

**Interagency Risk Assessment Consortium (IRAC)
Semi Annual Policy Council and Technical Quarterly Fall Meeting
September 17, 2008**

Technical Meeting 9:00 – 10:30 am

Introductions

Changes in IRAC agency representatives: Sherri Dennis has replaced Bob Buchanan as the CFSAN Co-Chair for the IRAC policy council. Richard Whiting is retiring from the Federal Government at the end of this month and a new CFSAN representative will be identified in the near future. Eric Grant and Wendy Hall have replaced David Oryang as the USDA/APHIS representatives. Isabel Walls will join IRAC as the USDA/FAS representative.

5 minute Updates

Centers for Disease Control (CDC)

- Mark-Alain Widdowson has moved to another viral branch at CDC and has been replaced with Aron Hall.
- The paper on the burden of foodborne illness is still continuing
- Due to a new reporting system, annual updates on food attribution; information will be provided closer to the end of the year.
- CDC is coordinating the review of the FDA/CFSAN risk profile on hepatitis A virus.
- The Codex Committee for Food Hygiene (CCFH) is considering conducting new work looking at viruses in food. The FDA/CFSAN norovirus risk profile is of interest to help this process.

Department of Defense

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

- A new Microbiologist position at CHPPM on the MRA Team closed 17 September, 2008.
- The Technical Guide 316 for Inhalation Microbial Risk Assessment is under CHPPM-review and we have high hopes to have it finalized by the end of the fiscal year. Once it is finalized, it will be available for distribution.
- CHPPM is looking for a few technical experts to serve as peer-reviewers and workgroup members for their Biological Military Exposure Guidelines. They have developed a process, identified some major weaknesses and potential numbers for *B. anthracis*, and now are in need of assistance to improve them. The process has undergone an internal-CHPPM review and now they are looking to expand our effort to include external reviewers. They are looking for people with strong math skills and/or experience in setting exposure guidelines (even if for chemical). Submit names of potential peer-review workgroup members to Brandolyn at brandolyn.thran@us.army.mil.
- The "Anthrax Report" that many IRAC member agencies have reviewed is being finalized as a "lessons learned" document.

Environmental Protection Agency

Office of Research and Development (EPA/ORD)

- EPA/ORD's National Exposure Research Laboratory has a new post doc, Dr. Mary Schoen, working with Nick Ashbolt. She will be developing methods and identifying research gaps in stochastic QMRA for animal-impacted recreational waters (current work underway along with the Doheny Beach CA epi study with SCWRRP), and also modeling in the effects of pipe biofilm pathogens (both fecal intrusions and growth of opportunistic pathogens) into drinking water microbial risk assessments. Mary came from Carnegie Mellon and has a Ph D. in environmental engineering on pathogen TMDLs.
- EPA/ORD is conducting a study titled: "Salivary antibody responses as an indicator of waterborne infections: pilot community study before and after installation of UV treatment". The goal of the study is to determine if a new and significantly improved water treatment plant has an impact on human exposure to a range of pathogens, including viruses (rotavirus and norovirus), parasites (*Cryptosporidium* and *Toxoplasma gondii*) and bacteria (*Helicobacter pylori*). This study is also an opportunity to develop new methods to detect antibodies in saliva.

Food and Drug Administration

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

- The risk profile on leafy green produce and risk assessment on *Listeria monocytogenes* and *Listeria monocytogenes* in smoked fish are almost ready to go out for peer review.
- Also there is some research on irradiation of produce to eliminate potential pathogens. The process will destroy the bacteria and cause minimal organoleptic problems with the produce.
- The risk profile hepatitis A virus has just undergone external peer review, and is currently being revised accordingly. It has also been sent to the IRAC member agencies for review.
- The norovirus risk profile is being finalized. The risk profile team will be briefing the risk managers in October.
- On Monday September 15, 2008, CFSAN celebrated the 50th anniversary of the food additives amendment to the Federal Food, Drug, and Cosmetic Act.
- On Tuesday, September 9, the National Academies of Sciences (NAS) Institute of Medicine (IOM) Food Forum sponsored the Managing Food Safety Workshop. They covered ways to improve communication and collaboration with industry. For additional information on the program and agenda go to <http://www.iom.edu/CMS/3788/53898.aspx>
- The risk profile on pathogens in cheese, which is currently focusing on soft cheeses is nearing completion and will be undergoing its first review by the program office risk managers mid-late October.
- Status of the CFSAN/Health Canada Joint Risk Assessment on *Listeria* in soft ripened cheese. Due to a spate of retirements among the team members, both the risk management and risk assessment teams are in transition. Nevertheless, the basic product pathway model has been developed and data gathering has been completed. The modeling team is in the process of transforming these data into distributions and parameters within the model. The modeling team has also developed a strategy for conducting a series of scenarios analyses both to compare the efficacies of various interventions and to gauge the relative importance of alternative assumptions within the model.

