Response to Comment:

Improvements for Poultry Slaughter Inspection Technical Report

May 16, 2008

NACMPI COMMENTS

FSIS Question No. 1 to NACMPI:

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.

NACMPI Comments:

1a.) 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.

No response necessary

1b.) 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.

FSIS is developing guidance levels for the regulated industry to meet for the control of pathogens of public health concern in poultry (i.e., Campylobacter and Salmonella). FSIS expects to develop performance categories for Campylobacter as currently is being done for Salmonella whereby the pathogen control performance of the regulated industry is assigned to one of three categories with the goal of getting all of industry into the category that represents the lowest frequency for the presence of Salmonella, and evidence that this low frequency is maintained over time. FSIS expects to use its volume adjusted percent positive rate to estimate human exposure to Salmonella and Campylobacter. FSIS will measure the effectiveness of its inspection system relative to pathogen control in broilers by comparing the impact on the expected number of human illnesses to the CDC Healthy People 2010 goal.

Performance Standards

1c.) 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?

FSIS expects to develop a post-chill performance standard for generic E. coli. Unlike the current regulatory basis for generic E. coli in which generic E. coli is used as a direct indicator of fecal contamination, FSIS recognizes that generic E. coli also is an indicator of sanitation control (insanitation), including air sacculitis. Insanitation relates to the wholesomeness of the food, as well as to the impact of the equipment and environment on minimizing contamination. If insanitation is improperly controlled, then FSIS has concern that the product being produced may be adulterated. Consequently, FSIS expects to issue an NR if an establishment exceeds the standard for generic E. coli and doesn't take corrective action, or if FSIS tests for generic E. coli and finds the standard is exceeded. FSIS recognizes the limitations of finished product testing for pathogens. A negative test doesn't mean that the product is not contaminated. Current technology is capable only of minimizing contamination on raw foods, particularly livestock and poultry products. The confidence interval associated with a negative test result, generally, is small. Thus, supplementing the pathogen testing with a measure for insanitation provides additional assurance that product is prepared and handled under conditions that minimize contamination.

<u>Fecal Contamination:</u>

1d.) 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.

FSIS agrees no change should occur to the existing zero tolerance standard (carcasses with visible fecal contamination shall be prevented from entering the chilling tank.) The Agency does agree that correlation of inspection and supervisory personnel, along with industry, to ensure consistency in application of procedures can be enhanced. The

Agency expects to assess how it can improve application of its procedures relative to this issue.

In the draft proposed poultry slaughter rule, FSIS will be considering new standards of identity regulations based on the post-chill conditions of poultry carcasses, rather than the pre-chill status. The Agency is considering proposing that findings of ingesta in the chiller, may be evidence of insanitary conditions at the establishment, and FSIS could take a regulatory control action on the basis of such a finding (§ 500.2(a)(1)).

<u>*Escherichia coli*</u>:

1e.) 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 rehang and pre-chill.

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

FSIS expect to propose a generic E. coli performance standard at post-chill and at rehang that will establish an advisory level for this indicator organisms. This standard will be used as a measure of sanitation. At this time, the generic E. coli performance standard will be based upon data from the ARS study discussed in Appendix H. This standard may be updated after analysis of the Nationwide Broiler Microbiological Baseline is completed in calendar year 2008.

<u>*Campylobacter*</u>:

1f.) 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.

FSIS is considering guidance categories for Campylobacter that is expected to cause the regulated industry to gain control for the presence of this pathogen of public health concern. The Agency is currently analyzing the first six months of the broiler baseline data to include in the draft proposed rule, as a preliminary Campylobacter standard, pending the results of the completed baseline study. FSIS will continue to assess the public health impact of addressing all or some Campylobacter species.

Salmonella:

1g.) 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.

FSIS currently develops Salmonella guidance based on the results from its qualitative Salmonella verification testing program. FSIS will use data gathered from the broiler baseline study currently underway to reevaluate the current Salmonella guidance and the public health impact of a quantitative standard.

Recommendations: Pathogen Subtypes:

1h.) 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.

FSIS is working with CDC and FDA to incorporate serotype information from all FSIS verification testing samples in its attribution work and its performance standard development. Presently, FSIS is assessing options for how to best use the serotype information to protect public health. In addition, FSIS expects to share the information with the establishments so that the establishments also can assess how best to use the information in reducing the likelihood of delivering broilers to slaughter establishments that are externally or internally contaminated with serotypes that are common causes of human illness.

1i.) 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. 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.

FSIS agrees that pre-harvest interventions might be helpful in reducing Salmonella loads on live birds. Although FSIS Agency does not have regulatory jurisdiction for pre-harvest activities, the FSIS does enforce the HACCP regulations that were designed to ensure that controls are applied before, during, and after product is handled in a properly functioning food safety system. FSIS encourages establishments to adopt any pre-harvest activities that reduce the likelihood of contamination coming into the slaughter operation.

1j.) 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.

FSIS agrees that FSIS laboratory verification testing for Salmonella, and when implemented, Campylobacter, is not done in real time and does not represent a specific lot. The limitations of selecting one bird per day for 51 consecutive days is intended to represent control over time. Thus, FSIS continues to believe that its verification testing program is one indication of how an establishment is maintaining process control.

1k.) 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).

FSIS is using its existing verification testing data and the results of the ARS/FSIS study to develop performance standards. As the proposed rule is developed, FSIS will refine its thoughts further as more current broiler baseline data become available, including enumeration and serotype data.

FSIS Question No. 2 to Committee:

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?

NACMPI Comments:

2a.) The Subcommittee has identified specific data gaps in their response to Question 1, regarding the microbiological performance standards.

No response necessary.

Recommendations:

2b.) 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.

FSIS fully agrees that Campylobacter is an important pathogen that will add valuable information to the inspection algorithm. FSIS is in the final stages of collecting information on Campylobacter presence and levels in FSIS broilers as part of the Agency's broiler baseline study. As this and other information become available, attribution estimates for Campylobacter will be developed and Campylobacter will be added to the algorithm. The current plans for the draft proposed regulation is to add criteria for Campylobacter and to implement a verification testing program similarly as currently conducted for Salmonella.

2c.) Fill the identified data gaps in:

- The association between fecal contamination and human health

  The reader is referred to the response comment 1d.

- The association between salmonella or campylobacter levels and public health

  FSIS has developed attribution estimates for Salmonella in FSIS regulated product and will do the same for Campylobacter using data from the broiler baseline study currently underway.

- analyze the impact of line speed on the incidence of fecal contamination pre-chiller and Salmonella/Campylobacter post chiller

FSIS will conduct a study to evaluate the relationship between line speed, fecal contamination, Salmonella and Campylobacter. The results of the study will be used to inform the rulemaking and Agency policy regarding line speed, fecal and pathogen contamination.

2d.) 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.

The peer review comments and responses to those comments are available on the FSIS website at:
http://www.fsis.usda.gov/PDF/Poultry_Slaughter_RA_Peer_Review_Jan08.pdf

Line Speed:

2e.) 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.

The reader is referred to the response for comment 2c regarding line speed.

2f.) As examples, the effect of line speed should be incorporated into the risk assessment, as well as differentiating between the type and number of NRs which are issued before and after the sampling point. In addition, the effect of Salmonella populations could be incorporated into the assessment.

FSIS currently has limited information on the relationship between line speed and Salmonella prevalence in (young chicken) slaughter plants. Analysis, using the limited data at hand and a multivariate stochastic regression model (see mathematical description of the risk assessment model) suggests no evidence of association between line speed and Salmonella prevalence at either rehang or at post chill.

Two activities currently underway within FSIS should provide better data depth and quality for use in this analysis in the future. First the Young Chicken Baseline study (YCBS) will be available for analysts' use by early 2009. Second, a control study specifically to look at the relationship between line speed and Salmonella prevalence is currently being planned for fall 2008.

2g.) 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.

FSIS measures its performance in relation to volume adjusted percent positives and CDC outbreak data. FSIS believes that the proposed poultry slaughter inspection improvements will be resource neutral for the Agency. FSIS respectfully disagrees that it should not move forward without increased data. The Agency believes that it has sufficient data on indicators of process control for purposes of a relative risk ranking for resource allocation.

The Agency has assembled three historical databases for verification of the public health risk ranking algorithm. Those databases are for young chicken slaughter, beef slaughter, and raw ground beef establishments for the time period November 21 through December 21, 2007. FSIS routinely collects all necessary data (e.g., pathogen verification testing results, regulatory noncompliance (NR) data, enforcement actions, recalls, etc.) to apply the ranking algorithm and to assign establishments to one of three levels of inspection (LOIs). The three verification exercises demonstrate that: (1) all necessary data for application of the ranking algorithm are currently available and that no additional data is needed, (2) the ranking algorithm is capable of separating slaughter and processing establishments into separate LOIs based on variation in key indicators of food safety process control and, (3) the ranking algorithm functions as intended and is ready for immediate application.

CDC publishes estimates of the national disease prevalence for a variety of pathogens on an annual basis. The Agency uses this data and direct measurements of pathogen loads on FSIS-inspected food products to evaluate the effectiveness of its regulatory programs. The Agency has developed performance objectives based on meeting CDC Healthy People 2010 goals and on a quarterly basis evaluates progress toward meeting these objectives using quantitative performance measures such as pathogen verification testing levels, volume-weighted pathogen loads on food products, and national disease prevalence rates (illnesses per 100,000) resulting from consumption of FSIS-inspected food categories. The Agency has the necessary data to predict and measure food safety progress. As the Agency and CDC refine attribution estimates for FSIS-regulated foods, FSIS believes that the measures of effectiveness will be similarly refined and not be contrary to current predictions.

PEER REVIEW COMMENTS

Peer Reviewer No. 1

Use of Pathogen Performance Standards

3a.) The performance standard for Salmonella seemed to have worked well in determining the effectiveness in controlling processes to produce safe meat and poultry products. There have been some issues with geographic and seasonal differences, but in general have led to improvements in process control and to lower levels of Salmonella contamination. These testing sets should continue. This is verified information that both the Agency and establishments can use to improve process control and to determine risk values.

FSIS agrees with the comment.

3b.) Concerns are developing in the industry that the Salmonella testing will be forced on the plants. This includes tests not just for presence/absence but for enumeration as well as serotyping. Establishments should not be forced to suffer the cost of this intense testing as it will cause severe economic impact on many of the mid-size poultry slaughter operations that fill some niche markets.

The current Salmonella Initiative Program (SIP) is a voluntary program that will require industry to provide laboratory test results to FSIS because the operations are operating under waivers to regulations. In the future, FSIS expects that establishments will need to conduct pathogen testing to demonstrate that its food safety system is minimizing the exposure of the public to pathogens of public health concern. The frequency and design of such testing has not yet been determined. FSIS would expect the frequency and design of the establishment's testing program to be based, in part, on the degree of control exhibited by the establishment for minimizing exposure.

3c.) Overall, the plan for risk assessment and assigning plants to a risk category are well thought out and clear. It would seem prudent to continually update criteria to ensure establishments are not excessively regulated so that the economic impact is too high for them to survive.

FSIS agrees with the comment. The risk analysis –as designed, allows for updating as additional criteria become available. The Risk Assessment Division is also exploring alternative tools, including marginal analysis, which could be employed by risk managers to relate economic impact and risk.

Peer Reviewer No. 2

General Comments

3d.) My comments will deal with the report on Poultry Slaughter due to limited time on my part. The concept of risk-based inspection is appropriate and should be the natural progression of regulatory evolution in determining where to put resources to do the most good. I am hopeful that some form of rational approach to meat and poultry inspection can be developed. However, I am also hopeful that the within establishment part of the inspection system detailed in this report will be changed or eliminated.

FSIS does not intend to remove the within establishment focused inspection activities. FSIS has evaluated the benefits of the proposed system improvements in relation to its past experience. The reader is referred to the report introduction for those lessons learned.

3e.) This report would have the reader believe that pathogens on raw poultry are caused by some failure of the process or loss of control of the process by which the live animal is converted into edible and wholesome product. Bio-mapping within the processing environment clearly demonstrates this is not the case. The slaughter and evisceration process significantly reduces the microbial loads from those measured at live receiving. FSIS introduced their concept of HACCP in 1995 with the Pathogen Reduction / HACCP rule which made HACCP mandatory beginning in 1998. We do not and probably will never have an "acceptable level" of pathogens on raw poultry, but for the benefit of the HACCP concept, the process of poultry slaughter is effective at reducing pathogens and the industry is largely compliant with current regulations.

FSIS agrees that the pathogen load on incoming flock will have an impact on final product contamination. The focus on process steps is to reduce pathogen loads or to prevent contamination.

3f.) The reality is that there is not a process for eliminating all the vegetative pathogens present, except for cooking and irradiation. For quality reasons and the ability to make whatever dish or recipe desired, consumers typically buy raw poultry instead of fully-cooked or canned. Also because of possible negative quality aspects as well as higher cost, irradiated poultry is not readily available in the marketplace for consumers to choose. According to Food Technology Service, Inc., a Florida company that does food irradiation, the foodservice industry, and especially hospitals and nursing homes, have increased their purchase of irradiated chicken. This is a situation where the safety is important to the purchaser and the purchaser is not the actual consumer of the product. Other than cooked, canned or irradiated, consumers expect or should expect that all raw poultry may contain some level of pathogens and handle accordingly.

FSIS agrees that consumers should appropriately handle and cook raw poultry, and the Agency provides consumer outreach with regard to the proper handling and cooking of raw poultry products as part of its effort to protect public health. We agree that not-ready-to-eat poultry (that is not fully cooked, canned or irradiated) can expect to contain some level of pathogens and consumers do need to follow safe food handling practices

(e.g., cooking fully, not cross-contaminating containers for cooked poultry that previously had held uncooked poultry, washing hands after handling raw poultry).

