RAC Meeting Minutes (December 18, 2003)

Quarterly Meeting

Agency Updates:

Centers for Disease Control and Prevention (CDC)
Welcome to Don Sharp - selected as new RAC technical representative for CDC.

- **International Conference on Emerging Infectious Diseases** (ICEID) is Feb 29-March 3 in Atlanta, GA.

- **CID articles** – 25 of them, to appear in Clinical Infectious Diseases in April of 2004

- **Consumers' Willingness to Pay for Food Safety**
  The Foodborne Diseases Active Surveillance Network (FoodNet) 2002 population survey data were analyzed. Respondents were asked about their willingness to pay for an imaginary vaccine that would protect them against major food-borne pathogens for a certain duration of time. Each respondent's choice to accept or reject the elicited amount ($25,$50, $75 and $100) is treated as a function of type of pathogen (*Salmonella, E. coli* and *Listeria*), duration of prevention (one year, five years, ten years and lifetime), respondent's demographic characteristics, current health status, and awareness of food safety. Some of the preliminary findings are (other variables remaining constant): 1. Sixty eight percent of respondents were willing to pay a minimum of $25. When the amount was increased to $100, the number of respondents accepting the bid went down to 45 percent. 2. Estimated willingness to pay was higher if a vaccine was presented as being effective for a longer period of time.
  3. Respondents were willing to pay significantly more for a hypothetical vaccine for *E.coli* than for vaccines for *Salmonella* or *Listeria*.
  4. Younger respondents were willing to pay significantly more than elderly respondents.
  5. Willingness to pay also varied by ethnicity. For example, Hispanic respondents were willing to pay more than non-Hispanic respondents for the same hypothetical vaccine.
  Contact person at CDC: Bishwa Adhikari

DOD Veterinary Services Agency (VSA) and U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM)
Eric Torring (DOD VSA) – nothing to report
Brandolyn Thran, (CHPPM) – nothing to report

EPA Office of Water
Stephen Schaub

- Moving forward agency wide to develop **EPA guidelines for conducting microbial risk assessment**. Working on final game plan to send to Science Policy Council.

- **For drinking water** – plan a meeting in near future to put together a thesaurus of terms within and outside EPA.

- Homeland Security Office is trying to develop **a rapid Risk Assessment for microbials in food and water**. The EPA Office of Water is supporting these efforts. Just getting started, appears to only involve EPA, not clear how it will go forward.

FDA/CFSAN
Dick Whiting

- October 16 - release of ***Listeria monocytogenes*** **Risk Assessment**

- December 4 - held Public Meeting

- The FDA Risk Management team issued an outline for implementation at the public meeting.

- Public acceptance of microbial RA among constituencies has grown greatly in the past four years.

- Currently in the **planning process for follow up RA's on *Listeria monocytogenes***. For example, may look more closely at selecting food categories, model through the process from raw materials to consumption and illness, and look at the impact of various interventions.

- Still challenging to get FDA program offices to understand what a risk assessment can actually do and to define exactly what should be calculated that improves their decision making.

- **WHO/FAO L. *monocytogenes* risk assessment** is in final editing stage internationally.

Marianne Miliotis

- ***Vibrio parahaemolyticus*** **risk assessment** modeling piece is due to be completed December 19, 2003 . New version of risk assessment includes much more output data to improve transparency. Hoping to publish mid May.

- **Foodborne Virus data feasibility evaluation** - literature review is complete. Five subject matter experts from CFSAN reviewed literature on five viruses – Hepatitis A, Noroviruses, Rotavirus, Astrovirus, and Adenovirus serotypes 40 and 41. Document on recommendations in preparation for review by FDA leadership team

- **Data feasibility and literature review for future *Listeria* RA** completed. Document on recommendations in preparation for review by FDA leadership team.

