Interagency Risk Assessment Consortium
Technical Quarterly Winter Meeting
December 19, 2007

Technical Meeting 9:00 am – 10:30 am

Introductions

First time participants were introduced: Katie Egan, DHHS/FDA/CFSAN; Wendy Fanaselle, DHHS/FDA/CFSAN; Gun Young Lee, visiting scientist at CFSAN from the FDA, Korea; Rosemary Hall, EPA/OPPTS/OSCP; Elizabeth Resek, EPA/OPPTS/OSCP

5 Minute Updates

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration/Center for Food Safety and Applied Nutrition (DHHS/FDA/CFSAN)
Richard Whiting

- *Listeria monocytogenes* (LM) risk assessments are continuing:
  - LM in smoked finfish: the analytical work has been completed and the document is being reviewed and revised.
  - LM in soft ripened cheeses in collaboration with Health Canada: data collection and modeling are under way. The Federal Register notice was published in December announcing the intent to conduct the risk assessment and requesting data from anyone who wishes to submit data. There are data gaps in processing and storage temperatures and lengths which will probably be addressed by convening an expert panel. The new RTI data that links home storage times and temperatures is being analyzed to determine the best method for being modeled.

Marianne Miliotis

- The Risk Assessment Coordination team has several new members:
  - Villie Flari, an ORISE student from CNSL, UK, will be with us for two years. She will primarily be working on the Highly Pathogenic Avian Influenza Risk Assessment.
  - Gun Young Lee, a visiting scientist from the FDA, Korea, will be with us for six months.
  - Sara Henry, a detailee who will be with us for three months.
  - David Oryang, from USDA/APHIS, will be joining us on a detail within the next few months

- FDA/IFT Risk Ranking Prototype Framework: DHHS/FDA/CFSAN awarded the contract to Decisionalysis to upgrade the prototype and make it available on the

web.

- Marianne Miliotis is currently in a team that is developing a white paper on the proceedings of the JIFSAN Workshop on Food Safety Prioritization, June 2007, which was co-sponsored by IRAC.

- CCFH: new work on *Vibrio* spp. The request for new work on Risk Management for *Vibrio* spp. was accepted by the "*ad hoc*" CCFH working group at the 39th Session of CCFH, October 29-November 4, 2007. Japan has the lead. The workgroup will meet in Kyoto, Japan, June 3-6, 2008.

- Marianne Miliotis was nominated and accepted on the US-Japan Development of Natural Resources (UJNR) panel for microbial toxins and participated in the annual meeting in Tokyo, Japan, November 5-10, 2007.

- Society for Risk Analysis Annual Meeting
    - Marianne Miliotis chaired a symposium on "Developing Risk Profiles: Different Approaches, Formats, and Uses" at the SRA annual meeting Dec 9-13, 2007. Robert Buchanan, DHHS/FDA/CFSAN, Kerry Dearfield, USDA/FSIS and Wendy Fanaselle, DHHS/FDA/CFSAN as well as Robert Lake, ESR, NZ gave excellent presentations at this symposium.
    - Sherri Dennis gave an excellent presentation on: "FDA/CFSAN's Perspective: The Use of Quantitative Risk Assessment in Decision-Making" and had a poster presentation on the US Food protection Plan.
    - Steve Gendel and Sherri Dennis co-authored a presentation on "Information Resources for Food Safety Risk Assessment".

- Foodrisk.org has undergone another upgrade and redesign. The site was moved to new servers at the University of Maryland, College Park, enabling a number of improvements. The most important of these include: a new search function that is faster, a more "user-friendly" interface, and allows more flexibility in viewing search results.

Sharon Edelson-Mammel

- Sharon is working on the references database for the "Pathogens in Cheese" risk profile and is one of the people working on the risk of soft and soft ripened cheese section

Gun Young Lee

- Gun Young Lee is a visiting scientist from FDA, Korea. She will develop understanding of current CFSAN risk projects and develop scope of research work to be completed during the 6-month visiting scientist program.

