RAC Meeting Minutes (October 1, 2003)

Quarterly Meeting

FSIS/Room 369, Aerospace Building
901 D Street SW
Washington, DC

9:00 – noon	RAC Technical Representative Meeting
9:00 – 9:15 am	Introductions
9:15 – 9:45 am	3 minute updates

Peg Coleman, USDA/FSIS

Reorganization and new hires. The proposed reorganizational structure for FSIS was approved recently, with the newly approved Risk Assessment Division (RAD).

Additional staff. Two scientists, Heather Hicks Quesenberry and David Goldblatt, joined the Risk Assessment Division. Two former USDA fellows with RAD, Neal Golden and Heejeong Latimer, accepted permanent positions with FSIS.

Dr. Lynda Kelley joined the Office of the Deputy Administrator for OPHS as the Strategic Manager for Research & Technology Transfer.

Dr. Mike Wehr was selected as the Director of the FSIS Codex Program Staff within the Office of International Affairs.

FSIS is coordinating with FDA in the roll out later this fall of the revised **FDA/FSIS risk ranking of ready-to-eat foods for *Listeria monocytogenes*.**

Clostridium perfringens risk assessment. FSIS is working with Cambridge Environmental to complete a risk assessment for *C. perfringens* in RTE meat and poultry.

BSE risk assessment. Terry Disney and Uday Dessai continue to work with the FSIS Office for Policy Planning and Development (OPPD), as well as colleagues from Harvard Center for Risk Analysis, Tuskegee University, APHIS, and the FDA Center for Veterinary Medicine, to develop scenarios to address policy questions and identify specified risk materials that require further management control.

***Salmonella* Enteritidis Risk Assessment (SERA) Revision**. RAD has established contracts with RTI to format the document and with SAIC to administer the external peer-review process for the revised SERA documentation. In addition, Louise Ryan of Harvard School of Public Health will serve FSIS under the Intergovernmental Personnel Act (IPA) in reviewing the new SERA model. Options were discussed for completing the remaining work on the project this fall; providing documentation to OPPD; and initiating the external peer review.

***Campylobacter* in poultry feasibility study.** FSIS is working to extend the data analysis for exposure assessment and dose-response assessment in the WHO/FAO Campylobacter risk assessment in poultry. Datasets for *Campylobacter* enumeration are available for analysis from FSIS and ARS, and datasets are being sought among RAC member agencies for dose-response studies with ferrets or in vitro assays to extend the inconclusive data for the two strains administered in human clinical trials. (*Campylobacter* dose response is one example under

consideration by the RAC Dose-Response Work Group for FY04.)

Lethality for RTE products. FSIS is conducting a risk assessment with the objective of modeling the impact of lethality performance standards for RTE products with Greg Paoli of Decisionalysis.

Donald Sharp, CDC/NCID

Clinical Infectious Disease supplement to be published within next 3-6 months will include 26 articles based on FoodNet data.

Reports presenting final 2001 FoodNet data and preliminary 2002 FoodNet data were published in April, 2003.

CDC's Prevention Effectiveness staff is developing an economic model to estimate the nationwide cost of all types of illness (foodborne and non-foodborne) due to *Salmonella* infections.

The Prevention Effectiveness staff is also conducting a willingness-to-pay/contingent valuation study using hypothetical vaccines against foodborne illnesses as a method to examine how the public views these illnesses from an economic standpoint.

Steve Schaub, EPA/OW

Microbial Risk Assessment - EPA/OW had a forum in July - trying to make the ILSI microbial risk assessment framework into to a fully fledged document/ protocol for EPA to conduct risk assessments RA on the microbial safety of water.

EPA/OW is working with EPA's Risk Assessment Forum Staff to develop agency risk assessment guidelines for both agency and contractors' use. Representatives of the RAC are participating in this effort.

Recently completed a workshop on the "Problem Formulation" for the OW for Protocols for different RA's-homeland security, water etc. The goal of the workshop was to make risk assessments more streamlined; define the roles of Risk Manager, Assessors, Communicators; setting up risk assessments, etc. Basically, a risk assessment quality approach.

Interagency work group on SARS virus to support WHO and countries that have had outbreaks. Specifically looking at environmental contribution, including animal sources, to provide risked based contributions- Dennis Juranek, CDC, is the lead.

Steve recently came back from a WHO workgroup meeting in Italy – U.S. representation included: CDC, USDA, NIOSH, and EPA. Workgroup found that outbreaks may have been increased due to the use of fans that cause spraying of water droplets containing virus.

Mary Bartholomew, FDA/CVM

Follow-up on **Court Case on fluoroquinolones in poultry** – briefs are up on CVM website; decision expected after new calendar year begins.

