REPLY TO PEER REVIEW COMMENTS FOR

FSIS RISK ASSESSMENT FOR GUIDING PUBLIC HEALTH RISK-BASED POULTRY SLAUGHTER INSPECTION

From January through February 2006, the 2005 *FSIS Risk Assessment for Guiding Public Health Risk-Based Poultry Slaughter Inspection* was independently peer reviewed under a contract with the Research Triangle Institute in accordance with the Office of Management and Budget peer review guidelines.[1] A list of peer reviewers is found in Appendix I; and the charge to the reviewers is found in Appendix II. Based on this peer review, the 2005 risk assessment was substantially revised to focus only on *Salmonella* contamination data, include data from PR/HACCP sampling programs in lieu of the original twenty poultry slaughter plants, and to use an approach from the scientific literature to model the public health impact. Therefore, many comments below are not germane to the current version (January 2008) of the risk assessment. Based on technical review and comments on the 2008 risk assessment received from stakeholders, such as the National Advisory Committee on Meat and Poultry Inspection, the risk assessment will be further revised and a second independent peer review of this risk assessment will subsequently be done.

[1] Office of Management and Budget's "Final Information Quality Bulletin for Peer Review" (December 2004): http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf. This bulletin establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents.

Below are itemized replies for each of the peer review comments received for the *FSIS Risk Assessment for Guiding Public Health Risk-Based Poultry Slaughter Inspection.* Though slight editing was done for corrections in spelling and grammar, reviewer comments are otherwise reproduced in this document verbatim.

Itemized Replies to Reviewer #1

Comment: The data sources are modest, largely derived from internal studies sponsored by various arms of USDA (FSIS and ARS), and mostly unpublished. It would, however, be unlikely that published work could be used to populate the risk assessment model, and the fact that 90% of the young chicken production is represented for the *Salmonella* prevalence data means that the data set is fairly comprehensive. However, the small sample size (20 plants) and the short time period (1 year) make this a limited data set with which to work. Furthermore, all data on prevalence and enumeration are reported and used as mean $\log_{10}$ values, without consideration of variability. For further discussion of ramifications, see *b* and *f* below.

Reply: Admittedly, the small sample size and sampling period limited the conclusions that could be drawn from the original 2006 draft risk assessment model, as was acknowledged in the report. In response to these and related comments, the model was refitted in 2006-2007 to incorporate data for the prevalence of *Salmonella* in poultry carcasses representing 154 young chicken slaughter establishments. These data came from the USDA/FSIS *Salmonella* HACCP sampling collection program for 2003-2005. This data will be supplanted by the completed 2008 young chicken baseline study in Fall 2008.

Comment: The overall approach used for modeling risk-based inspection versus non-risk based inspection, as described in the Report, has several shortcomings that undermines the suitability of the algorithm and insights from the analysis for use in risk management or policy decision-making. In this review, we have attempted to identify and expand upon the critical problems with the approach, and have also suggested alternative methodologies. However, we recommend that such suggestions be tested and their suitability verified using available data before any substantial conclusions be reached.

The first shortcoming is regarding the methodology used to quantify the relationship between selected so called “independent” variables with “dependent” variables. Specifically, only one “independent” variable is considered at a time and its effect on the selected dependent variable is quantified. Consequently, possible interaction effects between selected independent variables are left out of the analysis, meaning that this simplified regression model has limitations with respect to fully explaining the relationship between variables.

Reply: The original 2006 model did not consider complex multivariable relationships. However, the model was enhanced in 2006-2007 to multivariate version using some 34

explanatory variables simultaneously. These enhancements are described in detail in the current documentation of the model.

Comment: Although the Report mentions that limiting the analysis to one variable at a time is a weakness of the approach (Page 43), there is no discussion given to the magnitude of the impact of this limitation on the results. It would be expected that the regression model would behave differently when simultaneous variation of all independent variables is taken into account. Such an analysis can be done using a multivariate regression approach (Neter *et al.*, 1996; Sen and Srivastava, 1990). However, this approach cannot be applied easily to the Risk-Based Poultry Slaughter Inspection model, as selected variables for analysis violate the key assumption of regression analysis with respect to independency between inputs. This point and possible remedy solutions are further discussed in response to the charge question "*f*" and are not repeated here. By way of summary, selected variables have possible dependency structures that will introduce *multicollinearity*. It would be beneficial to consider the interaction effect of different variables in the model. For example, how enumerative values change may not only depend on the number of type 01 and 03 unscheduled procedures completed, but also to how these two sanitary procedures interact.

Reply: We agree. This comment is no longer pertinent due to enhancements in the current version. Please see reply to previous comment.

Comment: The authors seem to ignore the fact that regression models are only as good as their coefficient of determinations, i.e., R^2 values. The coefficient of determination explains how much of the output variability is explained (captured) by terms included in the regression model. The authors did not provide any indication in the Report regarding the magnitude of R^2 values for their simple one variable regression models. Although they did indicate in the Report that they would like to improve the goodness-of-fit of the regression models in the future (Page 43), there was no discussion about the reliability of results using the current model. The reviewers, however, suspected that R^2 values may be relatively low. In response to this and our own concerns, we modified the given code in order to estimate the R^2 values for each regression model in each bootstrap replication. A summary of our results is provided in Table 2 (see attached) as mean R^2 values based on 5,000 bootstrap replications for selected dependent and independent variables. Results show that R^2 values are quite low. For example, on average only 3% of the change in *Salmonella* prevalence between post- and pre-chill steps can be attributed to the change in the number of on-line inspectors. Typically, R^2 values are between as low as 0.03 and as high as only 0.16 for the relationships between different independent and dependent variables. Such drastically low R^2 values indicate that there is practically *no* association between, for example, prevalence or enumerative data in selected poultry slaughter plants and the number of on-line or off-line inspectors or the number of unscheduled sanitary processes completed in the plant. The reviewers believe that regression coefficients are not statistically significant either, and hence, there is not enough proof that they are even different from zero. We conclude that regression lines should not be used as the basis of further scenario analyses as performed in the current version of the Report. We suspect that such substantially low R^2 values may be indicative of either: (a) poorly chosen

independent variables, which actually do not have any relationship to the dependent variables; and/or (b) a small degree of variation in the dataset due to limited sample size (i.e., 20 poultry slaughter plants). In conclusion, the current modeling approach shows no relationship between the independent variables chosen and the dependent variables of pathogen prevalence and/or load.

Reply: The reason for the small R^2 values may be due to explanation "(a)," in which case the results from the model suggest that reallocating inspectors in the plant will not lead to an increase in pathogen prevalence and/or levels on young poultry carcasses. We also agree that explanation "(b)" offered by the reviewer is likely. As a result, we are collecting additional data that will be incorporated into the model with the 2008 young chicken baseline study. If incorporation of these additional data shows no improvement in explanatory ability, then we can conclude that the impact of changes to FSIS inspection resources would be inconsequential. If, however, explanatory ability increases, then recommendations that are more specific may be forthcoming. Please see replies above regarding enhancements to the current version of the model.

Comment: It may be that pathogen prevalence or enumeration values for broilers are not influenced by the number of inspectors or the number of sanitary procedures completed within the plants. Because incoming product frequently is contaminated at the pre-harvest level (particularly relevant for *Campylobacter*), the impact of number of inspectors is unclear, since simple inspection will not necessarily lead to identification of pathogen contamination. Even recognizing that there is substantial cross-contamination occurring during processing, controlling this would rely on the efficacy of the control steps implemented, not necessarily on the number of control steps. However, there may be other independent variables not yet considered which would be relevant for inclusion in the model. Likewise, alternative dependent variables might be considered as well. Careful design of the pilot study which FSIS proposes to do in the near future may be an ideal way to identify alternative variables.

Reply: We agree that the pilot study will help identify variables. The study design has been extensively reviewed at FSIS. Comments from peer reviewers and stakeholders have been incorporated. Results of the young chicken baseline study will be incorporated into this analysis when in Fall 2008.

Comment: The analysis is based on a very small sample size (i.e., 20 poultry slaughter plants). Consequently, there is not much variability in the dataset, and hence, linear effects of selected independent variables do not substantially contribute to that variability.

Reply: The sample size has been expanded.

Comment: We believe that by refining the scale of the analysis, further variability could be introduced into the dataset, and hence, selected independent variables are more likely to show statistically significant relationships with dependent variables.

Reply: We agree that the scale of the analysis limited the variability, and increased the scale of the analysis.

Comment: The FSIS risk assessment team used an averaging technique to estimate the annual prevalence and enumerative values for each of the selected poultry slaughter plants (Page 14 of the Report). This approach reduces inherent variability in the dataset with respect to both within and between plant variability. We suggest using a smaller time scale for the averaging process. For example, one can look at prevalence or enumeration data averaged weekly for the whole selected calendar year and then investigate if there is any relationship between number of inspectors (either on-line or off-line) or total number of unscheduled procedures completed within each week with selected dependent variables. Although the authors may argue that data for prevalence or enumeration values are not available on a weekly basis, this should not be of great concern because they can establish an *unbalanced* experiment for which the number of samples can be different for multiple inputs considered in the analysis. Experiments with unbalanced design are discussed elsewhere (e.g., Montgomery, 1997). It would also be possible to use a nested-plot design whereby poultry slaughter plants can be classified into, for example, 4 groups consisting of 5 slaughter plants with similar production volumes. Nested-plot (also known as split-plot) designs are discussed elsewhere (Neter et al., 1996). Taken together, by refining the scale of the analysis and using nesting approaches, the risk assessors may have enough data to populate different treatments of the factors' combinations, which they can use to test hypotheses such as the possible effects of slaughter plant volume, inspector type, or unscheduled procedure type on prevalence and enumeration data. Variability within and between poultry slaughter plants will also be quantified.

Reply: We agree that much of the variability was hidden in the averaging process used for calculating yearly values for prevalence enumeration. In the current version of the model, a single data point consists of a 1-month period within each plant.

Comment: The Executive Summary states that the risk assessment evaluates changes in the prevalence and/or level of microbial contamination (*Salmonella* or *Campylobacter*) on young chickens as a result of changes in assignment and activity of poultry inspection personnel. However, the risk assessment outcomes are expressed as either probability of change (increase or decrease) in prevalence or enumerative data, or probability of change in attributable illness, both as a function of assignment/activity changes. This may seem like a minor point, but the Report never actually specifies the degree to which changes in prevalence and counts might be impacted by changes in poultry inspection. Based on the four risk management questions summarized in the Report and above, the risk assessment modeling approach, while it does address the relative change in prevalence and enumerative values, does not provide clear estimates of a measurable impact of those changes on prevalence or counts. We must conclude that, in its current form, it is impossible to determine if the overall approach has utility for addressing the proposed risk management questions. Please refer to the response to the charge question "*b*" to identify problems that should be addressed before being able to evaluate the utility of the approach.

Reply: The report has been updated to specify the degree to which changes in prevalence and counts of *Salmonella* are impacted by changes in poultry inspection. The 2008 young chicken baseline study will allow us to reintroduce *Campylobacter* enumeration changes as well.

Comment: We believe that the model is not complex enough to adequately address the proposed risk management questions. The simplifying assumptions are such that they adversely affect the credibility of the results and the modeling approach. The limitations of the model with respect to general methodology and also sensitivity and scenario analyses are discussed in the responses to the charge questions "*b*" and "*f*" and are not repeated here. Simply, we believe that inherent variability in the dataset is not properly quantified. As explained in our response to charge question "*b*", authors averaged prevalence and enumeration data within each poultry slaughter plant during the selected calendar year. This approach substantially reduces the variability in the dataset, and hence, reduces the chance of quantifying any statistically significant effect on independent variables. Because the main objective of the work was to quantify such a relationship, the authors should refrain from using any methodology that reduces the data variability. As we suggested above, a solution is to refine the time scale of the analysis and focus on weekly variation of data rather than just annual averaging.

Reply: The data and complexity of analysis in the revised risk assessment model have been expanded considerably. We agree that much of the variability was hidden in the averaging process used for calculating yearly values for prevalence enumeration. In the updated version of the model, a single data point will consist of a 1-month period within each plant.

Comment: We believe that the methodology used for quantification of uncertainty, i.e., bootstrap simulation, is sound and sufficient.

Reply: N/A.

Comment: There are key limitations with respect to the modeling techniques that are fully discussed in our response to charge questions "*b*" and "*f*". These limitations are not repeated here.

Reply: N/A.

Comment: The reviewers' main concern is the lack of transparency of the source code. Very few informative comments are given within the visual basic code or inside Microsoft Excel worksheets. Thus, it was a tedious task to understand the modeling flow and connection between different cells in each worksheet. It was not possible to understand some sections of the model. For example, the purpose of defining a dummy variable for current HIMP as given in cell number "Q2" in the worksheet named "RawData" was not clear. Because most of the modeling structure is in the form of embedded equations inside different cells, it was not practical or even possible to verify

that the model had been accurately coded. However, we were able to execute the code and generate similar results as those given in the Report. For example, with a sample size of 10,000 we were able to reproduce a similar graph to the one given on Page 27 (i.e., Figure 1) for the change in *Salmonella* prevalence versus reduction in on-line inspectors, increase in off-line inspectors, and reduction in on-line to off-line inspector ratio.

