Interagency Risk Assessment Consortium
Summer Quarterly Technical Meeting
June 16, 2006

Business Meeting **9:00 am – 11:30 pm**

Welcome to our new USDA/ARS RAC technical representative: Andy Hwang, USDA/ARS/ERRC.

Introductions

3 Minute Updates:

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

ORD has published 2 papers:

1) Al Dufour *et al*. National Exposure in Community Water Ingestion During Swimming Activities in a Pool. Children ingest twice as much water as adults. J. of Water, April 4, 2006. Also available online.

2) A National Institute of Environmental Health pilot study on Titanium Oxide. This study is the first to show a reaction in brain cells in vitro to exposure to TiO2. A reaction does not mean that toxicity has occurred, although it indicates there has been a stimuli response. This *in vitro* study shows possible implications of nanoparticle toxicity of brain cells. Available online: http://pubs.acs.org/cgi-bin/abstract.cgi/esthag/asap/abs/es060589n.html

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

1) Galley proofs of the paper developed by the RAC Microbial criteria Work Group have been returned and the paper will be published soon.

2) Moffet Center has a team examining the term "commercially sterile" for new types of food processing techniques, e.g., high pressure, pulsed electric fields. The point of departure is the traditional canning process and the team is exploring what "commercially sterile" means for these new processes and how should standards be set? For example, in canned foods, the standard reduction is D = 12 log for *Clostridium botulinum*. A 10^{-9} chance of failure would be a more appropriate expression of the criteria for low-acid canned foods. We need to look at the final level, not the process used to reduce levels of the hazard.

3) The Codex Committee for Food Hygiene is currently working on related issues. At a workshop held in Kiel, Germany, earlier this year, participants looked at performance criteria, food safety objectives, microbiological criteria, etc. They were trying to take a probabilistic approach; i.e., take a deterministic model and turn it into a one-dimensional risk assessment using Monte Carlo simulation so variation/uncertainty in the process parameters can be taken into account. CFSAN is taking the lead in developing a draft annex using smoked seafood and *L. monocytogenes* as the example food that will be reviewed by the international working group and submitted for the fall CCFH meeting.

Marianne Miliotis

1) Virus Risk Profiles: Finishing up; just completing some evaluations and impacts of different intervention strategies.

2) Norovirus Cruise ship Field Trip planned for July 7th.

3) The new Executive Director of the Harvard Center for Risk Analysis, Mike Huguenin, would like to meet with the federal risk analysis community to discuss research directions we'd be interested in. He realizes that most of us have no available resources for funding, but he is interested in exploring research ideas that HCRA might be interested in taking on, so that they could then pursue funding from foundations or elsewhere for support. With the departure of John Graham and subsequently the rest of the Center, the Center is for all practical purposes decimated, and he is trying to re-invent it. This seems to be an opportunity for us to identify some research needs and get others to work on them.

Tanya Roberts has suggested the RAC sponsor a symposium for some time in January, 2007: Risk Assessment, Control options, and Economic Net Benefit (see attached proposal).

John Hicks

1) The *Listeria monocytogenes* and Hepatitis A Virus in produce risk profile teams are planning a field trip to look at a fresh produce plant and growing fields to obtain information on how produce is handled and processed in the plant and to see how growers handle produce in the fields.

2) The modeling on the *L. monocytogenes* risk assessment on smoked finfish is almost complete and drafting of the document has started

Vasilios (Bill) Frankos

1) New participant to RAC meetings. He is in the Office of Nutritional Products and Food Labeling at FDA/CFSAN. He is involved with complex mixtures used in dietary supplements.

2) He is working with ILSI (HESSE) on mixture risk assessments. Food is a mixture, so the work group is discussing on how to incorporate the food matrix (the different nutrients) into risk assessments.

Steven Gendel

1) Steve Gendel has recently joined CFSAN/ OSCI/JIFSAN. One of his current assignments is to serve as a project manager of the *L. monocytogenes* risk assessment in soft ripened cheeses joint effort with Health Canada for the CFSAN Research and Risk Analysis Coordination Staff.

2) The *L. monocytogenes* risk assessment in soft ripened cheeses joint effort with Health Canada is continuing.
    a. The team recently had a three-day training session with Greg Paoli on using the Analytica software. The training provided a framework for understanding the problem; it allowed the team to build a conceptual model. The team is looking at capabilities of on line systems, where they can do application sharing in real time on line collaborative meetings.
    b. The team also completed the draft risk assessment charge during that time.

3) FDA/CFSAN has submitted a proposal for a symposium on Food Allergens at the annual Society for Risk Analysis (SRA) meeting to be held in Baltimore, MD in December 2006.

