

**Interagency Risk Assessment Consortium
Semi Annual Policy Council and Technical Quarterly Spring Meeting
March 22, 2007**

Policy Council Meeting 9:00 am – 10:45 am

Introductions

Welcome to Brenda Halbrook, the IRAC technical and policy council representative for USDA/Food and Nutrition Services.

Work Group Updates

1. Data Utility

The Data Utility workgroup has been hard at work on their discussion paper titled, "Data Utility and Decision Making in Health Risk Assessments: A Multi-Disciplinary Perspective." The paper will be undergoing concurrent review by the technical members and policy council of the IRAC, beginning end of March. The Work Group requests comments back no later than April 12, so comment incorporation can be completed and Agency review can begin by May. The Work Group hopes to submit the paper to the Journal of Risk Analysis by June 2007 and thanks the IRAC in advance for their time spent reviewing the group's efforts.

2. Data Gaps Analysis

Initial efforts to publicize the Data Gaps list have had limited success thru (i) listservs and on the IRAC website, (ii) funding agencies to incorporate the list into funding programs and (iii) professional meetings.

Janell Kause and Andy Hwang provided the Data Gaps list to the attendees in the workshop "Enhancing ARS-FSIS Interaction to Address Risk Assessment Data Needs" at the annual ARS-FSIS Food Safety Research Planning meeting held in Shepherdstown, WV, February 21-23, 2007.

A general question was asked as to whether agencies put out public calls for data prior to starting a risk assessment. When we do put out the call, do we also put out criteria for quality of data? Calls for data are published in the Federal Register, but data are sparse, so calls for data are not accompanied by criteria.

3. Nutrition Risk Assessment

The workshop on "Nutritional Risk Assessment: Bridging Perspectives, Sharing Methodologies, Identifying Data Challenges" took place February 29-March 1, 2007 at NAS and was very successful! It appears that the "door between risk assessors and nutritionists has just been opened". There appeared to be 2 pieces: paradigms of recommended allowances and paradigms of how much is too much? We need to look at dietary patterns that lead to increasing/decreasing chronic disease.

- Realization that RA approaches may be applicable to NRA to establish nutrient intake recommendations, but many challenges:
 - Part of challenge is defining context for risk: concept of RA – UL
 - Did we use concept of uncertainty appropriately?
 - How do we use concept of uncertainty with RDA and UL's?
 - Health Claims: risk for chronic disease; dietary probability of benefit; who will benefit? Does a health claim create risk?
 - Tools needed to model risk: biomarkers, for food intake/exposure, disease, causal relationship
 - Importance of EBR evaluations
 - Recognition of uncertainty; data gaps!
 - How does all this translate to the consumer? Need to help them navigate the information they are getting
 - Difficult to compare different health outcomes: (economists use DALYs)

- At the end, consumers make final decision as to what they will eat; not discussed at this meeting: consumer behavior
- Diversity of perspectives: need for RA's, RM's (and Nutritionists) to have very in depth discussions at the beginning
- Need to remember what may benefit, may also be a risk
- One important issue that came up was: are we dealing with a risk-risk question or a risk-benefit question in nutrition risk assessment?
- Funding vs. quality applications to address critical issues.

This meeting was another good example of the role of the IRAC in leveraging in different activities: We obtained resources from different agencies and brought the funding up to a substantial amount with ILSI and NAS.

We need to consider next steps.

Possible next steps: give RA a try: pick a nutrient and RA model, plan a workshop, then evaluate for data gaps and appropriateness to nutrition. ILSI is interested in looking at iron fortification in foods and risk of malaria in Africa.

Next step for NRA work group: One other possible step is to get nutritionists, risk assessors, and epidemiologists together to discuss nutrition risk assessment data gaps and needs.

Possible participants: USDA/CSREES, USDA/ARS, USDA/FNS, USDA/ORACBA, FDA/CFSAN, DHHS/ASPE, and possibly NIH.

