RAC Meeting Minutes (June 22, 2005)

Agency Updates:

Department of Defense Veterinary Services Agency (VSA) and U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM)

Bradford Hildabrand

- The Department of Defense Veterinary Service is currently developing a new Information Management/Information Technology system that will allow us to better collect, analyze, and share risk assessment, food safety, and animal medicine information with other DOD and governmental agencies.

Brandolyn Thran

- Internal review of the working draft of the Inhalation Anthrax Risk Assessment for Soldiers in Garrison
    - 15 reviewers provided over 500 comments.
    - External review draft will be prepared by the end of August
- Planning on holding a workshop at the SRA annual meeting in December 2005 titled "For Creators and Users of Health Risk Assessments: Reading Between the Lines of an Environmental Health Risk Assessment."

The focus will be on common "problems areas" that are potentially confusing, misapplied and misinterpreted (e.g., hazard quotients, biological vs. statistical significance, identification of appropriate receptors).

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

- Still working on completing the Risk Profile on *Listeria monocytogenes* in fresh-cut fruit and vegetables.
- Risk Assessments on *L. monocytogenes* in soft cheese and *L. monocytogenes* in smoked fish: Federal Register notices have been published.

Marianne Miliotis

- The risk profile on Hepatitis A virus in produce has been reviewed by the CDC.
- The first draft of the Norovirus risk profile is ready for its first round of review.
- The *Vibrio parahaemolyticus* risk assessment is being finalized for publication in mid July.

FDA Center for Veterinary Medicine (CVM)
Mary Bartholomew

- NARMS project is being reviewed externally. The CDC portion has already been reviewed.
- FDA has submitted a proposal to SRA to hold a symposium on risk assessments conducted at the FDA. "Risk Assessment at FDA: Applications for Informing Science-based Decisions"

USDA Food Safety and Inspection Services (FSIS)
Janell Kause

- FSIS welcomes Dr. Kerry Dearfield as its new Senior Scientist for Risk Assessment. Dr. Dearfield will provide leadership and guidance in the development of food safety risk assessments at FSIS. Dr. Dearfield previously served as the Senior Scientist for Science Policy at EPA. During his 21-year tenure at EPA, he was principal author and editor of EPA's staff paper, *Risk Assessment Principles and Practices*, and was integrally involved in the development of EPA's peer review handbook, risk characterization guidance, and guidance on assessing the quality of scientific and technical information used in risk assessments. His professional experience and expertise, in addition to risk assessment, includes work on genotoxicity of environmental chemicals, toxicity of pesticides, and microbial source tracking. He has a B.S. in biology, and M.S. in biological sciences, and a Ph.D. in pharmacology.
- FSIS has revised its *Salmonella* Enteritidis in shell eggs and *Salmonella* in egg products risk assessments using more current industry and research data. In the Fall of 2004, FSIS had these risk assessments peer review and, subsequently, held a public meeting on these risk assessments. These risk assessments were further refined based on formal peer review and public comments. At this time, FSIS is providing courtesy briefings to FDA, CDC and ARS on these revised risk assessments. Both the risk assessment reports and models will be posted on FSIS' website in mid-July 2005. These risk assessments will be used by FSIS risk mangers in developing regulations, including pasteurization performance standards for egg products.
- FSIS has also revised its risk assessments for *C. perfringens* in ready-to-eat and partially cooked meat and poultry products and *Salmonella* in ready-to-eat meat and poultry products based on formal peer review comments. These risk assessments were presented to the public in March 2005 and will be further revised based on public comments. The risk assessments will be used by FSIS risk managers to develop performance standards for stabilization and lethality requirements in producing ready-to-eat meat and poultry products. FSIS expects to have the final reports and models on its website by the end of the fiscal year.
- FSIS has recently developed a risk assessment for verification sampling of *Listeria monocytogenes* among FSIS-regulated establishments that produce post-lethality exposed ready-to-eat meat and poultry products. This risk assessments utilizes FSIS' *Listeria* risk assessments, which has been formally peer reviewed and cleared through OMB, and the FDA-FSIS risk assessment for *Listeria monocytogenes* among ready-to-eat products. In additional the model considers other information, such as laboratory test results to target FSIS sampling. FSIS plans to have this novel risk-based approach for targeting their resource peer reviewed in accordance with OMB guidelines. In addition, FSIS plans to have a public meeting on this risk assessment in the Winter 2005.

