Interagency Risk Assessment Consortium
Summer Technical Quarterly Meeting
June 18, 2009
USDA/APHIS

Technical Meeting 9:00 -11:15 am

Introductions

Brief overview of technical rep responsibilities

Marianna Miliotis will be going on a 120 day detail and during this time will be unable to continue as the Technical Committee Chair. Heejeong Latimer-USDA/FSIS has volunteered to assume the responsibilities of the technical committee chair during this period.

5 minute Agency Updates

Introductions

Department of Defense

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

- NO Updates

Department of Defense/ U.S Army Veterinary Service Activity

- Reviewed document of President's food safety working group for the president. The document has a lot of information on risk-based inspections both domestic and international. Will increase the number of risk assessment carried out on international imports, will also increase the number of individuals required to do these jobs.

Department of Health and Human Services

Food and Drug Administration

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

New Commissioner, Margaret Hamburg, is on board. Risk-based activities will be playing a major role in agency planning

Staff Updates

- New JIFSAN intern student: Ruth Oni.
- Marianne will be going on a 120 day detail at CFSAN/OARSA as of June 22, 2009.
- **Risk Profiles**
    - HAV RP: Response to reviewers has been posted. Editing is complete, the document should be in final review and should receive clearance soon.
    - Pathogens in Raw Milk Cheese: Scope has been expanded to include soft, semi-soft, and hard cheeses. Document is being revised in response to the review by risk managers.
    - Norovirus: External peer review comments received and being analyzed.
    - Pathogen in Spices: New project – to look at common microbial hazards, current mitigation and control strategies, potential new strategies, and data gaps. The charge has been developed, literature search completed, and the document outline is completed. In the process of planning an industry meeting to help fill in data gaps.

- **Risk/Safety Assessments**

- Drug Residues in Milk (with Center for Veterinary Medicine): New risk assessment. In the process of developing the charge and outlining approach.
- Listeria Cross-Contamination at Retail (w/FSIS): A public meeting will be held on Tuesday, June 23, 2009, from 8:30 a.m. to 5 p.m. at L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW, Washington, DC 20024. The meeting will provide an opportunity for individuals, organizations and other stakeholders to discuss the scope and objectives of the Interagency Retail Lm Risk Assessment and to solicit comments and input on how FSIS and FDA may conduct the risk assessment. (See FR (74 FR 27276)) Pre-registration for this meeting is encouraged http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/. Construction of a model is in process and a survey of retail practices is nearing completion (5/9 supermarket, 0/3 mom & pop store).
- *Listeria monocytogenes* in Soft Ripened Cheese- Collaboration with Health Canada: Working on completing the details of the model.
- Listeria in Smoked Seafood: Final revisions of the document before going to peer review are in progress.

- **Other Issues**
  - IRISK: Beta testing in progress through RTI, currently there are discussions of possible collaborations with CFIA and HC. Steve Gendel will be the project officer. RFP for phase two was published on June 12 in FedBizOpps.
  - Uncertainty Analysis (with JIFSAN and INRA): PI has been notified that the project will be funded through ANR. As soon as the actual funding level is known, an advisory board will be formed to help identify documents for review and to provide expert input on the analysis of uncertainty terms.
  - GIS Modeling and Risk Assessment: Interagency Agreement with NASA in process. The initial focus is on *E. coli* and norovirus in California.
  - Rapid Risk Assessment Framework: To develop a framework for conducting rapid risk assessments during emergency, outbreak, or crisis situations. First draft report is in review.
  - 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) to be sent out to the other members. The work group met in Kyoto late May to finalize both documents before the next CCFH meeting.

Center for Veterinary Medicine (FDA/CVM)

- CODEX task force on antimicrobial Resistance work group. US is the lead for the electronic work group. The project has been ongoing for four years; four documents have been developed, Guidance, Risk Assessment, Risk Profile, Risk Management; these will be merged into one document. Task force will met in Seoul, Korea, in October. 2009 to review the final document.
- Drug residue in milk-collaboration with CFSAN: How big a problem there is with drug residue in milk? Do we need additional resources and time to prioritize.
- Developing a risk-based approach on circulating contaminants in feed such as mycotoxins, bacteria, dioxin, heavy metals.
- Looking to develop risk-based inspections for feed contaminants.
- Melamine problem with Animal Feed

Environmental Protection Agency

Office of Research and Development (EPA/ORD)

- Cumulative Risk Assessment Workshop July 28-30 is coming up. Will send announcement to IRAC.

