# 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 Rankling

- 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 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*