

**Interagency Risk Assessment Consortium
Technical Quarterly Fall Meeting
December 17, 2008**

Technical Meeting 9:00 -11:30 am

Introductions

Brief overview of technical rep responsibilities

5 minute Agency Updates

Department of Defense

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

- *USACHPPM Technical Guide 316: Microbial Risk Assessment for Aerosolized Microorganisms.* The technical guide is being finalized.
- *Physiological Assessment of Microbial Effects (PhAME) Work Group.* CHPPM has the Lead. The group is close to finishing technical report comparing classical and Bayesian statistics for inhalation anthrax dose-response analysis.
- *Exposure Guidelines for Inhalation Pathogens.* CHPPM is starting to establish a working group on derivation of exposure guidelines for inhalation pathogens. If anyone knows of anyone who might like to participate, please contact Brandolyn Thran at: brandolyn.thran@us.army.mil
- *Deposition and Resuspension of Particles.* CHPPM is starting to write a comprehensive report on 3 years work with Penn State University on deposition and resuspension of particles.
- *Microbiologist Position.* CHPPM is hoping to put out job announcement for a microbiologist soon.

Department of Health and Human Services

Food and Drug Administration

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

- *Risk Profiles*
 - Hepatitis A Virus in Fresh and Fresh-Cut Produce. Response to reviewers' comments is almost complete; the document is currently being edited by a CFSAN scientific writer.
 - Pathogens in Cheese. The draft document on soft cheeses is currently being reviewed by the dairy risk managers
 - Norovirus Transmission. The document is being revised after review by the risk managers. It will be sent for external review in January 2009.
 - *Listeria monocytogenes* in Fresh Fruit and Vegetables. Briefing of the risk managers took place January 22, 2009. The team is waiting for their comments.
- *Risk/Safety Assessments*

- *Listeria monocytogenes* Cross-Contamination at Retail. This project is in collaboration with USDA/FSIS. A federal register notice/data call is in clearance with hopeful publication date in early January. Model construction is in progress.
- *Listeria monocytogenes* in Soft Ripened Cheese This project is in collaboration with Health Canada. The basic model is in place; the team is working on improving implementation of some distributions/variables, and planning to meet with the risk managers in January.
- Other Risk/Safety Assessments Currently under External Review
 - Gluten (for Gluten Free labeling)
 - Melamine
 - Methyl Mercury
- *Other Issues*
 - Risk Ranking Tool. The produce risk ranking tool (developed by RTI under contract) will undergo external peer review early next year. An inventory of methods/ tools for risk ranking and risk prioritization (also via RTI) is under development and can be shared with IRAC interested members.
 - iRISK. This User-friendly web-based tool for ranking risk of hazard-food combinations in user's own repository: includes both microbial and chemical hazards. Contract completed end of September 2008. Training of CFSAN and folks from other agencies took place in October. Soon to be available on-line to the IRAC and others for beta testing.
 - Uncertainty Analysis (with JIFSAN and the French National Institute for Agricultural Research - INRA). This project will look at how risk and safety assessment documents use various terms and phrases to discuss and describe uncertainty, and how these usages vary between the more technical content and the summaries contained in abstracts or executive summaries.

Center for Veterinary Medicine (FDA/CVM)

- *CODEX taskforce on antimicrobial resistance*. The three documents Risk Management; Risk Assessment, and Preliminary Risk Management Activities (formerly Risk Profiles) will be merged into 1 final guidance document. United States has the lead for the harmonization efforts. The first draft should be completed by May, in anticipation for the meeting in Seoul, Korea in October, 2009.
- *Guidance document on genetically engineered animals*. The comment period closed November 18, 2008. CVM is currently reviewing and responding to the comments.

Environmental Protection Agency

Office of Office of Prevention, Pesticides, and Toxic Substances (OPPTS)

- *Nanosilver*. EPA OPP received a recent citizen petition for rulemaking on the EPA regulation of nanosilver as a pesticide. On November 19, 2008, EPA issued a federal register notice requesting public comments on the nanosilver citizen petition by January 20, 2009.
- *Melamine*. EPA and FDA have been meeting on melamine. It is not a pesticide but trichloromelamine is an antimicrobial pesticide and cyclopropyl melamine (cyromazine) is a related pesticide. EPA will share non-confidential business data, reviews and memos with FDA.