- CDER held a two-day symposium on Risk Assessment, Mike Broder EPA/ORD made a presentation on the EPA chemical RA.

United States Department of Agriculture

Animal & Plant Health Inspection Service (USDA/APHIS)

- USDA/APHIS is working on the development of a risk-based inspection process for biotech crop plants.
- APHIS Risk Analysis Systems represents APHIS on an interagency invasive species risk assessment working group set up by the National Invasive Species Council and the Aquatic Nuisance Species Taskforce. [Invasive species are broadly defined as "any species … that is not native to that ecosystem; and whose introduction does or is likely to cause economic or environmental harm or harm to human health". Although invasive plants and animals are most often considered for risk assessment, the definition does include human pathogens.]. We can serve as a conduit of information or contact among agencies on the IRAC and those agencies (USGS, etc.) involved with invasive species risk assessment.
- In response to earlier discussion on risk-based inspection, we commented that various groups in APHIS also engage in (or want to) such priority-setting activities. For example, Animal Care uses a risk-based approach for inspection of animal facilities under the Animal Welfare Act. [This discussion led to idea for risk-based inspection workshop described below].
- APHIS-Policy and Program Development in collaboration with APHIS-Plant Protection and Quarantine is conducting a risk based evaluation of the Agency's Asian Longhorn Beetle eradication program. The purpose is to develop options to decrease the likelihood of permanent establishment of Asian Longhorn Beetle in the United States and to increase the likelihood of success of the eradication program.
- APHIS-Policy and Program Development in collaboration with APHIS Veterinary Services conducted listening sessions on the future of the bovine tuberculosis eradication program. The purpose was to solicit public input on the future direction of the eradication program.

Agricultural Research Service (USDA/ARS)

- Nothing to Report

Food Safety Inspection Service (USDA/FSIS)

- Dixon update: Environmental dioxin-levels in US have been dropping over the past several years. During this time, FSIS has been monitoring levels in meat: beef and poultry every five years, and found that the trend in meat products is also decreasing.
- Interagency workgroup on Microbial Risk Assessment guidelines: A draft document is ready for finalization; it is currently being sent to a contractor to edit the entire document and to provide information and references where there is a need.
- Probabilistic RA- Workshop on Techniques for backing into some data.
- Working on several big and little documents Interagency FDA: Update on RA-*E.coli* from surface of steak to inside
- E. coli risk assessment updates – ARS is currently conducting a study on cooking, translocation, and growth of E. coli, which will be completed in Fall, 2009
- Catfish Risk Assessment – to evaluate public health benefit of catfish inspection within FSIS.
- Personnel update: FSIS is planning on hiring a GS-13 toxicologist and two FSIS fellows (The descriptions of the Fellowships will be sent though IRAC should others be aware of potential candidates).
- A case study on *Clostridium perfringins* in hot dogs which will be published in the Journal of Food Protection. The case study is based on the incorporation of the recently adopted

Codex risk management metrics. This will help determine performance objectives that reflect Appropriate Levels of Protection (ALOP)

- Biosludge – Interagency effort working with the EPA and the Alabama Department of Environmental Health on a biosludge issue in Decatur, AL. Perfluorinated compounds are being detected in the soil and water around where sludge was applied. These compounds are bioaccumulative and persistent. People are exposed by drinking contaminated water and possibly meat from feeding animals that come in contact with these compounds (both in water and products from grown in exposed fields).
- CODEX CAC meeting for approval of final measures of products:
    - CCFH: Microbiological Criteria for *Listeria monocytogenes* in RTE food (those that support growth and those that don't support growth of *L. monocytogenes*; including monitoring and testing).
    - CCFH: Code of Hygiene Practice for *Cronobacter sakazakii (formerly Enterobactersakazakii.)*: Criteria developed for infant formula, but not for follow-up formula.
    - CCFH: New proposal for norovirus and hepatitis A virus in shellfish and RTE food.
    - CCCF: Code of Practice for acrylamide in fried food. Code of Practice for PAHs in smoked products. Starting work on heavy metals, e.g., cadmium, lead, mercury. Continuing work on mycotoxins, e.g., fumonisins, aflatoxins, vomitoxin.
- CDC's ATSDR (Agency for Toxic Substances and Disease Registry) is holding a meeting on June 26, 2009 at the Reagan Building on a "National Conversation on Public Health and Chemical Exposure" to learn more about the health effects of chemicals to humans. There is no registration fee, but registration is required

Work Group Updates

Susceptible Populations Workgroup

Members of the Susceptible Populations 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 October 29-30 at the National Academy. The IRAC workgroup is now in the process of identify the best dates to hold the supplementary 1.5 day workshop focusing on other susceptible populations (such as the very young, pregnant woman, and the immune 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 filling in the details of the agenda and indentifying specific speakers and participants.

