

**Interagency Risk Assessment Consortium
Semi Annual Policy Council and Technical Quarterly Spring Meeting
March 12, 2008**

Technical Meeting **9:00 – 10:30 am**

Introductions

A warm welcome to Michael Ollinger, the new IRAC technical and policy council representative for the USDA/Economic Research Service.

5 minute Updates

Centers for Disease Control (CDC)

Andrew Maccabe

Dr. Andrew Maccabe, DVM, MPH, JD is the CDC liaison to FDA/CFSAN. He was formerly with the Association of American Veterinary Medical Colleges, and is currently with the National Center for Zoonotic, Vectorborne and Enteric Diseases (NCZVED), Food Safety Office.

Department of Defense

U.S. Army Center for Health Promotion and Preventive Medicine (DOD/CHPPM)

Brandolyn Thran

1. Work is proceeding on the derivation of exposure guidelines for *B. anthracis* as the first agent, with a goal of establishing the "thinking" for all agents.
2. Our efforts on dose-response modeling for *B. anthracis* will be presented at ASM as a poster.
3. The Pathogen Information Catalog (an access database to house dose-response data) is being expanded to include *Yersinia pestis* data.
4. The MRA Technical Guide is well underway and should be in internal review by April, and ready for others to see in June-timeframe.

Environmental Protection Agency

Office of Water (EPA/OW)

Stephen Schaub

- Office of Water is continuing to develop microbial risk assessment (MRA) protocols, procedures, tools, etc. to support its different water programs.
- Microbial Risk Assessment (MRA) Thesaurus of terms and definitions is available on the EPA/OW/Water Science website:
<http://www.epa.gov/waterscience/criteria/humanhealth/microbial/thesaurus/>
It has been sent to the World Health Organization (WHO) to be incorporated into their lexicon.
- The Interagency Microbial Risk Assessment Protocol is being revised to include dynamics and susceptibility modeling. The National Academy of Science has asked for community-based risk assessments.
- EPA will incorporate Risk Communication guidelines to its MRA guidance protocol by late summer/early fall.
- EPA's MRA protocols will support:
 - Upcoming risk assessments for microbiological criteria for States and localities to use instead of using EPA's numbers.
 - Development of quantitative microbial risk assessments to support coliform rule (ground and drinking water).
 - Interagency MRA guidelines effort

- EPA is working with the WHO to harmonize MRA guidelines for water applications.

Food and Drug Administration

Center for Food Safety and Applied Nutrition (FDA/CFSAN)

Richard Whiting

Risk projects are continuing.

- *L. monocytogenes* in smoked seafood risk assessment. The team is modeling the impact of possible changes in processing
- *L. monocytogenes* in soft cheeses (camembert and brie) risk assessment conducted jointly with Health Canada
- *L. monocytogenes* in fresh and fresh-cut vegetables risk profile
- Pathogens in Cheese Risk Profile

Sharon Edelson Mammel

- As part of the Pathogens in Cheese Risk Profile, a table was developed that summarizes the ability of different pathogens to survive (or not) in fresh and soft ripened cheese. Information from approximately 70 different journal articles was used in the table.

Marianne Miliotis

- IRAC Annual Report for FY07 is available at http://www.foodrisk.org/IRAC/annual_report/reports/FY2007.pdf
- Risk Profiles:
 - HAV
 - NV
 - Pathogens in Cheese: site visit plan
- Upgrade of Risk Ranking Prototype
- CCFH Code of Hygiene Practice for *Vibrio* spp.
- New Center Director, Dr. Steven Sundlof
 - Commissioner's 3-Part Plan
 - i. Develop leadership for the future
 - ii. Improve processes and enhance resources for a science-led agency
 - iii. Empower employees through effective communications
- World Congress on Risk:
 - IRAC is sponsoring the World Congress on Risk for \$1,000 as a Friend of SRA sponsor
 - There will be a workshop on "Use of Risk Analysis in the Development of Better Food Safety Standards".
Instructors: Amir Mokhtari, Research Environmental Scientist, Research Triangle Institute (RTI) International, Steve Beaulieu, Director, Risk Assessment and Environmental Modeling Program, RTI International. For more information: <http://rtidemo.rti.org/WRC2008>

Center for Veterinary Medicine (FDA/CVM)

Barry Hooberman

- CODEX has formed a Task Force on Antimicrobial Resistance. A meeting was held in Korea. The task force has been divided into three groups to develop different sections of a document:
 - Canada: Risk assessment guidelines
 - United States: Preliminary Risk Management Activities and Risk Profiling
 - European Union (EU): Risk Management strategies
- Risk-based inspection effort. CVM is working with FDA/CFSAN and FDA/ORA on risk-based initiatives for food safety. A document will be prepared within three months

- Upcoming meeting on animal feed safety systems to rank relative risks in animal feed for both chemical and microbial risks.
- [CVM has finished and published its evaluation of the safety of food from cloned animals. USDA will now deal with the issue of determining the manner which product from cloned animals will enter commerce.](#)
- CVM is working on genetically engineered animals. High level discussions chaired by the Office of Management and Budget (OMB) are being conducted on the approach to genetically engineered animals.

