

**Interagency Risk Assessment Consortium Quarterly Meeting
March 30, 2006**

Technical Meeting 9:00 am – 12:30 pm

Introductions

Welcome to our new RAC technical representatives: James Chen, FDA/NCTR and David Oryang, USDA/APHIS.

Presentation 1

Diarrhea Etiology and Risk Factors – an interim analysis by Donna M. Denno, University of Washington School of Medicine, Seattle, Washington, and Phillip I. Tarr, Washington University School of Medicine, St. Louis, Missouri.

Agency Updates

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

Tabitha Tucker

- Conducting a risk assessment on rift valley fever
- Close to completing risk assessment report on anthrax; hope to use RAC to review the document.
- Planning a Health risk assessment course for June 19-23, 2006 at Aberdeen Proving Ground, MD. The course is free, and can register on the CHPPM web site: <http://chppm-www.apgea.army.mil/>

Environmental Protection Agency Office of Research and Development (EPA/ORD)

Cindy Roberts

- The recently established Center for Advancing Microbial Risk Assessment (CAMRA) held its kick-off meeting February 6-8, 2006 in Pennsylvania. This was the first face-to-face meeting of the principal investigators. The focus of the Center is on biological agents; they plan to build a natural network for microbial risk assessment on knowledge and management. Two examples include developing microbial risk assessment models and evaluate different mitigation strategies. Information on the meeting will be posted on their web site.
- A workshop on Biosolids and Exposure Measurement was held March 16-17, 2006 in Ohio. Presentations included:
 - A report from the National Research Council identified better data and methods on biosolids and exposure measurements.
 - EPA has examined several issues relevant to exposure tolerance to biosolids.

- The EPA Science Forum will take place May 16-18, 2006 in the Ronald Reagan Building, Washington DC. Registration is free.

Environmental Protection Agency Office of Water (EPA/OW)

Stephen Schaub

Office of Water

- Continuing with development of thesaurus on microbiological terms used in risk assessment - ~185 page document. Once completed will post on the Clearinghouse.
- Developed human health ambient water criteria methodology; now an agency-wide document.
- Tiered downward using risk assessment approach to water-based microbiological hazards.
- Developing a microbial risk assessment protocol, which is an extended version of the human health tiered document.
- Co-sponsoring with EPA/ORD a workshop on acceptable microbial disease risk , October 6-8, Tucson, AZ, by the American Academy of Microbiology

EPA Risk Assessment Forum

- Developing internally a microbial risk assessment guidance document.
- Working in a parallel effort with USDA/FSIS for about 6 months on a microbial risk assessment guidance document. The steering committee involved consists of approximately 12 people, with Kerry Dearfield and Steven Schaub serving as co-chairs. This document will be taken down to a more practical level, the risk assessor level, i.e., to serve as a manual for the risk assessors. Currently evaluating 4 -5 different risk assessment frameworks (e.g., FAO/WHO, ILSI, etc.) to see how they might apply as the skeleton in the development of the document. Are there other frameworks to consider? Once the document has been drafted, will bring to the RAC for review.
- Looking at microbial risk assessment models being developed by EPA/OW
- Have a contract for risk communication tools and methods
- Sponsoring an immunotoxicology colloquium late fall in Washington DC on children's health and prevention, including microbial groups, to determine immune factors, disease , life stages, and how immunological factors influence microbial disease; will also look at different approaches that can be applied.

Food and Drug Administration Center for Biologics Evaluation and Research (FDA/CBER)

Hong Yang

- Two ongoing risk assessments:
 - 1) To assess increased risk of transfusion transmitted diseases (HIV, HBV, HCV and HTLV) associated with potential relaxation of blood donor deferral. Current policy defers Men who have Sex with Men (MSM) since 1977 from donating the

blood. The proposed deferrals are MSM having risk behavior in most recent one year period or MSM having risk behavior in most recent 5 years. In the last decade, new blood testing techniques including NAT (Nuclear Acid Testing) have been developed, which significantly improved sensitivity of testing and shorten the window period of the disease. CBER is conducting a risk assessment to reevaluate the scientific base of the current deferral policy in the NAT era. Preliminary results were presented at a FDA workshop in March 2006. The preliminary risk assessment identifies data gaps in some critical input parameters such as prevalence of the disease associated with risk behavior. More data are needed for a risk assessment that can support an informative regulatory decision.

2) To assess the risk of vCJD from human-plasma derived coagulant products. This is actually divided into two risk assessments.

