Dietary Exposure Assessment

Tools for Prioritizing Food Safety Concerns

Group 1 Report

Facilitator: Stephen Olin
Rapporteur: Leila Barraj
Subgroup leaders: David Hrdy
Stephen Beaulieu

The report was presented in two parts:

Chemical

- Focus on assessing level of concern in response to detection of a food chemical with potential safety concern
- Develop generic questions and draft list of tools for assessing dietary exposure to a chemical in food. Need for case example(s), identifying which data/questions were most important in leading to the initial decision regarding level of concern and when further study is warranted, leading to more extensive data collection.

Microbial

- Focus on developing a flexible, data driven approach to ranking, emphasizing the critical questions that should be asked to characterize the potential dietary exposures relative to other stressor exposures
- Recommend what data, ideally, would be available to rank dietary exposures, identify sources of information that are readily available for ranking purposes, and determine what the most significant data gaps are (i.e., data gaps likely to introduce the most uncertainty)

Notes on thought process: Generic Questions

Main issues for the group
The need to separate micro and chemical
What is needed for risk assessment compared to risk ranking

1. Dietary
- Is the substance in diet?
- What foods?
- Are there other potential foods?
- Are there other pathways of contribution to the exposure?
- Food as consumed versus Raw Agricultural Commodity?

2. What vulnerable populations are there?
- Regionality
- Age subpopulation?

3. What levels? [Unknown hazard with a high exposure is always a priority over a low exposure.]
- Regulatory limits such as MRLs or tolerances?
- Measurement instrument?
- Analytical method?

4. Sources?
- Adulteration
- Cross contamination
- Formation during food prep
- Processing

5. Chemical Properties – [If you have unknown hazard with a high exposure, then the research would be prioritized higher than an unknown hazard with a low exposure.]
- Is the chemical well characterized with regards to safe intake threshold?
- POD? TDI? RfD?
- Maximum level of exposure?
- Are there other associated chemicals?
- What factors could affect concentration?

6. How prevalent?
- Is it new?

7. Timing?
- Was it always there?
- Increasing/decreasing?
- Seasonality
- Half-life

CHEMICAL EXAMPLE

Tools for conducting Dietary Exposure Assessments for food chemicals
(Considered as inputs into DEAs; draft, subject to further analysis and revision)

Input in the DEA	Tools Available	Level of Confidence*	Level of Conservativeness (1 (most conservative) to 3)
Consumption Data	Physiological limits of consumption	High	1
	FBS (food balance sheet) assumed percentage (e.g., 10%)	Low	2 (?)
	Cluster diets	Low	2
	Food purchase/expenditure data	Low	1
	Model diet (incl. TDS simulated diet)	Medium-High	2
	Individual data – collated (means)	High	3
	Individual data – distributions	Very high	3
	FFQ	Low	2
	Specific surveys (e.g., intense sweetners)	High	3
	GEMS Large Portion database	High	2
	Market Research Data	High	3
Concentration data	Regulatory limits (e.g. MLs, MRLs) Maximum Permitted Concentration (MPC)	Low	1
	Actual levels of use (e.g. food additives, nutrient fortification)	High	3
	Trial data (pesticides)	Medium	2
	TDS data	High	3
	Analytical data (monitoring/ surveillance, research) *assuming accurate reproducible method and representative sampling	High	3
	Analytical data (monitoring/ surveillance, research) *assuming not accurate reproducible method or not representative sampling	Low	?
	Food composition data (some nutrients are considered for chemical exposure assessments)	High	3
	Market Share Data / % Crop treated	Medium	2
	Processing factors/ information	High	2
	LODs (assuming there are no detects)	Low	1
Methodologies	Budget method	Low	1
	Deterministic (point estimate)	Medium	1-3 (depending upon the inputs)

	Probabilistic	High	3 (depending upon the assumptions it may be lower)
	Biomarkers	High	2
	Cumulative (combination of chemicals with a common mechanism)	High	3
	Aggregate (combination of different pathways)	High	1-3
	Sensitivity analysis	High	1
Demographics	Convenience Survey	Low	1-3
	Population based	Medium	2
	Population and sub-population	High	3

* Each of these tools impact the level of concern in different ways. With higher levels of confidence in the tool, the more confident one can be with the resulting estimate of the level of concern.

See also Figure 6.1 in Chapter 6, *Dietary exposure assessment of chemicals in food*, in WHO harmonisation document: Principles and Methods for the Risk Assessment of Chemicals in Foods. More refined DEAs correspond to more confidence in exposure estimates, and therefore more confidence in level of concern

MICROBIAL EXAMPLE

Problem definition: For the purposes of exploring a potential framework for microbial agents, we selected an emerging pathogen as a "case study."