- The interagency project with USDA/FSIS on cross-contamination at retail has completed the first stage.

United States Department of Agriculture
Animal, Plant, Health Inspection Service (USDA/APHIS)

USDA/APHIS is planning a workshop in October at Texas A&M on Quantitative and Qualitative Risk Assessments. There will be participants from Africa. The workshop will cover plant and animal health in small workshop, on the topic of how to develop pest risk assessments (PRA).

Agricultural Research Service (USDA/ARS)

- Predictive Microbiology and Bioinformatics for Food Safety and Security of Microbial Food Safety Research Unit, ERRC-ARS-USDA is hosting the 45th meeting of the Interagency Botulism Research Coordinating Committee, September 14-18, 2008, in Philadelphia, PA. Meeting includes platform and poster sections. Themes for the platform sections are botulism in humans and animals, genomics, detection methods for botulinum neurotoxins, molecular food safety, small molecules for prophylaxis and treatment, pathophysiology and animal models, and vaccines and antibodies. There are 200 attendees from 10 countries.
- James Lindsay, ARS Senior National Program Leader for Food Safety, and Vijay Juneja, Lead Scientist of the Predictive Microbiology and Bioinformatic for Food Safety and Security research group, ERRC-ARS-USDA, attended the Annual Combase Consortium meeting during the FoodMicro2008 Conference in Aberdeen, Scotland. The meeting discussed various issues, including data inclusion, new models, and the implementation of mirror Combase server sites at ERRC and the Institute of Food Research, UK. The next formal meeting of the Consortium will be held at the Predictive Microbiology Conference, Washington, DC in late summer 2009.

Economic Research Service (USDA/ERS)

- Laurian Unevehr became director of the Food Economics Division.
- USDA/ERS/Economics Division has recently published two articles:
 - (i) Ollinger, M. and D. Moore. 2008. "The Economic Forces Driving Food Safety Quality in Meat and Poultry" *Review of Agricultural Economics* 30(2): 289-310. This paper determines Salmonella levels in private and public efforts on control of the organism.
 - (ii) Kuchler, F. 2008. "The Effects of Avian Influenza News on Consumer Purchasing Behavior: A Case Study of Italian Consumers' Retail Purchases." Available at: <http://www.ers.usda.gov/publications/err65/>. This paper discusses the economic impact of avian influenza virus

Food Safety Inspection Service (USDA/FSIS)

- FSIS is wrapping up its collection for the 2008 Dioxin survey. Every five years FSIS takes about 500 fat samples from four market classes: beef, pork, turkey, and chicken to:
 - Examine the trends of dioxin and dioxin-like compounds in animals/food products as compared to the earlier surveys.
 - Identify where elevated levels may be found. If found, they will try to determine what may be the source of dioxin (e.g., feedlot posts, soil, air, feed) to eliminate the source if possible. FDA performs the follow-up activity to identify the possible dioxin source.
 - The statistical analysis is not complete, but the trend seems to be decreasing on initial examination.
 - We hope the assessment will be finalized within the next six months.