Reply: The source code has been updated to increase its transparency. All modeling of equations, etc. are coded in Microsoft Excel. Visual Basic coding is used only as a means for simulation.

Comment: Reviewers believe limited and inadequate sensitivity analysis was performed. The methodology used for sensitivity analysis is based on the comparison of cumulative probability distributions of the model outputs when alternative scenarios are performed. For example, an increase in unscheduled sanitation procedures (type 01) is found to be most effective in lowering *Campylobacter* and *E. coli* counts, while an increase in unscheduled HACCP procedures (type 03) is found to be most effective in lowering coliform counts (Page 43). However, we believe that this methodology has critical shortcomings. As indicated in the Report (Page 43), the analysis is limited to single variable regression analysis. This suggests that simple comparison of the results in terms of possible differences in the shape of the model output distribution can provide misleading insight regarding model sensitivity. Figure 1 is an example of a misleading insight given in the Report. Figure 1 shows estimated change in *Salmonella* prevalence due to a change in the number of inspectors. Based on the results, there was an approximate 80% probability that *Salmonella* prevalence would decrease when the number of on-line inspectors was reduced. Similarly, there was a 70% probability that *Salmonella* prevalence would decrease when the number of off-line inspectors increased. However, when these two events happened simultaneously (i.e., the ratio of on-line to off-line inspectors decreases), we do not see any significant change with respect to *Salmonella* prevalence in most of the simulations.

A methodology that incorporates simultaneous variation of inputs should be used instead. One method is to use multivariate regression analysis (Cohen, 1983; Neter et al., 1996; Devore, 1999). However, due to dependency introduced in the inputs (e.g., ratio of on-line to off-line inspectors is a function of the number of on-line and off-line inspectors that are also used as independent input variables in the model), typical least square multivariate regression analysis techniques cannot be used. In multivariate regression analysis one should be concerned with the nature and significance of the relationship between the independent variables and the dependent variable. Typically, we want to find answers to questions such as: What is the relative importance of the effects of the different independent variables?; What is the magnitude of the effect of a given independent variable on the dependent variable?; Can any independent variable be dropped from the model because it has little or no effect on the dependent variable?; Or should any independent variables not yet included in the model be considered for possible inclusion? These questions typically represent the objectives of performing sensitivity analysis. For the case of the Risk-Based Poultry Slaughter Inspection model, because the independent variables are correlated among themselves, *multicollinearity*

among inputs exists (Mueller, 1996; Wang, 1996; Grapentine, 1997). *Multicollinearity* can cause ambiguity in answers to the above questions.

Multicollinearity affects the stability of the parameter estimates calculated in multivariate regression and discriminate analysis models. According to Mueller (1996), the problem of *multicollinearity* in its simplest form has been traditionally characterized by a high correlation between two or more independent variables in a regression equation. Erroneous interpretations of the results, mainly due to a lack of stability of coefficients across samples, can follow. *Multicollinearity* can also cause large forecasting errors and make it difficult to assess the importance of each independent variable in the model.

There are several methods that researchers can use to handle multicollinearity in regression and discriminate analysis (see Mueller, 1996; Wang, 1996 and Grapentine, 1997). We suggest using the *principle component analysis* approach to reduce the effects of multicollinearity. The objective of the principle component analysis is to identify a new set of orthogonal axes such that the coordinates of the data with respect to each of the axes give the values for the new variables, called principle component scores. The first new variable accounts for the maximum variance in the data and is a linear combination of the original variables, such that the new variables are uncorrelated among themselves (Sharma, 1996). Further detail is available elsewhere (Mueller, 1996; Sharma, 1996; Wang, 1996 and Grapentine, 1997). Moreover, the nested-design experimental approach discussed in the response to the charge question "*b*" should also be taken into account in this regard.

Mokhtari and Frey (2005) suggested a methodology to quantify uncertainty in the form of sampling distribution of *F* values when using Analysis of Variance (ANOVA). This type of sensitivity analysis approach uses bootstrap simulation to quantify the sampling distribution of sensitivity indices (i.e., *F* values). This methodology can be also adapted for application to the Risk-Based Poultry Slaughter Inspection model. In this case, because the sample size is very small (20 poultry slaughter plants), there is substantial uncertainty associated with the regression coefficients (as indicated in the Report). Similar to the methodology used in the current version of the model, random samples can be taken from *k*-dimensional inputs and output space. A multivariate regression model can be fitted to the resampled data taking into account the effect of dependency between inputs and the use of principle component analysis. At each bootstrap simulation, "statistically significant" inputs are ranked based on the relative magnitude of the partial sum of squares associated with each input as a sensitivity index (Gardner and Trabalka, 1985; Rose *et al.*, 1991). This process is repeated for alternative bootstrap replications. To the extent that the sensitivity analyses yield similar results about the rank ordering of inputs regardless of uncertainty, an analyst or decision maker will have greater confidence that the results of the analysis are robust to uncertainty. If the ranking of key inputs changes substantially from one bootstrap replication to another, the identification of key inputs would be uncertain. Some statistics such as mean rank or 95% confidence interval of ranks can be provided based on the results of the analysis for overall comparison of importance of inputs.

Reply: We recognize the problem of using single variable regression analysis and agree that multivariable regression would be a better approach. As the reviewer aptly points out, correlation between the independent variables presents a challenge. The enhancement of the model from a univariate analysis to a multivariate analysis in the current version makes much of what is said in the above comment moot. We benefited greatly from the reviewer's detailed comments, however, and expect to do more sensitivity analysis as we get updated data.

Comment: The authors to some extent failed to present the structure of the model in sufficient detail. Only the deterministic values of the prevalence and enumerative data were given based on the available data. However, information regarding the independent variables (e.g., number of inspectors or number of various measurements of completed/uncompleted PBIS procedures) is not tabulated in the report, and the reader was forced to look up this information in the Excel worksheets provided as a part of documentation. We summarized those values in Table 1 based on what we obtained from the provided Excel file. The authors should tabularize the information regarding all model parameters with sufficient detail.

Reply: Admittedly, most of the input data from the plants is not included in the documentation of the analysis. Given the bootstrapping procedure that was used to generate the stochastic model simulations, this did not seem relevant: independent draws from the pool of data were used in individual model iterations to generate parameter values.

Comment: It was difficult to understand the structure of the model from the information provided in the Report. Thus, reviewers were forced to refer to Excel worksheets and the visual basic code for this purpose. Some explanation is given in *Model Description* Section on Pages 23-26. However, the text in this section is poorly written which brings some ambiguity regarding the model structure and the analytical approach. A better approach would be to make the structure of the model clear in the documentation with further illustrative examples given with respect to the step-by-step execution of the model. For instance, we as reviewers had some difficulty in understanding how the two selected scenarios were implemented, which required continuous reference to the code and Excel sheet, a burdensome task. We suggest that the risk assessment team offer one illustrative example for a select pathogen (e.g., *Campylobacter*) at a specific section of the poultry slaughter plant (e.g., pre-chill). They could then present some of the bootstrap replications, providing a clear illustration of how the two selected scenarios were applied and executed in the model.

Reply: The model is documented more clearly in the updated report.

Comment: As discussed above, the authors chose Microsoft Excel using visual basic macro programming, which results in a black box model that cannot be easily check for programming errors. The huge number of parameters and equations included in the analysis are embedded within cells in different Excel worksheets. Thus, it is difficult to understand the flow of the model and the connection between different cells inside

alternative worksheets. The modeling should be more transparent, specifically to prevent users inadvertently making changes that result from the inability to see every detail of the programming. Furthermore, it would be beneficial to provide sufficient comments within worksheets and also the code to facilitate understanding of the modeling flow. One suggestion is to use a programming environment rather than using embedded equations in Microsoft Excel. The choice of programming environments depends on the skill of the modeler, the use of add-ins, and the scope of the analysis. For models that are extensive and that will be used for multiple analyses, a programming language environment and good software engineering practices are recommended. The choice of modeling environment should account for the trade-off, if any, between the skills of the analyst, resources, anticipated needs for future model refinements, and desired flexibility with regard to sensitivity analysis.

Reply: Microsoft Excel is a widely used and easily understood tool for this type of analysis; thus, we thought it appropriate here. The use of Visual Basic macro programming in this model is extremely limited and does not include any of the equations within the model. Visual Basic is simply used to simulate simultaneously all scenarios.

Comment: Finally, other aspects of the proposed rule, i.e., establishing new standards of identity for product, new chilling regulations, and new guidelines for on-line reprocessing are not addressed by the risk model and should probably not be included in the Report.

Reply: Information about new standards of identity, chilling regulations, etc. was added to give context to the risk-based initiative. We felt they enhanced the report as such.

Comment: At this time it is impossible to determine if the selected scenarios are adequate to capture all the significant differences that might be expected to occur when risk-based inspection is implemented. Please refer to the response to the charge questions "*b*" and "*f*" to identify problems that should be addressed before being able to evaluate the adequacy of the scenarios.

Reply: N/A.

Comment: In the statement of work, the authors stated that their intention was to examine the public health impact associated with the potential reallocation of USDA inspection personnel in poultry (broiler) slaughter plants. While this is laudable, the effort given to characterizing the public health burden associated with the consumption of contaminated broilers is minimal and the estimates are quite crude. The general approach was to use FoodNet data for the incidence of human salmonellosis and campylobacteriosis, and extrapolate these to the entire population using U.S. census estimates and under-reporting multipliers. These numbers are then modified using attribution factors (for foodborne, poultry, and broiler fractions), which allowed the risk assessment team to estimate the total foodborne illnesses attributable to the consumption of young chickens. However, the attribution estimates, which are derived from several sources (Mead et al., 1999; USDA ERS; and the FSRC), are expressed as single point estimates, and even the authors of these estimates admit that they are crude at best. There

is also no consideration of the dose-response relationship; one cannot assume that more or less linear reduction in human disease will occur as a function of reduced pathogen load, as this relationship is much more complex. Furthermore, it is not clear from the Report narrative exactly how these foodborne illness numbers were used in the analysis (see Figures 9-12). Because the human disease estimates are so uncertain, and the analysis really focuses on the impact of inspection activities on pathogen prevalence, we would suggest foregoing this part of the analysis.

Reply: We have enhanced the linkage to attributable human illnesses considerably in the current version of this analysis. Please refer to pages 14-18 of the current version of the risk analysis report for a description of how we are now modeling uncertainty about estimates of attributable human *Salmonella* illnesses. Then on pages 28-29, we discuss our method for modeling *Salmonella* illnesses avoided due to changes in establishment procedures.**http://www.fsis.usda.gov/PDF/Poultry_Slaughter_Risk_Assess_Jan2008.pdf**

Itemized Replies to Reviewer #2

Comment: Generally, the approach described in the document "Risk Assessment of Risk-Based Poultry Slaughter Inspection" (December 2005) address the four risk management questions that were presented. The first question asks, "Is there a measurable difference (relationship between pathogen prevalence/indicator counts and inspection resources and assigned tasks) between risk-based inspection systems for poultry and non-risk-based inspection systems for poultry plants using current inspection methods?" The report does not appear to discuss a relationship between pathogen prevalence and indicator counts, which may not be needed or appropriate. Note that this question (from page 2) is worded differently on page 7, where "indicator counts" has been removed.

Reply: The document has been updated so that the questions are worded consistently.

Comment: This reviewer agrees with the interpretation (p. 3) that reassigning inspectors to off-line duties may not lower the incidence of campylobacteriosis cases, since off-line inspection tasks focus on control of *Salmonella* rather than *Campylobacter*. Since the number of *Campylobacter* illnesses is predicted to increase when off-line inspectors are increased, but not when the ratio of on-line/off-line inspectors decreases, you may want to consider predicting *Campylobacter* illnesses based on prevalence, in addition to enumeration.

Reply: The current data being used in the analysis does not include *Campylobacter* – only *Salmonella*. The new data available in Fall 2008 will include *Campylobacter*. The analysis will be updated at that time.

Comment: Some of the microbiological data was from samples collected between October 2004 and September 2005, while the data on inspection activities was for calendar year 2004. Some people may expect the inspection and microbiology sample data to overlap the same time period.

Reply: Data for inspection activities have now been paired with *Salmonella* prevalence data for the same establishments and timeframes.

Comment: The criteria for selecting unscheduled procedures completed, as independent variables, needs further explanation. Why don't you include scheduled procedures completed for ISP code activities 01, 03, 05, and 08? And, how many of 13,339 ISP codes were unscheduled Type 01, 03, 05 or 08 procedures?

