May 29, 2012

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service (FSIS)
Patriots Plaza 3, 355 E Street SW
8-163A, Mailstop 3782
Washington, DC 20250-3700

RE: Docket No. FSIS–2011-0012

To Whom It May Concern:

The Consumer Federation of America (CFA)\(^1\) appreciates the opportunity to comment on the Food and Safety and Inspection Service’s (FSIS) proposed rule regarding Modernization of Poultry Slaughter Inspection (Docket No. FSIS–2011-0012).

**Salmonella and Campylobacter are critical public health problems**
CFA recognizes the importance of improving poultry inspection and reducing contamination from pathogens associated with poultry such as *Salmonella* and *Campylobacter*. According to the Centers for Disease Control and Prevention (CDC), approximately 42,000 cases of salmonellosis are reported in the United States each year.\(^2\) Raw or undercooked poultry is a frequent source of *Salmonella* illnesses. A report by the University of Florida’s Emerging Pathogens Institute ranked as fourth *Salmonella* in poultry in terms of causing the greatest disease burden to the public in both Quality Adjusted Life Years and cost of illness in dollars.\(^3\)

*Campylobacter* is one of the most common causes of diarrheal illnesses in the United States, affecting over 2.4 million people every year.\(^4\) *Campylobacter* cases typically occur as isolated, sporadic events rather than as part of identified outbreaks; however, illnesses from

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1. CFA is an association of nearly 300 non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy and education. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and food safety organizations. CFA’s Food Policy Institute was created in 1999 and engages in research, education and advocacy on food safety, food and agricultural policy, agricultural biotechnology, and nutrition.
Campylobacter are most frequently associated with poultry consumption. The University of Florida identified Campylobacter in poultry as causing the greatest disease burden to the public in terms of both Quality Adjusted Life Years and cost of illness in dollars. The CDC notes that a small number of Campylobacter organisms can cause illness, stating “even one drop of juice from raw chicken meat can infect a person.”

Unfortunately, the U.S. has made almost no progress in reducing illnesses from Salmonella or Campylobacter in the past decade. The incidence of Salmonella infections has remained at essentially the same level since 2003 and in recent years has been increasing. In 2010, the incidence of salmonellosis was 17.60 cases per 100,000, well above the 2020 National Health Objective of 11.4 cases per 100,000. Rates of Campylobacter have not declined substantially since 2002. The incidence of campylobacteriosis in 2010 was 13.60 cases per 100,000; well above the National Health Objective of 8.5 cases per 100,000 and at its highest level since 2001. In the most recent years, the incidence of Campylobacter illness appears to be rising.

Evidence in the marketplace further demonstrates the need to reduce contamination from these pathogens in raw poultry. Consumers are eating chicken more frequently and testing shows that they are exposed to contaminated poultry. In 2007, the FDA-NARMS Retail Food program found Campylobacter on 49.9% of raw chicken breasts tested. In January 2010 Consumer Reports magazine published a study of fresh, whole broilers bought in 22 states. The study revealed that Campylobacter was in 62 percent of the chickens tested and Salmonella was in 14 percent. Both bacteria were in 9 percent of chickens tested. The test showed a modest improvement since January 2007, when the magazine found these pathogens in 8 of 10 broilers, but the numbers are still far too high.

Meanwhile, the amount of meat and poultry inspected by FSIS has increased sharply. OMB Watch reports that the amount of meat and poultry inspected and approved by FSIS more than doubled in the past thirty years from 52 billion pounds in 1981 to approximately 107 billion pounds in 2011. OMB Watch attributes much of the increase to expanding poultry demand and notes that pounds of poultry approved by FSIS nearly quadrupled during this time period. The report also notes that the amount of inspection resources per thousand pounds of product dropped 35 percent since 1981, and that the number of workers employed per billion pounds decreased by 54 percent.

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While it is necessary to improve poultry inspection to better protect consumers from contaminated poultry, CFA has a number of concerns about the agency’s proposal on poultry slaughter. The proposal will replace federal inspectors sworn to protect the public health with plant employees who answer only to their company and will not be required to have any training. Plants will be allowed to set their own standards for pathogen testing and OCP defects on birds entering the chiller. Performance standards establishing limits on pathogen contamination on birds at the end of the slaughter line which have been in effect since the beginning of HACCP will be rescinded and replaced with guidance which does not have the force of law. These are key elements of the agency’s proposal. CFA does not believe that the proposal, taken as a whole, will provide the necessary level of safety for consumers and the agency should substantially revise the proposal before moving forward.