Within Establishment

3g.) This section is the one that gives me the most concern. FSIS intends to focus verification activities on "vulnerable points that have the most potential for microbial contamination if not controlled". These "vulnerable points" were established by FSIS experts, but the Agency does not indicate if the points and prompts have ever been validated. A new Public Health Information System (PHIS) will assign the inspector to do a "For Cause Procedure" following attaining some threshold level of NRs based on a risk algorithm. This For Cause Procedure consists of a series of questions that the inspector will answer yes/no and then decide if further enforcement action is necessary based upon answers "in the aggregate". As an example, the report describes the response if a plant exceeds the critical limit for visible feces, which happens to be zero visible feces prior to the chiller. Upon reaching a certain number of zero tolerance NRs, the PHIS will assign a For Cause Procedure to evaluate the Vulnerable Points. For poultry slaughter, FSIS has chosen scalding, evisceration and chilling as the three vulnerable points. At this point, the assigned inspector uses the Focused Inspection Prompts and Questions found in Appendix B. For discussion, I have brought the questions into this document and have put my comments in italics.

No response necessary.

3h.) Poultry comes to the processing plant with fecal material on their feathers and skin. The report talks about the possibility of cross-contamination from one bird to the next in the transport trucks and coops, but most/all birds have some degree of microbial load and contact with other birds will not make the situation worse or better. FSIS has determined that there are not any preventive measures to be taken in the live receiving / hanging / stun / bleeding processing steps.

The Agency believes that certain per-harvest interventions can help to minimize pathogen loads on birds entering slaughter establishments. Moreover, the Agency does believe that stress during handling and transport does increase the potential for fecal shedding of pathogens. FSIS does believe that cross-contamination among different flocks during transport to establishments may be an important issue that could be controlled.

3i.) Scalding is a process with a singular purpose – to apply the right time / temperature to the carcass to allow for feather removal and effect the removal of the cuticle to the desired level. The purpose of the scalding process is not for biological or pathogen control. It is in the company's best interest to do this properly because a loss of control does lead very quickly to carcasses with feathers or if too hot and/or too long, carcasses showing a cooked, oily appearance that is not suitable for sale. The scalder does remove a large amount of feces from the bird and many processors have added wash cabinets before the scalder, after the scalder, or both to contribute to the cleaning process. In the literature review in Appendix C, government scientists have documented that the process in general reduces the level of bacteria present. Most scalders, if not all, are counter-flow

where the clean water comes in at the exit end of the scalder. The decision of whether to use a multi-stage scalder or not should be based upon scalding efficiency and not necessarily on a difference in dirt removal. Additional Dirt removal can be done in other ways, such as the added wash cabinets. I would disagree with the FSIS experts that scalding does in fact constitute a vulnerable point.

FSIS disagrees with the comment. FSIS defines vulnerable points as "a point at which microbial growth or contamination may occur if process control is not maintained". FSIS believes that scalding is a vulnerable point because it is important for reducing microbial contamination. If process control at the scalder is not maintained, the ability of this process step for reducing microbial contamination is diminished.

3j.) My main concern with the Within Establishment PHRBIS however is in the application of the focused inspection activity. The procedure described would have me believe that any number of inspectors within a single establishment could in fact be assigned this For Cause Procedure in a relative short period of time. There is enough subjective evaluation in the prompts that it would be easy to start enforcement action. The text in the report on page 6 says that if the inspector decides that the establishment is not controlling the process in the aggregate (to be defined later), then the establishment might be failing to maintain sanitary conditions, or failing to implement SSOPs and may be producing product that is injurious to health. No company wishes to produce product that is injurious to health, but I am unclear on how FSIS would define that distinction in this situation and more importantly, how they would train their inspection force to make this value judgment from the questions used in the For Cause Procedure. We are speaking of raw poultry and the presence of pathogens such as Salmonella and Campylobacter does not constitute product injurious to health.

The within establishment component is designed to reinforce the food safety regulatory training that inspection personnel receive in order to determine whether an establishment is in compliance with FSIS regulations. FSIS inspectors carrying out procedures at vulnerable points will verify compliance with existing regulations. Multiple observations at vulnerable points may be used to support an NR or enforcement action. FSIS defines products injurious to health as product that may be harmful, damaging, or deleterious to health. A properly operating slaughter and dressing process is expected to prevent and reduce contamination events. A focus on vulnerable points by inspection personnel is expected to cause further improvements in pathogen control by the establishment.

3k.) On page 7 of the report in the footnote of the Focused Inspection Prompt Example, the word "might" is not present and the Agency says that if the inspector decides that the establishment is not employing adequate controls in the aggregate, then the establishment is failing to maintain sanitary conditions or failing to implement SSOPs and may be producing product that is injurious to health. The Agency continues with a different line of thought if the inspector determines that the establishment is not executing a pre-requisite program that is identified in the hazard analysis for any of the vulnerable points (it may not have to pertain to the NR that caused the For Cause Procedure), then the establishment is failing to validate the HACCP plan….which brings into question adequate supporting documentation….adequate hazard analysis…..adequate HACCP

plan. As you can see, this cascade from a zero tolerance NR to an inadequate HACCP plan may subjective and there is little guidance or training developed or in place from the Agency. This procedure places too much subjective authority on Agency personnel not trained to deal with these questions. It also could have a dramatic effect on the due process rights of facility managers who would be unlikely to challenge the findings of in-plant inspection personnel through the appeal process because using this For Cause Procedure, the inspector could continue on many paths to enforcement action. This could also mean conciliatory, unmerited and disproportionate expenditures to individual plants or companies based upon the inspectors assigned to that establishment.

FSIS has refined the within establishment component to more closely align prompts, vulnerable points, and questions. As reflected in the report, the revised questions ask if establishments are implementing their HACCP, Sanitation SOPs, SPS, and prerequisite programs at vulnerable points in order to control microbial growth and to prevent cross-contamination. The proposed within establishment system is designed to reinforce the FSIS inspection program personnel's training on food safety regulations, including HACCP. In addition to their existing training, FSIS inspection personnel will also receive training on how to carry out inspection procedures at vulnerable points and how to make decisions about regulatory compliance.

A methods evaluation will be undertaken to further evaluate and refine the within establishment component. FSIS is considering hold a workshop during which stakeholders (FSIS field employees, academics, industry, and consumer representatives) would evaluate the proposed prompts by playing out prompt scenarios for different product categories. The prompts would be refined based upon this workshop. In addition, a FSIS intends to undertake a field evaluation to refine the prompts. During the field evaluation, FSIS supervisory IICs and PHVs will carry out prompt scenarios in FSIS regulated establishments. A historical data analysis will also be carried out to determine the thresholds for the proposed prompts.

Vulnerable Points/Prompts

3m.) *Vulnerable Points & Question(s) to Answer:*

a.) Scalding

a. Does the establishment have control mechanisms to reduce the amount of dirt and organic matter entering the chiller *(I assume this should read scalder)* and are they being implemented? *(the first part is yes/no, but second part is subjective)*

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

b. Does the establishment have controls to maintain the optimum pH levels to reduce *Salmonella*? *(In most establishments, this would be no, but in reading the literature review in Appendix C, that optimum pH level is not known. With the level of organic matter present, it may be impractical to*

control pH in the scalder as is done in the chiller. This question may lead the inspector to pursue enforcement action when it may not be necessary.

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

c. Does the establishment have controls to maintain water temperature effective to reduce microorganisms? *(Scalder time/temperature is done to effectively remove feathers and appropriate for cuticle removal. The literature review in Appendix C only cites temperatures from one study, Yang et al. 2001, at between 50 and 60°C. Proper scalding temperatures will be above 50°C so the answer should be yes. However, the study cited also lists a dwell time of 5 minutes which would be unacceptable)*

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

d. Is the establishment implementing prerequisite programs at scalding, as per their hazard analysis? Is there adequate supporting documentation? *(This question is subjective and not well defined. The hazard analysis does not always list prerequisite programs nor would they necessarily be required in the hazard analysis. I don't know of any hazards at scalding and in teaching HACCP for 18 years, I would never include a prerequisite program in a hazard analysis at scalding.)*

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

b.) Evisceration/ On-Line Reprocessing

a. Does the establishment have controls to maintain equipment to accommodate changes in bird size? *(This question does not apply to turkey processing. It is also confusing – is it asking about controls or maintenance or equipment. Control of this process is very important to the processor whether done by hand or by machine for the quality of the product.)*

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

b. Does the establishment have controls in place to prevent cross contamination and are they implemented (ventilation, employee hygiene, equipment)? *(How do you define "cross contamination" in the poultry*

slaughter environment and does it really have any true public health significance?)

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

c. Does the establishment have controls in place and are they implemented to maintain conditions of use for interventions?

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

d. Is there evidence that the establishment controls and monitors parameters unique to its OLR system or other antimicrobial intervention to have an effective system that reduces micro-organisms?

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

e. Is establishment implementing prerequisite programs at evisceration / on line reprocessing, as per their hazard analysis? Is there adequate supporting documentation? *(This question is subjective and not well defined. The hazard analysis does not always list prerequisite programs nor would they necessarily be required in the hazard analysis.)*

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

c.) Chilling

a. For all chillers:
    i. Does the establishment have controls to maintain a high flow rate (a half a gallon per bird) or alternate method? *(I will assume that this should read for all <u>water</u> chillers. This question could easily lead to an implied requirement for overflow. The FSIS personnel would also need considerable guidance on alternate methods. For instance, does agitation suffice as an alternate method of whatever result that generated this prompt?)*

    This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

ii. Does the establishment use red water reuse to reduce microorganisms as per (416 (g) (3)? *(The correct citation is 9 CFR 416.2 (g) (3).)*

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

iii. Does the establishment have controls and are they being implemented to maintain effective chiller temperature? *(Establishments document conformance to temperature requirements 9 CFR 381.65.l on a daily basis. For the purpose of this question, maintaining chilling medium at or below 40°F would be sufficient to be effective at preventing pathogen growth, but may not be effective to meet the regulatory requirement in time. How would this prompt deal with hot boning and other variations?)*

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

iv. Does the establishment have post chill interventions and are they monitoring the effective level of that antimicrobial? *(Who defines effective without it being subjective?)*

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

v. Is establishment implementing prerequisite programs at chilling, as per their hazard analysis? Is there adequate supporting documentation? *(This question is subjective and not well defined. The hazard analysis does not always list prerequisite programs nor would they necessarily be required in the hazard analysis.)*

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

b. For air chillers:

i. does establishment have controls to prevent microbial load increase during chilling? *(How would the inspector evaluate this question without extensive data supplied by the plant?)*

This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

c. If using chlorine in a chiller: *(All of the following use the term effective. Who defines effective if not the plant? This could become a very subjective determination)*
    i. Does the establishment control an effective pH?
    ii. Does the establishment: monitor the effective level of free chlorine?
    iii. Does the establishment control the effective level of the antimicrobial?

    This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

d. If using another antimicrobial (than chlorine) in a chiller:
    i. Is there evidence that the establishment monitors/controls the effective level of the antimicrobial?

    This question has been removed from the report. The commenter is referred to Appendix B of the revised report for the new vulnerable point questions and guidance.

Potential Regulatory Citation(s):
416.1 Failure to maintain sanitary conditions
416.13 Failure to implement SSOP
417.5 (a) (1) & (2) decisions in hazard analysis not supported
416.1 Sanitary Dressing
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

Across Establishment Public Health Ranking Algorithm

3n.) This portion of the report focuses on how the Agency will address data from across the industry as a group and how they will direct inspection resources to force individual establishments to change processes to bring the establishments with the highest risk to a lower level of risk. Conceptually, as the highest risk plants move to a lower risk, the algorithm will reset and either these plants will still be the highest or other plants will now be under increased scrutiny. In other words, no matter how much improvement is achieved, there will always be some establishments in Level of Inspection (LOI) 3. The concept also assumes that if the Salmonella incidence is reduced, it will cause a concurrent reduction in human salmonellosis. In the ten years of the Salmonella Performance Standard, FSIS has documented first a decrease, followed by an increase followed again by a decrease. With all of the immense time and effort put into showing correlations, the Agency did not correlate data from the Salmonella Performance Standard for that 10 year period with impact on human health in order to validate their most basic of assumptions.

The purpose of the ranking algorithm is to focus FSIS resources on establishments with the greatest public health risk, and, as a result, some plants will always be in LOI 3. The algorithm is designed so plants will not remain in LOI 3, and can move to LOI 2 once an FSA is completed. The reader is referred to Appendix A to see FSIS progress in reducing Salmonella contamination and human cases of salmonellosis.

3o.) In the description of conceptual approach on page 13 of the report, the term contamination event is used but not defined in terms of poultry slaughter. Contamination event is certainly not clearly defined based upon the level of microbial load that the Agency acknowledges is present on or in the raw material (live poultry) for this process.

FSIS acknowledges that birds may come into slaughter establishments with high microbial loads, and that the slaughter process reduces those loads. The report has been revised to remove the word "event".

3p.) The eleven data sources for this algorithm are detailed in the report as:

- Production Volume *(Will large companies have greater regulatory risk due to this factor?)*

  Larger companies will not have a greater regulatory risk do to their greater production volume. Production volume is not a factor used in separating establishments into one of the three levels of inspection. The factors used in the public health risk ranking algorithm to separate establishments into three level of inspection are indicators of how well an establishment's food safety process control systems are performing. It does not matter how large or small an establishment is, if there are indications of a lack of process control, the establishment will receive more focused inspection. Volume is only used in LOI 2 and LOI 1 to rank order establishments with similar indicators of loss of process control.

