Interagency

Risk Assessment Consortium

Annual Report

December 31, 2010

Introduction

The Interagency Risk Assessment Consortium (IRAC) is an interagency collaborative network among Federal agencies with responsibilities and interest in food safety. The IRAC was established in 1998 in response to the Presidential Executive Order 13100 and subsequent planning and implementation documents of the President's Food Safety Council. The goals of IRAC are to improve risk assessment research, enhance the development and use of risk assessment tools, and serve as a forum to communicate about risk assessment and related research issues including enhancement of the use of quantitative risk assessment in the decision making regulatory process. Current IRAC membership includes 18 Federal agencies and offices. Each agency/office is represented on both the Technical Committee and the Policy Council. A list of the member agencies is provided in Annex I.

Over the past 12 years, the IRAC has expanded the range of issues addressed beyond food safety (microbial and chemical) risk assessment to include risk assessment research issues related to data quality, peer review, nutrients, nanotechnology, susceptible subpopulations, genomics, and proteomics.

Quarterly Meetings

IRAC held quarterly meetings of the Technical Committee in March, June, September and December 2010. The Policy Council met during the spring and the fall quarterly meeting to review the annual plan and work group updates. During the technical meetings, representatives of the member agencies and invited guests exchanged risk assessment and risk assessment-related research information informally, via agency updates and through presentations. The quarterly meetings served as a forum for IRAC member agencies to share information about risk assessments and keep abreast of the latest developments in risk assessment tools and their application in decision-making.

IRAC invited a number of guest speakers to present a variety of topics related to risk assessment and food safety, including the following:

1. International Health Regulations, by Jose Fernandez, Department of Health and Human Services.
   Dr. Fernandez reviewed the history, global context and implementation of International Health Regulations (IHR). The purpose of IHR is to respond to international spread of disease according to risk, while avoiding unnecessary interference with international traffic and trade. An example of a public health emergency of international concern (PHEIC) is the 2009 H1N1 influence outbreak. Since 2007, the U.S. has provided 18 notifications of potential PHEIC to the WHO. Dr. Fernandez discussed the role of the International Food Safety Authorities Network (INFOSAN) and some of the challenges of foodborne outbreaks for IHR.

2. Interagency Retail *Listeria monocytogenes* Risk Assessment and Retail Observation Study, by Sherri Dennis, FDA/CFSAN; Dare Akingbade, USDA/FSIS; and Dan Gallagher, Virginia Tech.
   The joint presentation by the interagency risk assessment team included an overview of background, risk management questions and issues, and modeling of cross contamination. This project is special in that a new paradigm has been set, including a greater level of collaboration, data developed specifically for the risk assessment, and stakeholder participation early in the process. This is the first time a retail cross-contamination module is included in an FDA/FSIS risk assessment. The presentation included a timeline of two dozen events, since 2001, related to the interagency efforts on L. monocytogenes *risk assessment. The objective of this project is to ascertain the impact on public health of current practices and potential interventions that reduce or prevent* L. monocytogenes *contamination in ready-to-eat food sliced, prepared and/or packaged in retail facilities.*

3. Water-Associated Pathogens: Food for Thought, by Nick Ashbolt, EPA.
   The presentation highlighted potential risks from water used in food production, including epidemiologic evidence of risk from parasitic protozoa, enteric viruses, E. coli *O157:H7, and amoeba-ciliate/biofilm. EPA has developed a water-food quantitative microbial risk assessment (QMRA) model that includes four steps. Several case studies were presented. Most QMRAs of water systems suggest that exposure assessment (in particular under-recognized exposure from enteric viruses and parasitic protozoa) is a greater source of uncertainty than dose-response. The QMRAs also help identify the importance of hazardous events and aid in targeting management options.*

4. Holyrisk project, by Beth Calvey, FDA/CFSAN.
   The Holyrisk project is a comparative empirical study of the EU and the U.S. that investigates the ways different forms of uncertainty are perceived, handled and expressed by experts throughout the food risk analysis process. The project has an Advisory Board of key regulatory institutions in EU and U.S., to provide comments at different stages of the project, to make the outcome practical. A launch meeting in March 2010 included a demonstration of software and interactive tools and an overview of the roles of participating institutions. Dr. Calvey indicated that IRAC can recommend experts to serve on the project Advisory Board.