- Currently there is no set level for dioxin in food in the U.S., so this survey is not designed for evaluating risk.
- Dr. John Johnston recently joined the Risk Assessment and Residue Division within the Office of Public Health Science, Food Safety and Inspection Service. Dr. Johnston will serve as a Senior Risk Analyst working within a multidisciplinary team of scientists, statisticians, and engineers to develop quantitative microbial and chemical food safety models to guide policies related to meat, poultry and egg products. Dr. Johnston formerly served as the Chemistry Project Leader for the USDA's National Wildlife Research Center within the Animal and Plant Health Inspection Service. Dr. Johnston brings experience in probabilistic modeling and working on issues related to residues in the environment. He holds a PhD in Food Toxicology from the Department of Food Science and Human Nutrition from the University of Florida, an MBA from Colorado State University, and a bachelor's in food science from Rutgers University.
- Dr. Joy Lee recently joined the Risk Assessment and Residue Division within the Office of Public Health Science, Food Safety and Inspection Service as the FY08 American Association for the Advancement of Science (AAAS) fellow. Dr. Lee holds a Ph.D. in neuroscience from Northwestern University and a bachelor's of science from Berkley in molecular and biological sciences. Dr. Lee's research includes the study of infectious diseases, including the transmission and impact of hepatitis. Dr. Lee will work on a variety of quantitative risk assessment projects to integrate the outputs into regulatory decision-making with regards to food safety policy for meat, poultry and egg products.
- QMRA Projects Update:
 - Under the 2008 Farm Bill, the Food Safety and Inspection Service within USDA was given the responsibility for the safety of catfish. Under the Federal Meat and Inspection Act, catfish will be included as an amenable species, and therefore will be subject to agency examination and inspection (continuous) when processed for human food. In conducting such inspections, FSIS is authorized to take into account the conditions under which the catfish are raised and transported to processing establishments. FSIS has met with academia, FDA, EPA and industry to identify those hazards of greatest public health concern and will prioritize them for inclusion in its testing program.
 - FSIS has been invited to serve as technical expert on avian influenza risks as part of a Food and Agriculture Organization of the United Nations (FAO), the World Health Organization for Animal Health (OIE), and the World Health Organization (WHO) technical consultation held in Verona, Italy, 7-9 October 2008. FSIS led an interagency quantitative food safety risk assessment for highly pathogenic avian influenza designed to evaluate the effectiveness of various federal mitigation measures should HPAI infect commercial flocks in the U.S. This risk assessment has been presented to the National Turkey Federation and is scheduled to be presented to the National Chicken Council and United Egg Producers in Oct. 2008.
 - FSIS is currently developing a number of risk analysis models that combine economic analysis with quantitative risk assessments as part of a tiered approach to determine which policy options require more complex risk assessment modeling to inform food safety decisions. These new methods would move the field forward in terms of better utilization of modeling in guiding food safety decisions.

Foreign Agricultural Service (USDA/FAS)

- FAS is involved in facilitating trade; they are looking at SPS issues for helping trade, and to support CODEX.

- A workshop was held in Nicaragua in August on microbiological criteria in foods for international trade. Both FSIS and FDA presented.
- FAS is planning on having future workshops on pesticides and microorganisms.
- FAS is working with EPA for pesticide risk assessment training, including biopesticides.
- FAS is also working with the Inter-American Institute for Cooperation on Agriculture (IICA) and FAO on workshops in Latin America to encourage participation in CODEX and to promote adoption of CODEX standards.

Items for FY 09 Annual Plan

IRAC workgroups

- Steve Gendel proposed a new work group that could possibly collaborate with an upcoming NAS/IOM 2009 workshop for which Kerry Dearfield is on the planning committee. The work group would be titled: "Susceptible Population Workgroup". The objective of the work group would be to determine "What is a susceptible population and how big is that population?" There seemed to be much interest among the IRAC representatives to forming this workgroup to define and potentially answer this question.
- Kerry Dearfield mentioned that the National Academy of Sciences (NAS)/ Institute of Medicine (IOM)/Food Forum is planning a workshop in 2009. Three topics were discussed as possible candidate workshops:
 - Functional foods
 - Nutritional status of the aging population
 - Glycemic problems with diabetics
 The IRAC proposed that if the Food Forum selects the aging population topic, then IRAC may be interested in providing sponsorship for the workshop.

General Comments on Improving the IRAC

The IRAC representatives discussed various ways to make the IRAC more visible to the risk assessment society. It was also discussed that we have more collaboration and more cooperation among the member agencies to better help each other.