- Attribution *(This factor needs much more public comment prior to inclusion. The Agency states that many of the factors that they would want to include in the attribution factor are insufficient. They have not specified what they would use for poultry and have actually confused the situation by indicating that they are wanting information related to FDA products like shell eggs which should not have any bearing on poultry processing.)*

  The Agency is not stating that the factors used to estimate foodborne disease attribution are insufficient. While some approaches are not currently fully developed, others like CDC outbreak data used in conjunction with expert elicitation are not. The methodology has been peer reviewed and is supported by CDC. FSIS, in conjunction with CDC and FDA is investigating methods, such as using serotypes and subtypes of pathogens to improve attribution estimates. FSIS will use those and other advances to improve foodborne disease attribution estimates as better information becomes available.

Salmonella Verification Testing

- Public Health Significant NRs (W3NRs) *(The correlation reported here may not have any bearing on public health and should not be used unless there is a proven causative effect.)*

  It is not possible to establish that any particular regulatory non-compliance will always result in the occurrence of a positive in a Salmonella test in the following week. The CMU analysis does show a statistically significant relationship between public health related NRs and Salmonella positives. That is, when a public health NR occurs there is a 3 times higher probability of a positive test for Salmonella occurring in the following week.

- Adulterated Product

  *The term **adulterated**, in the context of its use for poultry during slaughter, applies to any poultry product under one or more of the following circumstances: 1.) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for another reason unsound, unhealthful, unwholesome or other otherwise unfit for human food. 2.) if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Additionally ,poultry products are adulterated if they; come from poultry that has died other than by slaughter; are in containers composed of poisonous or deleterious substance and bear or contain added or unadded poisonous or deleterious substance.*

- Enforcement Actions
- Recalls
- Link to an Outbreak
- Food Safety Assessment
- Salmonella Performance Standards
- Salmonella Serotypes* not currently used

3q.) Turning to the example given on page 24, the report looks at a subset of 128 of 190 young chicken slaughter establishments using data from 2006. For Salmonella Verification Testing, one plant would be placed in LOI 3. If they had used the entire 190, 19 plants (10% would go to LOI 3. The example does not state how the subset was chosen, but the fact that only 1 of 19 plants was in the dataset suggests that the selection may not have been random. The Agency needs to explain rationale for subset selection and why the plants with high salmonella were not in the subset.

The verification example has been updated to use 2007 data. The verification example now includes 195 of the 195 young chicken slaughter establishments receiving FSIS inspection and Salmonella verification testing in 2007.

3r.) W3NRs account for the other 4 establishments placed in LOI 3. This report discusses an analysis using lift statistic to evaluate correlation between 3 classifications of NRs and a subsequent positive Salmonella result within the next 2 weeks. This analysis reported a significant correlation between an establishment receiving a health-related NR and having a subsequent positive Salmonella result. The figures presented make a strong case for the correlation, but correlation is not cause and effect. It would be important to study and understand the scientific basis and not just a correlation. Knowing that there is such a strong correlation is certainly reason for study of this relationship to understand causality. This report does not list the 66 W3NRs, but it would be interesting to know the frequency of their use compared to the 434 non-W3NRs. One possible explanation is that in plants with higher results on Salmonella testing, the inspection personnel may be instructed to find or respond by finding more reasons to issue W3NRs

If an establishment is not maintaining process control, it is likely to have NRs and positive pathogen test results. The reader is referred to Appendix D regarding the frequency of W3NRs. The statistical relationship between NRs and positive pathogen results took into account the temporal relationship between NRs and laboratory test results. A significant relationship between NRs preceding pathogen results was found.

3s.) The Distribution of Salmonella Results was used to separate LOI 1 and LOI 2. By this criterion, 90 establishments would be eligible for LOI 1. Using the W3NRs criterion, 115 establishments were eligible to the included in LOI 1. In the final application of the algorithm only 76 plants are in LOI 1, but the example does not explain the difference between eligible and actual.

The ranking algorithm uses multiple criteria to determine membership in each of the three LOIs. To be in LOI 3 only requires that one of the criteria be satisfied. To be in LOI 1 requires that all criteria be satisfied. Salmonella and W3NRs are two of the criteria that must be satisfied. Thus, to be in LOI 1, an establishment must satisfy both the Salmonella and the W3NR criteria. 90 establishments satisfied the Salmonella criterion, while 115 establishments satisfied the W3NR criterion. The intersection of these two sets (plants that satisfied both criteria) contained 76 plants.

3t.) By the example, less than 5% of plants were in LOI 3, but with the entire population, it would have been a minimum of 10% based upon Salmonella Verification Testing plus at least 4 more plants for the W3NRs. At any given time, that is a considerable amount of intensive inspection just for poultry without dealing with small and very small red meat plants.

As pointed out above, the example exercise has been updated to include all 195 young chicken slaughter establishments receiving FSIS inspection and Salmonella verification testing in 2007. Using this dataset, only 4 percent of young chicken slaughter plants were in LOI 3. Thus, the percent in LOI 3 actually decreased when all available ranking data was utilized.

3u.) I agree with the Agency that the Food Safety Assessment is the best assessment of the overall food safety system, and making it quantifiable might make it more objective and practical for the Across Establishment algorithm.

FSIS agrees with the comment.

3v.) One other data source proposed is Salmonella serotypes. The report lists 7 serotypes, but the Agency is using a list of 30 for evaluation of the industry today. On page 15 of the report, under Attribution, the Agency states that they have started a project to look at serotypes to better attribute human health issues to the food of concern. The Agency states that they will begin using serotypes in the algorithm and designation of Level of Inspection category. The problem with that is that there is nothing the processing plant can do to change serotypes. There is insufficient data to include that in the risk model. The Agency should continue with their research with CDC and FDA to better understand the attribution model.

Poultry slaughter establishments have varying degrees of control of Salmonella on their products and, in fact, efforts by slaughter establishments have resulted in a steady decrease in Salmonella levels on broilers over time. However, not all Salmonella have the same probability of causing human disease. Different Salmonella serotypes have different probabilities of causing illness. To obtain a better relationship between Salmonella presence on poultry and human illness rates, it is necessary to account for Salmonella serotypes. Thus, plants with more infectious Salmonella serotypes should receive more focused inspection than those with less infectious Salmonella serotypes. While an establishment may not be able to change the type of Salmonella serotype on its product, it can reduce overall presence of Salmonella on its products and thereby reduce the level of infectious Salmonella serotypes.

3w.) On page 21 of the report, the Agency states that LOI 1has two components: Routine plant inspection and Focused Verification Activities (new within establishment inspection system). The Agency states that LOI 2 has 4 components: Routine plant inspection and Focused Verification Activities (new within establishment inspection system), Focused in-plant Verifications at vulnerable points to verify the level of whether there is a food safety system problem and a higher priority for an in-depth Food Safety Assessment. This report describes the Focused Verification Activity at vulnerable points earlier in the report, but there is no discussion of the difference of the other Focused Verification Activities of LOI 1 versus the two Focused Verification Activities in LOI 2.

A further explanation of verification activities at vulnerable points occurring on a routine frequency has been added to the report. Inspection program personnel will carry out inspection activities at and answer questions about vulnerable points on a routine frequency in LOI II and III establishments in addition to carrying out those activities when a prompt occurs within the establishment.

Proposed Public Health-Related Performance Standards

3x.) On page 28 the report states "The Agency is considering proposing that young chicken slaughter establishments address the hazard of fecal matter in their Hazard Analysis and Critical Control Point (HACCP) plans." Whether officially in writing or not, that has been the enforced criterion in the field. I am not sure if the Agency means to exclude from this statement other poultry such as turkeys, fowl or ducks.

FSIS is considering formalizing zero tolerance as a CCP in young chicken slaughter establishments

3y.) The Agency considers zero tolerance for visible fecal NR to be an indication of loss of process control. If the establishment has repeated failures of the zero tolerance standard at some regular frequency, it actually may represent a stable process that is not capable of meeting the defect level standard. This is a more accurate representation of the situation than loss of control. The industry has been living and working with the zero tolerance standard since 1997 and many interventions have been put into place and the occasional, rare occurrence of visible feces prior to the chiller does not represent the human health hazard that the Agency claims. The Agency's literature review would indicate that these few carcasses would be microbially indistinguishable from other carcasses (Appendix C, page C15). I agree with the zero tolerance standard from the standpoint that it is not conceivable to me to establish any level of feces and call it acceptable, but that is different from stating that a process is out of control for an occasional defect that is rare when taken at the volume of non-defective carcasses that are produced. This is one of the reasons that the W3NR contribution to the Public Health algorithm may need considerably more attention.

A single W3NR was not used as a criterion for ranking. One of the top NRs found in poultry slaughter establishments related to food safety is for noncompliance with zero tolerance for visible fecal contamination.

3z.) The Agency is also considering a multitude of other performance standards such as a zero tolerance for septicemic or toxemic poultry carcasses before the chilling tank and will require that this condition be addressed in the HACCP plan. This would be consistent to removing FSIS inspection personnel from the processing line.

FSIS is considering an advisory performance standard for generic E. coli at rehang. FSIS expects to propose a zero tolerance for septicemic and toxemic carcasses pre-chill along with zero tolerance for fecal contamination.

4a.) FSIS is considering changing generic E. coli from a performance criterion to a performance standard as well as include an additional sampling point at rehang to document the reduction in numbers from the start of evisceration to the exit of the chiller. The public health rationale seems very weak for this requirement and the statistics of Appendix E is lengthy. For poultry, the organism is linked to air saculitis and / or infectious process (IP). Therefore, higher levels of E. coli may also relate to general

poultry health and not necessarily deviations in the evisceration process. More discussion of this proposed performance standard should occur.

FSIS expects to propose a generic E. coli performance standard for post-chill. This standard will be used as a measure of insanitation. The generic E. coli performance standard will initially be based upon data from the ARS study as discussed in Appendix H. The standard may be updated after data from the Nationwide Broiler Microbiological Baseline is analyzed, and as new data become available.

4b.) The last major change would be to require the plants to take over the testing of Salmonella and to begin a required testing program for Campylobacter. Many plants already test for Salmonella, but this may represent a major cost burden for a very small processor. In the Salmonella Initiative proposal, plants in Categories 2 and 3 would be required to enumerate Salmonella which is an expensive test – money being the reason FSIS does not enumerate Salmonella. Data from ARS would indicate that the process for young chicken production does reduce Campylobacter significantly (Berrang et al., 2007, Appendix C, page 20). Both of these changes should have public discussion prior to implementation.

A public comment period will follow the publication of the proposed poultry slaughter rule by FSIS. In addition, the Agency will develop a cost-benefit analysis as part of the proposed rule's regulatory impact analysis.

Peer Reviewer No. 3

Introduction

5a.) Page 3 – The second paragraph and the third paragraph need to be clarified. In paragraph 2, it states that 88.6 and 81.3 percent met the *Salmonella* performance standard. However, in paragraph three, it states that 49 percent of the establishments were in Category 1. In regards to the Category specification, more detail needs to added to explain the 88.6 and 81.3% numbers. Although the percentage is listed, it would also be helpful to provide data in the format of 120 of 132 establishments and even discuss the volume it represents.

FSIS has revised and clarified this portion of the report to better explain establishment performance and attribution for Salmonella illnesses. With respect to the percent of establishments meeting the performance standard, those numbers have been updated to use FY 2007 data. As shown on page 1, FSIS FY 2007 Salmonella verification testing data show that of the 195 Salmonella verification test sets completed in 2007 at broiler establishments, 98 percent met the Salmonella performance standard (192 out of 195 establishments), up from 90 percent in calendar year 2006.

5b.) Page 3 – As for *Salmonella* Category 1: the report states that the percentage increased to 73 percent in FY 2007. This is a 23% increase in a one year time frame. What are some of the changes that are occurring in the establishments to have better compliance? What are the sizes of establishments that are improving? Is the current system bringing about fairly measurable changes and could updating the performance standards also be positive?

Placement into Salmonella Category 1, 2, or 3 has been discussed in previous Federal Register Notices and is not the subject of this report. The reader is referred to the FSIS website for additional information on the Salmonella verification testing program.

Establishments are voluntarily improving their process control measures to improve their results on Salmonella Verification testing. Each establishment selects those changes that are most suited to their operations. The percentage of establishments in Category 1 is used as a measure of the effectiveness of the program and the percentage of establishment in each category is reported quarterly on the FSIS website. FSIS is currently carrying out a broiler and a turkey baseline studies and will use this data to update its Salmonella performance standard and establish new categories..

5c.) Pages 3 and 4 – Comment on the statement "FSIS believes that the proposed PHRBIS will be better able to protect public health by focusing and integrating our regulatory authority on establishment and points within the poultry slaughter process at which control of contamination can have the greatest impact." This is a very valid statement as there will be focus on plants that are not performing. However, there is concern about the statement "Similarly, it believes that the incorporation of performance standards in the PHRBIS will incentivize industry to decrease the amount of microbial contamination occurring during slaughter." Is there enough of a consequence in place

when the performance standards aren't met? Would the new enforcement provide the necessary incentives for establishments to change?

The statement about incentivizing industry has been removed from the report.

Beginning in June 2006, FSIS began risk-based, non-random, sampling to focus on establishments with the most positive Salmonella samples *and the greatest number of samples with serotypes of human health concern, as defined by CDC. In addition, under the improved poultry slaughter inspection system, all young chicken slaughter establishments in Salmonella Verification Testing Category 3 will be scheduled for a food safety assessment (FSA) and possibly intensified verification testing (IVT) to assess the status of the establishment's food safety systems. An additional risk management action was initiated in March 2008 in which broiler establishments in Categories 2 and 3 were listed, by name, on the FSIS web page in an effort to further spur individual establishments to gain greater control over Salmonella.*

Within Establishment Public Health Risk-Based Inspection

5d.) Page 5 – PHIS – It is good to have a new system that assists in identifying when establishments are not meeting standards or are not in control of their slaughter process. Figure 1. The last box states "The inspector will record answers to questions about vulnerable points and will decide if further regulatory actions are appropriate based upon responses in aggregate." The term aggregate needs to be clarified. Would an "aggregate" be two or more answers/responses that were not appropriate for control at vulnerable points or could one inappropriate response warrant further regulatory action?

