

**Interagency Risk Assessment Consortium
Technical Quarterly Winter Meeting
December 13, 2006**

Technical Meeting 9:00 am – 11:00 pm

Introductions

5 Minute Updates

Department of Commerce

National Oceanic & Atmospheric Administration (NOAA) Fisheries Services

Angela Ruple

Nothing new to report

Department of Defense

US Army Center for Health Promotion and Preventive Medicine (CHPPM)

Brandolyn Thran

- The anthrax risk assessment document is ready for a technical review by the IRAC. Brandolyn Thran will give a presentation to the IRAC at the next IRAC meeting in March.
- CHPPM is working on an inhalation RA document on Valley Fever (causative agent: *Coccidioides immitis*), which is endemic in the southwest United States. The same framework used for the anthrax risk assessment is being applied. Valley Fever is of interest to the Army because of the frequent desert training of the troops at installations in the southwest.

Environmental Protection Agency

Office of Water

Stephen Schaub

- The OW water-based microbial risk assessment protocol is ready for review by the IRAC. It uses the ILSI framework. There was some discussion as to whether it would be an IRAC review or individual review by IRAC member agencies. It was decided to have individual agencies review it, but the reviews will be consolidated and sent with an IRAC cover letter. Steve Schaub will give a presentation to the IRAC at the next IRAC meeting in March, and the review deadline is late March, early April.

The reviewers would be asked to focus on the following questions:

- a. Does it meet the requirements for water-based microbial risk assessment?
- b. Is it a credible risk assessment protocol?
- c. Is something missing, and is it out there?
- d. Do you foresee any possible problems with the protocol?

- The EPA/OW Risk Assessment thesaurus, which is >200 pages, is ready to be published. It mainly focuses on food and environmental media. There was some discussion as to how the information should be disseminated. One recommendation was to go through SRA; another suggestion was CODEX; yet another suggestion was to post it on foodrisk.org. However, we should get endorsement from SRA and the IRAC.
- EPA also has 2 draft risk assessments for review by anyone in the IRAC that is interested:
 - a. *Giardia* in water
 - b. *Cryptosporidium* in water

Food and Drug Administration

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

Richard Whiting

- The Center is progressing with its risk assessment on the impact of process mitigations on the risk from *L. monocytogenes* in hot- and cold-smoked finfish. The risk assessment team made their first presentation to the risk managers of the results of the mitigation scenarios December 14th. The focus of the model was to establish a baseline of risk, and then evaluate mitigations such as labeling, freezing, antimicrobials. The results are presented as a percent reduction from the baseline risk. After the meeting, the risk assessment team would complete the write-up and the draft report will go for public comment.
- A new risk profile is being developed by CFSAN on raw milk cheese. Sherri Dennis is the lead.
- The December meeting of the CODEX Committee for Food Hygiene (CCFH) in Houston was very productive. Several documents were advanced:
 - General Principles of Risk Management was passed and now will go to the parent CODEX committee for clearance
 - General Principles for *Listeria* Management document was also passed.
- FDA/CFSAN provided information for the annex to that document and developed a risk assessment on smoked fish RA using Analytica software. Germany is taking the lead to define Microbiological Criteria, Performance Objectives (PO's), and how they will be included in regulation. This is an ongoing effort with additional meetings planned for next year for setting PO's and regulatory control concepts in place.

Marianne Miliotis

- Virus Risk Profiles
 - HAV: Final draft will be sent to risk managers by the end of January.

- Norovirus: recent version just reviewed by Bob Buchanan; currently being revised and will be sent to all risk managers mid February, 2007.

We hope to complete both risk profiles by the end of March, 2007.

- The 10th International Symposium on Toxic Microorganisms sponsored by the US-Japan panel on Toxic Microorganisms was held November 7-9, 2006 at the CFSAN Wiley Building, College Park: “Meeting the Challenges of Toxic Microorganisms and Pathogens: Implications for Food Safety and Public Health”.
- SRA – Sherri Dennis
 - Risk assessment at FDA: Presentation on “Applications for informing science-based decisions”.
 - Chaired a symposium on “Food allergies: Issues in establishing thresholds
- Thai visitors: Thai FDA and National Bureau of Agricultural Commodity and Food Standards (ACFS) representatives visited FDA/CFSAN December 12, 2006 to obtain information on food safety aspects and risk assessment.
- Plug for funding for JIFSAN Food Safety Risk Prioritization workshop and for the Nutrition Risk Assessment workshop in 2007.