- *OPP met with Tea Industry.* Tea Industry interested in Global Standards Harmonization of import tolerances for tea. Until recently the US did not inspect tea for pesticide residues. Tea is grown in many countries that do not have strong regulation oversight and some chemicals used on tea are no longer registered in the US. Industry will provide EPA with a list of pesticides they are interested in and EPA will try to provide feedback on those that can go forward and those that have risk issues.
- *Colony Collapse Disorder.* OPP has lots of activity related to colony collapse disorder. This was discussed at an OECD working group on pesticides and how the US and Canada are responding to pollinator declines via testing programs, research, risk mitigation activities and communication/outreach efforts. The US and Canada are trying to improve protocols for pollinator studies and risk assessment methodologies. There was a recent Forum at University of Maryland with USDA that discussed pollinator declines and USDA research related to pesticides, nutrition and pathogens on these declines. EPA also met recently with the natural Resources Defense Council (NRDC) on this issue.

Office of Research and Development (EPA/ORD)

- *Symposium on Ground Water-Borne Infectious Disease Epidemiology.* EPA sponsored a symposium Dec. 2 – 4, 2008 at the Carnegie Institution of Washington to discuss research being conducted on groundwater-borne infectious disease epidemiology and pathogen occurrence in groundwater. The meeting consisted of a series of presentations by EPA researchers and researchers funded through EPA's Science to Achieve Results (STAR) grants program.
- *Child-Specific Exposure Factors Handbook.* In October, EPA published its final report on Child-Specific Exposure Factors Handbook (EPA/600/R-06/096F), which was prepared by the National Center for Environmental Assessment (NCEA). This report is an update of the 2002 interim final version of the handbook. It provides updated information on various physiological and behavioral factors used in assessing children's exposure to environmental contaminants including: Water ingestion; soil ingestion and non-dietary factors; inhalation rates; dermal factors including skin surface area and soil adherence factors; consumption of retail and home-grown foods; breast milk intake; body weight; activity pattern data; and consumer product use.
- *Nanotechnology.*
 - EPA/ORD/NCEA is working on nanotechnology case studies following material from “cradle to grave” using the Comprehensive Environmental Assessment. Two case studies are being developed on doing risk assessment on nanomaterials: one is being reviewed, and the second is being finalized. Possibly these can be presented to the IRAC during the summer quarterly meeting.
 - EPA/ORD is involved along with other EPA offices and Federal Agencies in an OECD nanotechnology harmonization effort to coordinate research internationally on various nanomaterials.
 - EPA's white paper on nanotechnology is available at: <http://www.epa.gov/osa/nanotech.htm>
 - An international workgroup/consortium is planning a series of workshops on “Analytical Tools for Characterization of Nanoparticles in the Food” to discuss the ongoing progress of the group. This is in the proposal stage (see abstract below) and so any input is requested from parties interested in being involved in this consortium.

NanoFood Abstract:

Applications of nano-sciences in the food field require new detection tools and technologies to support monitoring and risk assessment. Further, nanomaterials may be used as food additives or may migrate from food packaging into food sources. We have formed the NanoFOOD consortium consisting of European and American regulatory agencies and universities to develop appropriate methods for detecting and identifying man-made nano-particles in food and drinks. These methods will be applied in future risk assessment studies, in monitoring of consumer exposure and in environmental impact/dispersal studies. Case studies will be performed to examine the risks associated with specific engineered nanomaterials in food sources. Our proposal focuses on developing validated detection methods, reference materials and sample preparation. We intend to relate the results of this project to on-going research projects.

- *EPA's Risk Assessment Forum*
The link to the combined list of publications generated by EPA's Risk Assessment Forum is provided: <http://www.epa.gov/raf/pubalpha.htm>. A more general overview can be found at www.epa.gov/osa.
- *Second Annual MRA Conference*
EPA's National Homeland Security Research Center and National Center for Environmental Research is cosponsoring an expert workshop on dose-response challenges in microbial risk assessment in Atlanta, GA, April 21-23, 2009.