Reply: The rationale for including unscheduled procedure completed as independent variables was that they are useful as "decision" variables. That is, they are those that the risk manager may make changes. Experts in the field were asked to choose those procedure codes that they thought would be most relevant to the policy questions at hand.

Comment: For the scenario where inspectors are reduced in each plant to one per shift, please clarify if this is the same as one per line per shift.

Reply: This point is clarified in the revised report.

Comment: The report is well-written and formatted.

Reply: N/A.

Comment: The proposed inspection system has many similarities to the current HIMP "experiment". Somewhere the report should explain the specific differences between HIMP and the proposed system, and if the new system would replace the one used in HIMP plants. Perhaps the 4 HIMP plants data should not be included, since these plants have much different inspection procedures currently.

Reply: The report has been updated to include a brief discussion describing differences and similarities between HIMP and the proposed new system.

Comment: The data for *E. coli* and coliform tests appears to be minimally used in the risk assessment. Perhaps this information should be removed, or further incorporated into the assessment.

Reply: The current version of the analysis focuses exclusively on *Salmonella*.

Comment: The Conclusions section (page 43) remarks on predicted lowering of *E. coli* and coliform counts. Perhaps this should be removed. I cannot give a strong recommendation on how to include information or predictions of *E. coli*/coliform data. While the enumeration tests for these organisms may be required at this time, you may not want to predict how enumeration may change. Other reviewers or constituents may use your report to justify the use or removal of *E. coli* / coliform testing to indicate *Salmonella* presence or process control. This effort may distract from your goal to improve public health or reassign inspection personnel duties.

Reply: Please see previous comment.

Comment: You may want to clarify "plant volume" on page 26 and elsewhere. Does this refer to number of carcasses, or liveweight pounds?

Reply: This referred to the number of birds slaughtered per plant. The text has been revised to make this clear.

Comment: The two scenarios are good choices to study what could happen if risk-based inspection is implemented. I would be interested in seeing what may occur if unscheduled procedures are increased by 25%. Can you estimate the number of inspectors (per line/shift/plant) that would be needed to carry out 25% more unscheduled procedures?

Reply: Because there is no information available for the capacity of workers to perform unscheduled procedure checks, the risk assessment cannot estimate the number of inspectors needed to carry out 25% more unscheduled procedures. We agree, however, that this would be beneficial information for policy makers.

Comment: The interpretation that current inspection procedures better control *Salmonella* prevalence, rather than *Campylobacter* enumeration is appropriate to help explain why *Campylobacter* illness are predicted to increase when the number of off-line inspectors are increased.

Reply: N/A.

Comment: The approach to estimate illness is generally appropriate based on data that are available. While improvements in consumer cooking and handling of raw poultry could have a more significant impact on reducing the number of illnesses, this risk assessment was strictly focused on inspection and slaughter procedures. The model could additionally consider using data on *Campylobacter* prevalence. I assume that data are available, but not included in the risk assessment document. Even though there are good arguments for monitoring or controlling *Campylobacter* through a quantitative performance standard, a qualitative (presence or absence) determination with this organism is important too. The large reduction in *Campylobacter* counts in post-chill carcasses may not correspond to a large reduction in prevalence of contamination.

Reply: We agree that the approach to estimate illnesses was appropriate in this instance, as explained in our reply to the final comment by Reviewer #1 above. Please note that the current version of the analysis focuses exclusively on *Salmonella.*

Comment: The data presented in Table 8 shows that the *Campylobacter* populations were reduced, on average, by a factor of at least 1,000X. The potential reduction in illness (Table 12) is not nearly as significant. Is it possible that a reduction in *Campylobacter* prevalence is more appropriate factor to study?

Reply: *Campylobacter* is not included in the revised risk assessment. It is not clear whether *Campylobacter* is a more appropriate factor to study.

Comment: The change in number of illnesses in Table 12 is not significant compared to the total number of illness estimated in Table 9. I did not notice a similar conclusion in the report.

Reply: The suggested conclusion has been added.

Comment: P. 3 (top): Statement #2 is unclear ("The public health impact in the log enumeration….")

Reply: The text of the report has been clarified.

Comment: P. 3, bullet #4: The last sentence of this statement implies that *Campylobacter* is a more significant contributor to foodborne illness. Is that what you want to say here?

Reply: No. The text has been reworded accordingly.

Comment: P. 27: The phrase "of *Salmonella* prevalence" should be inserted twice into the last sentence, as follows: "Individually, results vary from 90% no increase of *Salmonella* prevalence for sanitation (type 01) procedures to about 60% no increase of *Salmonella* prevalence for unscheduled sampling (type 05) procedures."

Reply: The suggested change has been made.

Comment: Figures: The scale or units used on the x-axis of Figures 1-8 should be identified. The scale could be increased for some figures (2, 4, 6, 8, and 12) to make them easier to interpret.

Reply: These changes have been made.

Comment: Page 46, Tables 14 & 15: The variables "NC##" are not defined.

Reply: All variables are now defined in footnotes.

Comment: Page 37: In line 9 of the paragraph under "Reduction in on-line inspectors" change "*Salmonella*" to "*Campylobacter*" in the sentence: "The results show confidence that modeled changes will not increase *Salmonella*-related illness approaching a 70% likelihood of no increase in illness."

Reply: This change has been made.

Itemized Replies to Reviewer #3

Comment: The risk assessment evaluates different scenarios (regarding inspectors and inspection procedures) and their predicted effects on pathogen prevalence and numbers and ultimately on human illnesses. The model assumes a "cause and effect" relationship between pathogens (prevalence and numbers) and human illness. As the writers indicate in the limitations section, "a formal analysis between these changes and the level in the final product and the relationship between dose and illness has not been evaluated". Model predictions are based on univariable regressions and the assessment of multiple variables is not considered, but a suggestion is made on pages 43 that this will be done at a later time. Uncertainty in regression model predictions of numbers of human illnesses is captured through bootstrapping methods.

The model assumes that there will be no changes in patterns of consumption of young poultry when the risk-based system is implemented and that the sensitivity of detection of contamination problems with these pathogens will not be affected with a reallocation of inspectorial tasks. There is no obvious accounting for variability in predicted illnesses allowing for differences in age susceptibility or dose-dependent responses to pathogen load in humans. These model simplifications seem reasonable to me, given the underlying questions that the risk assessment is attempting to address.

The main strength of the model is its simplicity including its availability in Excel. However, this is also a weakness since it presents a very simple depiction of a complex biologic process. For example, issues of dose-response relationship in human illnesses do not seem to have been considered nor has the fact that many other factors (including cross-contamination) subsequent to chill will impact the prevalence and load of these pathogens on poultry-products ingested by humans. Two scenarios were used to evaluate the change in incidence of human illness: observations on re-hang and post-chill *Salmonella* prevalence, and log enumeration of re-hang and post-chill Campylobacter sampling. Log enumeration data for generic E. coli and coliforms were not used. Presumably, the primary reason for including the latter data in the report was to provide additional confidence about the change in microbial load.

Reply: See replies below.

Comment: I unable to comment on issues related to key studies and data that might be missing.
In my opinion, the risk assessment would benefit from increased transparency of data sources and a critical assessment of their quality and utility for their proposed purpose. In addition, a section of the report specifically dedicated to model assumptions would be helpful.

Reply: A discussion of data quality and utility has been added, as has a description of model assumptions.

Comment: There are a number of issues that warrant more careful consideration and discussion in the report.

- Comparability of *Salmonella* prevalence data based on different tests and sampling strategies, namely culture vs. PCR, and rinses vs. swabs vs. ground chicken (page 10). Ideally, the goal should be to use true prevalence rather than test-based (apparent) prevalence where the data are based on different testing methods, especially if methods have changed over time. To effectively make this adjustment, sensitivity and specificity estimates are needed for each test. To simplify calculations, it might be reasonable to assume perfect specificity of all culture and PCR methods. My assumption is that the authors have made the inherent assumption that all test methods have equivalent sensitivity and specificity.

Reply: We did assume that the various test methods yielded results with equal sensitivity and specificity. A discussion has been added to the text to explore this issue further.

Comment:

- Expert elicitation of poultry attributable fractions. The methods described to obtain these estimates from each expert should be given. What question were they asked – namely, were experts asked for their best guess of the proportion and a value that they were 95% sure that the proportion was above or below? How many experts were included and what was the variability in their estimates? The individual expert values and how the final values used in the predictions (0.3351 for *Salmonella* and 0.6936 for *Campylobacter*) were obtained should be described since these values have a major effect on the numbers of predicted illnesses. Websites with source documents should be provided in the reference list. References 18 and 19 provide minimal guidance about the scientific basis of the expert opinion.

Reply: Although we appreciate the comment, we only used published work of others within our model. We had no control over their expert elicitation studies.

- Critical evaluation of FoodNet data (page 17) and Performance-based Inspection System (PBIS) data (pages 22/23). The summary data for 2003 for FoodNet (MMWR – April 30, 2004) show 14.5 *Salmonella* cases per 100,000 rather than 14.4. This raises the general issue of quality of these data for the proposed risk assessment. Were data checks done to check for internal consistency, duplications, and omissions or were summary values from CDC used? For the PBIS data, there is adequate description of how the data were tabulated by ISP codes but no summary table by establishment, nor indication of what data checking procedures were used. It is unclear to me exactly how these data were used in the model, although I am assuming it was on a plant-specific basis.

Reply: Only a small fraction of the PBIS data was used in the model.

Comment: The model is based on a simple linear relationship between prevalence/numbers and human illnesses. There is little motivation/justification for this choice of a linear relationship. Why not some other functional form, e.g. curvilinear? If anything, the model is under-parameterized since there are many intermediate steps (e.g. transportation, handling at the retail level and by consumers) that might affect the final prevalence and level of contamination, and each independent variable has only been considered by itself.

Reply: Multiparameter equations have been fitted in the revised risk assessment. The human illness linkage has been greatly enhanced as well.

There is minimal capturing of the uncertainty associated with the predictions. Expert opinion is modeled as a point estimate rather than as a distribution. It is also likely that "slaughter plant" will be an important source of variability because of differences in chain speed, lighting, and skill and dedication of inspectors. This variability might even be time dependent as inspectors are rotated among plants. This will be difficult to numerical quantify but should at least warrant some qualitative discussion in the report.

Reply: We agree that "slaughter plant" is likely an important source of variability due to the points mentioned above. Values for factors such as chain speed, lighting, etc. were considered beyond our control and were therefore captured in the estimate of the intercept term for each replication of the simulation. The distribution of uncertainty surrounding these estimates was captured through bootstrap replication.

Comment: Some of the modeling issues have been discussed in section c). An alternative approach might be to develop a Bayesian model using Markov-chain Monte Carlo simulation as used by Hald et al. (Risk Analysis 2004; 24:255-269) for food attribution in Denmark. Presumably, a Bayesian regression approach was considered as an alternative but this would be more complex to implement.

I am unable to comment on the Visual basic code because of lack of familiarity.

The following mathematical and statistical issues warrant consideration:

- The correlation between independent variables (page 25, nos. 1 to 8) should be shown somewhere in the report (even in an appendix) since this will have important ramifications if a multivariable model is fit. It is unclear to me whether the total number of inspectors was fixed (within a plant) or allowed to vary. I would assume that the ability to quickly reallocate inspectors to other plants is limited.

Reply: In the revised analysis, multivariable regression is used; and, correlation between independent variables is documented.

Comment: Some of the numbers (cells highlighted in yellow) in Table 9 are incorrect according to my calculations

	Step	Campylobacter	*Salmonella*
Cases	1	12.6	14.4
Denominator	1	100000	100000
Population	2	290788976	290788976
Reports		36639	41874
Underreporting multiplier	3	38	38
Total illnesses	1x2x3 = 7	1392298	1591197
Foodborne fraction	4	0.8	0.95
Total foodborne illnesses	4x7 = 8	1113838	1511637
Poultry attributable fraction	5	0.6936	0.3351
Young chicken fraction	6	0.838	0.838
Illnesses (poultry)	9	772558	506550
Illnesses (young chickens)	10	647404	424489

Reply: The values for *Campylobacter* are not included in the revised risk assessment. Those for *Salmonella* have been updated accordingly.

Comment:

- Definition of an uncertainty model. Reference is made to use of an uncertainty model to estimate risk of human illness on page 8. The only source of uncertainty that appears to have been captured in the model is the uncertainty in the regression line parameters. Uncertainty in food attribution does not seem to have been considered. Moreover, it would be important to know whether there is relatively more or less uncertainty in the Salmonella estimates than in the Campylobacter estimates.

- I found the description of the notation used and the model on pages 24 to 25 difficult to follow. It would have made it easier to follow if it had been made explicit that "i" related to plants, and a brief description of "j"and "k" had been given directly after the first equation in which they were used. More detailed explanation could follow in later paragraphs. Some of my difficulty in understanding may have arisen because of lack of clarity in the superscripts in my printout. For non-scientists, perhaps a simple numeric calculation would aid in the understanding of the overall basis of the calculations.

