



Annual Report

December 31, 2012

Introduction

The Interagency Risk Assessment Consortium (IRAC) is a collaborative network of Federal agencies with responsibilities and interests in food safety. The consortium was established in 1998, in response to Presidential Executive Order 13100 and subsequent planning and implementation documents of the President's Food Safety Council. IRAC was re-chartered in 2011 to implement a recent recommendation from the President's Food Safety Working Group on coordination of risk assessment among Federal agencies.

IRAC aims 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. IRAC accomplishes many of its goals through the work of its Policy Council and Technical Committee, both of which include representatives from each of the 21 Federal agencies and offices that constitute the consortium's current membership (Appendix I).

Over the past 14 years, IRAC has expanded the range of issues that it addresses beyond food-safety (microbial and chemical) risk assessment. Research issues addressed by IRAC include data quality, peer review, nutrients, susceptible subpopulations, nanotechnology, integration of genomics data into dose-response analysis, and leveraging of epidemiologic and risk assessment methods. The consortium also addresses clarification of various approaches to assessing risks.

Quarterly Meetings

The Technical Committee met in March, June, September, and December. Members gave agency updates, and members and invited guests gave presentations. The Policy Council met during the Spring and Fall quarterly meetings to review the annual plan and work group updates.

IRAC members exchanged information about risk assessments and related activities that their agencies were conducting, updating, or revising:

- Interagency risk assessment of *L. monocytogenes* in retail delicatessens;
- Lettuce/enterohemorrhagic *E. coli*/irrigation-water risk assessment, using FDA-iRISK to support proposed produce rule;
- Risk assessment of *L. monocytogenes* in soft-ripened cheese;
- Determination of high-risk foods and most significant foodborne contaminants, to support rule-making under the Food Safety Modernization Act;
- Restructuring of the National Residue Program;
- Norovirus in bivalve molluscan shellfish;
- Risk assessment of *Salmonella* in ready-to-eat (RTE) meat and poultry products, to evaluate the public health impact of lethality performance standards;
- Risk assessment of *C. perfringens* in ready-to-eat meat and poultry products, to evaluate the public health impact of stabilization (cooling) performance standards;
- Risk assessment of the effect of changes in slaughter inspection on risk of illness from *Salmonella* and *Campylobacter* in poultry;
- Attribution-based modeling of *Salmonella* in beef;

- Cancer slope factor for nitrosamine in pumped bacon;
- Costs of foodborne illnesses and attribution of cost to foods;
- Costs of illness for chronic sequelae;
- Optimal food-safety sampling design, given a budget constraint;
- Composition of food commodities and long-term dietary exposure to pesticides and other chemicals;
- Risk assessment on coal dust;
- Risk assessment of food flavorings: occupational exposure to diacetyl and 2,3-pentanedione;
- Risk prioritization model (includes public health and non-public health factors).

The quarterly meetings also were a forum for members to **share general information about other activities and topics of interest at their agencies**. Risk profiles were among the topics discussed; for example, a profile on pathogens and filth in spices currently underway. Members also shared information about risk ranking regarding hazards associated with misused veterinary medicines, environmental contaminants, and other chemicals. Sodium nitrite as a toxicant was discussed. Members also discussed development of appropriate level of protection (ALOP) using *C. perfringens*, *Salmonella* and *Campylobacter*, and *Listeria monocytogenes* as examples. Other topics included environmental justice issues, climate-change adaptation, the One Health Initiative, and the need for a consolidated list of foodborne agents of concern, to help risk prioritization for testing and inspection of domestic and international services and foods. Many of these assessments and activities were collaborations among member agencies; some involved international partners.

The quarterly meetings also served as a forum for sharing information about **international risk-related activities**, including those conducted by Codex. IRAC members served on the U.S. delegation for the Codex Committee on Food Hygiene, the Codex Committee on Contaminants in Food, and the US delegation for the US-China Risk Assessment Technical Exchange Program. Members also served as trainers in food-safety risk assessment, through the Asian Pacific Economic Corporation Partnership Training Institute Network.

