Interagency Risk Assessment Consortium
Technical Representatives Quarterly Meeting Report

December 19, 2011

Welcome and Introductions

The Interagency Risk Assessment Consortium (IRAC) held its 2011 winter quarterly meeting of the technical committee on December 19th in Washington, DC. IRAC policy council co-chair Sherri Dennis, on behalf of the technical committee chair Isabel Walls who was unable to attend this meeting, welcomed the group and asked for self introductions. Technical and policy representatives and guests from various agencies (Table 1) participated on site or by the phone.

"5 minute" Agency Updates

Technical representatives in attendance gave a brief overview of food safety risk analysis projects and issues in their agencies that may be of interest to other agencies.

IRAC Work Group Updates

L. monocytogenes Dose Response Workgroup

Sherri Dennis reported that a small workgroup has developed a first draft of a manuscript based on the outcomes of the joint IRAC/JIFSAN Lm Dose-Response Workshop held in March. The manuscript includes a new and original diagram on *L. monocytogenes* infection steps, disease endpoints and molecular determinants. The draft manuscript is relatively long and will be further edited/ revised. The plan is to have a revised draft ready to be circulated to IRAC members for comments by next March. In addition, a symposium was presented at the SRA annual meeting to provide an overview of the outcomes of the workshop. Yuhuan Chen reported that the symposium at SRA includes three presentations, which provide an overview of the data and models for understanding the dose-response relationship; recent advancements in the knowledge of the physiopathology of *L. monocytogenes* infections, molecular subtyping, subtype/strain virulence, host susceptibility; and a summary of the recommendations for future advancements from the workshop.

Susceptible Population Workgroup

Jane van Doren reported that a small work group has been working on a manuscript, which will include a list of resources on assessing issues related to susceptible populations. The manuscript is near completion and will first be subject to clearance by the participating agencies (e.g., FDA, FSIS).

IRAC-IFSAC Webinar Series/Workshop

In preparation for the face-to-face meeting on attribution and risk assessment planned for February 2-3 in Washington, DC, a joint IRAC/IFSAN workgroup has hosted three webinars since October: 1) CDC methods of attribution ("top-down" approach for estimate risk from outbreak/illness data), 2) FDA iRISK model ("bottom-up" approach for estimating risk from contamination/processing/consumption/dose-response data), and 3) FSIS/CDC adaptation of the Danish model. In addition, as indicated above, FSIS plans to present a 4th webinar in mid-January to discuss the use of a combination of "top-down" and "bottom-up" approaches for attribution modeling. Sherri Dennis noted the face-to-face meeting will take place at a meeting

location that can accommodate approximately 30 people. An agenda will be shared with IRAC member when it is finalized; IRAC members interested in participating at the workshop should contact Sherri Dennis or Isabel Walls.

Other Activities

Sherri Dennis reported that the Norovirus Workgroup has met once to discuss objectives and scope of the project, including evaluation of data gaps and identification of focus area for the workgroup. The workgroup will also try to coordinate/leverage activities from various other groups addressing norovirus, such as the university consortium that received the 25M NIFA grant and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) subcommittee on norovirus. Kerry Dearfield noted that CCFH also has a working group on norovirus control and the codex document can be a resource for the IRAC workshop.

New Activities

Clarification of Various Approaches for Assessing Risk

Kerry Dearfield reported that there is need to communicate the values of various approaches for assessing risk to support risk management decisions. Depending on the risk management questions, different approaches (e.g., qualitative, semi-quantitative to quantitative) and different types of risk assessments (e.g., risk profile, risk ranking, risk-risk trade off, quantitative risk assessment) may be suitable to answer the questions/charges posed; there is no one-size-fit-all approach. IRAC members present shared similar view, and also noted that terminology is problematic and also needs clarification. Developing a white paper to clarify vocabulary and the use of different approaches to inform risk management would be helpful for FSIS to communicate their risk assessments to OMB, and would also be helpful for other IRAC agencies in their risk communication. Dearfield requested IRAC approval to move the project forward as a new activity for 2012; there were no objections for forming a workgroup. Dearfield indicated that a proposal with background, expected outcomes and timeline information (see Appendix below) was recently sent to IRAC members for review. A number of IRAC members have volunteered to join the workgroup: Kerry Dearfield, Denise Eblen and Janell Kause from FSIS; Kathleen Raffaele and John Ravenscroff from EPA; Frank Hearl from CDC/NOISH; and James Chen from FDA/NCTR. Additional IRAC members from EPA, FDA/CFSAN may be joining the workgroup. Spencer Garret from the NOAA Fisheries Service and Jim Lindsey from USDA ARS have expressed interest in reviewing the draft white paper. IRAC members interested in participating in the workgroup should contact Isabel Walls by mid-January.

Annual Meeting

An idea was previously proposed to convene an IRAC annual meeting in March, 2012, to highlight successful interagency projects. Given the ongoing and planned activities described above, it was noted that further discussion is needed on the timing, as well as to explore whether to have the meeting in conjunction with the annual meeting of a professional society (e.g., SRA) to make participations from IRAC members from different agencies more feasible.

Symposium for IAFP and Interactions with Professional Societies

Yuhuan Chen reported that three symposium proposals developed by IRAC members were accepted by IAFP for further development, including proposed topics on innovative data

collection, *Listeria* risk at retail, and milk residues risk assessment. Final proposals will be submitted to and further reviewed by the IAFP program committee for the 2012 annual meeting.

With regard to IRAC interactions with other professional societies, Sherri Dennis noted that such interactions would increase visibility for IRAC. Ideas suggested for raising awareness include developing a brochure for IRAC that can be distributed at professional meetings such as SRA and IAFP and possible co-sponsoring of workshops and symposia (funding may be needed).