<u>Center for Veterinary Medicine (FDA/CVM)</u>
Barry Hooberman

1) Animal feeds group is building an Animal Feed Safety System to look at feed contaminants. They are developing a relative risk ranking model to identify which contaminants pose the greatest risk and help CVM use its resources appropriately.

2) CVM is continuing to work on risk ranking approaches to determine priorities in the allocation of inspectional resources.

<u>National Center for Toxicological Research (FDA/NCTR)</u>
James Chen

1. Dr. Ralph Kodell presented a paper 'Hierarchical Probabilistic Models for Managing Uncertainty" at the FDA Science Forum in April.
2. Dr. Steve Anderson of CBER, again, has organized a symposium session "Risk Assessment at FDA" at the 2006 SRA Annual Meeting. I plan to give a talk "Probabilistic Approaches for Managing Uncertainty for Cancer and Non-Cancer Risk Assessment".

3. Angelo Turturro had completed the experimental component of the NCTR-EPA IAG project on a model for transmission kinetics of infection by Cryptosporidium parvum.
4. Martha Moore and Ralph Kodell currently have a CRADA with TERA (Mike Dourson) on evaluation of using dose-response in vivo mutation data, cell toxicity and replication to provide information on the choice of the tumor dose-response model. The project will compare the mutation dose-response and the time-to-observed-mutation data to the time-to-tumor and tumor incidence data to ascertain if carcinogenicity of a compound is caused by mutagenicity.

Joint Institute for Food Safety and Applied Nutrition (JIFSAN)
Wes Long

1) The JIFSAN Clearinghouse is close to hiring a full time web master; updates will be completed much faster.
2) JIFSAN is purchasing data from the University of Tennessee on consumer handling practices.
3) JIFSAN/UMD is launching a graduate certificate program in Food Safety Risk Analysis; they're accepting credit or audit enrollees (?)
4) JIFSAN is in the middle of its summer integrated Risk Analysis Program

NOAA Fisheries
Angela Ruple
Nothing New to report; hopefully NOAA will be back in newly constructed laboratories in a few weeks.

United States Department of Agriculture
Animal and Plant Health Inspection Service (USDA/APHIS)
David Oryang

1) *BSE Prevalence estimate for the U.S. released.* On April 28, 2006, USDA released the BSE Prevalence Estimate for U.S. USDA experts used two different methods, the BSurvE Prevalence B method and the Bayesian birth-cohort method, to analyze the prevalence of BSE based on all of the surveillance data. The findings of the two methods were similar, indicating that the most likely number of cases present in the United States is between 4 and 7 animals. Therefore, USDA concludes that the prevalence of the disease in the United States is less than 1 case per million adult cattle, based on an adult cattle population in this country of 42 million animals. Additional information can be found on the USDA web site at: http://www.usda.gov/2006/04/0143.xml

2) *National Animal Identification System (NAIS) implementation plan.* On April 6. 2006, Agriculture Secretary Mike Johanns announced the release of an implementation plan that outlines timelines and benchmarks for the establishment of the National Animal Identification System (NAIS), along with a plan for the initial integration of private and state animal tracking databases with NAIS. More details can be obtained at: http://www.usda.gov/2006/04/0120.xml .

3) *USDA Implements New Electronic System to Ease Import Process*. On April 3, 2006 USDA's Animal and Plant Health Inspection Service launched ePermits, a new electronic system to streamline the import process. This is part of the U.S. Department of Agriculture's overall eGovernment initiative to transform and enhance the delivery of its programs, services and information.
The new system, which is being released in multiple phases, is a Web-based tool that allows the electronic filing, processing and tracking of permit applications. Submitting applications and receiving permits via the Internet will save customers a tremendous amount of time and effort.
The current phase allows individuals to process permit applications on-line for certain plant protection and quarantine and biotechnology and regulatory services' notifications. Veterinary services is in the process of finalizing its system and plans to launch its ePermits section on July 3. More information can be obtained at: http://www.aphis.usda.gov/newsroom/content/2006/04/epsystem.shtml

4) *USDA Launches New Electronic System to Streamline Export Process*. May 17, 2006–As part of the U.S. Department of Agriculture's overall eGovernment initiative to transform and enhance the delivery of its programs, services and information, USDA's Animal and Plant Health Inspection Service today launched a new electronic system to streamline its export process.
The Phytosanitary Certificate Issuance and Tracking system (PCIT), currently in the second phase of a multi-phase effort, is an interactive, Web-based system that allows U.S. exporters to apply for phytosanitary certificates online, schedule commodity inspections and printout copies of their certificates. More information can be obtained at: http://www.aphis.usda.gov/newsroom/content/2006/05/egovxprt.shtml

