Interagency Risk Assessment Consortium
Spring Technical Quarterly and Policy Biannual Meeting
April 1, 2009

Technical Meeting 9:00 -10:45 am

Introductions

Brief overview of technical rep responsibilities

5 minute Agency Updates

Department of Defense

Center for Disease Control and Prevention (CDC)

- Updated FoodNet data will be published in the April 9 MMWR

Department of Defense/U.S. Army Center for Health Promotion and Preventive Medicine (DOD/CHPPM)

- Have received Center-approval on the Physiologic Effects of Microbial Effects (PhAME) Work Group Charter. This is a work group interested in dose-response modeling of microbial pathogens, specifically inhalation pathogens at this time. If anyone would like to be involved, or discuss expansion to ingestion or dermal exposure routes, please contact Brandolyn (Brandolyn.thran@us.army.mil) for more information.

- Ongoing efforts include the finalization of Technical Guide 316 (Microbial Risk Assessment for Aerosolized Microorganisms) and the Anthrax Reports. Continue technical work on the development of exposure guidelines for inhalation pathogens and the PhAME report for *B. anthracis* using historical data.

Department of Health and Human Services

Food and Drug Administration

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

New FDA Commissioner nominated: Margaret Hamburg, M.D.
New Deputy Commissioner: Joshua M. Sharfstein, M.D.

- Risk Profiles
  - HAV RP: response to the reviewers was posted on the FDA's website on the Peer Review Report page April 3. It was on the list of Accomplishments during President Obama's first 100 days of office
  - Norovirus RP: document was sent out for external review on Friday, March 27th.
  - Cheese RP: the document on soft cheeses is being revised in response to comments from the dairy branch managers. In the meantime, the team is currently working on semi-soft and hard cheeses.

- Risk/Safety Assessments
  - Joint FDA/FSIS *Listeria monocytogenes* Cross-Contamination at Retail. Currently working on model. A survey on current retail practices is being

prepared but will have to go through the approval process by the different review groups of the agencies.

- *Listeria monocytogenes* in Soft Ripened Cheese- Collaboration with Health Canada. The risk assessment team met with the risk managers on the model. First set of results will hopefully be out in by the second half of the year.

- Other Risk/Safety Assessments Currently under External Review

    - Gluten in foods – the draft has been revised in response to the peer reviews; the final draft will be posted on the FDA website for public comment.
    - Methyl Mercury in Fish- Risk of methyl mercury contamination while getting the nutrition benefits provided from eating the fish. There is the potential to regulate at point source contamination

- Other Issues
    - CCFH Activities: Risk Management document for control of *Vibrio parahaemolyticus* and *V. vulnificus* in molluscan shellfish – annex to the Risk Management document for control of *Vibrio* spp. in seafood was drafted by the US drafting group in February and sent to the Japanese work group members (Japan has the lead). Japan will be sending it to the other work group members to review before the meeting in Kyoto late May to finalize both documents before the next CCFH meeting in December 2009.

    - iRISK: the web-based risk ranking tool developed by Risk Sciences International (RSI) (prototype originally developed by IFT) is currently being tested by the Research Triangle Institute (RTI), who plan to use it for their produce project currently under contract with FDA (see below).
        i. The tools allow you to make changes to see what happens-Model a process, make a change and then compare the process or compare pathogens, etc.
        ii. Hoping to open it to more beta testers but testers will need some training on using the tool. If any IRAC representatives are interested, let Marianne Miliotis know.
        iii. A JIFSAN student intern with FDA/CFSAN is currently populating the database.
        iv. Article on the prototype from which iRISK is based, has been published in JFS. J. Food Safety **74**:R39-R45.

    - FDA Contract with RTI: RTI is planning on comparing 50 produce commodities and 20 hazards to determine the focus of their risk assessment.

Environmental Protection Agency

<u>Office of Research and Development (EPA/ORD)</u>

- EPA has conducted testing of agricultural sites in Alabama where sewage sludge was applied from a local wastewater treatment plant that receives wastewater from industrial sources, including facilities that manufacture and use PFOA and other perfluorinated chemicals. Results from the initial testing indicated elevated levels of perfluorinated compounds in the sewage sludge and the soil that received the sewage sludge. As a result, EPA conducted sampling of public drinking water, private wells and ponds, and soil in the area that ORD assisted with.
- EPA has developed a drinking water Provisional Health Advisories for PFOA and PFOS and is continuing to work with the State of Alabama, local officials, the U.S. Department

of Agriculture, and the Food and Drug Administration (FDA) on health and environmental issues.

