

**Interagency Risk Assessment Consortium
Fall Quarterly Technical Meeting
September 13, 2007**

Technical Meeting 9:00 am – 10:30 pm

Introductions

The Interagency Risk Assessment Consortium welcomed four new participants: Stephanie Nicholson, a new epidemiologist at USDA/FNS, and three from CFSAN: Mary Brandt, Wendy Fanaselle, and Babgaleh Timbo.

3 Minute Updates:

Department of Commerce

National Oceanic & Atmospheric Administration (NOAA) Fisheries Services
Angela Ruple

1. Analytical services for the USDC Seafood Inspection Program have moved from the Analytical Laboratory Services in Gloucester, MA to the National Seafood Inspection Laboratory in Pascagoula, MS. The Pascagoula Laboratory is now fully operational in its temporary facilities and plans are under way for construction of the new Laboratory facilities in Pascagoula.
2. NOAA Fisheries has acquired a new Lead Analyst at the National Seafood Inspection Laboratory in Pascagoula, MS. Dr. Calvin Walker, formerly with FDA & EPA, has joined the staff.

Department of Defense

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

- 1) Two new projects are starting up at CHPPM:
 - a) Bioaerosol Exposure Assessment using shower data provided by EPA-NHSRC;
 - b) Development of Biological Military Exposure Guidelines, which will also include Public Exposure Guidelines.
- 2) Continuing efforts include:
 - a) Involvement in the Interagency Microbial Risk Assessment Guideline writing team;
 - b) Finalizing the "Anthrax Report" that IRAC reviewed (THANK YOU again!)

Environmental Protection Agency

Office of Prevention, Pesticides and Toxic Substances
Deborah Smegal

1. Risk Assessments
OPP has completed risk assessments for a number of pesticides, including the phenoxy herbicides 2,4-D, MCPP and 2,4-DP-p.

Endosulfan revised risk assessment is undergoing public comment period. OPP met with USDA (Al Jennings/Wilfred Dunn).

N-methyl carbamate cumulative risk assessment is near completion: OPP met with USDA Office of Pest Management Policy (Al Jennings, Director)

EPA granted quarantine exemptions for para formaldehyde to decontaminate high security animal laboratories; and 3 pheromone products to USDA/APHIS to control light brown apple moth in California (invasive species).

2. Fumigants

These include: ethyl bromide, chloropicrin, metam sodium/potassium, dazomet, 1,3-dichloropropene. Risk management decisions to be complete in early 2008. EPA is currently receiving public comments on Agency's proposal on risk mitigation options.

3. Antimicrobials Division

A FR notice was issued on availability of guidance document "Implementation of Emerging Pathogens and Disinfection Hierarchy for Antimicrobial Products". The guidance proposes to utilize an organism hierarchy to identify products for use with emerging pathogens and to permit registrations. EPA is currently receiving public comments. The public comment period was extended by 60 days to the end of October.

4. Environmental Justice

OPP is developing a training module to better incorporate environmental justice concerns into EPA risk assessments

Office of Research Development/National Homeland Security Research Center

Tonya Nichols

1. Microbial Risk Assessment.

NHSRC is developing a program to determine what is needed to mitigate or clean up a site after a hazard has been released.

Food and Drug Administration

Center for Biologics Evaluation and Research

Hong Yang

1) Risk Assessments for vCJD

Four probable blood transmitted vCJD cases have been reported in the UK. No case has been reported in the US. CBER is conducting a risk assessment for potential risk of transmission of vCJD through blood transfusion in the US. CBER has finished the draft risk assessment, and are preparing the documents for peer review and the report to the next TSE Advisory Committee Meeting.

2) Risk/Benefit Assessments for Blood Donor Referral

CBER is continuing to conduct risk/benefit assessments to evaluate current blood donor deferral policy based on medical, geographic and behavioral risk factors. In the current system, donor deferral and blood testing provide an overlapping protection to ensure safety of blood supply. Continuing diminished donor pool and recent advances in blood testing technology motivate FDA's evaluation on current donor deferral policy and alternative donor deferral options that ensure enough blood supply while not jeopardizing blood safety.

a. They have completed a risk/benefit assessment to evaluate risk (increase of HIV, HBV, etc. infectious units in blood supply) and benefit (increase of blood supply) of alternative less stringent deferrals for Men who have Sex with Men. The manuscript for this risk/benefit assessment is in preparation.

b. CBER developed a draft risk/benefit assessment to evaluate current geographic deferral for malaria risk and alternative options of using new blood testing to replace donor deferral or to shorten the deferral period. They are currently refining the model.