Discussion of Possible New Projects for IRAC Work Groups

1. Effect of Climate Change on Food Safety

Global change may present unexpected phenomena, with unknown consequences for food and water safety and nutrition (See attached document). Spencer Garrett will get Wes Long in touch with NOAA's National Oceans Human Health Program. NOAA had several models, which can be shared with food safety folk. APHIS has been working with UMD on climate change and pest introduction, and also has climate phase models on pests on plants. As far as water is concerned, EPA is interested in change in climate effects on emerging and reemerging pathogens. Hurricanes also affect food safety; when they went through South America, there was a typhoid outbreak, and food from that area became infected. For example, there were higher toxin levels in canned ackee in Jamaica last year, where they had hurricanes for the first time in 20 years.

Propose to have a workshop and bring together climate modelers (NOAA; APHIS) and food production and food safety folk. The focus of the workshop and work group would be impact on nutrition. Need to first get the landscape/scope the issues.

[Citation: Ecological Niche Modeling and Spatial Patterns of Disease Transmission. A. Townsend Peterson. Emerg. Infect. Dis. Vol. 12. Number 12, p1822.]

Agencies/Centers interested in project: NOAA Fisheries, EPA/OW, USDA/APHIS, FDA/CFSAN.

2. On Farm Food Safety

Recent foodborne outbreaks in produce, esp. the spinach outbreak last September, have all food regulatory agencies concerned. Another worthwhile project for the IRAC to undertake is to promote a better understanding of the causes of food-borne illness outbreaks like the lettuce and spinach cases that occurred during the fall. Several agencies have an invested interest in this topic at all levels:

- Consumer concern at the salad bar and fresh-cut produce level: "How can I protect my kids in a kitchen? Can I treat the products that I feed kids in a school lunch program?"
- Role of wildlife and endangered species such as geese and feral pigs in produce contamination
- Recycled water into agriculture

- EPA has models on spread of pesticides in water developed by RTI that we could possibly adapt
- Other models that may be adapted include those on contamination of shellfish stocks; models on molluscan shellfish for different climates, such as rainfall, which would also affect on farm production of produce. These models may be able to determine ALOP (appropriate level of protection) levels.

One idea that seemed to be well accepted by the agencies was to form a group to conduct a data gaps analysis to determine the research needs, specifically "on farm" issues. USDA/ARS/ERRC in Whitmore, PA, has a Food Safety Intervention Research, and they might be interested in filling some of the data gaps. Also, USDA/CSREES has funding programs in which the research needs could be incorporated.

FDA/CFSAN is drafting a prospectus, and will send it out to the rest of the IRAC agencies.

Interested agencies so far include:

FDA/CFSAN; EPA/OW; FDA/NCTR; USDA/FNS; EPA/ORD; USDA/ARS/ERRC

3. Bisphenol A

Recent publication by Federal agency requesting the need for a new risk assessment model. It is an endocrine disruptor used in pesticides and also found in several plastics, such as baby bottles.

It was suggested we put this topic on the back burner for now.

4. Biomarkers for Food Safety

(i) Nanotechnology. This topic is really taking off. The Food Forum is considering a workshop on nanotechnology. It might be a good idea for the IRAC to partner with them as we did with the Nutritional Risk Assessment. The White House policy group is focusing on nanotechnology and food safety. FDA has not received any petitions for food additives. There is a federal-wide group on nanotechnology with several sub groups, but no involvement of food safety as yet. The Woodrow Wilson Center is looking at nanotechnology and food safety in an upcoming initiative.

JIFSAN and CSL are jointly holding a workshop on Nutrition and Food Safety: Nanotechnology in Food and Cosmetics, June 26-28, 2007.

(ii) Genomics/Proteomics. A work group was beginning to form last year, but not enough interest by IRAC representatives. Technology is increasing; USDA/FSIS is continuing with its efforts. The big issue for CFSAN is attribution. What are the critical features/parameters of this technology? What are the properties that we really want to go after? CDC has its own technology, so we need to work with them. There was also some debate on how far to drill; can we be too specific? Both virulence factors and antibiotic resistance are of interest; it is not just the serotype we need to be concerned about anymore. Gene expression often changes in the host leading to more uncertainty. We need a strategy for critical features and methodologies. This is a major issue; need to focus on performance criteria/issues rather than standard methods. Are we measuring dead or alive. We are measuring disease exposure. So, what should the IRAC do? Maybe determine how risk assessment should apply molecular methods.