The term aggregate has been removed from the report. A single observation at a vulnerable point or multiple observations may be used as support for a regulatory noncompliance.

5e.) Figure 2. Vulnerable Points needs to be in black. The example helps but it would be good to add the questions from Appendix B for Scalding to provide an example of the questions that were developed. There is also not a discussion of what the difference is between Prompt one, two and three.

FSIS respectfully disagrees with the reviewer, and believes that adding this information to the text of the report will interrupt the flow of the report.

5f.) Page 10 – First paragraph – Microbial contamination can also…This has been shown for *Salmonella*… This paragraph is unclear. Is the paragraph stating that the various pathogens and aerobic bacteria have been observed on internal and external surfaces of the carcass and then further contaminate the scalding water?

The report has been revised to clarify the discussion concerning microbial cross-contamination at the scalder.

5g.) Page 10 – Evisceration: The sentence – For example, *Salmonella*-positive carcasses have been seen to increase 2.4 percent during evisceration…It is unclear does the 7.0 log increase of *Campylobacter* come from direct exposure to intestinal content? Or is can the intestinal content have 7 logs? Also, does the *Campylobacter* count increase on the skin samples by 278 MPN/100 cm^3 and 0.41/1000 cm^3?

The report has been revised to clarify the discussion.

5h.) Page 11 – Paragraph – One of the main control measures for evisceration. On-line reprocessing is an automated washing system that may use antimicrobial agents…Suggest providing examples of those agents.

Examples of the use of trisodium phosphate and other antimicrobial agents are provided in the text.

5i.) Page 11 – Paragraph – The addition of antimicrobial…Suggest spelling out TSP.

The text was revised to indicate that TSP is trisodium phosphate.

5j) Suggest inserting a table after the literature review section…Developing a table that lists the main processing steps and microbial contamination observed, the effective intervention strategies and parameters, and results observed in regards to reductions of specific pathogens would assist establishments in identifying appropriate control mechanisms and critical limits.

FSIS respectfully disagrees. This information is presented in the literature review section. FSIS believes that inserting a table in the body of the report would interrupt the flow of the discussion.

Across Establishment Ranking Algorithm

5k.) Page 12 – Algorithm parameters – Suggest either explaining the 3 *Salmonella* categories and 4 *Listeria* RTE categories here or a note to see the glossary (see more about the addition of a glossary on page 7).

The report has been revised to point the reader to Appendix D for additional information about Salmonella Verification Categories, E. coli O157:H7 testing and the Listeria monocytogenes alternatives.

5l.) Page 14 – Production Volume – The approach of focusing on establishments with larger volume is valid. However, there is also concern that smaller establishments with lower volumes may be more at risk because they may not have implemented adequate intervention strategies for controlling microorganisms. Therefore, it may also be important to look at size of plants in regards to risk and implemented effective intervention strategies.

Production volume is not used as a factor in separating establishments into one of the three levels of inspection. The factors used in the public health risk ranking algorithm to separate establishments into three level of inspection are indicators of how well an establishment's food safety process control systems are performing. Thus, it does not matter how large or small an establishment is, if there are indications of a lack of process control, the establishment will receive more focused inspection. Volume is only used in LOI 2 and LOI 1 to rank order establishments with similar indicators of loss of process control,

5m.) Page 14 – Attribution – This section provides no reference to Appendix A and the work that was put into developing the algorithm. It also points out many limitations of outbreak data, case studies, risk assessments, expert elicitation. The explanation focuses mostly on the limitations of each set of data? A question could be asked then why use the data? Or can the combined data work? More discussion needs to be included that explains the value/benefit of each data set and how data can be used collectively to determine what foods are vehicles for specific pathogens and at what levels.

A statement referring to Appendix A has been inserted into the text. More discussion of the value of the data sources has been given.

5n.) Page 16 **–** Public Health Significant NRs – Specifically, each regulatory requirement was categorized into one of four categories…Suggest defining the four categories in the text or adding a statement "refer to glossary."

FSIS respectfully disagrees with the comment, and believes that inserting the requested information into the body of the report would interrupt the flow of the discussion. Additional information on public health significant NRs is presented in Appendix D.

5o.) The research by Carnegie Mellon University does demonstrate that the current inspection system is effective in reducing the presence of *Salmonella* by writing NRs and also by monitoring for zero tolerance. Therefore, it is appropriate to have establishments with more NRs and W3NRs receive more enforcement. Also, the question approach in Appendix B would assist both regulatory authorities and establishments in determining better control and monitoring mechanisms for microbial contamination.

No response needed

5p.) Page 18 – Class I. It would be better to have an example related to *Salmonella* in poultry rather than a focus on *E. coli* O157:H7 in ground beef. As this report focuses on the Poultry Slaughter Process, what type of products from poultry would be used to determine that loss of control has occurred in a slaughter establishment?

Performance related to generic E. coli control is being considered as one indication of insanitation in a poultry slaughter process.

Salmonella Performance Standards/Serotypes

5q.) Page 19 – *Salmonella* Performance Standards – The *Salmonella* standards focus on both broiler carcasses and ground chicken. However, is there any benefit to also having *Salmonella* standards for fabricated cuts since very few broilers are sold as whole carcasses?

In calendar year 2008, FSIS intends to begin the process of designing a baseline study in order to address fabricated poultry cuts (parts). As the Agency examines the data, FSIS may consider development of a new standard for fabricated poultry products.

5r.) Page 20 – *Salmonella* Serotypes – Further clarification is needed to discuss how the serotype data will be used. For instance: if an outbreak occurs and is *Salmonella* and a specific serotype could this then be linked back to an establishment that had positive *Salmonella* with the same serotype? There could also be discussion added on what are some of the typical serotypes found in poultry.

FSIS is in the process of determining how to fully use the Salmonella serotype data that is now being collected. The Agency plans to use Salmonella serotype data in the improved poultry inspection system to link an establishment to a foodborne outbreak and to help improve its foodborne disease attribution estimates for poultry products. In addition, FSIS will be sharing the information with the establishment in an effort to assist in identifying associations with particular source material suppliers.

Ranking Algorithm

5s.) Page 20 – Overview of the Public…Second, establishments in the category of focused inspection (LOI 2) are rank ordered. More information is needed to determine levels of potential public health impact. May refer to page 25 for more details.

The report was revised to add the suggested cross-reference.

5t.) Page 21 – Figure 5. Does a line need to be drawn between "Separate Establishments Based on Food Safety Process Control Indicators and the LOI1, LOI 2, and LOI 3 boxes? Does a line need to be drawn between "Rank LOI 2 Establishments Based on Potential Public Health Impact" to the lines after the LOI 2 box?

Figure 5 has been changed to incorporate this suggestion.

5u.) Pages 21-23 – Levels of Inspections – This section is very well defined and is a sound approach to separating out the three levels.

No response necessary.

5v.) Page 24 – Box 1. It would be helpful to have the number of plants and percentages for the data discussed as in the Resulting Levels of Inspection data. It would be better to put the Box 1 after the discussion on the ranking algorithm verification on page 24. It is

easier to understand the whole box after reading everything related to levels of inspection.

FSIS respectfully disagrees with the suggested changes about information content and placement. However, the document has been revised to add more examples.

5x.) Page 27 – *Salmonella* Verification Testing - As of December 2007, 74 percent of broiler establishments…Again, it would be helpful to provide both the percent and the number of plants. Also, how would data be categorized if looking at the volume produced by establishments and the size of an establishment? Is there any type of trend?

The number of plants has been added to the document.

5y.) Page 27 – Table 1 – Could the number of samples tested be added? For example 3% (3 of 100) samples were positive for *Salmonella*.

The requested information has been added to the document.

5z.) Page 27 – Table 2 – Is this data then used to define the numbers of plants in LOI 1, LOI 2, and LOI 3 as in Box 1 under W3NR Rate? It is much clearer defined in the box then in the Table.

Yes, cut points for public health related NRs (W3NRs), along with the other criteria, such as Salmonella verification test results and recalls, are used to define the numbers of plants in LOI 1, LOI 2, and LOI 3. More discussion has been added to the text.

6a.) Page 28 – Levels of Inspection – From the new ranking algorithm, does FSIS thinks the data warrants the higher number of plants that need to be in LOI 2? This is a question that will need to be answered from both a public health basis and a cost factor. Will further ranking of the establishments in LOI 2 reduce some of the intensified inspection?

The number of establishments in LOI 2 depends on the cut-points used. Different cut-points may be used for different food product classes. A cost benefit analysis is beyond the scope of the technical report.

Proposed Public Health-Related Performance Standards

6b.) Page 28 – Zero Tolerance for Fecal Contamination – This new policy doesn't change what plants should be doing to address fecal contamination and is scientifically sound.

No response necessary.

6c.) Page 29 – Septicemic and Toxemic Animal Diseases – Once an establishment addresses zero septicemic or toxemic conditions in their HACCP plans then a system must be in place to monitor for those conditions. There is concern that establishments will need to additionally train personnel or hire a veterinarian to monitor carcasses. What will the cost be to small and very small establishments? Also, establishments may

address septicemic and toxemic conditions in their HACCP plans but then state that an FSIS inspector monitors this issue and determine this to be an adequate control mechanism. There should also be concern from public that FSIS is no longer having a comprehensive inspection system that focuses on both diseases and microbial contamination.

The proposed rule, when published, will contain a regulatory impact section which includes cost-benefit analysis with a specific focus on small and very small plants. Generally, FSIS expects that establishments that are currently under traditional inspection (CFR 9 381.67; Young Chicken and Squab Slaughter Inspection rate Maximums under Traditional Procedures) would stay as traditional systems and, therefore, the FSIS inspectors would continue to inspect carcasses for septicemia/toxemia. The planned new inspection regarding the vulnerable points would take place by all inspectors in all poultry slaughter plants as described in this report.

6d.) Page 29 – Generic *E. coli* – A summary of analyses of the data and further explanation of the performance standards are presented in Appendix E…Suggest discussing the general findings of the study and the reason the data supports implementation of the new proposed rule. Generic *E. coli* sampling and testing has been done by the plants to reflect sanitation of their process. However, the new proposal doubles the amount of sampling/testing. The cost impact of this should be considered for the establishments especially small and very small operations. It will also be important to have training material available that address correct sampling procedures for both points in the process (rehang and post-chill). For the data to be useful, sample collection, shipping, and analysis need to be well defined and consistent.

The generic E. coli sampling is not expected to result in an increase in the number of samples required to be taken by the establishment; instead the number of samples likely will be divided among the two sampling points—one at rehang and one at post-chill. The report will be changed to clarify this.

6e.) Page 30 – In addition, instead of an advisory performance standard, a non-advisory performance standard could be set…This paragraph is unclear in regards to how non-advisory would be defined. What would be the implications under non-advisory if a plant would not met the reductions in generic *E. coli* levels from rehang to post-chill? The approach of conducting a risk assessment and economic analyses is appropriate and to further determine what is happening from a microbial aspect.

If through FSIS testing an establishment was found to exceed the performance standard at post chill for generic E. coli, the Agency expects to propose that it will issue an NR. This has been clarified in the report.

6f.) Page 31 – *Salmonella* and *Campylobacter* – It is very valid that the *Salmonella* performance standards need to be reviewed and a new baseline survey conducted to improve the timeliness of data for setting standards. *Campylobacter* is often a hard microorganism to isolate and recover. Therefore, it would be best to wait on the data from the survey to determine the presence/absence of *Campylobacter* on samples and to

also make sure the methods are well developed for sampling and analyzing this microorganism. By testing for another pathogen, there are also cost factors associated that will need to be addressed. What training will be provided by FSIS to educate establishments about sampling and testing procedures for both pathogens?

FSIS is considering using data available from its broiler and its turkey baseline studies to develop a Campylobacter standard and intends to also use this data to refine its Salmonella performance standards. The proposed poultry rule will include a cost-benefit analysis. FSIS intends to train the inspection workforce on the sampling and testing procedures for these pathogens.

6g.) The proposal of making testing of both *Salmonella* and *Campylobacter* mandatory is of concern. From a consumer standpoint, establishments are left testing for two serious pathogens linked to foodborne outbreaks. The consumer may be concerned about how those samples are taken and analyzed and how valid the results are since establishments are performing the tests. With FSIS testing for *Salmonella*, there were specified laboratories analyzing samples for *Salmonella*. In addition, all samples were collected, shipped, and analyzed according to defined procedures by FSIS.

FSIS will verify that establishments have appropriate procedures. Establishments, generally, are not required to use the same laboratory procedures used by FSIS. Oftentimes, establishments use procedures that are more specific or sensitive. However, establishments using procedures that are different are expected to demonstrate that they have proper supporting documentation.

6h.) There is a cost factor associated with sampling and instead of one pathogen, it will be two. What will the impact be for small and very small processors? How will FSIS ensure the integrity of the data that plants are providing? How will the sampling and testing procedures be specified? Establishments may also drop data if the results are not favorable? Do the plants then self-report if they are not meeting performance standards? These are some questions that need to be addressed further before moving forward with mandatory testing by establishments.

The Salmonella Incentive Program (SIP) is voluntary, so small and very small establishments can elect whether or not to participate in the program and, therefore, do not need to incur any additional cost. FSIS is working to develop procedures to ensure data integrity. Under SIP, establishments will be required to sample daily for Salmonella and weekly for Campylobacter as specified in FRN January 28, 2008, plants will not be required to notify FSIS if they have exceeded the performance standard. They are expected to monitor and take corrective actions. FSIS inspectors in the field will verify establishments are carrying out their testing procedures and taking proper corrective actions. Presently, FSIS inspection personnel are required to meet with management officials weekly. FSIS expects to take steps to strengthen the content of these weekly meetings so that testing results by the establishment will be more fully discussed.

