RAC Meeting Minutes (April 1, 2004)

Quarterly Meeting

Agency Updates:

Centers for Disease Control and Prevention (CDC)
Donald Sharp – nothing to report

Department of Defense Veterinary Services Agency (VSA) and U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM)
Eric Torring (DOD VSA) – nothing to report

EPA Office of Research and Development (ORD)
Jacqueline McQueen

- EPA released a 196 page paper on RA principles and practices, how and why EPA does risk assessments.
- Prions – EPA/OPPT will be regulating prions as a pest under the Pesticide Rodenticide Act. Chronic wasting disease in Midwest - elk studies waste was being sent down the drain and contaminating the water.

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

- Discussions with Health Canada on a possible combined risk assessment on *Listeria monocytogenes* in soft cheeses.
- WHO/FAO Risk Assessment Hazard identification booklet given out at CODEX meeting, March 29 – April 3, 2004.

John Hicks

- *Listeria monocytogenes* Risk Assessment was completed and published in October 2003.
- A data feasibility analysis was recently completed for *Listeria monocytogenes* and three product pathways: smoked finfish, fresh-cut vegetables, and soft unripened cheese. The focus of the proposed *Listeria* product pathway risk assessments is primarily processing (pre-retail).

Wes Long – nothing to report

Marianne Miliotis

- Thirteen manuscripts from the 1st International Conference on Microbial Risk Assessment have been reviewed and are now being processed for publication as Proceedings in a supplement to Journal of Food Protection.
- Possible new venue for public meetings: Aviation Museum, College Park, MD.
- Revised RAC charter is being sent to all member agencies for signatures. So far have signatures from 4 representative agencies.
- Revised *Vibrio parahaemolyticus* risk assessment has undergone first round of reviews, including in depth review of model by internal and external experts, and is currently undergoing second round of reviews prior to clearance.
- CFSAN has developed a Risk Management Framework for CFSAN.
- Virus data feasibility evaluation has been completed and research priorities have been recommended for foodborne Hepatitis A virus and Norovirus.

FDA Center for Veterinary Medicine (CVM)
Mary Bartholomew

- Litigation of fluoroquinolones - Judge ruled in CVM's favor on the issue of withdrawal from the market of fluoroquinolones for use in poultry.
- Dr. Lester Crawford is now acting Commissioner of the FDA.

FDA National Center for Toxicological Research (NCTR)
Angelo Turturro

- Continuing with identification of microbial hazards using NMR.
- Continuing with project on defining parameters for epidemiological studies on exposure to *Crypotsporidium*.

FDA Office of the Commissioner (OC)
Kara Morgan

- Dr. Morgan was hired to bring risk assessment knowledge and perspective to the Office of the Commissioner, so that we can better support center efforts.

NOAA Fisheries
Angela Ruple

- Introduction of Dr. John Tennyson, the Chief of the Risk Evaluation & Analysis Division in Pascagoula, MS who may potentially become more involved with the RAC.
- ISSC *V. parahaemolyticus* sub committee has been charged with addressing control strategies to prevent outbreaks.
- ISSC *V. parahaemolyticus* sub committee is also focusing on sporadic cases.

USDA Agricultural Research Service (ARS)
Mark Tamplin

- Dr. Tom Oscar recently published a manuscript in Risk Analysis (2004) on "Dose-Response Model for thirteen strains of *Salmonella*."
- USDA/ARS/ERRC will be advertising a vacancy in the next few months to carry on the process of risk model research started by Rolando Flores.
- ComBase workshops were conducted in Australia in March and Food Science Australia is interested in joining the US-UK initiative.
- Version 2.0 of ComBase will be posted within 2 weeks (visit www.combase.cc).
- ARS food safety research project plans are being prepared this fall — interested in knowing modeling research priorities that could be addressed in the next 5-year cycle (2005-2010).

