

Interagency Risk Assessment Consortium Technical Quarterly Summer Meeting June 25, 2008

Introductions

New participants introduced themselves: Lori Papadakis, FDA/CFSAN; Regis Pouillot, a visiting scientist with the Risk Assessment Coordination team, FDA/CFSAN from the French Food Safety Agency; Andrea Lemay and Leslie Newton, USDA/APHIS, Raleigh, NC.

5 minute Updates

Centers for Disease Control (CDC)

Andrew Maccabe

- *Burden of Foodborne Illness*. The update on Paul Meade's 1999 paper is near completion.
- *Attribution to Food Commodities*. OUTBREAKNET, an electronic outbreak reporting system consists of more than 3,000 state and local health departments in all 50 states. The objective is to capture all outbreak data; 12 to 15000 foodborne outbreaks have been reported per year since 1973. The initial paper recording system has changed into the electronic foodborne outbreak recording system, E-FORS, which will also include waterborne and other systems in 2009. E-FORS can divide outbreaks by commodity (17 categories) and agent. Over 54% of foodborne illness are viral, with almost all being calicivirus, mainly norovirus. Bacteria account for ~23% with *Salmonella* being the highest (~9%) of all foodborne outbreaks. With E-FORS, CDC will be able to publish foodborne outbreaks on an annual basis about 6 months after the close of the year. For 2007, the data will be reported in October 2008, as this is the first time.

Environmental Protection Agency

Office of Pesticide Programs (EPA/OPP)

Deborah Smegal

- ☐ *Training Program*. OPP has been conducting risk assessment training on website, available to people from other agencies and other countries. Covered topics such as how EPA performs risk assessment for pesticides. Topics include: general risk assessment, toxicity assessment, anticipated pesticide residues and dietary assessment, environmental justice, and occupational/residential assessment. One can also view past sessions, not just the new (live) sessions on the Environmental Science Connector web site. The contact person to gain access to the location is: Hamaad Syed: Seyed.hamaad@epa.gov
- ☐ OPP has completed risk assessments for several pesticides. Examples of recently released risk assessments for public comment include those on formaldehyde, and pentachlorophenol. EPA also completed the Reregistration Eligibility Decision (RED) for ethylene oxide, and concluded that the benefits outweigh the occupational risks to workers.
- ☐ EPA is developing a new toxicological reference database called TOXREF to capture relevant toxicity data to help predict the toxicity for new chemicals. This is part of EPA's TOXCAST research program.
- ☐ At a meeting in Germany, EPA presented its perspective on nanosilver as a pesticide. It is not yet registered as a pesticide, although silver is a registered pesticide. Nanosilver has been reported to be used as an antimicrobial in many consumer products on the market. Both EPA and FDA regulate certain products containing it.

Office of Research and Development (EPA/ORD)

Mike Broder

Interagency Microbial Risk Assessment Guideline. The Microbial Risk Assessment Guideline started as an EPA Risk Assessment Forum project that evolved into an interagency activity.

Cindy Roberts

- EPA is developing new recreational water indicator criteria for swimmers. This was a statutory requirement to be completed by 2005.
- EPA conducted four epidemiology studies on fresh water beaches where Publicly Owned Treatment Works (POTW) were the predominant source of contamination. A paper was recently published in *Epidemiology* (Wade *et al.*, 2008, see below for citation) presenting the fresh water study results and concluded that measurement of *Enterococcus* in water using a rapid qPCR method predicted swimming-associated gastrointestinal illness at the aforementioned beaches. Children at 10 years or younger were at greater risk for gastrointestinal illness following exposure.
- EPA also conducted three studies at marine beaches with POTW sources. One of these studies however only provides partial data because hurricane Katrina wiped out the study site in Biloxi, MS.
- In 2009, EPA expects to initiate an epidemiology study at a beach influenced by urban run-off and also to develop a quantitative risk assessment in areas impacted by agricultural animals.
- Other research will continue to until 2010. Additional information on this research can be found on the EPA website at:
<http://www.epa.gov/waterscience/criteria/recreation/plan/cpsplan.pdf>.
New criteria are expected in 2012.

Wade TJ, Calderon RL, Brenner KP, Sams E, Beach M, Haugland R, Wymer L, Dufour AP. High sensitivity of children to swimming-associated gastrointestinal illness: results using a rapid assay of recreational water quality. *Epidemiology* 2008; 19(3):375-83.