5. Linking GIS and Risk Assessment: A Collaboration between FDA and NASA, by David Oryang, from FDA/CFSAN.
   The vision of the project is to develop a system to provide an early warning of potential produce contamination events and locations. The presentation included a review of produce-related outbreaks, sources/vectors of E. coli *in the produce-growing environment, and an overview of geographic information (GIS) and how GIS and spatial modeling can be used to address food safety questions and predict risks. A model has been developed to characterize and predict the*

likelihood, amount, time and locations of environmental contamination of produce by enteric pathogens including E. coli *O157:H7 and norovirus (currently the model includes data on generic* E. coli *as an indictor). Findings from phase I of the project, including a case study with data from outbreaks traced to the Salinas Valley in California, were presented. Next steps include seeking additional data to populate the model and model validation.*

6. Foodborne Disease Attribution and Overview of Interagency Attribution Work Group, by Dana Cole, CDC; and Kristin Holt, FSIS.
   The presentation described several different points, from farm to table, where attribution of foodborne disease burden can occur. Resource needs, strengths and limitations of attribution using microbiological, epidemiological and expert elicitation approaches were discussed. Also included in the presentation are attribution efforts to date, by CDC, and an interagency work group; an overview of surveillance data and data from FoodNet special studies (also how these data are being used); and modeling approaches (e.g., adapting a Salmonella *Danish Model in attribution and the use of a "blending" approach). Attribution currently includes 17 food commodities, and the interagency work group is evaluating how to create subcategories among these commodities, as well as exploring the use of subtyping data. Next steps include identifying new projects and better catalogue attribution work being conducted by different groups.*

7. Food Commodity Intake Database, by Aaron Niman, EPA/OPP.
   The presentation provided an overview of the regulatory framework and risk assessment approach adopted by EPA's Office of Pesticide Programs (OPP); introduced its dietary exposure assessment methodology,including key surveys and data sources; and described the Food Commodity Intake Database (FCID). FCID uses data and information from the "What We Eat In America" (WWEIA), which is a food survey conducted as part of the National Health Assessment and Nutrition Examination Survey (NHANES). In the FCID database, information from WWEIA, including more than 5,000 food codes, are converted into approximately 540 different food commodities. Mr. Niman shared several examples of the FCID database output. Approximately 500 new recipes have been created. Work is underway to update FCID so that it is linked to consumption data collected in NHANES 2003-2006 and 2007-2008, and to develop a graphical user interface to assist users with limited database experience to access FCID. FCID enables users to estimate consumption of food commodities and eating occasions.

8. Ensuring the Safety of the Food Supply while Facilitating International Trade, by Isabel Walls, USDA/NIFA.
   The presentation included an overview of food safety as both a public health and economic issue, the need to ensure food safety while facilitating trade, and the role of capacity building in ensuring food safety. Dr. Walls shared information on the goal and four focus areas of the Asia Pacific Economic Cooperation Food Safety Cooperation Forum Partnership Training Institute Network

(APEC/FSCF/PTIN). PTIN held a workshop on risk analysis in Singapore, in August 2009; a workshop on export certification in Australia, in February 2010; and a recent workshop on supply chain management in China, in November 2010. The take-home message is that improving food safety and expanding international trade are compatible goals, and that risk analysis principles should be used when developing strategies to improve food safety.

Work Group Projects

The IRAC accomplishes much of its work through working groups formed to address specific topics or issues. These work projects are a means for IRAC member agencies to collaborate and share technical expertise regarding the issues in question, through a review and synthesis of data and information as well as convening workshops with leading experts. Outcomes of the work projects can be used by member agencies to fill data and information gaps in agency risk assessment efforts. The outcomes are also posted on the IRAC website at FoodRisk.org and sometimes published as papers in scientific journals to benefit the larger risk assessment community.
Below are the accomplishments and activities of these working groups for 2010.

Susceptible Subpopulations. Risk assessors and risk managers are often confronted with issues related to the fact that some members of the population are more susceptible than others when exposed to a hazard. Understanding why these differences exist and quantifying them are critical to accurately characterizing risk for specific populations, as is developing effective risk mitigation and risk communication strategies. The work group developed the workshop to improve our understanding of how consideration of susceptible populations differs for different types of hazards and how to develop common tools and approaches. A description of the workshop and its outcomes are provided below.

Nanotechnology and Risk Assessment. The work group continued to identify information sources for developing a white paper to identifying the challenges that need to be met in order to perform a risk assessment for engineered nanomaterials. IRAC members provided comments for consideration. The work group has initiated efforts to develop a draft.

L. monocytogenes Dose Response. An interagency Steering Committee was formed at the summer meeting and has met on a regular basis to plan the workshop. The purpose of the workshop is to facilitate an open dialogue among participating experts on the latest trends in *L. monocytogenes* epidemiology, pathology, interactions with hosts, virulence, state-of-the-art modeling, and better characterization of uncertainty. A better characterization of dose response will become more important in the future, as *L. monocytogenes* risk assessment efforts move from quantifying relative risk reduction to establishing food safety metrics to measure food safety progress. An agenda has been set, with presentations for approx. half of day-1 and breakout sessions for day-1 afternoon and day-2 morning. The Steering Committee has drafted a background document and questions for the breakout sessions. Invitations have been sent to participants. All speakers and moderators have been confirmed. The dates for the

workshop will be March 17 and 18, 2011. IRAC and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) are co-sponsoring the workshop.