Presentations

11:00 am – 12:30 pm

- 11:00 – 11:15 am: Kerry Dearfield (USDA/FSIS): *Update on the Interagency Microbiological Risk Assessment Guideline*
- 11:15 – 12:15 pm: Villie Flari (Central Science Laboratory, UK; DHHS/FDA/CFSAN): *Developing Rapid Risk Assessments*

As a result of the presentation on the Interagency Microbiological Risk Assessment Guideline, the IRAC agreed to review the draft guideline and provide comments to the draft by the end of October 2008. Comments should be sent via email to the co-leads of the project, Kerry Dearfield at FSIS and Stephen Schaub at EPA.

Policy Council Meeting

1:30 pm – 3:00 pm

Work Group Updates

Data Utility

The Data Utility group is sponsoring a symposium at the SRA Annual Meeting in December. After the symposium, the workgroup will have a teleconference to decide on future activities in this area.

- Two white papers have been developed for publication.
- Can it continue but focus on Food safety and Sampling plans needed for setting microbiological criteria, monitoring plans?
- Can the group segway and become the Sampling plan group?

The white paper developed by some members of the work group will be published in the December issue of Human and Ecological Risk Assessment.

Produce Safety

On July 8-9, IRAC co-sponsored a workshop on "Research Needs Prioritization for Conducting a Quantitative Risk Assessment of *E. coli* O157:H7 in Leafy Greens" jointly with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) at the Holiday Inn in College Park, MD. The purpose of the workshop was to identify and prioritize research data gaps for conducting a quantitative risk assessment on *E. coli* O157:H7 foodborne illness from the consumption of leafy green vegetables. The workshop brought together over 70 experts in a variety of scientific disciplines and practical applications from academia, industry, and government. Government representatives included NIH, CDC, FDA (CFSAN, ORA, NCTR), and USDA (FSIS, AMS, ARS, ERS, APHIS). A model based on the analytical hierarchy process (AHP) was pilot tested.

- A Lesson learned report is being prepared on the workshop, with some focus on data gaps.

Nutrition Risk Assessment

There is nothing new to report; the workgroup completed its objectives last year.

Discussion of future projects/workshops/symposia

- Kerry Dearfield discussed the topic of Nanotechnology and food, such as indirect additives (e.g., migration of materials from food packaging) and direct additives (e.g., embedding materials into food to enhance flavor, provide antimicrobial activity).
- Steve Gendel proposed a new work group that could possibly collaborate with the NAS/IOM committee. The work group would be titled: "Susceptible Population Workgroup". The objective of the work group would be to determine "What is a susceptible population and how big is that population?" There seemed to be much interest among the IRAC representatives to forming this workgroup to define and potentially answer this question.
- There was a discussion on the need to disband work groups after they have accomplished their objectives and that IRAC should encourage groups to have a definite beginning and endpoint and that if needed additional work is identified that the technical representative should submit a proposal for a new workgroup.
- The IRAC Policy Council determined that a new IRAC work group will be formed on "Susceptible Populations", which will focus on immuno-capability and dose response effect on risk assessment.
- The IRAC will co-sponsor the JIFSAN workshop on "Dietary Exposure Assessment Tools for Prioritizing Food Safety Concerns" which will take place November 18-19, 2008. This workshop is by invitation only.

The IRAC will continue to have seminars during the quarterly meetings

In attendance (* participated by phone):

Stephanie Briguglio, University of Maryland, JIFSAN
Catherine Chesnutt, USDA/FAS
Kerry Dearfield, USDA/FSIS
Sherri Dennis, DHHS/FDA/CFSAN
Sharon Edelson Mammel, DHHS/FDA/CFSAN
Steve Gendel, DHHS/FDA/CFSAN
Eric Grant, USDA/APHIS
Janell Kause, USDA/FSIS
Joyce Lee, USDA/FSIS
Andrew Maccabe, DHHS/CDC
Stephanie B. Mickelson, USDA/FNS
Marianne Miliotis, DHHS/FDA/CFSAN
Mike Ollinger, USDA/ERS
Regis Pouillot, DHHS/FDA/CFSAN
*Cindy Roberts
*Joyce Saltsman, DHHS/FDA/CFSAN
Ethel Taylor, Kansas State University
*Isabel Walls, USDA/FAS
Richard Whiting, DHHS/FDA/CFSAN