

November 1, 2006

Ellyn Blumberg
RBI Public Meeting
U.S. Department of Agriculture
Food Safety and Inspection Service
14th & Independence Avenue, SW
Mail Drop 405 Aerospace
Washington, DC 20250

RE: Comments on the Risked-Based Inspection System Public Meeting. (Docket No. FSIS-2006-0028)

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) public meeting on the proposed risked-based inspection (RBI) system. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

I. Background

FSIS is the agency within USDA responsible for ensuring the safety, wholesomeness, and accurate labeling of meat, poultry, and egg products. FSIS sets public health performance standards for food safety and inspects and regulates all raw and processed meat and poultry products, and egg products sold in interstate and foreign commerce, including imported products. FSIS is proposing to make its meat and poultry inspection system more risk based. The proposed system would allocate FSIS inspector's time at processing plants based on the relative risks presented by each establishment based on the product produced, the processes employed to produce it, and the volume of product. The Agency contends that this system will provide a more objective basis to allocate inspector resources to address food safety risks and public health concerns.

In furtherance of this effort, FSIS published two documents based on the twin pillars of its proposed RBI system: "Measuring Establishment Risk Control for Risk-Based Inspection" and "Measuring Product Inherent Risk for Risk-Based Inspection". CSPI welcomes the opportunity to comment on certain elements of these documents that were discussed at the October 10-11, 2006, public meeting held at George Mason University.

II. General Comments

CSPI supports the concept of a risked-based inspection system that would allow FSIS to improve its resource allocation and mitigate the impact of foodborne pathogens. However, CSPI has serious concerns regarding the implementation of a RBI system if it has not addressed fundamental issues that have the potential to impact public health. Outlined below are issues that must be addressed, otherwise FSIS could waste the time and resources it is looking to save and consumers could ultimately pay the price.

Expert Elicitation

FSIS asked RTI International to form a panel of experts to collect data on the relative risks posed to public health by various types of processed meat and poultry products. RTI recruited 23 experts to participate on this expert panel. These experts were identified by FSIS and RTI as having an understanding of food science, meat and poultry processing, and foodborne illness and are employed in industry, academia and federal government.

At the public meeting on October 10th and 11th, FSIS heard concerns from several participants regarding the make up of and the process used by the expert elicitation. The biggest concern was the composition of the expert panel which included mostly industry experts. Of the 24 experts that RTI International recruited, four were tied to major food companies and eight from land grant universities with ties to the industry. Additionally most of the academic experts shared the same organizational affiliation as another person on the panel. Participants at the public meeting also expressed concern about the seeming lack of boundaries for expert scoring. For example, the medium score for ready-to-eat dried meat was 2.0 while the maximum score assessed by one expert was 200,000,000. In another case, the median score for ready-to-eat dried poultry was 2.0 and the maximum score given by an expert was 300,000,000. These

² Pat Curtis and Chris Kerth, Auburn University; Catherine Cutter and William Henning, Penn State; P. Michael; Davidson and Ann Draughon, University of Tennessee; Dana Hanson and Lee-Ann Jaykus, NC State University.

¹ Keystone Foods, Oscar Meyer, Better Built Foods, and ConAgra.

discrepancies in scoring evince either a lack of agreement or a lack of understanding of the product ranking process the panel was charged with completing. Furthermore, the expert panel was instructed to disregard "severity" as a factor in the product ranking process.

FSIS should take the results of the expert elicitation and put it through an additional review with broader representation. At this review FSIS should:

- Include consumer and public health experts on the panel to assist in determining risk rankings.
- Add academic representation with medical expertise.
- Give experts the best available public health data to consider, including product attribution data.
- Provide clear and unambiguous directions on how to score the relative risk of various products and give clearly defined scoring ranges.
- Instruct the expert panel to consider severity, particularly as it relates to vulnerable populations, to be considered in ranking the inherent risk of products.
- Direct the experts to provide a rationale for their rankings and make the entire process open to the public.