Wes Long

- The Joint Institute for Food Safety and Applied Nutrition rolled out their first online course, **"Overview of Risk Analysis"** as a workshop in conjunction with the Society for Risk Analysis Annual Conference last week.

FDA Center for Veterinary Medicine
Barry Hooberman

- **The Draft Virginiamycin Risk Assessment** is complete and under senior management review. Discussions of RM strategies are ongoing.

- Reasonable certainty of no harm legal standard is a challenge to the risk assessors and risk managers and is currently being discussed.

- **A draft risk assessment on the human food safety and target animal safety of cloned food-producing animals** will soon be publicly available. A public meeting of CVM's Veterinary Medicine Advisory Council was held in November to discuss these issues.

- **Transgenic animal issues** are being raised, and may require risk assessment in the future; but regulatory responsibility and authority is unclear between FDA and other agencies. A lawsuit may be filed to get FDA to regulate genetically modified "glowing" aquarium fish.

- Greg Claycamp is working with CDER staff on **risk-based GMP's** for prioritizing GMP inspections and other activities.

NIH National Institute of Allergy and Infectious Diseases (NIAID)
Robert Hall

- NIH National Institute of Allergy and Infectious Diseases (NIAID) **The Food and Waterborne Diseases Integrated Research Network contracts were awarded**, and the following research units are now available to the Division of Microbiology and Infectious Diseases (DMID) under contract.

In addition, **the Regional Centers for Excellence** (RCEs) were awarded:

These two initiatives will provide a valuable mechanism to get needed research accomplished that is not suitable for grant mechanisms.

- If the RAC is interested, we could hold a meeting in Rockledge and have a **presentation from the Project Staff involved in the RCEs** and FWD-IRN.

- Planning continues on an **expert workshop to be sponsored by DMID, FDA, and the Gates Foundation on Pediatric Enteric Vaccines**. The estimated date is in the last week of April, just prior to the 3rd International Conference on Enteric Vaccines (Montego Bay, Jamaica).

- The (NIAID) has awarded a five year contract to The Institute for Genomic Research (TIGR) to establish the Pathogen Functional Genomics Resource Center (PFGRC). The PFGRC is a centralized facility providing the research community with resources necessary to conduct functional genomics research on human pathogens and invertebrate vectors of infectious diseases. TIGR is developing microarrays for many important pathogens including Listeria monocytogenes and Helicobacter pylori, Salmonella Typhimurium, and others. The application form to use in applying for these reagents is on the following websites More info.

USDA Agricultural Research Service (ARS)
Andy Hwang, works in the Predictive Microbiology and Risk Assessment group at ARS Eastern Regional Research Center

- **Pathogen modeling program** – V7.0 launched last week. New features include– embedded publications; also lag and no-lag time toggle feature available. Also includes FAQ's.

- **Version 2** of COMBASE will be finished early in 2004. 30,000 data points now (6,000 increase).

- Tom Oscar moving into the new building at UMES.

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

- **CSREES published 2 requests for proposals** – National Integrated FoodSafety Initiative – due December 19, 2003.

- The Epidemiological Approaches to Food Safety (NRI 32.1) deadline is March 16, 2004

USDA Food Safety and Inspection Service (FSIS)
Peg Coleman

- **Reorganization/new hires**. Michael Kasnia continues to serve as Acting Director of Risk Assessment Division. Selection of the permanent Director will be announced at the next quarterly RAC meeting. On December 28, Janell Kause will serve in a new position as Senior Public Health Scientist for the Office of Program Evaluation, Enforcement and Review of FSIS. She will continue her role as the co-lead for the RAC Peer Review Work Group.
- **Revised FDA/FSIS Risk Ranking of RTE Foods for *Listeria* Roll Out**. Carol Maczka and Janell Kause coordinated with FDA in the roll this fall of the revised Quantitative Assessment of the Relative Risk to Public Health From Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. This collaboration culminated in a public meeting held on December 4, 2003.