Reply: The language has been clarified in the revised text.

Comment: I was unable to find any section of the report that explicitly described the sensitivity analyses (if any) that were done. The use of a linear model means that the key determinant of changes in illnesses is the proportion of human *Salmonella* and *Campylobacter* illnesses that are attributed to young poultry. Hence as a minimum, I suggest that a range of plausible values be used. For *Campylobacter*, values such as 60% and 80% would seem reasonable to use, as would 25% and 45% for Salmonella. Note: May wish to endogenize uncertainty for these estimates in the model.

Reply: The revised model includes revised distributions in place of point estimates.

Comment: In my opinion, there are several areas where improvements could be made in the structure, layout, and general presentation of the report. Suggested improvements are made in the following sections. In the final section of the report, I have identified typographical errors and sentences where rewording would help clarity.

- Executive Summary. This clearly is in a very preliminary form but it would have been helpful to this reader have a clearer description of the strengths and weaknesses of the modeling approach, an assessment of variability and uncertainty, and results of sensitivity analysis, if done.

- The section on "Limitations of the analysis" requires more detailed discussion of the strengths and weaknesses of the model. It is unclear whether there is a plan to validate model predictions with data from establishments that participate in the new scheme.

- The sections on Salmonella and Campylobacter epidemiology in humans require expansion with more than just reporting of trends in human cases. At least some peer-reviewed publications that deal with food attribution (as used by the Food Safety Research Consortium) should be presented and there should be at least some discussion of the uncertainty associated with the estimate of the poultry attributable fraction (step 5 in Table 9).

Reply: The suggested revisions have been made.

Comment: The approach presented in this model seems fundamentally sound, although the implicit assumptions on which the model is based require better documentation – e.g. fixed number of inspectors, equal or better sensitivity of detection of contamination/problems despite change to no maximum line speed, etc. Are there any intangible benefits/downsides that should be considered as part of the resource reallocation e.g. improved (decreased) job quality, ability to recruit and maintain inspectors?

Reply: Estimating intangible (and largely subjective) benefits/downsides resultant from resource allocation (such as job quality and the like) was outside the scope of our analysis. Though this is an interesting idea, the primary drawback to doing this is that data are not available to arrive at objective conclusions on these points.

Comment: The key issues that warrant reconsideration are the simple proportional relationship between prevalence/counts and human illnesses, the use of predictions based on poorly documented attribution proportion for both pathogens, the lack of consideration of a lag structure in the data that would better relate pathogen levels and human illnesses temporally. Ideally, longitudinal data that would indicate that a reduction in pathogen prevalence and counts at the plant was transposed into lower prevalences/counts at a

retail level would provide at least more indirect assurance of the benefits of the risk-based approach.

Reply: The decision to equate pathogen load in young chickens to human illness was borne of two considerations: First, experience has taught us that "anchoring" risk assessments to surveillance data (including those from FoodNet) is often necessary to ensure stakeholder acceptance. Second, given the time constraints in conducting the risk assessment, we did not feel it appropriate to develop a full-blown dose-response model. As for uncertainty in the estimates of illness, we acknowledge that such uncertainty exists. However, there is as much if not more uncertainty is the currently available dose-response relationships for *Salmonella* and *Campylobacter*. We agree that data indicating a reduction in pathogens at the plant was transposed to reduction in pathogens at retail would have been valuable. Unfortunately, however, to the best of our knowledge, such data do not exist.

Comment: Page iv – Tables should be listed before Figures as page v; some page numbers are incorrect – appendix and references start on pages 45 and 55, respectively.

Reply: These formatting changes have been made.

Comment: Page 3 – I am not sure that "likelihood" is the best term here to describe the predictions

Reply: "Likelihood" has been replaced with "probability."

Comment: Page 3 – Fifth bullet – "may be more effective" than what?

Reply: This has been updated.

Comment: Page 5 – Targeted allocation of poultry slaughter resources…

Reply: This has been updated.

Comment: Page 6, line 2 and 3 – should "young chicken slaughter establishments" be defined for completeness?

Reply: Yes. The term is now defined.

Comment: Page 10 – I am not sure that "respiration" is the correct term – suggest "conditions"

Reply: The suggested revision has been made.

Comment: Page 12, line 4 – presence in food and water "suggests"

Reply: This has been updated.

Comment: Page 14, equation on line 10 should be "# of sample(s) per year

Reply: The suggested revision has been made.

Comment: Page 14, Table 6- it is not obvious to me why there should be should be such a large difference between "annual average prevalence" and "weighted prevalence within plant" for some plants e.g. 10 and 11. Perhaps a numeric example would help with understanding.

Reply: The suggested revision has been made.

Comment: Pages 14 to 17 – Do the plant numbers in the 3 tables have any meaning? For example, is plant 3 the same for all tables?

Reply: Yes. This has been clarified.

Comment: Page 15, footnote – "for" rather than "for4"

Reply: The suggested revision has been made.

Comment: Page 16, in the *Campylobacter* section, I am unable to work out where the number 40 comes from. There are 20 samples per plant collected 4 times per year. Are there 2 counts per sample?

Reply: Yes. This has been clarified.

Comment: Page 21, line 23 – perhaps use "document" rather than "chapter"

Reply: The suggested revision has been made.

Comment: Page 24, need to indicate here that "i" refers to plants

Reply: The suggested revision has been made.

Comment: Page 24, second last paragraph – the word data are plural so it should be "data were"

Reply: The suggested revision has been made.

Comment: Page 27, figure 1 caption – suggest making it explicit by adding "on chicken" after Salmonella prevalence so that the figure can stand-alone. Same comment applies to Figures 2 to 8

Reply: The suggested revision has been made.

Comment: Page 31 – Table seems out of place here. Suggest locate it later in the document

Reply: The suggested revision has been made.

Comment: Page 32 (34 and 36), line 2 – "Error! Reference source not found

Reply: This error was due to a mistake in cross-referencing. It has been corrected.

Comment: Page 35 – for completeness, the inspection codes might be included in the figure caption or as a footnote

Reply: The suggested revision has been made.

Comment: Page 38 – standard errors or standard deviations?

Reply: This portion of the text is not in the revised report.

Comment: Page 38 – Table 12 should be introduced earlier, perhaps on line 8 after "783 Salmonella related illnesses"

Reply: The suggested revision has been made.

Comment: Page 38, last paragraph – might be safer to indicated that illnesses are predicted to decline rather than use the word "decline" alone

Reply: The suggested revision has been made.

Comment: Page 39, figure 9 caption – suggest making it explicit by adding "in human" after illnesses so that the figure can stand-alone. Same comment applies to Figures 10 to 12.

Reply: The suggested revision has been made.

Comment: Page 43, conclusions section, paragraph 2, line 3 – are biased towards….

Reply: This has been updated.

Comment: Page 45 – For completeness, the 9 prevalences (P1 to P9) should be listed one under the other immediately after the second sentence

Reply: The suggested revision has been made.

Comment: Pages 55 to 57 – the reference format could be made more uniform. For example, sometimes "et al." is used when more than 4 authors, "and" is used to link

authors for some references and not others; the journal title is not abbreviated for the last reference (page 57)

Reply: The references have been made uniform.

Comment: Tables 1 and 2 - The term “confidence interval” is used but this is not really a confidence interval in the classical statistical sense.

Reply: As best we can tell, the term “confidence interval” did not appear in tables 1 or 2.

Comment: Table 2 – Should be “prevalence” rather than “prevalence”; “slaughter” rather than “slaughter”.

Reply: The suggested revisions have been made.

Comment: Graphs – x-axis should be “prevalence” rather than “prevalence”

Reply: We are confused by this comment. Graphs have been checked, however, for accuracy and revisions made if necessary.

Comment: Raw data table has multiple typographic errors

Reply: The typographic errors have been corrected.

Itemized Replies to Reviewer #4

Comment: The risk assessment has a strong utility for answering this question [Is there a measurable difference (relationship between pathogen prevalence and inspection resources and assigned tasks) between risk-based poultry inspection systems and non-risk-based poultry inspection systems currently in place in young chicken slaughter plants?]. The risk assessment team has established a good database, consisting of information collected over one year from twenty different plants, all with different patterns of on-line vs. off-line inspection and different levels of inspection procedures. Since this is not a designed experiment, but rather uses real world data, there are some limitations of the data used. For example, any conclusions regarding the effect of the ratio of on/offline inspectors needs to be tempered with the knowledge that in the dataset used in the RA, the number of online inspectors always exceeds the number of offline inspectors so the ratio is always greater than 1. If the proposed rule moves forward, those plants that switch to the risk-based inspection system should expand the database of observations and improve the data used in any subsequent risk assessments.

Reply: The database of observations has been expanded considerably in the revised risk assessment. As additional data become available, e.g. those for *Salmonella* enumeration from young poultry, the risk assessment will be updated accordingly.

Comment: The modeling approach has some utility for answering this question [How will a reallocation of inspection resources away from on-line procedures, either out of the plant or to other HACCP verification procedures and/or sanitation verification procedures, affect prevalence, as well as other process control indicators?], as the data used are concerned with on-line vs. off-line inspection and various sorts of HACCP and sanitation verification procedures.

Since the data use here don't actually represent true "reallocation" as such (i.e. allocation from plant 1 is compared to allocation from plant 2, rather than allocation within plant 1 compared to allocation within plant 1 at a different time), I am somewhat concerned that the strength of the conclusions may be over-stated.

That being said, there are no such data that can be used to study such reallocation, and we must do the best we can with the data we have. As noted above, should the proposed rule move forward, we would be provided with an excellent test bed to study "true reallocation" and I strongly encourage the agency to collect such data, if it is at all possible.

Reply: The reviewer's comments are appreciated.

Comment: I question the value of including the 08 unscheduled data in the analysis at all. The dataset includes no scheduled 08's (hence no unperformed 08's) and only 8 plants where unscheduled 08's occurred, and only 3 plants where significant (i.e. double digit) unscheduled 08's occurred. This very sparse dataset is a likely cause for the very slight effect on pathogen prevalence or level.

Since only 01, 03, 05 and 08 data are presented in the final analysis, I'm not sure what the value is for including the 04 and 06 data in the "RawData" part of the spreadsheet, or even for including them in the beginning of the report.

Reply: We agree with this comment**.** The 08 unscheduled data are those for biosecurity. We included the 08 category in the model so that as more data become available, the model may be updated to reflect unscheduled biosecurity procedure checks.

Comment: As noted elsewhere in these comments, it is clear that (while debatable) a 1% change in *Salmonella* prevalence could be expected to produce a 1% change in illness, the exact logic the risk assessors are using to relate a change in *Campylobacter* enumeration to human illness is not clear. A simple example, using actual numbers, rather than equations would go a long way towards improving the readability of the document.

Reply: A worked example is now included.

Comment: I have not noted any missing studies or data.

Reply: N/A

Comment: The bootstrapping approach used here is a clever one, and the risk assessment team is to be praised for their ingenuity and willingness to push the envelope in risk assessment methodology.

I am concerned, however, that the casual reader will simply skim the seemingly complex math and statistics and not realize that what essentially drives the results of the risk assessment is the correlation (or lack of correlation) between the microbial outputs (prevalence or enumeration) and the inputs (on-line inspectors, off-line inspectors, unscheduled inspections of various types).

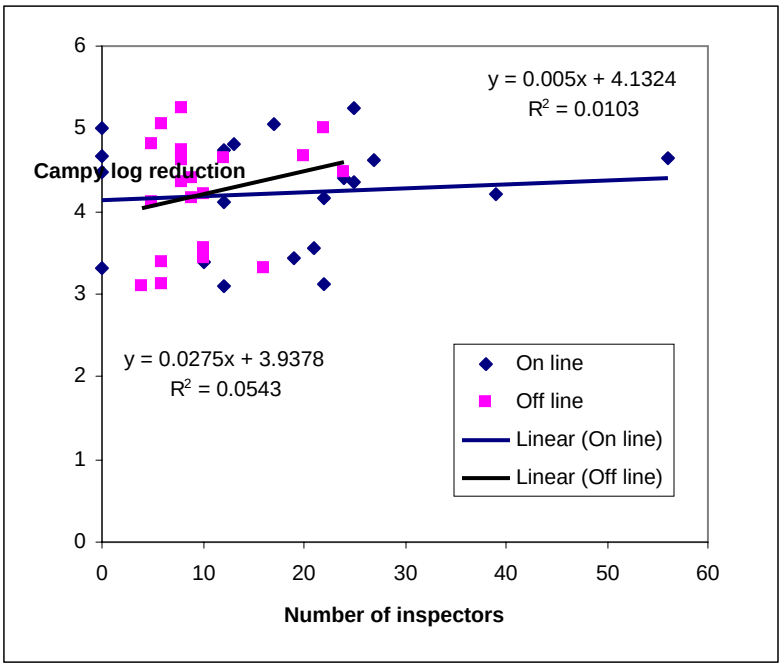
The risk assessment hides these simple correlations using many equations and the tables of uni- and bivariate correlations and transformations in the appendix.