Attribution Data and Data Infrastructure

Risked-based inspection and prioritization of food safety resources requires an understanding of the relationship between food and pathogen from farm to consumption. However this approach to food safety requires certain tools and data that currently do not exist. FSIS needs these tools and data to enable it to look at the food safety system as whole so that on the best available data and analysis the agency can identify the most significant risks from a public health perspective prioritize opportunities to reduce risk, and allocate their resources as needed.

The attribution of foodborne illnesses from specific pathogens to particular foods is a critical component of a risked-based inspection system. However, FSIS does not have accurate attribution data. Aside from an expert elicitation there are other methods that FSIS can look at to estimate food attribution percentages. This includes the use of outbreak data in which illnesses are traced back to their originating food and a risk assessment approach based on food contamination data, food consumption data, and algorithms for estimating resulting illnesses.

FSIS also needs a robust computer system and data infrastructure that can handle the agency's need to reassess plant performance once an RBI system is implemented. During the public meeting participants voiced serious concerns about the PBIS system currently used by the agency. These concerns included a lack of controls and issues of data integrity and reliability.

The data infrastructure employed by the Agency is crucial to the long-term success of a RBI system. FSIS should do a more thorough assessment of PBIS before moving forward.

Non-compliance Reports

FSIS has proposed using non-compliance reports as one of the variables in the algorithm to determine risk. However the use of non-compliance reports is problematic. Non-compliance reports can document a lack of adherence to any number of non-food safety requirements such as record keeping. FSIS must do a comprehensive analysis of the current non-compliance reporting system. This analysis should include a determination and ranking of non-compliance reports that are food-safety-related. As part of this process the Agency should enumerate the parameters by which it ranks the non-compliance reports and make these parameters available to the public.

Other concerns with FSIS's RBI proposal

A recent USDA Inspector General audit cast negative light on FSIS's *Salmonella* testing program. It suggests that the Agency has an incomplete database for its *Salmonella* testing program.³ The report evaluated the effectiveness of FSIS's process for scheduling and conducting microbiological testing of meat and poultry products. It found that controls need to be strengthened within the *Salmonella* testing program and that a significant number of establishments had been excluded because of ineffective controls. The report noted that in some districts 28% of the establishments that should have been included were excluded from the database.⁴ This problem should be remedied before RBI is implemented.

During the public meeting FSIS identified six components of a matrix that would be used to measure establishment risk control. They include food safety system design, food safety system implementation, pathogen control, in-commerce information, enforcement actions and food defense. These are generally appropriate parameters and each has an impact on food safety.

Timeframe for implementation of a risked-based inspection system

It has been reported that FSIS wants to begin implementing the RBI system in the first quarter of 2007. The comments at the public meeting demonstrate a need for FSIS to slow the process down and address certain key details. Implementation of a RBI system should not be

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³ USDA, Office of Inspector General Audit Report, "Review of Pathogen Reduction Enforcement Program Sampling Procedures," September 28, 2006 [hereinafter GAO Audit].

⁴ GAO Audit, at 4.

driven by FSIS budget demands or political interests. CSPI believes that there may be unintended negative consequences if FSIS rushes to implement a system clearly still in the nascent stages of development. FSIS should continue to use a transparent and inclusive process as it moves to strengthen the proposed RBI system.

III. Conclusion

As the public health agency at USDA responsible for ensuring the safety of the nation's meat and poultry supply, FSIS has a unique opportunity to implement an inspection system that could reduce the threat of foodborne hazards. CSPI supports the goal of a more science and risked-based food safety system that would allow FSIS to allocate its efforts and resources in a manner that makes the best use of available resources to reduce foodborne illness. But the recent public meeting highlighted a number of critical areas that require substantive work in order for an RBI system to move forward. FSIS should exercise due diligence and give serious consideration to the concerns regarding the expert elicitation, lack of attribution and *Salmonella* testing data, use of non-compliance reports, data processing needs, and the time frame for implementation of a risked-based inspection system.

Respectively submitted,

Ken Kelly, JD Food Safety Staff Attorney