United States Department of Agriculture

Animal, Plant, Health Inspection Service (USDA/APHIS)

Robert McDowell

- EPA/FDA/USDA released a joint statement on Event 32, a genetically engineered pesticide product that was discovered at low levels in some lots of seed corn distributed in 2007. The discovery was made by the producer and voluntarily reported to the federal agencies.
- APHIS is continuing to conduct risk assessments on animal and plant health relating to imported products.
- Under a recently approved process, APHIS is now allowing new imports of fruits and vegetables for consumption via a notice-based process. This alternative to formal rule-making speeds up the regulatory process considerably.
- Citrus issues: the discovery that a new bacterial disease of citrus in Florida, & citrus greening⁸, can be spread by seed stimulated methodological work on sampling to discover low levels of contaminated fruit in commercial shipments. This work may have wider application in sampling and inspection as risk mitigation activities.
- APHIS is developing a predictive model for Medfly outbreaks in Central America. The model, based on metronomical signals, will serve to alert risk managers when increased threat of Medfly introductions may occur.

Agricultural Research Service (USDA/ARS/)

Mary Torrence

- Mary has moved to USDA/ARS to serve as an ARS National program leader with Jim Lindsay. With her epidemiological background, she will cover more of the animal related research issues.
- USDA/ERS (Economic Research Service) has an Antibiotic Resistance in Microorganisms (ARMS) database, which addresses food safety questions for poultry, beef, and swine.

Economic Research Service (USDA/ERS)

Tanya Roberts

Tanya is retiring at the end of March, 2008. Mike Ollinger is her replacement. Tanya provided hard copies of several ERS publications:

- Tanya Roberts. 2006. New Pathogen Tests Trigger Food Safety Innovations in Food Safety. Available at: http://www.ers.usda.gov/AmberWaves/February06/findings/FIndings_DH1.htm
- Elise Golan *et al.* 2004. Food Safety Innovation in the United States – Evidence from the Meat Industry. Available at: www.ers.usda.gov/publications/aer831
- Julie Caswell *et al.* 2008. The Interaction of Public and Private Incentives in Promoting Food Safety Innovation in the U.S. Meat Industry. *In: Handbook of Innovation in the Food and Drink Industry.* The Hayworth Press, Taylor and Francis Group.
- Tanya Roberts. 2007. Willingness to Pay (WTP) Estimates of the Societal Costs of U.S. Food-Borne Illness. *Amer. J. Agr. Econ.* 89:1183-1188.

- Tanya Roberts. 2005. Economics of Private Strategies to Control Foodborne Pathogens. *Choices* 20:117-122.
- Tanya Roberts *et al.* 1999. Probabilistic Risk Assessment and Slaughterhouse Practices: Modeling Contamination Process Control in Beef Destined for Hamburger. *Probabilistic Safety Assessment PSA '99: Risk-Informed Performance-Based Regulation in New Millennium.* p 809-815.

Mike Ollinger

- Mike conducted the first survey on food safety innovations that plants have since adapted. FSIS has since conducted more additional surveys using the data for analysis:
 - Linking innovations and market activities
 - Linking regulatory efforts to *Salmonella* levels reported to FSIS
 - Technology has advanced

Mike has co-authored a manuscript with FSIS; waiting to hear their reviews. Several other papers some have been presented to conferences, others in various journal stages: HACCP costs, technology adoption. Mainly deal with meat and poultry issues.

Food Safety Inspection Service (USDA/FSIS)

Kerry Dearfield

- FSIS is designing new approaches, within statutory limits, to continually improve its effectiveness in reducing foodborne illnesses associated with consumption of meat, poultry, and egg products. Through these approaches, FSIS will try to focus its resources on those establishments, and points within establishments that pose the greatest risk for food safety issues. By focusing its resources on a public health-based manner, FSIS can better protect the food supply and, subsequently, the public's health, with resources available.
This includes the development of the Public Health Information System (PHIS) that will provide the infrastructure to collect, assess and respond to hazards and risks. PHIS will document specific procedures, product category, regulatory requirements, and the method of verification used. THE system will integrate seamlessly with other existing and planned systems permitting users to analyze data form multiple programs in a variety of different dimensions. Some of the key benefits of PHIS include: ability to use data at all levels to analyze management controls and ability to identify training needs.
- FSIS is working on some Codex CCFH initiatives:
 - RAD is working with the newly approved Codex risk management metrics using the FSIS *Clostridium* model as an example to identify food safety objectives (FSO's), performance objectives (PO's), and microbiological criteria (MC) for sampling, etc.
 - The US delegation has also been preparing for the CCFH working group that is drafting microbiological criteria for *Listeria monocytogenes* in ready-to-eat foods.
- The FSIS residue group is continuing work on residues, in particular dioxin. During 2007 to 2008, ~500 random samples are being taken from slaughterhouses across the United States to test dioxin levels in beef, swine, chicken, and turkey. There was a downward trend in dioxin levels in swine, chicken, and turkey, but not in beef seen from the earlier surveys. The objective of the current study is to continue monitoring the trends and to identify any potential sources of dioxin. Generally, dioxins are found in the environment, feed, soil, and wood used to fence cattle.

