

## **EXECUTIVE SUMMARY**

### **Quantitative Risk Assessment**

#### **FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection**

##### *Background*

The Food Safety and Inspection Service is proposing a new inspection system to change allocation of inspection personnel in poultry slaughter establishments. Under new inspection system guidelines, individual poultry slaughter establishments will decide whether to operate under a slightly modified version of the current inspection system (9 CFR § 381.76) or the proposed new system.

The intent of the proposed new inspection system is to allow FSIS resources to be used more efficiently. If this efficiency reduces the occurrence of foodborne pathogens such as *Salmonella* and *Campylobacter* on finished poultry products, then a net public health benefit may result. Improved efficiency should occur by allowing more time and flexibility for FSIS personnel to perform off-line verification activities based on human health risk factors specific to individual establishments. The proposed new system may also drive technological innovation by the industry because they will have greater control over carcass sorting and establishing maximum line speeds.

FSIS on-line inspectors currently conduct hands-on appraisals of every poultry carcass to ensure it is unadulterated, free of feathers, bruises, and defects and disease, while FSIS off-line inspectors verify that establishments maintain sanitary operations and perform other health- and safety-related assignments. Many of the on-line inspection tasks are related to food quality rather than food safety.

This risk assessment updates a 2008 risk assessment, originally presented in conjunction with a review by the National Advisory Committee on Meat and Poultry Inspection (NACMPI, [1,3](#)), with new data and a modified modeling approach. This version of the risk assessment takes into consideration public and stakeholder comments [Docket No. FSIS-2011-0012].

The original risk management questions were:

##### *Risk Management Questions*

*Can FSIS reallocate inspection activities in young chicken slaughter establishments without significant negative impact on microbial prevalence in the establishments?*

*How will the relocation of on-line inspectors to off-line duties, or other areas within or outside the establishment, affect human illness?*

*Where within the establishment can relocated inspection activities have the most impact toward reducing microbial prevalence and corresponding human illness?*

*What is the uncertainty about these effects?*

### *Structure and Scope*

This is a quantitative food safety risk assessment. It examines the relationships between variations in personnel assignments and inspection activities in FSIS poultry slaughter facilities compared to the prevalence of both *Salmonella* and *Campylobacter* on young chicken and young turkey and, subsequently, attributable human illness.

Logistic regression analysis is performed to estimate the relationship between off-line inspection procedures and contamination of carcasses with either *Salmonella* or *Campylobacter*. A stochastic simulation model uses the estimates from the logistic regression to forecast the effect of changes in off-line inspection *categories* on changes in human *Salmonella* or *Campylobacter* illnesses attributable to the consumption of young chicken and young turkey. The simulation model incorporates uncertainty about the regression coefficients, uncertainty about the expected change in off-line inspection activities with the new inspection system, and uncertainty in the current estimate of human illnesses, into its forecasts about the change in human illnesses that could occur as a result of implementation of the new inspection system.

Data used in the risk assessment came from several sources. Inspection activities data from FSIS's PBIS database were paired with *Salmonella* and *Campylobacter* prevalence data for the same establishments and timeframes:

Young chicken data comprise results of the FSIS Young Chicken Baseline study (July 2007 through September 2008, [8](#)) and PR/HACCP *Salmonella* verification program (July 2007 through September 2010).

Young turkey data comprise results of the FSIS "Young Turkey Baseline" (August 2008 through July 2009, [9](#)) and PR/HACCP *Salmonella* verification program (July 2007 through September 2010).

Estimates for the mean number of human *Salmonella* and human *Campylobacter* illness attributable to young chicken and turkey consumption were based on distribution parameters estimated from total foodborne illness and outbreak data from Centers for Disease Control and Prevention (1, [10](#), [12](#)).

