Issue 2: Supporting Data Analysis and Performance Standards.

Problem Definition: FSIS has carried out several data analyses and developed public health based performance standards to support its proposed Public Health-Risk Based Inspection System. Those data analyses include studies examining the relationship between noncompliance rates and laboratory verification test results and a risk assessment on poultry slaughter. The proposed public health based performance standards apply to poultry slaughter and include Salmonella, Campylobacter, and generic e-coli.

Initial comment: The questions asked by USDA-FSIS were very broad in scope, and perhaps can best be summarized as "What have we overlooked? What other factors should we consider?" Given the broad nature of the questions, it is not surprising that there were a broad range of comments, and that there was not agreement among all of the members with all of the comments.

1. Given your knowledge of contamination events, are their additional activities (e.g., inspection activities, performance standards) FSIS should consider to improve the proposed Public Health Risk-Based Inspection System? If so, please describe and provide your reasoning.

The subcommittee **expressed caution** in using preliminary data in the development of new standards, and suggested that the baseline data be reviewed by the National Advisory Committee on Microbiological Criteria for Foods. In the absence of cause and effect studies, the subcommittee generally supported the overall lowering of Salmonella and Campylobacter levels in broilers. The Agency is encouraged to use a science based approach to evaluate the significance of pathogen incidence and numbers on properly refrigerated raw poultry. The Agency acknowledged the fact that it is not feasible to eliminate "all" pathogens on a raw product short of using irradiation. Therefore what published data exists on Salmonella/Campylobacter numbers on raw poultry versus the minimum infectious dose risk it presents to humans? It is important to focus on the right parameters to effectively improve public health.

PERFORMANCE STANDARDS

Key Issue: The Agency also needs to describe how the various performance standards will interact. As an example, what would the Agency's response be to an establishment which was in compliance with both the *Salmonella* and *Campylobacter* performance standards, but was out of compliance with the *Escherichia coli* Biotype I/II performance standard?

Fecal Contamination:

When considering fecal contamination, the subcommittee felt that FSIS should determine if there is a definitive link between fecal contamination of young chicken carcasses and public health. There was further discussion of the FSIS definition of "fecal", and how this contamination impacts public health. Specifically, the difference between feces and ingesta needs to be clarified to determine what impact these have on public health.

Recommendation: In the absence of such data, the subcommittee recommends no change to the existing "zero tolerance" standard. It will be difficult to obtain sufficient data necessary to prove or disprove correlation or causality between fecal contamination and the presence of enteric pathogens, and the resources necessary for such a large and complex study may be better applied to other data gaps, such as additional baseline studies.

Escherichia coli:

The Agency proposes to create an *E. coli* Biotype I/II performance standard. It is our understanding that this will be based on data collect by an establishment at both re-hang and pre-chill.

Recommendation: The Agency needs to present the data and rationale used for the creation of the standard.

Campylobacter:

Not all *Campylobacter* species are considered to be pathogenic to humans. The current performance standard being proposed is a quantitative measure of all species. There was general agreement that a quantitative assay was more informative than a qualitative (presence/absence) assay. There was some discussion as to whether or not it should include all species of *Campylobacter* and the Agency should clarify their intent. The Agency currently has an ongoing, but not complete, baseline study for *Campylobacter* in young chicken carcasses. The Agency intends to use this baseline study, as it has in the past, to determine the acceptable quantitative levels of Campylobacter in young chicken carcasses.

Recommendation: The Agency should complete this baseline study and have the data reviewed both internally and externally. The Agency should present the data and rationale for the performance standard.

Salmonella:

A concern was raised over the present *Salmonella* performance standard as a qualitative measure, and that it might not fully capture the effectiveness of interventions. That is, if the *Salmonella* population on samples was below the infectious dose, what is the significance of the prevalence within a sample set?

Recommendation: The subcommittee urges FSIS to continue its' development of quantitative analytical methods for *Salmonella*, and to consider incorporating quantitative data (as it becomes available) into the development of new performance standards.