Enforcement Strategy

6i.) Page 31 – Enforcement Strategy – There is no reference to Table 4 in the text. In Table 4. Further explain what is meant by "Traditional Inspection."

This reference has been added to the text. The section on enforcement has been revised. Traditional inspection refers to the existing inspection done by FSIS under CFR 9 381.67 (Young Chicken and Squab Slaughter Inspection rate Maximums under Traditional Procedures).

6g.) Page 32 – Further explanation of what is meant by the phrase "removed from the program to traditional inspection" under both Failure to test for *Salmonella* by the establishment and Failure to test for *Campylobacter* by the establishment.

Further explanation of this phrase has been added to the text. Traditional inspection refers to the existing inspection done by FSIS under CFR 9 381.67 (Young Chicken and Squab Slaughter Inspection rate Maximums under Traditional Procedures).

Prompts

6h.) Appendix B – The questions are useful but a concern is that they do not have enough detail or suggested limits to assist the inspector. The information obtained from the literature review would be useful to improve this document and set of questions. Below are some suggestions. The document may also want to include a statement about reviewing control measures or critical limits as specified in a HACCP plan. Providing the additional data about effective critical limits observed in scientific studies may further assist in having the establishments implement a more effective pH level or temperature for controlling microorganisms during scalding.

The questions have been revised to guide inspectors thinking to ensure that establishments are implementing control and preventive measures at vulnerable points according to their HACCP, SSOPs, SPS, and prerequisite programs.

Further guidance and training will be developed for inspectors to assist them in making decisions about regulatory compliance when carrying out inspection procedures at vulnerable points. The improved poultry slaughter inspection system has been designed to reinforce the food safety regulatory training that inspection program personnel currently receive.

6i.) Under Scalding…Does the establishment have control mechanisms to reduce…?
A list of effective intervention strategies or scalding parameters would help the inspector determine this.

The reader is referred to the response for comment 6h.

6j.) Does the establishment have controls to maintain the optimum pH levels to reduce *Salmonella*? Provide some ranges that have proven effective.

The reader is referred to the response for comment 6h.

6k.) Does the establishment have controls to maintain water temperature effective to reduce microorganisms? Provide ranges that have proven effective.

The reader is referred to the response for comment 6h.

6l.) Does the establishment implementing prerequisite programs at scalding, as per their hazard analysis? Is there adequate supporting documentation?
Provide good examples of supporting documentation and what information is in a prerequisite program.

The reader is referred to the response for comment 6h.

Peer Reviewer No. 4

Review of USDA proposed poultry slaughter.

Some general comments:

7a.) While it makes sense to talk about a generic slaughter facility and there is some general discussion about the fact that most facilities are pretty similar, I think it would be important to quantify the degree of similarity. Is it possible that facilities could vary according to their "vulnerability points"?

The steps in the poultry slaughter process are highly similar across different establishments. Poultry slaughter establishments may differ in terms of the interventions in place at steps in the slaughter process. FSIS has developed the within establishment component of the improved poultry inspection system to take into account differences in interventions across establishments.

7b.) In many places, the text is vague in terms of efforts to describe increases and decreases, and needs to be more specific in order to make sense. For example on page 10, the following phrase is ambiguous: "For example, *Salmonella*-positive carcasses have been seen to increase 2.4 percent during evisceration (Lillard 1990)". Is this an additive 2.4% increase? A multiplicative increase? What is the baseline? Is 2.4% important? Another example occurs on page 11: The text states "Notermans et al. (1980) found that the incidence of *Salmonella* positive carcasses decreased 36.5 percent when carcass rinses were incorporated into the evisceration process compared to a 20.5 percent increase without carcass rinses. " How should this 36.5% be interpreted? Additively? Multiplicatively? What is the baseline?

The literature review in the main body of the report is intended to describe broad trends. The reader is referred to Appendix C for a more detailed write up of the existing literature on poultry slaughter.

7c.) Overall, I find the document hard to follow. I think it requires a fairly detailed knowledge of the system in order to follow the logic clearly. Depending on the audience, this may or may not be a problem.

FSIS has revised the improved poultry slaughter inspection report in response to comments from peer reviewers, stakeholders, and NACMPI. The Agency believes these revisions have improved the readability of the document.

Some specific comments:

7d.) Page 3: I like the way the goal is expressed in terms of the percentage of establishments that classify as category 1 by various time points. It is well quantified and easy to assess. It is important to keep variability in mind. For example, it would help to give confidence intervals for the percentages of positive samples in *Salmonella*

verification testing: it is not possible to evaluate whether a reduction from 16.3% to 11.4% means anything otherwise.

As FSIS gathers additional data and develops improved methods for performance measure calculations, it will consider alternate reporting formats to improve the transparency of its measures.

7e.) Page 5: Figure 1 is hard to read. I think the font might need to be larger. The same comment applies for most of the figures.

FSIS has had the document professionally edited to improve readability.

7f.) Page 5: What is the difference between a "critical control point" and a "vulnerability point"?

A Critical Control Point (CCP) is a point at which a microbiological, chemical, or physical hazard is reasonably likely to occur. A vulnerable point is a point at which microbial growth or contamination may occur if process control is not maintained. A vulnerable point may be a CCP.

7g.) Page 6: The second paragraph includes one extremely long sentence that is difficult to follow. It may be worthwhile polishing the paragraph and breaking into several different sentences.

FSIS has revised this section of the report.

7h.) Pages 9 onwards (literature review) are very helpful. However, some additional detail could be useful. For example, what does the literature say about some of the specific controls that can make the scalding step more effective? I would guess that things such as water temperature, duration of the scalding process etc make a difference. Does the literature address these points at all? The section on "on-line reprocessing" (page 11) provides a good example of a suitable level of detail. Detail related to chilling is pretty minimal (Page 12).

The reader is referred to Appendix C for further details from the poultry slaughter literature.

7i.) Page 12: please define "organoleptic (sensory) inspection" in more detail. Exactly what does this mean?

Organoleptic means using all of the senses (sight, taste, touch) for product inspection. Organoleptic is referred to in the report because it was the sole form of inspection used prior to the development of microbiological testing.

7j.) The list of items on page 13 (volume, inherent risk etc) make general sense, but the reader is left wondering exactly what these items mean. The items are described in more

detail a few pages later, so it might be wise just to add a sentence indicating the definitions and details will be provided shortly.

A sentence has been added to clarify the issue.

7k.) I don't follow the argument about attribution. It certainly makes sense to talk about the challenge of ranking risks associated with different types of food. But for the purpose of risk-based inspection of chicken slaughter facilities, wouldn't they all have the same attribution? Or do the facilities vary according to the types of poultry products they distribute? This needs clarification.

Yes, all chicken slaughter facilities have the same attribution. However, it is necessary to discuss the issue since attribution and volume will be used to rank order establishments of all types within LOI 2 and LOI 1, when the algorithm is applied to all processing and slaughter establishments.

7l.) Page 18: The section on "*Link to an Outbreak"* needs more detail. The section states: "Any establishment that is linked to a disease outbreak will receive a higher ranking." How would that outbreak linkage be established?

CDC monitors foodborne disease outbreaks on a national level. A "link to an outbreak" can be established by identifying specific food products associated with the outbreak and tracing these products back to the establishment that produced the product.

7m.) One concern with several of the proposed measures of "loss of process control" is that more well run companies might be more likely to have a qualifying event. For example, recalls: would it be possible that a more responsible and organized company might be more likely to detect a problem and thereby do a recall?

Most of the proposed measures of "loss of process control" are parameters that are determined by FSIS activities. For example, FSIS conducts the Salmonella verification testing and evaluates the facility on a daily basis for compliance with federal regulation (NR rate). A recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems. While recalls are voluntary, recalls often result for observations made by FSIS or CDC, such as product contamination or illness outbreaks. FSIS monitors all recalls of meat and poultry products produced by Federally-inspected establishments.

7n.) The planned new Public Health Information System (PHIS) sounds interesting. A little more information would be helpful. For example, who would fill this out? The facility itself or the USDA inspector?

The USDA inspectors will enter data into the information infrastructure on a recurring, timely basis similar to how procedures are documented now.

7o.) Top of page 20: "FSIS inspection personnel verify that establishments are meeting the standards by collecting randomly selected product samples… "How are the random

samples selected? How many samples per establishment? Do the number of samples vary by establishment size? Are their guidelines?

Appendix D describes the Salmonella verification testing program. The number of samples in a sample set depends on the product being sampled, but not on the establishment size. For example, for a facility processing young chicken carcasses, 51 samples are collected on 51 successive days when the establishment is slaughtering young chickens. Depending on frequency of production, product type, and availability of resources, the time to complete a set ranges from two months to over a year.

7p.) On page 23, there is discussion about identifying establishment is in lower percentile of percent positives on most recent *Salmonella* verification testing. For this to be meaningful, I think it is important to make sure that the *Salmonella* verification testing is based on adequate random sampling. I am not sure what the guidelines are on there nor exactly where it is discussed.

Establishments are not selected on a random basis for sampling. Product within an establishment is however selected on a random basis for sampling.

Since 2006, establishments are scheduled for Salmonella verification testing using risk-based, not random, criteria. Those criteria are intended to focus FSIS resources on establishments with the most samples positive for Salmonella.

7q.) Identification of a facility as category LOI1 relies on things such as NR rate etc. How is NR rate computed? Is there are standardization? If so, what is the denominator? If not, wouldn't this mean that small establishments might be more likely to be LOI1?

The W3NR rate is number of health related noncompliances in a given time period (i.e. one month) divided by the total times the FSIS inspector checked for compliance with health related NRs at the facility. The W3NR is a rate (percentage) and thus is standardized.

7r.) I find Box 1 a bit confusing. On the one hand you say that according to 2006 criteria, 49% are in LOI1 and 41% in LOI2, but then in the next section you say that 70% of the 128 facilities are in LOI1. I must be missing something here.

This part of the text has been modified to make it clearer.

7s.) I find some of the discussion on page 27 confusing also. I think part of the confusion is that sometimes you are talking about percentiles based on the 2006 data, other times you are talking about the sample of 128 facilities.

This part of the text has been modified to make it clearer.

7t.) A minor point is that the text states that the percent positives on the Salmonella verification sample set has a mean of 10.9 percent and then refers to Table 1. However,

table 1 does not show the mean, but only the quintiles. A similar concern applies for table 2.

One can tell by looking at Table 1 that the mean falls in the 3rd quintile.

7u.) Page 33 and 34: Since testing will be risk-based, I wonder if this will impact on the Agency's ability to estimate prevalence. If you allow for the possibility of false negatives (i.e. missing a true contamination event), then I think the risk-based sampling paradigm may lead to a biased estimate of prevalence. I would need to think about this more.

The Salmonella verification test results provide data on the rate of Salmonella positives in the samples analyzed across years. The sampling protocols were not designed to assess the national prevalence of Salmonella in FSIS-regulated products. Neither the random sampling conducted prior to 2006 nor the risk-based sampling conducted after 2006 take into account the production volume. Therefore, the results do not provide a good estimate of the prevalence of Salmonella in the nation's supply of those products tested. The data can, however, provide some indication of the changes in the number of establishments in the various Salmonella verification categories over time.

FSIS performs Salmonella baseline studies to determine prevalence. The results of nationwide baseline studies can be used to provide valid estimates of the prevalence of certain pathogens of public health concern and to permit valid statistical comparisons to be made over time. A 12-month Young Chicken (Broiler) Baseline Study is currently in progress, and additional baseline studies are under development.

PUBLIC COMMENTS

Public Comment No. 1

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February 6, 2008

National Advisory Committee on Meat and Poultry Inspection
United States Department of Agriculture
Food Safety and Inspection Service
14th & Independence Avenue, SW.
Room 1180--South Building
Washington, DC 20250.

Re: Comments on Public Health Risk Based Inspection System

On behalf of various clients, we respectfully submit these comments in connection with the National Advisory Committee on Meat and Poultry Inspection (Advisory Committee) public meeting and the consideration of the Public Health Risk Based Inspection System for poultry slaughter (PHRBIS)

As an initial matter, we support modernization of inspection based on public health criteria. In reviewing the materials, we noted the absence of any real discussion of the agency's Salmonella Initiative Program (SIP). Given the relationship between SIP, presented in an embryonic form to the Advisory Committee in October of 2006, and PHRBIS, we find the absence of any discussion curious and would recommend the complete SIP story be considered by the Committee.

In brief, when FSIS Salmonella numbers for broilers were close to 20%, the agency published a Notice in the February 2006 Federal Register. FSIS, through this Notice, indicated that it would consider both positive and negative incentives based on how the industry responded to these historically high Salmonella levels. As a positive incentive, FSIS was open to permitting increased line speeds at establishments demonstrating superior Salmonella control. As a negative incentive, FSIS promised to post individual establishment's Salmonella results unless a certain percentage of the industry was at one-half the Salmonella performance standard.

Realizing the impact of the historically high levels, many in the poultry industry took action to reduce these levels in anticipation that: (1) the positive incentives would provide on-going motivation to maintain Salmonella control efforts and (2) the incentive would motivate all in the industry to improve performance.

In only one year, both industry and FSIS Salmonella incidence rates for broilers were reduced by over 50%. In only one year, industry went from historical highs to historical lows. But this improvement came at a price. The average cost to reduce Salmonella incidence is approximately $500,000 per plant per year and this does not include the costs attributable to industry's intensive

Salmonella testing. We must note that now, in the vast majority of cases, this money is not being spent to comply with the performance standard or even to achieve Category 1 status, but to reduce incidence levels from 8 to 10% down to 0 to 2%. Absent positive incentives, establishments expending such resources are at a competitive disadvantage in the marketplace.

Given the success of a promised positive incentive, we are disappointed by the recent Federal Register Notice on SIP. There is the promised negative incentive, posting of at least Category 2 and 3 plants. Regrettably, there are new and multiple negative incentives affecting not only all broiler establishments, but (and this is beyond these comments) all species and products subject to a Salmonella standard.