**FSIS did not seek stakeholder input before announcing proposed changes**

Before addressing the substance of the agency’s proposal, it must be noted that FSIS’ approach to crafting this new proposal was flawed. The proposal represents a significant change to how poultry is inspected in the U.S. Yet the agency did not consult with its inspection advisory committee as required by law, nor did the agency hold public meetings to solicit the views of the public. Previous agency proposals that sought to substantially change parts of the federal inspection program have been debated and discussed in public forums so that stakeholder input could be provided prior to announcing a formal proposal.

By law, FSIS is required to consult with the members of the National Advisory Committee for Meat and Poultry Inspection before proposing substantial changes to its meat and poultry inspection program. NACMPI meetings typically last two days and provide committee members an opportunity to offer substantive comments to the agency. Committee members are typically tasked with addressing a particular topic and providing a consensus view of the committee to help guide the agency as it is developing policy.

In this case, the agency had already initiated a policy change through a proposed rule without consulting NACMPI and only convened the Committee at the insistence of consumer groups. The NACMPI meeting consisted of a two hour conference call and NACMPI members were not provided the opportunity to fully consider the proposal, adequately debate suggestions from committee members, and provide FSIS with consensus advice and guidance. Furthermore, because the agency was already in the rulemaking process when it convened this meeting, FSIS officials were reluctant to answer questions and told committee members that their comments and questions would simply be added to the existing Federal Register docket, fundamentally negating the advisory role and responsibility of the committee.

FSIS also did not consult with stakeholders until after this proposal was already announced and published in the Federal Register. FSIS did not hold a public meeting on the proposal as the agency has done with other significant proposed changes to inspection. Considering the number of substantial changes to poultry inspection that the agency is proposing, it is shocking that the agency would not hold a single public meeting to discuss the agency’s thinking and solicit stakeholder input prior to formally publishing its proposal. Consumer groups requested that the agency hold a public meeting on its proposal but the agency declined to grant that request.
In the future, FSIS should seek the advice of NACMPI and the input of the public prior to announcing substantial changes to the federal meat and poultry inspection program.

**FSIS data raises questions about HIMP pilot**
CFA questions FSIS’ reliance on data from the HIMP pilot program to justify the agency’s proposal on poultry slaughter and has several concerns with the data presented in support of the proposal. First, it should be noted that the HIMP pilot program consisted of plants which were self-selected and likely higher performing plants than others in the industry. Consequently data from the HIMP pilot program may not represent what FSIS is likely to see when the vast majority of poultry plants take part in the proposed poultry slaughter program. Moreover, the proposed program is not an exact replica of the HIMP pilot, raising further concerns about whether results from the HIMP pilot program can be extrapolated to the new program.

Second, FSIS touts the success of the HIMP pilot program by pointing to the low rate of food safety defects for Septicemia/Toxemia, as well as lower rates of NRs and lower rates of fecal contamination when compared to HIMP performance standards and/or to a set of comparison establishments. However, the data on food safety defects, NRs, and fecal contamination in HIMP may be a substantial under estimate. This is because in many HIMP plants critical control points are often located after the carcass inspector (CI) on the line. According to the agency’s own Evaluation of HIMP document, “sixty percent of the young chicken HIMP establishments have the CCP for FS-1 (Sep/Tox) before the CI,” which means that forty percent of HIMP plants locate the CCP after the CI. FSIS further states that “all 20 of the young chicken establishments have the CCP for FS-2 (fecal material) located after the CI. CIs do not create noncompliance records for visible fecal material when the CCP for fecal material is located after the CI” (emphasis added). If CCPs, particularly for fecal, are positioned after the CI and therefore no NRs are being written for fecal contamination by CIs, the statistics concerning rates of NRs and the rates of fecal are undoubtedly skewed. CFA could not identify anywhere in the document where FSIS took this effect into account in its data analysis.

Third, FSIS points to the fact that in CY2006-2008, the rate of *Salmonella* positives in HIMP plants was statistically significantly lower than in the non-HIMP comparison set of establishments. However, there was no statistically significant difference between the sets of plants in CY2009 and CY2010. CFA notes that in 2008, FSIS began publishing the names of plants in Categories 2 and 3 in its Salmonella Initiative Program (SIP). So it is possible that all poultry plants were making adjustments to their HACCP programs in response to SIP. The data for CY2009 and CY2010 should elicit questions about whether alleged improvements in *Salmonella* rates are a factor of the HIMP program, or whether they are more a factor of the industry’s performance as a whole under the SIP program.