Discussion on IRAC-sponsored workshop on "Risk Assessment, Economics, and Food Safety"

Tanya Roberts presented the draft agenda and prospectus for the workshop, which will be held at USDA/ERS, October 19, 2007. There have been new developments in valuation for food risks, morbidity, and willingness to pay. The objectives of this meeting are:

- 1) To introduce the concept of integrating risk assessment and cost benefit analysis.
- 2) Using this integration, to look at recent advances in valuation for food risks.

- 3) To examine economic incentives in the public and private sectors and how they contribute to safer food
- 4) To hear what policy makers and risk analysts in the public and private sectors think about economic incentives and the new economic valuation methodologies

Tanya will make some revisions to the draft agenda according to discussions and send it on to the IRAC representatives.

Additional Item

Richard Fite, USDA/APHIS announced a workshop in India on Animal, plant health and food Safety. There is a need for someone to present on risk assessment.

Presentations 11:00 am – 1 pm

1. DOD/CHPPM Anthrax Risk Assessment by Brandolyn Thran
2. EPA/OW Microbial Risk Assessment Framework by Steve Schaub, EPA/OW and Audrey Ischida, ICF

Both presenters thanked the IRAC for their review of the documents and requested the reviews be submitted by the end of March, 2007, if possible.

Technical Meeting 2 - 3:30 pm

5 minute Updates

Environmental Protection Agency

Office of Research and Development (EPA/ORD)

Cindy Roberts

- Heads-up on an upcoming meeting April 23-26, 2007, Cincinnati, OH organized by EPA/NCEA on Toxicology and Risk Assessment. There will be a session on Quantitative Microbial Risk Assessment.

Cindy Sonich-Mullin

- Part of Homeland Security; other members include Tonya Nicholls and Deborah McKean
- Homeland Security has a substantial risk assessment program: helps agency to prepare and respond to terrorism
- Homeland Security also conducts chemical and biological research

Tonya Nichols

- There is a database "Central Environmental Rapid Risk Assessment" with peer reviewed documents on aerosols, dose-response, and other categories. It is found on the EPA Science Connector Portal.

Environmental Protection Agency

Office of Water (EPA/OW)

Stephen Schaub

- Microbial Risk Assessment (MRA) Thesaurus. It is in the process of getting sign off by all the EPA offices before it is good to go on the web available as a draft.
- WHO meeting, Berlin, May, 2007. Microbial Risk Assessment for water guidelines
- Risk Assessment Forum. A workgroup held a symposium in February to look at immunotoxicity (chemicals in the environment) and impact of dose-response on these antimicrobials to see if it can apply to MRA protocols.

- Framework analysis of MRA. A total of 25 MRA frameworks were analyzed to see what features can be used in the water MRA framework.
- EPA has contracted out to develop a risk communication guidance document. It is almost ready.

Food and Drug Administration

Center for Biologics Evaluation and Research (FDA/CBER)

Hong Yang

- Risk assessments for potential of transmission of disease through biological products. They looked at the association of potential risk of variant Creutzfeldt-Jakob disease transmission through plasma:
 - Factor XI, made from UK plasma by UK manufacturer, has been used by a small patient group in the US
 - Factor VIII, made from US plasma, is used for hemophilia A patients in the U.S.

The risk assessment predicted an extremely low risk. The risk assessment is now at the risk communication level. FDA/CBER and CDC, under the HHS umbrella developed a package of risk communication message including issue summary, key message points, questions and answers and executive summary of risk assessment; HHS has started communication with hemophilia treatment center, physicians and patients advocacy groups. Documents will be posted on website after final clearance. FDA/CBER is also preparing to write manuscripts for these 2 risk assessments

- Risk assessment on the impact of emerging infectious disease on the blood supply.
 - CBER is evaluating the risk of blood transmitted infectious diseases such as hepatitis A Virus, hepatitis B Virus, and hepatitis C virus. They will look at donor deferral options, to see how risk will change and how it will affect the blood supply.
 - A project was evaluating the risk associated with male donors who have history of having sex with men. A manuscript is being prepared.
 - A risk assessment is being conducted on the impact of pandemic flu on the US blood supply.