Presentation

Robyn Lee, DOD/CHPPMpresented on "Sampling designs, their uses, and how they were/are used by USACHPPM"

Work Group Updates

The Microbiological Criteria Work Group has conducted frequent telephone conferences and drafted a working paper describing the protocol for establishing microbiological criteria. The working paper is undergoing a final round of review and revisions. It should be ready within a few weeks for review by the different agencies.

A summary of the protocol taken from the working paper is:

The Microbiological criterion is a set of values that are used to determine whether a specific lot of food is acceptable or not. These values include: the microbial test protocol and its sensitivity, the confidence that an unacceptable lot will be detected, the number of samples to

be taken and the number of positive samples that are allowed before rejecting the lot. Determining the microbiological criteria begins with an understanding of the distribution of contamination within a lot, particularly within a lot that just meets the acceptable level of the microbial hazard. This can be decided from a decision on the FSO or PO and on the small fraction of samples that can exceed these values. This information will define the 'just acceptable lot.' With this information, a microbial test protocol is chosen to have a sensitivity level appropriate for the contamination distribution. A confidence level for the MC and the c value are also chosen. With this information the number of samples required can be calculated.

The Peer Review Work Group has been updating, harmonizing, and finalizing the content of their paper on the peer review of food safety risk assessments, particularly to reflect OMB's Final Bulletin on Peer Review. Some work group members are beginning the process of clearing the paper through their respective agencies.

The Data Gaps Analysis Work Group has updated its data gaps list

The following data gaps have been added:
-*Listeria monocytogenes* in Smoked Finfish
-*Listeria monocytogenes* in Fresh-Cut Vegetables
-*Listeria monocytogenes* in Soft Unripened Cheese
-*Salmonella* spp. in raw Beef and Poultry
-*Salmonella* Enteritidis in Shell Eggs and Salmonella spp. in Egg Products.
-*Clostridium perfringens* and *Clostridium botulinum* in Ready-to-Eat and Partially Cooked Meat and Poultry Products.
-Hepatitis A Virus: Relationship of Virus Infection Associated with Handling and Consumption of Produce.
-Norovirus: Elucidation of the Mode of Transmission.

The updated list is posted on the RAC website.

The Data Gap work group would like to thank Sherri Dennis, John Hicks, Janell Kause, Carl Schroeder, and Neal Golden for providing the data gaps.

The Data Utility Work Group has submitted a proposal to the SRA for a symposium titled: "The Status of Data Utility in Health Risk Assessment and Decision Making: A Multi-disciplinary Review" for the SRA Annual Meeting in December this year. In the event it is not selected, the work group will use what was developed for an "independent" symposium later in the year."

The Data and Information Quality Work Group has no update to report at this time.

Risk Ranking Symposium

The symposium is advertised on the FoodRisk.org, and a draft agenda has been developed.

The Steering committee has had telephone conferences with both the speakers and the panel members.

In attendance (* participated by 'phone):

*Mary Bartholomew, FDA/CVM
*Kerry Dearfield, USDA/FSIS
John Hicks, FDA/CFSAN
Bradford Hildabrand, DOD/VMS
*Andy Hwang, USDA/ARS/ERRS
*Janell Kause, USDA/FSIS

Robyn Lee, USACHPPM
Marianne Miliotis, FDA/CFSAN
*Jacqueline McQueen, EPA/ORD
*Carl Schroeder, USDA/FSIS
Brandolyn Thran, DOD/CHPPM
Mark Walderhaug, FDA/CFSAN
Richard Whiting, FDA/CFSAN