There was some discussion among the IRAC representatives of planning an educational field trip for all IRAC representatives.

Sharon Edelson Mammel

- Sharon is still on detail with Sherri Dennis currently working on the *Listeria* in cheese risk assessment.
- She went on a training course on production of Hispanic cheeses. There has been a tremendous increase in consumption of all types of cheeses.

John Hicks

- The teams for the risk profiles on *Listeria* and Hepatitis A virus in fresh and fresh-cut produce visited 2 fresh produce processing plants early October.

Steve Gendel

- The risk assessment on *Listeria* in soft ripened cheeses being developed in collaboration with Health Canada is in its initial stages. A base charge document has been developed. The conceptual model was developed in Analytica in conjunction with training. The risk assessment team is starting the process of filling in some of the boxes in the model for the different stages of cheese production: from the cow to consumption. The team is still gathering data and looking at the data gaps. They are collaborating with the International Dairy Farmers Association (IDFA). Mary Brandt offered to provide new consumption data if needed for the risk assessment. Carl Schroeder (USDA/FSIS) noted that Heather Hicks Quesenberry and David LaBarre would be both be interested in becoming involved with this project.
- The team went to visit a cheese processing plant in Wisconsin

- A risk profile on raw milk cheeses and pathogens in general is currently being developed by CFSAN. The question arose as to whether outbreaks are due to big production cheese or artesian cheeses.

Center for Veterinary Medicine (FDA/CVM)

Linda Youngman

- There were several presentations by CVM at the SRA meeting early December in Baltimore
 - Gregg Claycamp presented on MRA guidelines and Inspection Site Selection based on risk.
 - Delores Beblo presented on the animal feed safety system, and how to use risk based decisions on this system.
 - Linda Youngman presented the risk assessment on resistant worms (Nematodes) in food animals. The risk assessment is addressing whether there are pockets of resistant worms in food animals – there is little evidence of resistance posing a problem in the U.S. at this point in time.
 - There was some discussion on presenting this risk assessment at USDA/FSIS and at an IRAC meeting.

Joint Institute for Food Safety and Applied Nutrition (JIFSAN)

Wes Long

- CENTRA is a web-based system that allows people from all parts of the world to interact and exchange knowledge online in real time. A Mexican risk analysis course is currently being run with Charlie Yoe (Notre Dame).
- JIFSAN is sponsoring a nanotech workshop June 28-29, 2007 to regulatory and risks of this technology. The concern is that consumers are exposed to products that may end up in food or cosmetics containing the material. E.g., titanium dioxide in sunscreens. FDA had a meeting with others a short while ago. The concern is nanomaterials in food products; nanodetectors, and nanoantimicrobials. The objective of the workshop is to identify food safety and risk assessment issues. The workshop will include practical approaches to the possible food aspects of the technology.
- A reminder that the JIFSAN online course on Risk Analysis overview started this month
- Graduate certificate program in Food Safety and Risk Analysis at UMD begins March 3, 2007, and can apply credits towards a Master's degree.

National Center for Toxicological Research (NCTR)

Jim Chen

- Martha Moore (Director of Division of Genetic and Reproductive Toxicology) and Jim attended the SRA meeting. Jim presented a talk at the FDA session organized by Steve Anderson, CBER. His presentation was an analysis of uncertainty in estimating human reference dose for chemical risk assessment. The analysis

methods were developed by the members of Biometry and Risk Assessment, NCTR, and are published in Regulatory Toxicology and Pharmacology, 2006.

Citation: **R.L. Kodell , J.J. Chen, R.R. Delongchamp, J.F. Young.** 2006.

Hierarchical models for probabilistic dose–response assessment. Regul. Toxicol. Pharmacol. **45**:265-272.

EPA has published a document, "Approach for Determination of a Mutagenic Mode of Action for Carcinogenicity under EPA's 2005 Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens". Martha Moore led the NCTR scientists to provide FDA consensus comments to this EPA document.

- Ralph Kodell retired in November and Jim replaced him as the NCTR Policy Council representative to the IRAC. NCTR has merged the two divisions: Division of Biometry and Risk Assessment and Division of Molecular Epidemiology into the Division of Personalized Nutrition and Medicine.