Presentations and Discussion

There were two presentations at the meeting: 1) CDC Estimates of Foodborne Illness Acquired in the United States, presented by Elaine Scallan from the Colorado School of Public Health and Mike Hoekstra from CDC; and 2) Proposing a Possible Approach for a Residue Level Of Concern for Cadmium in FSIS-Regulated Products, presented by Alexander Domesle from FSIS. In the first presentation, Hoekstra also presented highlights from technical appendices from the CDC papers on foodborne illness acquired in the U.S. - major pathogens and unspecified agents. Of note, unspecified agents comprise 80% of all estimated illnesses. Hoekstra shared information on selected method details, e.g., the use of the a multiplicative method, the PERT distribution, Monte Carlo simulation, definition of a case, determination of multiplier and uncertainty bounds for illness estimates.

Selecting a Public Health Outcome for a Chemical Risk Assessment

As part of the second presentation, Patty Bennett from FSIS provided an overview of the national drug residues program. Bennett reported that FSIS plans to expand the program beyond pesticides and veterinary drugs, and consider the hazards of other chemical exposures – for example environmental contaminants. For the past several years and at the request of FDA, FSIS has collected data on cadmium and lead in FSIS-regulated products. Alexander Domesle shared a summary of the comparison of health-based guidance values (HBGV) for cadmium established by several US agencies (EPA, ATSDR) and international expert bodies (EFSA, WHO/FAO). FSIS is proposing a residue level of concern for cadmium in FSIS-regulated products. FSIS is requesting IRAC input into approaches for selecting a HBGV and the Level of Protection using cadmium in FSIS-regulated products as a pilot.

FSIS posed several questions for IRAC input: 1) which criteria are appropriate to consider when FSIS chooses a health-based guidance value as the point of departure for this analysis? FSIS is interested in feedback specific to the cadmium health-based guidance values, as well as general criteria which may be used in future analyses. 2) Which level of protection (percentile) should FSIS choose at the end of the analysis? Conversely, what fraction of the population should be allowed to potentially exceed the "slice" of cadmium exposure allocated to meat and poultry products and thus be at risk of exceeding the health-based guidance value if exposure to cadmium from all other sources is at expected levels? Outcome of this project would be helpful to assess risk from other chemicals that do not have a tolerance level (e.g., the melamine incident in 2008).

Several suggestions were made by IRAC members at the meeting, including the consideration of high-exposure population (e.g., occupational related exposure), the use of NHANES

consumption data in the assessment, consideration of susceptible population in the assessment (e.g., the EFSA approach considers vegetarian female subpopulation), and EPA's rationale and approaches for setting pesticide tolerance. IRAC members who have comments on the questions above should send the information to Kerry Dearfield and Sherri Dennis. Sherri Dennis suggested that after FSIS compiles comments received, it may be helpful for FSIS to share a summary of the comments at a future IRAC meeting.

Table 1. Attendance (* participated by phone)

Aaron Niman	EPA OPP
Alexander Domesle	USDA FSIS
Andrew MacCabe	DHHS CDC
Elaine Scallan*	Colorado School of Public Health
Frank Hearl	CDC NIOSH
Gregg Claycamp	FDA CVM
Jane van Doren	FDA CFSAN
Janell Kause	USDA FSIS
Julie Callahan*	FDA CFSAN
Kerry Dearfield	USDA FSIS
Kiros Hailemariam	FDA CFSAN
Linda Abbott*	USDA ORACBA
Lesley Vazquez-Coriano*	EPA OW
Mike Hoekstra	CDC
Nakia Clemmons	Army Public Health Command
Neil Stiber	FDA ORA
Patty Bennett	USDA FSIS
Phil Yaeger *	FDA CTP
Robert McDowell *	USDA APHIS
Sarah Edwards	USDA FSIS
Sherri Dennis	FDA CFSAN
Wen Zou*	FDA NCTR
Wendy Fanaselle *	FDA CFSAN
Yuhuan Chen	FDA CFSAN

Appendix

Proposal for IRAC Activity

Clarification of the Various Approaches for Assessing Risk

BACKGROUND

Stakeholders in the risk analysis community often possess differing, sometimes very rigid, ideas about what is meant by the term "risk assessment." In reality, there is no one-size-fits-all "risk assessment" approach that can address all risk management issues, problems, and questions. Codex has ably addressed this issue, but confusion remains. The lack of understanding of the various approaches for assessing risk can unduly hamper effective communication.
The IRAC, by its collaborative nature of risk assessors from across the federal government, is an ideal body to provide clarification of the various approaches for assessing risk and informing risk managers and then to communicate this common understanding to the different stakeholders.

PROPOSAL

Form a workgroup of interested IRAC members to:

1) Develop a **white paper** detailing the various approaches for assessing risk that can be applied to address risk management concerns.
2) Develop an **outreach plan** to communicate these approaches to appropriate stakeholders.

EXPECTED OUTCOMES

A **white paper** describing and clarifying the various approaches for assessing risk would include:

1) a description of the various types of risk assessments tools and techniques (e.g., qualitative, risk ranking, semi-quantitative, safety evaluation, quantitative, etc.)
2) a description of what approaches for assessing risk can be appropriate for addressing risk management issues, problems, and questions
3) a description how the various assessments of risk can help elucidate risk management options that would aide risk managers in their decision-making process

The **outreach plan** would include a description of who the target stakeholders are, the essential message(s) to deliver, and the target opportunities/venues for this communication effort.

TIME FRAME FOR COMPLETION

It is expected that this should take less than a year's effort. IRAC participants in the workgroup would communicate and interact periodically during this period, most likely electronically by working on the sequential drafts. Communication will occur by email and any meetings will occur by phone. A potential target for completion of at least a mature draft would be the proposed IRAC public meeting being projected for the end of March 2012.