

RAC Meeting Minutes (September 15, 2004)

Quarterly Meeting

Introductions

Welcome to Heather Hicks Quesenberry as the new FSIS RAC technical representative to the RAC.

Agency Updates:

Centers for Disease Control and Prevention (CDC)
Donald Sharp

- CDC staff have seen Paul Frenzen's article on "Deaths Due to Unknown Agents" and appreciate the attention to this issue by USDA.
- CDC has been notified by states of more foodborne outbreaks this past two months than during the same period last year."

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

Brandolyn Thran

- Microbial risk project is continuing:
 1. Dose response workgroup for inhalation anthrax; working with Peg Coleman (now a consultant with Syracuse Research, NY), Dr. Charles Haas (Drexel University), Dr. Darrell Donahue (University of Maine), Ms. Robyn Lee (Statistician), USACHPPM), and Dr. John Cicmanec, Mr. Jeff Swartout and Dr. Mary Rothermich, USEPA-NCEA in Cincinnati. They're using old army data for anthrax and developing a new dose-response concept.
 2. Redefining Exposure Assessment - developing a model to better capture nuances of an exposure to an inhalation pathogen.
 3. Comparative analysis on risk of inhalation of anthrax relative to other inhalation risks.
- CHPPM is also developing a Health Risk Assessment Course on general environmental health risk assessment as a 3-day course in March.

EPA Office of Water (OW)

Stephen Schaub

- Efforts to develop thesaurus of terms for approaches for water medium using ILSI framework as default position for terms, hopefully harmonized with other agencies.
- AAAS fellow coming on board for 1-2 years to work on the full blown microbial risk assessment (ILSI) approach - focused on water.
- Process for developing a harmonized approach to risk based procedures to meet Clean Water Drinking Act.
- Framework to develop integrated risk information system (IRIS) documents under SDW act. Have one for chemical, but nothing for microbes.
- Developing human health methodologies for ambient water criteria.
- Risk Forum is to meet this month to talk about potential for interagency -wide guidance from a White house briefing - should we do this is the subject of the meeting. RAC Policy Council was briefed in the afternoon (see below)

FDA Center for Food Safety and Applied Nutrition (CFSAN)

Dick Whiting

- *Vibrio parahaemolyticus* risk assessment is near the end
- Two new risk assessment projects on *L. monocytogenes*:
 - A risk profile on *L. monocytogenes* in fruit and vegetables.
 - A risk assessment on *L. monocytogenes* in smoked seafood - a product pathway assessment. Much discussion in the Center as to the mechanism and extent of bringing industry and academia into the RA.
 - Collaborating with Health Canada on conducting a joint evaluation of *Listeria monocytogenes* associated with Fresh Soft Cheese (particularly cheese made from raw, unpasteurized milk).
 - CODEX Committee on Food Hygiene is meeting in Berlin during the week of September 20, 2004 to get a program up and running for developing food safety objectives based on risk assessment.

Marianne Miliotis

- Publication of 1st International Conference on Microbial Risk Assessment in *Journal of Food Protection* 67:Supplement, 2004
- CFSAN has implemented a center-wide seminar series on Risk Analysis.
- Two virus risk projects have also been initiated at CFSAN:
 - Develop a risk profile for Hepatitis A Virus to elucidate the relationship of the virus infection associated with the handling and consumption of produce.
 - Develop a risk profile for Norovirus to elucidate the vehicles of transmission.

David Carlson

- The FDA OC has initiated an effort to look at preliminary risks of nanotechnology in foods and all FDA products. A workgroup has been formed and meets quarterly.

FDA Center for Veterinary Medicine (CVM)

Mary Bartholomew - No updates

- Antimicrobial Resistance symposium - 28th and 29th September at Arlington Regency Hyatt. Co-sponsored by JIFSAN, SRA, FDA/CVM and several drug companies.