5) *USDA Amends Regulations Regarding the Importation of Animals and Animal Products From the European Union*. The U.S. Department of Agriculture's Animal and Plant Health Inspection Service is amending its regulations regarding the importation of animals and animal products into the United States from a region of the European Union (EU). This final rule will apply a uniform set of import requirements for classical swine fever (CSF) to the region consisting of the 15 member states that comprised the EU prior to its expansion on May 1, 2004. These member states (EU-15) are: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, the Republic of Ireland, Spain, Sweden and the United Kingdom.
(http://www.aphis.usda.gov/newsroom/content/2006/05/eu15csf.shtml)

6) *USDA Releases Requirements for Requests to Amend Import Regulations*. The U.S. Department of Agriculture's Animal and Plant Health Inspection Service announced that it has established regulations governing the submission of requests regarding changes to our import regulations for plants, plant parts or plant products.
The rule will help ensure that APHIS is provided the appropriate information to properly consider requests in a timely manner. Receiving the necessary information at the time an import request is made will facilitate the process for considering and responding to the request. Increased responsiveness to import requests will enhance

the standing of the United States as a trading partner. (http://www.aphis.usda.gov/newsroom/content/2006/06/imprtreg.shtml)

7) *Amended Regulations*. Several other regulations have been amended Please go to the APHIS newsroom to see all the recent regulatory changes. (http://www.aphis.usda.gov/newsroom/)

8) *Hot Issues Access*. You can get APHIS information on hot issues such as Avian Influenza, BSE, Asian longhorned beetle, citrus greening, and others, by linking to the following site: http://www.aphis.usda.gov/newsroom/hot_issues/index.shtml

9) *Implementation of initiatives to streamline the regulatory process*. There is a large and growing backlog of requests for the importation of agricultural products into the U.S. The lack of timely progress on these requests has a chilling affect on our ability to export. The Federal Government's risk assessment and regulatory processes are seen as an obstacle to more timely consideration of import requests. APHIS is establishing regulatory and SPS priorities, promulgating broader rules, streamlining its processes, utilizing information technology and adding analytical resources to expedite decision-making related to import requests. This will help APHIS to resolve trade barrier issues related to sanitary and phytosanitary (SPS) issues.

10) *Transgenic Animals and Crosscutting Issues*. The Animal and Plant Health inspection Service (APHIS) is responsible for protecting and promoting U.S. agricultural health, administering the Animal Welfare Act, and carrying out wildlife damage management activities. APHIS's Biotechnology Regulatory Services (BRS) program regulates the field testing, movement, and importation of genetically engineered (GE) organisms that are known to be, or could be plant pests. BRS also evaluates petitions for deregulation to ensure that products being considered for removal from regulation do not pose a threat to U.S. agricultural or environmental health. APHIS does not currently have any actions on transgenic animals (with the exception of insects and arthropods that damage crops), but there is a lot of regulatory work on transgenic plants (For more information, go to the Biotechnology Regulatory Services website at: http://www.aphis.usda.gov/brs/).
Crosscutting Issues: APHIS has authority to act to decrease problems with animal and plant health. These actions may indirectly impact human heath. There are some zoonotic diseases (BSE, Avian Influenza, Anthrax) that directly impact both animal and human health.
There is a general recognition and consensus that APHIS, FDA, FSIS, EPA, HHS, and DHHS need to work collaboratively to resolve/regulate crosscutting issues that impact humans, animals, plants, and the environment.

Agricultural Research Service/Eastern Region Research Center (USDA/ARS/ERRC)
Andy Hwang

1) ERRC-ARS is 9 months into its new 5 year plan. More information on ERRC research plans can be found on the ERRC website at http://www.ars.usda.gov/main/site_main.htm?modecode=19350000.

2) The microbiological food safety research at ERRC-ARS involves mostly in post-harvest food safety in meat and produce. Research areas include pathogen modeling, microbial stress responses, rapid detection method, and novel intervention technology (high pressure, electric field, and microwave heating). Current modeling work includes *E. coli* O157, *Salmonella* and *L. monocytogenes* in raw meat, ground beef, poultry, and in ready-to-eat foods.

3) They are modeling growth of pathogens: *E. coli* O157, *Salmonella* and *Listeria monocytogenes* in raw meat, ground beef, poultry, and in ready-to-eat food. ARS is looking at the genetic response of organisms to stress environments.

