National Advisory Committee on Meat and Poultry Inspection
October 12-13, 2006

Update on National Advisory Committee on Microbiological Criteria for Foods

Purpose

The purpose of this briefing is to present the Committee with an update on the actions taken by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) since the National Advisory Committee on Meat and Poultry Inspection May 2006 meeting.

Background

NACMCF provides impartial scientific advice to participating Federal agencies to use in developing integrated food safety systems from farm to table and to ensure food safety in domestic and imported foods.

NACMCF was established in 1988. It was formed in response to recommendations of the National Academy of Sciences for an interagency approach to microbiological criteria for food, and of the U.S. House of Representatives Committee on Appropriations, as expressed in the Rural Development, Agriculture, and Related Agencies Appropriation Bill for fiscal 1988.

Discussion

The NACMCF was re-chartered on August 3, 2006. This charter is on the Food Safety and Inspection Service (FSIS) website and runs through August 3, 2008.

The 2004-2006 NACMCF membership term ended on September 23, 2006. See Appendix A for 2004-2006 members.

Federal Register notices soliciting nominations for membership for the 2006-2008 NACMCF term were issued in June and August 2006. Work on selection of a new Committee for the next 2-year cycle is underway and ultimately the Secretary of Agriculture will appoint thirty members to serve on the NACMCF for the 2006-2008 term.

The Subcommittee on Determination of Cooking Parameters for Safe Seafood for Consumers met in Washington, DC from July 17-19, 2006. Subcommittee meetings were held in Washington, DC on September 18-21 on the topics of: 1) Determination of Cooking Parameters for Safe Seafood for Consumers, and 2) Assessment of the Food Safety Importance of *Mycobacterium avium* subspecies *paratuberculosis.* A Full

Committee Meeting was held on September 22, 2006 in Washington, DC. During this meeting the two subcommittees above reported their progress, summarized below. The following draft work charges were also presented to the Committee for comment by the Food and Drug Administration (FDA), and by FSIS, respectively: "Inoculated Pack/challenge Study Protocols", and "Determination of the Most Appropriate Technologies for the Food Safety and Inspection Service to Adopt in Performing Routine and Baseline Microbiological Analyses." See Appendix B.

Status of Subcommittee Work

1) Determination of Cooking Parameters for Safe Seafood for Consumers – On September 22, this group brought a near final document to the full Committee for discussion and comment. This FDA/National Marine Fisheries Service work charge will result in valuable information for consumers on how to cook seafood safely. It is anticipated that this document will be presented to the Full Committee for consideration of adoption at the next NACMCF Plenary Session (likely in the first quarter of FY 07).

2) Assessment of the Food Safety Importance of *Mycobacterium avium* subspecies *paratuberculosis* – This subcommittee met for the first time on March 23, 2006; work is ongoing.

Status of Completed Committee Reports

"The Analytical utility of *Campylobacter* methodologies" was recently posted on the FSIS website and it has been accepted for publication in the Journal of Food Protection.

"Response to the Questions Posed by FSIS Regarding Consumer Guidelines for the Safe Cooking of Poultry Products" is posted in Draft form on the FSIS website. The document was also recently accepted for publication in the Journal of Food Protection. In the near future a final version will be posted on the FSIS website.

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Attachments:

Appendix A – 2004-2006 NACMCF Members
Appendix B – New DRAFT Work Charges from the 9-22-06 Meeting

Appendix A 2004-2006 NACMCF Members

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Dr. Larry Beuchat
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Dr. Kathryn Boor
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Dr. Scott Brooks
Food Safety Net Services
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Dr. Peggy Cook
Safe Foods Corporation
Rogers, AR

Dr. Daniel Engeljohn
U.S. Department of Agriculture
Food Safety and Inspection Service
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Dr. Timothy Freier
Cargill, Inc.
Wayzata, MN

Mr. Spencer Garrett
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National Marine Fisheries Service
Pascagoula, MS

Dr. Patricia Griffin
U.S. Department of Health and Human Services
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Dr. Linda Harris
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University of California
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Dr. Walt Hill
Institute for Environmental Health
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Dr. Michael Jahncke
Virginia Polytechnic Institute and State University/VSAREC
Hampton, VA

Dr. Lee-Ann Jaykus
Food Science Department
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Ms. Barbara Kowalcyk
Safe Tables Our Priority
Loveland, OH