3) Blood Supply Model

As a part of the Pandemic flu preparedness, CBER is developing a blood supply model, which describes blood collection, blood demand and blood surplus in the US. The model predicts sustainability of the US blood supply and evaluates blood management strategies under emergency conditions.

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

Richard Whiting

- 1) Risk Assessment on *Listeria monocytogenes* in smoked finfish.
The team is in the final stages of revising the risk assessment and editing the document.
- 2) Risk Profile on *Listeria monocytogenes* in fresh and fresh-cut produce.
This is also in the final stages of writing up the document. It should be ready for review by the risk managers soon.
- 3) Produce Site Visits
The 2 risk profile teams on Listeria and hepatitis A virus in fresh and fresh-cut produce went on a site visit to lettuce growing fields and 2 processing plants, as well as to a storage and distribution center in California and Las Vegas in August.
- 4) The Joint FDA/Health Canada Listeria in Cheese Risk Profile is well under way and the team has begun the baseline modeling for Brie/Camembert cheeses.

Marianne Miliotis

- 1) USDA/ARS/BARC-FDA/CFSAN Joint Researchers Meeting
FDA/CFSAN researchers, epidemiologists, economists, and risk assessors met with researchers from USDA/ARS/BARC, August 21, 2007. The focus of this meeting was on Produce. We hope this is the first of many meetings; we already have some collaboration and there were discussions for additional collaborations.
- 2) Raw Milk Cheese Risk Profile
This risk profile is a priority for CFSAN's Office of Food Safety. The risk ranking exercise is complete. The team met with risk managers/advisors in June. The Charge is being revised, and team members are actively researching the literature to start developing the risk profile.
- 3) 2nd FDA Scientific Symposium
Nanotechnology: No small Matter at the FDA will take place October 23, 2007 at the FDA White Oak Campus.
- 4) Wendy Fanaselle joined the Office of Food Defense, Communication and Emergency Response/ Risk Assessment Coordination Team in February, 2007.
- 5) John Hicks left the Risk Assessment Coordination Team at CFSAN to go to USDA/FSIS.
- 6) FDA/IFT Risk Ranking Prototype Framework:
 - a. Published a solicitation for a contract to upgrade the prototype to make it available on the web. The contract was awarded to Decisionalysis
 - b. Working with FPA/GMA toxicological committee to upgrade the chemical portion of the prototype to make it useful to government and industry
- 7) ORISE fellow: from the Central Service Laboratories, U.K. will be joining us in October.

- 8) Task Order: Scientific Writing Support for Microbial Risk Assessment: Prepare a report which clearly and transparently describes the model including the assumptions, data used and model output.
- 9) Foodrisk.org undergoing major renovations and has asked for input (test url format) from the IRAC representatives.

Wendy Fanaselle

- 1) FDA/CFSAN issued a contract on the Geographic Information System (GIS) model. FDA/CFSAN would like to use it for ecological niche modeling in produce.

United States Department of Agriculture

Animal and Plant Health Inspection Service (USDA/APHIS)

Robert McDowell

- 1) USDA/APHIS is still working on the citrus canker problem
- 2) USDA/APHIS is also working on the BSE Minimal Risk Rule
- 3) They have started to implement plant and plant product risk assessments.

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

Andy Hwang

1. Dr. James Lindsay of ARS National Program, and Drs. Vijay Juneja and John Luchansky of ERRC/ARS/USDA attended the Combase consortium meeting on September 16, 2007, and the 5th International Conference on Predictive Microbiology in Foods in Athens, Greece, September 16-19, 2007.
2. ARS has signed a Combase collaborative agreement with the University of Tasmania.