It is possible to "fish out" these relationships using the information from the "RawData" portion of the spreadsheet, and let me state unequivocally that the risk assessment team is to be praised most highly for including this raw data in the information provided to the reviewers.

To illustrate my point I am including a few simple correlation plots from the data. Constructing these plots helped me to make some sense out of what were some rather nonsensical findings of the risk assessment.

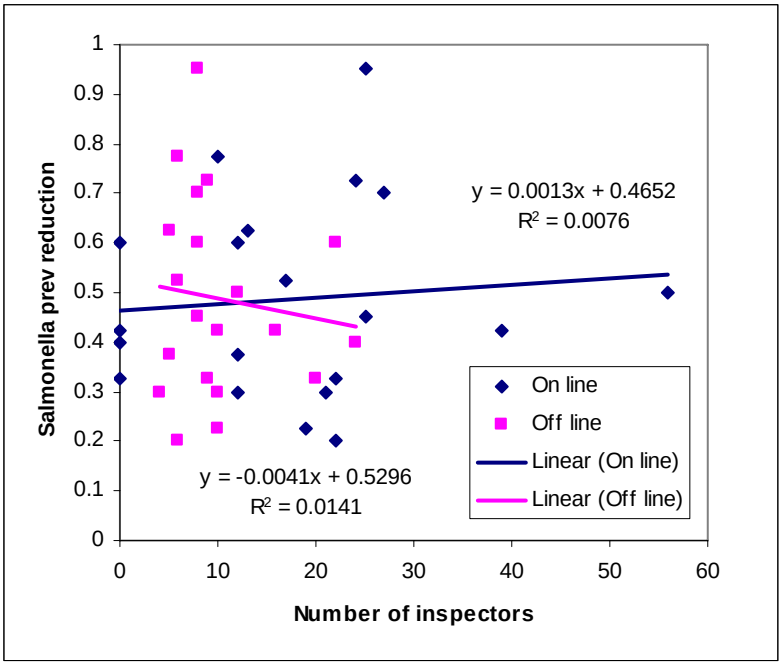
The chief source of confusion was the finding that reducing on-line inspectors caused *Campylobacter* to fall (which makes sense and which agrees with the *Salmonella* findings), but that increasing off-line inspectors causes *Campylobacter* levels to rise.

To try to understand this, I decided to go back to the raw data and plot the relationship between *Campylobacter* log reduction and the number of inspectors. This yields the plot below:



The first point that is apparent is that the correlation with any of the data is quite weak, but that there is some correlation. Given that the agency needs to move forward with the modernization of the inspection system, and this is the best (only?) data available, the team should not be faulted for using it.

The second (and more important point) is that increasing on-line and off-line inspectors are both correlated with increasing *Campylobacter* log reductions. A similar plot of the *Salmonella* correlations shows that the on and off line slopes are inversely related:



This relationship leads to the more sensible findings for *Salmonella*.

A third (and perhaps most important point) is that two plants have very high numbers (39 and 56) of on-line inspectors. Now my analysis is an admittedly simplistic one, and I have not bothered to search exhaustively for the correct transformations for either the prevalence, enumeration or number of inspectors, but the analysis does lead to some interesting findings as follows:

It is well known that R^2 can be quite sensitive to situations where one or two points lie well to one end of the continuum of points. If we exclude these points from both the *Campylobacter* and *Salmonella* analyses, some interesting findings emerge: The *Campylobacter* on-line correlation essentially drops to zero (R^2 = 7E-05), while the *Salmonella* correlation improves (R^2 = 0.0272).

In short, I believe the puzzling finding of the unexpected relationship between increased off-line inspectors and an increase in *Campylobacter* enumeration is due to the great power that those two plants have in the analysis. I encourage the risk assessment team to re-run the analysis omitting the data for those two plants.

Reply: We thank the reviewer for these helpful insights. The analysis has been rerun and appendices have been included to assist the more technical reader in interpreting the quantitative model. Additional data have also been added to the model thus reducing the power of individual outliers.

Comment: The risk assessment uses the difference between re-hang and post chill as an indicator of the risk reduction. This needs to be justified. An argument could be made

that post-chill values alone could be most representative of the risk posed to the public. Now this may be a moot point since the final counts and reductions are correlated, but some discussion and justification are needed. Discuss as team.

Reply: Discussion has been added to provide justification. In the current version of the analysis, only post-chill data are used. We still defend, however the use of difference data – as this helps account for variance in incoming pathogen levels on the carcasses.

Comment: The model is of an appropriate level of complexity, given the data that are available. While the model itself is fairly simple, as noted elsewhere in this review, the presentation of the model gives the impression of great complexity. A simpler presentation of the model may improve understanding and acceptance.

Reply: We have simplified the model presentation.

Comment: Parameterization is appropriate, except as noted elsewhere, I suggest removing 08 data from the analysis since these data are very limited, and their impact on the results are minimal. It would be sufficient to simply note that these data are limited, were modeled, but were omitted from the final because of little effect on prevalence or enumeration.

Reply: The 08 unscheduled data are those for biosecurity. We included the 08 category in the model so that as more data become available, the model may be updated to reflect unscheduled biosecurity procedure checks.

Comment: See above regarding the 08 data and need to simplify the presentation.

Reply: See above reply.

Comment: I believe the bootstrapping approach is adequate to characterize uncertainty in the relationships and variability in the data.

Reply: N/A.

Comment: See above regarding comments on two plants with high numbers of on-line inspectors.

Reply: These two plants have less influence in the current analysis.

Comment: The mathematics and equations appear to be adequate. As noted elsewhere in this review, the clarity of the explanation of the equations could be improved.

Reply: We have sought to clarify explanation of the equations.

Comment: The methods used for estimating the parameters appear to be adequate. As noted elsewhere in this review, the clarity of explanation of the bootstrapping approach, and the relationship between the input and output data could be improved.

Reply: We have sought to clarify this point.

Comment: The calculations in the spreadsheet appear to be accurate. The nature of models developed in Excel is that while they are easy to build, they are very difficult to check for errors.

Reply: N/A.

Comment: There is no formal "sensitivity analysis" as such. A search of the report documentation for the word "sensitivity" does not find any instances of this word. The nature of Figures 1-12 are such that it is possible to compare the slope of the cumulative probability plots to determine which inputs the model outputs are most sensitive to. Tables 11 and 12 likewise essentially constitute a sensitivity analysis, although they are not described as such. The model outputs are most sensitive to inputs where the difference between the mean and standard deviation (or median and 95^{th} percentile) is greater. The authors could add a table, or better yet a figure that compares the magnitude of these differences for all the independent variables, and their relationship to zero (or no change in illness).

Reply: We agree with the reviewer's comment. We have added additional appendices that address this issue.

Comment: The report is generally understandable, but detailed page-by-page comments have been provided elsewhere in this review, which may help to improve clarity and completeness.

Reply: N/A

Comment: The risk assessment team is to be applauded for attacking such a complex problem. Despite the numerous issues and concerns detailed in this review, I find the overall approach to be fundamentally sound. Indeed, I can imagine no other approach that would use real-world data to try and address this complex issue. Fundamentally, I believe that there is strong scientific support for a more risk-based approach to meat and poultry inspection, the key question is how to get there! This study takes the best available data and lays out, in a risk-based way, the probability, or likelihood that certain changes will, or will not increase or decrease risk. Studies such as this one can only give indications as to what the results of changing the inspection system might be. If such studies indicate that such a change represents little increase in risk (and may in fact decrease risk) then the way forward is clear.

Reply: N/A

Comment: The scenarios presented here are generally adequate. It might be useful to be able to model more complex scenarios such as decrease in on-line inspections coupled with an increase in various levels of type 01, 03 and 05 procedures.

Reply: More complex scenarios have been developed that combine decreases in online inspectors with increases in unscheduled type 01, 03, and 05 procedures in separate scenarios.

Comment: The approach taken to estimate illnesses appears to be reasonable, however, as noted elsewhere in review, it is not exactly clear how the changes in *Campylobacter* concentrations are related to changes in illness. This should be clarified in the report. The underlying data used to provide baseline estimate are sound, and are the appropriate data to use.

Reply: Please note that the current version of the analyses does not include *Campylobacter* results – but this will be included in the next version, using the Fall 2008 young chicken baseline sampling data.

Comment: Page 2: When "young chickens" are first mentioned, it should be noted that these used to be called "broilers".

Reply: The suggested revision has been made.

Comment: Page 3: "If the number of on-line FSIS inspectors is decreased…" by how much?

Reply: The section in question is not included in the revised risk assessment report. We have edited the risk assessment to provide information about percentage of reductions/increases in inspectors when making statements similar to that highlighted above.

Comment: Page 3: It is not clear what 05, 01 and 03 mean in the context of these sentences: "Increasing unscheduled sampling procedures (05) conducted by FSIS inspectors is most effective at decreasing the level of Campylobacter contamination compared to other unscheduled sampling procedures (01, 03)." It is clear from reading the rest of the document, but the executive summary should stand on its own.

Reply: We agree. The text has been revised so that the Executive Summary can be understood as a stand-alone document.

Comment: Page 7: "Other aspects of the proposed rule including the establishment of standards of identity for products coming off the line, new generic E. coli testing procedures, potential changes to current chilling regulations and new on-line reprocessing guidelines, are not addressed in the quantitative analysis". Why are these other aspects not addressed? Is it simply because the data are not available to address them?

Reply: The risk management questions did not include the aspects discussed above. In future updates of the risk assessment, however, we may be able to address these. The risk assessment will be presented publicly and we will work with stakeholders to refine questions and risk assessment analyses.

Comment: Page 7: Hazard identification usually also identifies the population of concern… in this case the target population is general public.

Reply: The text has been clarified on this point.

Comment: Page 8: Grammar error: "This risk assessment has estimated … and HAS considered…"

Reply: The suggested revision has been made.

Comment: Page 11: Abbreviation "GBS" not needed, since term is never used again.

Reply: The suggested revision has been made.

Comment: Page 12: "By this is meant…" is awkward phrasing.

Reply: The sentence has been revised.

Comment: Page12, Tables 4 and 5: Why are percentages expressed only to the nearest whole percent? E.g. 1292/1297 = 99.6% not 100 as shown.

Reply: The revised report includes values to two decimal points.

Comment: Page 13-14: It is not possible to check the calculations for "Weighted prevalence within a plant" since monthly data are not provided.

Reply: N/A.

Comment: Page 15: Typo, number in middle of phase: "methodologies for4 both sets".

Reply: The error has been corrected.

Comment: Page 17: Why does prevalence and concentration go down after chilling? Is this real reduction or just injury? Perhaps the concentration goes down because the organisms are not recoverable from cold chicken skin.

Reply: Prevalence and concentration go down after chilling because bacterial cells are washed away and/or destroyed. There has been much research conducted to address the issue of decreases in bacteria on poultry following chilling (see http://www.fsis.usda.gov/PDF/Slides_022306_JNorthcutt.pdf for a summary). Though

viable-but-non-culturable bacteria may account for some of the decrease, the majority is believed due to destruction of cells.

Comment: Page 18: Extra CR Typo: "(Table 10)."

Reply: This error has been fixed.

Comment: Pages 22-23: The discussion of ISP codes is quite complex and the reader would benefit from a table or tables explaining the different prefix, letters codes and suffixes. Also, since only 01, 03, 05 and 08 are used in the model, it is not clear what the point of discussing 04 and 06 codes might be.

Reply: ISP codes 04 (Economic/Wholesomeness) and 06 (Other Inspection Requirements) are used in the model. We considered the suggested table; however, the narrative description seemed more appropriate. The table did not seem to add information.

Comment: Page 23: Possible missing word or punctuation. Should the text read "as would be expected AS prevalence…"? Adding a comma after expected would also be acceptable.

Reply: The suggested revision has been made.

Comment: Page 24: What does "½ log" mean in this context? Also, the reason for including both re-hang and post-chill data are not clear. Wouldn't post-chill alone be most representative of the risk? Later on this page the document mentions ½ natural log transformations. Terminology should be consistent (i.e. always use natural log) and the reason for transformation should be referenced the first time it is used.

Reply: Discussion of "½ log" has been removed. Post-chill alone would indeed be most representative of exposure, and thus risk. The reason for examining both pre-chill and post-chill, however, is to examine the effect of various mitigations (such as chilling) in reducing contamination of *Salmonella* on poultry.

Comment: It is not exactly clear how illness reduction is calculated for the *Campylobacter* data. In the case of *Salmonella*, it is logical that a 25% decline in prevalence will lead to a 25% decline in illness. How are these calculations made for *Campylobacter* when the data are in concentration or log concentration? Does a log reduction in *Campylobacter* correspond to a log reduction in human illness?