Tonya Nichols

- The Joint U.S. Environmental Protection Agency and Department of Homeland Security Conference on Real-World Applications and Solutions for Microbial Risk Assessment held April 8-10, 2008 was a big success. There were over a 100 attendees. The talks were mission-directed for every agency, and focused mainly on hazard identification and exposure. A follow-up meeting is being planned for May/June, 2009 focusing more on dose-response. For additional information on the 2008 meeting, go to:
http://es.epa.gov/ncer/events/news/2008/04_08_08_calendar.html

Food and Drug Administration

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

Richard Whiting

- The risk profile on pathogens in soft cheeses is continuing as is the risk assessment on *L. monocytogenes* in soft ripened cheeses in collaboration with Health Canada.
- The risk profile on *L. monocytogenes* in fresh and fresh-cut produce is being revised after review by the former Senior Science Advisor, Robert Buchanan

Marianne Miliotis

- *IRAC Awards.* At the CFSAN Awards ceremony in June, the IRAC received an FDA award for interagency leveraging and collaboration.
- *Office moves at CFSAN.* Due to the reorganization of CFSAN offices in 2008, employees moved offices so that the organizational Offices were grouped together.
- *Risk Profiles.*
 - The risk profile on hepatitis A virus in fresh and fresh-cut produce was sent for external review to experts outside the government as well as to IRAC representatives for review by government experts.
 - The risk profile on transmission of norovirus from food workers to Ready-To-Eat foods is being revised
- *CCFH Code of Hygienic Practices for Vibrio spp. in seafood.* Marianne and Andy DePaola represented the U.S. and participated in the CCFH workgroup to develop a Code of hygienic practice for *Vibrio spp.* in seafood June 3-6, 2008 in Kyoto, Japan.

Sharon Edelson Mammel

- The team working on the “Pathogens in Soft Cheeses” risk profile went on a site visit to Tropical Cheese Industries, Perth Amboy, NJ, at the beginning of May to better understand how cheese is manufactured and see first-hand industry control measures. Tropical Cheese Industries focuses on Hispanic cheeses, but manufactures other milk-based products such as yoghurt and yoghurt-based drinks.

Lori Papadakis

- A GIS symposium on food is being planned for September, 2008.

Regis Pouillot

- Regis is a veterinarian by training, and is currently working as a modeler on an interagency project with USDA/FSIS on cross-contamination at retail. The aim is to obtain data and have good collaboration with industry and other information providers.

Center for Veterinary Medicine (FDA/CVM)

Barry Hooberman

- *Risk Ranking Initiative.* Barry is a member of an FDA inter center risk ranking work group at the FDA Commissioner’s level. Risk across all FDA products is compared. There is a contract with the National Academies/ National Research Council to put together an expert panel.
- *Risk-based Steering Committee.* Barry is also a member of this group. It coordinates risk-based activities across the FDA food Centers: CFSAN, CVM, and ORA (Office of Regulator Affairs).
- *Antimicrobial Resistance due to Treatment of Animals with Antimicrobials*
 - Congress is showing renewed interest in banning antimicrobials used for growth promotion in animals due to concerns about antimicrobial resistance leading to loss of treatment options for human pathogenic disease. EU has banned such use of antimicrobials.

- The Codex Task Force on Antimicrobial Resistance had their first meeting last October, hosted by South Korea. Three working group meetings were held in Brussels in May to develop guidance documents on Preliminary Risk Management Activities, Risk Assessment, and Risk Management that describe a risk-based approach to addressing antimicrobial resistance due to the use of antimicrobials in animals, plants, and food processing. The next meeting of the Task Force will be in October, 2008 (again in Seoul, South Korea).
- FAO/WHO had a workshop in Rome in November, 2007 that developed a framework for addressing antimicrobial resistance issues and prioritizing risk management actions.

United States Department of Agriculture

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

David Oryang

- *Streamlining the regulatory process: Importation of animals and plants.* The current risk assessment and regulatory process is inefficient. For example, if a country that has had foot and mouth disease in the recent past wants to export beef to the United States, a risk assessment and rulemaking could take up to 3 yrs before allowing the import. Each and every country needs to go through the same process. APHIS is looking at ways to streamline the regulatory process. Instead of making country by country evaluations and rules, the new broad rules will be based on broad risk assessments that present the mitigations required to allow imports from countries of different animal/plant health status and infrastructure. In this way, one broad rule could allow multiple countries to export beef to the USA, under conditions/mitigations that are dependent upon each countries SPS status and infrastructure.
- *Expert Elicitation:* APHIS is developing agency-wide standards and a process for expert elicitation. This will structure the process of bridging data/information/understanding/modeling gaps, and create formal scientific documents that can be referenced and cited in multiple risk assessments.
- *SRA Annual Meeting: (December 7-10, 2008).* David Oryang will be presenting on "Use of multi criteria decision analyses to prioritize risks and allocate resources" as part of the symposium on "Innovative Risk-Based Approaches in Federal Regulatory Agencies".
- *ESRI User Conference:* The 2008 ESRI user conference will take place on August 4–8, 2008, in the San Diego Convention Center, in San Diego, California. It is the largest gathering of GIS users in the world. For more information visit: <http://www.esri.com/events/uc/index.html>
- *Visitors:* Andrea Lemay and Leslie Newton, USDA/APHIS. Andrea is a plant pathologist and risk analyst. She is looking at the risks posed by different pathways (planes, trains, ships) via which infected imported plants come into the United States. APHIS is looking for microbes that are pathogenic to plants, not humans.