FDA National Center for Toxicological Research (NCTR)

Angelo Turturro

- NCTR met with FDA counterterrorism (CT) folk; strong link between CT and NCTR microbiological projects. Focusing on microbial risk assessment: *Cryptosporidium* was highlighted as a category type 2. Most bacterial enteropathogens are type 2 agents.
- Identification and characterization using real time PCR.

Joint Institute for Food Safety and Applied Nutrition

Wesley Long

- JIFSAN summer risk analysis program: over 300 registrants; 12 took all courses; there were several graduates from taking the core risk analysis classes.

USDA Agricultural Research Service (ARS)

Jim Lindsay

Project with National Alliance for Food Safety: extension of NFPA (National Food Processors Association) study on *L. monocytogenes*; ~approx. 1 year study to begin October 1, 2004 with focus on delis. This study, which was developed by and is being supported by both FSIS and ARS, will include sampling and analysis of RTE packaged foods and those sliced in the deli in

California, Georgia, Wisconsin, and Tennessee. The objective of this study is to quantify the levels of *L. monocytogenes* in ready-to-eat (RTE) processed meat and poultry products sliced in retail supermarket delis compared to levels in RTE processed meat and poultry products sliced and packaged at a USDA or state inspected meat and poultry processing plant. These data will be used to: Estimate actual consumer exposure to *L. monocytogenes* from RTE processed meat and poultry products. and to conduct a risk assessment of *L. monocytogenes* in RTE processed meat and poultry products to support science-based strategies for addressing the occurrence of *L. monocytogenes* in these foods in the U.S.

Andy Hwang

- Two new models will be posted at www.arserrc.gov/mfs/pathogen.htm in the next 2 weeks.
 - *Salmonella* thermal inactivation in ground beef; time to 5- and 6.5-log reduction as a function of temperature, NaCl, sodium lactate and sodium pyrophosphate
 - Growth of *E. coli* O157:H7 in sterile raw ground beef as a function of temperature (8 to 45C).
- Working on a project with the Economic Research Service (lead-Tanya Roberts) to measure the impact of models in food processing operations.
- Working with the ARS National Software Support Center in Ft. Collins on a project to archive model software code in the Objects Modeling System (<http://oms.ars.usda.gov>) format. This will result in establishing the code in an industry-standard cross-platform format, and will facilitate the construction of multiprocess models.
- Predictive Microbiology and Process Risk Models CRIS project is developing its next 5-year project plan and we appreciate any input from RAC members.
- The ComBase (August 27) workshop at CFSAN was a great success. We appreciate the assistance of Marianne Miliotis and Dick Whiting.

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

Mary Torrence

- RFA is out for general research initiative; deadline is some time in December - check web site.
- USDA/CSREES research awardee will be presenting at the next RAC quarterly meeting in December on a Food Safety model for poultry chill tanks.

Margaret Venuto

- National Integrated Food Safety Initiative RFA to be released mid October, due in late Dec. RFA will be different this time in terms of the priority issues for funding - more focus on emerging food safety issues and pathogens; \$14 million. Deadline is end of December.
- Check agency website for funding opportunities under national integrated website http://www.csrees.usda.gov/nea/food/in_focus/safety_if_national.html or contact Jan Singleton (202.401.1954) or Margaret Venuto (202.720.6145).

USDA Food Safety and Inspection Services (FSIS)

Heather Hicks Quesenberry

- **New Employees.** The Risk Assessment Division (RAD) is proud to welcome Silvia Kreindel to its Regulatory Affairs and Exposure Modeling Branch. Dr. Kreindel began as a Risk Analyst on August 9, 2004. She is most recently from the Massachusetts Department of Agriculture and the Harvard Center for Risk Analysis and is now an integral part of the RAD BSE Risk Assessment team. Dr. Chuanfa Guo will also join the Modeling Branch, beginning on September 20, 2004. On detail from the FSIS Office of Field Operations, Dr. David LaBarre has joined the Technical Analysis and Evaluation

Branch of RAD. Dr. LaBarre is a member of the *Listeria monocytogenes* Risk Assessment Team, where he has already made valuable contributions in data analysis. RAD is also anticipating the announcement of a new Division Director in the coming weeks.