Emerging pathogen: e.g., Clostridium difficile

The initial step should involve characterizing the type of pathogen (e.g., is it zoonotic? an animal pathogen?) to inform subsequent steps in the framework. For example, the framework can be organized around (1) the prevalence and "concentration" of the pathogen in food commodities, (2) the consumption rates (e.g., percent population) of food commodities that may be contaminated, and the severity of the foodborne illness associated with the particular pathogen.

"Concentration" data:

- Is it foodborne?

  Best case: Published study/data reported to CDC/MMWR report

  What we have: Sporadic cases, anecdotal evidence, outbreak data

- What foods?

  Best case: case control, food survey, outbreak data

  What we have: human data, data on survival/growth in different environments & foods, resistance, germination

- Imported/domestic?

  Best case: ERS data, monitoring data on imports, USTR?

  What we have: Information about disease in country of origin

- Other non-microbial indicators of its presence (antibiotics):

  Best case: Publication linking antibiotic use and disease and food commodity

  What we have: Some organism has caused disease in subpopulation, but we don't have further info

- Sources/reservoir (where on farm to fork continuum):

Best case: broad survey/monitoring data

What we have: sporadic cases/outbreak data

- What factors affect cell numbers in as consumed foods:

  Best case: baseline information, predictive microbiology, PMP model, literature, rigorous lab studies

  What we have: expert judgment

- How prevalent (e.g., on farm, in environment)? Regional and seasonal factors that affect prevalence such as temperature, moisture, and pH.

  Best case: nationwide surveillance data, baseline data

  What we have: data from small surveys, some EPA data (environmental ecological surveys)

- Measurement instrument?

  Best case: AOAC/ISO approved standardized analytical method (food specific protocols)

  What we have: clinical methodologies

Consumption data:

- What foods?
  - Serving size (distribution)
  - Frequency of consumption
  - Demographics:(age/gender/sensitive subpopulations/geographic/ethnicity)
  - High-end consumers (extreme tail)

  Best case: 24-hr diaries, current, large enough sample size, increased power for susceptible populations, increased power for regional differences, specificity of food commodity, consumer behavior

  What we have: same as for chem. (see white paper)

Questions relating to hazard or severity of disease:

- Which strain(s) cause human illness?
- What syndromes?
- Dose response?
- Infectious dose?
- Evidence of hospitalization and/or death?

Next steps to operationalize framework:

- Criteria to establish relative importance of inputs listed above (weights)
- Criteria to establish level of confidence in data sources
- Data gaps (and how easy to get):
    - Data on sensitive subpopulation and or other high risk demographic (easy)
    - Data on industry practices (producers, processors, retail, food service, distribution) – (medium)
    - Data on consumer behavior (easy)
    - Prevalence & level data for pathogen (medium to hard, depending on scope)
    - Information about food practices in and outside US (in US: easy/medium, Outside US: medium to hard depending on country)
    - Information about imports (medium)
    - Epi studies to establish link between food, pathogen and illness (medium to hard)

DATA GAPS/ RESEARCH NEEDS

Input into the DEA	Chemical agent	Microbial agent
Concentration data	Data at 'as consumed' level.	Data at 'as consumed' level.
	Low levels of detection	Data on pathogen strains
	Methodology of new compounds of interests	Better traceback methods for farms to identify sinks and sources
Consumption data	More days of data to better estimate chronic exposures	Data at 'as consumed' level.
	Over sampling of specific sub-population groups.	More detailed food descriptors in consumption surveys
	More detail in FFQ data.	Consumer behaviour data
	Rolling surveys to keep data as up to date as possible	More data on vulnerable sub populations
		Data per serve or eating occasion.
	Better recipe data to break down to raw commodities.	Better recipe data to break down to raw commodities
Methodologies	Better info on aggregate and cumulative exposure assessment methodologies	Better info on pathogen indicators, relationships between pathogen growth and survival and environmental characteristics

Criteria for using DEAs in determining Level of Risk

- All DEAs should have level of uncertainty in the data and exposure estimate quantified as high, medium, low (as per white paper).
- If level of concern is low, and screening methods used to get worst case estimate or overestimate of dietary exposure, then no more DEA work needed.
- If Level of Concern medium or high, check if screening methods used for DEA, or if most specific data or methods possible have been used. If not, refinements to the DEA should be made, level of uncertainty updated and Level of Concern re-estimated. (Or is this getting out of risk ranking and more into risk assessment??)
- If Level of Concern high and DEA have high level of uncertainty, need to refine DEA.