For establishments with on-line reprocessing systems (OLR) (virtually every broiler establishment), under the plain language of the Notice, FSIS will unilaterally terminate OLR at any establishment in Category 2 or 3. Termination of an intervention cannot be desirable from a public health perspective. From a legal perspective, such a termination is inconsistent with the express terms of the waivers which specify when termination can occur; nothing in the waiver justifies termination simply on the basis of Category status.

Likewise, for establishments under the HACCP-based Inspection Model Project (HIMP), the Notice, as written, provides that FSIS will unilaterally terminate permission to operate under this project at any establishment in Category 2 or 3. Once again, an action is contrary to the termination provisions of the contract between the HIMP establishments and the agency.

Even for establishments operating in Category 1, FSIS will impose increased costs of doing business. As a condition of operating an OLR system, remaining in HIMP, or maintaining/receiving any other food safety waiver, an establishment must agree to conduct this additional sampling. Although the number of analyses it limited, the costs of each represent additional thousands of dollars per plant per year.

To be sure, there is a positive incentive for line speeds but the incentive is limited to five plants, through the addition of inspectors.

We have reduced Salmonella incidence and have expended significant resources. We will continue to improve Salmonella control, but:

- We will not submit to termination of waivers on grounds not specified in the approval of those waivers.

- We will not agree to an additional waiver provision to conduct expensive testing to provide the agency with data, especially when the agency has not demonstrated a need for, nor a planned application of, such data.

If FSIS extends not only the comment period, as we understand was suggested by a committee member during the public meeting, but also delays implementation of the provisions dealing with termination of waivers and additional sampling, we are confident the agency will reconsider its position on the issues we have noted and update its current thinking on SIP.

Otherwise, we will vigorously oppose SIP, as currently written, in each and every forum available to us.

On the issue of PHRBIS generally, to paraphrase a comment made last year by another stakeholder on RBI, the new system is "not ready for prime time." That said, as we all proceed to modernize inspection, we hope the agency, the Advisory Committee, and all stakeholders will consider the SIP story and the effectiveness of a positive incentive approach.

It is said that when the penalty for failure far outweighs the reward for innovation, the best one can hope for is mediocrity. We cannot settle for a modern inspection system that is anything other than superlative.

Thank you for your consideration of these views.

Respectfully submitted,

Dennis R. Johnson

OFW:drj

8a.) *FSIS has added additional information regarding the Salmonella Initiative Program (SIP) to the Technical Report for Improvements for Poultry Slaughter Inspection. After receiving comments on the January 28, 2008 Federal Register Notice (FRN) on Salmonella policies, including the SIP, FSIS informed stakeholder informally that the comment period would be extended; FSIS is still working on publishing an official notification*

Public Comment No. 2

COMMENTS ON THE FOOD SAFETY AND INSPECTION SERVICE PROPOSALS TO MAKE BASIC CHANGES IN PROCESSING AND SLAUGHTER INSPECTION

Submitted by
CONSUMER FEDERATION OF AMERICA

RE: Docket No. FSIS-2008-0003]

March 24, 2008

9a.) The papers presented to the NACMPI continue USDA's inappropriate claims about its *Salmonella* data and CFA, again, urges the FSIS to cease misusing the *Salmonella* verification data as representing the national prevalence of contamination, asserting that the *Salmonella* performance standard is public health based, and attempting to mislead the public by arguing that the fact that most plants are able to meet the *Salmonella* performance standard is responsible for a reduction in some types of foodborne illness.

FSIS does not believe that the Agency's laboratory verification testing provides true prevalence data. The Agency does believe that its verification data can be used to estimate population exposure. The Agency volume adjusts its percent positive rate from FSIS verification data to make the results more representative of population exposure. FSIS is studying what is occurring in plants and at retail to better understand how each step from farm to table contributes to foodborne illness.

9b.)) Among the issues the FSIS must address in developing a public health based program are the following: **CFA urges the FSIS to stop relying on misuse of the *Salmonella* verification testing data to justify its programs and stop making inappropriate claims about what the *Salmonella* data represent.**

The reader is referred to response 9a. FSIS does use its verification testing to measure performance. In addition it uses this data to inform program development, such as the SIP. As FSIS collects enumeration and serotype information, it will use this data to inform its policies and measure its performance.

9c.) The FSIS continues to cite data from verification testing as though it represents a national prevalence the data represent only what happened in one plant on one day—the day the tests were taken. The hazard identification in the risk assessment begins by citing the summary of data from the FSIS routine testing program. The FSIS exposure assessment states "*Prevalence* of *Salmonella* on young chickens in slaughter establishments was determined using data from the FSIS microbiological baseline data collection from the years 2003 through 2005. (Draft Risk Assessment, Nov. 2007) (emphasis added). The Office of Inspector General and the National Advisory Committee on Microbiological Contamination have both told THE FSIS it cannot

legitimately cite the data as national prevalence data. (National Advisory Committee on Microbiological Criteria for Food, Response to Questions Posed by the FSIS Regarding Performance Standards for Food (Broilers), Feb. 14, 2004, page 12.)

The Agency recognizes that PR/HACCP Salmonella verification testing results do not represent nationwide prevalence data, and the data are not presented as such. However, this is a valuable data set, representing more than 40,000 samples annually. In this risk assessment FSIS risk analysts used commonly accepted quantitative methods (i.e. the Beta Inverse function) to estimate establishment-level prevalence, and with this information extrapolated to a national prevalence based on weighted production volume. This information was integral in estimating the relationship between the percentage of samples testing positive for Salmonella, and human illness.

9d.) The *Salmonella* performance standard is not a public health based standard but is a reflection of the industry's capacity to control *Salmonella* a dozen years ago. It is an industry performance based standard, a reflection of industry's ability to control process. The HACCP regulation established the *Salmonella* standard at a number that half of the industry was able to achieve. There were no data then or now to relate the performance standard to a public health objective.

FSIS is monitoring its performance in relation to the Healthy People 2010 goals. As of the second quarter of 2008, FSIS estimates it met the Healthy People 2010 goal for Salmonella illnesses from broilers. FSIS will use the SIP and baseline data to evaluate and refine performance measures.

9e.) Further, the *Salmonella* standard has not been updated since the baseline data for the HACCP regulation 12 years ago. It has in fact become an obstacle to improving industry process control. Because it has not been changed it permits slackers to continue to do just enough to meet the industry "average" of 12 years ago.

The reader is referred to response 9d.

9f.) Even if the *Salmonella* data represented the prevalence of carcasses contaminated with *Salmonella*, it would not be an accurate picture of the human health risk from *Salmonella* because the performance standard only reflects the number of carcasses that are contaminated, not the level of contamination on each carcass.

FSIS does not currently use enumeration to measure Salmonella performance and the data are not currently available for this application. FSIS may consider using enumeration data to inform its performance standard as it analyzes data from the SIP and other Agency initiatives.

9g.) At some level the risk of illness is related to the dose of *Salmonella*, the number of organisms present on a carcass. THE FSIS acknowledges that it has no enumeration data at all. Page 45 of the draft risk assessment speaks optimistically that these data will be forthcoming, some day, but the Agency proposes to begin the program without having any idea of the level of *Salmonella* contamination on poultry. In the absence of the most

basic public health related data, the Agency cannot justify referring to this as a public health based program. The FSIS continues to assert that reductions in levels of *Salmonella* found in verification testing, compared to the beginning of the HACCP program, are directly related to reductions in foodborne illness.

The reader is referred to the response for 9f. FSIS does believe that the Salmonella verification testing program is public health based because reducing Salmonella on products will reduce human exposure to a recognized foodborne pathogen.

9h.) While *Salmonella* related illnesses declined immediately after HACCP was introduced, the number of illnesses per hundred thousand population have not continued to decline. The CDC FoodNet Report for 2006 stated that *Salmonella* and E. coli O157:H7 are, despite initial declines after HACCP near the baseline levels. If there is a relationship between the *Salmonella* performance standard and the rate of *Salmonellosis* cases, it would appear to be going in the wrong direction.

The reader is referred to response 9d.

9i.) **CFA stresses that the FSIS must not move forward on any program it calls, "public health based" without fully integrating the risk from *Campylobacter* and implementing programs specifically designed to control it.** The FSIS plans for processing and slaughter inspection changes completely ignore the risk to human health created by *Campylobacter.*

FSIS plans to use data available from its broiler baseline study (and turkey baseline when available) to develop a Campylobacter advisory standard. When Campylobacter testing data become available, the Agency will utilize this information for ranking establishments with the public health risk ranking algorithm.

9j.) The FSIS (citing Mead, et al, 1999) acknowledges that *Campylobacter* is the most common cause (47%) of bacterial foodborne illness in the U.S. but ignores the pathogen in its risk assessment and program structure. The CDC reports that *campylobacter* is associated with 2 million cases of foodborne illness each year, twice as many as S*almonella*. In its FoodNet Report for 2006, the CDC stated that progress in reducing the number of cases of *Campylobacteriosis* has stalled, with no improvement since 2001. Poultry is the food most commonly associated with *Campylobacter* contamination.

The reader is referred to response 9i.

9k.) Yet the FSIS in developing a program that it claims is related to protecting public health, has constructed a risk assessment that excluded any consideration of illness caused by *Campylobacter*, has designed a program that has no steps to control *Campylobacter,* and has established no performance standard for *Campylobacter*.

The reader is referred to response 9i.

9l.) The FSIS says it will establish performance standards for *Campylobacter* at some future time but it is not likely to be soon. The HACCP program used *Salmonella* as the standard for process control because when the program was first adopted, the Agency thought *Salmonella* was the most common cause of bacterial foodborne illness. At least as early as 2000, the FSIS learned that *Campylobacter* caused more illness than *Salmonella*. At one point the Agency had a major program underway to address *Campylobacter* concerns and set a performance standard but the Agency has never taken action to implement controls. The Agency began promising to collect and report *Campylobacter* baseline data ten years ago and still does not have it. It tried to collect the data in 2001 but stopped. In 2004, the NACMCF told the Agency how to do the collection. THE FSIS made another effort in 2005 and sent out instructions to inspectors for collecting the data. The instructions were withdrawn with no public explanation as to why. New instructions were sent out in May of 2007. It is now 10 months later and the Agency can say only that the data are being collected not when it will have them complete. The Agency also promises a performance standard for *Campylobacter* but does not state when it will be established, nor how it will be shaped to be a public health based rather than an industry capability standard.

The reader is referred to response 9i.

9m.) Because it has not been able to manage an attack on this very serious pathogen, the FSIS has constructed a program that ignores it. There is no justification for proposing something called a public health based" program without having mechanisms for controlling *campylobacter.*

FSIS acknowledges the public-health significance of Campylobacter. The Agency intends to address Campylobacter control through an advisory performance standard for the pathogen in the proposed rule that would be implemented in an approach similar to that for Salmonella (i.e., verification tests will be collected by FSIS and establishments would be placed into categories regarding their degree of control for this pathogen). The reader is also referred to response 9i.

9n.) The proposed programs for poultry slaughter relate only to generic E. coli and *Salmonella* control. Controlling *Salmonella* does not assure that *campylobacter* will be controlled.

The reader is referred to response 9i.

9o.) The FSIS proposes to permit plants to increase their line speeds if they can show control of *Salmonella* but give no consideration to the illnesses that may be caused if these actions increase the levels of *Campylobacter.*

Establishments in the improved poultry slaughter inspection system would be required to demonstrate control for Campylobacter and Salmonella while participating in the program. Establishments that do not maintain adequate control would be expected to conduct intensified verification procedures, including providing FSIS with information about the pathogens so that the information can be placed into PulseNet.

9p.) The decision not to include consideration of illnesses caused by *campylobacter* is a reflection of the FSIS's imperative to develop and implement a program before it has adequate data on which to base it.

FSIS acknowledges the public-health significance of Campylobacter. The Agency intends to include provisions for this pathogen in the proposed rule. Establishments in operating under the improved inspection system would be required to control for Campylobacter and Salmonella as part of their continued participation in the program. When Campylobacter testing data become available, the Agency will utilize this information for ranking establishments with the public health risk ranking algorithm.

Public Comment No. 3

Center for Foodborne Illness Research & Prevention (CFI)
P.O. Box 206 Grove City, Pennsylvania 16127

March 24, 2008

U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW
Room 102 Cotton Annex
Washington, DC 20250

Re: NACMPI meeting on February 5th & 6th, 2008 on Public Health, Risked Based Inspection System (PHRBIS) for Poultry

10a.) The Center for Foodborne Illness Research & Prevention (CFI) appreciates the opportunity to comment on USDA's Food Safety & Inspection Service proposal for Public Health Risk-Based Inspection System (PHRBIS) and the National Advisory Committee on Meat and Poultry Inspection (NACMPI) meeting on February 5 – 6, 2008. These are CFI's initial comments on this issue and should not be considered complete. It is recommended that FSIS review CFI's February 2007 comments on the *Resolve Report* as many of those comments still apply.

No response necessary.

Background

10b.) CFI is a national, nonprofit health organization dedicated to preventing foodborne illness through research, education, advocacy and service. Founded in 2006, CFI hopes to lead America in creating innovative, science-based solutions for the food challenges of the 21st Century. CFI's activities are designed to develop better food protections for all Americans. CFI believes that federal, state and local government, as well as farmers; food processors/distributors/retailers; medical providers; educators; policy makers and consumers share the responsibility of building an environment that promotes food safety throughout the farm to fork continuum. No one sector can achieve this goal alone, so CFI is committed to collaboration in its efforts to improve food safety.

No response necessary.

The Impact of Foodborne Illness

10c.) Foodborne disease is a serious public health issue and the cost to American society is very high. The Centers for Disease Control and Prevention (CDC) estimate that annually, 76 million people in the United States suffer a foodborne illness; 350,000 are hospitalized; and 5,000 die. While everyone is at risk, the most vulnerable populations to

develop serious complications due to foodborne illness are children, seniors, pregnant and postpartum women and individuals with a compromised immune system.