National Center for Environmental Assessment (EPA/ORD/NCEA)

- NCEA has no real updates on nanotechnology. They are continuing work on the case studies, and moving towards a workshop, though no dates are set at this time.

National Homeland Security Research Center (EPA/NHSRC)

- Reminder of upcoming EPA/CDC Workshop on the State-of-the-Science for the Determination and Application of Dose-Response Relationships in Microbial Risk Assessments, April 21-23, 2009. For additional information, go to: http://www.scgcorp.com/microbialrisk/registration.asp

United States Department of Agriculture

Food Safety Inspection Service (USDA/FSIS)

- Interagency Microbiological Risk Assessment (MRA) Guideline
    - A writer/editor will soon be editing the document.
    - The wording in the introduction will be modified to make it clearer that this document is a general purpose guideline for federal agencies. FDA/CFSAN volunteered to provide this language modification.
- Risk Management Metrics. FSIS is incorporating the recently adopted Codex risk management metrics into case studies to help develop methods to determine Performance Objectives that would reflect Acceptable Level of Protection (ALOP) values. This would help develop sampling plans. FSIS will be publishing these studies, the first example of this approach being with *Clostridium* in hot dogs.
- Codex Committee on Contaminants in Food.
    - Two Codes of Practice are being recommended for adoption by the Codex Commission. Representatives from FSIS and FDA/CFSAN are participating.
        - Acrylamide in Food
        - Polycyclic aromatic hydrocarbons (PAHs) in Smoked Food
    - New work is being proposed for lead and cadmium in food; there will be a call for data and experts in the near future.
    - Much work is currently being done on various mycotoxins; e.g., aflatoxins, fumonisins, deoxynivalenol (DON).
- Codex Committee on Food Hygiene (CCFH).
    - A Code of Hygiene Practice for *Salmonella* and *Campylobacter* in Poultry is being developed. A technical meeting will be held in May on good hygienic practices in broilers.
    - CCFH has started new work on viruses in Ready-to-Eat food and shellfish.

USDA/FSIS/RAD (Risk Assessment Division)

- Highly Pathogenic Avian Influenza Risk Assessment. FSIS has recently received public comment on the interagency risk assessment for highly pathogenic avian influenza for poultry and eggs. The risk assessment team will prepare a document outlining responses to public comments, including revisions to this draft risk assessment. This risk assessment has been shared with the World Health Organization and is being used to guide emergency planning in the U.S. An updated risk assessment is expected by the end of September 2009.

- Comparative *Listeria monocytogenes* Risk Assessment. FSIS is currently requesting public comment on a draft quantitative food safety risk assessment for *Listeria monocytogenes* that compares the risk of listeriosis from consumption of prepackaged ready-to-eat (RTE) deli meat versus RTE deli meat that is sliced and packaged at retail. The risk assessment analyzes the comparative risk of listeriosis from prepackaged RTE deli meat versus RTE deli meat that is sliced and packaged at retail using data from a study by the National Alliance for Food Safety and Security (NAFSS) and new consumer survey data from Research Triangle Institute (RTI) International, Tennessee State University, and Kansas State University. This draft risk assessment indicated a high proportion of listeriosis cases associated with deli meats were from those sliced at retail. This risk assessment, along with the agency's response to peer review comments, and the risk assessment model were posted on the FSIS website (http://www.fsis.usda.gov/PDF/Comparative_RA_Lm_Exec_Summ.pdf; http://www.fsis.usda.gov/PDF/Comparative_RA_Lm_Report.pdf) on April 3, 2009.

Presentations **11:00 am – 1:00 pm**

EPA Activities Related to Nanoscale Materials by Philip Sayre, Ph.D., Associate Director, Risk Assessment Division, Office of Pollution Prevention & Toxics, EPA/ORD

FoodRisk.org: an Online Resource for Food Safety Risk Analysis by Juliana Ruzante, Risk Analysis Program Manager, University of Maryland/JIFSAN, College Park.