United States Department of Agriculture

Agricultural Research Service/Eastern Region Research Center (USDA/ARS/ERRC)

Andy Hwang

In December of 2006, Dr. John B. Luchansky (USDA/ARS Microbial Food Safety Research Unit) was a panelist for a round table discussion on food safety between the Ministry of Science and Technology (MOST) of the People's Republic of China and USDA/ARS in Nanjing, China. The focus was on detection, characterization, and control of foodborne pathogens, as well as on predictive microbiology and process risk modeling. The Chinese are keenly interested in predictive microbiology and risk assessment, and were quite pleased to learn that a Chinese version of the PMP was available. As a result of this meeting it is expected that there will be numerous mutually beneficial collaborations between American and Chinese scientists and Agencies. The Microbial Food Safety Research Unit of the USDA/ARS excels in the development, dissemination, and validation of models predicting the fate of pathogens in the food supply and contributing these data to the development of risk assessments by regulators worldwide.

Economic Research Service (USDA/ERS)

Tanya Roberts

- The ERS BSE analysis on how much consumer spending has changed since "mad cow" was found in the U.S. is almost ready to be published. Found that consumer spending did not change much!
- Tanya will work with Kerry to prepare a presentation in preparation for the fall workshop/symposium on "Risk Assessment Control Options and Economic Net Benefits". This will be provided to the IRAC at the March meeting.

Food Safety Inspection Service (USDA/FSIS)

Carl Schroeder for Janelle Kause

Risk Assessment Division (RAD)

- The risk assessment on avian influenza was presented to the FSIS Senior Management Council. This will be followed by a final peer review. Neal Golden is the lead.
- FSIS is in the process of modifying the BSE risk assessment based on extensive public comments. Chuanfa Guo is the lead.
- FSIS/RAD was well represented at the SRA annual meeting in Baltimore.
 - i. Held a symposium with CDC FoodNet on attribution to food commodities. They received good feedback!
 - ii. Kerry Dearfield and Steven Schaub co-chaired a symposium on microbial risk assessment (MRA) guidelines. This was very successful and they received good feedback!
- FSIS/RAD is working with USDA/ARS, namely John Luchansky, in planning for the annual ARS/FSIS research conference in February 2007. A workshop to facilitate communication between ARS researchers and FSIS risk assessors will be convened.
- Shabbir Simjee, who used to be at FDA/CVM, and is now in the UK, is editing a book on foodborne infections. Members from USDA/FSIS and FDA co-authored a chapter on Risk Assessment. The book is due out next spring. This is an example of a good IRAC effort. Foodrisk.org (JIFSAN clearinghouse) is also mentioned in the chapter.

Kerry Dearfield

- The MRA symposium at the SRA annual meeting mentioned above clearly showed an interagency effort. There was a tremendous response, really high interest in the symposium. The MRA group plans to continue meeting on a monthly basis. They hope to have a workable draft by the end of next year, perhaps at the next SRA annual meeting. They plan to present at other meetings, e.g., ASM, IAFF. The abstracts are currently on the SRA web site; they will try to get the links to the abstracts at the minimum.
- The MRA chapter mentioned by Carl, the symposium at SRA, and the publication of the paper “Determining the microbiological criteria for lot rejection from the performance objective or food safety objective” in the International Journal of Food Microbiology volume 110, 2006, are all great examples of collaboration by IRAC members agencies! There was much discussion about bringing awareness of the IRAC and producing more IRAC publications and having more IRAC symposia in the future. We should try to publish future workshops as proceedings in a journal. Marianne Miliotis and Wes Long published an article about the IRAC in the Food Safety Magazine June/July, 2006.

Office of Risk Assessment and Cost Benefit Analysis (USDA/ORACBA)

Michael McElvaine

- ORACBA continues work on regulations of BSE with FSIS and APHIS.

- A lecture on epidemiologic and economic modeling of FMD modeling was given at APHIS Thursday, November 14, 2006.
- Mark Powell attended a TSE advisory meeting at FDA the week of December 11, 2006.
- ORACBA hired new agricultural economist, Eliza Majduszka, previously on the faculty of Rutgers University, originally from Rutgers, who is interested in the Nutrition Risk Assessment project.
- Michael McElvaine reminded the participants of the SRA Biological Stressors Specialty Group We need to start thinking of subjects for SRA symposium for the SRA meeting next December.

