

RAC Meeting Minutes (June 19, 2003)

USDA/APHIS

4700 River Rd,

Riverdale, MD

June 19, 2003

9:00 - 9:15: Introduction

10:00 am: 3 minute updates

Janell Kause-USDA/FSIS

- New AAAS Fellow -Dr David Goldblatt, from the Swiss Federal Institute of Technology, Zurich, Switzerland will join FSIS/RAD
- A BSE scenario analysis was developed by Terry Disney based on the BSE thinking paper published earlier.Â Should BSE enter the U.S., this analysis will provide the USDA/FSIS' decision-makers various mitigation options to effectively control or reduce human exposure
- FSIS has awarded a 90-day contract to Dr. Edmund Crouch, Cambridge Environmental, to perform a risk assessment on *Clostridium perfringens* in RTE and partially cooked foods.Â This risk assessment will inform management decision-making regarding the RTE rule on stabilization of RTE product
- FSIS responses were provided to OMB on the *Listeria* risk assessment.Â The current model will be extended in light of additional risk management needs and peer reviewers' comments; particularly for development of targeted verification sampling plans for *Listeria*.Â More information is available at: <http://www.fsis.usda.gov/oa/topics/lm.htm>
- FSIS is continuing work on a risk assessment for *Salmonella* Enteritidis in shell eggs and *Salmonella* spp. in egg products.Â Current work is focused on analyzing FSIS baseline data for *Salmonella* prevalence in liquid egg product sampled at production facilities.Â FSIS plans to have a draft risk assessment completed this fall.
- FSIS is working with Greg Paoli, Decionalysis Risk Consultants, Inc., Canada, to investigate the impact of lethality standards for *Salmonella* spp. on the risk of salmonellosis from RTE meat and poultry products.

Richard Whiting-FDA/CFSAN

- *Listeria monocytogenes* Risk Assessment should be finished by the end of the month, will go for review.Â Late summer roll out.
- Counter Terrorism RA- Done inhouse; Looked at agent, food, and time schedule - they were used to help determine where additional research could help prevent or improve the response to a foodborne terrorism event.

Robert Hall-NIH/NIAID

- End of fiscal year, research agenda for grants in place for next fiscal year on food and waterborne disease.Â Several contracts in place to address important issues in general areas.
- May 23, 2003 - Meeting on Botulism Toxins, improved systems of detection

Clinical Trials-next meeting will discuss where that is headed

Angelo Turturro-FDA/NCTR

- Premium on Bioterrorism equipment
- *Cryptosporidium* research is continuing
- New Building - getting it up and running
- Developing new rapid detection methods - Microarrays, PCR- quick analysis of bugs, esp. pathogenic gene complexes

Wes Long-FDA/CFSAN

- Plug for courses on Risk Analysis Professional Training through JIFSAN.
- 3 Day Joint CSL/JIFSAN Meeting on Food Safety and Nutrition: Risk Analysis occurred June 11-13, 2003; ~50 people attended. Case Studies were used to describe the increasingly important role of risk analysis; specifically in food safety decisions and communication to the public. Presentations will appear on the JIFSAN website: <http://www.jifsan.umd.edu/proceedings.htm>

Mary Torrence-USDA/CSREES

- May 22, 2003 CSREES awardee presentations took place on Epidemiologic Research in Food Safety Issues
- USDA Risk Assessment working group has been established including all USDA agencies, with FSIS as the chair; will coordinate risk assessments and will have a big review role for FSIS risk assessments; a press release will come out at the end of June, 200
- New Book on Microbial Food Safety just published - coedited by Mary Torrence and Richard Isaacson - look for it on Iowa State website

Jackie McQueen-EPA/ORD

- Guidelines for risk assessment for children - a handbook on child-specific exposure factors was prepared by National Center for Environmental Assessment, ORD, EPA, which consolidates all children's exposure factors into one document. It provides a summary of available and up-to-date statistical data on factors assessing children's exposures. This document can be accessed at: www.epa.gov/ncea
- Use of third party human studies to evaluate pesticide safety has been approved - in recent ruling, court overturned EPA's policy on moratorium on human studies, pending results of NAS review.

Rolando Flores-USDA/ARS

CRIS unit at ARS has a new employee, Dr Andy Wong who is working on salad dressing and *isteria*

ARS and the UK Institute of Food Research launched the relational database ComBase on Monday. The web address for those interested is <http://wyndmoor.arserrc.gov/combase/>.

Steve Schaub-EPA/OW

- EPA introduced its recreational water studies- 9 beaches (5 marine, 4 fresh water: lakes and some streams) over the next 5(?) years to look for exposure to marker organisms (enterococci and *E. coli*) that deal with gastrointestinal disease; they're looking for new methods for rapid identification of indicator organisms using current methods; correlation with actual incidence of illness-strict guidelines on the volunteer subjects
- The EPA Risk Assessment Forum has started a process for developing an agency-wide guidance for microbial risk assessment (MRA). A steering group has been established to develop a strategy to develop guidelines for MRA in air, and water. These guidelines will be strictly for EPA and their contractors

- EPA/OW moving forward with a MRA protocol for OW: they are developing guidelines for proper procedure for managers and communicators; problem formulation and ways to develop a conceptual model

Mary Bartholomew-FDA/CVM

- CVM underwent NOH Process - cross examination and oral testimony on fluoroquinolones in poultry - RA was one of the supporting pieces of information for withdrawing fluoroquinolones from poultry - awaiting court decision
- Close to completing draft on Virginiamycin