Change scenarios predict how prevalence of both *Salmonella* and *Campylobacter* and ultimately annual human illnesses might change based on 4 categories of decision variables (scheduled-and-

performed procedures [SP], unscheduled procedures [U], scheduled-not-performed procedures [SNP], and non compliances [NC]). As Agency guidance has heretofore been unspecific about the types of offline inspection procedures that could improve from the new inspection system, an “indiscriminate” scenario is propagated in which all 4 categories of decision variables are randomly changed. Uncertainty distributions for each of these change decision variables is developed using information provided in the FSIS HIMP report (13). *We assume that off-line inspection activities after the voluntary implementation of the new inspection system will parallel off-line inspection activities in current HIMP establishments.*

### *Model Results*

*Indiscriminate scenario:* These results describe estimated changes in both poultry slaughter establishment prevalence and in attributable human illnesses associated with an indiscriminate change across all 4 decision variables – based on the premise that unspecified changes (increases in terms of procedures performed, decreases in terms of unperformed procedures and non-compliances) might occur across all off-line inspection activities.

*Discriminating scenario where unscheduled procedures are targeted for increase:* These results describe estimated changes in both poultry slaughter establishment prevalence and in attributable human illnesses associated with a targeted increase in unscheduled inspection procedures while holding other decision variables constant – based on the observation that in HIMP establishments up to 60% more unscheduled procedures are performed than in non-HIMP establishments. Given that more unscheduled procedures are a likely focus the new inspection system, this specific scenario is of interest.

*Predicted annual changes in Salmonella and Campylobacter prevalence in chicken establishments:* When off-line procedures are indiscriminately changed in young chicken establishments, the analysis predicts an average decline of 2 percent (mean) (.005, .04) (10<sup>th</sup> and 90<sup>th</sup> percentile, respectively) in the percentage of positive *Salmonella* samples. The analysis also predicts that there could be a small increase -.0002(-.018, .007) in the percentage of positive *Campylobacter* samples. This could be due to the effect that non compliances – a poorly understood explanatory variable in this model, have on the predicted estimates for *Campylobacter*.

If only unscheduled inspection procedures in young chicken slaughter establishments are targeted for increase the analysis predicts a average decline of 2 percent (mean) (.008, .038) in the percentage of positive *Salmonella* samples. The analysis also predicts that there is a small decline .005(-0, .017) in the percentage of positive *Campylobacter* samples.

*Predicted annual changes in human illnesses attributable to chicken establishments:* There is an 87 percent probability that human illnesses will decline if all off-line inspection procedures are changed ‘indiscriminately’ (as described above) in young chicken slaughter establishments. *Salmonella* illnesses are expected to decline by an average of 4,203 (mean) (872, 8,089) (10<sup>th</sup> and 90<sup>th</sup> percentile, respectively), while *Campylobacter* illnesses could increase by 462 (-2,668, 1,067). However, the modes of these distributions indicate a decline of 3,181 *Salmonella* illnesses and 0 *Campylobacter* illnesses from young chicken.

If only unscheduled inspection procedures in young chicken slaughter establishments are targeted for increase, there is a near 100 percent probability that human illnesses will decline. *Salmonella* illnesses are expected to decline by an average of 4,044 (1,390, 7,301), while *Campylobacter* illnesses could decrease by 868 (0, 2,728). Similarly, the modes of these distributions show declines of 2,483 *Salmonella* illnesses and 0 *Campylobacter* illnesses related to increases in unscheduled procedures.

*Predicted annual changes in Salmonella and Campylobacter prevalence in turkey establishments:* When off-line procedures are indiscriminately changed in young turkey establishments, the analysis predicts an average decline of 4 percent (-.02, .11) in the percentage of positive *Salmonella* samples. The analysis also predicts that there could be a decrease of 17 percent (-.015, .32) in the percentage of positive *Campylobacter* samples.

If only unscheduled inspection procedures in young turkey slaughter establishments are targeted for increase the analysis predicts a average decline of 3 percent (-.004, .08) in the percentage of positive *Salmonella* samples. The analysis also predicts a similar decline of 17 percent (.021, .32) in the percentage of positive *Campylobacter* samples.

*Predicted annual changes in human illnesses attributable to turkey establishments:* There is also an 87 percent probability that human illnesses will decline if all off-line inspection procedures are changed indiscriminately in young turkey slaughter establishments. *Salmonella* illnesses are expected to decline by an average of 311 (-146, 834), while *Campylobacter* illnesses are expected to decline by 119 (9, 252). The decline in the mode of 161 *Salmonella* illnesses and 0 *Campylobacter* illnesses from young turkey is expected.

