

IRAC FY2019 Annual Report
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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 assessments. 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 then 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 23 Federal agencies and offices that constitute the consortium's current membership.

Over the past two decades, 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, dietary exposure and more recently, rigor and reproducibility in risk assessment. IRAC also has continued to explore evolving approaches to assessing food safety risks and application of risk assessment in decision-making. In addition, IRAC member agencies make their risk assessment tools more easily available 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
 - National Center for Toxicological Research
- ❖ National Institutes of Health
 - National Institute of Allergy and Infectious Diseases

■ **Environmental Protection Agency**

- ❖ Office of Pesticide Programs
- ❖ Office of Water

■ **National Oceanic & Atmospheric Administration**

- ❖ National Marine Fisheries Service

■ **U.S. Agency for International Development**

IRAC FY19 Objectives

IRAC successfully advanced the three overarching objectives identified in the FY19 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 FY19, the IRAC Policy Council held 2 meetings to discuss accomplishments and establish an annual plan for the following year. The IRAC created and broadly shared the FY2018 end of the year report and an annual plan for FY 19 by posting it on the IRAC website and sharing it with signatory Agencies. In FY19, the IRAC Policy Council developed a memorandum and implemented a process for IRAC Interagency technical/scientific review of risk assessment reports, models, and related tools. This peer review process facilitates interagency scientific review by providing a forum where IRAC peer reviewers can provide critical technical input on mathematical modelling, use of scientific data, and provide suggestions for additional analyses and/or alternate analytic approaches. The memorandum providing a description of the process was provided to IRAC committee members and posted to the IRAC website.

Strengthen Outreach and Engagement of Federal Partners. In FY19, to facilitate outreach and engagement with federal partners, IRAC held a spring and summer Technical committee meeting (April and June). The winter Technical meeting, scheduled for January, was cancelled due to the government shutdown. At the Technical Committee meetings, presentations were given by member agency representatives as outlined below (under quarterly meetings). The meeting minutes, updates, and cleared presentations were posted on the IRAC website. IRAC also completed updates to the website to reflect a focus on risk information & tool sharing. In FY19, IRAC reached out to Accelerating the Pace of Chemical Risk Assessment (APCRA), a government-to-government initiative whose goal is to promote collaboration and dialogue on the scientific and regulatory needs for the application and acceptance of new approaches and methodologies in regulatory decision-making. APCRA has agreed to share additional information about their activities in FY20.

Facilitate Interagency Coordination and Information-Sharing. To continue enhanced interagency coordination and information sharing, IRAC exchanged information through quarterly meetings, IRAC work groups, and presentations. In FY19, IRAC implemented a process for interagency review of IRAC member agency products. The USDA-FSIS BSE risk assessment was peer reviewed through IRAC using the interagency process in April 2019. A report outlining the IRAC reviewers and agencies involved, summary of reviewer comments, and impact of the IRAC review were posted on the IRAC website. Two workgroups; the Reproducibility and Replication issues in science: 'Quantitative analyses of Biases in Epidemiology and its Role in Risk Assessment' workgroup and the 'Dietary Exposure' workgroup completed all planned activities in FY19. Workgroup products, presentations, and final deliverables were posted to the IRAC website. IRAC also established a new workgroup to focus on how IRAC can better facilitate professional

development of IRAC member agency staff and improve information sharing across federal member agencies (see workgroup projects below). In FY19, IRAC also addressed the goal to share data sets, models, and related tools developed by federal agencies by posting the following information to the IRAC website:

- **Poultry FARM (food assess risk models):** The poultry FARM website contains products from research efforts developing predictive models to ensure the microbiological safety of poultry products. This research was a collaborative effort between USDA-FSIS and University of Maryland Eastern Shore and products on the website include publications, presentations, models, and data.
- **GenomeGraphR:** This tool is a web application for foodborne pathogen whole genome sequencing data integration, analysis and visualization.
- **Salmonella in Sprouts Risk Assessment:** Risk Assessment of *Salmonellosis* from Consumption of Alfalfa Sprouts and Evaluation of the Public Health Impact of Sprout Seed Treatment and Spent Irrigation Water Testing.
- **Listeria Market Basket:** Survey for *Listeria monocytogenes* in and on Ready-to-Eat Foods from Retail Establishments in the United States (2010 through 2013): Assessing Potential Changes of Pathogen Prevalence and Levels in a Decade.