- **Regulatory Peer Review and OMB Bulletin**. Carol Maczka and Janell Kause are part of an FSIS work group that has developed comments on the August 29, 2003 Office of Management and Budget proposed bulletin on regulatory peer review. These comments will be submitted as part of a USDA response to the OMB on this issue. In addition, this FSIS work group is also working to develop guidelines/standard operating procedures for peer review of regulatory analyses, including risk assessments, within FSIS.

- **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 Elke Jensen, Mike Kasnia, Carol Maczka, and Dan Gallagher (Virginia Polytechnic Institute and State University) to collect data and modify the current FSIS *Listeria* risk assessment to evaluate the risk of listeriosis from deli meats sliced and packaged in-plant versus at retail. This project involves the collection of state and industry retail *L. monocytogenes* contamination data for deli meats and will involve additional support from Martin Wiedmann at Cornell University.

- ***Listeria* Verification Sampling**. Project Leader Heather Hicks-Quesenberry will be working with. Dan Gallagher of Virginia Polytechnic Institute and State University to modify the FSIS Listeria risk assessment to evaluate the effectiveness of targeted Listeria verification sampling protocols.

- ***E. coli* O157:H7 Verification Sampling**. Project Leader Uday Dessai will be working with Wayne Schlosser to develop targeted verification sampling protocols for E. coli O157:H7 in beef.

- ***Clostridium perfringens* risk assessment**. Neal Golden is serving as Project Leader with Edmund Crouch of Cambridge Environmental contracted to complete a risk assessment for C. perfringens in RTE meat and poultry. Uday Dessai is the COTR for the contract. Once complete, this risk assessment will be externally peer-reviewed and revised in response to those comments. It will then 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**. Terry Disney, Uday Dessai, Carol Maczka, and Elke Jensen continue to work with other staff in the FSIS Office of Public Health Science, the 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 high-risk materials that require further management control.

- *Salmonella* Enteritidis Risk Assessment **(SERA) Revision**. Project Leader Carl Schroeder continues to work with the SERA team and RTI to prepare a draft of the revised *Salmonella* Enteritidis in shell eggs and *Salmonella* spp. in egg products risk assessments. This draft will initially be provided to the FSIS OPPD for internal review in December. Carl is also managing the contract with SAIC to administer the external peer-review process for the revised SERA documentation.

- ***E. coli* Risk Assessment (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 certain data gaps identified by the NAS report.

- ***Campylobacter* in poultry risk profile/feasibility study**. Project Leader Peg Coleman expanded her work on a feasibility study for campylobacteriosis to address the needs of the Codex Committee on Food Hygiene work group for a campylobacteriosis risk profile. Additional data analysis is underway relating to both exposure assessment and dose-response assessment from the WHO/FAO draft *Campylobacter* risk assessment in poultry. Analysis of USDA datasets for *Campylobacter* enumeration and intervention are underway, and risk factors identified by epidemiologic studies are under study. In addition, new human data were presented to the RAC Dose-Response Work Group by colleagues at the Naval Medical Research Center on December 17 that address dose-response assessment issues for campylobacteriosis.

- **Lethality for RTE products**. Elke Jensen and Carl Schroeder serve as co-leads on a risk assessment with the objective of modeling the impact of the Salmonella lethality performance standards for ready-to-eat (RTE) meat and poultry products with Greg Paoli of Decisionalysis. This risk assessment will subsequently be externally peer reviewed, revised, and used to inform, along with a cost-benefit analysis, to inform the FSIS rulemaking on lethality performance standards for RTE meat and poultry products.

- **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.

- **Use of risk assessment approach in food biosecurity**. Carol Maczka and Abdel Kadry continue to work with other 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. Also, 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. Also, the information will be used to inform the procedures we follow under the Homeland Security color-alert system.

- **Use of Risk Assessment in FSIS Recall and Trace Back**. Project Leader Abdel Kadry is providing FSIS/ Recall Management Division (RMD) with toxicological evaluation and hazard characterization 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 regulated products Disposition**. 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.