Office of Water (EPA/OW)

- *Microbial Risk Assessment Protocol for Water-Based Media*. The draft MRA protocol is undergoing peer review and then will be examined as a "consultation with the EPA's Science Advisory Board
- *Microbial Risk Assessment Approaches for Environmental Media*. EPA/OW's work with the World Health Organization on harmonization is to build on commonalities and general tools, methods, and approaches for risk assessment that span all of the various risk assessment needs for various environmental media and various countries' or regions' requirements. They will look at ways to also harmonize the WHO Lexicon with the MRA Thesaurus of terms and definitions.

United States Department of Agriculture

Animal & Plant Health Inspection Service (USDA/APHIS)

- *Standards for Importation of Beef*. APHIS is in the process of aligning our BSE regs for beef and cattle with those of the OIE.
- *Phytosanitary Risk Assessment*. In October, in collaboration with USDA's Foreign Agriculture Service (FAS) and the Texas A&M University, several APHIS staff members (PPD RAS) provided training in phytosanitary risk assessment for a group of African academics.

Agricultural Research Service (USDA/ARS)

- *Research*. ARS is continuing to do research for FSIS.
- *ComBase*. The ComBase Consortium has agreed in principal to allowing ComBase to be translated into Japanese, and the database to be located in Japan National Food

Research Institute in Tokyo. There are a few legal issues to resolve but it looks a go. This could eventually lead to other locations and languages.

- *European Safety Authority (EFSA) consultation meeting on Campylobacter in food Commodities*. EFSA is looking for interventions at the farm level. More data and better rapid detection methods are needed. The report of the meeting will be out in late spring, 2009.

Economic Research Service (USDA/ERS)

- *Recent Food Safety Publications*.
 - Buzby, Jean C., Laurian J. Unnevehr, and Donna Roberts. 2008. *Food Safety and Imports: An Analysis of FDA Import Refusal Reports*, Economic Information Bulletin No. (EIB-39) 47 pp, September. This report examines U.S. Food and Drug Administration (FDA) data on refusals of food offered for importation into the United States from 1998 to 2004. Available at: <http://www.ers.usda.gov/Publications/EIB39/>
 - Kuchler, Fred, Mark Ribadou, and Lisa Mancino. 2008. "Market Failures: When the Invisible Hand Gets Shaky." *Amber Waves*. Volume 6 (5): 34-39. In one section of this paper, the article argues that food safety concerns continue to make headlines because consumers are unwilling to pay higher food prices in return for increased safety or there is an information gap that is causing the market for food safety to fail, i.e. consumers don't believe what manufacturers claim. The paper then asserts that companies overcome the information gap through third-party certification and branding, but, since these practices are not universal, consumers' demands for safety may go unmet without government oversight.

Food Safety Inspection Service (USDA/FSIS)

- *Risk Management Metrics Document*. USDA/FSIS is incorporating this metrics issue into its risk assessments. At SRA they put forward how to apply ALOPS, SOP, PO, etc. to construct sampling plans. E.g., the USDA/FSIS *Clostridium perfringens* risk assessment.
- *Codex Committee on Food Hygiene 40th Session*.
 - *Enterobacter sakazakii* in infant and follow up formula. The Committee did not determine criteria for *E. sakazakii* in follow-up formula, but agreed that criteria were needed for *Salmonella*.
 - *L. monocytogenes* in Ready-to-Eat Food. Microcriteria for foods that do and don't support growth were passed and submitted to the Commission for approval. The use of metrics as an alternate way of setting criteria was also included. The guideline also focuses on environmental and process control testing.
 - The *Salmonella* and *Campylobacter* in broilers proposed draft guidelines document is still under way. It includes hygienic practices from farm to fork.
 - The Leafy Green Vegetable Code of Hygienic Practices document was sent back to the workgroup for continuing work.
 - The Code of Hygienic Practices for *Vibrio* spp. in seafood document was moved to Step 3.
 - New work on norovirus in food was accepted.