No response necessary.

10d.) Each year in the United States, there are approximately 1.4 million cases of *Salmonellosis* that cause an estimated 400 deaths. According to USDA's Economic Research Service (ERS), each of those cases costs an average of $2,126 in lost wages and medical costs. According to another ERS report, foodborne illnesses account for about 1 of every 100 U.S. hospitalizations and 1 of every 500 U.S. deaths. In fact, the ERS estimates that each year in the United States, five foodborne illnesses -- *Campylobacter*, *Salmonella*, *E. co*li O157:H7, *Listeria monocytogenes* and *Toxoplasma gondii* -- cause $6.9 billion in medical costs, lost productivity and premature deaths. These estimates do not include many other foodborne illnesses nor does it reflect any of the hidden costs that victims and their families suffer.

No response necessary.

10e.) Further, the acute stage of foodborne disease can be only the start of the problem. The Food and Drug Administration (FDA) estimates 2 to 3 percent of foodborne illness victims develop secondary long-term medical problems, and that represents an estimated 1.5 million lingering health problems per year. *Salmonella* is one of the leading predictors for reactive arthritis, a painful, chronic and potentially debilitating condition that causes joint inflammation. *Campylobacter* is believed to be a leading cause of Guillian-Barre Syndrome, an autoimmune reaction that causes paralysis and kills between five and ten percent of its victims. *E. coli* O157:H7 and other foodborne diseases are almost the exclusive cause of HUS, the relentless condition characterized by cascading organ failure. One-third of HUS survivors will suffer life-long medical problems such as high blood pressure, diabetes, kidney failure and brain damage. In fact, HUS caused by *E. coli* O157:H7 is the leading cause of acute kidney failure in children in the United States.

No response necessary.

Public Health Risk-Based Inspection

10f.) In 2006, FSIS spent a considerable amount of time and resources eliciting feedback from food safety stakeholders on their Risk-Based Inspection (RBI) proposal. As alluded to in the *Resolve Report*, risk-based inspection is an ideal that most stakeholders recognize as a necessity for "achieving the next level of food safety." CFI believes that FSIS's new proposal for Public Health Risk-Based Inspection System for Young Chickens is simply a variation of the original RBI proposal.

FSIS began the process of developing a RBI program that would assign more inspection resources to processing establishments that posed a greater food safety risk in 2004. In 2007 the RBI algorithm underwent review by consumer groups, industry sources and the USDA Office of the Inspector General (OIG) and suggestions for improvement were

made. In response to these suggestions, the public health risk ranking algorithm was developed. While the aim of the algorithm has remained the same (i.e., identify those processing and slaughter establishments that may need more focused FSIS inspection activities), the details of the ranking algorithm are completely different. It is believed that changes in the algorithm make it responsive to reviewer comments and provide a stronger technical and scientific basis for public health risk based inspection

10g.) As stated in our February 2007 comments on the *Resolve Report*, it is becoming more and more apparent that we need a scientifically driven system that uses robust data to assess risks associated with food production and distribution, and then weight those risks to determine where limited resources would provide the highest level of food safety in order to protect public health. The development of such a system is an enormous task and needs to be undertaken seriously with due diligence.

The improved poultry slaughter inspection system is science based and utilizes the Agency's best available data. As FSIS acquires further public health related data (e.g. Campylobacter test results, Salmonella serotype data), the Agency will update the inspection system to incorporate the new information.

Resources

10h.) FSIS must have in place enough trained personnel to effectively implement any inspection system. CFI recommends the development of a team of experts with the appropriate statistical, database management, process control, IT and public health experience. This team should be given management authority and be accessible to the public to answer in-depth questions.

FSIS has established a team of experts with these backgrounds to develop the poultry slaughter inspection improvements and the new information infrastructure. Those groups are working in collaboration with one another. The Agency has presented the results of these efforts publicly, and will continue to keep stakeholders informed as work continues.

10i.) FSIS inspectors will play a critical role in the successful implementation of RBI. Yet, as stated in the *Resolve Report*, the current inspection work force "faces many challenges including chronic shortages, lack of authority to address problems in 'real time,' political pressures, inadequate training, and low morale." Furthermore, the *Resolve Report* states, "Training is extremely important and it should be science-based, not just explaining how to fill out the forms." Unless inspector work force and training issues are addressed, there is little hope for the successful implementation of any inspection system.

FSIS acknowledges the importance of training for execution of the proposed improved poultry slaughter inspection system and intends to fully train its inspection force prior to implementation.

10j.) Based on the level of resource commitment required by the PHRBIS initiative we believe that FSIS does not have the adequate level of personnel at all levels. PHRBIS will demand a high level of expertise in statistical analysis, process quality control, database administration, and technical support. Therefore, FSIS should be planning to appropriately staff management personnel to lead efforts at mitigating deficiencies in its current staffing, as well as seeking adequate funding for additional training of its field inspectors.

FSIS is developing a new information infrastructure with a predictive analytic component to support analyses by Agency Headquarters staff. The proposed improved poultry slaughter inspection system will be resource neutral with respect to inspection activities conducted by FSIS field staff, and will allow the Agency to deploy EIAOs where needed. The proposed within establishment system is designed to reinforce the FSIS inspection program personnel's training on food safety regulations, including HACCP. In addition to their existing training, FSIS inspection personnel will also receive training on how to carry out inspection procedures at vulnerable points and how to make decisions about regulatory compliance.

Technology and IT Infrastructure

10k.) As with any management system, it is critical that IT infrastructure be resourced in a manner that the program can be effectively implemented, applied, and updated. This may require a substantial investment in computing resources such as hardware and software. It is evident that for the PHRBIS system to be feasible, inspectors must have adequate access to the data they need when they need it. The system must also efficiently receive various inputs and be updated in a timely and consistent manner. Processes need to be in place in order to validate the accuracy of system data.

FSIS' new information infrastructure will be a web-based system that integrates and consolidates the systems and data that support food inspection, import and export activities, auditing, sampling scheduling, and analysis. The information infrastructure will enable near real-time data collection for reporting and analysis and will allow for greater information sharing. It will use Agency data streams, including humane handling information, domestic and international programs, and public health and informatory automated model predictions. Data will be collected and combined and analyzed for patterns.

The information infrastructure will be built using leading edge technology, and will move the Agency to web-based applications, taking full advantage of improved broadband capabilities and providing real-time data collection and reporting. This modern design will provide the Agency with increased flexibility to meet current needs; additionally, it will provide the ability to adapt as requirements change and evolve in the future. This streamlined system will provide improved security of data, and facilitate accurate data collection, analysis and interpretation.

The information infrastructure will work in conjunction with the Agency's Assurance-Net management control to help ensure the validity of data.

Data/Process

10l.) While there will always be limitations to any data, the Agency must develop the system in a transparent manner so that it is trusted by all food safety stakeholders. As with RBI, FSIS must develop a detailed process for building *improved poultry slaughter inspection system* before embarking on the implementation of such a system. Such a "roadmap" should clarify the process for 1) defining public health objectives and identifying data needs; 2) collecting, validating and integrating data needs; 3) developing, updating and validating the risk ranking model; and 4) implementing and enforcing the risk ranking model. If FSIS does not carefully develop this process prior to implementation, it could have the unintended consequence of hurting, rather than improving, public health.

As described in Appendix A, FSIS has developed public health based performance measures. FSIS will use those measures to evaluate the proposed poultry slaughter inspection improvements. In developing the improved poultry slaughter inspection system, FSIS has thoroughly reviewed and evaluated the Agency's data sources as shown in Appendix D. In order to better integrate the Agency's data, FSIS is redesigning its information infrastructure, as discussed in response 10c, to fulfill its data needs. FSIS is using its historical data to evaluate the proposed public health risk ranking algorithm and will continue to refine the algorithm based upon its results. FSIS will also undertake a methods evaluation for the within establishment component of the improved poultry slaughter inspection system FSIS is also in discussion with the National Academy of Sciences to review the proposed improved poultry slaughter inspection system in addition to the already completed peer reviews of the system.

Define Objective and Data Needs

10m.) The first step in the process of building PHBIS is to define its public health objectives. Unfortunately, Americans are still being sickened by preventable foodborne illnesses. We must find a way to improve public health by preventing foodborne illness. Concrete public health goals will provide the justification for and means of assessing any inspection system.

FSIS has developed public health based performance objectives, as described in Appendix A, and will use those objectives to evaluate the effectiveness of the poultry slaughter inspection improvements under consideration.

10n.) Most stakeholders agree that the quality of any data-driven inspection system is wholly dependent upon the robustness of the data that supports it. The goals and objectives will dictate the type of data that FSIS will need to adequately assess the effectiveness of any inspection system in achieving those goals and objectives. Therefore, the next step in this process would be to identify data needs and then determine what data is available and what must be obtained. Once FSIS has the necessary scientific data and data infrastructure, then they can begin to design and implement – on a small scale – public health risk-based inspection.

FSIS respectfully disagrees. The Agency believes the poultry slaughter inspection improvements under consideration are public health-based and utilize data appropriate for examination of public health relative risk. FSIS is volume weighting percent positive pathogen testing results to obtain better estimates of population exposure, as described in Appendix A. In addition, the Agency is working with CDC and FDA to incorporate sporadic illness and serotypes into FSIS estimates of attribution.

10o.) During the NACMPI meeting, several data needs were identified. Three are addressed here: foodborne illness attribution, *Campylobacte*r and line speeds. FSIS should continually seek feedback from all stakeholders to identify data needs and potential means for fulfilling those needs.

FSIS is currently in discussion with the National Academy of Sciences regarding review of the improved poultry slaughter inspection system under consideration and the Agency's attribution methodology. In addition, the proposed rule will allow for a public comment period during which stakeholders may provide further comment on FSIS' proposed campylobacter standard and line speed analysis. For further information on Line speed the reader is referred to response 10r.

Foodborne Illness Attribution

10p.) Nearly all stakeholders have identified, at one time or another, attribution data as a critical need for implementing a successful public health risk-based inspection system. Comprehensive attribution data will provide the most objective and reliable means of assessing the effectiveness of RBIS. As a result, it is essential that FSIS continue to collect, analyze, and monitor data intended to quantify attribution to foodborne illness. FSIS must work with other agencies and state and local public health departments to develop a proactive product-tracing system that will provide it with the necessary attribution data.

FSIS is employing its proposed attribution methodology in order to estimate foodborne illness attribution for all of its product types. No other data source (e.g., risk assessments) provides a comprehensive picture of foodborne illness for all of FSIS' regulated products. FSIS has decided to use the outbreak data from the CDC for its attribution methodology. Based upon FSIS' review, the Agency believes the CDC data is the most complete data on foodborne illness available. FSIS is working with CDC and FDA to incorporate sporadic illness and serotype information in its attribution estimates. However, as shown in Appendix A, whether or not CDC or expert elicitation data are used, all of the attribution estimates are remarkably similar.

Campylobacter

10q.) Campylobacter, which is commonly found in poultry, is the leading pathogen for causing human illness in the United States and is believed to be a leading cause of Guillian-Barre Syndrome, an autoimmune reaction that causes paralysis and kills between five and ten percent of its victims. Despite this, FSIS currently does not have a method for capturing the occurrence of this bacterium within its testing and inspection practices. Nor does the current algorithm address or outline methods for including *Campylobacter* in PHRBIS. CFI views this omission as a potentially serious gap and agrees with NACMPI's recommendation that FSIS should complete its performance standard baseline study on *Campylobacter* as soon as possible.

FSIS is currently collecting Campylobacter data through its broiler baseline study and will use this data to establish an advisory performance standard. As this and other information become available, attribution estimates for Campylobacter will be developed.

Line Speeds

10r.) During the two day NACMPI meetings, line speed was discussed on several occasions as a potential incentive for the poultry industry to improve on its pathogen control technologies or interventions to offset their investment. Concerns about line speeds included: 1) the association between line speed and the incidence of fecal contamination at pre and/or post chill; 2) the effectiveness of specific interventions when line speeds are increased; 3) how will line speed be incorporated into risk assessment, and 4) is it mandatory that line speeds be recorded.

FSIS is considering recording line speed when verification samples are taken in the proposed improved poultry slaughter inspection system. FSIS will evaluate the relationship between fecal contamination, and line speed, and is currently undertaking an analysis of pathogen levels in poultry slaughter. FSIS will also incorporate line speed in its poultry slaughter risk assessment models. FSIS will expect establishments to ensure the efficacy of interventions are maintained if line speed is increased.

10s.) As an advisory agent for FSIS, NACMPI should not be focused on the expenses of food production; instead, NACMPI needs to concentrate on the public health mandate that FSIS is required to fulfill. Based on that assumption, line speed should **not** be used as an incentive for PHRBIS until repeated scientific and statistically valid studies have been conducted, demonstrating that line speed does not affect pathogen levels in end food products. The lack of such studies is one of the gaps in the current inspection system. In fact, due to recent developments, as the Agency looks more deeply into line speeds, it should include worker safety (both inspector and plant employee) and documented cases of animal abuse as factors to be investigated.

The reader is referred to the response for comment 10r. In addition, FSIS will consider worker safety issues related to line speed in its regulatory impact analysis. Industry will be required to ensure, and FSIS will verify, that animals are treated humanely and that

good management practices are used as line speeds increase.

10t.) CFI agrees with NACMPI's recommendation that FSIS conduct an analysis of the impact of line speed on public health, and CFI concurs that any data gaps in line speed records need to be filled so that the Agency has a more solid base for making decisions about this issue**.**

The reader is referred to the response for comment 10r.