Developing an Understanding of the Transmission Pathway as a Means of Potential Control Options by Wendy Fanaselle, DHHS/FDA/CFSAN

Policy Council Meeting: 1:30 – 3:00 PM

New Work Group Updates

Susceptible Populations Workgroup
A work group has been formed consisting of representatives from FDA, USDA, CDC, and EPA. Members of the workgroup (as representatives of IRAC) are working with the IOM Food Forum to organize a two day workshop on susceptibility in the aging population which will be held this fall (date to be determined). To supplement the Food Forum meeting, the IRAC workgroup is planning a 1.5-2 day workshop focusing on other susceptible populations (such as the very young, pregnant woman, and the immuno-compromised). The workgroup has developed a structure for the workshop in which all the participants will start by looking at cross-cutting issues and data resources, followed by breakout sessions focusing on issues specific to either chemical or biological hazards. At the end of the workshop, the entire group will reconvene to integrate the results from the breakout groups. The overall goal of the workshop will be to review what is known about the make up of the susceptible populations for the different types of hazards, the level of susceptibility in these populations, and the data available to quantify the size of each population. The workshop participants will be asked to identify and prioritize critical data gaps identified during these reviews. The workgroup is in the process of developing a specific agenda and starting to identify potential speakers and participants.

Nanotechnology and Risk Assessment Work Group

- A work group has been formed consisting of representatives from FDA/CFSAN; EPA/OPPTS; EPA/ORD, USDA/FSIS; USDA/ARS

- A first workgroup meeting was held on the 25th of February 2009. During the meeting it was agreed that the objective of the IRAC workgroup on "nanotechnology and risk assessment" would be to: *"Apply a "straw man" approach with the view to identifying the*

challenges that need to be met in order to perform a Risk Assessment for engineered nanomaterials".

- It was decided that such an objective could be met by following a series of steps:
    - Identify types of questions that need to be answered (STEP 1)
    - Explore different methodologies, including ones related to expert opinion elicitation to acquire information on the questions (STEP 2)
    - Build a framework for acquiring answers to questions/unknown factors relevant to risk assessment of engineered nanomaterials (STEP 3)

- For the moment, the IRAC workgroup on "nanotechnology and risk assessment" will focus its efforts on delivering STEP 1. It was suggested the workgroup will build on from the WOODROW Wilson case study framework (see note 1 below for www info). In order to encompass as many as possible of the unknown factors and uncertainties relevant to risks and benefits of engineered nanomaterials to public health we decided to:
    - Work with a number of hypothetical products that might reflect real scenarios.

- In order to produce an outcome that would relate to the objectives of many federal agencies we decided to address products and scenarios for different applications, in particular three exposure routes:
    - Dermal
    - Pulmonary
    - Oral

- Workgroup members, so far, have produced a number of ideas for hypothetical and actual products; these were discussed in the second workgroup meeting held on the 2nd of April 2009.

A prospectus with goals and deliverables is currently being developed based on this update.

Experimental Design to Support Risk Assessment (EDSRA)

The Data Utility Work Group was successful at identifying the characteristics associated with data quality and data utility and landed at a point where the next logical step was to attempt to assist with the collection of data with better utility, hence the disbanding of the Data Utility Work Group and the forming of the new Experimental Design to Support Risk Analysis Work Group.

The EDSRA Work Group will tackle topics to include, but not limited to:

- Attempt to tease out what is "*really*" needed by Risk Assessors to address the risk. managers questions (what is the biggest bang for the buck? what fills the largest data gap?) and illustrate how an effective experimental design or sampling plan can get it.
- Development of Work Plans.
- The importance of having an "Analysis Plan"
- Strengths and Weaknesses of various Sampling Plans
    - Media (e.g., air vs. water vs. food) differences?
    - Research vs. epidemiology (public health protection or outbreak investigations)
    - How to "get around" resource limitations
- Statistical methods to help design "useful" experiments for risk analysis
- Funding sources/options – so now we know what we need, how do we get the data?

Meetings/Workshops/etc.