USDA/FSIS/RAD (Risk Assessment Division)

- *Risk Assessment Profile in Beef Establishments*. This study looked at various intervention strategies to see how they might affect the risk profile with respect to *E. coli* O157:H7; to see what contaminants are in the beef, and how they can be defined in risk assessment profiles.

- *Non Intact Beef Risk Assessment.* USDA/ARS is conducting research to provide data for this risk assessment.
- *Catfish Regulation.* Dr. John Johnston, Senior Risk Analyst within the Office of Public Health Science/Risk Assessment Division, is leading the development of a quantitative risk assessment for various hazards associated with catfish. This risk assessment, along with cost-benefit analysis, will be used to inform FSIS' rulemaking for catfish and be presented to OMB in spring 2009.

Foreign Agricultural Service (USDA/FAS)

- *Mission of FAS.* The mission of FAS is to support US exports for all commodities and to determine how trade barriers affect exports from the US. FAS also promotes, plans, and implements capacity building activities in support of strategic objectives.
- *Workshop on Microbial Standards.* In collaboration with other federal agencies, including FDA, FSIS, IPPS, ICMSF, a workshop was held in Nicaragua on how to set Microbiological Standards. Central America revised some of their standards based on this workshop. Central American Countries set their own private standards, based on no real scientific evidence vs. those determined by CODEX.
- There are proposals to set standards for pesticides in China.

Work Group Updates

- *Produce Safety.* The draft "Lessons Learned" document from the Leafy Greens Research Needs workshop has been prepared and is currently under review by the work group. This will be followed with a review by all project participants. The model will be revised based on these lessons and document review, and then re-run with the entire group (via web-ex meeting).
- *Data Utility.* The work group organized and held a poster platform session on "Practicing the Science and the Art: Real World Case Studies in Sample Collection for Chemical and Microbial Risk Assessment" at the SRA Annual Meeting, December 8-10, 2008. A paper based on a workshop in 2004 and a symposium at SRA in 2005 was published in the December 2008 issue of Human and Ecological Risk Assessment. Citation: Thran, B.H. and L.V. Tannenbaum. 2008. The Concept of Data Utility in Health Risk Assessment: A Multi-Disciplinary Perspective. Human and Ecological Risk Assessment 14(6)1104-1117.

IRAC Annual Plan (Separate document attached)

The Interagency Risk Assessment Consortium (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.

Work Groups

The IRAC accomplishes much of its work through work groups formed to address specific topics or issues. Work groups should 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. New work groups for FY09 include:

- *Sampling Plans*

The group will focus on sampling plans. A prospectus with scope, goals, and deliverables of the group is being developed. Some ideas for the workgroup include: Education on the DQO process that some agencies use, and find out what processes other member agencies use, and how the agencies are developing their sampling plans at the present time.

- *Nanotechnology*

There were several suggestions for projects for this group, one possibility being developing an inventory of all ongoing work, including:

- NTP-National Toxicology-tox testing on nano silver-tentative
- Wilson center-case study on nano silver in food
- IFT report on nanoparticles in food (2007)
- JIFSAN workshop on nanotechnology (2006)
- ISLI/EPA Risk/Safety assessment of nano technology and inhalation (2005)
- WHO/FAO Expert elicitation on nanotechnology to be coming out soon
- National Nanotechnology Institute
- International conference on the environmental Implications and Applications of Nanotechnology to be held June 9-11, 2009 at the University of Massachusetts, Amherst.

- *Susceptible Population Workgroup*

The workgroup will attempt to identify the different susceptible subpopulations. They will also try to identify the data gaps. Formulate a planning committee to figure out what would be needed to present at a conference. If the scope of the workgroup is bigger than just food, EPA/ORD would be interested. USDA/FSIS is interested in education on susceptible subpopulations. Current information is that 18% of the population is 60 years or older. Also in what way do you consider a person susceptible, there are many different ways a people can be considered susceptible, and how does this affect the outcome. The question on whether immunotoxicants should be included in the scope of the project. EPA has developed a guideline on how to evaluate immunosuppressive chemicals.

