

Interagency Risk Assessment Consortium Quarterly Technical Meeting

December 14, 2005

9:00 am – 1:15 pm

Introductions

Welcome to our new RAC technical representatives:

Barry Hooberman, FDA/CVM

Janell Kause, USDA/FSIS

Cindy Roberts, EPA/ORD

Welcome to our guest participants:

Hong Yang, FDA/CBER

David Oryang and Eric Grant, USDA/APHIS

Jean Buzby, USDA/ERS (presenter)

Tonya Nichols, EPA/NHSRC (presenter)

Agency Updates:

Department of Defense Veterinary Services Agency (DOD/VSA)

Bradford Hildabrand

- Food poisoning among high ranking Air Force officials led to the initiation of risk or vulnerability assessments by food defense teams to help investigate food risks. Any pointers or help on doing these assessments would be appreciated.

Department of Defense US Army Center for Health Promotion and Preventive Medicine (CHPPM)

Brandolyn Thran

- The anthrax risk assessment has been completed. It is going through its second internal review, and then will be sent to the RAC for review. This has been a work through process effort.

Environmental Protection Agency Office of Research and Development (EPA/ORD)

Cindy Roberts

- EPA/ORD is working closely with EPA/OW on microbial risk assessment framework for surface water criteria.

Environmental Protection Agency National Center for Environmental Assessment
(EPA/NCEA)

Michael Broder

- Nothing to report other than what is described in the presentation by Tonya Nichols (see below).

Environmental Protection Agency National Homeland Security Research Center

Tonya Nichols

- As described in the presentation, the biggest project currently undertaken is the development of a microbial risk assessment framework. Different scenarios are being applied to the framework, which was originally intended for deliberate contamination.

Food and Drug Administration Center for Biologics Evaluation and Research
(FDA/CBER)

Hong Yang

- CBER is currently conducting risk assessments on possible disease transmission through blood, the focus being on vCJD, and mainly with Factor XI, which is made in the United Kingdom. CBER is also evaluating Factors VIII and IX, which are made in the United States, and should therefore be of lower risk than Factor XI. The major risk would be through travel to European countries. The risk assessments are being conducted to determine the risk to the patients receiving blood derived coagulant factors and how to communicate the risk to them.
- CBER is conducting 2 other projects: a) estimate risk of blood transmitted Human Immunodeficiency Virus (HIV) under current blood deferral policy and other deferral options that considered by FDA and b) Risk of infectious disease transmitted by the tissues which are recently recalled due to malpractice in tissue collection.

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

Dick Whiting

- The symposium on "Relating Microbiological Testing and Microbiological Criteria to Public Health Goals" jointly sponsored by the International Commission on Microbiological Specifications for Foods (ICMSF), the Interagency Risk Assessment Consortium (RAC), International Life Sciences Institute (ILSI), International Association for Food Protection (IAFP), and Institute of Food Technologists (IFT) held at the Kellogg Center, Gallaudet University, Washington, DC October 31- November 1, 2005 was a great success. The ICMSF group then held a 10-day workshop to write an initial draft of a new book in their series on microbial food safety.

Marianne Miliotis

- The 2 risk profiles being developed at CFSAN on Norovirus and Hepatitis A virus have both been reviewed by the risk managers at FDA and by CDC experts. They are currently being revised accordingly.
- Reviews and comments by RAC member agencies on the FDA-funded IFT Risk Ranking Framework have been sent to the Principal Investigator.

John Hicks

- The FDA-funded project to develop a framework for peer review of risk assessments is coming to a conclusion. Product will be evaluated on how to do a peer review on RA on Food Safety.
- The risk profile on *Listeria monocytogenes* in fresh-cut produce and risk assessment on smoked salmon are following the farm-to-fork pathway.

Food and Drug Administration Center for Veterinary Medicine (FDA/CVM)

Barry Hooberman

- CVM is currently running BSE scenarios in animal feed; Gregg Claycamp is the lead on this project.
- CVM is finishing its food safety risk assessment that establishes whether food from cloned animals is safe to eat.

Food and Drug Administration National Center for Toxicological Research (FDA/NCTR)

Angelo Turturro

- EPA-funded *Cryptosporidium* risk assessment – found that it is a transmitted epidemic and children are the breeding ground for outbreaks. The report has been submitted to EPA.
- NCTR is willing to help USDA/EPA with writing of microbial risk assessment guidelines.

JIFSAN

Wes Long

- The University of Maryland has approved a 4-course graduate certificate for Risk Analysis

United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS)

David Oryang

- Final BSE-Japan rule (allowing import of beef from Japan under certain conditions) was published December 14, 2005.
- APHIS is considering a second BSE/Canada rule. The agency is exploring regulatory options for allowing entry of additional commodities from Canada.
- APHIS is considering methods for risk communication if additional BSE cases were to occur in the U.S., Canada or Japan.
- BSE is a cross-cutting issue involving FDA, FSIS, and APHIS.
- APHIS is also involved with Avian Influenza

United States Department of Agriculture Cooperative State Research, Education, and Extension Service (CSREES)

Mary Torrence

- Grant process is currently closed.
- The Food safety network funded last year involved 20 universities:
 - One project with FSIS on peer review;
 - One project with FDA doing a small pilot field audit on Roma tomatoes.
- CSREES has collaborative projects with MEDVETNET network of the European union:
 - Intervention methodology in poultry for Salmonella pre and post harvest
 - Salmonella in pork; review of the literature.
 - CSREES is funding a case/control pediatric diarrheal disease project in Seattle, WA for reportable and undetermined etiology. The study has an incredible data bank with several controls for each case. The investigator has extra samples to share for future outbreaks.

