

# RAC Meeting Minutes (December 16, 2004)

## Quarterly Meeting

### Introductions

Welcome to the newly nominated Bradford Hildabrand (DOD/Veterinary Services), Brandolyn Thran (DOD/CHPPM), and Margaret Venuto (USDA/FNS) RAC technical representative to the RAC for their agencies.

### Agency Updates:

Centers for Disease Control and Prevention (CDC)  
Donald Sharp

- CDC staff provided input to two federal agency risk assessments:
  1. USDA/FSIS risk assessments for *Salmonella* Enteritidis in shell eggs and *Salmonella* spp. in liquid egg products."
  2. FDA/CFSAN Risk Assessment on *Vibrio parahaemolyticus* in raw oysters

Department of Defense U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM)  
Brandolyn Thran

- DOD/CHPPM is continuing its project on dose-response for inhalation pathogens, especially anthrax. They are developing a white paper and would like to submit it to the RAC for review.
- Health Risk Assessment course will take place March 15-17, 2005. It integrates human and ecological health; does not focus on microbial risk assessment, although it will be covered. The course will also focus in risk managers.

EPA National Center for Environmental Assessment (NCEA)  
Michael Broder

Held EPA Microbial Risk Assessment Workshop in Cincinnati, November 18-19, 2004. The meeting included discussions on essential expertise needed in the microbial risk assessment group and included evaluation of the process for developing a pathogen risk assessment framework. Actively looking to hire new people to do pathogen risk assessments. The hires will be in Cincinnati. Will hold follow up meeting to address implementation.

FDA Center for Food Safety and Applied Nutrition (CFSAN)  
Dick Whiting

- CFSAN is continuing with a second risk assessment on *Listeria*:
  - Risk Profile on fresh cut veggies.
  - Risk Assessment on smoked seafood (notice going out shortly asking for data).
  - Collaborative Risk Assessment on soft and semi soft cheese-work with Canada (recent outbreak with Brie).
- Risk Management Framework document is complete and training is ongoing - getting risk assessment ideas into risk management thinking.

Sherri Dennis

- Several FDA-funded grants and cooperative agreements to be completed, e.g., Risk

Ranking Framework for Foodborne Hazards (Project Officer: Marianne Miliotis) to be completed in March, 2005.

- New contract on development of a Peer Review Process (Project Officer: John Hicks).
- Contract to put FDA/FSIS *Listeria monocytogenes* risk assessment into a more user-friendly format.
- Responding to the Data Quality challenge on methyl mercury in fish; wrapping up negotiations with OMB.

Marianne Miliotis

- *Vibrio parahaemolyticus* Risk Assessment Interpretive Summary has been sent to OGC for review.
- Draft Risk Profile on Hepatitis A virus in produce nearing completion.
- Risk Profile on Transmission of Norovirus was started early December.

David Carlson

- Nothing to report.

John Hicks

- Nothing to report.

FDA Center for Veterinary Medicine (CVM)

Mary Bartholomew

- Final streptogramin-resistant *Enterococcus* Risk Assessment is in draft form and has been put out for comments; considering linking it to clearing house so CVM can get input.
- Link also to the NARMS meat samples, the report put out in September.
- Risk Assessment group evaluating environmental risks, i.e., risk ranking.
- Data Quality standards set for new animal drug submissions

FDA National Center for Toxicological Research (NCTR)

Angelo Turturro

NCTR microbiological projects focusing on microbial risk assessment are continuing.

Joint Institute for Food Safety and Applied Nutrition

Wesley Long

JIFSAN has adopted a new tagline: "Supporting Decision Making to Address Food Safety Risks." The new tagline emphasizes that the function of JIFSAN is to provide research, education and outreach to support decision making.

- At the SRA conference – broad recognition that the Risk Analysis Clearinghouse is a good resource and a good launch off point for internet searches related to risk analysis.
- Still need to work to gain broader recognition of Clearinghouse as a resource for information.
- Challenge RAC to think of types of information we would like the Clearinghouse to provide.
- Food Safety Risk Analysis online courses will start February 1.
- New phase now with courses: beginning to offer general Continuing Education Units (CEU's).

NIH National Institute of Allergy and Infectious Diseases (NIAID)

Robert Hall

- Attended international *Listeria* meeting ISOPOL XV (International Symposium on the Problems of Listeriosis) in Uppsala, Sweden in September.
- Next meeting to be held in 2007 in the U.S.; Balasubra Swaminathan, CDC is the chair; developing program and web site (maybe link to Clearinghouse) - looking for ideas for the program.


NOAA Fisheries  
Angela Ruple

- Mercury survey in fish – sampling and analysis is complete; data being analyzed for total mercury; will also analyze Methyl Mercury.
- Working with FDA/CFSAN Office of Seafood and ISSC to incorporate some of the findings of the FDA *Vibrio parahaemolyticus* risk assessment into management and guidance for the raw oyster industry.