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

Richard Whiting

- *L. monocytogenes* in cheese risk assessment conducted jointly with Health Canada is under way. They are in the data collecting phase.
- CCFH activities this summer include:
 - *Listeria*; validation; risk management: how you define setting food safety objectives and performance objectives; *Salmonella* and *Campylobacter* in broilers.
 - Nega Beru, FDA/CFSAN together with Kerry Dearfield, USDA/FSIS is involved in chemical contaminants in food.

Marianne Miliotis

- Risk Assessment Coordination Team (RACT):
 - CFSAN Reorganization became effective March 12, 2007: RACT is now in the Office of Food Defense Communication, and Emergency Response (OFDCER)
 - We have a new hire: a Risk Assessment Project Manager: Wendy Fanaselle
- Virus risk Profiles
 - Hepatitis A Virus: the 3rd draft is currently being reviewed by Dr. Buchanan and is concurrently being revised accordingly
 - Norovirus: the 2nd draft was reviewed by Dr. Buchanan and is being revised accordingly

- JIFSAN Food Safety Risk Prioritization workshop will take place June 4-6, 2007. Once we have more information and a finalized agenda, it will be put on the JIFSAN website, but it's by invitation only! Sponsors are academia, industry, and government.
- CCFH
 - The request for new work on *Vibrio* spp. was put on the burner at the 38th session; we were asked to resubmit again this year; it was sent to the CCFH *ad hoc* working group for new work in May 1, 2007.
 - The US will also put a request for new work on produce (CFSAN will be the lead) and EHEC (USDA/FSIS will be the lead)
- Food Products Association toxicological committee is interested in assisting in review of chemical component and further development of the model. It will probably take off from where the JIFSAN workshop leaves off.
- We have submitted an abstract on "Developing Risk Profiles to Assist Regulatory Decision Making" for the IAFP annual meeting; and it's been accepted as an oral presentation.
- We are preparing to submit two symposia for the SRA meeting in December:
 - One on Nutrition Risk Assessment (Department of Health and Human Services Assistant Secretary for Planning and Evaluation [ASPE] has the lead)
 - One on "Developing Risk Profiles: Different Approaches" – tentative title.

Sharon Edelson Mammel

- The FDA/CFSAN risk assessment web site has been updated and can be found on the CFSAN internet website: <http://www.cfsan.fda.gov/list.html> From here use the pull down menu for risk assessment

Wesley Long

- With the reorganization, Wes has been transferred into the Division of Education and Communication in the Office of Food Defense, Communication and Emergency Response.
- He is serving in the capacity of a risk communicator and is looking for his peers in the IRAC member agencies

John Hicks

- The risk assessment on *L. monocytogenes* in smoked finfish is almost complete and the team would like to present it to and have it reviewed by the IRAC
- The risk profile on *L. monocytogenes* in fresh cut produce is complete and almost ready for review by risk managers. The risk profile is a fairly detailed document, approximately 85 pages in length. In structure and content it is essentially a qualitative RA.

National Center for Toxicological Research

Rajesh Nayak

- The recent outbreak of *E. coli* O157:H7 and *Salmonella* underscores the necessity to address the threat of these food borne pathogens in our food supply, particularly in fresh fruits and vegetables. Current research is predominantly geared towards addressing the post-harvest component of food safety, and limited attention is given to the preharvest, on-farm component of food safety. We are currently using bacterial DNA fingerprints and molecular epidemiological analysis to study the genetic diversity and antimicrobial and pathogenicity traits of different *Salmonella* species in pre-harvest poultry environment so as to source track the bacterial origins, delineate transmission pathways and establish proactive, pre-harvest control of food borne pathogens in the "farm-to-the-fork" continuum.

- In collaboration with FDA's Center for Food Safety and Applied Nutrition (CFSAN) and USDA's Agricultural Research Services (ARS), two *Salmonella* biochips are being developed and validated for rapid and accurate identification of multiple virulence and antimicrobial resistance genes in *Salmonella* serovars. The joint effort between the FDA Centers and USDA will be useful in transferring microarray technology from the research stage at CFSAN and NCTR to the FDA field laboratories and law enforcement mobile labs.
- We are developing two independent integrated comparative databases of *Salmonella* Heidelberg and Javiana, two "emerging" serovars, from clinical, animal and food-related outbreak populations in the United States, so as to monitor the allelic genotype diversity, antibiogram phenotypes and virulence gene determinants to assess the threat of infections in case of accidental outbreaks or biological warfare.
- In collaboration NCTR/ARL Bioterrorism Mass Spectrometry (MS) project, we are developing methods for rapid detection of bacterial pathogens such as *Salmonella* and pathogenic *Escherichia coli* O157:H7 using pyrolysis and MALDI-ToF MS technology with multivariate statistical and artificial neural network pattern recognition.

