



**NCTR**  
National Center for Toxicological Research  
U.S. Food and Drug Administration



U.S. Food and Drug Administration

*Office of Women's Health*



# Interagency Risk Assessment Consortium



# Annual Report



December 1, 2005



**Office of Prevention, Pesticides,  
and Toxic Substances**

*Office of Research & Development*

**INTERAGENCY RISK ASSESSMENT CONSORTIUM  
AGENCY REPRESENTATIVES**

**Policy Council Members**

Robert Buchanan, FDA/CFSAN (Co-chair, Policy Council)  
Gregg Claycamp, FDA/CVM  
Kerry Dearfield, USDA/FSIS (Co-chair, Policy Council)  
Spencer Garrett, NOAA Marine Fisheries Services  
Ralph Kodell, FDA/NCTR  
Arthur Liang, CDC  
James Lindsay, USDA/ARS  
Michael McElvaine, USDA/ORACBA  
Jacqueline McQueen, EPA/ORD  
Margaret Miller, FDA/OWH  
Judy Nelson, EPA/OPPTS  
Tanya Roberts, USDA/ERS  
Stephen Schaub, EPA/OW  
Mary Torrence, USDA/CSREES  
Margaret Venuto, USDA/FNS  
Gary Vroegindewey, DOD/VSA

**Technical Member Representatives**

Mary Bartholomew, FDA/CVM  
Sharon Edelson Mammel, FDA/CFSAN (Executive Secretary)  
Robert Hall, NIH/NIAID  
Heather Hicks Quesenberry, USDA/FSIS  
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Katherine Hollinger, FDA/OWH  
Wesley Long, FDA/CFSAN (JIFSAN liaison)  
Michael McElvaine, USDA/ORACBA  
Jacqueline McQueen, EPA/ORD  
Marianne Miliotis, FDA/CFSAN (Chair, Technical Committee)  
Tanya Roberts, USDA/ERS  
Angela Ruple, NOAA Marine Fisheries Services  
Stephen Schaub, EPA/OW  
Donald Sharp, CDC  
Mark Tamplin, USDA/ARS  
Mary Torrence, USDA/CSREES  
Angelo Turturro, FDA/NCTR  
Margaret Venuto, USDA/FNS  
Richard Whiting, FDA/CFSAN

## **INTERAGENCY RISK ASSESSMENT CONSORTIUM ANNUAL REPORT FY05**

The Interagency Risk Assessment Consortium (RAC) was established in 1997. Through the RAC, federal agencies with risk analysis responsibilities collectively work together to enhance communication and coordination to promote the conduct of scientific research that will facilitate risk assessments.

Below is a list of the RAC accomplishments for FY05 and planned activities for FY06. Additional information about the RAC activities and meeting minutes are available on the web at [http://www.foodriskclearinghouse.umd.edu/Risk\\_Assessment\\_Consortium.htm](http://www.foodriskclearinghouse.umd.edu/Risk_Assessment_Consortium.htm).

### **ACCOMPLISHMENTS FOR FY05**

Each year the RAC develops an annual plan of activities and specific topic areas related to food safety risk assessments. The activities are designed to meet the charter goals. Below are the RAC accomplishments for FY05, which include information sharing and networking, quarterly presentations, other specific working group projects, and sponsoring symposia, workshops, etc.

#### **Information Sharing/ Networking**

The RAC continued having its technical quarterly meetings, where the technical representatives of the member agencies exchange risk assessment and research-related information.

#### **Presentations**

The RAC has continued to include technical presentations on a variety of topics related to risk assessment and food safety during each quarterly meeting. This year, we attempted to have some presentations focus on topics to help the work groups. The topic of two of the presentations was on sampling plans by different agencies. These included:

- "FDA Food Sampling Approaches" by Ronald Roy, FDA/CFSAN
- "Sampling designs, their uses, and how they were/are used by USACHPPM" by Robyn Lee, DOD/CHPPM

Other presentations included:

- "The Concept of Using Simulation Modeling in Food Safety" by Robert Wills, Mississippi State University, a current grantee of USDA/CSREES.
- "Cumulative and Aggregative Risk Evaluation System (CARES)" by Beth Julien and Mary Fox

#### **Specific Projects**

The RAC accomplishes much of its work through work groups formed to address specific topics or issues. Below are the accomplishments and activities of these working groups from FY04.

1. Data Gaps Analysis. The list of data gaps for selected microbial risk assessments posted on the RAC website has been updated.
2. Peer Review. Developed a draft discussion paper that included topics introduced during its September 2003 public meeting. While the decision was made not to finalize this paper or publish it (because of the release of OMB's Peer Review Guidelines in December 2004), it served as a useful resource to those in the workgroup. The workgroup was a valuable forum to discuss how peer review was handled among various agencies for food related risk assessments.
3. Data Information and Quality. A draft document was developed that compiled publicly available procedures for how various government agencies ensure quality of risk assessments. In particular information and links to OMB and various federal agency

Data Quality Guidelines were made available. A questionnaire was developed and sent to the RAC member agencies to obtain additional information on data quality issues specific to risk assessments. The document is being revised based on the responses to the questionnaire.

4. Data Utility. A symposium titled, "The Status of Data Utility in Decision Making: A Multi-disciplinary Review" was accepted at the 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. The group is also considering hosting a similar symposium independent of SRA, since we might reach a different audience.
5. Microbiological Criteria. This 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 agencies represented on the working group.

### **Workshops**

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.