Tools for Prioritizing Food Safety Concerns Workshop
June 4-6, 2007
Greenbelt, Maryland

Summary

Background

Many risk prioritization efforts are associated with the need to effectively deal with emerging food safety issues. Generally, these emerging issues are identified in two ways: an outbreak (microbial) or evidence of harm (chemical) occurs and there is a need to track down the responsible agent; or an "unwanted" agent (chemical or microbial) is found in a food and there is a need to determine if it poses a potential public health risk.

The need for a workshop was identified after multiple conversations with various groups who were each working on different approaches and methodologies for ranking and prioritizing health risks associated with either chemical or microbial contaminants in food. These approaches were being developed to address the needs of each group to make rapid decisions with little information and to allocate scarce resources such that the greatest public health benefit is achieved. The need for an acceptable, common framework was recognized, so that the rationales behind decisions are readily understood.

The missing link was that the various groups were not talking to each other, and each had valuable insight that may assist in the ultimate development of a Conceptual Framework for Prioritizing Food Safety Concerns. This workshop was conceived as a first step towards that goal.

The Workshop brought together invited representatives of various organizations who use or develop tools for risk screening, ranking, and prioritization. The group as a whole represented a wide range of relevant expertise (e.g., risk assessment, risk communication, risk management, microbiology, chemistry, toxicology, food science, dose-response modeling, exposure assessment, decision analysis, and economics) and affiliations (government, consumer representatives, industry and academia, domestic and international).

Objectives

1. To develop recommendations on approaches or criteria useful for prioritizing potential risks of chemical and microbial contaminants in foods, as potential tools for resource allocation and decision-making.
2. To develop recommendations on next steps to advance the use of prioritization tools, including identification of critical knowledge gaps and research needs.

Process

The format of the workshop, a breakout group setting, was designed to facilitate discussion. The participants were divided into four multidisciplinary breakout groups to discuss a common set of core questions (Table 1) to assist in the development of recommendations as described in the objectives above. Each breakout group prepared reports to be shared with the entire group at the closing plenary session.

Prior to the breakout group sessions a series of presentations were given in an opening plenary session to provide the participants with background on the need for a science-based process/framework for prioritizing potential risks from chemical and microbial contaminants in food. Presentations also served to update participants on approaches and methodologies in ranking and prioritizing health risks that are currently in use or in development, and issues associated with their use.

In the closing plenary session, summary reports from the breakout groups were presented. The group discussed the breakout recommendations including strengths, aspects needing further development, key knowledge gaps and research needs and identification of next steps.

Discussion/Recommendations

Several common themes and conclusions were identified by breakout groups in their discussions of the assigned questions:

- There are several important acceptance criteria for a risk prioritization framework to be useful in decision-making. The goal of such a framework is to enable the most effective allocation of resources for the protection of public health. It must be science/data-based, rigorous, provide consistent results and should be validated. It must be transparent and simple, while applicable to a wide range of situations. It must be flexible to allow for input of a variety of kinds of decision criteria, both scientific and societal.
- There may be different objectives for use of a risk prioritization framework, depending upon the user, or upon the risk management question being asked. For example, such a framework could contribute to broad program decisions on staffing and general priorities, and it could also provide a common basis for industry and government responses to the detection of a low-level contaminant in a food matrix.
- There was recognition of a distinction between risk ranking and risk prioritization, risk ranking being one potential input into risk prioritization. There is a need for agreement on common definition of terms to ensure clarity in the process and in communication to stakeholders.
- Priority setting based on risk involves a continuum of decisions. Decisions can be made with little information, but more information, and higher quality information, yields higher confidence in the decision. There is a need to develop a toolbox so that the appropriate tool is used for a given situation.
- For risk prioritization, grouping or "binning" of agent exposures into categories of low, medium and high risk was viewed as more practical and feasible than numerical ranking. As a first step, screening tools for chemical agents, such as TTC, SAR or others, were viewed as useful in rapidly identifying situations of very low concern for which little or no further effort need be devoted to risk characterization. For initial screening, important considerations are the need for quality exposure data or modeling approaches, as well as characterization of the range of uncertainty associated with the judgment of very low potential for risk. Availability of additional data may require re-assessment of the risk level. If screening-level assessment indicates the need for further analysis, a risk characterization process based on risk assessment principles provides input to a comparative assessment of public health impact, which in turn is a key input into the ultimate risk prioritization and the decision-making it is intended to support (e.g., resource allocation).
- It was recognized that there are significant differences between risk assessment for chemical versus microbial agents that affect the ability to prioritize across chemical and microbial risks. These include differences in the origin and comparability of most hazard data (animal or in vitro for chemicals vs. human data for microbes),differences in the time-to-onset and detectability of induced health effects in the population (in foods, generally, chronic effects are the concern for chemicals and acute illness for pathogens), and public perception. At present, the most workable approach for prioritization is to categorize risks separately for chemical and microbial agents and use an appropriate metric for public health impact to prioritize them. This will need to appropriately balance short-term vs. long-term health impact. This is an area that requires more work.
- The assessment of risk mitigation options was generally viewed as a "post-prioritization" step in resource allocation, as the framework is designed to prioritize risks. However, there may be instances where mitigation options are obvious early on, and could reduce the need to expend efforts toward further characterizing risk.
- Making the framework transparent to stakeholders, especially consumers, is critical to its acceptance.