Workgroup Participants: Steven Gendel (FDA); Andrew Maccabe (CDC); Fred Angulo (CDC); Rebecca Brown (EPA); Kerry Dearfield (USDA); Janell Kause (USDA); Heejeong Latimer (USDA); Morrie Potter (FDA); Stephen Schaub (EPA)
Debbie Smegal (EPA); Marian Olsen (EPA); Sherri Dennis (FDA)
Manashi Dey (FDA); Stephanie Briguglio (FDA); Regis Pouillot (FDA)
Mary Brandt (FDA)

IRAC workgroup on nanotechnology and risk assessment

- The workgroup has started defining a number of hypothetical nanomaterial scenarios that would address all possible exposure routes, i.e. oral, dermal, inhalation, migration from coated containers.
- The workgroup has agreed that eliciting Expert Opinion would be imperative in view of lack of available data.
- For the moment, the workgroup is considering applying a pilot research approach (i.e. Multi Criteria Decision Model) in order to elicit information from Experts on the possibility of exposure and the possible hazard(s) related to the hypothetical nanomaterial products.
- A number of criteria (e.g. size, possibility for aggregation, surface chemistry, degradability, etc) to review possibility of exposure and possible hazard(s) related to hypothetical nanomaterial scenarios have been selected, and currently the workgroup is working on defining those precisely.
- Three main end points would be produced regarding the possibility of exposure and the possible hazard(s) related to the hypothetical nanomaterial scenarios:
    - Indirectly inferred weights for the criteria: these could be presented either separate for each Expert and/or aggregated for the group of Experts. The weights would provide the information about which criteria have been judged to be most important by the Experts when reviewing the possibility of exposure and the possible hazard(s) related to the hypothetical nanomaterial scenarios. We would expect that the indirectly elicited weights of criteria would reveal the differences that possibly exist within the different exposure routes addressed by the hypothetical nanomaterial scenarios.
    - Correlations between the different weights and criteria: in the event we would obtain a high number of consistent Experts then correlations between the elicited weights of the criteria could be revealed. Such results would provide information on possible interrelationships between the different criteria as regards their importance for reviewing the possibility of exposure and possible hazards related to the hypothetical nanomaterial scenarios.
    - Ultimately, we would expect that information derived from end points a and b would allow us to state questions need to be asked in order to perform a risk assessment of nanomaterial scenarios.

Review of Annual Plan 09: To help shape the Annual Plan for FY10.

Workshops:

- Co-host with SRA Biological Stressors specialty group, CBER, and JIFSAN: ” New and Old Approaches for Risk Assessment: Perspectives of Different Agencies, Institutions, and Industry
    - At same location as SRA and will right after SRA ends, 1.5 days Thursday to Friday
- Susceptible population: 2 workshops
- Risk Based Approach for Animal Inspection: Wendy Hall (USDA/APHIS) will take the lead.

Bring together all IRAC agencies interested in/working with risk-based Risk Based Inspection; Potential to do the workshop after the December IRAC quarterly meeting. Potential to start the workshop in the late morning before breaking for a short lunch. Would then have the entire afternoon for the workshop.

Janelle Kause (FSIS), Barry Hooberman (CVM)

Possible new work group:

- Chemical Risk Assessment:

E.g., Cadmium in Meats to feed into a model-Will need a framework, there are data gaps. A risk profile on cadmium in Shellfish has been done.
Examples of possible chemicals: brominated compounds, dioxin, melamine, perfluorinated compounds, and other persistent organic pollutants.

In attendance (* participated by phone):

Stephanie Briguglio, Orise
*Mike Broder EPA/Office of the Science Advisor
*Kerry Dearfield, USDA/FSIS
Sharon Edelson-Mammel, DHHS/FDA/CFSAN
Steve Gendel, DHHS/FDA/CFSAN
Eric Grant USDA/APHIS
*Wendy Hall USDA/APHIS
*Andy Hwang USDA/ARS
*Barry Hooberman-FDA/CVM
Heejeong Latimer-USDA/FSIS
Robert McDowell-USDA/APHIS
*Stephanie Mickelson USDA
Marianne Miliotis, DHHS/FDA/CFSAN
Regis Pouillot, DHHS/FDA/CFSAN
Timothy Stevenson-DOD/VSA
*Mary Torrence USDA/ARS