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Ms. Virginia (Jenny) Scott
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Dr. John Sofos
Department of Animal Sciences
Colorado State University
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Dr. Sterling Thompson
Hershey Foods Corporation
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Dr. Irene Wesley
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Dr. Donald Zink
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College Park, MD

Appendix B 9-22-06 Draft Work Charges

FDA DRAFT Charge on Inoculated Pack/Challenge Study Protocols

September 22, 2006

Background. The restaurant and retail food store industry, totaling nearly 1.5 million establishments in the U.S. and their suppliers, routinely uses inoculation/challenge testing to determine whether a specific food requires time-temperature control for safety (TCS). A food establishment, including restaurants, retail food stores, delis, caterers, and institutions or vending commissaries that provide food directly to the consumer, is defined in the Food and Drug Administration (FDA) Food Code.

When laboratory testing is used to support a change in how the product is handled in a food establishment (*e.g.*, refrigerated to unrefrigerated holding, extending shelf life, increasing ambient temperature storage or eliminating the need for date marking), this data is submitted to a state or local regulatory agency or directly to the FDA in the form of a variance application for approval. Food establishments or manufacturers submitting this laboratory data to support their proposals must ensure the study is appropriate for the food and pathogen of concern and incorporate the necessary elements into the study to yield a valid design and conclusion.

A variance from any provision in the FDA Food Code must also show that no health hazard will result from the modification or waiver and product handling is under control using a HACCP plan. Examples of foods in which the need for TCS was questioned include puff pastries with savory meat, cheese or vegetable fillings; churros (fried dough) batter held un-refrigerated; sliced pasteurized processed cheese held at ambient temperature for more than 4 hours; certain cheeses held unrefrigerated; *etc*. State and local regulators who evaluate a variance application based on this laboratory evidence need criteria to help them determine whether the study was adequately designed and whether the conclusions are valid.

The definition of potentially hazardous food (PHF) or time/temperature control for safety food (TCS food) was amended in the 2005 FDA Food Code to include pH and a_w interaction tables, allowing the hurdle concept to be used in the determination of whether TCS is necessary or not (Chapter 1 Definitions, 2005 FDA Food Code, available at http://www.cfsan.fda.gov/~dms/fc05-toc.html). The two interaction tables as well as a decision making framework were developed by the Institute of Food Technologists (IFT) and provided to FDA in the report, "Definition and Evaluation of Potentially Hazardous Food," December 31, 2001, IFT/FDA Contract No. 223-98-2333, Task Order No. 4 (available at http://www.cfsan.fda.gov/~comm/ift4-toc.html). When the pH and a_w Interaction Tables and the decision making framework are insufficient to show that a food does not require TCS, further product assessment using inoculation/challenge testing is likely required.

The IFT Report with its recommendations to FDA left a number of unanswered questions regarding the understanding and implementation of a product assessment when pH and a_w are unable to determine if TCS is required. This was confirmed in a survey of stakeholders (attached) conducted by the Conference for Food Protection (CFP) in 2005.

Charge: Because of the many questions raised by regulatory and industry users on the definition of potentially hazardous food (PHF) or time/temperature control for safety food (TCS food), the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is asked for its guidance to clarify these issues.

1. What are the appropriate criteria that must be considered for an inoculated pack/challenge study to determine if a food requires time/temperature control for safety (TCS)? For example, pathogen species/strain selection, use of surrogate organism, number of pathogen strains, inoculation level(s), incubation temperature(s), length of incubation/duration of study, food product physical properties, etc.

2. What are the appropriate uses of mathematical growth and inactivation models? Under what conditions can these models be used as a substitute for inoculated pack/challenge studies? Of the models currently available, which one(s) are most suitable for use and what are the limitations of these models?

3. What are the limitations for applying the results of an inoculated pack/challenge study on one food to another similar food?

4. If the existing inoculated pack/challenge study protocols, *e.g.*, those published by the American Baking Association, NSF International, and others, which are most suitable for application to a wide variety of foods and what are the limitations of these protocols? Are there existing protocols that are appropriate for specific food/pathogen pairs?

5. Develop a decision tree to aid in the design of an appropriate inoculated pack/challenge study. Test or "desk check" the decision tree using the following five foods: meat filled puff pastry, (baked) cheese pizza, chopped lettuce, cheese (blocks or slices), and lemon meringue pie.

6. Identify the basic knowledge, skills, education, training, experience, and abilities necessary for a multidisciplinary work group or individual to be qualified to design, conduct and evaluate an inoculated pack/challenge study and the pursuant results.