Fourth, one of the major assumptions in FSIS’ Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection is that if the new system “either reduces (or does not change) the occurrence of foodborne pathogens such as *Salmonella* and *Campylobacter* on finished poultry products, then a net public health benefit may result.” CFA questions how a “net public health benefit” will occur if there is no change to the incidence of pathogens on poultry products. FSIS should not predicate a significant restructuring of the poultry slaughter inspection program on the basis that there will be no change to the incidence of contamination of poultry products. CFA has always maintained that any substantial change to meat and poultry inspection should result in significant improvements to public health.
Effect of proposal on Campylobacter illness rates is “ambiguous”

As discussed previously, Campylobacter in poultry is an important public health issue that needs to be addressed. However, it is unclear whether FSIS’ poultry slaughter proposal will actually reduce Campylobacter illness rates; in fact, rates may increase.

FSIS has very little data on Campylobacter levels in poultry establishments. Until the agency implemented its new performance standard for Campylobacter last year, FSIS had never systematically tested for the pathogen in poultry plants. The agency first began conducting Campylobacter verification sets in July 2011 and so far has only competed 42 young chicken and 15 young turkey sets. After six months of testing, FSIS has reported that poultry plants appear to be meeting the new standard, while young turkey plants are well above the standard. However in its most recent progress report, FSIS admits that “available information is very limited at this time.”

CFA is very concerned that FSIS’ proposed changes to poultry slaughter are being proposed in the absence of any good data on Campylobacter. As a result, substantial uncertainty arises in the agency’s assessment of how the proposal will impact Campylobacter illness rates. The agency’s Risk Assessment specifically states that “this analysis suggests ambiguous effects of the proposed rule with respect to Campylobacter occurrence on chicken carcases.” The analysis predicts a small increase in the percentage of positive samples when off-line procedures are indiscriminately changed, but a small decrease when unscheduled procedures are analyzed. The analysis predicts that annual Campylobacter illnesses attributable to chicken establishments could increase with changes to off-line inspection procedures, while illnesses attributable to turkey establishments could decrease slightly.

The Risk Assessment goes on to suggest that “the positive Salmonella implications of HIMP” could be applied to Campylobacter, yet the agency provides no justification for this statement. Several studies point to the difficulty of making correlations between controlling for Salmonella and controlling for Campylobacter. In FSIS’ six month progress report on its Campylobacter verification testing, the agency found that “the vast majority of Campylobacter set failures occurred in sets that passed the Salmonella performance standard,” although it noted that it was too early to draw any long-term conclusions.

In conversations with agency officials, they have admitted that data on Campylobacter is not robust which results in substantial uncertainty in the risk assessment model. At best, FSIS is

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anticipating no net change in annual Campylobacter illnesses from chicken or turkey establishments. Again, substantial changes to meat and poultry inspection should result in significant improvements to public health, not simply maintain the status quo. If the agency’s proposed changes to poultry slaughter inspection are truly intended to improve the public health, the agency needs a much better understanding of Campylobacter rates currently and how the agency’s proposal will impact those rates. FSIS should postpone implementation of its proposal until it has collected additional data on Campylobacter and is better able to estimate the impacts of its proposal on reducing the pathogen. CFA would expect that any subsequent analysis should demonstrate a respectable decrease in Campylobacter (and Salmonella) before the agency would move forward.

**FSIS should codify new performance standards**

In its proposal, FSIS proposes to eliminate the pathogen performance standard regulations in 9 CFR 381.49(b); these are the existing Salmonella pathogen reduction performance standards. FSIS has now developed new performance standards for Salmonella (and Campylobacter), but the agency is not proposing to codify the new standards into regulation. CFA strongly disagrees with this approach.

As noted previously, the U.S. has made little progress in reducing illnesses from Salmonella and Campylobacter. While poultry is not the only source of these pathogens, it is frequently associated with illnesses from both Salmonella and Campylobacter. FSIS points to its baseline data to show progress in reducing Salmonella contamination. However, FSIS data for Salmonella is based only on whole chickens. FSIS has no data on chicken parts which is the most common way that chicken is sold. The agency has embarked on a chicken parts baseline, but that baseline is far from complete. Consumers Union testing has showed high levels of Salmonella and Campylobacter contamination in whole chickens available at retail.

Rather than codify the new standards, FSIS has indicated that the agency plans to rely on enforcement of the new standards through guidance. Guidance does not have the force of law and is almost always directed at FSIS inspectors and not at plants. In addition, FSIS’ guidance on the new Salmonella and Campylobacter standards does not contain explicit language obligating industry to meet the new performance standards. The current language in 9 CFR 381.49(b) places an explicit obligation on the part of the establishment that its raw poultry may not test positive for Salmonella at a rate exceeding the performance standard. This obligation on the establishment is important. Failure to meet the performance standard is a clear indication that an establishment’s HACCP controls are inadequate and the plant must re-evaluate its HACCP plan.