Reply: Information for *Campylobacter* is no longer included in the report.

Comment: Page 25: It is not immediately clear why variables 3 and 8 are needed, since they can be derived from variables 1 and 2 and 4-7 respectively.

Reply: Parameter estimates were made from combinations of 1-2 and 4-7. These were derived from simulation and are not otherwise attainable.

Comment: Page 25: Why "350 thousand" and not 350,000?

Reply: The suggested revision has been made.

Comment: Page 25: In the sentence "Once parameter estimates for slope ( ) and intercept ( )…" why are the symbols superscripted?

Reply: This section is no longer included in the report.

Comment: Page 25: Why the capitalization: "First, ON-line inspectors"?

Reply: This has been corrected.

Comment: Page 26: Explain how the 5,000 iterations mentioned here related to the 350,000 iterations mentioned on page 25.

Reply: The "5,000" value was an error. The current analysis utilized 20,000 iterations not 350,000.

Comment: Page 27: Extra CR Typo: "of scenarios (Figure 2),"

Reply: The suggested revision has been made.

Comment: Page 27, figure 1: Yellow is quite hard to read, I suggest another color. There is something wrong with the x-axis labels. The lines are evenly spaced, but the tick labels are not, i.e. 0.003, 0.005, 0.008, and 0.01. This may be rounding error. In any event, I suggest that x-axis be labeled in percent, e.g. 2, 4, 6, rather than 0.002, 0.004, 0.006 etc.

Reply: New colors have been used and the x-axis label updated as suggested above.

Comment: Figure 1 also does not stand on its own: What were the reductions or increases associated with each line?

Reply: Information has been added to the text immediately above the figure.

Comment: The caption for Figure 1 is not exactly correct; it should read "number OR RATIO of inspectors."

Reply: The model examined number of inspectors for particular inspection activities, not necessarily the ratio in all cases. Therefore, we believe the caption is appropriate as written.

Comment: Figure 2, page 28: This figure is also hard to read. Red and green lines are obscured by the blue line. The figure does not stand on its own, as the reader has no way to know what 01, 03, 05 or 08 mean.

Reply: The figure has been updated for clarity. In addition, a discussion has been added to explain the contents of the figure.

Comment: Page 29: If this page is intentionally blank, indicate this.

Reply: The page was inadvertently blank. The report has been revised.

Comment: Page 30-31, Tables 11-12: The column header "iterations > 0" is not terribly helpful. This column represents the fraction of the time the risk assessment predicts that the described change in the independent variable results in an increase in pathogen prevalence or concentration. Perhaps a header like "fraction of time risk increases" would be more helpful. On the other hand, the results may be viewed more favorably if the header were "fraction of the time risk decreases" and 1 minus the percentage shown where used instead.

Reply: The tables in question are not included in the revised risk assessment.

Comment: Page 30, Table 11: The *Salmonella* numbers in this table appear to be incorrect. These should prevalence changes should be small numbers, not 10^3 or 10^4. Why is there no separate line for the change in 08 type inspections? This is mentioned on page 38, but should be noted here. See my suggestion below on removing type 08 from the report altogether.

Reply: The table in question is not included in the revised risk assessment.

Comment: Page 31, Table 12: Why is median decrease in ratio of on-line to off-line inspectors listed as "(-31)" and not "(-)31"? As above, why is there no separate line for the change in 08 type inspections? This is mentioned on page 38, but should be noted here. See my suggestion below on removing type 08 from the report altogether.

Reply: The value "(-)31" is given in the revised report. As stated in the report: "Because we used calendar year 2004 data for the original analysis, unscheduled biosecurity (type 08) procedures are not frequently recorded in the data that and therefore results are not reported in Table 11 and Table 12."

Comment: Page 32: "Figure 3 and Figure 4Error! Reference source not found."

Reply: This error has been corrected.

Comment: Page 32, Figure 3: Yellow is hard to read, Figure doesn't stand alone, what were the reductions or increases associated with each line? Caption should read "number OR RATIO of inspectors." X-axis is for change in level, but the scale doesn't seem suited

to this. The scale shows values of 0.01 or 0.02, but change in levels from Table 11 shows numbers like 10^3 or 10^5.

Reply: The specific figure in question is not in the revised report. More generally, **t**he colors of the lines were generated automatically by the graphing program. We have worked to increase resolution and feel all colors are discernible. The model examined number of inspectors for particular inspection activities, not necessarily the ratio in all cases. Therefore, we believe the caption is appropriate as written. We have also checked to ensure that values in tables and figures are consistent throughout.

Comment: Page 32: "Removing on-line inspectors seems to lead to no change or a reduction in enumeration"… are on-line inspectors REDUCED or REMOVED?

Reply: "Removing" has been changed to "reducing."

Comment: Page 32: "When those inspectors are added to off-line ranks, we cannot predict a reduction in *Campylobacter* enumeration with confidence." This seems totally non-intuitive. This finding should be discussed. Note that it is discussed later (page 38) but warrants some discussion here as well. This is likely to be a key weakness exploited by anyone wishing to dismiss the model as invalid.

Reply: Data for *Campylobacter* are no longer included in the model. The reason for doing so was that we were able to obtain much more data for *Salmonella*. If additional data are generated, we may then include them in updated versions of the model.

Comment: Page 33, Figure 4: Can't see differences between lines, especially 05 and 08. Symbols for 05 and 08 obscure other lines. Use colors or different symbols. The scale shows values of 0.01 or 0.02, but change in levels from Table 11 shows numbers like 10^3 or 10^5.

Reply: The particular figure in question is not included in the revised report. As a general matter, we have gone through the report to examine each of the figures, increase resolution, and in many instances size of the figures. We believe each figure is clearly discernible.

Comment: Page 34: "Figure 5 and Figure 6Error! Reference source not found."

Reply: This error has been fixed.

Comment: Page 34, Figure 5: Caption should read "number OR RATIO of inspectors." X-axis is for change in level, but the scale doesn't seem suited to this. The scale shows values of 0.01 or 0.02, but change in levels from Table 11 shows numbers like 10^3 or 10^5.

Reply: The specific figure in question is not in the revised report. More generally, **t**he colors of the lines were generated automatically by the graphing program. We have worked to increase resolution and feel all colors are discernible. The model examined

number of inspectors for particular inspection activities, not necessarily the ratio in all cases. Therefore, we believe the caption is appropriate as written. We have also checked to ensure that values in tables and figures are consistent throughout.

Comment: Page 35, Figure 6: Can't see differences between lines, symbols obscure other lines.

Reply: We have gone through the report to examine each of the figures, increase resolution, and in many instances size of the figures. We believe each figure is clearly discernible.

Comment: Page 36: "Figure 7 and Figure 8.Error! Reference source not found."

Reply: This error has been corrected.

Comment: Page 36, Figure 7: Yellow is hard to read.

Reply: Colors in the figures were generated automatically by the software used to generate them. We have gone through the report and worked to increase clarity and resolution of all figures. We believe each is clearly discernible.

Comment: Page 38: "a 77% likelihood of no increase in illness" … actually it's stronger than this - a 77% likelihood of A DECREASE OR no increase in illness.

Reply: The statement in question is not in the revised risk assessment.

Comment: Page 38: "The results show confidence that modeled changes will not increase Salmonella-related illness approaching a 70% likelihood of no increase in illness" … I think you are actually talking about *Campylobacter* (Fig 10) here, not *Salmonella*.

Reply: The statement in question is not in the revised risk assessment.

Comment: Page 38: "Similar decreases in illness occur on average for both Salmonella (-346) and Campylobacter (-343) scenarios". State explicitly what these numbers mean: "Similar decreases in illness occur on average for both Salmonella (346 FEWER CASES PREDICTED) and Campylobacter (343 FEWER CASES PREDICTED) scenarios.

Reply: The statement in question is not in the revised risk assessment.

Comment: Page 38: "However, when HACCP (type 03) or sampling (type 05) unscheduled procedures are increased similarly … while *Campylobacter* illnesses increase on average". As above, this is totally non-intuitive and really needs a careful critique.

Reply: The statement in question is not in the revised risk assessment.

Comment: Page 38-39: "Because we used calendar year 2004 data for this analysis, unscheduled biosecurity (type 08) procedures are not frequently recorded in the data that and therefore results are not reported in Table 11 and Table 12." If this is really the case, then the whole report can be simplified and all type 08 procedures removed from the analysis and report entirely.

Reply: The 08 unscheduled data are those for biosecurity. We included the 08 category in the model so that as more data become available, the model may be updated to reflect unscheduled biosecurity procedure checks.

Comment: Page 40, Figure 10: There appears to be a 4th line here: lightly dotted and following the green line.

Reply: The figure in question is not included in the revised report.

Comment: Page 41, Figure 11: Figure legend cropped by box.

Reply: This has been corrected.

Comment: Page 42, Figure 12: Why is the x-axis asymmetric, extending out to -20,000 cases? Why the long tail on type 08 distribution?

Reply: The figure in question is not included in the revised report. All other figures have been checked for axis symmetry and other formatting issues.

Comment: Page 42: "It is limited by assumptions made early on in an already compressed analysis period," this sounds a little whiney: like risk assessors complaining they didn't have enough time.

Reply: It appears we expressed ourselves clearly. The statement in question, however, has been removed.

Comment: Page 43: "We were limited in this analysis, but perhaps not for the next, in that only 1 calendar year's data was available." Do you mean that in the next iteration of this risk assessment that more years' worth of data will be available? If so, just say this directly.

Reply: Yes. Additional data will be available. Importantly, those for enumeration of *Salmonella* on young poultry will be available in the next year following completion of a baseline study.

Comment: Page 43: "Additionally, the estimated change in illnesses is assumed proportional to the changes in prevalence and enumeration. That is, a formal analysis between these changes and the level in final product and the relationship between dose

and illness has not been evaluated." See comments above (comments on page 24) regarding exactly how human illness reduction is calculated.

Reply: This comment pertains to calculations for *Campylobacter* is no longer included in the report. *Campylobacter* data are no longer included in the report.

Comment: Page 43: "functional form of the regression equations" is a bit jargony. It is not clear what "variety of lag structures" means.

Reply: The language has been clarified. When we refer to lag structures, we are referring to lags in time between observations of the independent variable vs. the dependent variable.

Comment: Page 43: "Our scenario results indicate consistently an approximate 80% likelihood that *Salmonella* illnesses attributable to young chicken will either decrease or remain the same." If what? What is missing here is the idea that this is the likelihood of illness IF the inspection system is modified as proposed.

Reply: The language of the report has been modified accordingly.

Comment: Page 43: "There is a 70% likelihood that *Campylobacter* illnesses attributable to young chicken plants will either decrease or remain the same" This statement sweeps the increase in illness from increase in off-line inspector (Figure 3) under the rug.

Reply: Data for *Campylobacter* are not included in the revised report.

Comment: Page 43: "Blanket reassignments of on-line inspectors to currently aligned off-line procedures may not be useful in lowering *Campylobacter* and other indicator organism counts." In fact, your data indicate that these changes will likely INCREASE campy counts!

Reply: Information about *Campylobacter* is not included in the revised risk assessment.

Comment: Page 43: Typo: "are biasED towards"

Reply: This particular instance has been removed in the updated risk assessment. In addition, we have done multiple proofreadings in an effort to fix errors of this type.

Comment: Page 43: "inspectors to completions of unscheduled health procedures" awkward.

Reply: This language is not included in the revised risk assessment.

Comment: Page 43: "a 40% likelihood that *Campylobacter* counts will be lowered or remain the same" again you misrepresent your findings. The analysis shows a 60% chance *Campylobacter* counts will increase.

Reply: Information about *Campylobacter* is no longer included in the risk assessment.

Comment: Page 43: "increases in unscheduled sanitation procedures (type 01) are most effective". ARE most effective, or APPEARS to be most effective, based on the risk assessment assumptions.

Reply: The language of the report has been modified to focus on associations between inspector profiles and *Salmonella* contamination.

Comment: Page 43: "increases in unscheduled sanitation procedures (type 01) are most effective in lowering *Campylobacter* and generic *E. coli* counts" This finding suggests that it might be possible to offset the on-line/off-line Campy rise with increased type 01 inspections. Can the current model evaluate this scenario?

Reply: Data for *Campylobacter and* generic *E. coli* are not included in the revised risk assessment.

Comment: Page 45: "Ultimately, only the four differences between P2 and P3; P4 and P5; P6 and P7; and P8 and P9 were modeled." These variable names are introduced here, but defined later in the paragraph. Definition in a table would be appropriate or define each term as it is introduced.

Reply: We have revised the report and attempted to define each term at first mention.

Comment: Page 45: "Prevalence was transformed to correspond to a normal distribution using the logit transform." This is called a logistic transformation in the body of the document. Terminology should be consistent.

Reply: The terminology has been revised for consistency. In those instances where specific "logistic models" are described, the terminology has remained unchanged.