Workshops and Symposia

IRAC workshop "Susceptible Populations and Food Safety" was held January 20-21, 2010, in Greenbelt, MD. The workshop brought together experts in both chemical and microbial hazards in food and water, to develop a common concept of susceptibility that can be used by risk assessors and risk managers. During the workshop, available data and tools that can be used to characterize the relative susceptibility of populations were identified, and research needs were discussed and prioritized. The workshop included a number of presentations from subject matter experts and two breakout sessions, to address issues in defining susceptible populations for chemical and microbial hazards. Summaries of the breakout group discussions, presentation slides and other workshop information are available at http://www.foodrisk.org/irac/events/2010-01-10/index.cfm. A small working group will draft a manuscript based on the outcomes of the workshop, which will be submitted for publication in a scientific journal.

Agency Collaborations

The Joint Institute for Food Safety and Applied Nutrition (JIFSAN) provides support to the IRAC by hosting a website (www.foodrisk.org), where information about IRAC, including the charter, quarterly minutes, annual plans and reports, and workshop details, is made available. The IRAC supports the JIFSAN efforts by helping identify and make available new risk-assessment content to be posted on the FoodRisk.org website.

IRAC member agencies collaborated on the development of risk-assessment models, including:

- Interagency (FSIS, APHIS, FDA) Highly Pathogenic Avian Influenza Risk Assessment for Poultry and Eggs (published May 2010).
- Interagency (FDA, FSIS) *Listeria monocytogenes* at Retail Risk Assessment (Completed peer review of the model. Responses to peer-review comments in progress. Held several briefings for industry and consumer groups. Expect to issue draft report for public comment in 2011).

Additional Information for CY2010

IRAC Charter Update. A Steering Committee was established at the spring meeting, to update the IRAC Charter, which had been last revised in 2003. The Steering Committee developed a draft update, which went through multiple comments among technical and policy representatives of IRAC agencies, as well as further comments from IRAC member agencies. Currently the IRAC Policy Council is co-chaired by CFSAN and FSIS. IRAC discussed the possibility of having a third co-chair from CDC. Rather than serving in a co-chair capacity, CDC decided to continue participation in IRAC through representation on both the Technical Committee and

Policy Council. The new Charter further refines various Articles in the previous version, including refined IRAC goals that encompass three broad aspects: 1) improve risk assessment research, 2) enhance the development and use of risk assessment tools, and 3) serve as a forum to communicate about risk assessment and related research issues, including enhancement of the use of quantitative risk assessment in the decision-making regulatory process. The new Charter reflects a recent recommendation from the President's Food Safety Working Group that a Risk Assessment Coordinating Council be formed. A signing ceremony has been planned for February 8, 2011. Signatories from most of the IRAC member agencies have been confirmed. The new Charter will guide IRAC efforts, as we move forward.

Funding IRAC Website. Currently funding support for the website is provided by FDA. More funding is needed to maintain and update the website. Other Federal agencies are encouraged to provide funding to support the website. A small work group prepared a memo to help IRAC technical and policy representatives approach their agencies on funding support. A new agreement letter was developed and circulated, to provide a mechanism for IRAC member agencies to contribute funds to sustain the website maintenance, new document and information uploads, and new web tools.

New Executive Secretary. Dr. Yuhuan Chen, FDA/CFSAN, was tasked to serve as executive secretary of the IRAC Technical Committee in 2010. IRAC thanks Ms. Sharon Edelson-Mammel, FDA/CFSAN, who served as the previous executive secretary.

Annual Plan. IRAC is developing its annual plan of activities for CY2011, which will be made available at www.foodrisk.org.

Annex I

IRAC Member Agencies

Center for Food Safety and Applied Nutrition, Food and Drug Administration, HHS

National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, HHS

National Center for Toxicological Research, Food and Drug Administration, HHS

National Institute of Allergy and Infectious Diseases, National Institutes of Health, HHS

Center for Veterinary Medicine, Food and Drug Administration, HHS

National Institute for Occupational Safety and Health, CDC, HHS

Food Safety and Inspection Service, USDA

National Institute of Food and Agriculture, USDA

Agricultural Research Service, USDA

Food and Nutrition Service, USDA

Economic Research Service, USDA

Office of Risk Assessment and Cost Benefit Analysis, USDA

Animal and Plant Health Inspection Service, USDA

Office of Pesticide Programs, EPA

Office of Water, EPA

Office of Research and Development, EPA

US Army Public Health Command (Provisional) DOD

National Marine Fisheries Service, NOAA, DOC

For more information, including the names of the technical and policy representatives from each IRAC member agency, see http://www.foodrisk.org/irac/index.cfm.