

RAC Meeting Minutes (March 26-27, 2003)

**CFSAN/FDA
5100 Paint Branch Parkway, College Park
March 26 & 27, 2003**

Wednesday, March 26

9:30 -9:40 a.m: Introductions

9:41 - 10:10 a.m: 3 minute updates

Peg Coleman & Michael Kasnia - (USDA/FSIS)

- The FSIS Listeria risk assessment evaluates the effectiveness of post-lethality interventions in mitigating the risk of illness from *L. monocytogenes* in deli meats. In January 2003, OMB was briefed on this risk assessment. A public meeting for this risk assessment was held on February 26, 2003. FSIS responses to public comments and peer review input have been developed and included in the docket for the FSIS RTE rule. For more information on this risk assessment, see: <http://www.fsis.usda.gov/oa/topics/lm.htm>.
- FSIS is working with ARS to revise the growth and cooling curves used in the *C. perfringens* risk assessment. Data for this assessment were provided by academia, industry and other governmental agencies. Completion of this risk assessment is expected in the next few months.
- Salmonella Enteritidis in shell eggs and egg products risk assessment will be revised using FSIS baseline data being collected on the level of Salmonella prior to pasteurization of egg products. Egg baseline data is expected in April 2003, with the completion of the risk assessment model and documentation later this summer.
- FSIS is working with Decisionalysis to develop a risk assessment for Salmonella in ready-to-eat meat and poultry products to evaluate the effectiveness of various lethality standards. A preliminary model and report will be completed in mid-April. Risk assessors will continue to work with risk managers to refine the model to provide outputs to inform specific risk management questions.
- FSIS provided input to an USDA/ORACBA project on sensitivity analysis (led by Chris Frey, North Carolina State University). The tools developed from this project will be posted on the RAC clearinghouse website.
- FSIS will participate in an upcoming (end of April) 2-day workshop on risk analysis with the Pan American Health Organization. FSIS plans to present case examples involving Salmonella in eggs and BSE.

Wendy Fineblum Hall - (USDA/APHIS)

- Hosting a Risk Communication Forum on April 2 from 1:30-4:00 at APHIS Conference Center, rooms C & D, 4700 River Road, Riverdale, MD. Featuring Prof. Katherine McComas, U. MD, who will give a primer on risk communication in the regulatory context and Dr Buchanan, who will discuss communication between CFSAN risk managers and CFSAN risk assessors.

Tanya Roberts - (USDA/ ERS)

- Official roll out on April 24 at 9:00 am for the foodborne cost calculator, an online model.
- Performance standards conference on Oct. 22

- She participated in the Joint FAO/WHO workshop on Risk Characterization of Microbiological Hazards in Food, 23-28 February, Copenhagen on the economics chapter.

Michael McElvaine - (USDA/ORACBA)

- Proceedings from conference on sensitivity analysis will be published.

Mary Torrence (USDA/CSREES) Has invited the following speakers for the next RAC meeting on June 19:

- Philip Smith, Texas Tech., will discuss risks from food crops grown with perchlorate-contaminated water.
- Catherine Logue, N. Dakota State U., will present food safety risk assessment (contamination of turkeys in processing and risk of human foodborne illness).

Rolando Flores (USDA/ARS)

- Submitted a paper describing effect of temperature on the behaviour of E. coli O157:H7 in raw, irradiated ground beef to Int. J. Food Microbiol..
- Researching competition models for behaviour of E. coli O157:H7 in raw ground beef containing defined and undefined spoilage flora.
- Currently modeling growth of Listeria monocytogenes on cured ham slices (aerobic & anaerobic) including effects of previous temperature history.
- New PMP 7.0 version will be available this spring. Includes the following: new model for E. coli O157:H7 in sterile raw ground beef from 5- 47° C; model for thermal inactivation of Salmonella in beef; lag & no lag predictions in existing growth models; help section with frequently asked questions; and associated model references will appear within the output screen.
 - Will be available on CD and internet-downloadable version
 - Will be available in 3 languages: English, Chinese & Spanish
- ComBase Internet browser will be launched this spring.
- Studied distribution of E. coli O157:H7 in beef grinding. One manuscript published (small scale grinding) and another in preparation (Mid scale grinding).
- Also researched L. monocytogenes distribution in grinding.
- Will investigate distribution of Salmonella in grinding process.
- Submitted an article on distribution of E. coli O157:H7 in beef produced by bowl-cutter to J. Food Prot.
- Continuing research in the development of transfer coefficients for E. coli O157:H7 in fabrication step of beef processing.
- Starting to evaluate pathogen viability in the chilling process of beef carcasses at -3 to 5° C and water activities above 0.9.