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

- Two grant programs:
    - Proposals for the National Research Initiative's Epidemiological Approach to Food Safety have been received - decisions on awards will be made in June, 2004.
    - Food Safety Coordinated Agricultural Program (CAP)- a grant program that funds a team of researchers with expertise in a particular area, (for example, a rapid response to food safety issue), to address a specific and emerging/current issue in food safety; $5 million grant for 4 years - decision on proposals will also be made in June, 2004.

USDA Food Safety and Inspection Services (FSIS)
Janell Kause FSIS

- Major focus on hiring; the Risk Assessment Division has lost people to promotion and transfer; they will take the time to hire the replacements. Looking for modelers with focus on engineers, familiar with program and good communicators.

Peg Coleman

- **Reorganization/new hires.** In March, three scientists associated with risk assessment at FSIS accepted new positions. Carol Maczka will serve as the Assistant Administrator for the Office of Food Security and Emergency Preparedness, FSIS. Elke Jensen joined Dow-Corning Corporation in Midland, Michigan. Peg Coleman will serve as Senior Scientist for Syracuse Research Corporation in Syracuse, NY. Abdel Kadry and Uday Dessai were selected as Branch Chiefs in the Risk Assessment Division (RAD). Jude Smedra, an intern from Oklahoma State University, is working jointly with RAD and APHIS through May.

USDA Office of Risk Assessment and Cost Benefit Analysis (ORACBA)
Mark Powell – Nothing to report

Presentations

CDC representatives made four presentations:

- FoodNet: Documenting important declines in several foodborne diseases (Jennifer Nelson)
- FoodNet CID supplement highlights (Fred Angulo)
- Attributing the burden of foodborne diseases to specific foods (Fred Angulo)
- FoodNet *Listeria* case-control study (Cindi Snider)

Work Group Updates

1. Data and Information Quality Guidelines
   Kara Morgan, Senior Advisor for Risk Analysis, Office of the Commissioner, US FDA, has joined the work group.
   The group had developed a five page summary document based on a compilation of publicly available procedures for how various government agencies ensure data quality.

   The group has also developed a brief questionnaire to guide solicitation of feedback from RAC members in what they have learned about data quality issues at their respective agencies. This will enable the group to develop a more far-reaching document (of which our earlier five pager will provide a good introduction) to discuss issues in data quality, including methods to ensure quality, potential drawback of not having any data if rigorous standards are applied, lessons learned, etc.

2. Data Gaps Analysis
   Work group lead is now Andy Hwang; Mark Tamplin will remain an active member of the group.
   A document containing lists of data gaps identified in published microbial risk assessments by the US Food & Drug Administration, US Department of Agriculture's Food Safety & Inspection Service, and the World Health Organization/Food and Agriculture Organization of the United Nations has been completed and posted on the Clearinghouse RAC website. Each data gap is identified by exposure assessment category, the type of information needed, and a brief explanation of the specific data gap.
   Data gaps include those from risk assessments on *Listeria monocytogenes* in Ready-To-Eat (RTE) food; *E. coli* O157:H7 in ground beef; *Campylobacter* spp. in broiler chickens; *Vibrio parahaemolyticus* in finfish, *V. parahaemolyticus* in bloody clams; *V. parahaemolyticus* in raw oysters; *V. parahaemolyticus* in export shrimp.

3. Peer Review

Information obtained from the September 30, 2003 Symposium on Peer review, co-sponsored by the RAC, JIFSAN and SRA, provided a "baseline" for current thinking on regulatory peer review. Using the ideas and information generated from this symposium along with information gathered by work group members from the National Academy of Sciences November 18, 2003 symposium on peer review, the work group has drafted several sections of a discussion paper on peer review (meetings in November 2003, February 2004, and March 2004). This discussion paper will present the various approaches of regulatory peer review of risk assessments and their strengths and weaknesses.

