

INTERAGENCY RISK ASSESSMENT CONSORTIUM ANNUAL REPORT FOR CY09¹

Introduction

The Interagency Risk Assessment Consortium (IRAC), an interagency collaborative network among Federal agencies with food-safety responsibilities and/or interest, was formed in response to the 1997 Food Safety Initiative (FSI). That initiative called for enhanced communication and coordination among Federal agencies and promotion of scientific research to inform risk assessments, thereby providing support for the regulatory agencies in fulfilling their food-safety risk-management mandates. Current IRAC membership includes 19 Federal agencies or sub-agencies. Each agency is represented by a technical and a policy-council representative. 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 December 2008, April 2009, June 2009, and September 2009. The Policy Council met during the spring quarterly meeting to review the annual plan and work group updates. During the technical meetings, the representatives of the member agencies exchanged risk assessment and risk assessment-related research information informally, via agency updates and through presentations. Presentations included a variety of topics related to risk assessment and food safety, including the following:

- Global Threshold Project, by Steve Olin, International Life Sciences Institute
A new, mode of action approach to dose response assessment for bioactive compounds with low-dose exposure including allergens, nutrients, and pathogenic microorganisms referred to as Key Evens Dose-Response Framework was presented. Following the presentation, there was discussion about the possibility of IRAC and ILSI co-sponsoring a workshop to further explore the approaches to establishing thresholds under development within the “Global Threshold” project.
- A Quantitative Risk Assessment of *Listeria monocytogenes* in French Cold-Smoked Salmon, by Régis Pouillot, FDA/CFSAN
This presentation was an opportunity for IRAC risk assessors to learn about and review different methodological approaches to a process-pathway risk assessment.

¹ Note: In January 2010, IRAC changed its annual planning for a fiscal year to a calendar year format. This annual report reflects accomplishments during both Fiscal year 2009 and calendar year 2009.

- Developing an Understanding of the Transmission Pathway as a means of Potential Norovirus Control Options, by Wendy Fanaselle, FDA/CFSAN
This presentation was an opportunity for IRAC members to learn about CFSAN's approach to developing risk profiles, discuss the value of applying a systems approach of risk assessment to better understanding norovirus transmission in a community, and contribute to an evaluation of current and potential new control measures.
- EPA Activities Related to Nanoscale Materials by Philip Sayre, EPA/ORD
This presentation was an introduction nanotechnology and provided health research needs and the key characteristics of nanoparticles to be useful for determining potential adverse effects, such as size, shape, surface area. This information provided the IRAC Nanotechnology and Risk Assessment work group with background information to begin their work in the development of a discussion document.
- FoodRisk.org: An Online Resource for Food Safety Risk Analysis by Juliana Ruzante, University of Maryland/JIFSAN
Foodrisk.org hosts IRAC's website, and this was an opportunity to discuss how IRAC can support and further assist with development of the website's content. Following this discussion, IRAC members provided new information (see below) to be made available at foodrisk.org .
- Update: IRAC Work Group on Nanotechnology and Risk Assessment, by Villie Flari, FDA/CFSAN
Following this presentation, IRAC discussed next steps for this workgroup. It was decided that the workgroup will prepare an outline of a white paper documenting its efforts and recommendations for further work on nanotechnology risk assessment, including a possible expert elucidation for better understanding of data gaps in current knowledge .

Work Group Projects

The IRAC accomplishes much of its work through working groups formed to address specific topics or issues. Below are the accomplishments and activities of these working groups for 2009.

Data Utility. The work group organized and held a poster platform session on “Practicing the Science and the Art: Real World Case Studies in Sample Collection for Chemical and Microbial Risk Assessment” at the 2008 annual Society for Risk Analysis meeting. A paper based on the 2004 IRAC workshop and a 2005 symposium at SRA was published. Citation: Thran and Tannenbaum. 2008. The Concept of Data Utility in Health Risk Assessment: A Multi-Disciplinary Perspective. Human and Ecological Risk Assessment 14(6)1104-1117. This work group has completed its original objectives. A related work group that would continue exploring issues related to data utility, with emphasis on sampling plans, has been proposed for 2010.

Produce-Safety Data Gaps. A “lessons learned” document and model resulting from the Leafy Greens Research Needs workshop held in 2008 has been drafted and is under review by the work group. Further work to develop the model is under consideration. The background information assembled by the work group and obtained during the workshop is assisting in FDA/CFSAN’s development of a quantitative risk assessment for leafy greens contaminated with *E. coli*.

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 are developing effective risk mitigation and risk communication strategies. See below for a description of the workshops developed by this work group to improve our understanding of how consideration of susceptible populations differs for different types of hazards and how to develop common tools and approaches.