John Cicmanec - (EPA/ORD)

- Looking at homeland security treatment effectiveness of killing or disinfecting various infectious agents in water.
 - Boiling water spreads organisms
 - Anthrax spores are more resistant to chlorination than Giardia, but less than Cryptosporidium
- Chronic wasting disease (CWD) - Lymphnode biopsy procedure for preclinical diagnosis

Stephen Schaub (EPA/OW)

- Looking at food chain control. Re-evaluating policies.
- Studying BSE & SE in blood supply.
- Counter terrorism using C. botulinum

Jackie McQueen - (EPA/ ORD)

- Provided Web address for information quality guidelines: (www.epa.gov/qualityguidelines/index.html#reqcorr)
- 5 year plan: Safe Food, Drinking Water, and Safe Communities Multi-Year Plans.
 - Safe Food Multi-Year Plan supports implementation of 1996 Food Quality Protection Act; Drinking Water Multi-Year Plan; and Safe Communities Multi-Year Plan (includes biotechnology research for food & computational toxicology).
 - Homeland Security Research Center focus is on developing methods to clean up contaminated buildings, protecting nation's drinking water and improving risk assessment techniques.
- EPA's science forum is May 5-7, 2003. There is no registration fee, but need to pre-register for this forum.
- Petition on atrazine

Angela Ruple- (NOAA fisheries)

- Looking at total mercury levels in Gulf of Mexico, fish associated with oilrigs and highly migratory fish. Equipment is up & running.
- Attended Interstate Shellfish Sanitation Conference (ISSC) Vibrio parahemolyticus management meeting. Annual ISSC meeting is in August.

Erik Tarring DOD/VSA

- Studying vulnerability of food supply and infrastructure.
- Rapid diagnosis for select agents.

Robert Hall (NIH/ NIAID)

- He has replaced Dennis Lang, who moved to NIEHS in N. Carolina.
- Located in Enteric and Hepatic Diseases Branch in Division of Microbiology and Infectious Diseases
- Branch oversees extramural activity in enteric bacterial and viral diseases.
- Background in Vibrio, Listeria, and Campylobacter.

Mary Bartholomew - (FDA/CVM)

- Looking at BSE antibiotic resistance.
- Court case on fluoroquinolones. See Oct. & April regulations
- Involved in April 25th FDA Science Forum session on cancer risks. Dr. Albert Keeney will present genetics of structure function model.
- John Bowers also participated in the Joint FAO/WHO workshop on Risk Characterization of Microbiological Hazards in Food, 23-28 February, Copenhagen.
- Previously there was a workshop on Guidelines for Risk assessment and the Exposure Assessment is now out for review.
- Revised Listeria monocytogenes and Vibrio parahaemolyticus risk assessments nearing completion - In the L. monocytogenes risk assessment, most food categories have similar risks as estimated in the earlier draft." In the V. parahaemolyticus risk assessment, although there were some modeling changes, the overall results are similar to the previous model's results. Both will be completed this spring.

Wes Long (FDA/CFSAN)

- Discussed JIFSAN's professional development training program. Last summer they piloted a 14-day web-based risk analysis overview course. Funding came from a CSREES grant. Currently working on web-based risk assessment and risk communication courses.

Cristina McLaughlin (FDA/CFSAN)

- Significant changes in Food Safety Risk Analysis Clearinghouse:
 - New section on nutrition labeling
 - Working on epidemiology section with emphasis on a thesaurus on risk assessment terms.
 - NFPA Listeria risk assessment was published on the Clearinghouse March 27, 2003.

Marianne Miliotis - (FDA/CFSAN)

- An application of *V. parahaemolyticus* risk assessment model was proposed to ISSC as a possible alternate plan for reducing illness due to this organism at the *V. parahaemolyticus* management meeting earlier this month.
- First International conference on Microbial Risk Assessment (ICMRA) - Proceedings: Expecting 2 more documents by the end of the month, then will proceed with publishing.
- Last May CFSAN initiated implementation of the CFSAN Risk Analysis Framework. Three risk assessments have been selected and about to start the data feasibility evaluation.
- Announced 2003 CSL/JIFSAN Joint Symposium on Food Safety and Nutrition: Risk Analysis, June 11-13 at Inn and Conference Center, U. MD. Registration for government is \$175 due before May 116, 2003.

10:15 - 11:15 a.m: 5 minute work group updates

Dose-Response Work Group - Marianne Miliotis (CFSAN)

1) Mechanistic dose-response data from animals, humans and tissue culture - Peg Coleman (FSIS) and Marianne Miliotis (CFSAN).

- Objectives are:
 - 1) compiling and interpreting mechanistic data for modeling variability (host, pathogen, environment, and interactions) for dose - response;
 - 2) interpreting evidence for selected pathogens; and
 - 3) describing potential improvements to current dose-response models for predicting adverse endpoints in humans from foodborne or waterborne hazards.
- Status:
 - Angelo Turturro (NCTR) presented "Target Dose Concept Applied to Microbial Risk Assessment" at the September quarterly meeting.
 - Peg Coleman discussed "Mechanistic Dose-Response Data From Animals and Humans" at this meeting.
 - Marianne Miliotis (CFSAN) will highlight "mechanistic Dose Response Data From in Vitro Studies at the fall quarterly meeting.