4) József Baranyi is a visiting scientist from the Food Research Institute, UK, at ARS since April, 2006 and will remain for the next 8 months. He is improving the ComBase web site, implementing new predictor tools for it, and developing a model for microbial competition, such as *E. coli* and background microflora in ground beef. He is also exploring new approaches to modeling microbial interactions.

5) ARS is generating data for use in quantitative risk assessments.

6) Moserrate Hernandez, a visiting scientist from Mexico, and Dr. Allen Sheen from ERRC-ARS attended a 3-day class on quantitative risk assessment at Princeton University, NJ

<u>Cooperative State Research, Education, and Extension Service (CSREES)</u>
Mary Torrence

1) Review panels have met but awarded grants have not been made official yet.

2) Robert Mandrell's (ARS) grant was expedited and has received funding and is collaborating with University of California and the FDA to look at produce fields in the Salinas Valley.

<u>Food Safety Inspection Service</u>
Office of Public Health/Risk Assessment Division (USDA/FSIS/OPHS/RAD)
Janell Kause

1) *Risked-based sampling verification*.
i. The Risk Assessment Division (RAD) has developed a model for risk-based *Listeria* sampling that contains parameters informed by two prior food safety *Listeria* risk assessments: 1) the 2003 FDA/FSIS risk assessment for *Listeria monocytogenes* (Lm) in ready-to-eat (RTE) foods; and 2) the 2003 FSIS risk assessment for *Listeria* in deli meats. This risk-based algorithm for FSIS microbiological sampling for Lm in RTE meat and poultry products has been independently peer reviewed according to OMB Information Quality Peer Review guidelines and has been presented to the USDA Office

of Risk Assessment and Cost-Benefit Analysis. This risk-based algorithm will be made available to the public on FSIS' website.

ii. FSIS is also developing a risk-based algorithm for microbiological verification sampling of *E. coli* O157:H7 in ground beef and trim. The parameters of this risk-based sampling algorithm are informed by the 2001 FSIS risk assessment for *E. coli* O157:H7 in ground beef and through formal expert elicitation methods to identify risk factors. Data from the FSIS Beef Trim Microbiological Baseline along with compliance data will be used in this algorithm. Also, FSIS has invited Dr. Roger Cooke with Resources for the Future to present on methodologies of characterizing uncertainty garnered from expert elicitation input. Dr. Cooke's methodology will be considered in further development of the risk-based algorithm for targeted microbiological sampling of *E. coli* O157:H7.

iii. FSIS has also developed a risk assessment for risk-based poultry slaughter inspection to evaluate the public health impact of reassigning inspection activities.

2) *Cross-contamination models*. FSIS is pursuing development of cross-contamination models and will be releasing a request for information through the federal register this summer. Initial efforts are under way to work with Steve Hathaway (NZ) and others to build better cross contamination models. FSIS is interested in collaborating with others to build a cross-contamination model that is more robust than current cross-contamination models and developing a module that can be modified and used in a variety of food safety risk assessments. FSIS is currently seeking to see if there is interest among other federal agencies working on food safety issues.

3) *Avian influenza*. The RAD is considering the feasibility of conducting a risk assessment on avian influenza.

4) *Society for Risk Analysis Annual meeting*. FSIS co-convening several symposia panels at the annual SRA meeting in December 2006, including: 1) a Risk-Based Verification Sampling symposium panel co-convened with FDA; 2) an Attribution Modeling panel co-convened with CDC (see update by Dr. Carl Schroeder for more details); and 3) a Microbial Risk Assessment Guidelines panel co-convened with EPA (see update by Dr. Kerry Dearfield for more details). FSIS staff will also present on an FDA-lead Risk-Benefit symposia panel and present a recently revised *Salmonella* dose-response model.

Kerry Dearfield

1) *Microbiological Risk Assessment Guidelines.* Continuing its joint effort with EPA on developing guidelines, FSIS and EPA proposed a 2- part symposium for the SRA meeting in December 2006 on "The Interagency Microbiological Risk Assessment Workgroup: Development of guidance for microbiological risk assessment" to look at the perspectives of the different participating agencies - commonalities and unique items to conducting a risk assessment. The FDA/Center

for Veterinary Medicine (Gregg Claycamp) has joined the effort, so now there are 3 agencies involved, and they are hoping the Department of Defense will also join the group. The group hopes to bring the guidelines down to a practical level.

2) *EPA dioxin document*. The report by the National Academy of Sciences on the document will be delayed until at least 07/10/06. FSIS is waiting to see the implications for dioxin in food. FSIS is planning to continue its ongoing survey of dioxin in meat and poultry products, and actively putting the survey proposal into its 2008 initiatives.