Nanotechnology and Risk Assessment. The work group developed a “straw man” approach, with a view to identifying the challenges that need to be met in order to perform a risk assessment for engineered nanomaterials. A report of the findings of the workgroup will be finalized in 2010 and made available to IRAC member agencies to consider, further develop, and use in expert elicitations and other efforts to further our understanding of this topic area.

Workshops and Symposia

IRAC, SRA and JIFSAN co-sponsored a two-day work shop on “New Tools, Methods and Approaches for Risk Assessment,” in Baltimore, MD, December 10-11, 2009. Mr. Mike Taylor provided the opening keynote of the workshop. Approximately 70 participants attended. Proceedings of the workshop are under development.

IRAC and the IOM Food Forum co-sponsored a two-day workshop on “Providing Healthy and Safe Foods as We Age,” October 29-30, 2009, in Washington, DC. The workshop included experts in various disciplines, who discussed size, demographics, and health status of populations over age 50, with particular attention to the food safety and nutrition concerns that arise in these populations. Proceedings of the workshop, to be published, are underdevelopment.

IRAC mini-symposium on Risk-based Inspection and Sampling Programs, Riverdale, MD, December 2, 2009. The term “risk based” is often used by federal agencies to describe their inspection and sampling programs. However, this term is not well defined, and its meaning often depends on the context in which it is used. This min-symposium brought together Federal agencies that develop, manage, or implement inspection and sampling programs (FDA, USDA-FSIS, USDA-APHIS, DOD) to discuss common issues and challenges in designing, validating, and verifying the impact of risk-based inspection and sampling programs. It is anticipated that the issues identified in this workshop could

be used to plan a more comprehensive workshop to further the development and use of risk-based programs.

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 plan and report, 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 at FoodRisk.org website. In 2009, IRAC members provided the following information:

- USDA/FSIS microbiological risk-assessment models
- EPA's Microbial Risk-Assessment Thesaurus
- FDA's Food-Handling Practices Model

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 (issued for public comment December 2008).
- Interagency (FDA, FSIS) *Listeria monocytogenes* at Retail Risk Assessment (public meeting on scope and approach held June 2009).

IRAC representatives also served in a peer review capacity and commented on FSIS's draft catfish risk assessment.

Additional Information for CY2010

Dr. Isabel Walls (USDA, NIFA) was identified by FDA/CFSAN (IRAC's lead agency) to serve as the chair of the IRAC technical committee in 2010.

IRAC thanks Dr. Marianne Miliotis (FDA/CFSAN) for serving as past IRAC technical committee chair since 2003.

IRAC is developing its annual plan of activities for CY2010, which will be made available at www.foodrisk.org.

IRAC Member Agencies

Annex I. IRAC Member Agencies

Department of Commerce

National Oceanic & Atmospheric Administration/ National Marine Fisheries Service
(DOC/NOAA/NMFS)

Department of Defense

US Army Center for Health Promotion and Preventive Medicine

Environmental Protection Agency

Office of Prevention, Pesticides, and Toxic Substances (EPA/OPPTS)

Office of Research and Development (EPA/ORD)

Office of Water (EPA/OW)

National Center for Environmental Assessment (EPA/ORD/NCEA)

National Homeland Security Research Center (EPA/NHSRC)

DHHS/ CDC

National Center for Infectious Diseases/Division of Foodborne, Bacterial and Mycotic
Diseases (DFBMD)

Enteric Diseases Epidemiology and Laboratory Branches

Department of Health and Human Services (HHS)

Centers for Disease Control and Prevention (CDC)

FDA/Center for Food Safety and Applied Nutrition (FDA/CFSAN)

FDA/Center for Veterinary Medicine (FDA/CVM)

FDA/National Center for Toxicological Research (FDA/NCTR)

National Institutes of Health (NIH)

DHHS/FDA/ Office of Women's Health (DHHS/FDA/OWH)

DHHS/NIH/ National Institute of Allergy and Infectious Diseases (DHHS/NIH/NIAID)

U.S. Department of Agriculture

Agricultural Research Service (USDA/ARS)

Animal and Plant Health Inspection Service (USDA/APHIS)

National Institute of Food and Agriculture (USDA/NIFA)-formerly CSREES

Economic Research Service (USDA/ERS)

Food Safety Inspection Service (USDA/FSIS)

Food Safety Inspection Service/Risk Assessment Division (USDA/FSIS/RAD)

Food and Nutrition Service (USDA/FNS)

Foreign Agricultural Service (USDA/FAS)

Office of Risk Assessment and Cost Benefit Analysis (USDA/ORACBA)

For more information, including the names of the technical and policy representatives from each IRAC member agency, see www.foodrisk.org (Note, for some agencies, no representative is listed)