Interagency Risk Assessment Consortium
Technical Committee and Policy Council Spring Meeting Report

March 8, 2012

Welcome and Introductions

The Interagency Risk Assessment Consortium (IRAC) held its 2012 spring quarterly meeting of the technical committee and policy council on March 8 in Patriot Plaza III, 9th Floor, in Washington, DC. Chair of Technical Committee Isabel Walls 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.

Presentations and Discussion

Dr. Ii-Lun Chen from FDA's Center for Tobacco Products (CTP) gave a presentation on risk assessment of investigational tobacco products. Four members of the risk team at CPT also shared their experiences and some of the challenges in assessing risk associated with tobacco products, which have known harmful effects. There are approximately 90 substances in tobacco products that are known hazards or are potentially harmful. CTP is interested in learning from experiences of other IRAC members to help them address issues such as: how to prioritize risk among the hazards, how to evaluate risk and determine that a modified product poses risk that is no greater than the risk of an existing product, validated biomarkers, exposure vs. illness, effect of changes in manufacturing processes on end product toxicity, cumulative risk and behavioral changes in response to a product with a claim for reduced risk. CTP is also evaluating research from NIH and collaborating with NCTR to help fill data gaps, and is interested in learning from the experiences of other IRAC members in particular on risk assessments for chemical hazards.

IRAC Work Group Updates

<u>IRAC-IFSAC Risk Assessment as a Method for Determining Attribution to Foodborne Illness</u>
Sandy Hoffmann reported that a 2-day workshop on attribution and risk assessment took place February 2-3 in Washington, DC. Participants discussed the relationship between risk assessment and epidemiological methods and how they can complement each other. Workshop participants agreed that both approaches are useful and they may depend on each other and complement each other. For example, epi data can be used to anchor/validate risk assessment results, while risk assessments may discover and point to areas where epi might not have looked

at previously for foodborne illness attribution. A small work group is working on a white paper based on outcomes of the workshop.

L. monocytogenes Dose Response Workgroup

Sherri Dennis reported that a small workgroup has met the milestone (by the spring meeting) of having a solid draft of a manuscript based on the outcomes of the joint IRAC/JIFSAN Lm Dose-Response Workshop. The workgroup is going through a last round of revision of the manuscript, which will incorporate comments on the draft from members of the workgroup. The workgroup anticipates sharing a draft of the manuscript with IRAC members in April.

New Workgroup: Clarification of the Various Approaches for Assessing Risk

Kerry Dearfield reported the workgroup has one more call for IRAC members to join the efforts. Currently the workgroup includes volunteers from FSIS (two members), FDA (two members), NCTR (one member), NIOSH (one member), EPA (three members), and possible participation from ARS and FAS. Dearfield has compiled text from various relevant sources and he indicated the workgroup is ready to start the work. The goal is to develop a white paper that can be used in communication with USTR and other decision makers. One of the key concepts is that a range of risk assessment tools are available, and the tool to select depends on the problem and risk management questions. Both a qualitative and a quantitative tool can be an appropriate approach depending on the questions. Different tools can fit for different purposes (e.g., can be a quantitative risk assessment or a risk profile). It was noted that SPS has a number of case laws that do not differentiate much between qualitative vs. quantitative risk assessments; rather, the emphasis is on assessment of risk that is appropriate for the circumstances (i.e., fit for purpose).

Norovirus Project

Sherri Dennis reported that the initial work group has tried to map out a conceptual model and identify data gaps; however, we need to make a call for someone who is willing to lead the project. There are several other groups working on norovirus issues, including NACMCF, a consortium for a large project (25M) funded by NIFA, and CCFH. After discussion, it was decided that IRAC would hold off the norovirus work, and will resume the work until we learn more about what the other groups are doing, so that we can determine how to connect IRAC efforts with the other efforts.

Policy Council Meeting

Review of draft 2011 Annual Report

Isabel Walls asked members to review the draft annual report and send any comments/edits by April 8.

Annual Plan for FY 12

IRAC Strategic Plan

We discussed collaboration and outreach to other organizations. A suggestion was made to reach out to the Capital Area Food Protection Association to hold a joint meeting on risk analysis in the fall. It was also suggested that IRAC reach out to JIFSAN and invite the new director of

the risk analysis program, Dr. Clare Narrod, to give an update and discuss how to increase IRAC visibility through FoodRisk.org.

Workshop for Chemical Food Safety Risk Assessment

Isabel Walls noted that based on members feedback, chemical risk assessment will be a focus for FY12. After discussion, it was decided that IRAC will sponsor a workshop on the topic, to be held in conjunction with the summer quarterly meeting. Sherri Dennis noted that FDA has a number of risk assessment or risk assessment-like products and the chemical risk assessment group may be interested in providing a speaker for the workshop. Kerry Dearfield indicated that FSIS would be interested in presenting the national residue program. Isabel Walls will send out a call to other IRAC members for speakers and participation at the workshop.

Succession Planning

Isabel Walls noted that she would be stepping down as Technical Committee Chair at the end of 2012. Sherri Dennis proposed that procedures be established for succession planning for IRAC Technical Committee Chair. We discussed the suggestion that the Executive Secretary would serve for one year, and in the second year serve as the Chair of the Technical Committee. There was also a suggestion about setting up an Advisory Council of past Technical Chairs to advise on IRAC activities. Whether there should be a time limit for serving as secretary and or chair was also raised. IRAC members are requested to provide comments on having a succession plan. For FY12 annual plan, Isabel Walls will develop a draft for IRAC members to review.

Table 1. Attendance (* participated by phone)

Andrew MacCabe	DHHS CDC
Frank Hearl	CDC NIOSH
Ii-Lun Chen	FDA CTP
Isabel Walls	USDA NIFA
Gregg Claycamp*	FDA CVM
Jane van Doren	FDA CFSAN
Janell Kause	USDA FSIS
Kerry Dearfield	USDA FSIS
Kimberly Benson	FDA CTP
Mark Powell*	USDA ORACBA
Nathan Hurley	FDA CTP
Phil Yaeger	FDA CTP
Sherri Dennis*	FDA CFSAN
Stephanie Mickelson*	USDA FNS
Yuhuan Chen	FDA CFSAN