Carl Schroeder

Under the auspices of Food Net, Carl and Elaine Scallan (CDC) have put forward a proposal for a symposium at the SRA meeting in Baltimore on discussions of various models of attributing illness to different food commodities:

1) Danish model on *Salmonella*

2) John Painter (CDC) on analysis of FoodNet culture data

3) Sandy Hoffman (RFF) on expert elicitation

4) George Maldonado (University of Minnesota) on a "blending" approach to attribution using data fro outbreaks and case control studies

5) Mike Batz (RFF) on the Foodborne Illness Risk Ranking Model (FIRRM).

<u>Office of Risk Assessment and Cost Benefit Analysis (USDA/ORACBA)</u>
Michael McElvaine and Rita Deng

Rita is a fellow with ORACBA working with the Nutrition Risk Assessment work group.

<u>Visiting Scientist with USDA/ARS/ERRC</u>
József Baranyi

1) Dr. Baranyi is working with Mark Tamplin on ComBase. An advanced newer version was presented at the Risk Assessment conference in Sydney, Australia earlier this year. The main development is the addition of another search engine; it is also more application oriented. It has an increased database on pathogens and their growth rates. The background is developing nicely on the dynamic changes in response to different conditions. In a year there will be a combined ComBase and Predictive Microbiology Program. The Australians have joined ComBase; now is a UK, US, Australian partnership.
2) Dr. Baranyi is also working on developing models for microbial competition as stated by Dr. Andy Hwang. He is also looking at the interaction between species; e.g., growth of *E. coli* in ground beef together with the indigenous flora. Modeling the interaction with other microbes can be analysed by Network Theory methods. These methods could be useful for example to derive links between species, similarly as researchers are

analyzing how different side effects of a drug is the result of the network of links between genes, proteins and other chemicals.

Work Group Updates

Data Gaps Analysis

Data Gaps workgroup will currently not be adding any new data gaps to the existing data gaps list. The workgroup continue to publicize the data gap list so that universities and research institutes may take the identified data gaps into consideration when conduct research to fill these gaps. The workgroup would like to link the data gaps list to FDA and USDA for them to add the list to their funding process. The work group is currently identifying experts in different fields to assist in ranking the data gaps, prioritizing the research needs, and determining and referencing data gaps that have been filled.

Omics

Work group is forming with Jim Withee (USDA/FSIS/OPHS) as the lead. He is looking for more members among the member agencies. We need to have initiatives for food safety dealing with genomics. There is a need to bring the microbial food pathogen community into genomics. The chemical world is already very engaged, but not the microbiologists. Genomics can be used not only for identification of the problem (virulence and resistance genes), but also to look at the host response (biomarkers, precursor effects, etc.) and to the pathogen. Kerry and Jim Withee have briefed Norris Alderson. RAC member agencies should try to get involved with the NAS symposium in late June on genomics, proteomics, arrays, etc. to try to include microbial genomics.

Nutrition Risk Assessment

The work group has been planning a 2-day workshop in the second quarter of FY07 to scope points of consensus and foster multidisciplinary communication and methodology development of nutrition-related risk assessment. Scientific disciplines involved in the workshop include nutrition, dietetics, toxicology, epidemiology, pharmacology, clinical medicine, economics, risk analysis, and other related sciences. ILSI and the IOM Food Forum are also active participants of the planning group for the workshop. A workshop strawman highlighting the goals, content, and outcomes, as well as a preliminary program, has been drafted, revised, and distributed for comments. Existing resources from previous US and European efforts that have attempted to shape decision making processes in nutritional risk assessment have been gathered and organized to contribute as part of the Clearinghouse website.

Data and Information Quality Work Group

The work group has been dissolved. The briefing paper will be accepted as a deliverable. The information already gathered will be captured under the interagency methods and framework activity that Kerry is leading. The group will close-out with a summary of what has been done since the briefing paper was completed.

Presentations

- "An Introduction to Expert Elicitation for Environmental Decision Making in a Regulatory Process" by Neil Stiber, EPA/ORD

- "Update on FoodNet Activities" by Elaine Scallan, CDC/ FDDB

In attendance (* participated by phone)

József Baranyi
Kerry Dearfield
Rita Deng
Sharon Edelson-Mammel
Vasilios (Bill) Frankos
Steve Gendel
John Hicks
Christine Hileman
Barry Hooberman
Andy Hwang
*Janelle Kause
Wesley Long
*Michael McElvaine
Marianne Miliotis
David Oryang
Cindy Roberts
Tanya Roberts
*Angela Ruple
Carl Schroeder
Shiowshuh Sheen
Neil Stiber
*Mary Torrence
Richard Whiting

Several other RAC member agency employees attended the presentation session only.