(i) Factor XI. This product is made in the UK and used by a small number of US patients in an Investigational New Drug study. This product shows a potentially high risk.

(ii) Factor VIII. This product is made in the U.S. The risk is relative low, but used by larger population, mainly, hemophilia patients. Prevalence of asymptomatic vCJD is highly uncertain, and therefore, risk outcome is highly uncertain. Based on input from the TSE advisory committee, the risk assessment has been updated. CBER is currently working on how to communicate the risk.

- CBER is interested in Analytica training. If any other member agencies are interested in taking the course in DC area, we may be able to work with Analytica to put together a training course.

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

Richard Whiting

- Two risk assessments on *Listeria monocytogenes* under way:
 - (i) *L. monocytogenes* in smoked finfish
 - (ii) *L. monocytogenes* in cheese in collaboration with Health Canada. Two cheeses will be evaluated: brie and camembert
- Dr. Robert Buchanan participated in the next Kiel conference (Kiel 3) April 1-8, 2006 in Kiel, Germany to review and discuss 7 working papers: one general paper on how to set food safety objectives (FSO's), and 6 papers on setting FSO's for specific food-pathogen pairs.

Marianne Miliotis

- Continuing development of the virus risk profiles on transmission of norovirus and hepatitis A virus in fresh produce. Format of virus risk profiles has been

revised to make them more risk manager-friendly, i.e., rewriting them to be used as a tool by the RM's.

- Exciting news is that we're planning a field trip of the RP team to go visit a docked cruise ship in Miami May 2, 2006. Focus of our risk assessment is "Options for Reducing Norovirus Transmission from Food Handlers to Ready-to-Eat Food". We will give a brief presentation on the background of the reason we are there, and will be taken on a tour of the ship, including the kitchen and eating facilities to find out:
 - 1) What controls (e.g., gloves; no ill workers; disinfecting surface contact areas) are in place for preventing norovirus transmission in the kitchen, eating facilities, such as buffet bars, restaurants, day care facilities aboard ship, etc.?
 - 2) What disinfectant methods are used and how effective are they in preventing transmission and/or in clean-ups after an outbreak?
- IFT Risk Ranking Project is now complete. We have the final report.
- We are really trying to promote the RAC, so Wes and I wrote an article on the RAC, which will be in the next issue of the Food Safety magazine.

Sherri Dennis

- Last year the team for the *L. monocytogenes* risk assessment on smoked finfish visited a seafood plant to help with model development. This was so successful that the CFSAN Staff College is funding similar trips for other ongoing risk assessments this year via the Professional Development Funding Program.
- An Expert Elicitation group has been established. It is trying to raise awareness of the subject by sponsoring seminars.

John Hicks

- In addition to the risk assessments on *Listeria* in smoked finfish and in cheese, CFSAN is also continuing to develop a risk profile on *L. monocytogenes* in fresh cut produce.
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Food and Drug Administration Center for Veterinary Medicine (FDA/CVM)

Gregg Claycamp

- CVM microbial risk assessments involve basic microbial food safety related to antimicrobial use in animals.
- Most new antimicrobial drug applications fall under the qualitative risk assessment framework in Guidance for Industry #152. The default in this guidance is a qualitative risk assessment; however, quantitative assessments are both encouraged and preferred.
- Working with the Office of Compliance on risk-based prioritization of inspections for GMPs and other compliance programs
- Established an animal feed safety system collaboration with industry that covers a diverse array of potential hazards in animals feeds. The overlap with microbial risk assessment is that exposure to microbial toxins remains a significant concern.

- The environmental team is attending an interagency group through OSTP looking at pharmaceuticals and the environment.

Food and Drug Administration National Center for Toxicological Research
(FDA/NCTR)

James Chen

- James (Jim) is a biostatistician and new to NCTR
- William Slikker is the acting Center Director for NCTR
- Angelo Turturro has retired
- The EPA IAG *Cryptosporidium* risk assessment project is complete. A paper was published in Risk Analysis, October issue, on how good the model fits the data.
- Dr. Ralph Kodell, Director of Division of Biometry and Risk Assessment will present: “Hierarchical Probabilistic Models for Managing Uncertainty” at the 2006 FDA Science Forum.
- Division of Biometry and Risk Assessment at the NCTR has been developing new procedures using the dose-response model to estimate the reference dose from animal models.
- Jim would like to talk to other biostatisticians of the RAC member agencies.

