

RAC Meeting Minutes (September 28, 2005)

Technical Meeting, 9:00 am – noon

Introductions

Welcome to Kerry Dearfield (USDA/FSIS), Policy Council co-chair and Gary Vroegindewey (DOD/Veterinary Services), Policy Council representative.

Agency Updates:

Department of Defense Veterinary Services Agency (DOD/VSA)

Col. Gary Vroegindewey

- DOD conducts over 3,500 audits of plants in 83 countries per year. Looking at primarily high risk foods and standardization of processes and food defense.
- DODVSA sponsors a tri-service Food Risk Evaluation Committee and Army Food and Water Safety and Security Committee to evaluate food risks and vulnerabilities.
- A technical guide USACHPPM TG#188, U.S. Army Food and Water Vulnerability Assessment Guide has been published; it is a for official use only.
- There has been a cultural shift for vulnerability: before looked at accidental or natural contamination, now looking additionally at purposeful contamination
- DOD has developed a system, Joint Biological Agent Identification and Diagnostic System (JBAIDS) for the Science and Technology (STO): a rapid PCR process for detecting biological agents, includes a requirement for food: each module created for testing must be tested and validated.
- Several issues to consider: US-based issues; seafood issues; central region: Iraq and Afghanistan mainly – concerned about accidental and intentional foodborne illness.
- Primary focus of DOD Veterinary Service is to protect US forces and contractors.

Environmental Protection Agency Office of Research and Development (EPA/ORD)

Jacqueline McQueen

- Office of Research and Development and Office of Water (OW) have organized a workgroup to look at VFARS - virulence factors/criteria that can be used in ranking and prioritizing pathogens for research and or regulatory determination for OW's CCL decisions. The group will be developing issue papers.
- ORD is developing a report/synthesis document on methods and approaches for developing waterborne estimate of risks from exposure in US waters. Primary focus of this work is endemic disease. It is due out in late/spring early summer 2006.
- ORD NCEA has recently completed and cleared a report on secondary disease transmission. The report deals with models and approaches for estimating/considering person-to-person spread of waterborne infections and illness. This is a dynamic model. ORD's report discusses two models/approaches that can be applied. If the RAC members are interested, I will forward the citation when it is available.
- ORD just held a symposium on Cyanobacterial Harmful Algal blooms and toxins. There were both national and international speakers. If the RAC members want more information on the symposium and the proceedings, I will forward the website.

Environmental Protection Agency Office of Water (EPA/OW)

Stephen Schaub

• Office of Water Microbial Risk Assessment Activities.

- (i) In process of developing a full blown risk assessment protocol for Microbial risk assessment in water media. Draft protocol received from contractors undergoing internal EPA review.
- (ii) Developed an ~ 180 page thesaurus of terms used in microbial risk assessment, especially to support RA in water. It started with OW terms, then included terms from CODEX, FAO/WHO, all EPA offices and can be used for all microbial risk assessments. Possibility of using JIFSAN as a means for vetting the document and see what gaps are present.
- (iii) In the middle of a microbial risk assessment on *Cryptosporidium* in drinking water; it will be used to develop ambient water criteria, using human feeding trial data on *C. parvum* and *C. hominis*.
- (iv) Developing a human health methodology guidance document for future criteria methods – will be used as a protocol for establishing ambient water quality criteria.

Risk Assessment Forum Activities.

- (i) Very active in trying to catch up with folks in the Chemical Risk Assessment Group; looking at efforts to evaluate U.S. and international frameworks for possible use by EPA for guidelines to see which framework best fits their needs for different situations. Indoor air, pathogens, etc – all into one framework
- (ii) Established connection with immunotoxicologic group to maybe plan for a colloquium in the future on immunotoxicology and dose-response to address specified microbial challenges and the interface with microbial risk assessments.

Food and Drug Administration Center for Food Safety and Applied Nutrition (FDA/CFSAN)

Dick Whiting

- *Listeria monocytogenes* risk assessment in smoked fish underway, partially spurred by CODEX committee. One CODEX expert committee is looking at how to put microbial risk assessment principles into use and the other committee is looking at specific pathogens in certain foods, e.g., *L. monocytogenes* in smoked fish. Dick and Bob Buchanan on FAO/WHO expert panel to conduct this risk assessment.
- *Listeria monocytogenes* risk assessment in soft cheese started up again; needed to get people; joint project with Health Canada.
- The 2nd International Quantitative Microbial Risk Assessment Conference will be held in Sydney during February 2006 (Dick Whiting is on planning committee).

Sherri Dennis

- Draft report on approaches to establish thresholds for allergen and gluten in food. Issued in June for public comment and evaluated by the Food Advisory Committee in July. The draft report is available on the web at www.cfsan.fda.gov/~dms/wh-alrgy.html and is currently being revised.