Marianne Miliotis-FDA/CFSAN

- *Vibrio parahaemolyticus* Risk Assessment should be completed by late summer, early fall
- CFSAN has started the data feasibility determination phase of a Virus Risk Project, which is a combination of 3 proposals:
 - Transmission by bare hand contact with Norwalk-like virus (Norovirus)
 - Incidence of foodborne virus-associated illnesses on interstate conveyances
 - Foodborne Virus data gap analysis
- CFSAN is working with SRA and JIFSAN to hold a workshop on Regulatory Peer Review
- Under a cooperative agreement with FDA/CFSAN, as part of the extramural food safety program, the Institute for Food Technologists (IFT) is developing a risk-ranking framework to evaluate potential high threat microbiological agents, toxins, and chemical agents in food

10:15 - 11:45 Workgroup Updates and other issues

Dose-Response Workgroup

Dose Response Grants ex 1998:

Dose response model for *Listeria monocytogenes* ended FY 2000

Dose response model for *Cryptosporidium parvum* ended in December 2002

Dose response model for *Vibrio* spp. was terminated in March 2002.

Compilation of Mechanistic dose-response data:

To be continued in FY04

Proposal by Wes Long to collaborate with NIH to add dose response groups to trials already in process.Â

Performance Standard Workgroup

Planning for 2-day public meeting October 21 and 22, 2003 is in progress.

Data Gaps Workgroup

The data gaps information collected by the work group has been organized into several tables.Â They will be sent to the workgroup within the next week.Â After receiving feedback from the group, the tables will be updated, the product will be shared with the RAC, and then posted on the Clearinghouse RAC website.Â This will be a dynamic product, in that the content will change as the data gaps are filled and new ones are identified.

Public Meetings

- 1) SRA workshop on Peer Review of Federal Documents. The possibility of making the SRA Peer Review workshop into a joint JIFSAN-SRA-RAC public meeting was discussed and will be further evaluated during a meeting of the workgroup in July.
- 2) Performance Standards public meeting is described above.

FY04 Annual Plan

1. Projects to be Continued from FY03:
 1. Presentations
 - i. Presentations by agency representatives on current risk assessments
 - ii. Update on CDC projects that impact risk assessments to be determined
 1. ATSDR (CDC) may be interested in joining RA
2. New Projects

Two work groups were proposed for FY2004 and some members identified:

- 1) *Peer Review* (of Risk Assessment and other Federal Documents) Workgroup

Description:

The process for conducting peer reviews of regulatory risk assessments has been well laid out in the EPA Science Policy Council handbook on peer review (December 2000). These documents and others are likely to provide a starting point for the development of peer review guidelines for food safety microbial risk assessments used to inform regulatory decision-making under current OMB guidelines. Such guidelines are essential for determining the adequacy of a peer review process for regulatory risk assessment. Without such guidelines, a risk assessment may not be targeted enough to provide adequate scientific supports for the estimation of benefits in a cost-benefit analysis. Consequently, regulations based on such a cost-benefit analysis could be deemed *arbitrary and capricious* by a judge.

Several issues to be considered by the workgroup were discussed.

Deliverable(s):

- Discussions on possibility of the RAC coordinating with SRA and JIFSAN on the SRA workshop on peer review for regulatory agencies to hold a public meeting
- Develop a concept paper on recommended guidelines for conducting peer review for regulatory agencies

Current Members:

1. Mary Bartholomew (co-Lead), FDA/CVM
2. Barry Hooberman, FDA/CVM
3. Mike Kasnia, USDA/FSIS
4. Janell Kause (Lead), USDA/FSIS
5. Marianne Miliotis, FDA/CFSAN
6. Stephen Schaub, EPA/OW
7. ? Others

2) *Data and Information Quality Guidelines in Risk Assessment Work Group*

Description:

Data quality is essential to risk assessment. Guidelines for determining which data to include in risk assessments are needed to improve risk assessment methodology. Furthermore, development of a uniform system of weight of evidence included in risk assessments would likely help in developing predictions that more accurately reflect the real world.

Issues to be considered by the workgroup were discussed.

Deliverables:

- OMB guidelines (can post on clearinghouse website)
- Collection of all agencies that have data quality guideline in relation to OMB- Main site on clearinghouse with the needed links to other websites.
- Review notes from previous meetings on Data Needs for clearinghouse
- RAC White paper document based on compilation of member agencies' guidelines and previous meetings

Current Members:

1. Mary Bartholomew, FDA/CVM
2. Sherri Dennis, FDA/CFSAN
3. Uday Dessai, USDA/FSIS
4. Stephen Schaub, EPA/OW
5. Carl Schroeder (Lead), USDA/FSIS
6. ? Others

Noon - 2 pm: **Risk Assessment Seminars**

"Food Safety Risk Assessment Research at NDSU"

By Catherine Logue, North Dakota State University

"A review of the screening ecological risk assessment for perchlorate emphasizing unused and developing data resources"

By Philip Smith and Dr. W. Andrew Jackson, Texas Tech

Attendees: (via phone*)

Mary Bartholomew (FDA/CVM)*
Sharon Edelson-Mammel (FDA/CFSAN)
Rolando Flores (USDA/ARS)*
Robert Hall (NIH/NIAID)
Mike Kasnia (USDA/FSIS)
Janell Kause (USDA/FSIS)
Wesley Long (FDA/CFSAN)
Michael McElvaine (USDA/ORACBA)
Jacqueline McQueen (EPA/ORD)
Marianne Miliotis (FDA/CFSAN)
Tanya Roberts (USDA/ERS)*
Stephen Schaub (EPA/OW)*

Carl Schroeder (USDA/FSIS)
Mary Torrence (USDA/CSREES)
Eric Topping (DOD)
Angelo Turturro (FDA/NCTR)
Richard Whiting (FDA/CFR)