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

- Grants due date passed; all submissions are in.
- CSREES funded a Food Safety - Coordinated Agricultural Project (CAP).
- Food safety research focused on pre-harvest practices; Highest priority is food safety issues.
- Food research and response network, made up of a consortium of 17 universities; waiting for response on expertise on *Salmonella*, *Campylobacter*, and *E. coli*.
- Follow up on outbreaks, will assist states that don't have the resources to follow up on outbreaks.
- March will have an overview of research grants; request for data/research needs from other agencies.

USDA Economic Research Service (ERS)  
Tanya Roberts

- New publication, Tim Josling, Donna Roberts, David Orden, "*Food Regulation and Trade: Toward a Safe and Open Global System*" 2004. For more information contact Donna Roberts at ERS: 202-694-5193.
- A recent report by ERS: "[The Economics of Food Safety: The Case of Green Onions and Hepatitis A Outbreaks](#) By Linda Calvin, Belem Avendaño, and Rita Schwentesius Outlook Report No. (VGS30501) 22 pp, December 2004."  Using the example of recent hepatitis A outbreaks in the United States associated with green onions from Mexico, this report examines the economics of food safety. It reviews the incentives to adopt additional food safety practices and the economic impact of an outbreak on green onion growers in Mexico.

USDA/Food Safety and Inspection Service (FSIS)  
Janell Kause

- **Meeting Between Food Safety and Inspection Service Risk Assessors and Risk Mangers.** On December 7th, the Risk Assessment Division and Office of Policy, Program, and Employee Development senior management met to discuss risk management priorities for FY2005. This meeting occurs annually as part of the FSIS standard operating procedures for risk analysis. The purpose of this meeting is to ensure risk assessment priorities align with risk management needs to develop policies based on science, specifically those that require risk assessments under Executive Order 12866 as part of rulemaking. This meeting clarified risk management priorities for FY2005 and the future direction of rulemaking in FSIS. This meeting went very well and it was decided that the two groups would meet one more time in the next few weeks before the Risk

Assessment Division finalizes its risk assessment priorities for FY2005.

- **FSIS/Office of Public Health Science/Risk Assessment Division Organizational Update.** The FSIS Risk Assessment Division continues to expand. On November 15th, Ms. Janell Kause was appointed the Division Director for the FSIS Risk Assessment Division. Ms. Kause has several years of governmental experience working for the Office of Public Health Science and the Office of Program Evaluation, Enforcement and Review. She brings a strong background in risk policy and public health. Also, on September 20th, Dr. Chuanfa Guo joined the Regulatory Affairs and Exposure Modeling Branch as a permanent employee. He obtained his Ph.D. in Biostatistics from the Johns Hopkins University Bloomberg School of Public Health in October, 1998. Before coming to FSIS, Dr. Guo was an Assistant Professor of Biostatistics at the University of Hawaii and the University of Maryland at Baltimore. He has experience in creating and applying statistical methods for quantitative research in biomedical and public health sciences. His expertise includes statistical methods for modeling risk factors and predictors for human diseases, design and analysis of epidemiological investigations, estimating and forecasting disease incidence and prevalence in populations. Finally, FSIS will be appointing a Senior Scientist for the Risk Assessment Division in early 2005.
- ***Listeria monocytogenes* verification sampling.** In January 2005, the Food Safety Inspection Service will begin verification sampling for *Listeria monocytogenes* in ready-to-eat (RTE) products that are exposed to the processing environment after the last lethality step, in accordance with 9 CFR 430 the Interim Final Rule to Control *Listeria monocytogenes* (LM) in RTE meat and poultry products. This sampling program, to be implemented in two phases, was designed by the Risk Assessment Division staff with cooperation from Office of Public Health Science staff in Microbiology Division and Laboratory Sample Data Management Staff, and Office of Policy, Program and Employee Development staff in the Technical Service Center. The initial phase will run from January 2005 through the remainder of the fiscal year, awaiting the collection of additional data. In the next several weeks, the Agency will be issuing a Notice describing this program as well as other Docket publications associated with verification sampling and the final version of the RTE Rule for *Listeria*.
- **Risk Assessments of *Salmonella* Enteritidis in Shell Eggs and *Salmonella* spp. in Liquid Egg Products.** These risk assessments were developed to provide information to FSIS risk manager to develop pasteurization performance standards for eggs and egg products. They were developed using the 1998 FSIS-FDA *Salmonella* Enteritidis Risk Assessment for shell eggs and egg products and incorporating current scientific information and data. These risk assessments have since been independently reviewed by a team of scientists external to FSIS through a contractor and further refined. FSIS held a public meeting on these risk assessments on October 22, 2004 and, as a result, has received additional data from the United Egg Producers to further refine the egg products risk assessment. These risk assessments are expected to be reviewed by the USDA Office of Risk Assessment and Cost-Benefit Analysis and to receive final review by the Office of Management and Budget in 2005.
- ***Salmonella* spp. in Raw Beef and Poultry Risk Assessments:** On October 18, Food Safety and Inspection Service officials, Greg Paoli of Decision Analysis, and Edmund Crouch of Cambridge Environmental Inc. met to have the "kick-off" meeting for *Salmonella* spp. in Raw Beef and Poultry Risk Assessments. This meeting marks the inception of these two risk assessments that are to be developed to assess the public health impact of foodborne *Salmonella* spp. on U.S. consumers.
- ***Salmonella* Ready-to-Eat Risk Assessment.** On October 12th, the Risk Assessment Division (RAD) completed the response to external peer review comments document for the recently completed draft risk assessment, "Impact of Lethality Standards on

Salmonellosis from Ready-to-Eat Meat and Poultry Products". The risk assessment report and model were revised accordingly to the reviewer's comments. RAD risk assessors anticipate handing the completed report and model over to the Office of Program, Policy and Employee Development in the near future.