John Hicks

- In-house team of *L. monocytogenes* risk assessment in smoked fish has been tasked to collaborate with FAO/WHO group.

Marianne Miliotis

- *V. parahaemolyticus* risk assessment – published in July!!!
- Virus risk profiles: Hepatitis A Virus risk profile has been reviewed and currently being revised according to Risk Managers' comments. Norovirus Risk Profile is almost ready for review.
- IFT Risk Ranking Project: Basically complete; waiting for model and user guide for FDA review before finalization.
- Plug for the ICMSF/ILSI/RAC/IAFP/IFT Symposium on The Relationship of Microbiological Testing and Microbiological Criteria to Public Health Goals – October 31- November 1, 2005.

Food and Drug Administration Center for Veterinary Medicine (FDA/CVM)

Gregg Claycamp

- Publishing a short analysis of comments on Vancomycin Antimicrobial Risk Assessment, which was published last year for comment. Some respondents said the use of the human drug of concern is going down and being replaced with other drugs.
- Anecdotal reports that community levels of streptogramin resistance is increasing.

Mary Bartholomew

- Fluoroquinolone judgment: The Commissioner rendered his decision in support of the Administrative Law Judge and against Bayer and the Animal Health Institute (AHI) in the matter concerning Baytril, a fluoroquinolone for use in poultry. Bayer and the AHI requested a stay to permit more time to market the drug on the basis of need in the poultry industry. The Commissioner denied the stay. The time for Bayer to appeal to an outside court has passed and they are taking drug off the market. (Risk assessment related discussion comprised much of the evidence in this case.)
- New staff person Dolores Beblo is coming on board in November as a new risk modeler; she has a quantitative background

Food and Drug Administration National Center for Toxicological Research (FDA/NCTR)

Angelo Turturro

Microbial group

- Carl Cerniglia is continuing his work on characterization of foodborne pathogens using quantitative PCR methodology
- The risk assessment project funded by EPA on the Sensitivity of subpopulations to *Cryptosporidium* is being finalized.

JIFSAN

Wes Long

- The retirement of Dr. David Lineback, JIFSAN Director and Arthur Miller, FDA JIFSAN Associate Director, was noted. Dr. Maureen Story becomes the Interim JIFSAN Director and Elizabeth Calvey the FDA Acting Associate Director.
- In August JIFSAN offered the 2nd Summer Integrated Program in Food Safety Risk Analysis, attracting participants from FDA, USDA, industry, and from international governments. JIFSAN is currently piloting the fourth of its series of on-line risk analysis courses – Food Safety Risk Management. University of Maryland is conducting a study to

determine if these four on-line courses should be offered as a component of a food safety graduate education. The JIFSAN Food Safety Risk Analysis Clearinghouse continues to seek content from Clearinghouse users at www.foodrisk.org.

United States Department of Agriculture Agricultural Research Service/Eastern Region Research Center (USDA/ARS/ERRC)

Andy Hwang

- ERRC-ARS-USDA established 3 new S Co-operative Agreements (SCA) as part of the National Alliance for Food Safety and Security:
 - Michigan State University ("*Listeria monocytogenes* contamination of deli meat slicers: Risk and communication"-Ewen Todd and Elliot Ryser)
 - University of Wisconsin ("*Construction and characterization of a reporter strain for the identification of physicochemical parameters influencing growth, stress tolerance, and virulence of Escherichia coli* O157:H7"-Charles Kaspar)
 - University of Tennessee. Ann Draughon. Acetate, Lactate, and Diacetate Levels in Ready-To-Eat (RTE) Processed Meat and Poultry Products Collected at Retail and Correlation with Occurrence of *Listeria monocytogenes*
- An SCA is being established with Rutgers University (Don Schaffner) to build a predictive microbiology portal that will assist small and very small processing companies with predictive microbiology information. This project is funded by FSIS Strategic Initiatives, Partnerships and Outreach Staff.
- During the week of September 5, ERRC was visited by two scientists from VTT. They have developed a qualitative risk assessment tool (HYGRAM) that is currently used by Finnish industries to identify processing and sanitation/hygiene hazards. They are interested in working with MFS to integrate this tool with the PMP and ComBase.
- A search committee has been formed for the Vice-Flores processing engineering position. We also will be advertising for a Computational Biologist.
- Dr. Montserrat Hernandez of Queretaro University will be with us for 1-year to produce models for the distribution of lag phase as a function of physiological states.
- There will be a ComBase committee meeting at the 2nd International Microbial Risk Assessment Conference in Sydney, in which we anticipate that Food Science Australia-University of Tasmania will join as the third full member of the ComBase Consortium.

United States Department of Agriculture Food and Nutrition Service (FNS)

Margaret Venuto

- The Food Safety Unit is being represented in the USDA Risk Assessment Committee headed by Kerry Dearfield.