JIFSAN

Wes Long

- JIFSAN now has established a 9 course program of Food Safety Risk Analysis courses.
- The distance learning approach offers 4 courses so far. Over 250 students have enrolled since its inception in 2004.
- The JIFSAN program has been accepted, with some modifications, as part of a graduate certificate program.
- The summer risk analysis program will offer 6 of the 9 courses in Washington DC this summer over a 3 week period.
- Information on all these courses can be found on the Clearinghouse web site: <http://www.foodrisk.org>

NOAA Fisheries

Angela Ruple

- NOAA Fisheries in MS is recovering and rebuilding from Hurricane Katrina.
- For the last 7 months they have been assessing microbial and chemical risks left from the hurricane.
- Four people from the staff participated in the JIFSAN distance learning courses.
- Employees are working in temporary locations in modular structures.

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

David Oryang

- APHIS is developing methods for risk-based targeting of inspections. At the Center for Plant Health Science and Technology (CPHST), APHIS is developing geo-spatial methods that are geographic and climate-based, looking at the outbreak histories of pests internationally, and relating them spatially to climate/season. In this way predictive tools can be developed to target inspections (resources) at the most appropriate times,(i.e., to guide inspectors what, where, when, and how much to inspect).
- APHIS is involved in issues of the invasive potential of plant pathogens and developing tools for new and innovative methods of prediction.
- BSE
 - APHIS is proposing to amend the regulations on the importation of certain additional commodities from minimal risk regions (Canada).
 - In January there was a new case of BSE in Canada.
 - APHIS is using the Harvard risk assessment to determine the exposure level. It has been updated to reflect the impacts of regulatory changes put in place over the past three years.
 - In March there was a BSE case in AL, U.S. More information can be found on the APHIS website.
- Avian Influenza. The Emergency Management Center was activated. A surveillance plan for migratory birds has been formulated. More information can be found on the APHIS website.

United States Department of Agriculture Agricultural Research Service/Eastern Region
Research Center (USDA/ARS/ERRC)

Mark Tamplin

- Dr. Shiowshuh Sheen is a new employee at ERRC; he is working on contamination modeling in processing and leading the process modeling work.
- ERRC is in the 6th month of the new 5 year research plan. The following projects are under one big umbrella project:
 - Network theory modeling of microbial competition
 - Modeling pathogens in formulated foods and smoked salmon
 - Surface transfer in slicing, e.g., *L. monocytogenes* in sliced gravad salmon
 - Developing better methods of model robustness - looking to hire a computational biologist
 - Developing methods to identify cellular markers during the different growth phases: lag, exponential, and stationary - to start in October by a visiting scientist
- Visiting Scientists
 - Kaarina Aarnisalo, from VTT Finland is a visiting scientists at ERRC from March – May, 2006 will work on the Salmon surface transfer project

- Montserrat Hernandez, from the University of Queretaro, Mexico, is a visiting scientist at ERRC from Sept. 2005-Sept 2006, she is developing models for single cell lag time distribution as a function of stressors
- Joseph Baranyi, from UK, will be a visiting scientist at ERRC from April 2006-Dec 2006; he will work on modes of microbial competition.
- Completed 2 projects for FSIS
 - *Bacillus anthracis* in ground beef, and *Yersinia pestis* in ground beef
- In collaboration with FSIS, ERRC is working on a Predictive Microbiology Portal project. It is estimated to be completed by June-July, 2006. It is linked to on-line data, such as ComBase, models and regulatory information to help simplify and interpret models for small and very small businesses. Risk assessors can also use this portal.

United States Department of Agriculture /Food Safety Inspection Service/Office of Public Health (USDA/FSIS/OPHS)

Kerry Dearfield

- FSIS is focusing risk assessment efforts on risk-based verification sampling and inspection for a variety of pathogens, including: *Listeria monocytogenes*, *Salmonella*, and *E. coli* O157:H7. These efforts are aimed at efficiently utilizing FSIS resources.
- Due to an increased prevalence of *Salmonella* in poultry; FSIS is focusing its risk assessment efforts to address this issue.
- FSIS has completed several of its large scale quantitative risk assessments, including *Salmonella* Enteritidis in shell eggs, *Salmonella* spp. in egg products, *C. perfringens* in RTE meat and poultry products, *Salmonella* in RTE meat and poultry products, risk-based Lm verification, and BSE. These are complete and found on the FSIS website.
http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp
- Heads-up on 2 meetings:
 - FDA Science Forum: Conference Center, Washington, DC, April 18-20, 2006.
 - Society for Risk Analysis (SRA) workshop on OMB proposed risk assessment bulletin, George Washington University, May 23-24, 2006 (http://www.sra.org/docs/OMB_Registration.pdf).