Carl Schroeder

- **Draft RA's for *Salmonella* Enteritidis in shell eggs and Salmonella species in egg products**. Will pass on to managers by end of the year.
- NAS toxicogenomics group is planning a public meeting in April 2004 - targeting use of "omics" technologies in risk assessment. Carl will forward info to RAC.
- **RA for lethality standards for RTE meat products** also coming to an end, ready for policy review.

Welcome to David Goldblatt - a new AAAS Risk Policy Fellow at FSIS - working on peer review, the ECRA revision, and *Salmonella* spp. risk assessment and performance standard activities.

Welcome to Abdel Kadry. Abdul wants to explore how the RAC can help identify human resources to evaluate RA. Can the RAC help? (Suggestion from Margaret Venuto to use CSREES database of reviewers).

USDA Office of Risk Assessment and Cost Benefit Analysis (ORACBA)
Michael McElvaine

- Working on **EPA pesticide issues** in Washington state.

- A number of OMB initiatives coming down in the next six months

Workgroup Updates:

Dose-response workgroup
Report from Lead - Peg Coleman (FSIS)
The RAC DRWG expanded its membership and scope for FY 2004. New participants include: Dave Tribble and Pat Guerry, US Naval Medical Research Center; Lynda Kelley and Neal Golden, FSIS Office of Public Health and Science; Steve Anderson and Dennis Kopecko of FDA Center for Biologics Evaluation and Research; Rich Raybourne, FDA Center for Food Safety and Applied Nutrition; and Steve Schaub EPA Office of Water. The scope in 2003 was a more general compilation of data on animal and human models for dose-response for many enteropathogens. In 2004, the group selected campylobacteriosis as its first case study to develop in more detail. The group met on October 28 and December 17 to discuss human, ferret, and in vitro data for campylobacteriosis. Future seminars are planned in the next two quarters to develop additional case studies that will be compiled into manuscript format by work group members in summer 2004. The goals of the manuscript are to incorporate additional mechanistic data into dose-response models to more realistically describe variability in each aspect of the disease triangle (host, pathogen, and environment, and interactions).

Data quality workgroup
Report from lead - Carl Schroeder (FSIS)
- After discussions at the RAC summer meeting, a workgroup was formed – brainstormed four questions or tasks

1. Summary of OMB guidelines
2. Collection of web site links for agencies with data quality guidelines
3. Summary of data needs for Clearinghouse web site
4. Development of a RAC document based on member agencies' data quality guidelines

-The workgroup produced a 5-6 page document which was made available at the last meeting.

-At the last RAC Policy Council meeting, October 1, 2003, the Policy council recommended a change in the focus of the workgoup. Carl recommends that the group meet with Carol Maczka and Bob Buchanan to better articulate objectives.

- Workgroup will reconvene after clarification from policy council.

Risk-Risk workgroup
Workgroup lead is Elke Jensen
Report by Margaret Venuto
Workgroup members include: Margaret Venuto (CSREES), Abdel Kadry (FSIS), Mark Walderhaug (CFSAN), Angelo Turturro (NCTR), Stephen Schaub (EPA OW).
-Workgroup meeting held November 14, 2003. Objectives and goals were to be drafted and sent to the rest of the group for review and comments:
-Workgroup discussions included:

-rename group?
-Balancing chemical vs. microbial risk
-Addressing x-agency issues relative to risk - risk comparisons
-Agency experiences
-Common issues germane
-How should results be presented
-Seeking a series of presentations based on agency experiences
-Concept paper – useful to those who want to develop risk-risk comparisons
-Steve named a group who is interested in talking,
-EPA NCEA may be able to provide some insight in comparative risk

Data gap analysis workgroup –
Workgroup lead is Mark Tamplin. Mark wants to step down as the lead. Andy Hwang may take over as lead.
-Group revised spreadsheets and getting it ready for posting on the CH website. Hope to present at meetings to get the word out to researchers.