Work Group Updates

1. Data Gaps Analysis Work Group

The goals of the Data Gaps Workgroup for FY07 are as follows:

- Promote awareness of the list of data gaps with researchers in government, academic institutions, industry, and trade associations. Several approaches to achieve this goal have been initiated and include:
 - Janell Kause and Andy Hwang will provide the list to attendees during the annual ARS-FSIS Food Safety Research Planning meeting, to be held in Shepherdstown, WV, February 21-23, 2007.
 - A weblink to the Data gaps list on www.foodrisk.org has been added to the FSIS risk assessment. A similar link will be added to the CFSAN website, once the planned re-vamping of the risk assessment webpage has been completed.
 - The group has discussed identifying an example that demonstrates a successful collaboration where research addressed a data gap identified in a completed microbial risk assessment and the outcomes from the research had a measurable impact.
- Review and update, as appropriate, the current list. To achieve this goal, experts, as noted below, have been identified to review the Data Gaps List and indicate which data gaps have been or are being addressed (e.g., adding references of research/reports that addressed a specific data gap).
 - Hepatitis A virus, Norovirus, and *Vibrio parahaemolyticus* in shellfish: Marianne Miliotis, CFSAN/FDA
 - *Listeria monocytogenes* in smoked finfish and Lm in fresh-cut vegetables: John Hicks, CFSAN/FDA
 - *L. monocytogenes* in cheese: Steve Gendel, CFSAN/FDA
 - *Salmonella* in eggs and egg products and *Salmonella* in RTE meat and poultry products: Carl Schroeder, FSIS/USDA
 - *Clostridium perfringens* in RTE products: Neal Golden, FSIS/USDA
 - *L. monocytogenes* in ready-to-eat meat and poultry products: Heather Hicks-Quesenberry, FSIS/USDA
 - *E. coli* O157:H7 in ground beef: Wayne Schlosser, FSIS/USDA

- *Salmonella* in poultry and beef: Heejeong Latimer and Neal Golden, FSIS/USDA
- BSE in cattle: Chuanfa Guo, FSIS/USDA

2. Data Utility Work Group

- The work group is currently developing a discussion paper based on the workshop held in September 2004 and the symposium held at the 2005 SRA meeting. The paper will focus on what is data utility and how can it be improved for risk assessments? The symposium was used to obtain ideas from the different agencies and commodities: food, water, and environment.

3. Nutrition Risk Assessment Work Group

- The Nutrition Risk Assessment Work Group continues work toward the Feb 28-Mar 1, 2007 Workshop, "Nutritional Risk Assessment: Bridging Perspectives, Sharing Methodologies, Identifying Data Challenges." Preliminary program and almost all speakers are set at this point. Next steps are facilitating communications among the speakers in order that they may prepare better presentations which will meet the outlined goals. Although the program is not posted yet on the NAS IOM webpage, it is posted on the IRAC web site at foodrisk.org, and you may contact anyone on the work group for copies of preliminary program and registration information. Full workshop information will be posted at NAS IOM website very shortly. There is no registration fee to attend this workshop but you will need to register ahead of time because of space limitations. We are still seeking additional funds from agencies in order to complete all of the goals of the workshop, especially for publication of a proceedings book which will allow widespread dispersal of the presentations and discussions at this seminal workshop. Please contact Marianne Miliotis if you are able to transfer some funds for this project. The program and registration form are attached and enclosed in the IRAC meeting package.

The IRAC technical representatives also discussed possible budgeting for IRAC activities by the individual member agencies.

The next IRAC technical and policy council meeting will be March 22, 2007.

Presentation 11:00 am - noon

“Foodrisk.org” by Steve Gendel

In attendance (* participated by phone)

Mary Brandt
 *Mike Broder
 *James Chen
 *Nancy Crane

Kerry Dearfield
Sharon Edelson-Mammel
Steve Gendel
*John Hicks
*Andy Hwang
Wes Long
Michael McElvaine
Marianna Miliotis
*Tanya Roberts
*Angela Ruple
*Steve Schaub
Carl Schroeder
*Brandolyn Thran
Richard Whiting
*Linda Youngman