Cooperative State Research, Education and Extension Service (USDA/CSREES)

Mary Torrence

- 1) The FY 2008 National Research Initiative (NRI) Request for Applications is posted on the CSREES website: url: <http://www.csrees.usda.gov/funding/nri/nri.html>
- 2) The Epidemiology and Food Safety programs are still separate but under the same title: Epidemiology and Food Safety.
The Epidemiology program focuses on intervention strategies, control measures, and public health impact. The Food Safety program focuses more on the epidemiology.

Food Safety Inspection Service (USDA/FSIS)

Kerry Dearfield

Interagency Microbiological Risk Assessment Guideline Workgroup

- The workgroup is drafting a guideline document that is moving along; a first readable preliminary draft is projected for November 2007.
- Some of the preliminary draft will be presented at the December 2007 meeting of the Society for Risk Analysis.
- The workgroup would like the IRAC to review the draft document, probably early in 2008.
- The guidelines follow the CODEX template for conducting risk assessments and also include planning, scoping, etc. for microbial risk assessments.
- Once drafting is complete, the draft will be peer reviewed, and issued for public comment, etc.

Food Safety Inspection Service Office of Public Health/Risk Assessment Division
(USDA/FSIS/OPHS/RAD)
Janell Kause

1) Interagency Highly Pathogenic Avian Influenza Risk Assessment

This risk assessment was initiated in the fall 2006 at the request of stakeholders to evaluate the potential human health risk of HPAI from the consumption of poultry and eggs should this pathogen enter the U.S. The U.S. Department of Agriculture (USDA), Food Safety and Inspection Service led this effort in collaboration with the Food and Drug Administration, Center for Food Safety and Applied Nutrition and the USDA Animal and Plant Health Inspection Service. FDA/CFSA and USDA/APHIS that involves evaluating the foodborne risk of illness from HPAI associated with poultry and eggs. This was an excellent collaboration between FSIS, FDA and APHIS. The risk assessments have been completed and undergone formal, independent peer review in accordance with OMB guidelines for peer review. In addition, these risk assessments, one for eggs and another for poultry, have received technical review from several federal agencies, including the Agricultural Marketing Service, Centers for Disease Control and Prevention, Food and Drug Administration, Food Safety and Inspection Service, Agricultural Research Service, and USDA's Office of Risk Assessment and Cost-Benefit Analysis. A public meeting will be held jointly by USDA/FSIS, FDA/CFSAN, and USDA/APHIS in the spring 2008.

2) The Food Safety and Inspection Service, Office of Public Health Science, Risk Assessment Division added three new employees:

- Dr. James Withee who is a Ph.D. molecular biologist that served as a AAAS Fellow with the Risk Assessment Division for 2 years and joined the staff to lead risk-based O157 sampling in the Agency.
- Dr. Eric Ebel, who is a veterinarian/epidemiologist and well known modeler in the areas of quantitative food safety microbial risk assessments that recently worked on BSE surveillance for APHIS; and
- Dr. Michael Williams, who is a Ph.D. statistician who worked on risk-based sampling algorithms for APHIS and has joined FSIS to further develop our quantitative models for risk-based allocation of resources.

Carl Schroeder

1) Third Sino US Food Safety Delegation Conference: 9/18-9/19, 2007

The delegation discussed the use of risk assessments to facilitate trade between the two countries.

2) Book Chapter

Members of USDA/FSIS and FDA co-authored a chapter in a book that was released last month: Schroeder, C.M. E. Jensen, M.D. Miliotis, S.B. Dennis, and K.M. Morgan. 2007. Microbial Risk Assessment. In: Foodborne Diseases edited by Shabbir Simjee.

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

Michael McElvaine

1) There have been no new major regulatory issues affecting human health or the environment passing through Departmental clearance this quarter.

- 2) ORACBA continues to work with the various USDA Agencies on such issues as vCJD and trade, methyl bromide, pesticide dispersal models, *Listeria monocytogenes* modeling, and value of life in cost-benefit analyses.
- 3) ORACBA hosted a Risk Forum October 16 at 10 am at the South Agriculture Building in DC. Dr. Mary Fox of Johns Hopkins presented some of her research, "Legacy of US WWI Chemical Weapons Research: Case-Study of Environmental Epidemiology, Risk and Community Health Assessment in Washington, DC". For more information on the lecture or building admittance, please contact Linda Abbott at linda.abbott@usda.gov.