FSIS DRAFT Charge on Determination of the Most Appropriate Technologies for the Food Safety and Inspection Service to Adopt in Performing Routine and Baseline Microbiological Analyses.

September 22, 2006

Background

Microbiological analysis is central to the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) food safety mission. Because microbial data are critical to developing data-driven quantitative risk assessments and serve as a keystone of policy decisions and regulatory actions, the Agency continually seeks improvement for laboratory and in-plant testing capabilities. For instance, the Agency has recently benefited from the addition of polymerase chain reaction (PCR) technology to its laboratory methodologies. While PCR is not a substitute for traditional microbiological methods, it has proved to be a rapid, accurate screen that improved the cost and speed at which FSIS samples are processed. First generation microbial methods simply detected a given bacterial species in a food product, but FSIS now depends on a suite of analyses for regulatory actions, monitoring, and risk assessment. Currently, serotype determination by immunoassays, antibiograms, and pulsed-field gel electrophoresis (PFGE) are all important features of FSIS analysis. The adoption of these and other technologies has increased both the sensitivity and specificity of FSIS analyses, while at the same time decreased the amount of time needed to generate results.

Improved technologies for microbial analysis hold the potential to provide FSIS with even more useful data at a reduced cost and time. This will further strengthen Agency risk-based initiatives and science-based programs. Genomic assays, for example can provide rapid detection of the complete set of DNA sequences indicative of any known microbial food safety hazard (antibiotic resistance, virulence factors, markers etc.). Likewise, the field of nanotechnology holds the potential for real-time detection of trace microbial contamination. Nanosensors can even gain access into hard to reach process areas/crevices that form harborage sites for pathogens and other microbes. FSIS could benefit from these advancements not only by enhancing the depth and spectrum of microbial analysis but also from both a reduction of turn-around time and cost. The implementation of improved technologies would also benefit industry and consumers by increased detection of pathogens before contaminated product reaches the marketplace.

Work Charge

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) should provide guidance to assist with the Agency's goal of moving into the next generation of microbiological testing methods. To do so, NACMCF should review the current status of molecular methods, including genotyping assays, nanotechnology, and other available or evolving technologies for potential applicability to FSIS microbial analysis and explore their roles for incorporation into FSIS microbiological testing programs at both the laboratory and in-plant level.

The Agency recognizes that this charge might best be approached by NACMCF in two stages. The first would focus on laboratory methods for pathogen detection, and the second on in-plant testing to reliably assess process control. Analyses for use in FSIS laboratories versus within plants are likely to require different technologies. Analyses carried out in FSIS laboratories will be used for baseline monitoring of national microbial trends and regulatory sampling. In-plant sampling may primarily help in assessing process control and real-time monitoring of plant performance.

FSIS requests that NACMCF examine the merits of available technologies for application to FSIS microbial testing with a focus on:

- Selectivity and sensitivity
- Adaptability to various matrices (including foods, the processing environment, and human clinical samples)
- Scope of analyses (including species identification, serotype equivalence, antibiotic resistance, PFGE equivalence, and additional indicators of microbial hazards, such as virulence factors)
- Enumeration
- Data acquisition and transfer
- Speed
- Ability to be effectively incorporated into FSIS methods
- Cost and resource efficiency

Charge Questions
(Please consider both laboratory and in-plant uses for each of the following)

1. What are the most appropriate technologies FSIS should consider for improved laboratory and in-plant microbiological analyses? What are the main issues FSIS needs to address for the validation of these methods? Are there examples of the successful use of these technologies domestically or internationally by government agencies or institutions that can be provided?
2. Consider specifically the accuracy, applicability, and validation of an assay capable of detecting thousands of single nucleotide polymorphisms (SNPs) in a single reaction. Would such an assay be timely, cost effective, and capable of screening specimens to monitor process control? Would it be capable of differentiating multiple microbe species in a single sample? Could it have application for differentiating bacterial subspecies (particularly relevant for salmonellae which are currently characterized by serotype), or detecting antibiotic resistance genes and virulence factors?
3. Which of the recommended technologies are applicable for immediate use and which for future implementation?
4. What technologies will improve enumeration of pathogens and indicator organisms?
5. What is the type and format of analytical data that should be captured from laboratory analyses and from in-plant testing to be most valuable to improving food safety?
6. What technologies, especially from those suitable for FSIS testing, would provide the type of data useful in risk assessment attribution models for human illness? What tests could assist in yielding data that would translate into a risk profile for a given product/operation?