Richard Whiting, FDA/CFSAN

***Listeria monocytogenes* Quantitative Risk Assessment on RTE Food** (see Peg Coleman's update) is complete; CFSAN is currently giving briefs; targeted date for public release on October 15-16/03.

Setting up meetings with trade associations, etc.

Mark Tamplin, USDA/ARS

COMBASE was released to the public in July 2003; contains ~20,000 records of growth, inactivation and survival of bacteria. Version 2.0 will be released in December 2003. There will be an additonal 8000 records. Began Beta testing PMP 7.0 in September; has lag/ no lag feature for estimation of growth. PMP 7.0 also includes *E. coli* in sterile ground beef model as well as a thermal inactivation model of salmonella in beef. A decision-support tool (Expert System) will be completed by the end of the year. This will be an Internet resource to assist persons in locating ComBase data records, PMP models, PDF versions of related publications, and other information. ARS is working with Decisionalysis, Inc. on this project. There is a new vacancy in the Predictive Microbiology group with the departure of Rolando Flores to another ARS research unit. Andy Hwang, previously with Nestle, joined the group last Spring and will focus on non-thermal inactivation of pathogens in formulated foods.

Margaret Venuto, USDA/CSREES

CSREES are funding research for three initiatives this year:

1. National Integrated Food Safety Initiative: $14 million 12/19/03. Due date for applications is December 19, 2003
2. Ensuring Food Safety
3. Epidemiologic Approaches to Food Safety. Due date for applications for 2 and 3 is March 15, 2004.

Eric Torring, DOD/VSA

Introduced Brandolyn Thran from ARMY/CHIPPM

Wes Long, FDA/CFSAN

Applauded the Peer Review Symposium co jointly sponsored by JIFSAN, SRA, and the RAC; this symposium emphasizes that the focus of the RAC is on current issues

JIFSAN Training opportunities: upcoming Risk Analysis classes

a. Intro to Food Safety Epidemiology class last week in October: Tue Oct 28-Thur Oct 30, 2003.
b. Introduction to Food Safety Risk Management first week in November: 3, 5, 7, 2003.

Jackie McQueen, EPA/ORD

EPA Science inventory on data base goes public on November 17, 2003, - big section on peer review activities of EPA: what level, internal or external. Basically what EPA is interested in. Also includes research activities going on at EPA. Fax sheet with the information almost ready, will be distributed when ready.

John Cicmanec, EPA/ORD

Member of same SARS work group as Steve Schaub; also present at meeting in Annapolis looking at **zoonotic illness in water**. Found parasite, *Fasciola hepatica*, in Bolivia water. *Campylobacter* in dairy herds (WHO will release a book on this at end of the year), and update on *E. coli* 0157:H7 in Europe.

In Cincinnati, Homeland Security Research Center, funds are available for research and risk assessment.

Developed a framework for the Microbial release of agents of terror, using attenuated organisms. They have a weaponized strain of *B. subtilis.*

John is presenting a poster on the "Infectious dose of weapons grade *B. anthracis* at the SRA meeting in December.

Margaret Miller, FDA/OWH

OWH is not doing any risk assessments, but **sponsored a meeting with children's advocates** to address the issue that risk assessments should include children and the susceptible subpopulation.

Marianne Miliotis, FDA/CFSAN

CFSAN had an **All-Hands meeting and weight loss ceremony** September 30, 2003. Commissioner McClellan and Secretary of HHS, Tommy Thompson attended.

***Vibrio parahaemolyticus* Risk Assessment** - snag in modeling, waiting for additional information to continue, and will probably be complete early spring.

CT RFAs. CFSAN has funded 5 applications in response to CT RFAs.

Robert Hall, NIH/NIAID

Contract activities regarding foodborne disease moving forward.

Biodefense activities - NIH/NIAID granted eight "Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE)" awards to various institutions. NIH/NIAID is also funding construction of two National Biocontainment laboratories (NBL) and

nine Regional Biocontainment laboratories (RBL).

A Clinical trial concept to study the *Vibrio cholerae* 0139 Bengal-15 vaccines has been provisionally approved. Approximately 100 volunteers will participate. David Bernstein and Mitchell Cohen, (University of Cincinnati School of Medicine) are the principal investigators (PIs). NIH is currently developing the clinical protocol in collaboration with the PIs to maximize the information that can be obtained from this trial. Would like it to tie in with a biodefense repository (out on contract), which can provide standardized reagents for field laboratories; anything that can be useful to the research community. NIH is working closely with CDC to prevent overlap of culture collections.

