

RAC Meeting Minutes (March 30, 2005)

Quarterly Meeting

Agency Updates:

Department of Defense Veterinary Services Agency (VSA) and U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM)
Brandolyn Thran

- Continuing work on exposure assessment and developing an algorithm for taking ambient (environmental) levels of pathogens to a biological effective dose (BED) for use in the exposure assessment.
- The Environmental Health Risk Assessment course was conducted two weeks ago; thirty students participated and class went well. Taught on the reviewer level- what to look for. Another course is planned in 6 months.
- The Anthrax risk assessment draft is coming together; hoping for reviewers from the RAC to review the draft probably early summer.

EPA National Center for Environmental Administration (NCEA)
Michael Broder
Deferred update to Stephen Schaub

EPA Office of Research and Development (ORD)
Lynn Papa

- Nothing to report

EPA Office of Water (OW)
Steven Schaub

- See below on EPA's Development of Microbial Risk Assessment Guidelines

FDA Center for Food Safety and Applied Nutrition (CFSAN)
Dick Whiting

- Risk Profile on *Listeria monocytogenes* in fresh-cut fruit and vegetables: draft in review process; will become public soon.
- Risk Assessments on *L. monocytogenes* in soft cheese and *L. monocytogenes* in smoked fish: Federal Register notices have been published.
- Public petition for setting a tolerable level of *L. monocytogenes* in foods that don't support growth: FDA is considering a response.
- AOAC has contract with FDA to look at sampling, the errors, data quality, and other underlying issues; to be completed in September/October, 2005.
- Codex Committee on Food Hygiene is planning a joint expert microbial risk assessment (JEMRA) consultation later this year to look at issues on food safety objectives, performance objectives, and how to set microbiological criteria. FAO/WHO has put out a

call for volunteers to be members of this consultation (for more information go to FAO/JEMRA web site).

Sharon Edelson Mammel

- Preparing for FDA Science Forum, April 28-29, 2005 and IAFP, August 14-17, 2005

David Carlson

- FDA is starting a joint risk assessment with Health Canada on *L. monocytogenes* in fresh soft cheeses: Brie and Gouda (based on data availability and recent outbreaks in Canada). Main goal is to compare pasteurized vs. unpasteurized.
- CFSAN put out a press release on raw milk cheeses from Mexico and other South American countries; possibly due to the tuberculosis cases in Brooklyn, NY.

Marianne Miliotis

- The risk profile on Hepatitis A virus in produce is being finalized for review.
- The first draft of the Norovirus risk profile is nearing completion.
- The *Vibrio parahaemolyticus* risk assessment has been reviewed by the CDC and we're addressing their comments; we're trying to reconcile the epidemiology with the predicted number of illnesses.
- The Institute for Food Technologists risk ranking grant is nearing completion; A 6 month no cost extension has been granted to fine-tune the model to provide ranking for both microbial and chemical hazards in foods.

FDA Center for Veterinary Medicine (CVM)

Mary Bartholomew

- *Enterococcus faecalis* risk assessment - CVM is addressing public comments received after the public meeting; CVM will not be pursuing an NOH.
- Risk Ranking project on hazards in animal feeds is continuing
- Fluoroquinolone – CVM is hopeful that once Dr. Lester Crawford is confirmed as Commissioner of the FDA, action will be taken.

Joint Institute for Food Safety and Applied Nutrition

Wesley Long

- The JIFSAN summer integrated program on Risk Analysis starts July 25, 2005 and runs through to August 10, 2005. Continuing education credits will now be available. For more information see [JIFSAN web site](#).

NOAA Fisheries

Angela Ruple

- Nothing to report

USDA Agricultural Research Service (ARS)

Andy Hwang

- ARS is in the process of writing their 5-year research program for 2005-2010.
 - Research includes modeling of growth, survival and inactivation of *L. monocytogenes*, and *E. coli* O157:H7 in ready-to-eat foods. Call for particular needs from RAC member agencies that can be included in project plan.