Presentations **11:00 am – 12:30 pm**

11:00 – 11:45 am: Kerry Dearfield (USDA/FSIS): *Update on the Interagency Microbial Risk Assessment Guidelines*

11:45 – 12:30 pm: Peg Coleman (Syracuse Research Corp., NY): *Exercising a Panel Peer Review Process for Microbial Risk Assessments*

Policy Council Meeting **1:30 pm – 3:00 pm**

Work Group Updates

Nutrition Risk Assessment

The report from the Nutrition Risk Assessment workshop Feb 28-Mar 1, 2007 was published on November 19, 2007 by the National Academy of Sciences. The IRAC workgroup met February 28, 2008 for a discussion and brainstorming session on next steps. We identified two possible paths for continued work:

a) The first was to give risk assessment a try: select a nutrient, develop a conceptual risk assessment model and plan a workshop with experts to identify data gaps and evaluate the appropriateness of the model for nutrition. The Institute of Medicine (IOM) had a conference on Daily Recommended Intakes (DRI's) in September 2007 that may have already covered similar areas. They are putting out a contract for Vitamin D DRI update in the near future.

b) The second possible step is to gather nutritionists, risk assessors, epidemiologists, toxicologists, and other experts in ancillary areas to discuss nutrition risk assessment data gaps and needs. This might also include development of a conceptual model.

The group has begun to develop a prospectus but we are very early in the process at this point.

Data Utility

The Data Utility Work Group is back in action! A kick-off conference call was held to start planning and organizing a symposium on sampling plans to be held (if accepted) at the Society for Risk Analysis Annual Meeting in December 2008. A document with a draft abstract and schedule of speakers is being provided to the IRAC Policy Council and Technical Representatives at the 12 March meeting for feedback.

Produce Safety

The IRAC Produce workgroup met on Wednesday, March 5 and is in the process of completing flow diagrams of the hazards and potential interventions for each stage in the Farm-to-Table model for *E. coli* O157:H7 in Leafy Greens. The work group reviewed the flow diagram for the farm level, and assignments were made for completing the flow diagrams for the other stages in the model. The work group is also working on a research data base for all existing research and another data base on published research on *E. coli* O157:H7 in leafy greens. Lori Papadakis is developing the data base in the FDA E-Room. The work group reviewed the template for the database and agreed to forward web site links or data they had to Lori for inclusion in the data base. The work group is also working on developing a decision tree to help in identifying the risk factors that have the highest degree of risk, which will be utilized in the workshop as a tool in prioritizing needed research on *E. coli* O157:H7 in leafy greens. The work group plans to meet again in April to finalize the flow diagrams and plans for the workshop potentially planned for July.

Discussion of future projects/workshops/symposia

IRAC will serve as a cosponsor of the following upcoming and/or potential meetings listed below:

- 2nd World Congress on Risk in a "Friend of SRA capacity", July 8-12, 2008
- JIFSAN Dietary Exposure Tools Workshop date not established as yet
- Produce Safety Workshop to identify data gaps for conducting a farm to fork risk assessment, July 2008
- Data Sampling symposium(a) at the SRA 2008 Annual meeting.

In attendance (* participated by phone)^a:

Mike Broder, EPA/OSA

Kerry Dearfield, USDA/FSIS

Sherri Dennis, DHHS/FDA/CFSAN

Sharon Edelson Mammel, DHHS/FDA/CFSAN

Wendy Fanaselle, DHHS/FDA/CFSAN

*Barry Hooberman, DHHS/FDA/CVM

Gun-Young Lee, Korean FDA

Kristina McLaughlin, DHHS/FDA/CFSAN

Andrew Maccabe, CDC

Robert McDowell, USDA/APHIS

Marianne Miliotis, DHHS/FDA/CFSAN

Mike Ollinger, USDA/ERS

Tanya Roberts, USDA/ERS

*Steve Schaub, EPA/OW

* Brandolyn Thran, DOD/CHPPM

Mary Torrence, USDA/ARS

Richard Whiting, DHHS/FDA/CFSAN