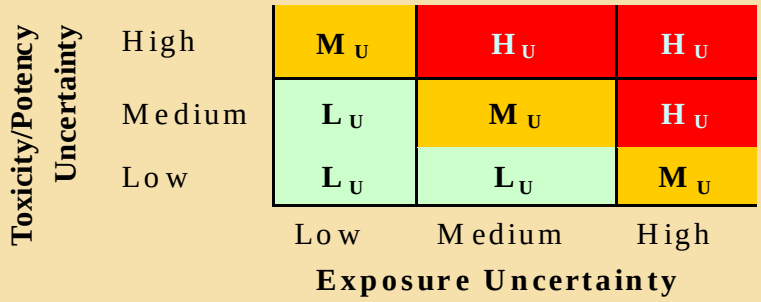
Consumption Data	Level/Concentration Data	Short-term Exposure		Long-term Exposure	
		Combined Uncertainty	Assessment Tier	Combined Uncertainty	Assessment Tier
Specific food intake from national survey (NHANES, CSFII)	Estimates based on processing parameters or physico-chemical parameters	M	2	H	1
	Use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

OPERATONAL RISK MANAGEMENT



RISK, UNCERTAINTY SCENARIOS AND DECISION CONFIDENCE



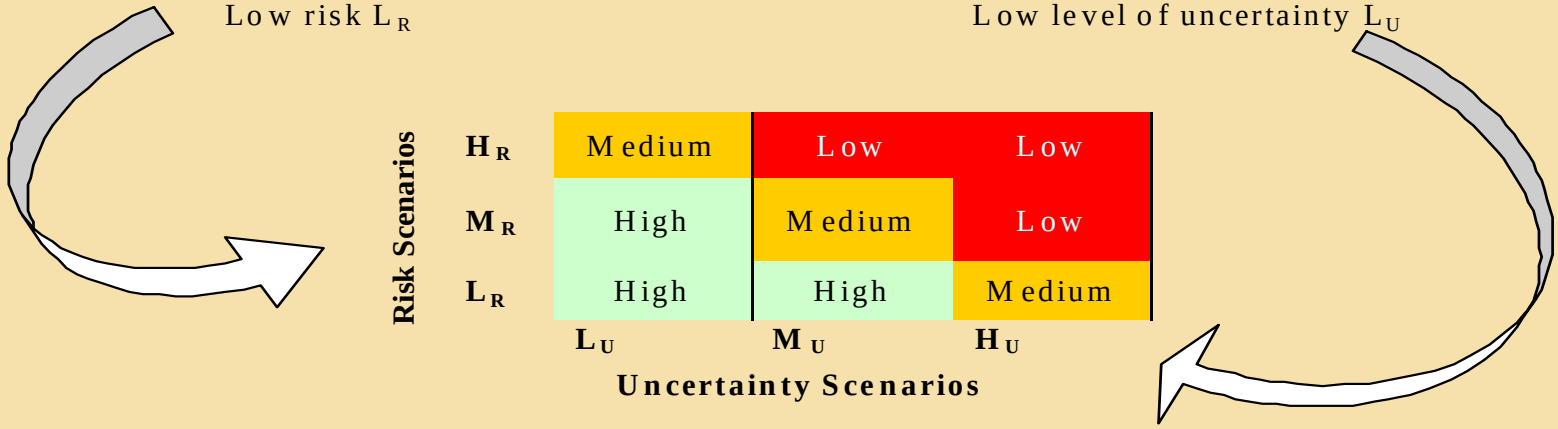


A. Risk Scenarios

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