ENVIRONMENTAL PROTECTION AGENCY

Office of Water/Office of Science and Technology (EPA/OW/OST)

Stephen Schaub

- The American Academy of Microbiology published the Proceedings of a colloquium, October 2006, on Clean Water: what is acceptable microbial risk? The report examines the risks related to pathogens in the water supply and provides recommendations for areas of research, communication needs, and methods of microbial risk assessment. Available at: http://www.asm.org/colloquia.
- EPA Thesaurus of microbial risk assessment terms has been released on the EPA website. There is no cross linkage of hot-linked terms to look at related terms. It is currently in PDF format, and will be put in html. Once this is done, there will be a link to the website from the FoodRisk.org website.
- The Microbial Risk Assessment for water-based media is being revised.
- Microbial Risk Assessments specific for use in recreational water is under development.
- EPA has provided funding to the World Health Organization (WHO) to start an effort to develop harmonization of microbial risk assessment approaches; they are working with Jamie Barton (WHO) to get critical people together.

Office of Prevention, Pesticides and Toxic Substances/Office of Pesticide Programs (EPA/OPPTS/OPP)

Deborah Smegal

- EPA is seeking comments on a Starlink white paper. EPA recommends withdrawal of FDA guidance to test for StarLink protein Cry9C in corn grain. After 7 years StarLink virtually removed from food supply and EPA concludes that additional testing has no added protection for human health. See http://www.epa.gov/pesticides/biopesticides/pips/starlink_corn.htm

- EPA's Office of Pesticides Program (OPP) held a conference call with India regarding export requirements for milk and milk products. FDA (CFSAN and CVM) and USDA (AMS, APHIS and FAS) also participated. India requested certification for pesticides, especially that organochlorines did not exceed the Organization for Economic Co-operation and Development (OECD) maximum residue levels (MRLs). The US will propose language that could be used to certify safety in the required sanitary certificate. A number of other issues remain that would require similar certification such as the absence of bacteria, toxins, hormones and drugs in milk.

- The U.S. Biotechnology Database lists US approved biotechnology plant products. A workgroup met recently, which includes representatives from USDA, FDA, US geological Survey (USGS), and EPA to discuss data entry and draft SOPs for the database. The list is available at: http://usbiotechreg.nbii.gov.

- EPA's Office of Pesticides Program (OPP) staff recently conducted Risk Assessment and Tolerance Setting Training for the Mexico equivalent of EPA OPP.

Office of Prevention, Pesticides and Toxic Substances/Office of Science Coordination and Policy (EPA/OPPTS/OSCP)
Elizabeth Resek

- Endocrine disruptive chemicals program: the Office of Science Coordination and Policy has prepared a Policies and Procedure document for ~72 chemicals to be tested. It is currently up for public comment. It will then go to the EPA Safety Advisory Panel (SAP) in March 2008 for review.

UNITED STATES DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service (USDA/APHIS)
David Oryang

- Genetic Engineering: APHIS oversees the development and introduction (importation, interstate movement and environmental release) of GE organisms. APHIS regulates GE products in cooperation with FDA and EPA. Products are regulated according to their intended use, with some products regulated under more than one agency. APHIS has been safely regulating GE organisms since 1986 and has overseen the deregulation of more than 70 GE crop lines. (For more, go to: http://www.aphis.usda.gov/biotechnology/index.shtml)
  - APHIS seeks public comment on a petition to deregulate corn line MON 89034, which is genetically engineered (GE) for insect resistance. Notice of this action was published in the Dec. 13, 2007 Federal Register. Consideration will be given to comments received on or before Feb. 11, 2008. (For details go to: http://www.aphis.usda.gov/newsroom/content/2007/12/gedcorn_brs.shtml)
  - The corn line MON 89034 is engineered for resistance to European corn borer and other related pests, which can cause yield reductions through damage to corn plants. MON 89034 also is subject to regulation by the EPA and the FDA. Monsanto has submitted documents to FDA in accordance with its regulations. Under EPA regulations, MON 89034 falls under a temporary exemption based on comprehensive assessments of the genetic material involved.
  - APHIS has prepared a draft environmental assessment (EA) to determine whether deregulating the corn could have a significant impact on the environment. After a thorough review of the scientific evidence, APHIS' current preferred action is to deregulate the corn based on the fact that it does not present a plant-pest risk.
  - If APHIS grants the petition for deregulation, the corn and its progeny would no longer be regulated articles. The product then could be freely moved and

planted without the requirement of permits or other regulatory oversight by APHIS. APHIS is seeking comments on the petition and invites comments on the environmental assessment. Consideration will be given to comments received on or before Feb. 11, 2008.