Quarterly Meetings

The IRAC Technical Committee met on April 11, 2019 and June 13, 2019. Members gave agency updates, and invited guests gave presentations (described below). Paul Jordan from Department of Defense, Defense Health Agency (DHA), presented an overview of DHS's mission and activities related to food safety. The Policy Council met during a separate meeting on December 12, 2018 to discuss FY18 accomplishments, plans for FY19, and workgroup proposals. The Policy Council met again on April 12, 2019 to evaluate mid-year accomplishments, review new interagency peer review process, and discuss the new professional development workgroup and plans for the pilot.

Additionally, during the Technical Committee meetings, presentations relevant to food safety were given including:

- ***A Graphical Tool to Better Explore Links between Environmental, Food and Clinical Strains of Pathogens.*** Presented at the April 11th technical committee meeting by Regis Pouillot, Ph.D., Contractor, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration
- ***How does a shift in consumption between rice and oat infant cereal change cancer risk? A risk-risk analysis.*** Presented at the June 13th technical committee meeting by Sofia Santillana-Farakos, Ph.D. Interdisciplinary scientist, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration

Work Group Projects

IRAC workgroups are a means for IRAC member agencies to collaborate and share technical expertise regarding specific topics or issues. Members collaborate on scientific issues, review and synthesize data and information, and convene workshops featuring experts. Workgroup products can be used by member agencies to inform or 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. Workgroup products are posted on the IRAC website on its “Events” page (<http://foodrisk.org/irac/quarterly-meeting-minutes/>), and often published as papers in scientific journals and/or presented at national scientific conferences to benefit the larger risk assessment community. Accomplishments resulting from the current project is described below.

■ Informational Exchange/Professional Development Opportunities Workgroup

This work group was established in FY19 and is chaired by Sherri Dennis (FDA-CFSAN) and Max Teplitski (USDA-NIFA) with additional members from these two groups. A goal of the workgroup is to provide opportunities for staff in IRAC member agencies to engage in a structured informational exchange with other agencies to assist professional development and networking at operational, personal, and strategic levels. The workgroup developed a pilot program for informational exchange opportunities that included the member agencies presented below. The workgroup proposal was posted to the IRAC website. In FY19, two exchanges were held, as described below, and additional exchanges are anticipated to occur in early FY20. Upon completion of the pilot, an evaluation will be conducted using results from semi-structured interviews given to the participants as an assessment of the exchange opportunity to identify best practices and possible future implementation of a permanent exchange program.

Pilot Program Participants in FY19:

- **FDA-CFSAN:** CFSAN’s Division of Risk and Decision Analysis (DRDA) hosted a 1-day interactive educational experience on August 26, 2019. Participants from IRAC member agencies included: Ahmed Kablan (USAID), Lindsay Ward-Gokhale (USDA-FSIS), Jean Pascale (USDA-NIFA), and Max Teplitski (USDA-NIFA). At this professional exchange, CFSAN/DRDA provided an overview of DRDA branches and their roles regarding food safety, discussed FDA’s total diet study, and presented technical information that showcased models and tools and safety/risk assessment methodology.
- **USDA-NIFA:** NIFA hosted a 1-day professional exchange on August 6, 2019. As a part of the exchange, A participant from CFSAN (Heather Schaefer) observed deliberations of a panel reviewing grant proposals and conducted a series of interviews with NIFA’s program leadership.