

FY2018 Report

Introduction

The Interagency Risk Assessment Consortium (IRAC) is a collaborative network of federal agencies with responsibilities and interests in the conduct and use of food-safety risk assessment. It was established in response to Presidential Executive Order 13100, in 1998, to enhance cross-agency coordination of food-safety risk-assessment activities and to provide support for the emerging field of quantitative microbiological risk assessment and application in guiding federal food-safety policies. In 2011, in response to a recommendation from the President's Food Safety Working Group, the IRAC was re-chartered¹ to further enhance coordination and information-sharing among federal agencies.

The consortium aims to improve risk-assessment research, enhance the development and use of risk-assessment tools, and serve as a forum for communication 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 22 Federal agencies and offices that constitute the consortium's current membership.

Over the past 20 years, IRAC has explored a range of issues related to the conduct and use of federal food safety (microbial and chemical) risk assessment. Research topics addressed by IRAC include data quality, peer review, food safety and nutrition, susceptible sub-populations, nanotechnology, microbiomes, genomics, and, more recently, consideration of assessing dietary exposure and rigor and reproducibility in risk assessment. IRAC also has continued to explore evolving approaches to assessing food-safety risks, application of risk assessment in decision-making, and enhanced outreach to the risk assessment community. In addition, IRAC encouraged members to make risk assessment tools more easily available to the public, on the Consortium's host website, at Foodrisk.org.

¹ 2011 IRAC Charter available at: <http://foodrisk.org/irac/charter>

IRAC Signatory Agencies:

■ Department of Agriculture

- ❖ Agricultural Marketing Service
- ❖ Agricultural Research Service
- ❖ Animal and Plant Health Inspection Service
- ❖ Economic Research Service
- ❖ Food and Nutrition Service
- ❖ Food Safety and Inspection Service
- ❖ National Agricultural Statistics Service
- ❖ National Institute of Food and Agriculture
- ❖ Office of the Chief Scientist
- ❖ Office of Pest Management Policy
- ❖ Office of Risk Assessment and Cost Benefit Analysis

■ Department of Commerce

- ❖ National Oceanic and Atmospheric Administration

■ Department of Defense*

- ❖ Defense Health Agency

■ Department of Energy*

- ❖ Los Alamos National Laboratory

■ Department of Health and Human Services

- ❖ Centers for Disease Control and Prevention
 - National Center for Emerging and Zoonotic Infectious Diseases
 - National Institute for Occupational Safety and Health
- ❖ Food and Drug Administration
 - Center for Biologics Evaluation and Research
 - Center for Food Safety and Applied Nutrition
 - Center for Veterinary Medicine
 - Office of Foods and Veterinary Medicine
- ❖ National Institutes of Health
 - National Institute of Allergy and Infectious Diseases

■ Environmental Protection Agency

- ❖ Office of Pesticide Programs
- ❖ Office of Water

■ U.S. Agency for International Development

* *New IRAC member agency in FY18.*

IRAC FY18 Objectives

IRAC successfully advanced the three key overarching objectives identified in the FY18 Annual Plan:

- *Enhanced Governance and Operation of the IRAC*
- *Strengthen Outreach and Engagement of New and Existing Federal Agencies*
- *Facilitate Information Exchange and Sharing Tools, Data, and Models*

Selected achievements toward these objectives are detailed below.

Enhanced Governance and Operation of the IRAC. In FY18, the IRAC worked to streamline operations and improve communications. The IRAC created and broadly shared the FY2018 Annual Plan by posting it on the IRAC website and sharing it with signatory Agencies in December 2017. The IRAC Policy Council issued a memorandum to supplement the 2011 IRAC charter that outlines a plan for improved operation and governance of the IRAC for policy council member agency representatives. The memorandum summarizes input received in FY18 from member agency representatives on the IRAC Policy Council on a plan to enhance coordination and communication within IRAC and stakeholders. The memorandum was discussed at the March 2018 meeting and a final version was sent out to IRAC members during the end of FY18. Also, in November 2017 the IRAC Policy Council reviewed/cleared “IRAC Work Group Project Summary & Action Plan: Exploration of the Implications of Whole Genome Sequencing on the Conduct and Application of Risk Assessment in Food Safety Decision-Making.” In FY18, the IRAC also continued to work with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) to modernize the IRAC website (located at <http://foodrisk.org/irac/home>), making workshops, meeting notes, and proposals easier to access.

Strengthen Outreach and Engagement of Federal Partners. In FY18, IRAC participated in two workshops showcasing innovation in risk analytics, models, and tools to advance food safety risk analysis. The IRAC Policy Council co-chairs (Sherri Dennis and Janell Kause) provided an overview of the IRAC, highlighting risk analytic tools, models and data for advancing food safety risk analysis, at the JIFSAN Annual Steering Committee in November 2017. In December 2017, the co-chairs also participated in a JIFSAN facilitated technical workshop entitled “Approaches to Connecting, Sustaining and Advancing FDA-iRISK and a Community of Risk Assessment and Predictive Modeling Resources.” In September 2018, IRAC welcomed two signatory members, Defense Health Agency, Veterinary Service Branch, Department of Defense (DOD) and Los Alamos National Laboratory, Biosecurity and Public Health, Department of Energy (DOE), along with their Technical Committee (Paul Jordan, DOD and Tracy Erkkila and Karen Davenport, DOE) and Policy Council (Col Clayton Chilcoat, DOD and Tracy Erkkila, DOE) representatives. IRAC also recognized 2 new representatives (Steve Foley, FDA-NCTR, Dionne Toombs, USDA-OCS, and Shanker Reddy) from existing IRAC member agencies.