10:15 – 10:20 am: 5 minute work group updates

Dose-Response Work group

- Presentation by Angelo Turturro on "Target Dose for Microbial Pathogens" (September 2002)
- Presentation by Peg Coleman on "Mechanistic Dose-Response Data from Animals & Humans" (March 2003)
- In addition to focusing on data and models, there will be an expansion in membership and frequency of work group meetings to provide more opportunities to address more specifically the data gaps for dose-response modeling that offer potential clarification using mechanisitic approaches. *Campylobacter* dose response is one example under consideration. This will also help identify data gaps, and provide information as to how to fill them.

Data Gaps Analysis Work Group

- A draft Excel workbook file containing descriptions of data gaps for 9 national and international risk assessments was produced and circulated among the workgroup members.
- The workbook will also include data gaps for risk assessments that are currently in progress
- Discussion on how to post information on RAC clearing house.

Performance Standards Work Group

Currently inactive

Bioterrorism Work Group

Due to security reasons, this work group was made inactive.

Data and Information Quality Guidelines Work Group

A hard copy of a summary document prepared by the workgroup will be forwarded to the RAC members

Peer Review Work Group

- A symposium was held September 30, 2003. A summary of the meeting, which will include the abstracts and presentations, will be posted on the RAC website. The Peer Review Work Group will also develop a discussion paper based on the meeting and the recently released OMB guidelines. This paper will include the various approaches utilized.

- It is possible that this group will plan for a follow-up 2nd symposium 1 year from now. There is possibility of this meeting being a product of the Peer Review and the Data Information and Quality Work Groups.

11:00 – noon FY04 Annual plan

- Carry over presentations listed for FY03 with suggested CDC presentations such as: update of FoodNet including a brief listing of on-going and proposed specialized studies (surveys or case-control studies); Listeria case-control study; overview of food attribution data.
- Additional presentations:

Sampling plan design impacts the utility of data for risk assessments. It was recommended to having presentations to help us understand the scope and impact of the problem, possibly as an all-day meeting.

Suggestion: Presentation on the effect of non-homogeneity of the matrix on sampling plans

Noon – 1:00 pm Presentation:

Food Handling Practices Model" by David Kendall, RTI

2:00 – 3:45 pm **RAC Policy Council meeting**

2:00 – 2:10 pm Introductions

2:10 – 2:45 pm RAC Accomplishments

The RAC accomplishments, presentation, work group, and public meeting accomplishments were presented to the RAC Policy Council members.

9 presentations

Dose-Response Workgroup

Two of the four presentations in the work group objectives have been given, the other 2 will take place in FY04

Looking at *in vitro* and *in vivo* (animal and human) studies. Scope of the work group in FY 2004 will emphasize mechanistic data: relative measures of host susceptibility; pathogen variability measured from *in vitro* and animal and human clinical studies; rates of pathogen excretion and attachment; rates of host cell sloughing, repair, and lesion formation; efficacy of host physiological and immune defenses; and biomarkers for activation of immune defenses.

Will address more specifically the data gaps for dose-response modeling that offer potential clarification using mechanisitic approaches.

Few examples that can than be formed into a manuscript, formed into a more targeted way. Work group will explore examples more thoroughly; e.g., *Campylobacter*.

During the discussion, it was suggested that the work group contact the Japanese group that had a break through in dose response for *Salmonella*. At end of day, Japanese restaurants of certain sizes have to save a frozen sample of each entrée served that day for 2 weeks, just in case there is an outbreak. In 2000 (2001), there was an outbreak of *Salmonella* in Japan, which was traced back to a frozen sample. The frozen samples were used for enumeration of the *Salmonella*.

Data gap analysis work group

It was encouraged that data gaps are filled not just identified; it was suggested to possibly put the list of gaps on the web and describe how the data gaps can be filled. Another possible mechanism would be to present the information at a meeting, like IFT, where scientists attend, so that they can help fill these data gaps.

Peer Review Work Group

Make information available on RAC Website. See morning notes on peer review group accomplishments. The proposal of having a joint Peer review and Data quality symposium in approximately one year was also discussed.

Data Information and Quality Work group

There was much discussion on the objectives of this work group. Some of the comments provided by the representatives include:

a. Data quality issues were brought up at peer review symposium September 30, 2003 -no task yet that has really brought those two things together.
b. Have general principles on data quality level, need to discuss what has to be done to take it to the next level.
c. Need a weight of evidence ranking.
d. Acknowledge when you have low quality data; some thought that this was rather risky because risk managers would decrease their confidence in the RA if they thought it was based on low quality data.

   It was suggested that derivation of a "suitability rating" might be more appropriate. It would consider the qualities mentioned in the data quality guidelines and things like age of data, foreign data or not, animal versus human, etc.
e. The question was raised, who will be using data quality guidelines, the assessors or the managers or the peer reviewers? How you weight or use these data depends on who is going to use it. Originally thought the idea was that they would be of use to the assessors.
f. One has to consider not just the quality of the data per se but whether the results of the RA depend on the quality of the data. At some points in the model, poor data will not influence the model outcome much so that it would not be worthwhile to spend more money on better data.
g. Suggested that the work group look at how member agency risk assessors have dealt with data quality in their RAs for ideas, i.e., how problems have been addressed. E.g., the FDA/FSIS *Listeria* risk assessment, weighting of data was captured in the uncertainty. Data for the U.S. FDA/USDA *Listeria monocytogenes* risk assessment were weighted differently, based on country and year.

