

IRAC-IFSAC Work Group  
**Leveraging Epidemiological and Risk Assessment Methods**

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Members:

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## Background

In making risk-based decisions about food safety interventions and allocation of resources, regulatory agencies need to know how many cases of foodborne disease are attributable to each food commodity they regulate. A variety of methods are currently available to attribute cases of foodborne illness to the responsible food vehicle. For example:

- In 2003, FDA and FSIS collaborated to develop a quantitative, predictive model to rank the risk of listeriosis from consumption among 23 ready-to-eat food categories (<http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm>). The risk assessment model provided information for the agencies to determine which foods to focus attention to reduce listeriosis.
- FSIS and CDC have partnered in the development of an adaptation of a source attribution risk assessment model developed by Hald et al (the Danish Model). The publication by Guo et al 2011 describes the attribution of Salmonella cases among six food types.
- FDA in partnership with IFT, RTI, RSI and JIFSAN are developing web-based tool to enable comparative risk assessment for microbial and chemical hazards in foods at all stages of the food supply system. A working version of the tool is available for beta-testing, a library of hazard-food scenarios has been developed and is undergoing validation. A public version is planned for 2012.
- The University of Florida (Batz et al 2011) released the outcome of the Foodborne Illness Risk Ranking Model (FIRRM) for over 160 hazard-food pairs identified in foodborne outbreaks.
- FDA in partnership with RTI developed a risk ranking model for hazards in fresh produce (Anderson et al, 2011; manuscript available on-line at <http://dx.doi.org/10.1016/j.foodcont.2011.04.028> and model available at <http://foodrisk.org/exclusives/rrt/>).

Each approach and model has strengths and weaknesses, and most of them still need methodological development to understand their ability to meet the stated needs. Through various applications and interpretations of these methods, there are several different estimates of

attribution fractions circulating in the literature, and that is a source of confusion for stakeholders and provides potentially conflicting information to the regulatory agencies in terms of priorities.

In the short term, there is a need to use methods that are fully developed to estimate most likely values and plausible bounds of uncertainty around these point estimates, acknowledging the weaknesses of those methods. In the longer term, there is a need for a research strategy to improve these point and uncertainty estimates with scientifically sound and data-driven methodologies that all agencies agree provide the attribution fractions and uncertainty estimates. A strategic plan will describe a path forward for achieving the development of scientifically sound methods to generate attribution information that is timely, accurate, current and specific. Ultimately, regulatory agencies require the ability to make decisions and report on their food safety performance in terms of changes in numbers of illnesses attributable to the foods they regulate. To achieve this goal, regulatory agencies desire consensus on the source attribution of infections due to exposure to specific foods contaminated by certain foodborne pathogens.

Established in 1998, the Interagency Risk Assessment Consortium (IRAC) include membership from 17 federal agencies or sub-agencies and is charged to (1) improve risk assessment research, (2) enhance the development and use of risk assessment models and tools, and (3) serve as a forum to communicate about risk assessment and related research issues including enhancement of the use of quantitative risk assessment in the decision-making regulatory process. The IRAC is uniquely positioned to assist regulatory agencies to achieve their goal for consensus on the source attribution of infections due to exposure to specific foods contaminated by certain foodborne pathogens.

Established in 2011, the goal of the Interagency Food Safety Analytics Collaboration (IFSAC) is to improve coordination of Federal food safety responsibilities among CDC, FSIS and FDA by addressing cross-cutting priorities for food safety data collection, analysis and use as outlined in the key findings of the President's Food Safety Working Group. The analytic projects to be undertaken by IFSAC are envisioned to be substantively different from the risk assessment and risk analysis issues typically addressed by IRAC. However, the IFSAC charter specifically states that interaction and communication with IRAC is important for coordination as data and information from either group may inform the other.

The three agencies represented at IFSAC wish to develop a shared understanding of how risk assessment is and should be used for attribution, and how these agencies can leverage their respective risk assessment models such that there is understanding among the agencies on how this methodology is being used to estimate foodborne illness source attribution fractions.

## **Proposal**

That a workshop on "Risk Assessment as a Method for Determining Source Attribution to Foodborne Illness" be organized and convened to answer the following questions:

1. What risk assessment is and is not (to include an overview of previous use of risk assessment approaches in attribution efforts)?

2. How should a risk assessment approach be used to inform efforts in the area of foodborne illness attribution? i.e. what criteria must be satisfied to use a risk assessment approach and when used, its role relative to other attribution models
3. What are the data needs to further develop risk assessment models that can be used for attribution?
4. How might risk models (including Hald, iRISK and FIRRM) best be used to inform attribution efforts?

## **Expected Outcomes**

A workshop through which the questions (above) are answered by the IRAC steering committee through development of a workshop agenda, and preparation of summary documents resulting from workshop discussions. These summary documents will provide:

1. Recommendations regarding how risk assessment, and specifically the risk models could be used to inform agencies on attribution
2. A common understanding of the role of the risk assessment approach in informing attribution efforts

### **Timeframe for completion**

It is anticipated that the workshop will require 2-3 days for completion, and should begin as soon as it is logistically possible, scheduled for February 2012.

### **Budgetary requirements**

Federal agencies are responsible for providing travel funding for staff participation in the workshop. If non-government speakers and participants are invited, travel funding maybe required. Unless a suitable government facility is identified, funding will be needed to provide meeting space.

## **Activities Following the Workshop**

The workgroup will develop a white paper based on the outcomes of the workshop on attribution and risk assessment that took place February 2-3, 2012 in Washington, DC. There will be a short version intended for policy makers and a longer version intended as a manuscript for publication.

## **Current Status**

The 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 in 2012. IRAC members also reviewed and commented on the draft titled “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.