

Interagency Risk Assessment Consortium
Fall Technical Quarterly and Policy Biannual Meeting
September 30, 2009

Technical Meeting: 9:00 – 10:30 am

Introductions

Brief overview of the responsibilities of the IRAC technical representatives.

5 minute Agency Updates

Department of Health and Human Services

Food and Drug Administration (FDA)

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

- FDA has created an Office of Foods with Deputy Commissioner reporting directly to the Commissioner. The agency is currently in the process of filling that position. The purpose of this office is to provide coordinated leadership for food safety activities in CFSAN, CVM, and ORA.
- The Commissioner has appointed Mike Taylor as a special advisor for foods. Mike has previously been with FDA and FSIS, and most recently was at Georgetown Univ. He has been receiving a substantial number of briefings on internal agency programs and offices, and has been meeting with external stakeholders in government (OMB, Congress, etc.) and industry.
- CFSAN has put several contracts in place for risk assessment activities for the coming year including:
 - Risk Sciences International for continued development of iRisk
 - RTI for Risk Prioritization Work
 - NASA (through an IAG) for incorporation of GIS data in food safety risk assessment
- The public meeting for the Interagency (FDA/FSIS) Listeria retail risk assessment was held on June 23 to provide clarification on the approach and data needs. There was a great deal of discussion and good input; no issues have surfaced that would suggest that the approach being used needs to be changed. (See FSIS update for additional comments about this risk assessment).
- CFSAN had an opportunity to act as a reviewer for a risk assessment conducted by Exponent on Salmonella in raw almonds, which was carried out to support the use of a 4 log reduction as pasteurization under the Almond Board labeling program. CFSAN thought that the risk assessment was well done and suggested some alternate scenarios to test in the model.
- CFSAN Econ team is doing a lot of work on combining cost-benefit analysis and risk assessment RA. This includes work on valuation of illness and about uncertainty and policy decisions from the econ perspective.
- The CFSAN Dietary Supplement program is doing a lot of safety assessment work related to pre-market notifications. They are also using “safety signals” generated by adverse event reports and toxicology research to identify potential problems.
- FDA will host a public meeting on October 28 to discuss the US position on the documents which will be on the agenda for the CCFH meeting November 16-20 in California. These include:
 - A report from JEMRA

- A proposed draft annex on Leafy Green Vegetables for the Code of Hygienic Practice for Fresh Fruits and Vegetables. FDA is reviewing document. Criticism is that it is not substantial enough to become code of practice at this point.
- Cocoa and chocolate processing – proposal to look at Codex document to set microbiological criteria.
- A proposed draft annex on Control Measures for *Vibrio parahaemolyticus* and *V. vulnificus* in Molluscan Shellfish
- A proposed draft Code of Hygienic Practice for Control of Viruses in Food
- A proposed draft Code of Hygienic Practice for Control of *Salmonella* and *Campylobacter* in poultry. Biggest concern is that the European Commission has policy not to use active chlorine during processing. JECFA says there is no toxicity at levels typically used; the European Commission says water is just as effective and wants to use it for leafy greens and seafood.

Environmental Protection Agency (EPA)

Office of Water (EPA/OW)

- The week of September 21, there was a meeting with the advisory board for microbiology in water. Advisory document have been developed for how to do a risk assessment for microbial hazards in water. Guidelines are not fully developed so it is not yet called a guidance protocol.
- Meeting in November in Switzerland to finalize WHO's technical content for international drinking water quality guidelines (using a risk-based approach). Also will meet to discuss international harmonization of microbial risk assessment for environmental media, with goal to develop a set of principles for microbial risk assessment, and also to harmonize WHO's use of risk assessment terms.
- EPA is trying to get the microbial risk assessment Thesaurus to go international.

Department of Defense update – not present today

US Department of Agriculture (USDA)

Agricultural Research Services – No Updates

Food Safety and Inspection Service, Office of Public Health Science, Risk Assessment Division (USDA/FSIS/OPHS/RAD)

- Administrative:
 - New AAAS fellows – Drs. Erica McCoy and Nora Pihkala
- Catfish RA

The purpose of the FSIS Catfish risk assessment is to evaluate the potential public health effects of catfish inspection program to be implemented by FSIS –reviewed by external peer reviewers, interagency including CDC, EPA, FDA, NOAA, OMB, and other program area within USDA such as Office of Risk Assessment and Cost-Benefit Analysis (ORACBA). We will be working on are currently working on responses to their comments and incorporating changes into the updated risk assessment.
- Interagency *Listeria* Retail Risk Assessment
 - This is a risk assessment developed by FSIS and FDA that will evaluate retail cross-contamination of Lm on a variety of ready-to-eat foods and allow us to better understand changes in practices, polices, or interventions to further reduce listeriosis.