IRAC is planning at least three workshop/meetings this calendar year, 2009.

1. Joint IRAC – SRA (Biostressor Specialty Group) Workshop on State of the State of RA in the different agencies, institutions.

- Planning Committee made up of representatives from EPA/OPPTS; EPA/OW; FDA/CBER; FDA/CFSAN; FDA/CVM; USDA/APHIS; USDA/ARS; USDA/FAS; USDA/FSIS.
- Steve Anderson has submitted a description of the workshop for the next SRA newsletter.
- Focus of workshop will be on the holes in our current applications; i.e., how do we incorporate new technologies and methodologies in our current activities?

Potential areas include:
i. Use of animal (and other potential) models for dose-response for microbial risk assessment
ii. Application of new tools in risk assessment; e.g., proteomics, genomics, (nanotech?)
iii. Impacts of typical immunotoxicants on life stages of immunity after exposures to different microbes and chemicals
iv. Metrics and Tools for Risk and Benefit Analysis
v. Use of medical and public health databases to determine risks

- A format for the workshop is being developed.
- Duration would be ~1.5 days
- Location to be determined, potentially somewhere central, e.g., Washington or Baltimore
- Meeting would be held towards the 4th quarter of the calendar year, possibly immediately after the 2009 SRA annual meeting.

Two additional workshops are being planned by the IRAC Susceptible Populations Workgroup (see work group update above)

Other Issues

(i) Discussion on potential collaboration with DOD/VSA on risk assessment/risk ranking for food served to the Army
DOD has concerns because there are not enough auditors to quickly inspect all the locations where food is being processed for use by the military overseas. They therefore they need to make the best choices of which establishments to audit. They need to be able to prioritize very quickly. DOD/VSA is looking to collaborate with other IRAC member agencies to help them with this prioritization. DOD will follow up with responsive agencies.

(ii) Discussion on potential collaboration with JIFSAN on nutrition risk assessment
Nutrition Risk Assessment Work Group has been on hiatus since the 2007 workshop jointly co-sponsored by IRAC, DHHS/ASPE, ILSI, and the IOM/Food Forum.

Dr. Kathy Ellwood, Director, Nutrition Programs Staff, Office of Nutrition, Labeling and Dietary Supplements, CFSAN, would like to collaborate with IRAC in developing a risk assessment model with the focus on fortification nutrients. Kathy will develop a prospectus to be sent to the Nutrition Risk Assessment Work Group and other interested members.

In attendance (* participated by phone):

Dare Akingbade, USDA/FSIS/RAD
Shirley Bohm, DHHS/FDA/CFSAN
*Rebecca Brown, EPA/ORD
Elizabeth Calvey, DHHS/FDA/CFSAN
Kerry Dearfield, USDA/FSIS
Sherri Dennis, DHHS/FDA/CFSAN
Sharon Edelson-Mammel, DHHS/FDA/CFSAN
Kathy Ellwood, DHHS/FDA/CFSAN
Wendy Fanaselle, DHHS/FDA/CFSAN

Villie Flari, DHHS/FDA/CFSAN
Steve Gendel, DHHS/FDA/CFSAN
Eric Grant USDA/APHIS
Wendy Hall, USDA/APHIS
Janelle Kause-USDA/FSIS
*David LaBarre, USDA/FSIS
Heejeong Latimer, USDA/FSIS
Joy Lee, USDA/FSIS
Andrew Maccabe
Cristina McLaughlin, DHHS/FDA/CFSAN
*Stephanie Mickelson USDA
Marianne Miliotis, DHHS/FDA/CFSAN
Mike Ollinger, USDA/ERS
David Oryang, DHHS/FDA/CFSAN
Regis Pouillot, DHHS/FDA/CFSAN
*Cindy Roberts, EPA/ORD
Juliana Ruzante, JIFSAN
*Joyce Saltsman, DHHS/FDA/CFSAN
Philip Sayre, EPA/OPPT
Timothy Stevenson, DOD/VSA
*Sara Taft-EPA
Scott Thurmond-DHHS/FDA/CFSAN
Babgaleh Timbo, DHHS/FDA/CFSAN
*Mary Torrence, USDA/ARS
+ several other CFSAN employees attended the presentations.