USDA Economic Research Services (ERS)

Tanya Roberts

- Just published article: "New Pathogen Testing Technologies and the Market for Food Safety Information," by Laurian Unnevehr, Tanya Roberts, and Carl Custer in the latest issue of AgBioForum available online at www.agbioforum.org/.
- ERS authors have a chapter in the new RFF Press book, *Toward Safer Food: Perspectives on Risk and Priority Setting*. Information about "Toward Safer Food" is also available at http://www.rff.org/rff/rff_press/bookdetail.cfm?outputID=8037

USDA Food and Nutrition Service (FNS)

Margaret Venuto

- FNS is involved in the Interagency Vulnerability Assessment Group, which also includes representatives from FSIS, Agricultural Marketing Service (AMS), and possibly FDA in the future. The Group is using the CARVER-SHOCK as the main part of the assessment, on foods of high popularity and consumed at high frequency and that pose greater vulnerability to threat in the school lunch program. The initial phase will include assessment of chicken nuggets and patties.

USDA Food Safety and Inspection Services (FSIS)

Uday Desai

- The *Salmonella* and *E. coli* risk assessments public meeting went well.
- Recently completed two risk assessments and conducted a public meeting March 24, 2005 on *Clostridium perfringens* and *Salmonella* in ready-to-eat food. Comment period is held open for 45 days from this date.
- FSIS is developing new areas of risk assessment:
 - Global modeling so that all risk assessments are conducted under one umbrella: risk assessments will use Analytica
 - An approach to conducting risk-based verification sampling for *E. coli* O157:H7 – target those plants, which have a higher risk of having *E. coli* O157:H7 present in their product.

Carl Schroeder

- FSIS SERA program - Two risk assessments were presented in October 2004: *Salmonella* Enteritidis in shell eggs and *Salmonella* spp. in liquid egg products. Public meeting went well; following public meeting FSIS is revising the model based on public comments; industry is also now submitting data because they consider the predicted illnesses too high.

New business

- RAC-sponsored risk ranking symposium is being planned for August 18, 2005 as a follow-up to the IAFP symposium. Suggestions have been made as to format of the symposium. We propose to have a full day session with about 6 presentations, with the computer lab being open so that people can have hands-on experience with the different models. We hope to have the presenters focus on specific questions to be determined rather than present an overview of their model, with an end result of building a matrix of model vs. responses to questions.

EPA Thoughts on Improving the State-of-the- Art in Microbial Risk Assessment

- Stephen Schaub provided an overview of EPA's thoughts on improving microbial risk assessment. EPA would like to enhance its ability to conduct microbial risk assessments (MRA) and OMB has requested a more integrated approach to national guidelines for conducting risk assessments. There is also discussion as to whether there should also be some harmonization with international guidelines such as those of FAO/WHO. It would appear that combined efforts of the different agencies and harmonization are needed to provide a consistent approach to improving our collective MRA capabilities.
- EPA is conducting several projects on developing MRA guidelines for which they would like input and review of drafts of these efforts:
 - MRA framework (EPA/ILSI) - completed
 - Full MRA protocol based upon framework – draft by late summer 2005.
 - Thesaurus of terms and definitions with defaults based upon the EPA/ILSI framework and a new protocol - draft by late summer 2005.
 - Microbial Human Health Methodology for Risk Based Water Quality Criteria Setting - Draft in April
 - Guidance Development Projects Identified by the EPA Risk Assessment Forum include:
 - #1 MRA Framework for Structuring Risk Assessment Guidance (Current Activity)
 - #2 MRA Thesaurus for Across Media/Program Needs (Current Activity)
 - #3 Risk Assessment Peer Review Procedures for EPA*
 - #4 Review New Risk-Based Human Health Methodology for Developing Water Quality Criteria
 - #5 Selection of Microbial Dose Response Modeling Approaches for Low-Dose Health Criteria/Standards & Regulation Use*
 - #6 Develop Balanced, Scientifically Credible, Approach to Establishing Tolerable/Acceptable Risk Levels for Criteria/Regulation Setting*
 - #7 Identify and Characterize Uncertainty Factors in MRA and Establish Default Approaches to their Application*
 - #8 Establish MRA Risk Characterization Guidelines to Uniformly Prepare MRA outcome & Package for Risk Managers/Communicators
 - #9 Standardize Risk Assessment Protocols for Genetically Modified Microorganisms
 - #10 Determine Procedures for Appropriate use of Laboratory, Survey and Epidemiological Data (and Surrogate Systems) and to Best Apply Data of Various Qualities to Assessments*
 - #11 Establish Risk-Risk Characterization Protocols (including multi-media Contaminants & Multiple Pathogens)*
 - #12 Provide Review and Technical Input to MRA Protocol for Water-Based Microbial Contaminants
 - #13 Harmonize MRA Guidance Approaches Between EPA and Other Federal & International Agencies*