- FSIS identified CDC personnel that will be invited to participate in the monthly meetings of Interagency Lm in retail group. Plans are being made to have in the future an ORISE fellow stationed at CDC who would also assist in the development of data for this risk assessment.
 - A laboratory-style study that will mimic the retail environment will be conducted by FSIS in FY2010.
 - Beef Slaughter Establishment Risk Assessment Project
 - Objective: To reduce the risk of *E. coli* O157:H7 illness associated with beef consumption using a four-step risk management strategy.
 1. Declare a risk management objective
 2. Develop several options that would allow the Agency to achieve the objective
 3. Estimate the effect of each suggested policy to help decision makers choose the best option
 4. Measure progress towards the objective once policies/regulations are initiated.
 - Update
 1. The current risk of O157:H7 illness from beef consumption has been characterized. Areas of variation in the risk (i.e. the infrequent but severe events) were characterized and brought before FSIS leadership to help in selection of a risk management objective.
 2. A risk management objective of reducing the seasonal spike in O157 we see each year was selected.
 3. We will have a Seasonal Risk Management Options Brainstorming Session on October 14th to discuss specifically the seasonality of *E. coli* O157:H7 and the risk management question; “How to Reduce the Seasonal Variation in the incidence of *E. coli* O157:H7 in Beef?”
 - Next steps
 1. Analyze options collected at the brainstorming session to rank effectiveness based on achieving the seasonal risk management objective
 2. Present the results to leadership to help inform their decision about new policies
 3. Develop a method for measuring progress towards the objective before new policies are implemented.

FSIS/OPHS, Office of Assistant Administrator

- Last year, Codex passed an FSO. FSIS is considering adopting performance objectives. Risk assessments wouldn't change, but will bring performance objectives into risk management.
 - *C. perfringens* in hot dogs study coming out soon in Journal of Food Protection. Take the risk assessment, model it for public health illness, and go back and say what type of performance objectives will be put in place, then figure out microbiological criteria and sampling plan. This is very intensive modeling even initially.
 - *Listeria monocytogenes* in RTE foods. Mention that CFSAN looked at Lm; FSO looks same as PO. PO is easier than FSO.

- *Salmonella* and *Campylobacter* in poultry is a major one. There are metrics issues: how to compare *Salmonella* vs. *Campylobacter* illnesses (i.e. level of pathogen vs. prevalence rate).
- Positive *E. coli* in beef next. Decision-makers are in full support of this.
- Microbial risk assessment guidelines (interagency WG with EPA): contractor revising document for consistency, plan to have it done by the end of the year. The document borrows from many sources including EPA and military. It is intended to put information into one place, but does not supplant existing agency protocols. This document is one year behind.
- US Codex in associated with USTR and Dept. of Commerce is trying to get the US delegation to participate on a number of committees in an effort to explain the US decisions regarding trade (to reiterate that decisions are risk- and science-based).

Food and Nutrition Service (USDA/FNS)

- FNS will be conducting a workshop on produce safety in schools. There is currently an emphasis on increasing the amount of fresh produce in schools, including through farm-to-school and school garden programs.
 - Need to address food safety risks of fresh produce and develop mitigation strategies
 - Tentatively planned for the end of October
 - Inviting about 30 representatives from industry, universities, school foodservice program operators, and federal agencies
 - The workshop is invitation-only to keep the size small enough to allow for open discussion.

Cooperative State Research, Education, and Extension Service (USDA/CSREES)

- CSREES has been renamed the National Institutes of Food and Agriculture. This transition will occur on October 1, 2009.
- Will be modeled after the National Institutes of Health (NIH) and have 4 institutes.
 - Food Safety and Nutrition
 - Food Production and Sustainability
 - Youth and Community Development
 - Bioenergy Climate and Environment
- Dr. Roger N. Beachy has been selected to lead the organization.
- Top priorities are:
 - Bioenergy,
 - Global climate change,
 - Nutrition and health,
 - Food safety, and
 - International food security.

Animal and Plant Health Inspection Service (USDA/APHIS)

- Richard Fite and Eric Grant have been tasked to provide capacity building for Universities in developing countries (in cooperation with Tuskegee and Texas A&M).
- Will be traveling to Egypt in October to provide capacity building training in the form of a 1 week-long, "SPS Workshop on Understanding Risk", in Cairo Nov. 16th-20th.