Presentation: 11:00 am – 12:30 pm

FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products" by Janell Kause, USDA/FSIS/OPPHS/RAD, Ann Draughn, University of Tennessee, and Dan Gallagher, Virginia Polytechnic Institute and State University.

Policy Council Meeting: 1:45 – 3:00 pm

IRAC work group updates

1. Data Utility

A discussion paper based on the symposium at the annual SRA meeting December 2005 is being developed.

2. Nutrition Risk Assessment

- (i) February-March, 2007 Workshop Regarding the transcription from the workshop, all that remains is final review of galleys by the authors and sign off by the National Academy of Science (NAS). NAS is hopeful that the report can be published by late September, 2007.
- (ii) Next Steps for Work Group: Schedule a meeting once the report is finally published to discuss what next steps should be.
- (iii) SRA: Michael has been in discussion with the co-chairs of SRA program committee about presenting information and outcomes of the conference at the SRA meeting in early December. They said that there is a real possibility of a cancellation on the oral presentation sessions. If that happens, they would be pleased to have us present. In any case, we might be able to present a poster.

3. Produce Safety Work Group

A work group was formed, including representatives from USDA/ARS/BARC, USDA/FSIS, FDA/CFSAN, and FDA/NCTR. A prospectus was developed and the deliverables of the work group include:

- (i) Conceptual model for a farm to table risk assessment for a specific food (e. g, green leafy vegetables) and a specific pathogen (*E. coli* O157).
- (ii) Initial consideration of how to approach issues related to geographical and seasonal variability.
- (iii) A list of data needs for each component of the conceptual model, including possible intervention/mitigation strategies.
- (iv) A plan for distributing the list of data needs to individuals, institutions, and organizations with interest in conducting and/or funding food safety research.

FY08 Annual Plan

The IRAC will continue holding technical quarterly meetings, where the technical representatives of the member agencies exchange risk assessment and risk assessment – related research information. The semi annual Policy Council meetings will also continue.

Presentations at the IRAC quarterly meetings will also continue:

- i. Continue presentations by agency representatives on current risk assessments.
- ii. Continue presentations by member agencies on issues related to risk assessment.
- iii. Presentations by other organizations, e.g., ILSI, academia.

IRAC Work Groups

The following work groups will continue their efforts:

- Nutrition Risk Assessment
- Data Utility
- Produce Safety

Workshops/Meetings/Mini symposia

- Host or co-host at least two public meetings
 - Conference on Risk Assessment, Economic Analysis, and Foodborne Illness Regulations: The meeting is scheduled for Friday, November 16, 2007 at the USDA/ERS building. The speakers have been invited, and the organizing committee is waiting for confirmation.
 - Co-host a follow-up meeting to the JIFSAN June 2007 Food Safety Prioritization Workshop

Other possible meetings the IRAC may sponsor include:

- Symposium with the focus on statistical sampling
- Workshop on public health-based metrics: from theory to practice
- Antibiotic Resistance: its impact on animal and public health
- Increase participation and host symposia in professional society meetings, e.g., Society for Risk Analysis.
- Hold mini symposia during the IRAC quarterly meetings
 - Possible themes include:
 - chemical risk assessments
 - pesticide residues and their impact on animals/people

In attendance (* participated by phone)

Mary Brandt, FDA/CFSAN
Bob Buchanan, FDA/CFSAN
Kerry Dearfield, USDA/FSIS
Alison Edwards, FDA/CFSAN
Barry Hooberman, FDA/CVM
Janell Kause, USDA/FSIS/RAD
Robert McDowell, USDA/APHIS*
Michael McElvaine, USDA/ORACBA
Marianne Miliotis, FDA/CFSAN
Tonya Nichols, EPA/ORD/HSNRC*
Stephanie Nicholson, USDA/FNS*

Tanya Roberts, USDA/ERS*
Angela Ruple, NOAA Fisheries Service*
Carl Schroeder, USDA/FSIS
Deborah Smegal, EPA/OPPTS
Brandolyn Thran, DOD/CHPPM*
Mary Torrence, USDA/CSREES*
Richard Whiting, FDA/CFSAN
Hong Yang, FDA/CBER
Additional people came to hear the presentation on the FSIS *Listeria monocytogenes* risk assessment