- In November, 2007, APHIS concluded an investigation into alleged compliance infractions by The Scotts Company, LLC. The investigation related to regulated genetically engineered glyphosate-tolerant creeping bentgrass. Under a settlement agreement, Scotts has agreed to pay a civil penalty of $500,000 which is the maximum penalty allowed by the Plant Protection Act of 2000. This is a severe civil penalty and underscores USDA's strong commitment to compliance with its regulations. (For details go to: http://www.usda.gov/wps/portal/usdahome?contentidonly=true&contentid=2007/11/0350.xml)
- In October, 2007 -- USDA concluded the "Genetically Engineered Rice" Investigation. The investigation, which was conducted by the APHIS Investigative and Enforcement Services in coordination with USDA's Office of the Inspector General, focused on the unintentional release of trace amounts of regulated genetically engineered rice detected in two commercial varieties of long-grain rice. Based upon the findings of the investigation, APHIS will not be pursuing enforcement against the developers of the regulated rice.. (For details go to: http://www.usda.gov/wps/portal/usdahome?contentidonly=true&contentid=2007/10/0284.xml)
- In November, 2007, APHIS amended its citrus canker regulations to eliminate the pre-harvest grove inspection for all Florida citrus moving interstate. Instead, the amended regulations will require samples of each lot of citrus at the packinghouse be inspected to ensure the fruit is disease-free. This rule was published in the Nov. 19 Federal Register. (for more details go to: http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB/.cmd/ad/.ar/sa.retrievecontent/.c/6_2_1UH/.ce/7_2_5JM/.p/5_2_4TQ/.d/1/_th/J_2_9D/_s.7_0_A/7_0_1OB?PC_7_2_5JM_contentid=2007%2F11%2F0340.xml&PC_7_2_5JM_parentnav=LATEST_RELEASES&PC_7_2_5JM_navid=NEWS_RELEASE#7_2_5JM)

- On November 30th, 2007, the USDA announced a partnership with the National Cattlemen's Foundation in cooperation with the National Cattlemen's Beef Association (NCBA). The partnership will facilitate the registration of additional cattle premises as part of the National Animal Identification System (NAIS). (for more info go to: http://animalid.aphis.usda.gov/nais/index.shtml) NAIS is a voluntary program and consists of three components: premises registration, animal identification and tracing. The premises registration component of NAIS ensures the availability of a nationwide communications network to assist livestock owners and animal health officials in the event of an animal disease event. A total of 426,671 premises nationwide have been registered to date. The goal of NAIS is to protect the health of U.S. livestock and poultry and the economic well-being of those industries. When NAIS is fully

established, it will enable APHIS to quickly and effectively trace an infectious animal disease to its source. By choosing to participate in NAIS, livestock owners will join a national disease response network built to protect their animals, their neighbors, and their economic livelihood against the devastation of a foreign animal disease outbreak.

Robert McDowell

- The USDA has Harmonized Cattle Trade with Canada, in Line with International Animal Health Standards. In September, 2007, APHIS expanded the list of allowable imports from countries recognized as presenting a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States. Currently, Canada is the only minimal-risk country designated by the United States. (For more info: http://www.aphis.usda.gov/newsroom/hot_issues/bse/index.shtml)

- APHIS is developing a global BSE risk assessment based on international standards.

- APHIS is close to completing risk characterization on transgenic microorganisms.

- APHIS is collaborating with Procter and Gamble in Europe and the European Union to conduct a battery of tests for carcinogenicity, *in vivo*, *in vitro*, and *in situ*. The European Commission cannot perform laboratory studies *in vivo*, therefore there is a push to develop prediction models. They are developing methodology to evaluate a variety of tests and to determine uncertainty. Procter and Gamble is providing two toxicologists and a mathematician. APHIS is providing veterinary and human paradigms of diagnostic evaluation.

- Training: During 2008, APHIS will conduct workshops on:
  - Monte Carlo simulation
  - Latent class variables: diagnostic ability to find and classify rare items
  - Introduction to Bayesian Statistical Analysis
  - Zoonoses transmitted via seafood.

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

- ARS and its ComBase partners have proposed to form a Predictive Modeling group in the Professional Development Group in the International Association for Food Protection (IAFP). The proposal was discussed by the IAFP Executive in November 2007 but the vote was delayed until August 2008 at the IAFP meeting. Part of the issue is that meetings on Predictive Microbiology have historically been held in Europe; a recent one, the International Conference on Predictive Modeling in Foods (ICPMF) was held in Athens, Greece in September

2007. However, the ICPMF will be held in the US in 2 years. The final site is still under discussion.

Economic Research Service (USDA/ERS)
Tanya Roberts

- Tanya is organizing a session at the International Association for Food Protection annual meeting in 2008 on data needs for risk assessment
- The CCFH Risk Characterization document is undergoing final review.