Comment: Page 45: "This enumeration data was transformed by taking one-half the common logarithm". The text says "natural log". These are NOT the same.

Reply: This was a typo in the original analysis. This transformation is not being used in the current analysis since enumeration is not being modeled.

Comment: Page 45: It appears that from the dependent variables paragraph that what is being modeled is the reduction from re-hang to post-chill. This was not at all clear from the text. The text on page 24-25 should be clarified.

Reply: The Model Description section of the report, including discussion of dependent variables, has been expanded to provide more detail and clarity. Again, please note that the current version of the analysis is not using the reduction – just post-chill prevalence estimates as the dependent variable.

Comment: Page 45: "Number Cruncher Statistical Systems 2004 version software" The reference #23 lists the year as 2000 not 2004.

Reply: The reference has been updated.

Comment: Page 45-46: This reviewer would have found it helpful and interesting to review the normal probability plots generated for each dependent and independent variable. I strongly suggest that at least some representative normal probability plots appear in the revised version of the risk assessment.

Reply: Representative normal probability plots now appear in the revised version of the risk assessment.

Comment: Page 46: "(P1-P9) are given" should this be "WERE given"?

Reply: This language is not included in the revised report.

Comment: Page 46: What is variable NC04? This is never defined.

Reply: Variable NC-4 describes non-compliances for wholesomenss procedures. It is defined in Table 7 of the revised report.

Comment: Page 48-49: Tables 13 and 14 contain some duplicates entries, which should be removed from Table 14: P1-P3, ON, OFF, ON/OFF, etc. If there is some reason why these need to be listed in Table 14, it's not clear from the text, and the text should be revised.

Reply: All tables have been revised to avoid duplicate entries.

Comment: Page 51: Likewise, there are entries in Table 15 that duplicate Table 13 entries and these should be removed, or the reason for inclusion clarified.

Reply: All tables have been revised to avoid duplicate entries

Comment: Worksheet "Start", Overview text box: The "i" in *E. coli* is mistakenly not italicized.

Reply: This has been fixed.

Comment: Worksheet "RawData", Cells J2:L2: Numerous typos.

Reply: These have been fixed.

Comment: Worksheet "RawData:, Cell C5, Tools, Formula Auditing, Trace dependents, Double click on arrow head, select first entry in list

([RBPSI_simulation39.xls]Scenario02!C6), This cell is in a column headed “Campy Pre-Post Chill difference enumeration data 04”. It is not clear why Salmonella prevalence data are being used to calculate Campy enumeration data.

Reply: Information for *Campylobacter* is not included in the revised risk assessment. All worksheets have been updated accordingly.

Itemized Replies to Reviewer #5

Comment: Indication for a quantitative microbial risk assessment to evaluate the public health benefit of moving from the current poultry slaughter inspection system to a "risk-based" inspection system: Adequate indication and rational are presented for the development of the described "risk-based" inspection system".

Reply: N/A.

Comment: Please see comments [in italics] under column 4 of Table 1

Table 1. Summary of differences between the current inspection system (CFR § 381.67) and the proposed new system for young chicken slaughter establishments.

1	2	3	4
	Current Inspection System	**Proposed New System**	*Data needed to assess the difference*
Carcass Sorting	FSIS determines condemnation of carcasses; establishments do not sort carcasses.	Establishments are required to sort carcasses and ensure carcasses are not adulterated before entering chilling tanks.	*Ascertainment of the adequacy of the establishment's performance of this task is missing. Differences can be measured by comparing prevalence of the target organisms (Salmonella and Campylobacter) in carcass samples randomly picked from the lines that are currently under the FSIS supervision and after the establishment taken over.* *Design verification activities to focus on those aspects of process where loss of control is more likely to occur or where a loss of control would have serious public health consequences and to intensify inspection if there is evidence that the plant is losing, or has lost, control after the implementation of the new system.* *Use consumer complaint and other data from*

			outside plant to guide in-plant verification activities after the implementation of the new system.
Performance Standards	Establishments will continue to address CFR § 381.65(e).	Establishments must meet the food safety performance standards for poultry slaughter defects (zero fecal, zero septicemia /toxemia) as well as animal disease performance standards.	*Use of performance standards to measure control after establishment personnel taken over on on-line activities. Acceptable measurements should be listed (http://www.fsis.usda.gov/OPHS/baseline/contents.htm)*
Line Speed	Establishments will adhere to regulatory limits (CFR § 381.67). Line speeds are dependent on slaughter class.	No maximum line speeds. Rather, limits on line speed will be based on establishment's ability to maintain process control and meet performance standards.	*Use of performance standards to measure control after establishment's personnel taken over on on-line activities.* *Efforts by FSIS personnel should be spent to detect any drawbacks that may be associated with "no maximum" speed of the line policy. If no drawbacks, final approval can be provided for this change in policy.*
Generic E. coli *Process Control*	Current CFR § 381.94(a) will apply.	New process control performance standards will be adopted.	*Define the new process control performance standards*
Standards of Identity	New proposed Standards of Identity regulations will provide a standard of quality for whole chickens. All establishments will be required to maintain a process control plan to ensure that whole chickens meet the proposed standard of identity.	Standard of Identity regulations for standard of quality of whole chickens.	*No significant differences*
Time and Temperature	Establishments will adhere to CFR § 381.66.	Current poultry chilling requirements in CFR § 381.66 amended to provide more flexibility to establishments.	*Describe the amendment briefly.*
On-line Reprocessing	Establishments will adhere to CFR § 381.91.	On-line reprocessing of pre-chill poultry carcasses accidentally	*Define the On-line reprocessing of pre-chill poultry carcasses.*

	contaminated with digestive tract contents at slaughter.

Reply: Though we appreciate the reviewer's comments, we have not added the column to the table. The table was provided solely for background. We believe that many of the comments suggested go beyond the scope of the risk assessment. Issues of data required to address differences between systems are discussed with risk managers. In the report, attempts have been made to address those data needs deemed most critical. We also wish to avoid making statements about what FSIS inspectors efforts should be spent doing (for instance, in detecting "drawbacks associated with 'no maximum' speed of the line policy." These are policy decisions best left to policy makers. Instead, in the report, we attempted to lay out objective evidence, from which policy makers can make informed decisions.

Comment: This report indicated that reallocation of inspection resources will be to off-line PR/HACCP. However, question # 2 of the reviewer's charge does include the impact of such reallocation to out of the plant. Additionally, the report states that analysis between these changes and the level in final product and the relationship between dose and illness has not been evaluated. My suggestions for both scenarios are as follows:

a. Reallocation of inspection resources away from on line-procedures out of the plant:
This will represent "professional working force reduction". Impact should be assessed by conducting a pilot experiment in which the performance standards (% positive for *Salmonella*, *Campylobacter*, and *E. coli* of representative randomly collected from on-line poultry carcass samples from large, and small establishments) should be compared using samples drawn scientifically (randomly) from the on-line poultry carcasses before the reallocation of inspection resources from on-line to out of the plant and after the reduction. Test for proportions (X square) of samples positive for the target bacteria before and after the force reduction will reveal the impact. Acceptable difference (tolerance of small increase in the proportions of poultry carcasses that are positive for the target organisms should be defined).

b. Reallocation of inspection resources away from on line-procedures to off-line PR/HACCP verification procedures and/or sanitation verification procedures:
Similar design to the first scenario (a) should be conducted. However, it is hoped that the final comparison between the bacterial contamination (prevalence data) will be performed on samples of the poultry carcasses processed before and after the increase of resources at the off-line PR/HACCP verification procedures and/or sanitation verification procedures to reveal if implementation of such reallocation will improve the quality of the poultry product from the establishments in terms of the reduction in the prevalence of the listed pathogens in the final products.
Data on prevalence and enumeration data for campylobacter and salmonella on carcasses before and after various processing steps such as scalding, defeathering, evisceration, washing and chilling, should be generated.

Time that should be given after the filling of the additional positions at the off-line PR/HACCP verification procedures and/or sanitation verification procedures should be considered before a meaningful analyses could be performed. One month after the manning of those positions may be a reasonable time to reveal the positive impact (reduction in prevalence of *Salmonella*, *Campylobacter*, and the non-specific *E. coli*) in samples of the poultry products leaving the establishment.

c. Model indication for changes in Salmonella prevalence:
Results can be viewed in Figures 1 and 2. These results are consistent across the various measurement scenarios. Approximately 70-90% of the time the model predicts that *Salmonella* prevalence will not increase because of considered changes to inspector assignments. In the second series of scenarios (Figure 2), the model simulates 25% increases in the number of unscheduled procedure completions for all health-related procedures (procedure codes 01, 03, 05, and 08). Almost 90% of the time, the model predicts that *Salmonella* prevalence will not increase when all four-health procedures are increased. Individually, results vary from 90% no increase for sanitation (type 01) procedures to about 60% no increase for unscheduled sampling (type 05) procedures.

Reply: We thank the reviewer for suggestions regarding future data gathering efforts.

Comment: Baseline data for the prevalence/counts of *Salmonella, Campylobacter*, and the nonspecific *E. coli* should be established before such reallocation is implemented. To the baselines data, the following data can be compared to reveal the impact of higher completion rates for inspection system procedure (ISP) assignments effect on prevalence/counts, as well as other process control indicators such as the un-scheduled tasks to follow-up on necessary inspection for sanitation and other procedures:

i. Prevalence and enumeration data for *Salmonella, Campylobacter*, and the nonspecific *E. coli* on carcasses before and after various processing steps such as scalding, defeathering, evisceration, washing and chilling.

ii. Prevalence and enumeration data for *Salmonella, Campylobacter*, and the nonspecific *E. coli* on carcasses comparing various methods of chilling (e.g. air chilling, water chilling, water chilling with chlorine).

iii. Prevalence and enumeration data for *Salmonella, Campylobacter*, and the nonspecific *E. coli* on carcasses comparing different scalding temperatures or alternate scalding configurations (e.g. multi-tank scalding systems).

iv. Data describing the actual cross-contamination between positive and negative flocks and within flocks during the different slaughter processes.

Reply: We thank the reviewer for these suggestions. A baseline program is ongoing that will yield enumeration data for *Salmonella* on chicken. The resultant data will indeed improve the model.

Comment: Impact of the reallocation would eventually be evaluated as an enhanced ability to evaluate and perform a better HACCP system for the reduction of *Salmonella* and *Campylobacter* in poultry carcasses produced by large and small establishment. Since this model is rather simplistic, the following data should be planned for the construction of the next models:

- Outbreak and epidemiological data, specifically indicating: *Salmonella* and Campylobacter cell number in the implicated poultry amount consumed, accurate estimates of the size of ill and exposed populations, accurate characterization of the population including age profiles, medical status, sex and other potential susceptibility factors.

- Characterization and quantification of the impact of the food matrix effects, host-pathogen interactions and virulence factors and their effect on the probability of infection and/or illness due to *Salmonella* and *Campylobacter.*

- New dose-response models that improve the ability to estimate the probability of illness due to *Salmonella* and *Campylobacter.*

Reply: We thank the reviewer for specifying these particular data needs.

Comment: In this risk assessment project, the risk assessment were based on only two scenarios; 1) the public health impact between observations on re-hang and post-chill Salmonella prevalence sampling and 2) the public health impact in the log enumeration of re-hang and post-chill *Campylobacter* sampling using surrogate data from ARS prevalence and enumeration data for pre- and post-chill in broilers (PBIS database for calendar year 2004; FSIS volume data for plants for 2004); and CDC data on estimates of human salmonellosis and campylobacteriosis.

It is therefore unrealistic, using this scenario analysis, to have accurate or valid estimates of the changes in number of illnesses attributable to inspection resource reallocation. However, the model's estimate can be use as a useful tool to guide the management of inspection force to ensure a more efficient utilization of the professional manpower that is effective in the enhancement of the mitigation of the risk associated with the contamination of the poultry products with salmonella and Campylobacter pathogens.

Reply: Data for *Campylobacter* are not included in the revised model, while those for *Salmonella* have been greatly expanded. The revised assessment is designed to focus on associations between *Salmonella* contamination on young poultry and specific inspection tasks. We agree that the model is useful for guiding efficient and effective inspection.

Comment: [Have all key studies and data been identified?] Yes, with the few defined assumptions and small numbers of the variables the model was based on, key studies that are pertinent to the establishment of this model were used.

Reply: N/A.

Comment: [Have the data been correctly interpreted, analyzed, and used in the risk assessment?] Yes.

Reply: N/A.

Comment: The report used the Nationwide Young Chicken Microbiological Baseline Data Collection Program. November 1999 – October 2000. http://www.fsis.usda.gov/Science/Baseline_Data/index.asp. (Nov 1999 - Oct 2000) for the *Salmonella* prevalence estimated from PR/HACCP samples. and *Salmonella* prevalence estimated from the FSIS chicken rinse study. These data are the most comprehensive data regarding the prevalence of microbiological contamination of poultry on the national bases. Therefore, the input data are valid and appropriate in the risk assessment report.