Center for Veterinary Medicine (FDA/CVM)

Linda Youngman

- Animal cloning: a draft risk assessment was released on 12/28/06
 - Comments are very favorable so far (for the most part)
 - Have received, I believe, over 1,000 public comments so far
 - A great deal of media interest
 - Gregg Claycamp left CVM to join CDER (mid-February), continues to do risk assessment work for FDA
 - Barry Hooberman is on detail to another CVM office to work on biotechnology risk assessment issues and reviews
 - Dolores Beblo is working on numerous risk assessment projects including:
 - AFSS (animal feed safety system), Salmonella contamination in animal feed – another public meeting coming up in May '07
 - Risk-based inspection site selection models for ORA, Dolores gave a talk at the CVM field committee meeting on Feb 27 '07, very well received and ORA will begin to utilize
 - PK/PD modeling in reviews of new animal drug applications
 - Linda Youngman is working on risk assessment projects including:
 - Resistant nematode worms in food animals
 - Microbiological risk assessment models for reviews of new antimicrobials

United States Department of Agriculture

Animal, Plant, Health Inspection Service (USDA/APHIS)

David Oryang

- BSE Minimal Risk Rule. Proposed Rule was published January 4, 2007. The comment period ended on March 12, 2007. APHIS received 100's of comments. The risk assessment was also formally peer reviewed and comments were mostly favorable. APHIS is now responding to the public comments and peer review comments. The proposal expands what APHIS had published in 2005. The proposed rule and supporting analyses are on the APHIS BSE Information website. See the news release: "USDA Proposes to Allow Additional Imports from BSE Minimal-Risk Countries"

(http://www.usda.gov/wps/portal/!ut/p/s.7_0_A/7_0_1OB?contentidonly=true&contentid=2007/01/0001.xml)

- OIE country classification for BSE. In October 2006, the U.S. Department of Agriculture submitted an application and supporting documents to the World Organization for Animal Health (OIE) to formally request country classification for bovine spongiform encephalopathy (BSE) risk. The US was given a preliminary controlled risk classification, with a final classification to be given in May, 2007. For more details see the Mar 9, 2007 Statement by Dr. Ron DeHaven (APHIS Administrator) Regarding OIE Risk Recommendation

(http://www.aphis.usda.gov/newsroom/content/2007/03/OIE_statement3-9-07.shtml).

- Citrus Canker: Florida has citrus canker. For many years, APHIS has been in eradication mode, but has now shifted to management mode. On Jan. 10, 2006, the established program was modified to stop the practice of destroying trees within 1,900 feet of an infected tree and APHIS started working with State partners and industry to develop a new science-based approach for managing citrus canker. In March 2006, APHIS released the draft Citrus Health Response Plan, which focuses on maintaining the health of Florida's citrus while acknowledging that eradication is no longer possible. The plan establishes accepted standards to propagate, produce, harvest, process and ship healthy Florida citrus. More details about citrus canker can be found on the APHIS website at:

http://www.aphis.usda.gov/newsroom/hot_issues/citrus_canker/citrus_canker.shtml

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

Andy Hwang

- The annual ARS-FSIS food safety research planning meeting was held in Shepherdstown, WV, in February 2007. A special session "Enhancing ARS-FSIS Interaction to Address Risk Assessment Data Needs" led by Janelle Kause (FSIS) and John Luchansky (ARS-ERRC) was held to discuss FSIS research data needs over the next five years and the mechanisms to incorporate these needs into ARS's 5-year research Action Plan.
- ComBase: The relational database now contains more than 40,000 research data sets. It is managed by a Consortium from the USDA-ARS-National Program Staff; USDA-ERRC; the Australian Food Safety Center of Excellence; the UK-Food Standard Agency; and the Food Research Institute (FRI), Norwich, UK. The Combase Executive and Scientific Committees are scheduled to meet at the International Predictive Microbiology Meeting in September 2007, held in Athens, Greece to discuss future expansion of Combase, and incorporation of new data sets.