In addition, IRAC also facilitated information sharing and outreach and engagement with federal partners through several presentations given by member agencies and outside organizations as outlined below (under quarterly meetings). IRAC also completed updates to the IRAC website to reflect a focus on risk information & tool sharing.

Facilitate Interagency Coordination and Information-Sharing. The IRAC Work Group working on the application of whole genome sequence (WGS) data to advance food safety risk assessment completed and made public an interagency Action Plan for moving forward to advance the use of WGS in risk assessment. IRAC also exceeded the goal to share 10 or more data sets, models, and related tools developed by federal agencies (see link on IRAC website: <http://foodrisk.org/irac/open-data-tools/>). IRAC member agencies shared 32 data sets, tools, and/or models for assessing risk and these models were posted to the IRAC website. A work group entitled “Reproducibility and Replication issues in science: Quantitative analyses of Biases in epidemiology and its Role in Risk Assessment” was proposed in February 2018 and established the same year, culminating in the conduct of an interagency workshop in September 2018. For increased interagency coordination and information sharing, IRAC exchanged information through quarterly meetings, IRAC work groups, and presentations. IRAC also established additional points of contact for IRAC member agencies. Details about these activities are provided below.

Quarterly Meetings

The Technical Committee met in December 2017 and in March, June, and September 2018. Members gave agency updates and both IRAC members and invited guests gave several presentations (described below). The Policy Council met during a separate meeting in March 2018 to evaluate mid-year accomplishments and made decisions leading to supplemental guidance and streamlined organizational role to further enhance IRAC governance and operation.

IRAC members exchanged information about risk assessments, related models and data (see: <http://foodrisk.org/irac/quarterly-meeting-minutes/>).

Presentations relevant to food safety were given including:

- Visual analytics of Pathogens: Presentation on the Antimicrobial Resistance Dashboard and Pathogen Dynamic Graph to visualize various pathogen genotypes spatially and temporally. Presented at the December 2017 meeting by Dan Janies, Ph.D., Department of Bioinformatics, University of North Carolina at Charlotte.
- USDA Agricultural Marketing Service Boneless and Ground Beef Procurement Program: An Analysis of Common Microbial Indicators and Lab Confirmed Pathogens among Beef Products Destined for the National School Lunch Program: Overview of the USDA Agricultural Marketing Service's (AMS) role in procuring boneless and ground beef products for the National School Lunch Program. Presented at the March 2018 meeting by Scott Vial, M.S., REHS, University of Minnesota and Darin Doerscher, Livestock & Meat Marketing Specialist
- Application of an updated Cramer et al. decision tree to safety assessment. Presented at the June 2018 meeting by Szabina Stice, Ph.D., Food and Drug Administration, Center for Food safety and Applied Nutrition.

- Farm economics of antibiotic resistance. Presented at the June 2018 meeting by Stacy Sneeringer, U.S. Department of Agriculture, Economic Research Service.

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 can be used by member agencies to make improvements in food safety risk analysis – from enhancing innovation in modeling or improving rigor to garnering enhanced review or input to filling key data gaps. Work group products are posted on the IRAC website at on its “Events” page (<http://foodrisk.org/irac/quarterly-meeting-minutes/>), and sometimes are also published as papers in scientific journals and/or presented at national scientific conferences, to benefit the larger risk assessment community. Accomplishments resulting from these projects are described below.

■ Characterization and Evaluation of Dietary Exposure Assessment Approaches and Needs

This work group established in FY17, chaired by Judith Spungen (FDA-CFSAN), includes participants from USDA-FSIS, USDA-ARS, FDA-CFSAN, FDA-CVM, EPA-OW, and EPA-OPP. A goal of the work group was to provide a systematic comparison of data sources and analytical tools used by various U.S. federal agencies for dietary exposure assessments. In FY18, IRAC representatives on the work group met regularly to discuss and share information on the approaches and procedures their agencies used for conducting dietary exposure assessment and how this information is used with their decision-making context. The dietary exposure work group is working on finalizing a document that summarizes work group activities and major findings. The final summary document will be posted to the IRAC website in FY19.

■ Reproducibility and Replication Issues in Science. Quantitative Analysis of Biases in Epidemiology and its Role in Risk Assessment.

This work group, established in FY18, chaired by Richard Forshee (FDA-CBER) and David Miller (EPA-OPP), included participants from FDA-CBER, FDA-CFSAN, FDA-CVM, FDA-OFVM, USDA-AMS, USDA-APHIS, USDA-OPMP, EPA-OPP, and USDA-FSIS. The primary goal of this work group was to increase awareness among IRAC member agencies involved in risk analysis of issues associated with interpretation and communication of epidemiological effect size findings and their associated biases and influence in assessing risk. A second goal was to provide information and background on the potential of more recently available techniques and software to better and more quantitatively evaluate biases in these estimates and their direction. The efforts of this work group culminated in a 2-hour interagency workshop that provided cross-agency awareness on the types of scientific biases in epidemiology relevant to risk assessment, why this is important to consider, and types of analyses and currently available tools to evaluate the impact of these biases. Due to the strong interest among IRAC member agencies, this work group has decided to build upon these efforts with a follow-up workshop in FY19.