- **SERA Revision.** Project Leader Carl Schroeder continues to work with the SERA team to complete the revised Salmonella Enteritidis in shell eggs and Salmonella spp. in egg products risk assessments. These assessments have been peer reviewed and a public meeting is tentatively scheduled for mid-October, 2004.
- **Lethality for RTE products.** Carl Schroeder also serves as leader on a risk assessment team with the objective of modeling the impact of the Salmonella lethality performance standards for ready-to-eat (RTE) meat and poultry products. Greg Paoli was contracted to develop the risk assessment model. This risk assessment has been externally peer reviewed and is under revision. A public meeting will be scheduled for the near future.
- **Clostridium perfringens risk assessment.** Neal Golden is serving as Project Leader to conduct a risk assessment for *C. perfringens* in ready-to-eat and partially cooked meat and poultry products. Now complete, this risk assessment has undergone an external peer-reviewed and been revised in response to those comments. Risk assessment results have been presented to FSIS managers and the report, comment-response document, and model are in the process of being officially handed over to OPPED. The risk assessment will be used, along with a cost-benefit analysis, to inform the FSIS rulemaking on stabilization standards for ready-to-eat and partially cooked meat and poultry products.
- **BSE risk assessment.** Branch Chief Uday Dessai, Terry Disney, Wayne Schlosser, Silvia Kreindel and Mike Kasnia continue to work with other staff in the FSIS Office of Public Health Science, the Office for Policy, Program and Employee Development (OPPED), as well as colleagues from Harvard Center for Risk Analysis, APHIS, and the FDA Center for Veterinary Medicine, to model BSE mitigations currently in place, develop scenarios to address policy questions and identify high-risk materials that require further management control. Numerous briefings are being presented to decision-makers throughout FSIS. Terry Disney has been part of the U.S. technical team involved in preliminary discussions with Japan regarding reopening of Japanese markets for U.S. beef.
- Representing the Risk Assessment Division, Terry Disney, Senior Risk Analyst, has been collaborating with USDA's Office of Risk Assessment and Cost Benefit Analysis to outline a methodology for blending economics and environmental analysis with risk analysis in an integrated policy support approach. The workgroup presented a paper at the AAAS meeting early this year, and will be presenting another paper at the SRA meetings in December 2004. This work is entitled A Framework for Combining Risk Analysis with Cost-Benefit and Environmental Analysis to Improve Regulatory Analysis. Authors are C. A. Narrod, L. C. Abbott, W.T. Disney, J. W. Glauber, J. D. Schaub; U.S. Department of Agriculture.
- **SOPs for eliciting information and data from industry sources.** Mike Kasnia is preparing standard operating procedures (SOPs) for RAD and OPHS for the collection of data from industry for future risk assessment work. Historically, industry specific manufacturing and operational data account for a high percentage of data gaps. Initial meetings with industry representatives have been positive.
- **Risk Assessments for Salmonella in Beef and Poultry** Heejeong Latimer and Neal Golden have been designated as the team leaders for the Salmonella in Beef and Salmonella in Poultry risk assessments, respectively. Greg Paoli, of Decision Analysis, and Edmund Crouch, of Cambridge Environmental, have been contracted to develop the

model for these assessments.