Collect, Validate and Integrate Data

10q.) Once FSIS has developed a set of elements it considers important to developing a risk ranking model, it must now develop processes that would enable it to manage this data. Once all applicable sources are identified, the Agency should develop standard processes which it will follow with respect to the collection, integration, standardization and validation of the data.

Sound data management processes should include:

a. Standard formats (e.g. Units of measurements, conversions).
b. Data dictionary so that all Agency personnel are clear on meaning of the data field.
c. Standard validation processes to ensure data quality, including random audits of raw input data.
d. Collection and validation of data on a timely basis at regular and pre-defined intervals (e.g. Monthly, weekly, etc.).
e. Sufficient data security measures as well as a process to archive historical data.

In addition to these requirements, the Agency needs to evaluate how it will integrate data from various sources within the Agency as well as from third party sources including industry, consumer groups, and academia. Again, the elements listed above should be consistent across all sources, and a central database administrator should be charged with managing the data base. To be effective, this administrator must have sufficient qualifications, budget and authority to ensure these minimum requirements are met.

FSIS believes that its new information infrastructure will address these concerns. The reader is referred to the response for comment 10k. The Agency is developing a plan to integrate third party data into the information available to support the proposed improved poultry slaughter inspection system.

Develop, Update and Validate Risk Ranking Model

10r.) The purpose of PHRBIS is to predict and identify establishments that do not have process control so that FSIS can allocate resources more effectively to achieve public health goals. Classical statistical modeling is the process used to identify and weight variables that predict an outcome. FSIS's concrete public health goals and objectives

will determine the outcome that FSIS is attempting to predict – that is the dependent variable. Once the dependent variable is identified, the process of identifying and weighting predictive indicator variables (i.e. independent variables) can then be undertaken. The first step in the modeling process is to identify all potential variables (both quantitative and qualitative) that could predict the outcome. Once a comprehensive list is made, data is collected, integrated, standardized, validated and finally used to ascertain which variables are, with some degree of confidence, predictive of the outcome and weight the ones that are appropriately.

FSIS has evaluated all available data and utilized the most important information for development of the risk-based inspection approach proposed in the improved poultry slaughter inspection system. The reader is referred to Appendix D for additional information.

10s.) Any model developed using classical statistical modeling techniques must be submitted for peer and technical review. We strongly urge the Agency to validate any model(s) to determine whether the model is effective at predicting risk. This can only be done by applying the model to a historical set of plant data where the outcome (dependent variable) is known. If the model is found to have a high predictive value, it can then be implemented. From a public health perspective, it is most important that the model accurately classifies plants as having poor process control as being "high risk." While misclassifying plants with good process control as "high risk" is problematic for industry, it is not an important public health issue. The probability of misclassification should be examined statistically and reported in a transparent manner.

FSIS will conduct a historical analysis prior to implementation of the public health risk ranking algorithm under consideration to validate it and to evaluate its predictive ability.

10t.) Finally, developing a statistical model is a circular process. Statistical models tend to lose predictive power over time. For this reason, it is essential that the PHRBIS model employ the most recent data and it should be re-estimated on a regular basis as conditions in the population change. To facilitate this process, it is important that the Agency develop a regular schedule of model updates which include validation and that appropriate analytic staff is available to do this work.

FSIS agrees that the proposed method needs to be flexible and that its utility should be re-evaluated on a routine basis.

Implement and Enforce the Risk Ranking Model

10u.) It is not sufficient to just develop a public health risk-based inspection system. An inspection system must be implemented effectively as well. As with food safety systems, neither a well-designed system that is poorly implemented nor a poorly designed system that is correctly implemented will achieve FSIS's goals of reducing foodborne illness. CFI agrees with NACMPI's recommendations that NACMCF should review FSIS' proposed PHRBIS before implementing it.

FSIS is seeking a review of the proposed improved poultry slaughter inspection system by the National Academy of Sciences prior to implementation of the new system.

10v.) Once again, FSIS has chosen an aggressive timeline for implementing its Public Health Risk Based Inspection System for Poultry. After the public meetings on Risk Based Inspection (RBI) that were held throughout 2007, it should have been clear to FSIS that food safety stakeholders and Congress are not willing to move quickly on an unproven system, especially if that system has no data to support its premises. In many ways, PHRBIS resembles RBI, so it is unclear FSIS' intent in structuring another aggressive timeline for implementation. Many of the limitations addressed in the RBI public meetings are still unresolved. It is apparent that FSIS still does not have the data systems nor resources in place to support a risk based inspection program. Rather than devising new proposals for achieving a more cost-effective inspection system, the Agency should work to find ways to resolve its deficiencies in order to develop sustainable, long-term solutions capable of maximizing resources while serving public health goals.

FSIS has come to management conclusion with OIG concerns regarding the previously proposed Risk Based Inspection System (RBI). FSIS is developing a new information infrastructure system and has informed its development based on an evaluation of the current data system which identified data gaps and needs. The improved slaughter inspection system will use data collected in the new information infrastructure. FSIS believes that the proposed slaughter inspection improvements are resource neutral.

10w.) CFI recommends that the agencies involved in the inspection and surveillance of food work together to improve their statistical and IT infrastructures. CFI agrees with NACMPI that FSIS should ask for dedicated funding to develop an IT system that will be compatible with its goals.

The reader is referred to the response for comment 10k. In addition, FSIS is working with CDC and FDA to refine its attribution methodology by incorporating serotype and sporadic illness information in its attribution estimates.

10x.) Finally, the Agency needs to continue to consult with counsel to make certain that an increase or decrease in the level of inspection is enforceable under current law. This would include the legality of the prescribed additional procedures and resulting enforcement actions. CFI recommends that the Agency conduct an evaluation with legal counsel of the current proposed PHRBIS program and present these findings to NACMPI at its spring 2008 meeting.

The within and across establishment components of the improved poultry slaughter inspection system under consideration are within the regulatory authority of the Agency and fulfill its obligations under the PPIA. The proposed poultry slaughter rule will be reviewed by FSIS' Office of General Counsel.

Conclusion

11a.) In 2006, the United States once again experienced a devastating foodborne illness outbreak – this time with produce. This occurrence was followed by major FDA recalls for peanut butter and pet food, while FSIS struggled with poultry pot pies and a huge increase in products contaminated with *E. coli* O157:H7. Recently, in February 2008, FSIS issued its largest-ever meat recall because the producing plant had not followed mandated procedures. Taken together, this record has undermined the public's confidence in the food supply because it indicates that the food oversight deficiencies are so severe that major corrective actions are needed.

FSIS believes that the improved poultry slaughter inspection system will help to improve its inspection activities and will help to address problems the Agency has experienced in the past. The reader is referred to the revised introduction to the report for lessons learned.

11b.) In fact, in January 2007, the Government Accountability Office issued a report to Congress adding the federal oversight of food safety as a high risk area because of the risks to the economy and to public health. In addition, on the GAO 2007 High-Risk List, the following is noted about *Transforming Federal Oversight of Food Safety*: "Legislation is likely to be necessary, as a supplement to actions by the executive branch, in order to effectively address this high risk area." CFI concurs with this assessment.

FSIS believes that it has sufficient regulatory authority to carry out its food safety mission and that the implementation of the improved poultry slaughter inspection system will increase the Agency's ability to provide public health protection from foodborne illness.

11c.) The January 2007 *Resolve Report* on Risk Based Inspection made the recommendation that FSIS develop "substantive topics to be the focus of stakeholder input." CFI believes that discussing substantive topics will lead to: 1) clarity of purpose in developing public health goals; 2) refinement in USDA's ability to monitor food safety practices; 3) the dedication of Congressional funding to build stronger food surveillance and food attribution programs; and most importantly, 4) open discussions on substantive food safety topics that will help FSIS to develop a scientific approach in designing and implementing its various federal and state programs. CFI is encouraged with the efforts that FSIS has already expended in this effort, however, more remains to be done.

Thank you for your comment. More substantive topics remain to be discussed and FSIS will continue to engage with stakeholders as the Agency attempts to improve its ability to protect public health.

11d.) CFI is committed to working with USDA and FSIS to minimize foodborne illness through more effective food safety regulation. We appreciate this opportunity to comment on the February 5th & 6th, 2008, NACMPI meetings, and we look forward to continuing our dialog with the Agency on important food safety issues.

FSIS thanks CFI for its comments.

Respectfully submitted,

Michael Kowalcyk
NACMPI Member
Center for Foodborne Illness Research & Prevention

Barbara Kowalcyk
Director for Food Safety
Center for Foodborne Illness Research & Prevention

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Public Comment No. 4

Subject: Comments on upcoming NACMPI discussion of young poultry slaughter

12a.) Hi, I saw the notice in this morning's Federal Register about the upcoming NACMPI meetings on standards for young poultry slaughter. I just wanted to provide two main comments.

No response necessary.

12b.) The first point I would like to make is that the Committee should bear in mind the impact of regulations on small producers. Family farmers and part-time food producers make up a material proportion of US food production, and their numbers have been growing in response to consumer demand for fresh, organic, locally-grown food. To the extent that these small farmers constitute a distributed food production system, they make our country more resilient in the face of potential attempts to disrupt our critical food-supply infrastructure. Yet, these same producers are individually unlikely to have the resources to comply with mandatory, state-of-the-art inspection and processing systems that, on their face, make so much sense. The larger commercial operations, as much as they might squawk (sorry, bad pun), are better positioned to absorb such costs and pass them on to their much larger customer base. I urge the Committee to incorporate exemptions to any new standards for these small producers. Such exemptions could be based on total volume of production (e.g., up to 5,000 birds per calendar year), total value of production (e.g., the first $500,000 of products produced per calendar year), or total number of customers served (e.g., producers with a customer base of fewer than 500 individual entities). Other proxies for size are available and may be better suited to this purpose, as long as the small producer is held harmless by any new standards.

Before the improved poultry slaughter inspection rule is implemented, a cost benefit analysis will be conducted and the impact on small and very small establishments will be considered. Plants currently under traditional inspection may choose to remain under traditional inspection instead of participating in the improved poultry slaughter inspection system.

12c.) The second point is that in reading through the notice in the Federal Register it didn't strike me that the Committee is responding to a particular problem; the genesis of this meeting seems to be that "FSIS' traditional method of inspection for young chicken slaughter establishments was designed before microbial contamination was recognized as a leading cause of foodborne human illness." While I applaud the proactive and forward-thinking nature of this stance, too many regulations get started in such an innocuous manner but then transform into many-tentacled monsters with grave unintended consequences. The second part of the agenda for this meeting reinforces this concern: "... [to discuss] how a similar approach could be used for inspection in processing and other slaughter establishments." If the Committee were to focus on creating a gold standard inspection system that is purely voluntary, it would truly add value with much less likelihood of developing those unintended consequences - especially with exemptions

built in as discussed above.

FSIS believes that it has sufficient scientific support to implement the within and across establishment components of the proposed system. No regulatory changes are needed for the Agency to proceed with further development and implementation of those components of the improved poultry slaughter inspection system. .

Thank you for your time.

Sincerely,

/s/

Donald Parks
Olney, MD

Public Comment No. 5

National Advisory Committee on Meat and Poultry Inspection
United States Department of Agriculture
Food Safety and Inspection Service
14th & Independence Avenue, SW.
Washington, DC 20250

Docket Number: FSIS-2008-0003

February 5, 2008

Dear Advisory Committee Members:

13a.) The United Food and Commercial Workers International Union is proud to join forces with consumer advocates to oppose the U.S. Department of Agriculture Food Safety and Inspection Service's proposal to water down workplace safety and food inspection regulations at the nation's poultry slaughter establishments.

FSIS does not believe the improved poultry slaughter inspection system will reduce workplace or food safety. The poultry slaughter inspection improvements under consideration will increase the level of inspection in establishments with evidence of a loss of process control. FSIS will consider the impact of line speed on workplace safety in its regulatory impact assessment for the improved poultry slaughter inspection system rule.

13b.) The "Public Health-Based Slaughter Inspection System" proposal will remove maximum line speed regulations and further subject poultry workers to dangerous workplace conditions.

The reader is referred response 13a.

13c.) Although line speeds directly impact worker safety and health, no consideration is being given to these issues by FSIS. Poultry workers already suffer illnesses and injuries at rates higher than other manufacturing workers, and line speeds have been linked to musculoskeletal disorders and debilitating injuries—including lacerations and amputations.

The reader is referred response 13a.

13d.) Poultry workers often face physically demanding, repetitive work, during which they stand for long periods of time in production lines that move very quickly while wielding knives or other cutting instruments. They often work in extreme temperatures and make up to 40,000 repetitive cutting motions per shift.

The reader is referred response 13a.

13e.) Despite this negative impact on the health and safety of poultry workers, worker safety plays no role under the PHBSIS proposal.

The reader is referred response 13a.

13f.) While the plan to deregulate line speeds in young chicken slaughter facilities does not yet have consensus support, FSIS is already giving consideration to pushing this plan beyond broilers into pork and beef. Given the grave impact this will have on worker safety and health throughout the meat and poultry industry, we ask that FSIS consider the impact of deregulating line speeds on workers *before* allowing broiler slaughter plants to set their own line speeds.

The reader is referred response 13a.

13g.) Although FSIS claims that this plan will lead to an increased use of, and improvement in technology, a 2005 GAO report shows that any increasing reliance on technological features of slaughter and processing requires workers to perform an increasing number of repetitive motions.

The reader is referred response 13a.

13h.) For more than 100 years, the UFCW has been fighting to improve the working conditions of food workers and the safety of our food, and currently represents more than 250,000 workers in the packing and processing industries.

The reader is referred response 13a.

13i.) Over 100 years ago, Upton Sinclair wrote *The Jungle* in an effort to shed light on the unhealthy and dangerous working conditions in meat packing plants, and it is amazing that the poultry industry would be allowed to turn back the clock and dismantle one of our last lines of defense against workplace injuries.

Sincerely,

Mark Lauritsen
International Vice President
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United Food and Commercial Workers International Union
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