Peer review workgroup (PRWG)
Workgroup co- leads are Mary Bartholomew (FDA/CVM) and Janell Kause (USDA/FSIS); update presented today by Marianne
-Summary of September 30, 2003 Peer Review workshop is currently being reviewed by the Policy Council co-chairs.
-Working on an outline for the discussion paper that will be the deliverable of the work group. There have been several meetings to discuss the issue. Next meeting planned for Jan 13.
-Looking at possible joint symposium on peer review and data quality. Decided to wait until OMB guidelines are final before holding the meeting and finalizing the peer review discussion paper. (Regulatory agencies received an extension through January for responding to the OMB bulletin.)
-Nov 18, NAS had workshop on regulatory peer review was attended by many members of the PRWG.

Future presentations on Sampling

Marianne and Wes gave an overview. Sampling plan design impacts the utility of data for risk assessments. It was recommended at the October 1, 2003 RAC meeting to have presentations to help us understand the scope and impact of the problem, possibly as an all-day meeting.

Through the discussion, at least four different issues were identified, and several audiences.

Audiences:

1. Risk Assessors who try to use data from surveys, surveillance, and studies to make predictions about the status quo and the likelihood of future events.
2. Researchers who design and conduct sampling plans or programs
3. Risk Managers who must respond to limited data (e.g., when only 1 positive sample is obtained in an e coli outbreak, what does this say about the other 1 million servings?)

Issues:

1. Methodologies – e.g. MPN method and individual sample size (quantity)
2. Statistical validity
3. Sampling Strategies - representativeness and sample size (how many samples need to be taken?)
4. Dose reconstruction

Discussion by RAC included mention of a number of existing sampling programs, for example:

- FSIS has 25 years of drug residue data, but have struggled to find usefulness in terms of RA
- EPA OW has sampling frequency, quantity ,and size issues frequently recur in rulemaking efforts
- CDC mentioned FDA-funded UNC study to extract viruses from food matrices
- The Hart Building Anthrax cleanup – how clean is clean enough?
- EPA OW has a treatise on sampling
- screening at Salt Lake City Olympics
- the Japanese have a restaurant food retention program.

-Because of the many issues and perspectives of potential audiences if the presentations were to be held as a public meeting, a suggestion was made to develop a scoping paper for the RAC Policy Council by the March meeting.
-,The RAC might want to come up with an issues paper ahead of time to help frame the meeting.

-A discussion also arose about whether this group really ought to be a part of the data quality workgroup, since the issues are inter-twined. Both use the same conceptual analysis – what do you need to get a good answer that you can rely on? It was decided, however, to keep it as a separate work group at least for the present.
-A possible name for the workgroup is the “Data Utility Workgroup.”
-Possible Workgroup volunteers:

Mary Bartholomew (CVM perhaps)
Peg Coleman (FSIS)
John Newland (CFSAN)
Michael McElvaine (ORACBA)
Steve Schaub (EPA OW)
Andy Hwang (ARS)
Brandolyn Thran, DOD/CHPPM

Presentations:

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”

In attendance:

Peg Coleman, USDA/FSIS
David Goldblatt, USDA/FSIS
Robert Hall, NIH/NIAID
Barry Hooberman, FDA/CVM
Andy Hwang, USDA/ARS/ERRC
Abdel Kadry, USDA/FSIS
Wes Long, FDA/CFSAN
Michael McElvaine, USDA/ORACBA*
Marianne Miliotis, FDA/CFSAN
Stephen Schaub, EPA/OW
Carl Schroeder, USDA/FSIS
Don Sharp, CDC
Brandolyn Thran, DOD/CHPPM
Erik Torring, DOD/VSA
Margaret Venuto USDA/CSREES
Richard Whiting, FDA/CFSAN

* Attended by conference call