Tools for Prioritizing Food Safety Concerns

Report from Group 2

JIFSAN Workshop
June 4-6, 2007

Nga Tran, Facilitator

Q1. What considerations affect the setting of priorities for food safety concerns and how? (E.g., legal/regulatory requirements, relative hazard or risk, risk perception, quality of available information, etc.).

Q5. What scientific, policy and public perception issues arise in comparing/ranking chemical risks?

Priority setting is a continuum of decisions:

1) Fundamental technical decisions: Do we test? i.e. possibility of harm. What should we test? i.e., Prove safety (should we put a particular chemical in a food that could cause harm to a particular sub population?)/safety assessment

2) Purpose of ranking -- Industry vs. government
   Industry: rapid decision tool
   Government: prioritize resource allocation

   1) Divide chemicals into 2 categories:
      a. Inadvertent/unexpected (post market)
      b. Deliberate/intended (pre market/post market)

   Focus of risk ranking is post market

Legal/regulatory considerations

- Acknowledge legal regulatory constraint -- Depends on chemical; if issue is a chemical approved for a specific food, but added to other foods, then it's a problem – standard food adulteration.
- Many regulatory decisions are ranking processes; not to rank food additives directly, but to determine data gaps - e.g., RED BOOK
- Once a food additive has been approved, may be used in several foods and if intake/exposure > ADI, then will be ranked higher, e.g., pesticides. – RANKING

Public perception considerations

- Unknowns:
  - If contaminant is due to a chemical we know nothing about, then it is a concern, we need to do something: screening analysis to establish a threshold level.
  - If the contaminant is unknown, e.g. as with melamine, then it is a public concern. It is harder to get the message across.

- The questions the public will ask include:
    1) Will this give me cancer? We need to consider public perception. e.g., a carcinogen in food, even if low/no exposure. Toxicologists may rank carcinogens, but the public ranks them all the same!
    2) Will it affect my unborn baby?
    3) If it's in infant formula, will it affect my baby?

If they can get some of the answers, it will reduce their fear.

- Education: we need to inform people of the problem/what they should fear. It could also be a control/mitigation issue; can you do something about the risk? With acrylamide, eat less fried food.

- What is adverse and how does the public perceive that?

Data Information Quality Considerations (Scientific Issues)

- Priority setting for resource allocation

  1. Consider non risk information,
     a. Market Information –food imports
     b. Compliance data
  2. Public Health outcome: QALY's, DALY's, etc. Determination of these is very subjective and different from country to country.

- Relative hazard versus risk information

  - Need to distinguish between hazard and risk. A chemical may be a hazard, but has no or low exposure, then it is not a risk.

  - Type and quality of data appropriate for what decision (e.g. find more information or to take action

  - Even in absence of perfect information, still need to do something immediately

Questions 2, 3, and 6 all involve effect of data on risk ranking, so were combined.

Q2. How can various kinds of information or data be used (or how are they being used) to rank or prioritize chemical risks?

- What do you call data?
- Never have a complete data set.
- It is important how you interpret the data. Raw data vs. analyzed information; how can we bring the different types of information to the same level to use in risk ranking?

Tool Box (information that could be used for ranking)

See Chart –tools appropriate for what purpose? Continuum of decisions

Other data to consider:

- Persistence
- Bioaccumulation
- Gene/tox data (yes, no)
- Metabolic transformation

We have a continuum of decisions and array tool box, so the key question is which tool is appropriate for what decision?

Exposure Data -- How do we use exposure for risk ranking and what data are available?

- We can go from poundage levels in food to use levels to intake levels. We can use crude estimates to refined estimates
- If exposures are < TTC, then not a problem; if around or > TTC, then concern.
- Units, cumulative risk, duration considerations:
    - It is important that the units of exposure match those of dose-response.
    - With MRA no concern about cumulative risk, but with CRA, it is a concern.

- Uncertainty in exposure concentration (issues for both microbes and chemicals). **Use the data we have**, but recognize uncertainty

- Consider data quality guidelines

Q3. What is the minimum of information/data necessary to rank or prioritize risk?

- Rephrase:
  - What is the type and quality? Quality of information impacts the risk ranking.
  - How do you represent uncertainty in risk and in risk ranking?