Economic Research Service (USDA/ERS)

Tanya Roberts

- USDA's annual Agricultural Outlook Forum had a session on Food Safety Innovations in the public and private sector, 1:30 on Friday, March 9, 2007. The slides for the 3 speakers are on the USDA web site at <http://www.usda.gov/oce/forum/>
- ERS conducted an economic analysis on BSE and found the impact on beef sales limited to two weeks. See "Did BSE Announcements Reduce Beef Purchases?" by Fred Kuchler (fkuchler@ers.usda.gov) and Abebayehu Tegene, available on the ERS website at <http://www.ers.usda.gov/Publications/ERR34/>
- ERS researchers have two other new publications of general interest to IRAC with Paul Frenzen as a co-author (pfrenzen@ers.usda.gov):
 - FoodNet report on acute diarrheal disease: 20% sick people visit doctors; 2% are hospitalized, and 0.6 acute diarrheal episodes per person per year. Jones, T. F., M. B. McMillian, E. Scallan, P. D. **Frenzen**, A. B. Cronquist, S. Thomas, and F. J. Angulo. A population-based estimate of the substantial burden of diarrhoeal disease in the United States; FoodNet, 1996-2003. *Epidemiology and Infection*. Available online:

<http://journals.cambridge.org/action/displayIssue?jid=HYG&volumeId=135&issueId=02>

- Report on irradiation and acceptance of irradiation - Hoefer, D., S. Malone, P. Frenzen, R. Marcus. E. Scallan, S. Zansky. Knowledge, attitude, and practice of the use of irradiated meat among respondents to the FoodNet Population Survey in Connecticut and New York. *Journal of Food Protection* 69(2006):2441-2446.
- ERS is in the process of updating its cost of foodborne illness estimates.

Food Safety Inspection Service (USDA/FSIS)

Kerry Dearfield

- The multi agency Microbial Risk Assessment work group is making good progress. The goal is to have some type of working draft by the end of this calendar year. Jamie Bartram, WHO, might be interested in international harmonization. He would like to have another document, besides the CODEX framework.
- The Interagency Avian Influenza risk assessment for poultry, eggs and egg products is currently undergoing formal independent peer review and a parallel interagency review (CDC, APHIS, FSIS, FNS, AMS, and FDA) over the next few months. The scope of this risk assessment is on foodborne exposures and is designed to evaluate the effectiveness of various emergency preparedness and response measures by the federal government and industry. Other agencies are developing AI risk assessments to consider exposure routes other than food (i.e., person-to-person spread, occupational, etc.).

Discussion.

There was a discussion as to whether the IRAC would like a “special” meeting before the summer June technical meeting to have presentations on the risk assessments on avian influenza and *Listeria monocytogenes* in smoked finfish. It has since been decided that it would be better to wait until the June meeting, which will take place June 14th, 9 am – 1 pm.

In attendance (* participated by phone)^a:

*Michael Broder, EPA/NCEA
Robert Buchanan, FDA/CFSAN
Kerry Dearfield, USDA/FSIS
Sharon Edelson Mammel, FDA/CFSAN
Richard Fite, USDA/APHIS
*Spencer Garrett, DOC/NOAA Fisheries
Eric Grant, USDA/APHIS
John Hicks, FDA/CFSAN
Andy Hwang, USDA/ARS/ERRC
*Janell Kause, USDA/FSIS
Kathleen Koehler, DHHS/ASPE
Wes Long, FDA/CFSAN
Robert McDowell, USDA/APHIS
*Deborah McKean
*Jacqueline McQueen, EPA/ORD
Marianne Miliotis, FDA/CFSAN
*Rajesh Nayak, FDA/NCTR
*Tonya Nichols, EPA/ORD
David Oryang, USDA/APHIS
*Cindy Roberts, EPA/ORD
Tanya Roberts, USDA/ERS
Steve Schaub, EPA/ORD
*Cindy Sonich-Mullin, EPA/ORD
Brandolyn Thran, DOD/CHPPM

Richard Whiting, FDA/CFSAN
Hong Yang, FDA/CBER
*Linda Youngman, FDA/CVM