- #14 Review Various Media RA Case Studies to Insure Products are Technically Correct and Complete – also Determine How These May Inform Future Guidance Development Activities
- #15 Refine Approach to Characterize Human Immune Response for Dose Response Modeling and Estimation of Secondary Transmission Rates*

The questions addressed to the RAC included: can we and how should the RAC member agencies coordinate and work closer together? Is there a mechanism for formalizing relationships to work together more effectively? One answer was to get EPA management to contact management of the different agencies and formally request assistance. This was further discussed during the RAC Policy Council meeting (see below).

Presentation

Ronald Roy, FDA/CFSAN presented on "FDA Food Sampling Approaches"

RAC POLICY COUNCIL MEETING

Work Group Updates

Data and Information Quality Work Group

Dr. Celine Nadon (FSIS Microbiology Branch) has joined the workgroup.

The workgroup has met and reviewed feedback based on (i) our five-page document reviewing the actions different agencies were taking in response to the OMB directive on data quality, (ii) our questionnaire distributed among the RAC members to learn more about what RAC members perceived as the foremost challenges in ensuring data quality and what they were doing, if anything, to address these challenges, and (iii) our talk titled *The Risk Assessment Consortium Working Group on Data and Information Quality: Towards a "Best Practices" Approach* presented as part of a symposium on data quality at the 2004 Society for Risk Analysis General Meeting.

We propose authoring a brief article for a trade journal such as *Food Safety Magazine* (i.e., for the *Ask the Regulator* series) or *Meat and Poultry*, etc. to summarize the RAC workgroup's activities and what we have learned. Any such document would be cleared through the RAC and its member agencies prior to submission for publication. We would next like to explore developing a public meeting on data quality to be followed by potential development of a technical report.

The RAC Policy Council chair noted that this is an area of high interest and suggested a synopsis of the OMB Data Quality Act and how it affects regulatory agencies be prepared and provided to the stakeholders to give them a better understanding of the data quality requirements. It was also recommended by the RAC policy council that the work group seeks input from pesticide and chemical risk assessors.

Dose-Response Work Group

The DRWG is going on hiatus for a while. This would provide members of this work group an

opportunity to join some of the other work groups, which require more members.

Peer Review Work Group

The Peer Review Working Group discussion document has undergone revision by the EPA WG member, Jackie McQueen, to ensure that the discussion about public comment specifies how the EPA views public comment. Subsequently, FSIS WG member, David Goldblatt, has made several changes and is reviewing the document to make sure it that it indicates future compliance with the final OMB Peer Review guidelines published in December 2004.

Much discussion evolved around the issue of public comments. Although public review may not be actual peer review, public comments are still useful. It was pointed out that with EPA's IRIS program, the program is posted on the web, and although public comment is not sought, EPA will accept and address public comments.

The RAC Policy Council Chair highly recommended the work group ensure the document is consistent with the OMB guidance issued in December 2004. Specifically, use of the terms "highly influential" vs. "influential" peer review, when considering significance of the issue. It was also noted by the RAC policy council chair that with the new OMB guidelines, there is the option of using government experts for review of documents that are too sensitive for public review. It was suggested a letter be sent from the RAC to the different government agencies asking for a list of people with specific expertise in their areas.

Data Gaps Analysis Work Group

The group continues to seek feedback for the data gaps list "Data Gaps List for Selected Microbial Risk Assessments." In addition to the announcement of the list through FSNET, the group plans to distribute the list in the upcoming annual meetings of International Food Technologists and The International Association of Food Protection. The group would also like to seek feedback from RAC members and their assistance in distributing the list. The list is available on the Clearinghouse [Data Gaps Analysis Work Group Accomplishments](#) page.

Microbiological Criteria Work Group

A six-member team has recently been formed which includes 2 modelers and one statistician with a specific task in mind. The RAC Microbiological Criteria work group was charged with assisting the CODEX effort by developing principles for relating microbiological criteria to public health goals and the stringency of food and water control programs.

The Group recently held a conference call and discussed its objectives and products that it would create. Steve Schaub described EPA's similar activities on controlling pathogens in drinking water and suggested our objectives are "to provide a criterion methodology for the United States food and water agencies and to assist CODEX develop international methodology." It was noted that two international working groups will be starting this fall to further refine the concepts of performance objectives, food safety objectives and microbiological criteria and to demonstrate their application for improving food safety. Bob Buchanan suggested this RAC group advance ideas and develop examples that represent current US thinking on these concepts to assist the US participants in these meetings.