Reply: N/A.

Comment: The risk assessment model is based on the estimates of changes in human illness that were considered as a function solely of predicted changes in *Salmonella* prevalence or *Campylobacter* counts on chicken and that these estimates assessment assume that changes in microbial contamination on chicken are proportional to predicted changes in the number of related human illnesses. These assumptions are limited because they ignore several factors such as:

1) dose-response modeling that improves the ability to estimate the probability of illness,
2) food matrix effects,
3) host-pathogen interactions,
4) virulence factors and their effect on the probability of infection and/or illness.

Therefore, one can state that the model may not be complex enough to adequately address all risk management questions.

Reply: Data for *Campylobacter* are not included in the revised risk assessment, while those for *Salmonella* have been greatly expanded. We agree that extrapolating from prevalence of *Salmonella* on poultry to human illness is difficult. As enumeration data for *Salmonella* on poultry become available, the model will be strengthened by their inclusion.

Comment: The model looks simplistic and reasonably parameterized.

Reply: N/A.

Comment: The team adequately described the limitation of the model. Therefore, the simplifications will not significantly detract from the model utility.

Reply: N/A.

Comment: The model adequately characterized the uncertainty and the variability was addressed sufficiently.

Reply: N/A.

Comment: Model techniques, as described by the authors, including the mathematics and equations, seem to be appropriate.

Reply: N/A.

Comment: Data analysis and source code are accurate.

Reply: N/A.

Comment: Most important variables in the model been were identified and adequate sensitivity analysis has been provided.

Reply: N/A.

Comment: This risk assessment model is well documented. The report was clearly written and sounds complete in addressing the areas it meant to address.

Reply: N/A.

Comment: With the assumptions and limitations that were addressed in the report, I find the report described an acceptable overall approach for modeling the risk-based inspection (in terms of results of the reallocation of the inspection resources of-line to PR/ HACCP activities within the same establishment) versus the current arrangement of the FSIS inspection resources within poultry slaughtering establishments. I would like to reiterate the aspects that should be considered in future efforts in this area

The risk assessment model is based on the estimates of changes in human illness that were considered as a function solely of predicted changes in *Salmonella* prevalence or *Campylobacter* counts on chicken and that these estimates assessment assume that changes in microbial contamination on chicken are proportional to predicted changes in the number of related human illnesses. These assumptions are limited because they ignore several factors such as dose-response modeling that improves the ability to estimate the probability of illness; food matrix effects; host-pathogen interactions; [and] virulence factors and their effect on the probability of infection and/or illness.

Reply: We agree that extrapolating from prevalence of *Salmonella* on poultry to human illness is difficult. As enumeration data for *Salmonella* on poultry become available, the model will be strengthened by their inclusion.

Comment: A part from further explanation that may be needed for the predicted increase in campylobacter prevalence expected post implementation of the risk-based inspection, I find the selected scenarios, as described and rationalized in the report, adequate in capturing the significant differences expected to occur when risk-based inspection is implemented.

Reply: Information for *Campylobacter* is not included in the revised risk assessment.

Comment: The report used data from Incidence of illness from *Campylobacter* and *Salmonella* based on U.S. population estimate for 2003. It accounted for underreporting, estimating proportion of infections that are foodborne, estimating proportion of foodborne infections from poultry. The estimates on the proportion of foodborne infections from young chickens were based on data from the Economic Research Service (ERS) were used to estimate the proportion of poultry-related *Campylobacter* and *Salmonella* infections that are due to young chicken, which comprises approximately, 84% of poultry production in the U.S. in 2004. The final estimates for annual illnesses from foodborne illnesses from *Campylobacter* and *Salmonella* on young chickens, therefore, are valid and appropriate.

Reply: N/A.

APPENDIX I: PEER REVIEWER BIOGRAPHIES

- **Dr. Lee-Ann Jaykus and Dr. Amirhossein Mokhtari.** Dr. Jaykus is an associate professor in the department of food science at North Carolina State University. She earned her PhD in Environmental Sciences and Engineering from the University of North Carolina at Chapel Hill in 1993. Dr. Jaykus's research activities focus on application of molecular biological methods for the detection of pathogenic microorganisms in foods. Current research projects involve the development of nucleic acid amplification technology for the detection of human enteric viruses (human enteroviruses, hepatitis A virus, Norwalk virus) in shellfish, fresh produce, and ready-to-eat food commodities. Additional research includes developing similar methods for the detection of *Listeria monocytogenes* and *Salmonella* from dairy food products, with specific focuses on bacterial concentration and refining molecular methods to facilitate the real-time detection of foodborne pathogens. She is also actively involved in the application of quantitative risk assessment methods for the evaluation of public health risks of foodborne pathogens. Dr. Mokhtari is a postdoctoral fellow training under the direction of Dr. Jaykus. He has a Ph.D. in Environmental Engineering from North Carolina State University (NCSU) and specializes in uncertainty, variability, and sensitivity analyses and quantitative exposure and risk assessment.

- **Dr. Joseph Eifert** – Dr. Eifert is currently an Associate Professor and Extension Specialist in the Department of Food Science and Technology of Virginia Tech. His research program focuses on the prevention and reduction of microbial pathogens in processed foods, and surface microbiological sampling procedures. His Extension program emphasizes microbiological safety and quality issues for poultry processors and food safety education for a variety of audiences. Additionally, he teaches the graduate course "Food Regulatory Affairs". Dr. Eifert received his graduate degrees in food science and technology from Virginia Tech, and his B.S. degree in biology from Loyola Marymount University. Previously, he worked as a laboratory manager for the Nestlé USA Quality Assurance Laboratory in Dublin, Ohio, and as an analytical chemist for the U.S. Food and Drug Administration in Los Angeles, California.

- **Dr. Ian Gardner** – Dr. Gardner is a Professor of Epidemiology in the School of Veterinary Medicine at the University of California, Davis. His main expertise is in analytic epidemiology and his research interests include diagnostic test evaluation, risk analysis for livestock diseases and food safety, development of methods for certification of pathogen freedom in animal populations, and the epidemiology and transmission of Johne's disease in cattle. He is an author of more than 190 peer-reviewed publications and has served on many national and international committees, panels, and review teams. He is the leader of the Epidemiology and Biostatistical Core for the Food Safety Research and Response Network (www.fsrrn.org).

- **Dr. Donald Schaffner –** Dr. Schaffner is an Extension Specialist in Food Science and Professor at Rutgers, The State University of New Jersey. His research interests include quantitative microbial risk assessment and predictive food microbiology. Dr. Schaffner has authored more than 100 peer-reviewed publications, book chapters, and abstracts. He has been the recipient almost $3 million in grants and contracts, most of which has been in the form of competitive national grants. He has educated thousands of Food Industry professionals through numerous short courses and workshops in the United States and more than a dozen countries around the world. Dr. Schaffner has also served on expert committees for US National Academy of Sciences, the World Health Organization and Food and Agriculture Organization of the United Nations, and has chaired two expert workshops on microbial risk for WHO/FAO. He was most recently a member of Institute of Food Technologists Expert Panel that developed a quantitative risk-ranking framework for the Food and Drug Administration. Dr. Schaffner is currently serving a 5-year term as Editor for the journal Applied and Environmental Microbiology. In May 2005, he was also appointed to serve on the National Advisory Committee on Microbial Criteria for Foods (NACMCF). Dr. Schaffner is active in several scientific associations including the International Association for Food Protection, the Institute of Food Technologists, the Society for Risk Analysis, and the American Society for Microbiology. He holds a B.S. in Food Science from Cornell University and a M.S. and Ph.D. in Food Science and Technology from the University of Georgia.

- **Dr. Mahdi Saeed –** Dr. Saeed, DVM, MPH, PhD, ACVPM, is a full professor of Food Safety Epidemiology and Public Health with joint appointments in the National Food Safety Center, College of veterinary medicine, and the Department of Epidemiology at the College of Human Medicine of Michigan State University. His main area of research is the epidemiology and risk assessment of food borne diseases, and the development of prevention plans for of food borne illnesses. Currently he is collaborating with the Michigan Department of Community Health and other professionals in a study of comparative epidemiology of *Salmonella* cases in Michigan. He is using data from the last 10 years to describe the nature of *Salmonella* outbreaks and sporadic infections. He focuses on identifying the foods related to contamination and evaluating risk factors in order to plan for effective control and prevention measures. Dr. Saeed has developed and taught on-line courses on risk assessment and the public health impact of food borne illnesses. The course is a part of a newly initiated Web-based master's degree program. The on-line option has attracted many professionals seeking further education who do not have time for the traditional classes offered at Michigan State University. He is the editor-in-chief of *Salmonella* Enterica Serovar Enteritidis in Humans and Animals: Epidemiology, Pathogenesis and Control, a book cited in medical journals and chosen by reviewers as one of the best 200 out of 2,800 medical books. Saeed wrote four chapters of the book and recruited contributors from around the world who were experts in their field. Dr.

Saeed received his PhD degree at Washington State University in 1983. He then took a position as assistant professor of infectious diseases at St. Louis University School of Medicine. He worked there for four years before joining a training program at the University of Washington School of Public Medical Health and Community Medicine in the areas of epidemiology and infectious diseases. Dr. Saeed earned an MPH degree in Epidemiology and Public Health. During his research, Dr. Saeed discovered the important role of food, and exposure to animals as risk factors in an illness called *Campylobacter* gastroenteritis.

APPENDIX II: CHARGE TO PEER REVIEWERS

Peer reviewers were charged with evaluating the risk assessment and responding to the following questions:

a. Evaluate whether the risk assessment modeling approach has utility for addressing specific risk management questions[2].

b. Review the available data and derived variables in conjunction with the underlying assumptions used in this risk assessment.

    1) Have all key studies and data been identified? If not, the reviewer must provide additional data sources and citations (where appropriate).
    2) Have the data been correctly interpreted, analyzed, and used in the risk assessment? If not, the reviewer must provide alternate interpretations, analysis, or suggested utilization of the data.
    3) Please address the validity and appropriateness of all input data in the model.

c. Review the complexity of the model. Is the model too complex or not complex enough to adequately address the risk management questions? Is the model over or under parameterized? Are there simplifications that will not detract from the model's utility? State whether the model adequately characterizes the uncertainty present and whether variability has been addressed sufficiently. In areas where the reviewer identifies limitations, weakness, or inadequacies, the review must provide alternate data, data analysis, and/or modeling approaches.

d. Evaluate the risk assessment model source code and mathematics. The model is a bootstrap regression model in Microsoft Excel with Visual Basic for applications

[2] This risk assessment was developed to inform the specific FSIS risk management questions provided below:

(1) Is there a measurable difference (relationship between pathogen prevalence and inspection resources and assigned tasks) between risk-based poultry inspection systems and non-risk-based poultry inspection systems currently in place in young chicken slaughter plants?

(2) How will a reallocation of inspection resources away from on-line procedures, either out of the plant or to other HACCP verification procedures and/or sanitation verification procedures, affect prevalence, as well as other process control indicators?

(3) How will higher completion rates for ISP procedure assignments affect prevalence, as well as other process control indicators (this includes un-scheduled tasks to follow-up on necessary inspection for sanitation and other procedures)?

(4) Using scenario analysis, what will be the change in number of illnesses attributable and/or $ cost due to inspection resource reallocation?

used to collect and summarize the results. There is a total of about 350 lines of code.

1) Are the modeling techniques (model mathematics and equations) appropriate? If not, the reviewer must provide alternate modeling techniques.
2) Are the methodologies used in the risk assessment for estimating parameters from the data appropriate (i.e., follow scientifically accepted methodologies)? If not, the reviewer must provide an alternate approach.
3) The reviewer should examine and verify that the data analysis and source code are accurate.

e. Evaluate whether adequate sensitivity analysis has been provided. Have the most important variables in the model been identified? Has an important variable been left out? If so, the reviewer must provide an alternate approach or application for sensitivity analysis and/or identify those parameters that should have been included.

f. Comment on the adequacy of the risk assessment model documentation. Is the report clearly written? Is it complete? Does it follow a logical structure and layout? If not, the reviewer must provide an alternate outline and/or approach for adequately and clearly documenting this risk assessment.

g. Is the overall approach for modeling risk-based inspection versus non-risk-based inspection, as described, fundamentally sound? If not, what problems exist and how should they be addressed?

h. Are the selected scenarios adequate to capture all the significant differences that may be expected to occur when risk-based inspection is implemented? If not, what additional scenarios should be included?

i. Evaluate the approach taken to estimate illnesses due to *Salmonella* and *Campylobacter*. Is the approach a reasonable approach given that the model's main focus is to estimate changes in prevalence and level? If not, what additional approach should be taken? Evaluate the utility of underlying data used to estimate baseline estimates of 2004 *Salmonella* and *Campylobacter* illnesses attributable to young chickens in the US. Should other data be considered, if so, what additional data should be included?