United States Department of Agriculture Food Safety and Inspection Services (FSIS)

Kerry Dearfield

- The USDA Risk Assessment Committee composed of representatives from all USDA agencies is being revived and first meeting is Monday, October 3, 2005.
- Two Division Director positions open in Office of Public Health Science (OPHS):
 - Microbiology Division
 - Human Health Science Division

Janell Kause

- **Risk Assessment Division activities:**

- Staffing
 - James Withee from Stanford has joined the staff as an AAAS Science and Policy fellow.
 - 5 open positions: 3 GS-14 and 2 GS-13
- Projects
 - Three quantitative risk assessments from plant to table have been completed and will be posted on USDA web site week of October 3, 2005
 - *Salmonella* Enteritidis Risk Assessment (SERA) in eggs and egg products, originally conducted in 1998 – additional data were included and the model itself was revised. Pasteurization performance standards have been developed.
 - *Clostridium perfringens* Risk Assessment in Ready-to-eat (RTE) meat and poultry has been revised based on peer review and public meeting comments.
 - *Salmonella* Risk Assessment in RTE food was included in regulatory impact analyses.
 - In FY06, FSIS will be wrapping up the BSE risk assessment, which was conducted in collaboration Harvard University. It will be used to help finalize the interim rule for BSE.
 - Risk Assessment Division is currently focused on risk-based verification for *L. monocytogenes*. It's a novel approach using risk ranking algorithm of both FDA/USDA and USDA *L. monocytogenes* risk assessments with real-time microbial testing data. It allocates sampling and rank on a monthly basis. Due to be sent out for peer review September 28, 2005.

Presentation

Beth Julien, ILSI and Mary Fox, Johns Hopkins University presented on "Cumulative and Aggregate Risk Evaluation System (CARES)."

Policy Council Meeting, 1:30 – 3:30 pm

Highlights of 4th Quarter:

Microbiological Criteria Work Group

A new RAC work group, the Microbiological Criteria Work Group, was formed to assist the CODEX effort by developing principles for relating microbiological criteria to public health goals and the stringency of food and water control programs. A white paper entitled "Determination of Microbiological Criteria" has been drafted and sent for review to the member agencies represented on the work group.

Workshops/Symposia

1. The workshop on "Food and Waterborne Pathogen Risk Ranking Models: From Theory to Practice" was held August 18, 2005 in the Wiley Building Auditorium. Over 70 people attended from academia, industry, government, and consumer representatives, including several international participants. It was a full day workshop with presentations on specific aspects of the different models, such as purpose model was developed, structure of model, software used, data gaps, and assumptions made to develop the model in the morning; an informal critique of each model during lunchtime, and model demonstrations and an opportunity for

“hands-on” experience in the afternoon. During the lunchtime panel meeting, a representative each from academia, industry, government, and consumer discussed the role of risk ranking in decision making from their perspective. The workshop provided a forum for researchers, managers, consumers, and assessors interested in risk ranking models and techniques to share ideas and experiences and an understanding of how the models can be used in decision making, taking into account their advantages and limitations.

2. A symposium titled, “The Status of Data Utility in Decision Making: A Multi-disciplinary Review”, proposed by the Data Utility workgroup is scheduled for the next annual meeting for Society for Risk Analysis to be held in December 2005. The symposium will investigate data utility issues associated with four health risk assessment disciplines (human and ecological chemical risk assessment, food and water microbial risk assessment) in order to increase awareness between disciplines and stimulate dialogue that may facilitate future improvements regarding data utility in health risk assessments. A discussion paper will be developed based on the symposium.

3. The RAC is co-sponsoring the ICMSF/RAC/ILSI/IAFP/IFT symposium on “Relating Microbiological Testing and Microbiological Criteria to Public Health Goals October 31-November 1, 2005. Several representatives from RAC member agencies are in the program.

There was much discussion about issues to be included in the RAC FY06 annual plan (separate document).

In attendance (* participated by phone):

*Gary Bangs, EPA/ORD/NCEA/Risk Assessment Forum

*Mary Bartholomew, FDA/CVM

*Michael Broder, EPA/NCEA

Robert Buchanan, FDA/CFSAN

Gregg Claycamp, FDA/CVM

Kerry Dearfield, USDA/FSIS

Sherri Dennis, FDA/CFSAN

Sharon Edelson-Mammel, FDA/CFSAN

Robert Hall, NIH/NIAID

John Hicks, FDA/CFSAN

Andy Hwang, USDA/ARS/ERRS

*Janell Kause, USDA/FSIS

Wes Long, FDA/CFSAN-JIFSAN

Marianne Miliotis, FDA/CFSAN

*Stephen Schaub, EPA/OW

*Angelo Turturro

*Margaret Venuto

Gary Vroegindewey, DOD/VSA

Mark Walderhaug, FDA/CFSAN

Richard Whiting, FDA/CFSAN