The two meetings include:

- i. A WHO/FAO Joint Expert Committee on Microbial Risk Assessment (JEMRA), which will probably meet near the end of the year in Kiel, Germany.
- ii. An ICMSF/ILSI symposium and working group, which will meet in Washington in early November. The RAC will participate with ILSI and ICMSF in developing the 2 day symposium for this latter meeting (see below).

The work group exchanged reprints and other documents to begin its deliberations. Regular conference calls will occur leading up to these two international meetings.

Data Utility Work Group

The Data Utility Work Group invited Ron Roy to the quarterly RAC meeting to discuss sampling plans. This talk was designed to help educate the group in regards to sampling plan and data collection issues so we may better design a discussion paper and fall seminar.

Risk-Risk Work Group

No update, but possible project to be discussed during the Policy Council meeting.

Risk Ranking Symposium

A group has been formed to organize the symposium for August 18th, as described above in new business.

ILSI/ICMSF/RAC Symposium

The symposium is being planned for the first week of November, at Gallaudet University, Washington, DC The focus of this symposium will be developing principles for determining microbiological criteria.

FAO/WHO will be conducting two consultations on how to use micro RA's to establish health based microbiological criteria, performance criteria (as described previously by Richard Whiting). Many groups are currently working on this; one group is the International Conference on Microbiological Specifications for Food (ICMSF). The symposium will last 2 days and will focus on how to use RA to set criteria. The RAC policy council chair requested and obtained the RAC's blessing to offer the RAC as co-organizer/co-sponsor. This could enable some of the RAC members to participate in the 5-day work shop following the symposium. Focus this year is to generate examples for the consultation. The RAC will send letters to member agencies for contributions towards the symposium. Depending on the amount of money collected, there will be a registration fee to defray costs. This would be an opportunity to raise visibility of the RAC worldwide. General support from policy council recorded. This is a joint industry, NGO, international activity.

Possible project for Risk-Risk Work Group

There's a possibility that an international FAO/WHO risk assessment be requested on microbial risk to the public if use of active chlorine products that come into contact with food is banned.

Basically, this could be better termed "Risk Optimization Activity". Discussion followed on real world examples, such as pandemic outbreak of cholera in Peru after chlorination of drinking water was stopped. Another example includes removal of chlorine from chill tanks for poultry.

Role of the Risk-Risk work group would be to gather data for the risk assessment or become involved in the FAO/WHO risk assessment as part of the expert consultation. The RAC needs to play a part in the international arena.

EPA Microbial Risk Assessment Guidelines

In response to Stephen Schaub's request that the RAC play a role in reviewing and/or working more closely with EPA on the various projects listed above, the RAC policy council co-chair reminded the RAC policy council designees and technical representatives that the RAC is a formal MOU of 17 agencies that support each other in their risk assessment activities. It was recommended, however, that before a letter is sent out to either the Policy lead or chief scientist of the different agencies, the RAC member agencies first conduct a self-assessment test; i.e., what resources do they have? How much can they provide? What are the successes and failures?

In attendance (* participated by phone):

Mary Bartholomew, FDA/CVM

*Mike Broder, EPA/NCEA

Robert Buchanan, FDA/CFSAN

David Carlson, FDA/CFSAN

*Uday Dessai, USDA/FSIS

*Sharon Edelson-Mammel, FDA/CFSAN

Andy Hwang, USDA/ARS/ERRS

*Wesley Long, FDA/CFSAN

*Michael McElvaine, USDA/ORACBA

Cristina McLaughlin, FDA/CFSAN

Marianne Miliotis, FDA/CFSAN

*Lynn Papa, EPA/ORD

* Tanya Roberts, USDA/ERS

*Ronald Roy, FDA/CFSAN

*Angela Ruple, NOAA Fisheries

Stephen Schaub, EPA/OW

*Carl Schroeder, USDA/FSIS

*Brandolyn Thran, DOD/CHPPM

Mary Torrence, USDA/CSREES

Iris Valentin-Bon, FDA/CFSAN

Margaret Venuto, USDA/FNS

Richard Whiting, FDA/CFSAN