Food Safety and Inspection Service/Office of Public Health Science (USDA/FSIS/OPHS)
Kerry Dearfield

- Interagency Microbiological Risk Assessment Guideline Work Group
  The workgroup presented a successful symposium at the SRA annual meeting in December. Feedback from attendees at the symposium was excellent and will be incorporated into the draft guideline. A first draft of the document is close to review, and will first go to the various workgroup members' offices (e.g., EPA, USDA, DOD) to check on internal requirements, and then to the Interagency Risk Assessment Consortium for its first external commenting. The document will then go the EPA Science Advisory Board (SAB) for a formal external consultation.

Janell Kause

- The Food Safety and Inspection Service (FSIS) is developing a probabilistic risk assessment evaluating various performance standards for *Salmonella, Campylobacter*, and generic *E. coli* (based on the relationship with *Salmonella* and *Campylobacter*) to guide policies related to poultry slaughter performance standards. This risk assessment along with another developed to evaluate the effectiveness of inspection activities within poultry slaughter establishments will be presented at a public meeting in February 2008. These risk assessments are currently under review by the National Advisory for Meat and Poultry Inspection committee.
- FSIS is also finalizing the Interagency Highly Pathogenic Avian Influenza risk assessment developed in collaboration with the Food and Drug Administration and Animal and Plant Health Inspection Service with emphasis on developing an alternative dose-response relationship with the Centers for Disease Control and Prevention.

Office of Risk and Cost Benefit Analysis (USDA/ORACBA)
Michael McElvaine

- ORACBA staff made several presentations at SRA in San Antonio.
- ORACBA will be hosting a Risk Forum, TBA, in late January or February.

Work Group Updates

Nutrition Risk Assessment

The summary of the Nutritional Risk Assessment workshop, which took place February, 2007 arrived just after Thanksgiving. The Summary is available from National Academy Press: http://www.nap.edu and www.iom.edu/fnb. The work group will review and consider next steps when we meet early next year.

Data Utility

The Data Utility paper based on the workshop and SRA symposium was submitted to Risk Analysis October, 2007. We have not heard anything back yet. Brandolyn and Tonya Nichols met at the SRA annual meeting, and discussed the possibility of submitting a symposium on Data Collection for SRA 2008.

Produce Safety

Wendy Fanaselle, FDA/CFSAN/RACT has taken the lead for this project. The draft risk models are now being completed for review by the Produce Workgroup at the next workgroup meeting. Babgaleh Timbo, an epidemiologist at FDA/CFSAN, is reviewing produce outbreaks to identify commonalities and differences. Proposed meeting dates will be given out at the next IRAC meeting, for the next workgroup meeting sometime in January.

Conference

"Risk Assessment, Economic Analysis, and Foodborne Illness Regulations," November 16, 2007, was well attended and generated a lot of discussion. All the speakers showed up, including the busy Federal policymakers in the final roundtable. The slides for the presentations are posted both on the AAEA FSN section website and on the IRAC website (www.fsn-aaea.org and www.foodrisk.org).

Presentation 11:00 am – 12:30 pm

11:00 – 11:30 am: "Health Canada: Potential Opportunities for Collaboration" by Dr. Wendy Sexsmith, Acting Chief Scientist, Health Canada.

11:30 am – 12:30 pm: Discussion

In attendance (* participated by phone)
Kerry Dearfield, USDA/FSIS
Katie Egan, DHHS/FDA/CFSAN
*Sharon Edelson-Mammel, DHHS/FDA/CFSAN
Wendy Fanaselle, DHHS/FDA/CFSAN
Rosemary Hall, EPA/OPPTS/OSCP
*Sara Henry, DHHS/FDA/CFSAN
*Andy Hwang, USDA/ARS/ERRC
*Janell Kause, USDA/FSIS
GunYoung Lee, visiting scientist, FDA. Korea
Robert McDowell, USDA/APHIS
*Michael McElvaine, USDA/ORACBA
Marianne Miliotis, DHHS/FDA/CFSAN
*David Oryang, USDA/APHIS
Elizabeth Resek, EPA/OPPTS/OSCP
*Tanya Roberts, USDA/ERS
*Stephen Schaub, EPA/OW
Deborah Smegal, EPA/OPP
Richard Whiting, FDA/CFSAN

Plus others from DHHS/FDA/CFSAN attended the presentation part of the meeting.