



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



Interagency

Risk Assessment Consortium

Annual Report

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Office of Prevention, Pesticides,
and Toxic Substances

Office of Research & Development

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. IRAC was re-chartered in 2011 to implement a recent recommendation from the President's Food Safety Working Group for risk assessment coordination 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 much of its goals through the work of its Policy Council and Technical Committee.

Current IRAC membership includes 19 Federal agencies and offices. Each agency/office is represented on both the Policy Council and the Technical Committee. A list of the member agencies is provided in Appendix I. Over the past 13 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 2011. The Policy Council met during the spring and the fall quarterly meetings to review the annual plan and workgroup 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 the decision making regulatory process.

IRAC members shared information on a wide range of topics related to risk assessments. Quantitative risk assessment (QRA) conducted in 2011 at the various agencies to inform risk management decisions included the followings:

- *L. monocytogenes* in ready-to-eat products (e.g., cheese) and preparation environment (e.g., deli), drug residues in milk
- Norovirus in bivalve molluscan shellfish
- *E. coli* O157:H7 in beef slaughter
- *Salmonella* and *Campylobacter* in poultry slaughter updated with new data
- Non-O157 STEC in non-intact beef
- Eggs and egg products movement in controlled zones with regard to avian influenza control, chemicals in different plants
- Diacetyl and other compounds related to occupational health.

In addition to QRA, IRAC members also shared information on risk profiles (e.g., pathogens and filths in spices, non-O157 STEC in beef), risk ranking for hazards associated with veterinary

medicine, a risk evaluation index for products/processes, and attribution of foodborne illnesses to food commodities. IRAC members shared experiences in developing guidance documents, e.g., efforts involved in developing the document “Microbiological Risk Assessment Guidelines for Food and Water”, and a guidance document for harmonizing risk assessment for non-cancer and cancer-causing chemicals.

A number of data collection and research efforts were undertaken at various IRAC member agencies, e.g., a large scale market basket survey for *L. monocytogenes* ready-to-eat foods, sampling for *L. monocytogenes* in the deli environment, mock deli study to investigate bacterial transfer potential, the AMS Microbial Database Program, the National Residue Program for expanded testing of chemicals in poultry and meat products, a study on consumption of fresh and heat-treated vegetables, a study on the impact of antimicrobials on human gut bacteria, the development of foodborne illness disease outcome trees. One of the IRAC members (NIFA) awarded two multi-year grants (\$25M funding each) for research and data collection for norovirus and Shiga-toxin producing *E. coli* (STEC).

IRAC member agency representatives shared information and/or access to tools and databases that can be used to support risk assessments, e.g., , the EPA Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FDIC), the ERS Foodborne Illness Cost Calculator, the NCTR Foodborne Pathogen Knowledgebase, the EPA benchmark dose (BMD) dose-response analysis tool, the EPA Integrated Risk Information System (IRIS), the FDA iRISK tool, and the FDA PREDICT (Predictive Risk-based evaluation for Dynamic Import Compliance Targeting) tool for screening import products. IRAC also served as a forum for sharing information on risk-related activities conducted at Codex.

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

- *NIOSH Risk Assessments and Occupational Exposure Limit Developments (aka Food Flavorings and Other Delights)*, by Frank Hearl from NIOSH
- *One Health Initiative*, by Joe Anelli from APHIS with input from Pat Basu from FSIS
- *NOAA Fisheries’ On-going Efforts in Response to the Gulf Oil Spill*, by Spencer Garrett from the NOAA National Seafood Inspection Laboratory/Office of Sustainable Fisheries
- *PFC Rapid Risk Evaluation*, by Kerry Dearfield from FSIS
- *The Contribution of the Progeny of Cloned Cattle to Beef Exports: a rapid risk assessment example*, by Mark Powell from ORACBA
- *Prediction of Salmonella Serotypes Based on PFGE Patterns and NCTR Foodborne Pathogen Knowledgebase*, by Wen Zou from NCTR
- *Risk Prioritization at FDA*, by David Oryang from CFSAN
- *CDC Estimates of Foodborne Illness Acquired in the United States*, by Elaine Scallan from the Colorado School of Public Health and Mike Hoekstra from CDC
- *Proposing a Possible Approach for a Residue Level of Concern for Cadmium in FSIS-Regulated Products*, by Alexander Domesle from FSIS

Workgroup Projects

The IRAC accomplishes much of its work through workgroups 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.

