Tools for Prioritizing Food Safety Concerns

Report from Group 1

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General Focus

- **Chemical contaminants in foods**
  - Organic anthropogenic
  - Natural toxins
  - Elementals
- **Microbial pathogens (secondarily)**
- **Prioritization for resource allocation**

Questions 1 & 5 – Considerations that affect prioritization of food safety concerns

- **Potential hazard**
  - Severity/duration of effect
  - Reversibility
  - Other
- **Exposure**
  - Prevalence in diet
  - Levels in diet
  - Biomarkers of exposure
- **Susceptible populations**

Questions 1 & 5 – Considerations that affect prioritization of food safety concerns (cont'd)

- **Quality of available information**
  - Confidence/uncertainty in prioritization
- **Public perception**
  - Chem/micro differences
  - Questions regarding conflicts of interest
  - Need for stakeholder involvement
- **Requirement: sound scientific basis and transparency in prioritization process and evaluations**

Questions 2 & 3 – Use of data in prioritization

- **Scenario – unexpected contaminant in food**
- **Analytical detection**
  - Identification → need for confirmation
  - Prevalence
    - Scope of contamination
    - Isolated incident?
    - Persistence? (in food supply)
  - Level(s) found
  - Where did it come from?

Questions 2 & 3 – Use of data in prioritization (cont'd)

- **Exposure characterization**
  - Estimate high-end exposures
  - Exposure distribution
  - Consider biomarker data (if available)
  - Biopersistent?
  - Possibility of extreme heterogeneity in samples (especially for microbial pathogens)
- **Apply TTC as a pre-screen**
  - Does exposure fall in "Minimal concern – lowest priority" category?
  - Note: Pre-screen also may be possible for some pathogens.

Questions 2 & 3 – Use of data in prioritization (cont'd)

- **Beyond TTC, data requirements depend on level of concern based on:**
  - Exposure ("infectivity" for microbes)
  - SAR
  - Tox endpoints
    - Severity/duration of effect (micro: "sequelae")
    - Reversibility
    - Other
  - Sensitive populations

Questions 2 & 3 – Use of data in prioritization (cont'd)

- **Other factors**
  - Public perception/culture
  - Intentionally added (e.g., terrorism)
  - Mitigation potential
- **For some chemicals, may know a lot about hazard (acrylamide; some but not all heat-formed compounds); for others, may only have SAR.**

Question 4 –
Quantifying public health impacts of chemical risks

- **Characterizing hazard/risk**
  - Safety assessment → ADI, TDI, RfD; excedence implies increasing risk potential – not quantification of risk.
  - Margin of exposure – compare NOAEL/BMD with human exposure
  - Cancer – (sometimes) estimate upper bound on risk (extrapolated) – for comparison of risks, not absolute risk quantification.
- **Health metrics**
  - QALY, DALY, p-DALY – proposed to be used to compare/integrate risks across chemical & microbial contaminants

Question 6 – Comparing hazards/risks: effect of type of data available

- **Issues**
  - For chemicals, almost always relying on extrapolation from animal data (or less) → much greater uncertainty in risk characterization than for microbial pathogens
  - Should we attempt quantitative estimate of human health impact at all, if we have only animal data?
  - Epidemiology data may be better but seldom available.
  - Prioritization based on qualitatively different kinds of data (e.g., epi *vs*. animal tox *vs*. in vitro *vs*. SAR) is likely to be less reliable.

Question 7 –
Chemical risk prioritization framework: criteria for acceptability to all stakeholders

- **Transparent**
- **Simple**
- **Sound scientific basis**
  - Best available data
  - Conservative
- **Well-documented**
- **Adaptable to incorporate advancing science**
- **Applicable to wide range of chemicals/pathogens and scenarios**

Question 7 –
Chemical risk prioritization framework: criteria for acceptability to all stakeholders

- Engenders confidence that framework is health protective and in the best interest of the public
- Provides for stakeholder input
- Based on goal of effective resource allocation for protection of human health

Further Work

- Evaluate metrics for combined prioritization of chemicals and pathogens – p-DALY, other?
- Define process for further development of this prioritization framework
- Test and validate TTC pre-screen
- Continue exploration of approaches for rapid hazard screening (e.g., ToxCast)
- Increasing focus on exposure will require data on occurrence in foods.

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