Tools for Prioritizing Food Safety Concerns

Report from Breakout Group 3

JIFSAN Workshop

June 4-6, 2007

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Clarifying Objectives

► Different objectives for different users: <u>industry</u>

- Product and company/industry reputation focus, rapid decision-making
- Surprises/unknowns (expect increasing frequency)
- Cost-effectiveness – don't worry about *de minimis* risks

Clarifying Objectives, cont'd.

► Government agency
  - Public health focus
  - Accountability
  - Resource allocation
  - Generally, known hazards but occasionally surprises/unknowns
  - Cost-effectiveness – don't worry about *de minimis* risks

► Academic
  - Can have broad focus
  - Output expected to be valid and useful (but not necessarily aligned with regulatory, cost or other practical considerations)

Suggested Goal for Framework

"Optimizing public health"

Clarifying Scope

► Unavoidable contaminants

► Safety

► Uncontrollable by consumer

► NOT:

  ▪ Nutrition

  ▪ Terrorism

Clarifying Decision Focus

► For purposes of our discussions, Group 3 focused primarily on the use of risk ranking and prioritization for *resource allocation* planning

► Framework should enable identification of

- Public health priorities (worst problems)

- Mitigation priorities (best solutions for each)

- Risk assessment and/or research priorities

Prioritizing Food Safety Concerns: A Unified Framework

► Pre-screen: As dictated by available information, pre-screen to eliminate certain hazards from need for further, more detailed prioritization in Steps 1-3 (e.g., use TTC-TIE* approach)

*Threshold of Toxicological Concern or Toxicologically Insignificant Exposure

3-Step Process

► (1) Identify and rank public health outcomes - worst problems

► (2) Identify the universe of potential risk mitigation options

► (3) Identify where you can make the most difference – best solutions (includes efficacy, cost-benefit, cost-effectiveness, risk tradeoffs)

But Inevitably Followed By A "Step 4", Outside the Framework

► Initiation of Risk Management –

- Consideration of all the other factors outside the prioritization framework that influence the risk management decision:

  ► Politics

  ► Stakeholders

  ► "Optics" (public perceptions)

- Make transparent the difference between the risk rankings and the other influences – compare "objective" estimates with what was actually decided

  ► Risk managers might not realize they are impacted by all the "other stuff"

The 7 Questions

► Some are best addressed within the context of a particular Step in the Framework, e.g.

  ▪ How the kinds of/quality of information or data influence the approach

  ▪ How types of data are being used currently

  ▪ Is there a minimum data set/amount of info necessary

  ▪ Does the type of data affect the comparability of hazards/risks

► Here we discuss the general questions first...

Question 4: How are adverse public health impacts of chemical risks quantified?

► **Differences between chemical and pathogen risk quantification**
  - Chemical risks are typically theoretical, pathogen risks are actuarial
  - Cancer risks
    - ► Lifetime probability can be annualized, hence some basis for comparability to microbial risks
  - ADIs / RfDs:
    - ► Not necessarily comparable to cancer or to microbial ("oranges" vs. "varieties of apples")
    - ► Rarely concerned with probability of harm below the ADI/RfD – to compare with pathogen risks would need accepted probabilistic tools for this (a potential issue for acrylamide if neurotoxicity is determined to be a key endpoint for risk assessment...?)

Question 4: How are adverse public health impacts of chemical risks quantified?, cont'd.

► Pathogens:
  ▪ Have real cases – illness or mortality
  ▪ Some uncertainty in attribution (don't know the source of all foodborne illness)
  ▪ Most focus is on acute exposure, but data on chronic conditions are growing
  ▪ Relatively small number of known pathogens; some new virulence in known pathogens and new pathogens will likely emerge

► Chemicals:
  ▪ Often don't have human effects data – e.g., lead in cookware, candy; mercury in fish (uncertainty)
  ▪ Most focus is on chronic exposure
  ▪ New chemical concerns increasingly likely

Question 5: What public perception issues arise in comparing/ranking chemical risks? How?