Invited **speakers gave presentations** on a variety of topics at the quarterly meetings , including:

- *Risk Assessment of Investigational Tobacco Products*, by Li-Lun Chen, FDA CTP;
- *Chemical Hazard Assessment at FDA*, by Allen Rudman, FDA CFSAN;
- *Future Directions of the National Residue Program*, by Patty Bennett, USDA FSIS;
- *Dietary Exposure Assessment Activities at EPA OPP*, by Aaron Niman, EPA OPP;
- *Chemical Food Safety Issues and Food Allergies in Schools*, by Stephanie Mickelson, USDA FNS;
- *Chemical Food Safety, CDC Perspective*, by Tom Sinks, CDC NCEH ATSDR;
- *NIFA Funded Research on Chemicals, Mycotoxins and Nanoparticles in Foods*, by Jodi Williams, USDA NIFA;
- *Framework for Human Risk Assessment to Inform Decision Making*, by Rita Schoeny, EPA OPD;
- *Partnership: Key for Success in Food Safety Education and Training*, by Clare Narrod, UMD JIFSAN

Resource Sharing and Services

Members **shared information and/or access to tools, databases, and documents** that can be used to support risk assessments; e.g., the EPA Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FDIC), the EPA Integrated Risk Information System (IRIS), and the FDA-iRISK tool. FDA conducted a two-day training workshop for FDA-iRISK, which was attended by 20 risk assessors from FDA and other IRAC member agencies (FSIS, APHIS, DHS, and FNS). Documents that were shared included “Exposure Science for the 21th Century” (available at <http://www.epa.gov/nerl/features/nrcreport.html>), and “Environmental Decisions in the Face of Uncertainty” (available at http://www.nap.edu/catalog.php?record_id=12568).

Members **reviewed and provided input** on the FSIS/EPA microbial risk assessment guidelines, which were finalized in 2012 and published on the EPA and FSIS websites (available at http://www.fsis.usda.gov/PDF/Microbial_Risk_Assessment_Guideline_2012-001.pdf), with a link posted on www.FoodRisk.org.

Work Group Projects

IRAC work groups are a means for IRAC member agencies to collaborate and share technical expertise regarding specific topics or issues. Members review and synthesize data and information and convene workshops featuring experts. The work groups’ products – the outcomes of their efforts – can, for example, be used by member agencies to fill data and information gaps in risk assessment projects. The products are posted on the IRAC website at www.FoodRisk.org and sometimes are published as papers in scientific journals, to benefit the larger risk assessment community. Several work groups continued projects from 2011 into 2012. Accomplishments resulting from these projects are described below.

- **IRAC-IFSAC Risk Assessment as a Method for Determining Attribution to Foodborne Illness**
This work group, which was facilitated by a steering committee (Sherri Dennis, Isabel Walls, Kara Morgan, and Sandy Hoffmann), planned and held a two-day workshop on attribution and risk assessment, February 2-3, 2012, in Washington, DC. Based on the outcomes of the workshop, a smaller work group that included members from FDA, FSIS, CDC, ERS, NIFA, and others developed a draft white paper. The draft was reviewed by their respective agencies. IRAC members then reviewed and commented on the draft called “Leveraging Epidemiological and Risk Assessment Methods to Improve Food Safety Decision Making.” The report is intended for distribution within the Interagency Food Safety Analytics Committee (IFSAC) agencies (FDA, FSIS, and CDC), to help increase their decision makers’ understanding of epidemiologic and risk assessment methodology and the potential value of initiating collaborative projects. Several projects were suggested in the paper. The work group also considered developing the paper into a publishable manuscript, for broader distribution.

- Clarification of the Various Approaches for Assessing Risk
This work group chaired by Kerry Dearfield included participants from FSIS, FDA, NCTR, NIOSH, and EPA. A manuscript was developed to make stakeholders and risk managers aware of the various types of risk assessments needed to inform specific types of food-safety management decisions. One of the key concepts is that a range of risk assessment tools is available, and the tool to select depends on the problem and risk management questions. The emphasis is on assessment appropriate to the circumstances (i.e., “fit for purpose”) – use of different tools (e.g., a quantitative risk assessment vs. a risk profile) that fit different purposes. IRAC members provided input and review for the drafting of a white paper that formed the basis of the manuscript. The manuscript currently is undergoing clearance by the agencies, and will be submitted for publication in a peer-reviewed scientific journal in 2013.
- *L. monocytogenes* Dose-Response Work Group
Following a successful workshop on *L. monocytogenes* dose-response in 2011, co-sponsored by IRAC and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a small work group developed a draft manuscript based on the workshop outcomes. The manuscript was subsequently reviewed by IRAC member agencies and cleared by the co-authors’ agencies. It was published in a peer-reviewed journal: K. Hoelzer, Y. Chen, S. Dennis, P. Evans, R. Pouillot, B. J. Silk, and I. Walls. 2013. New data, strategies, and insights for *Listeria monocytogenes* dose-response models: summary of an interagency workshop, 2011. Risk Analysis. e-pub ahead of print: DOI: 10.1111/risa.12005. <http://onlinelibrary.wiley.com/doi/10.1111/risa.12005/abstract>.