4. Risk-Risk
   A workgroup has been formed and one conference call meeting has been held. Description and goals of group have been developed.
   Lead: David Carlson
   Members: Abdel Kadry, Stephen Schaub, Angelo Turturro, Margaret Venuto, Mark Walderhaug
   Description: The project will address cross-Agency issues relevant to risk-risk comparisons and tradeoffs, especially the balancing of chemical and microbial risk. Scope of workgroup will be defined by needs of RAC member Agencies.
   Deliverables: The workgroup is organizing a series of presentations by experts from the RAC member Agencies (and others) on Risk-Risk efforts. Agency representatives will first be invited to speak to the RAC to provide input on Agency experiences with risk-risk decisions and Agency needs and questions about risk-risk comparisons. A public symposium, with invited experts in risk-risk issues, may be organized after input from RAC Agencies. The goal of the workgroup is to create a discussion paper that will address the needs of RAC Agencies and provide a framework (and contacts) for Agencies to respond to risk-risk issues.

5. Data Utility
   The Data Utility Work Group (DUWG) has been formed to organize a series of presentations on sampling plans that will help provide quality data to risk assessments.
   Lead: Brandolyn Thran
   Members: Andy Hwang, Michael McElvaine, Stephen Schaub
   Description: The goal of this workgroup is to organize a meeting with several presentations to address the many issues concerning sampling plans.
   Deliverable: A meeting or series of meetings to cover the wide span of issues related to sampling plans.
   One conference call meeting has been held and the following issues were identified as potential topics for the presentations.
   1. Sampling Strategies: How many samples? Where to sample? Adequacy of sampling plan?
   2. Sampling Techniques (Methodologies): Actual sample collection from media
   3. Statistical Validity: Does samples (or sampling strategy) meet statistical requirements to make inferences/conclusions? Is appropriate statistical treatment applied to data?
   4. Dose Reconstruction: Estimation of dose from sampling data
   5. Data Quality: To be addressed by Data Quality Work Group

6. Dose-Response
   The RAC DRWG expanded its membership and scope for FY 2004. New participants include: Dave Tribble and Pat Guerry, US Naval Medical Research Center; Lynda Kelley and Neal Golden, FSIS Office of Public Health and Science; Steve Anderson and Dennis Kopecko of FDA Center for Biologics Evaluation and Research; Rich Raybourne, FDA Center for Food Safety and Applied Nutrition; and Steve Schaub EPA Office of Water. The

scope in 2003 was a more general compilation of data on animal and human models for dose-response for many enteropathogens. In 2004, the group selected campylobacteriosis as its first case study to develop in more detail. The group met on October 28 and December 17 to discuss human, ferret, and in vitro data for campylobacteriosis. Future seminars are planned in the next two quarters to develop additional case studies that will be compiled into manuscript format by work group members in summer 2004. The goals of the manuscript are to incorporate additional mechanistic data into dose-response models to more realistically describe variability in each aspect of the disease triangle (host, pathogen, and environment, and interactions).

Policy Council Meeting

The policy council representatives reviewed the progress of the RAC towards FY04 annual plan goals, and commented on proposed FY05 goals. The policy council and technical representatives agreed to complete current projects before proposing new ones.

In attendance (* participated by 'phone):
Mary Bartholomew FDA/CVM
David Carlson FDA/CFSAN
Peg Coleman USDA/FSIS
Sherri Dennis FDA/CFSAN
Sharon Edelson Mammel FDA/CFSAN
David Goldblatt USDA/FSIS
Andy Hwang USDA/ ARS/ERRS
John Hicks FDA/CFSAN
Janell Kause USDA/FSIS
James Lindsay USDA/ARS
Wesley Long FDA/CFSAN
*Carol Maczka USDA/FSIS
Cristina McLaughlin FDA/CFSAN
*Jacqueline McQueen EPA/ORD
Marianne Miliotis FDA/CFSAN
Kara Morgan FDA/OC
Clark Nardinelli FDA/CFSAN
*Mark Powell USDA/ORACBA
*Angela Ruple NOAA Fisheries
*Scott Severin DOD/VSA
Donald Sharp CDC
*Mark Tamplin USDA/ ARS/ERRS
*John Tennyson NOAA Fisheries
Erik Torring DOD/VSA
Angelo Turturro FDA/NCTR
Margaret Venuto USDA/ CSREES
Richard Whiting FDA/CFSAN
Mark Walderhaug FDA/CFSAN