- Complete unknown (breakdown products from processing) vs. partial information
  - Focus on partial information as starting point

- Type of data: information needed depends on decision to be made

- Starting points for ranking can be partial information

    - ID (include breakdown products) -- How can you characterize the risk of the different breakdown products? Semi quantitative analysis, no analytical standards.
    - Structure/activity relationships screening (SAR) – look for structural alerts
    - Confidence in SAR to determine threshold levels (1-5, 5 being highest confidence):
        - Genotoxicity/cancer: 4.5;
        - Reproductive developmental: 1;
        - Neurotoxicity: 2-3.
        - Could use threshold levels (TTC) for ranking.
        - Standard methodology important

    - In vitro data
    - Concentration in food
    - Frequency in food
    - How probable is it to be found in food

- For microbes, need to determine whether it is a hazard before doing a risk ranking.

6. **Does the type of available data exert an effect on the comparability of hazards/risks? How?**

- Quality of analytical methods used to determine levels will impact Risk Ranking.
- We need to understand the process that generated the data.
- Inequality in data quality:
    - If one chemical is tested a lot, there will be more questions concerning the chemicals not tested as much.
    - Toxicity concern comes from testing; microbial concern comes from epidemiologic data.

- We can use regulatory data bases such as IRIS, TDI,ADI, etc but need to be careful about policy judgment imbedded in these values
- Decision quality is dependent on data quality.
    - Can't make a decision with no data;
    - Difficult to make a decision with poor data
    - But with poor data, can prioritize for which issues need to get more information

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

- To address this question, need to consider mortality and morbidity with severity, duration, and reversibility (Many possible health economic metrics: QALY, DALY, etc)

- How much should the public be involved at this stage?
  - Most of the morbidity and mortality data are provided by epidemiological information.
  - But need public input for value judgment

- Potentially fatal risks: Microbial-related deaths and carcinogens in food – differential uncertainty

  - Carcinogens conservative and hypothetical vs. microbial lethality observed
  - Microbial: exposure uncertainty
  - Carcinogens: dose-response uncertainty

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

- This is the capstone question! Final outcome of the meeting.

Acceptable Criteria for Regulators and Industry:

- What is the RM question? What is the purpose for the prioritization?
- First 5 important for general Risk Prioritization Scheme

1. Science-based
2. Data driven (actual vs. theoretical)
3. Consistency with approach (how you treat info you get, how you treat
endpoints for chemicals and microbes), comparable metrics
4. Data quality
5. Systematic and Transparent
6. Public outrage factor
7. Nature/types of foods
   Exposure; subpopulation affected
   Societal value
8. Controllability: mitigation/reduction – feasibility/practical
9. Peer review – reality check

Additional acceptance criteria for Industry:

In addition to the above criteria, the desired attributes for a risk ranking tool for industry would be:

1) has to be timely to put small problems aside quickly
2) has to provide reliable results
3) Has to be simple for managers to use and interpret
4) Best and worst case scenarios consideration

[Simplicity and reliability not always hand in hand
Consistency and reliability not always hand in hand]

Example Approach: Threshold of Toxicological concern (TTC)

- A screening approach to set small problems aside
- Not a risk ranking approach - more of estimating its safety/toxicity: protection up to 95th percentile.
- Explainable
- Scientifically supported
- Appropriate for screening/prioritize for additional testing

- JECFA and EFSA use TTC for safety evaluation for low exposure substances in different foods (to make a RM decision and then go back to verify)

- Issues that need to be considered: Uncertainty in TTC so exposure data critical – need lower uncertainty

Consumer acceptability of risk ranking framework

As for government and industry, but change in order.
1. Do no harm – don't create a higher risk, i.e., unintentional consequence of an action (e.g., fish industry)
2. Public outrage factor
3. Transparency
4. Consistency of messages
5. Availability: electronic access (Google)
6. Source of information – credibility
    - Risk ranking should be peer reviewed and validated

TTC approach – acceptability to public
- Government reassurance of a plan; should approve of approach
- Education of journalists

Additional discussion about how to rank across different rank chemical with microbial risks:

- Uncertainty of estimates in cancer cases too large!
- Impact of risk mitigation for cancer not as evident as that of pathogens (e.g., LM).
- Best option now is to compare best estimates.
- Indication of confidence in the quality and uncertainty of the ranking output needs to be provided to the risk managers qualitatively.

Do what we can based on what we have today and continue to build upon for the future.

Pragmatism is the operative word!

Group 2 Participants

- Nga Tran (Facilitator)
- Susan Barlow
- Clark Carrington
- Yuhuan Chen
- Mike Doyle
- Mark Feeley
- Michael Ginevan
- Barry Hooberman
- Marianne Miliotis
- Ian Munro
- Dave Schmidt