Workshops and Symposia

As noted above, IRAC and the Interagency Food Safety Analytics Committee (IFSAC) co-sponsored a workshop, “**Leveraging Epidemiological and Risk Assessment Methods,**” on February 2-3, in Washington, DC. The workshop was a follow-up to a series of webinars, in 2011, held by IRAC and IFSAC. Approximately 30 participants attended the workshop and discussed the relationship between risk assessment and epidemiologic methods and how they could complement each other.

IRAC held a “**Workshop on Chemical Food Safety Risk Assessment,**” on June 14, following the IRAC Summer quarterly meeting. The workshop included six speakers, from CFSAN, FSIS, CDC, FNS, EPA, and NIFA. More than 30 attendees participated. The agenda and slides were posted on the IRAC website (<http://foodrisk.org/irac/events/>).

IRAC co-organized the symposium “**Making a Difference: Data Collection for Risk Assessments through Innovative Approaches,**” on July 23, at the IAFP annual meeting in Providence, Rhode Island. Also during the annual meeting, information about IRAC was shared at the meeting of the IAFP Microbial Modeling and Risk Analysis Professional Development Group, including distribution of a new tri-fold brochure about IRAC (its role, its roots, examples of how it advances risk assessment, and a list of members).

IRAC co-sponsored a symposium, “**The Interagency Risk Assessment Consortium's Role in Federal Government Risk Assessment and Related Activities,**” with the Capital Area Food Protection Association, on September 27. It included seven speakers from IRAC member agencies (NIFA, CFSAN, FSIS, EPA OPP and FNS) and was well attended.

Agency and other Collaborations

JIFSAN provided support to IRAC by hosting a website (www.foodrisk.org) where risk assessment guidance documents, datasets, risk assessment tools, and information about IRAC, were made available. Foodrisk.org also hosted the IRAC home page (<http://foodrisk.org/irac/>), which included the new charter, quarterly meeting minutes, annual plans and reports, work groups, and archived events.

Among the collaborative postings enabled by JIFSAN was “What We Eat in America - Food Commodity Intake Database 2003-2008,” by EPA’s Office of Pesticide Program, which JIFSAN posted to Foodrisk.org (<http://fcid.foodrisk.org/>) as an “exclusive.” This database provides estimates of food consumption expressed as food commodities (as opposed to foods *per se*; *i.e.*, “as eaten”), which can be of more utility in some situations, such as assessing long-term exposure to chemical hazards in foods.

FDA, FSIS, and ARS collaborated on data collection to support risk assessments, including the continuation of the market basket survey for *L. monocytogenes* in RTE foods.

Annual Plan

IRAC is developing its annual plan of activities for the coming year, which will be made available at <http://foodrisk.org/irac/>. IRAC developed a strategic plan in 2011, which is available at this website.

Current IRAC Membership

Department of Health and Human Services

- ❖ Center for Food Safety and Applied Nutrition, Food and Drug Administration, DHHS
- ❖ National Center for Emerging and Zoonotic Diseases, Centers for Disease Control and Prevention, DHHS
- ❖ National Center for Toxicological Research, FDA, DHHS
- ❖ National Institute of Allergy and Infectious Diseases, National Institutes of Health, DHHS
- ❖ Center for Veterinary Medicine, FDA, DHHS
- ❖ National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, DHHS

U.S. Department of Agriculture

- ❖ 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
- ❖ Agricultural Marketing Service, USDA
- ❖ National Agricultural Statistics Service, USDA

Environmental Protection Agency

- ❖ Office of Pesticide Programs, EPA
- ❖ Office of Water, EPA
- ❖ Office of Research and Development, EPA

Department of Defense

- ❖ U.S. Army Public Health Command (Provisional), DoD
- ❖ Veterinary Service Activity, DoD

Department of Commerce

- ❖ National Marine Fisheries Service, National Oceanic and Atmospheric Administration, DoC

Department of Homeland Security

- ❖ Office of Health Affairs, DHS

For more information, including the names of the technical and policy representatives from each IRAC member agency, visit <http://foodrisk.org/irac/>.



NCTR
National Center for Toxicological Research
U.S. Food and Drug Administration



**Office of Prevention, Pesticides,
and Toxic Substances**

Office of Research & Development



United States Department of Agriculture
National Institute of Food and Agriculture