- **Risk Assessments for *Salmonella* and *C. perfringens* in Ready-to-Eat Meat and Poultry Products.** These risk assessments were developed to inform FSIS rule-making with regard to ready-to-eat meat and poultry products. The *Salmonella* risk assessment was developed to inform the development of a lethality performance standard and the *C. perfringens* risk assessment was developed to provide information for the development of a stabilization performance standard. Both standards are developed as part of the FSIS RTE Rule expected to finalize in 2005. Both risk assessments have been refined in response to comments from independent scientific peer review. Both risk assessments will be presented at a public meeting in 2005, further refined, and used, along with a cost-benefit analysis, to establish performance standards for RTE meat and poultry products.

USDA/Food and Nutrition Service (FNS)  
Margaret Venuto

- She recently joined the newly formed Food Safety Unit at FNS.
- Have active and passive surveillance systems to follow outbreaks, especially focus on schools.

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

- Involved in BSE in animals risk assessment for Canada in an advisory capacity ; waiting for departmental clearance; need to have it published soon, because of final rule to open border to Canada.
- Looking at application of risk assessment at pre-harvest level.

Work Group Updates (see [group descriptions](#))

Data Gaps Analysis

The workgroup met and considered improving the data gaps list by tracking which data gaps have been completed; by including newly completed risk assessments for data gaps and data gap needs of other agencies for future risk assessments.

The work group also discussed how best to get the word out about the data gaps list, maybe by using organizations that do a lot of research or universities; also giving a presentation at a scientific meeting.

Peer Review for Regulatory Risk Assessments

The work group met in November 2004 to discuss revision to the concept paper for peer review of risk assessments conducted by federal agencies. Paper is well on its way and will hopefully be completed early 2005.

Data Utility

Work group is on hiatus until January, waiting for comments from the RAC policy Council designees, before it is finalized for posting on the RAC web page.

Data Information and Quality

The work group received a 60-70% response from RAC member agencies to their "Best Practices" questionnaire, and is currently analyzing the information. Plan to summarize findings in a paper to be completed in FY 05. Carl Schroeder recently presented some of the findings at the Society for Risk Analysis Annual Meeting in Palm Springs, CA, Dec. 5-8, 2004.

### Dose Response

The work group was not able to meet this quarter, but Neal was able to contact Dr. David Tribble of the Naval Medical Research Center, Silver Spring, MD, regarding the progress on the *Campylobacter* vaccine trials. Data produced from such a study could be used to further the *Campylobacter* dose-response relationship.

During the RAC meeting the possibility of getting together with Mary Torrence, USDA/CSREES, re data needs was discussed.

### Risk-Risk

The risk-risk workgroup continues to seek representatives from member agencies to speak at RAC meetings to (a) learn about important risk-risk issues that member agencies have previously dealt with, and, (b) ask the speakers how the risk-risk workgroup can help their agencies and whether there are specific needs or questions the agencies have regarding risk-risk issues.

### New Business

Richard Whiting, FDA/CFSAN presented an introduction on a risk-based approach to establishing microbiological criteria. There was much interest and discussion. This presentation was in preparation of starting a new work group within the RAC to look at Microbiological Criteria.

### Presentation

Robert Wills, Mississippi State University, a current grantee of USDA/CSREES presented on "The Concept of Using Simulation Modeling in Food Safety".

In attendance (\* participated by 'phone):

Mary Bartholomew, FDA/CVM  
Mike Broder, EPA/NCEA  
David Carlson\*, FDA/CFSAN  
Sherri Dennis\*, FDA/CFSAN  
Sharon Edelson-Mammel, FDA/CFSAN  
Neal Golden\*, USDA/FSIS  
Robert Hall\*, NIH/NAID  
John Hicks\*, FDA/CFSAN  
Heather Hicks Quesenberry\*, USDA/FSIS  
Bradford Hildabrand, DOD/VS  
Janelle Kause\*, USDA/FSIS  
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Mike McElvaine\*, USDA/ORACBA  
Marianne Millotis, FDA/CFSAN  
Tanya Roberts, USDA/ERS  
Angela Ruple\*, NOAA Fisheries  
Carl Schroeder\*, USDA/FSIS  
Donald Sharp\*, CDC  
Brandolyn Thran\*, DOD/CHPPM

Mary Torrence, USDA/CSREES  
Angelo Turturro, FDA/NCTR  
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