► Distinguish public perception of factual issues from valuation issues

► Public perceptions vary with:
  - News and events
  - Questions asked
  - Who's delivering the messages

Question 7: What criteria should a chemical risk prioritization framework meet in order to be accepted by regulators, industry and consumers?

► Flexible and transparent:

- Includes all relevant data

- All possible decision criteria for included; user can select which to use (value judgment)

- Useful information for decision making in many sectors (government/consumers/industry) at many levels (e.g., Agency-program-office)

Question 7 (Cont'd) : What criteria should a chemical risk prioritization framework meet in order to be accepted by regulators, industry and consumers?

► Rigorous and science-based
  ▪ Data trump no data (even "bad" data must be considered)

► Transparent
  ▪ Process
  ▪ Results

► Valid
  ▪ "Face-validity": results are not only scientifically meaningful, but also look reasonable to educated/reasonable lay person

Step 1, cont'd.: Identify/rank public health impacts

► Factors that affect your approach (Questions 2, 3, 6):

- Type/quality of data-weight of evidence
- Necessary data: chemical composition → (Q)SAR
  - ► Intake can always be estimated/modeled
  - ► ADME can be estimated to some extent
    - Current tools OK for gene tox, cancer; developmental tox coming (ILSI); other endpts need work

Step 1:
Identify/rank public health impacts

► Risk = Hazard x Exposure

- Decide how you will categorize hazards (relates to regulatory authority, ability to mitigate)

  - ► Pathogens: by "eating occasion/food, primarily acute exposure concern

  - ► Chemicals: across total diet, primarily chronic exposure concern

  - ► Challenges for comparing micro and chemical risks emerge at this level (see slides 11-12, above)

Step 1, cont'd.: Identify/rank public health impacts

► Type of available data <u>do</u> affect hazard rankings

- Wt-of-evidence differences, endpoint differences

- Organize chemicals in non-overlapping bands (low/medium/high risk "bins")

- Include uncertainty characterization – explicit "uncertainty score" for each hazard

Step 2:
Identify Potential Mitigation Options

► Create the "dream list" - determined by:

- Available data/info – similar compounds
- Expert judgment/brainstorming
- *Ex post* (mitigation)and *ex ante* (prevention) options
- No feasibility assessment at this stage – don't constrain thinking

Step 3:   Identify Where You Can Make the Most Difference

► Feasibility Analyses – does it work, how much does it cost, and unintended consequences

- Legal, regulatory authority
- Technological considerations
- Sociobehavioral factors – consumer behavior, perceptions, preferences
- Risk-risk tradeoffs (e.g., nutrition impacts of altered food choices)
- Cost-effectiveness/cost-benefit

  ► May include product acceptability, nutrition, etc.

Step 3:
cont'd.

► **Efficacy of mitigation**
  - Quantitative risk reduction/exposure reduction
  - $ Valuation of health outcomes

► **Accepted tools/approaches exist for all these**
  - Regulatory impact analysis
  - Cost-effectiveness/cost-benefit
  - Socioeconomic
  - There may be guidance for $ valuation of chemical risks (e.g., EPA, ERS, OMB)

Knowledge gaps/tools & data needs

- ► Non-cancer effects:
  - ▪ Probabilistic tools for endpoint quantification
  - ▪ Severity functions:
    - ► What is magnitude of risk at what % above RfD
    - ► Quantifiable measure of public health
- ► Lack of unified ranking for chemical and microbial risks

Knowledge gaps/tools & data needs (cont'd)

- ► Exposure:
  - ▪ US food consumption survey data limited for estimating chronic exposure
    - ► Limitation: only 1, 2 (or in very latest NHANES 3) days of data; other countries have 7 days
    - ► Current estimates of chronic exposures are often too conservative (skewed high for many foods not consumed daily)
    - ► Seasonality problem
    - ► Subpopulations – ethnicity coverage
    - ► New foods