If only unscheduled inspection procedures in young turkey slaughter establishments are targeted for increase, there is a 94 percent probability that human illnesses will decline. *Salmonella* illnesses are expected to decline by an average of 242 (-30, 603), while *Campylobacter* illnesses could decrease by 118 (12, 249). The distribution modes indicate a decline of 90 *Salmonella* illnesses and 0 *Campylobacter* illnesses related to increased unscheduled procedures in young turkey establishments.

## *Conclusions*

The risk assessment provides answers to each of the four risk management questions.

*Can FSIS reallocate inspection activities in young chicken slaughter establishments without significant negative impact on microbial prevalence in the establishments?*

In general, the probability that indiscriminate changes in off-line inspection procedures will increase the annual rate of human illnesses is small, and there is a greater probability that such changes would contribute to no net change or even reductions in human illnesses. Nevertheless, this analysis suggests ambiguous effects of the proposed rule with respect to *Campylobacter* occurrence on chicken carcasses. The larger probability of increased *Campylobacter* illnesses

from contaminated chicken carcasses is primarily driven, however, by the non-compliance decision variable. This decision variable is poorly understood and the intended effect of changes in this category of procedures is arguable. The frequency of non-compliance reports could decrease either because plant performance improves or because incidents of non-compliance are less frequently detected and reported. It is noteworthy that removing the effect of this decision variable in alternative scenarios substantially reduces the probability that the human illness rate might increase.

This latter conclusion is further supported by consideration of the HIMP structural variable in the chicken-*Campylobacter* regression model (see Appendix). That model suggests that participation in HIMP was associated with a reduced prevalence of *Campylobacter*. Although *Campylobacter* occurrence was not considered in an analysis of HIMP establishments (13), these regression findings suggest that the positive *Salmonella* implications of that HIMP analysis also apply to *Campylobacter*. While not a focus of this risk assessment, the regression model's implication about HIMP establishments should provide some measure of confidence about the effects of the proposed rule – which intends to replicate HIMP across a wider swath of the poultry industry.

*How will the relocation of on-line inspectors to off-line duties, or other areas within or outside the establishment, affect human illness?*

Most likely point estimates from a scenario that indiscriminately changes all four decision variables in our analysis suggest a net reduction (mode) of 3,342 *Salmonella* illnesses attributable to both young chicken and young turkey establishments. This analysis assumes that the total annual *Salmonella* illnesses rate attributed to poultry is centered about 174,686 (1). Therefore, the proposed rule might be expected to prevent 1.9% of these illnesses per year.

Most likely point estimates from the same scenario suggest that there will be no net change in the annual rate of *Campylobacter* illnesses in either chicken or turkey establishments.

*Where within the establishment can relocated inspection activities have the most impact toward reducing microbial prevalence and corresponding human illness?*

The most reliable implication from the regression models is that increasing unscheduled procedures seems to reduce pathogen occurrence on carcasses. The other decision variables suggest ambiguous effects from their intended changes when those effects are considered across all four pathogen-product models.

*What is the uncertainty about these effects?*

Our modeling approach includes uncertainty about regression coefficients that relate the frequency of inspection activities to pathogen prevalence, uncertainty about the change in future inspection activities, and uncertainty in the baseline annual rates of human *Salmonella* and *Campylobacter* illness attributable to poultry. These sources of uncertainty translate into substantial uncertainty about forecasted changes in illness rates.

This analysis necessarily focuses on the “down-side” potential of the proposed rule, i.e., the probability that proposed changes to inspection may cause illness rates might increase. This focus seems appropriate for a proposed rule that intends to change inspection processes in

slaughter establishments. Significantly, however, the uncertainty about changes in illness rates includes “up-side” potential that illnesses avoided could be substantially larger than the model values cited.

The uncertainty that surrounds these forecasts suggests monitoring opportunities for FSIS following implementation of the proposed rule. For example, FSIS can periodically assess aggregate inspection procedures and compare these to the baseline predictions from this model. Such comparisons will empirically measure the changes occurring for the decision variables in the model and reduce the current uncertainty about these model inputs. Also, under the proposed rule, FSIS will continue to monitor the pathogen prevalence on carcasses among participating and non-participating establishments. The pathogen verification testing data can be used to assess correspondence with its expectations following implementation of the proposed rule.