Potential Workshops/Meetings/Mini Symposia

- *Susceptible subpopulations workshop.*

One potential deliverable of the susceptible population work group would be to co-sponsor a workshop with the National Academies' Institute of Medicine's (IOM's) Food Forum on "Accessibility in aging population"

- *Potential co-sponsorship with the SRA Biological Stressors Specialty Group (BSSG).*

Several topics have been discussed as possible themes:

- Enabling technologies: bioinformatics/informatics, info sharing, nanotech, genomics, proteomics
- Global thresholds in collaboration with ILSI and BSSG
- Product Safety: RA and Epi
 - Food, biologics, water, environment, air, drugs, devices
- State of the State of RA in the different agencies, institutions, etc.
 - What we have done, and where we are; what agencies are currently doing that is different from other agencies.

One possibility would be to tack on to an already established meeting, or have a small meeting this fiscal year locally, and have a larger symposium at a national scientific meeting such as IAFP, SRA, or ASM.

The possibility of using presentations from the "State of the State of Risk Assessment", if selected for this symposium to be used as a teaching tool for APEX initiate-tools for Asian developing economies was discussed.

Other Issues

- *Review of the Interagency Microbial Risk Assessment Guideline.* Steve Schaub, EPA/OW) thanked the CFSAN representatives for their extensive review and indicated that they would incorporate comments into revisions to the guidance.
- *The EPA Microbial Risk Assessment Thesaurus.* EPA/OW will pursue linkage of their Thesaurus of MRA Terms and Definitions to foodrisk.org and have established a small coordination team to get this accomplished. At this time EPA will want to maintain ownership and insure integrity of the Thesaurus but in the future it could be expanded or modified to consider a broader scope of inclusion of comprehensive food risk assessment terms and definitions.
- On the 2nd day in one break-out group the chemists and biologist separated to address a list of questions developed by the break-out group on day one. Of interest was that the reports back from these two sub-groups were very similar. Information was requested on available documents from EPA that relate to screening level exposure assessments either pre-market or post-market. Several participants provide information.

Presentations 11:45 am – 01:00 pm

- 11:45 – 12:15 am: “Global Threshold Project” by Steve Olin, ILSI
- 12:15 – 12:45 pm: “A Quantitative Risk Assessment of *Listeria monocytogenes* in French Cold-Smoked Salmon” by Regis Pouillot, DHHS/FDA/CFSAN
- 12:45 – 1:00 pm: “Developing an Understanding of the Transmission Pathway as a Means of Potential Control Options” by Wendy Fanaselle, DHHS/FDA/CFSAN *
- * Due to meeting running over, Dr Fanaselle was not able to complete her presentation; this will be rescheduled for the next IRAC meeting, to be held April 1, 2009.

In attendance (* participated by phone):

Dare Akingbade, USDA/FSIS/RAD
Stephanie Briguglio, JIFSAN intern
*Mike Broder, EPA/ORD
*Rebecca Brown, EPA/ORD
Elizabeth Calvey, DHHS/FDA/CFSAN
Kerry Dearfield, USDA/FSIS
Sherri Dennis, DHHS/FDA/CFSAN
Denise Eblen, USDA/FSIS/RAD
Sharon Edelson-Mammel, DHHS/FDA/CFSAN
Wendy Fanaselle, DHHS/FDA/CFSAN
Villie Flari, DHHS/FDA/CFSAN
Steve Gendel, DHHS/FDA/CFSAN
Eric Grant USDA/APHIS
Maureen Gwinn, EPA/ORD
Wendy Hall USDA/APHIS
*Barry Hooberman, DHHS/FDA/CVM
Joy Lee, USDA/FSIS/RAD
Cristina McLaughlin, DHHS/FDA/CFSAN
Marianne Miliotis, DHHS/FDA/CFSAN
Mike Ollinger, USDA/ERS
Regis Pouillot, DHHS/FDA/CFSAN
*Angela Ruple, NOAA Fisheries

Steve Schaub, EPA/OW
*Cindy Roberts, EPA/ORD
*Joyce Saltsman, DHHS/FDA/CFSAN
Debbie Smegal, EPA/OPPTS
*Sarah Taft, EPA/ORD
*Brandolyn Thran, DOD/CHPPM
*Mary Torrence, USDA/ARS
Isabelle Walls, USDA/FAS