Recommendations: Pathogen Subtypes:

1. The Agency needs to clarify the role of CDC top "30" list of *Salmonella* serovars or *Campylobacter* species pathogenic to humans in the development and evaluation of performance standards.

2. Also the Agency should clarify their desire for an establishment to use the serotype data as a guide for other possible interventions especially any that can be applied pre-harvest. Current pre-harvest interventions for Salmonella - typically include vaccines that contain a few serotypes of concern as a means to reduce Salmonella entering the production facility.

3. FSIS must remain aware of the regulatory limitations with which it can regulate over these pre-harvest interventions. FSIS should also remain aware of such limitations when considering the CDC top "30" serotypes.

4. The Agency needs to remain aware that the microbiological performance standard data is historical, and meant to represent the overall operation, and not meant to represent a specific lot of product.

5. While the Agency has made significant progress in addressing data needs, there still remain significant gaps in the available data (e.g., baseline studies), how the data will be used to develop regulations and performance standards. Continuing to move ahead within the proposed schedule assumes that the additional information they have been asked to provide will not significantly change the proposed process. It would be inappropriate to implement the proposed plan prior to collecting, analyzing, and incorporating the various data (e.g. Baseline studies).

2. Are there additional data sources or variables that FSIS should consider for its data analyses supporting the proposed Public Health Risk-Based Inspection System? Are there additional analyses that the Agency should consider performing to enhance the development of the proposed system?

The Subcommittee has identified specific data gaps in their response to Question 1, regarding the microbiological performance standards.

Recommendations:

1. The Agency's algorithm for inspection is based on *Salmonella*. *Campylobacter* results in the largest number of human cases of bacterial food borne illness. The current risk algorithm for young chickens does not include factors for human illnesses related to *Campylobacter*. This is a potentially serious gap in both the data and the algorithm. The subcommittee recommends that the Agency include *Campylobacter* in the inspection algorithm.

2. Fill the identified data gaps in:
    a. The association between fecal contamination and human health
    b. The association between salmonella or campylobacter levels and public health
    c. analyze the impact of line speed on the incidence of fecal contamination pre-chiller and Salmonella/Campylobacter post chiller

3. The subcommittee commended the Agency on its' Risk Assessment work. The subcommittee recommended that this be further refined with the addition of new data and brought back to the committee as a final product. The peer reviews and the responses to the reviews should be shared with the Committee.

Line Speed:

Line speed came up several times during the discussion. Many issues were discussed as potential concerns, but it was generally agreed that the Agency should have an analysis of the impact of line speed on public health. With the evolution of the various inspection programs from traditional to HIMP, FSIS has certainly considered the impact of line speed and the subcommittee recommends any such data gap be filled to eliminate any concerns. In addition, if there is any concern as to whether specific interventions are valid at various line speeds this should also be addressed.

As examples, the effect of line speed should be incorporated into the risk assessment, as well as differentiating between the type and number of NR's

which are issued before and after the sampling point. In addition, the effect of Salmonella populations could be incorporated into the assessment.

4. The Agency is encouraged to test the new system with historical examples. Considering the significant decline in Salmonella incidence based upon FSIS verification testing between 2006 and 2007, what change if any can be detected in foodborne illnesses attributed to poultry products from CDC? The proposed PHBIS for poultry will require significant changes in resources for the Agency and the industry if implemented. The Subcommittee encourages the Agency to fill in the data gaps before performing a test run on the System. Once accomplished, a clearer direction can be established as to how much impact this new system may have on process control and regulatory compliance. Without definitive data to correlate, one assumes this will improve public health. What changes in inspection would occur as a result of the new system, in comparison to what happened under the previous system? In addition, FSIS needs to consider how long it will take to see the impact of the proposed PHBIS on CDC indicators of foodborne illness in humans. History has shown that it takes years for CDC to generate reports and this will have a significant impact on measuring the value of the proposed FSIS public health based inspection system.