Dietary Exposure Assessment
Tools for Prioritizing Food Safety Concerns

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Group 2
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Chemicals and Microbes

• Too many differences to address in parallel now
  – Terminology
    • Future Need – Dictionary or Terminology List
  – No TTC-Equivalent Default for Microbes
    • Default exposure is 0 – which is not useful in this context
  – Growth vs non-growth
  – Seldom actually need to address “new” microbes
  – No SAR-Equivalent for Microbes
  – Acute vs chronic
    • Greatest overlap is between acute toxins and microbes
  – QMRA is highly flexible
Chemicals and Microbes

• Recommendation –
  – Develop frameworks independently and then figure out where overlap exists
Chemicals

• **Screening vs Ranking** –
  – Single chemicals vs comparisons
  – Ranking **needs** consistency
    • Both hazard characterization and exposure assessment (methods and measurements)

• **Data quality and quantity issues**
  – Future Need – Identification of data needs
Chemicals

• Degree of characterization of the hazard does not directly affect how the exposure assessment is done.

• If relevant regulatory/safety standard exists, you can make a quick Y/N decision without exposure assessment
  • What is relevant?
  • Do we need criteria for relevance?
Chemicals - Tiering

- TTC is a “default RfD”

**Screening – Tier 0 and Tier 1**

- **Tier 0:** assume an appropriate level* is present in the entire diet (FDA: 3 kg food + beverage/person/day) (the mother of all defaults in US); compare to relevant TTC threshold. If exposure is lower than the chronic TTC threshold (0.5 ppb in your stuff, = 1.5 μg/p/day), “have a nice day.” If exposure is higher, go to Tier 1.
  - High confidence that the 3 kg/p/day diet is overestimate
  - FDA transparency has improved but needs to get better

* Future Need - Need criteria and approaches for deriving an appropriate value
Chemicals - Tiering

• Tier 1 –
  – Use predetermined “default” consumption estimates for commodities, or food categories, or ingredients, or products
  – EPA Exposure Factors handbook useful?
  – Future Need – developing these defaults from existing data
  – Future Need – Develop guidelines on which consumers to use (e.g., “reasonable high end individual”)
  – Could be a desk exercise
Chemicals - Tiering

• **Tier 1 – detection in commodity:**
  – Assume that 100% of the commodity, ingredient or food in the diet contains the level that you detected; compare exposure to the TTC threshold. If exposure is higher, more information is needed.
  – If you have information allowing you to set boundaries on duration of the potential exposure, you may be able to use the subchronic TTC threshold (higher). If there is still a concern, further refinements are needed, i.e., screening assessment is not enough.
  – **Future Needs - Criteria for confidence in exposure duration determination?**
Chemicals - Tiering

- *Tier 2*: consideration of “reality” factors
- Physical-chemical characteristics, partitioning, environmental/processing fate, cooking and consumer handling, farm to fork pathway
- Distribution of contaminants (temporal, spatial, amounts, etc.)
- Generates data that can be used for risk ranking (tier 0 & 1 do not)
Chemicals - Tiering

• Tier 2
  – Apply Detailed Consumption Data
  – Uncertainties in existing data bases become more important
  – Need to identify population at risk, and to determine what you know about their consumption patterns
  – Future Need – Characterization of applicability of existing data bases for this application (i.e., Exponent Paper)
  – Future Need – Characterization of special diets/consumers and infrequently consumed foods
Data Resources

• Need to capture advantages and limitations of the available data sources

• Need to identify data gaps & approaches to filling them
  – Tiered Approach?
  – Need risk ranking framework

• Need criteria for assumptions to use when confronted with a data gap
  – Possibly derived from other established approaches (e.g., EPA)
  – Criteria for dealing with sparse data
Uncertainty

• Need to capture in a systematic way
• Needs to accompany rankings
• The uncertainty that matters is one that might change a ranking
  – In the context of the operative assumptions
  – Sensitivity analysis
Risk Ranking

- One tool for risk management
- Management needs will influence process and risks metrics
- May need to indicate which factors have greatest influence on relative risks (i.e., hazard vs. exposure)
- Bin there, do that
Other Considerations

• The 800 lb gorillas
  – Risk communication considerations
    • Provide context for consumers
  – “Hazard index” concept
  – Uncertainty
Parking Lot

- What characterizes/distinguishes a “well defined” and “poorly defined” hazard (science continually developing)

- Chemicals that fall outside the TTC data set – need to articulate any uncertainties in applying the lowest TTC threshold (we think the 500-600 chemicals are representative data set. (Note that some classes of chemicals are intentionally omitted from the TTC scheme – e.g., metals, proteins)
  - NOTE to NR: need to check if TTC data set includes any endocrine disruptors