2) 3 clinical and animal DR grants - Marianne Miliotis (CFSAN)

- LM in Rhesus monkeys - UGA: published 1 paper in collaboration with CFSAN personnel; currently extending studies on a contract with FDA/CFSAN.
- *Cryptosporidium parvum* -TUFTS/UTX Med School: delivered several presentations and papers. Project is completed with following conclusions: mouse model is unsuitable surrogate to the majority of *C. parvum* isolates, but useful for discerning isolate-specific differences in pathogenicity.
- *Vibrio* spp. - UMD: Animal study results presented at 101st Am. Society for Micro. May 20-24. Project has been terminated.

Performance Standards Work Group - Janell Kause (FSIS)

- A proposed 2-day public meeting is planned on "Perspectives Regarding Performance Standards: Risk Assessment and Economics" to be held October 21-22, 2003.

- The Oct. 21st risk assessment session is awaiting approval from FSIS later this month. Given FSIS present commitments for public meetings and the soon to be delivered NAS report on performance standards, FSIS has elected not to co- host this meeting at this time.
- The Oct. 22nd economic portion will be held at the Economic Research Service Building, 18th & M Street, Washington, DC.

Biological Terrorism Treat Assessment Tools/Methodology Work

Project withdrawn due to security issues. Long (CFSAN)

Microbial Risk Assessment Framework - Wes Long (CFSAN)

- Draft "Interim Observations on the Practice of Microbiological Risk Assessment" by Charlie Yoe has been reviewed by the work group and is ready to be presented to RAC Policy Council for review and clearance.

11:15 - 12:00 a.m.: Begin FY 2004 annual plan discussion (data quality)

The afternoon session featured the following presentation:

- EPA's Council for Regulatory Environmental Modeling - Pasky Pascual, EPA/ORD, lead for EPA's Council for Regulatory Environmental Modeling.
 - Announced symposium on use of computerized environmental models: May 14th, 1-3 p.m. at Woodrow Wilson International Center for Scholars, 5th floor conference room. Located near Federal Triangle, Washington, D.C. (<http://wwics.si.edu/index.cfm?fuseaction=about.directions>)
- RAC Dose-Response Work Group's "Mechanistic Dose-Response Data from Animals & Humans" - Peg Coleman

4:00 p.m: meeting ended

Thursday, March 27

9:30 am -1:00 pm Continue FY04 annual planning

1:00 pm -4:00 pm Policy Council meeting

- 1:00 pm -2:00 pm Presentations on Food Safety Risk Analysis Clearinghouse by:
- Cristina McLaughlin (CFSAN/FDA)
 - Hitesh Patel (UMD)
 - Jennifer Hinton (UMD)

2:00 pm-4:00 pm The policy council representatives reviewed the progress of the RAC towards FY03 annual plan goals, discussed and approved Charter revisions, and commented on FY04 goals. The Draft "Interim Observations on the Practice of Microbiological Risk Assessment" by Charlie was presented to RAC Policy Council for review and clearance. RAC Policy Council was asked to comment by the end of April. Revisions are scheduled to be completed by May 16, 2003.

In attendance:

Peg Coleman USDA/FSIS
 Janell Kause USDA/FSIS ('phone)
 Michael Kasnia USDA/FSIS

Carol Maczka USDA/FSIS
Robert McDowell USDA/APHIS
Wendy Fineblum Hall USDA/APHIS
Michael McElvaine USDA/ORACBA
Rolando Flores USDA/ ARS
Mary Torrence USDA/ CSREES
Tanya Roberts USDA/ ERS ('phone)
John Cicmanec EPA/ORD ('phone)
Jacqueline McQueen EPA/ORD
Stephen Schaub EPA/OW ('phone)
Angela Ruple NOAA Fisheries
Spencer Garrett, NOAA Fisheries
Erik Tarring DOD/VSA
Robert Hall NIH/NIAID
Mary Bartholomew FDA/CVM
Barry Hooberman FDA/CVM ('phone)
Angelo Turturro FDA/NCTR
Robert Buchanan FDA/CFSAN
Sherri Dennis FDA/CFSAN
Richard Whiting FDA/CFSAN
Cristina McLaughlin FDA/CFSAN
John Hicks FDA/CFSAN
Mary Bender FDA/CFSAN
Wes Long FDA/CFSAN
Marianne Miliotis CFSAN/FDA
Sharon Edelson-Mammel FDA/CFSAN
Carole Shore FDA/CFSAN

Agencies represented:

Veterinary Service Activity (DOD/VSA)
Environmental Protection Agency, Office of Research and Development (EPA/ORD)
Environmental Protection Agency, Office of Water (EPA/OW)
Center for Food Safety and Applied Nutrition (DHHS/FDA/CFSAN)
Center for Veterinary Medicine (DHHS/FDA/CVM)
National Center for Toxicological Research (DHHS/FDA/NCTR)
National Oceanic and Atmospheric Administration Fisheries (NOAA Fisheries)
Animal Plant Health Inspection Service (USDA/APHIS)
Agricultural Research Service (USDA/ARS)
Economic Research Service (USDA/ERS)
Food Safety Inspection Service (USDA/FSIS)
Office of Risk Assessment and Cost Benefit Analysis (USDA/ORACBA)
Cooperative State Research, Education, and Extension Service (USDA/CSREES)