- **ECRA Revision.** Neal Golden and Wayne Schlosser serve as co-leaders on a new team to begin addressing public comments and recommendations of the National Academies committee for revision of the E. coli O157:H7 risk assessment in ground beef. The team will also coordinate the development of an expert elicitation designed to address data gaps identified by the NAS report.
- **Comparative L. monocytogenes Risk Assessment for Deli Meat Sliced and Packaged at Retail versus In-plant.** Project Leader Heather Hicks Quesenberry will be working with Dan Gallagher of Virginia Polytechnic Institute and State University to compare the prevalence of L. monocytogenes in meat from retail and commercial processing environments.
 - Mrs. Quesenberry is the COTR for a Cooperative Agreement with the National Alliance for Food Safety and Security. NAFSS will complete a national study of L. monocytogenes in Deli Meat in 2005. This is the same study as was mentioned above by Jim Lindsay.
 - Mrs. Quesenberry is also the COTR for a Cooperative Agreement with the Association of Food and Drug Officials, AFDO, to collect laboratory data on L. monocytogenes from 63 food safety agencies across the United States. Data from these projects will be analyzed and contribute to the comparative risk assessment.
- **Listeria monocytogenes Verification Sampling.** Project Leader Heather Hicks Quesenberry is working with Dan Gallagher of Virginia Polytechnic Institute and State University to modify the FSIS Listeria risk assessment to generate and evaluate targeted, risk-based Listeria verification sampling protocols. These protocols will become part of the finalized FSIS Interim Rule to Control L. monocytogenes in RTE Meat and Poultry.
- **Use of Risk Assessment Approach in Food Biosecurity.** Technical Analysis Evaluation Branch (TAEB) Chief Abdel Kadry and AAAS Fellow David Goldblatt continue to work with colleagues from FDA/CFSAN, USDA/FNS and scientists from academia, and a contractor to examine various scenarios by which terrorists could tamper with the food supply. In addition, they study the best mitigation strategies and agency preparedness. The information generated from this project has been used to inform the upper management of laboratory testing needs for biological and chemical agents. In addition, the information will be used to inform the procedures followed under the Homeland Security color-alert system.
- **Use of Risk Assessment in FSIS Recall and Trace Back.** Abdel Kadry, with participation from Carl Schroeder and Heather Hicks Quesenberry, is providing FSIS/ Recall Management Division (RMD) with toxicological evaluation, hazard characterization and exposure estimates in the recall cases that involve chemical contamination or mis-labeling. The Recall Committee recommends class determinations for each of the examined cases.
- **Use of Risk Assessment in FSIS Disposition of Regulated Products.** Abdel Kadry leads this team addressing chemical risk assessment (hazard identification and hazard characterization) with the FSIS Technical Service Center (TSC). The information is used in disposition of products that exposed to chemical or physical adulterants.

Janell Kause

- **Risk-Based Approach for FSIS Equivalence Determinations for Imported Beef Products.** Janell Kause, Senior Public Health Scientist, and Daniel Engeljohn (Deputy Assistant Administrator of the Office of Policy, Program and Employee Development) co-lead an FSIS intra-agency team comprised of scientists and risk analysts, policy, and

international experts in establishing risk-based U.S. equivalence criteria for the importation of beef products from countries that pose a high risk or undue risk of BSE. FSIS is currently collecting information regarding the various risk mitigation practices that are employed in these countries and evaluating their relative public health impact.

- **Development of Risk Management Questions for Salmonella in Beef to Target FSIS Risk Assessment Efforts.** As part of its risk analysis process, FSIS is currently developing risk management questions to guide FSIS' development of a targeted risk assessment to inform the development of performance standards for Salmonella in beef and poultry. The scenario analyses conducted using a peer reviewed risk assessment for Salmonella in beef and poultry will provide information on the relative reduction in foodborne illness associated with this pathogen in beef products. The benefits of these potential performance standards will be weighed against the costs as part of Agency's decision-making process in establishing risk-based performance standards for Salmonella in beef and poultry.

Presentations

1. "Tissue Culture and Dose Response" by Marianne Milliotis
2. "Folic Acid Fortification: Making the Decisions" by Jean Rader, FDA/CFSAN.

Policy Council Meeting

The policy council representatives reviewed the progress of the RAC towards FY04 annual plan goals, and approved proposed FY05 goals.

RAC-sponsored Symposium

"Data Collection and Utilization in Risk Assessments and Management Decisions" held on September 14, 2004 at the College Park Aviation Museum.

Presentations

December 2003 RAC Quarterly Meeting

Carol Maczka, USDA/FSIS, RAC policy council co-chair, gave a presentation on "The USDA Food Safety Risk Assessment Committee."