   Include additional categories that people could use to complete their RA's.
h. Need criteria for critiquing data, better than just listing the problems.
i. There is also the issue of surrogate data.
j. What will fall into one group or another, you are getting into peer review. Precision and accuracy, studies may agree but they all may have problems with data, such as data from a few years ago
k. What's available depends on discipline, how relative is it, sometimes you have to go with the data you have
l. Some countries had bad data, so they put characteristics into the prevalence data's. Let users know, but put everything in.
m. Also depends on what these data will be used for; if for regulation, and data are poor,

then need to call for more research.
n. Need to look at definition of “transparency”; need to look at data in terms of putting some “uncertainty” estimate.
o. It was decided that the work group revise their objective and send it to the Policy Council for approval.
p. More members were recommended to join the work group.

2002 ICMRA manuscripts for proceedings are currently being reviewed by JFP reviewers

2:45 -3:00 pm **Wrap-up of FY03**

RAC has been really active and got a lot done.

The question was asked as to how often has RAC been asked by parent agencies, to take part or review risk assessments; how often has the RAC been utilized as a resource?

Some examples of how the RAC has been utilized by other agencies, include:

a. The EPA’s OW has received support from representatives from CFSAN, FSIS, CVM, and OWH in its development of a Microbial Risk Assessment process for the OW.
b. In addition, the RAC was asked to provide insight to the EPA’s OW based upon recent member agency experiences in conducting Microbiological Risk Assessment.
c. The RAC has also reviewed risk assessments conducted by member agencies.
d. Need to find opportunities to remind agencies that we are here; e.g. a periodic newsletter; post accomplishments and how the RAC can help member agencies on the RAC web site.

3:00 – 3:30 pm **RAC FY04 Annual Plan**

The FY04 annual plan as discussed in the morning session was brought to the Policy Council.

Examples of possible presentations for sampling techniques, as an all-day meeting recommended include:

a. ARS million hot dog sampling study for *Listeria monocytogenes*
b. The Japanese frozen sample study
c. Problems associated with creating sampling plans to support surveillance and regulatory activities. Examples include:
    i. Detection of peanut allergens in a variety of foods.
    ii. Detection of histamine in shrimp and tuna
    iii. Detection of *Salmonella* in/on fresh whole cantaloupe.

The Policy Council suggested that an **additional work group be formed to develop a framework for a chemical vs. microbial risk-risk assessment**. EPA has much experience with balancing chemical intervention with microbial risk, e.g., study on drinking water in New Orleans – huge document has been published.

Another example would be presence of Histamine in tuna fish.

A recommendation was to kick off work group by inviting EPA to present on their risk-risk assessment experiences (Stephen Schaub will recruit speakers).

In attendance:

Mary Bartholomew, FDA/CVM
Robert Buchanan, FDA/CFSAN
John Cicmanec, EPA/ORD*

Peg Coleman, USDA/FSIS|
Uday Dessai, USDA/FSIS
Sharon Edelson Mammel, FDA/CFSAN
Spencer Garrett, NOAA Fisheries*
David Goldblatt, USDA/FSIS
Robert Hall, NIH/NIAID*
Heather Hicks Quesenberry, USDA/FSIS
Andy Hwang, USDA/ARS/ERRS
Mike Kasnia, USDA/FSIS
Janell Kause, USDA/FSIS
Lynda Kelly, USDA/FSIS*
Ralph Kodell FDA/NCTR
Wes Long FDA/CFSAN
James Lindsay, USDA/ARS*
Carol Maczka, USDA/FSIS
Robert McDowell, USDA/APHIS
Michael McElvaine*
Marianne Miliotis, FDA/CFSAN
Margaret Miller, FDA/OWH*
Jacqueline McQueen, EPA/ORD
Kristen Naschansky Gray, FDA/CFSAN (Visiting scientist)
Steve Schaub, EPA/OW
Carl Schroeder USDA/FSIS
Scott Severin, DOD/VSA*
Don Sharp, CDC/NCID/DBMD/FSO
Mark Tamplin USDA/ARS/ERRS
Brandolyn Thran U.S. ARMY/CHPPM
Eric Torring, DOD/VSA
Angelo Turturro, FDA/NCTR
Margaret Venuto, USDA/CSREES
Richard Whiting, FDA/CFSAN

* Attended by conference call