Next steps

- Publication of the risk prioritization framework concepts that emerged from the discussions
- Convene additional workshops to gain further insight into outstanding questions and information gaps

TABLE 1: Questions considered by each breakout group

1. 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)?
2. How can various kinds of information or data be used (or how are they being used) to rank or prioritize chemical risks?
3. Is there a minimum amount of information/data necessary to rank or prioritize risk?
4. How are adverse public health impacts of chemical risks quantified?
5. What scientific, policy and public perception issues arise in comparing/ranking chemical risks?
6. Does the type of available data exert an effect on the comparability of hazards/risks? How?
7. What criteria should a chemical risk prioritization framework meet in order to be accepted by regulators, industry and consumers?

APPENDIX A: Participant list

Planning Committee

Dave Lineback, PhD. (Chair)	Joint Institute for Food Safety and Applied Nutrition
Robert Buchanan, PhD.	Food and Drug Administration
Phillip Bolger, PhD.	Food and Drug Administration
Elizabeth Calvey, PhD.	Food and Drug Administration
Richard Lane, PhD.	Unilever
Paul Mazzocchi, PhD.	Joint Institute for Food Safety and Applied Nutrition
Jianghong Meng, PhD.	Joint Institute for Food Safety and Applied Nutrition
Marianna Miliotis, PhD.	Food and Drug Administration
Sanford Miller, PhD.	Center for Food Nutrition and Agriculture Policy
Steve Olin, PhD.	ILSI Research Foundation
Nancy Rachman, PhD.	GMA-FPA
Katherine Squibb, PhD.	University of Maryland/School Medicine
Michael Taylor, PhD.	University of Maryland/School of Public Health
Thomas Trautman, PhD.	General Mills, Inc.
Sally Vater, PhD.	The Procter and Gamble Company

Workshop Participants

A complete list of workshop participants is posted at:
http://www.jifsan.umd.edu/Tools/Workshop_Paticipants_List.pdf

APPENDIX B: Breakout Groups Presentations

Presentations are posted at http://www.jifsan.umd.edu/tools_2007.htm.

Group 1, Facilitator, Dr. Steve Olin:
http://www.jifsan.umd.edu/presentations/tools_2007/PDF/Group_1_Wkshp_Presentation.pdf
Group 2, Facilitator, Dr. Nga Tran:
http://www.jifsan.umd.edu/presentations/tools_2007/PDF/Group_2_Wkshp_Presentation.pdf
Group 3, Facilitator, Dr. Nancy Rachman:
http://www.jifsan.umd.edu/presentations/tools_2007/PDF/Group_3_Wkshp_Presentation.pdf
Group 4, Facilitator, Dr. Bernadene Magnuson:
http://www.jifsan.umd.edu/presentations/tools_2007/PDF/Group_4_Wkshp_Presentation.pdf