John Painter, CDC gave a presentation on "Allocating the burden of Foodborne illness by food commodity- the role of outbreak reports"

April 2004 RAC Quarterly Meeting

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)

June 2004 RAC Quarterly Meeting

"Economic Incentives for Food Safety Innovation: Case Studies in the U.S. Meat Industry" by Tanya Roberts, USDA/ERS.

September 2004 RAC Quarterly Meeting

"Folic Acid Fortification: Making the Decisions" by Jeanne Rader, FDA/CFSAN

Work Group Updates

1. Data Gaps Analysis

The Data Gaps workgroup sent an announcement to FSNET to publicize that "Data Gaps for Selected Microbial Risk Assessments," is available on the RAC website. The purpose of this announcement is to invite food safety researchers and risk assessors to rank the data gaps to identify research priority.

2. Dose-Response

1. The DRWG continues their seminar series. Marianne Millotis will present on "Tissue Culture and Dose Response" from 11AM-12 at the Interagency Risk Assessment Consortium Quarterly Meeting, Sept. 15th.
2. The DRWG was asked to provide input toward a newly developing proposed metric of microbial infectivity for the EPA. Audrey Ichida of ICF consulting Inc., and Walt Jakubowski joined the phone conversation to facilitate the discussion. An initial reaction to their approach was provided to give guidance to the development of this metric.

3. Peer Review

During this quarter, the Peer Review work group (PRWG) held two meetings (phone conference on June 23rd and a face-to-face meeting in College Park, MD on August 25th) to discuss further revisions to the manuscript: "Peer Review of Food Safety Risk Assessments." Further revisions included incorporating EPA's information on cost of a peer review based on the approach used and its rigor; refining the tables ranking the different kinds of peer review (e.g., panel, intra-agency, inter-agency, expert panels, NAS review, etc.) based on five criteria: 1) transparency; 2) rigor; 3) objectivity; 4) independence; and 5) resources. The discussion paper currently contains most of its content and is being revised by the work group this month. The PRWG planned to consider the finalized OMB bulletin on peer review in finalizing its draft manuscript. The Office of Management and Budget, however, indicated that the recently revised (April 15, 2004) draft OMB peer review bulletin has not been finalized based on public comments. Moreover, OMB does not have a date set for the release of a finalized OMB peer review bulletin. In the meantime, the PRWG has solicited input from the RAC policy council on the depth, content and utility of the peer review manuscript. Based on these comments, the PRWG will revise the manuscript in the first quarter of FY2005 with planned work group meetings in October and November 2004."

4. Data Information and Quality

Questionnaire was sent out to all the RAC member agencies to assess current practices for ensuring data quality in risk assessments. Results of questionnaire are pending based on responses received.

5. Risk-Risk

The risk-risk workgroup previously decided to invite representatives from member agencies to speak at RAC meetings. This will hopefully allow us 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. Today we heard from the first speaker in our series, Jeanne Rader, Ph.D., from FDA/CFSAN. Dr. Rader talked about the FDA decision to promote fortification of cereal products with folic acid. We heard that folic acid fortification can help prevent neural tube birth defects by increasing folic acid intake in pregnant women and women of childbearing years. Fortification is not without risks, however, as B vitamin deficiencies are possible in at risk

populations, including genetically disposed individuals and the elderly. In essence, risk may be shifted from one population to another and a decision was made that enhanced health due to folic acid fortification outweighed potential alternative risk tradeoffs due to either folic acid or vitamin B deficient diets. Potential speakers for upcoming RAC meetings have been identified and the workgroup is still working on expanding the list of potential speakers.

6. Data Utility

The Data Utility Work Group organized the symposium on "Data Collection and Utilization in Risk Assessments and Management Decisions" to be held on 14 September 04 at the College Park Aviation Museum. Approximately 50 people attended the half-day symposium. It is the Work Group's hope that this symposium is the first in a series dealing with Data Utility issues.