- Objectives:
 - To increase understanding of risk concepts and applications for Egypt's SPS issues
 - To enable trainers to assess level of understanding by participants, and Egypt's needs for training in this area
 - To identify influential persons involved in Egypt's risk process and invest in their greater understanding through follow up training
- Fite and Grant were invited by the Ghana's Minister of Agriculture on Monday for their country's briefing on Ghana's Agribusiness development and will be traveling to Ghana for similar training as Egypt.
- Discussion:
 - JIFSAN does train the trainer in risk assessment (microbial and chemical). JIFSAN does on-line training.
 - Michigan State University got money from USAID to do international capacity building in India. Have developed open source materials based on Codex guidelines. Food safety knowledge network. Isabelle Wallace will send out the link/materials.

Presentations/Discussion: 10:45 am – 12:30 pm

IRAC Work Group on Nanotechnology and Risk Assessment by Villie Flari, Risk Analyst, ORISE Fellow, Risk Assessment Coordination Team, OFDCER, CFSAN, FDA

IRAC Work Group Updates and Discussion

- Susceptible Populations Work Group
- The work group has targeted Wednesday-Thursday, January 20-21 (full day Wed and 1/2 day Thurs) for the workshop.
- A basic agenda has been developed and speakers and participants are being selected and invited.
- The format will have an opening session with presentations on general issues related to understanding the meaning of the concept “susceptible population,” and on data resources that can be used to estimate the number of individuals in the various “susceptible” groups. This will be followed by two parallel working sessions, on chemical hazards and pathogens, to address issues and data needs specific to each area. These groups will be asked to discuss and respond to a set of questions and to identify and rank data gaps and research needs. This will be followed by a final general session to report the results from the workgroups to identify common needs and approaches.
- Funds for the meeting have been transferred to CFSAN's meeting organizing contractor. As the details of the meeting are developed, any needs for additional sponsorship by the IRAC FY2010 budget or other agencies will be communicated through Heejeong Latimer.
- The idea is that all this can be put together into a white paper or publication based on workshop discussion.
 - Recognize different terminologies
 - Identify data needs
 - Communicate needs beyond us
- The model is supposed to be heavily active participants (not passive). Need people to be facilitators. Thereby invite only (50-75 people).

- The Food Forum workshop on “Providing Healthy and Safe Foods as We Age” will take place on October 29-30, 2009. The full program and registration info are available at <http://www.iom.edu/CMS/3788/4598/70939.aspx> . This workshop will focus on the active aging population and will look at food safety, nutrition, and risk communication issues.

Policy Council Meeting: 1:30-3:00 pm

Meetings/Workshops/Other Issues

IRAC-Risk Based Inspection Workshop

Planning workshop for risk assessment inspection. Details follow:

- Tentative date for December 2nd, 2009 (following quarterly meeting).
- Focus on federal agencies (particularly IRAC members).
- IRAC technical meeting would be 9-11am, then this meeting would start after that.
- FDA/CFSAN and FDA /CVM have expressed interest in presenting. USDA/FSIS has 2 presenters (David LaBarre (USDA/FSIS/OPHS) and Don Anderson (USDA/FSIS/OPEER)).
- APHIS focuses more on animal safety and plant safety, etc. Therefore focus on methodologies, but not necessarily on the goals that will be the outcome of the methodology (therefore not on hazards).
- Probably a working lunch. Was going to be at APHIS, but maybe will change to venue that will include food.
- Keep just one panel format (no breaking up into groups). Individual agencies will decide whether presenters are on panel or if separate people fill panel.
- No paper or anything to come out of it. More to hash out ideas, but don't need to come to conclusions. Would like names of attendees in advance. Up to 10 or 12 people from each agency. Looking for maximum attendance of 40 to 50.

In attendance (* participated by phone):

Mary Brandt, DHHS/FDA/CFSAN

*Mike Broder, EPA/ORD

Kerry Dearfield, USDA/FSIS

Sherry Dennis, DHHS/FDA/CFSAN

Sharon Edelson-Mammel, DHHS/FDA/CFSAN

*Villie Flari, DHHS/FDA/CFSAN

Steve Gendel, DHHS/FDA/CFSAN

Eric Grant, USDA/APHIS

Heejeong Latimer, USDA/FSIS

Erica McCoy, USDA/FSIS

*Stephanie Mickelson USDA/FNS

Lori Papadakis, DHHS/FDA/CFSAN

*Carlos Penia, DHHS/FDA/CFSAN

Nora Pihkala, USDA/FSIS

*Juliana Ruzante, UMD

*Stephen Schaub, EPA/OW

*Isabel Wall, USDA/CSREES

Wendy Hall, USDA/APHIS