United States Department of Agriculture Food Safety and Inspection Services (FSIS)

Kerry Dearfield

- In a collaborative effort, FSIS and EPA have initiated an effort to write microbial risk assessment guidelines. These guidelines will be more comprehensive than the materials found in various microbial risk assessment frameworks. The focus is on the microbe, rather than an adverse end point. The working group would like to have the RAC review it once it has been drafted. This effort welcomes other members from the RAC if they desire to contribute, particularly FDA/CFSAN.

Janell Kause

- FSIS is currently working on a project on cross-contamination in consumers' homes. They're examining a similar study by the Netherlands, and working with USDA/ARS to fill specific data gaps with the focus on Salmonella in poultry. The USDA/FSIS/Risk Assessment Division plans to model this issue.
- FSIS is considering holding a technical meeting in late February early March, 2006 on the Harvard BSE risk assessment, which has been updated in terms of design and data since its 2001 publication.

United States Department of Agriculture Office of Risk Assessment and Cost Benefit Analysis

Michael McElvaine

- Symposium on “Foodborne Pathogens in Meat and Cheese” at the Annual Society for Risk Analysis meeting December 4-7, 2005, in Orlando, FL had great presentations.
- ORACBA is involved with APHIS on the BSE Risk assessment model.
- At the Institute of Medicine and The National Academies – sponsored symposium on “Challenges in Managing Food-Derived Risks”, December 13, 2005, Washington, DC, emphasis was on risk assessments for nutrition.

Work Group Updates

Microbiological Criteria Work Group

As stated in the objectives of the workgroup, a white paper entitled “Determination of Microbiological Criteria” has been drafted and sent to the RAC Policy Council for comments before submission for publication. It has been submitted to the International Journal of Food Microbiology.

The international ICMSF/RAC/ILSI/IAFP/IFT symposium on “Relating Microbiological Testing and Microbiological Criteria to Public Health Goals”, which took place October 31 to November 1, 2005 was a great success. Approximately 150 people attended; both international and national representatives of government, industry and consumers participated. Several members of this workgroup participated either as speakers or as moderators.

The work group feels it has accomplished its objectives, and can now be dissolved.”

Data Gaps Analysis Work Group

No updates to report

Data and Information Quality Work Group

The Data and Information Quality work group (DIQWG) has been able to make some small steps, such as developing a paper of best practices used by other agencies and delivering a presentation at the SRA about issues in data quality. There is currently a joint effort between FSIS/USDA and EPA to develop microbial risk assessment guidelines. There are discussions as to whether the DIQWG should dissolve and become part of this new effort.

Data Utility Work Group

A successful symposium was held at the annual meeting for the Society for Risk Analysis in Orlando, FL. Approximately 20 people attended the symposium titled, “The Status of Data Utility in Health Risk Assessment and Decision Making: A Multi-disciplinary Review”. The symposium provided good insights to the Data Utility workgroup who will now continue their efforts of developing a discussion paper for publication in a peer-reviewed journal (perhaps Risk Analysis) regarding data utility issues. The group will take a holiday break and begin work towards their goal in January 06. The efforts of all the group members is greatly appreciated by the group lead, we continue to be successful because of the involvement of all members. The work group will continue to identify data utility issues across different formats.

Discussion on FY06 Annual Plan

Potential new workgroups

Three potential new workgroups were discussed. Before they can be put in place, we need to have a lead person, description, and deliverables of each work group. Below is a list of the work group and lead:

1. *Applications of Omics in Food Safety Risk Assessments*, Jim Withee, USDA/FSIS (Lead).

There is an existing group that is currently focusing on chemicals, which can be extended to include microbes and food safety. This will help identify contamination, sequellae and can help with sampling plans.

2. *Nutritional Risk Assessment*, Michael McElvaine, USDA/ORACBA (Lead)

As mentioned above, there is much emphasis on nutritional risk assessments, including malnutrition; overnutrition; nutrition imbalance; effect of low carbohydrate diet, and effect of decreasing folates in the diet.

3. *Co-ordination among RAC member agencies in response to natural disasters*, Angelo Turturro, FDA, NCTR (Lead)

Potential public meetings

Sponsoring of different possible workshops/symposia was discussed. These included:

- A workshop on risk ranking of foodborne hazards
- A symposium on nutritional risk assessments with other interested groups.

Presentations

- “Food Safety Standards and Private-Public Sector Cooperation” by Jean Busby, USDA/ERS
- “NHSRC Research Program in Support of Microbial Risk Assessment” by Dr. Tonya Nichols, EPA/ NHSRC.

The meeting adjourned at 1:15 pm.

In attendance (* participated by phone):

*Michael Broder, EPA/NCEA
Jean Buzby, USDA/ERS
Kerry Dearfield, USDA/FSIS
Sherri Dennis, FDA/CFSAN
Sharon Edelson-Mammel, FDA/CFSAN
Eric Grant, USDA/APHIS
John Hicks, FDA/CFSAN
Bradford Hildabrand, DOD/VSA
*Barry Hooberman, FDA/CVM
*Janell Kause, USDA/FSIS
Wes Long, FDA/CFSAN-JIFSAN
Michael McElvaine, USDA/ORACBA
Marianne Miliotis, FDA/CFSAN
Tonya Nichols, EPA/NHSRC
David Oryang, USDA/APHIS
Cindy Roberts, EPA/ORD
Brandolyn Thran, DOD/CHPPM
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