Several workgroups continued projects from 2010 and accomplished additional milestones in 2011. In 2011, a few new ideas were proposed, including proposed activities on cumulative and aggregate risk, norovirus, rapid risk assessment and decision making, residential gardening, foodborne illness source attribution, and clarification of risk assessment approaches. The Policy Council and Technical Committee reviewed four proposals for new workgroups:

- Identification of Research Needs to Inform a Quantitative Risk Assessment for Norovirus in Food throughout the Food Supply System
- Residential Gardening Interagency Initiative
- Risk Assessment as a Method for Determining Source Attribution to Foodborne Illness, and
- Clarification of the Various Approaches for Assessing Risk.

Two new workgroups were formed in 2011 and initiated the new projects: one for norovirus and one for risk approaches. Below are the accomplishments and activities of other workgroups in 2011.

L. monocytogenes Dose-Response Workgroup

The workgroup organized and presented a successful workshop on *L. monocytogenes* dose-response March 17-18, 2011, after a year-long planning process. The Steering Committee included representatives from four IRAC member agencies (FDA, FSIS, CDC and NIFA). Following the workshop, a small workgroup developed a draft manuscript based on the workshop outcomes, and made plan to circulate the draft to IRAC member agencies for review in the first quarter of 2012.

Susceptible Population Workgroup

A small workgroup continued in 2011 to work on a manuscript based on the outcomes of a susceptible population workshop held in 2010. The manuscript discussed issues such as how to define sensitive and susceptible population and data gaps such as a lack of information on susceptible individuals in outbreak investigation, and included a list of resources on assessing issues related to susceptible populations. The workgroup planned to have a draft ready and subject to clearance by the participating agencies in 2012.

IRAC-IFSAC Workgroup on Risk Assessment and Foodborne Illness Attribution

The workgroup was a joint effort between IRAC and the Interagency Food Safety Analytics Collaboration (IFSAC). The joint workgroup organized a series of webinars to prepare for a face-to-face meeting. IRAC hosted three webinars in October-December, 2011:

- CDC methods of attribution (“top-down” approach for estimate risk from outbreak/illness data)
- FDA iRISK model (“bottom-up” approach for estimating risk from contamination/processing/consumption/dose-response data)
- FSIS/CDC adaptation of the Danish model.

A fourth webinar was planned for January 2012 to discuss the use of a combination of “top-down” and “bottom-up” approaches for attribution modeling. The workgroup also developed a draft agenda and a list of questions to address through case studies for the face-to-face meeting on attribution and risk assessment planned for February in Washington, DC,

Workshops and Symposia

A workshop on *L. monocytogenes* dose-response was held March 17-18, 2011 in Washington, DC. The workshop was co-sponsored by IRAC and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). Approximately 45 experts participated in an in-depth review of new modeling framework and data, and what should be the focus for research in the future. The workshop included a dozen presentations and two breakout sessions, which focused on scientific discussion not policy. An online forum was established on FoodRisk.org to facilitate information exchange among the participants before and after the workshop. A symposium was presented at the SRA 2011 annual meeting to provide an overview of the outcomes of the workshop, which included three presentations: a) an overview of the data and models for understanding the dose-response relationship; b) recent advancements in the knowledge of the physiopathology of *L. monocytogenes* infections, molecular subtyping, subtype/strain virulence, host susceptibility; and c) a summary of the recommendations for future advancements.

Agency Collaborations

The Joint Institute for Food Safety and Applied Nutrition provides support to the IRAC by hosting a website (www.foodrisk.org), where information about IRAC is made available, including the new charter, quarterly minutes, annual plans and reports, and workshop details.

IRAC member agencies collaborated on peer review of risk documents and data collection to support risk assessments, including:

- Peer review of the FSIS risk profile for non-O157 STEC and scenario analysis. IRAC hosted a webinar for FSIS risk assessors to present the risk profile and IRAC members provided written comments on the risk profile.
- Peer review of a draft guidance document on microbial risk assessment for food and water drafted by several IRAC member agencies. IRAC members provided written comments on the draft guidance.

- A large scale market basket survey for *L. monocytogenes* ready-to-eat foods, an interagency collaboration among FDA, FSIS and ARS.

Additional Information for CY2011

IRAC Charter Update – Signing Ceremony

A signing ceremony for the updated IRAC charter took place on February 8, 2011. Approximately 25 representatives and signatories from IRAC member agencies attended the ceremony at the USDA Whitten Building in Washington, DC. The new charter was posted on the IRAC website, which was re-designed in 2011.

Annual Plan

IRAC is developing its annual plan of activities for CY2012, which will be made available at www.foodrisk.org. IRAC developed a strategic plan in 2011, which is available at the website.

Appendix 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
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/>.