Eric Grant

- Eric just got back from Ghana where bushmeat is sold roadside, animal is sometimes poisoned. People buy and eat smoked meat (ruminant) that has been poisoned. The question arose whether FDA or USDA has been monitoring these activities from some of African Gourmet stores. Eric asked several questions on feeding, reproduction, and proper hygiene in the farm including the causes, symptoms, preventive control and treatment of all known ailments associated with grasscutter farming. Presently demand far outstrips supply as evident by the price of a family of grasscutter beef of 1 male and 4 females (\$10 –\$15) or even just by the amount road side sellers sell a unit of roasted grasscutter.

Food and Nutrition Service (USDA/FNS)

Stephanie Mickelson

- FNS has been involved with norovirus, particularly in school lunch programs. A paper will be published in the fall.

Food Safety Inspection Service (USDA/FSIS)

Kerry Dearfield

Assessment Policy Council Co-chair. Robert Buchanan has retired from the federal government to work at the University of Maryland. To replace him, Sherri Dennis has been appointed the FDA co-chair with Kerry, the USDA co-chair.

- *CCFH for Listeria monocytogenes.* Kerry and Richard Whiting were part of the delegation that represented the United States on the work group that is developing microbiological criteria for Lm. CCFH will be incorporating an approach based on the risk management metrics recently passed by the Codex (such as performance objectives, food safety objectives) and develop an annex describing environmental monitoring and process control testing for *L. monocytogenes* in ready-to-eat products.
- *Future Challenges in Food Safety.* An international meeting was held in the Netherlands June 9-12, 2008 to discuss and explore future challenges in food safety. Many topics were discussed including:
 - o A major emphasis on viruses, particularly norovirus and rotaviruses.
 - o Future and current challenges for coordinating and using databases for data collection and for risk assessment purposes were discussed.
 - o There was also a move to look at dose-response, seeing as dose response is not well developed with respect to microbial aspects.
 - o Climate change has a big impact on how we look at food availability, food safety, and food security. The group discussed its effect on potable water, shifting of crops, insect vectors, emerging pathogens, etc.

Janell Kause

- *Cross-contamination of L. monocytogenes at Retail.* Janell, together with Sherri Dennis and Regis Pouillot from FDA/CFSAN, and Dan Gallagher from Virginia Technical College, are working on a new risk assessment project looking at transmission and cross contamination of *L. monocytogenes* at retail for inclusion in a retail risk (funding is available to obtain data). The risk assessment will look at current literature on transmission and cross contamination models for food safety risk assessments (very few exist because there are not enough data).
- The FSIS Risk Assessment Division has recently been expanded to include residues risk assessments (in addition to conducting microbiological risk assessments) and has changed its name to the "FSIS Risk Assessment and Residue Division". FSIS/OPHS/RARD will collaborate with EPA and FDA who have conducted some risk assessments on residues.
- Janell also noted that the IRAC should serve as a venue to conduct interagency risk assessments, or components of such risk assessments of interest among agencies.

Work Group Updates

Nutrition Risk Assessment

Nothing to report.

Data Utility

A symposium titled "Practicing the Science and the Art: Real World Case Studies in Sample Collection for Chemical and Microbial Risk Assessment" was accepted as a poster platform symposium for the SRA annual meeting December 7-10, 2008.

Produce Safety

A two-day workshop was held July 8-9, 2008 on "Research Needs Prioritization for Conducting a Quantitative Risk Assessment of *E. coli* O157:H7 in Leafy Greens" using the "Analytical Hierarchy Program" (AHP). The workshop was attended by experts from industry, trade associations, academia, and federal and state governments. A summary report of the outcome and recommendations for the future on the use of decision analysis tools to identify data gaps will be prepared and distributed to the workshop participants.

In attendance (* participated by phone):

*Mike Broder, EPA/ORD
Kerry Dearfield, USDA/FSIS
Sharon Edelson Mammel, DHHS/FDA/CFSAN
Eric Grant, USDA/APHIS
*Barry Hooberman, DHHS/FDA/CVM
Janell Kause, USDA/FSIS
Andrea Lemay, USDA/APHIS
Andrew Maccabe, CDC
Marianne Miliotis, DHHS/FDA/CFSAN
*Tonya Nichols, EPA/ORD
Leslie Newton, USDA/APHIS
*Stephanie Mickelson, USDA/FNS
David Oryang, USDA/APHIS
Lori Papadakis, DHHS/FDA/CFSAN
Regis Pouillot, DHHS/FDA/CFSAN
Babgaleh Timbo, FDA/CFSAN
Richard Whiting, DHHS/FDA/CFSAN