Gary Banks, EPA, proposed to the RAC Policy Council on the possibility of the RAC working towards developing interagency guidelines for microbial risk assessment.

RAC Annual Plan FY05

1. Continue from FY04:

a. Presentations

- i. Continue presentations by agency representatives on current risk assessments.
- ii. Continue presentations by member agencies on issues related to risk assessment.

b. Work Group Projects

- i. Dose-Response on mechanistic dose-response data Continue dialog with NIH, CSREES and other RAC linked researchers, as well as NMRC to obtain more information. Continue dose-response seminar series.

Develop a manuscript to incorporate additional mechanistic data into DR to better describe variability in host, pathogen and environment. Tentatively, manuscript would address difficulties with current dose-response approach of risk assessment and identify specific examples from previous risk assessments of how a more mechanistic approach to dose-response could better facilitate risk analysis. Example pathogens could then be used to demonstrate how dose-response data could be improved using published or unpublished data. Such organisms may include

B. anthracis, Campylobacter, Cryptosporidium, Helicobacter, or Salmonella. DRWG agreed that as an initial approach, the group would identify how Campylobacter animal dose-response data could help to assist the development of a human Campylobacter dose-response relationship. Additionally, the group is interested in using Cryptosporidium as a model organism to demonstrate how more mechanistic data are needed to develop more representative dose-response relationships.

- ii. Data Gaps Analysis

Continue to update/expand the Data Gaps Analysis worksheet as data gaps are filled and new gaps are identified. Rank the data gaps (prioritize the "specific need"). Specify pertinent elements, e.g., products, parameters and ranges, to be investigated in research that addresses specific data gaps.

- iii. Data Quality Guidelines
Plan to continue work on a more far-reaching document (of which the earlier five pager will provide a good introduction) to discuss issues in data quality, including methods to ensure quality, potential drawbacks, lessons learned, etc. This document will be based on the response to the questionnaires provided to the member agencies on their data quality practices.
- iv. Peer Review
Revise and complete discussion paper on regulatory peer review of risk assessments based on the comments of the RAC Policy Council members. Once completed and cleared by the RAC Policy Council members, the PRWG plans to publish the manuscript and post an executive summary on the RAC Clearinghouse web site. The PRWG is also discussing the possibility of holding a joint symposium with the Data Utility and/or Data Quality work group(s).
- v. Risk-Risk
Develop a concept/discussion paper based on presentations by representatives from member agencies to speak at upcoming RAC meetings. This will hopefully allow us to (a) learn about important risk-risk issues that member agencies have previously dealt with, and, (b) determine how the risk-risk workgroup can help their agencies and whether there are specific needs or questions the agencies have regarding risk-risk issues.
- vi. Data Utility
Consider a second workshop with the focus on statistical sampling. Possibly develop a discussion paper on useful sampling strategies based on the two meetings to serve as a reference for member agencies.
- vii. An additional project for FY05 was proposed by the RAC Policy Council: "Risk-based approach to establishing microbiological criteria"

In attendance (* participated by 'phone):

- Gary Banks, EPA
- *Mary Bartholomew, FDA/CVM
- Robert Buchanan, FDA/CFSAN
- David Carlson, FDA/CFSAN
- *Sharon Edelson Mammel, FDA/CFSAN
- Neal Golden, USDA/FSIS
- Heather Hicks Quesenberry, USDA/FSIS
- Andy Hwang, USDA/ARS/ERRC
- Abdel Kadry, USDA/FSIS
- Janell Kause, USDA/FSIS
- *Jim Lindsay, USDA/ARS
- *Wes Long, FDA/CFSAN
- Marianne Millotis, FDA/CFSAN
- Judy Nelson, EPA/OPPTS
- Stephen Schaub, EPA/OW
- *Don Sharp, CDC
- Brandolyn Thran, DOD/US CHPPM
- Mary Torrence, USDA/CSREES
- Angelo Turturro, FDA/NCTR
- *Margaret Venuto, USDA/CSREES
- Richard Whiting, FDA/CFSAN