United States Department of Agriculture Office of Risk Assessment and Cost Benefit Analysis (USDA/ORACBA)

Michael McElvaine

- ORACBA is seeking an agricultural economist at the GS 13, 14, 15 level
- Jim Schaub is dealing with Methyl Bromide.
- Linda Abbott is working with ARS on the Conservation Water Pesticide program.

- Mark Powell is working with APHIS on BSE, focusing on prevalence.
- Michael McElvaine is participating in a food safety conference in Moscow sponsored by the University of Maryland through a grant by the USDA Foreign Agricultural Service, mid to late April to discuss international issues.

New Work Group Updates

Omics Work Group

Work group is forming with Jim Withee (USDA/FSIS/OPHS) as the lead. He is looking for a co-lead among the member agencies.

Nutritional Risk Assessment Work Group

A work group has been established with Michael McElvaine as the lead. Members include: Sherri Dennis, Wes Long, Marianne Miliotis, Donna Robie, Elizabeth Yetley, Etta Saltos, and Nancy Crane. The kick-off meeting took place March 21, 2006. The group is still seeking additional nutritionists from RAC member agencies.

Presentation 2 1:30 – 2:30 pm

The OMB Proposed Risk Assessment Bulletin by Nancy Beck, Office of Management and Budget. Approximately 40 people attended this presentation.

Policy Council Meeting 2:45 – 4:00pm

The RAC policy council representatives agreed that the symposium cosponsored by the RAC held October 31- November 1, 2005 “ICMSF/ RAC/ ILSI/ IAFP/ IFT Symposium - Relating Microbiological Testing and Microbiological Criteria to Public Health Goals” would be accepted as the RAC’s annual meeting open to the public for FY2005. The remainder of the fiscal year will focus on planning meetings and identifying means of transferring funding for these meetings among the RAC member agencies.

Other RAC Issues discussed include Agency policy issues that the RAC policy Council can help with, such as

- i. Continuing to have the RAC serve as a peer review mechanism, especially for sensitive documents.
- ii. EPA, FDA and USDA are working with ILSI on the evidence-based approach and its use in risk assessment.
 - a. How to look at different pieces of evidence and how much they provide to address questions in risk assessment at hand
 - b. How does one weight the different pieces against each other for a particular decision?

A workshop is being planned in early fall/October; maybe the RAC can co-sponsor it?
- iii. Industry is pressing FDA on trace amounts of certain toxicants in food. Three major symposia are being planned.

- We need to determine levels of acceptable risk; we can use risk assessments to help us do this.

4) APHIS is planning a training session by Warner North on Risk Analysis for its employees. There will probably be 1-2 sessions a month for a period of 12-14 months. There is a possibility for including other agencies.

In attendance (* participated by phone)^a

*Michael Broder, EPA/NCEA
 Robert Buchanan, FDA/CFSAN
 James Chen, FDA/NCTR
 Gregg Claycamp, FDA/CM
 Kerry Dearfield, USDA/FSIS
 Sherri Dennis, FDA/CFSAN
 Sharon Edelson-Mammel
 Richard Fite, USDA/APHIS
 Eric Grant, USDA/APHIS
 John Hicks, FDA/CFSAN
 *Barry Hooberman, FDA/CVM
 Andy Hwang, USDA/ARS/ERRC
 *Janell Kause, USDA/FSIS
 Wes Long, FDA/CFSAN
 Michael McElvaine, USDA/ORACBA
 Cristina McLaughlin, FDA/CFSAN
 Jacqueline McQueen, EPA/ORD
 Marianne Miliotis, FDA/CFSAN
 Kara Morgan, FDA/OC
 David Oryang, USDA/APHIS
 *Cindy Roberts, EPA/ORD
 Donna Robie, FDA/CFSAN
 *Angela Ruple, NMF
 Stephen Schaub, EPA/OW
 Shiowshuh Sheen, USDA/ARS/ERRC
 Mark Tamplin, USDA/ARS/ERRC
 Tabitha Tucker, DOD/CHPPM
 Michelle Twaroski, FDA/CFSAN
 Richard Whiting, FDA/CFSAN
 Hong Yang, FDA/CBER

^aSeveral other RAC member agency employees attended the presentation by Nancy Beck only.