FSIS has argued that the agency has the authority to set and enforce performance standards, but that the court ruling in Supreme Beef Processors Inc. v USDA precluded the agency from suspending inspection services if a plant fails to meet the Salmonella performance standards. Consequently, the agency argues that the best way to address Salmonella is to implement its performance standards through guidance and continue to implement the Salmonella Initiative Program. Such an approach would mean that only standards for E. coli O157:H7 will be part of a regulation setting a performance standard. Instead, FSIS should replace 9 CFR 381.49(b) with a

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codification of the new *Salmonella* and *Campylobacter* performance standards with explicit language obligating establishments to meet the new standards. CFA believes that this approach is most protective of public health, particularly for a pathogen like *Salmonella* for which we have seen little progress in reducing illnesses.

**FSIS must have specific authority to set and enforce performance standards**

Furthermore, to remedy the concern raised by the agency regarding the *Supreme Beef* court case, FSIS should actively seek authority from Congress to set and enforce pathogen reduction performance standards. FSIS now addresses the failure of plants to meet *Salmonella* standards by sending in staff to conduct Food Safety Assessments. This staff is in addition to the inspection staff already in the plant. The result is taxpayer money spent to support expensive efforts by FSIS to provide technical assistance to meat and poultry plants that are unable or unwilling to meet the current standards. Taxpayer dollars should not continue to subsidize the operation of these poor performing plants. Instead, FSIS should seek and Congress should provide the agency with the specific authority to fully enforce its pathogen reduction performance standards.

**Establishments should be required to test for Salmonella and Campylobacter at a specified frequency**

CFA agrees with FSIS’ proposal to require establishments to develop, implement, and maintain written procedures to prevent contamination of carcasses and parts throughout the entire slaughter and dressing operation. It is important that establishments work to prevent contamination at all points along the slaughter and dressing process, rather than simply applying an antimicrobial treatment at the end of the process. CFA also agrees with the agency’s proposal to require establishments to develop, implement and maintain written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chilling tank. However, CFA is concerned that other elements of this proposal such as the reduced inspection presence on the slaughter line, the proposed increase in line speeds, and a lack of training of establishment sorters will lead to less than rigorous enforcement of this requirement. FSIS should consider how these elements and others might impact effective enforcement of this requirement and make the necessary changes to assure adequate enforcement.

CFA also agrees with FSIS’ proposal to require establishments to test for microbial organisms at both pre-chill and post-chill locations to verify the effectiveness of the establishment’s preventive controls. This is a good step which will provide the agency with a better understanding of the level of contamination of birds entering and leaving the chiller, and whether or not steps taken during the slaughter process are working effectively.

However, CFA does not agree with the agency’s decision to allow each establishment to develop its own sampling plan and determine which organisms to sample. This approach will not assure that establishments are testing for the two most important pathogens related to poultry – *Salmonella* and *Campylobacter*. It will also not provide FSIS with comparable data across the industry which will be important to determine whether pathogen contamination is being reduced. Since it is likely that the vast majority of poultry plants will participate in this new program, the public must be provided with assurances of uniform behavior and data collection that can demonstrate that plants are producing poultry safely and reducing pathogenic contamination. FSIS has provided no justification for allowing every plant to develop its own sampling program with only the *Salmonella* and *Campylobacter* performance standards as a means to verify compliance.
FSIS should require plants to adopt a standard sampling program in which plants sample to a frequency, designated by FSIS, which is statistically valid. FSIS should require plants to test for both *Salmonella* and *Campylobacter*. The public needs to be assured that plants are testing for the two most common pathogens associated with illnesses from poultry. Plants could still test for additional pathogens or indicator organisms as warranted. It should be noted that FSIS requires plants participating in the Salmonella Initiative Program to test for *Salmonella, Campylobacter* and generic *E. coli* or other indicator organisms and share that data with FSIS. CFA’s recommendation to test for specific pathogens would therefore be consistent with the testing requirements in the SIP program. FSIS should also require plants to conduct testing for a specific period of time that can be statistically justified to provide baseline testing data before the agency moves forward on any changes to its poultry slaughter inspection program. This will provide FSIS with a baseline of testing data from which the agency and the establishment can determine how changes to poultry slaughter impact pathogen rates in the plant.

**FSIS should set specific standards for OCP defects**

FSIS is proposing to allow each establishment the ability to design and implement its own measures to address OCP defects and assure the establishment is producing ready-to-cook poultry. FSIS will not set specific acceptable OCP defect levels that plants must meet. Instead, if an inspector observes “persistent, unattended removable animal diseases or trim and dressing defects”, or if the plant is unable to “consistently produce product that meets the ready to cook poultry definition,” FSIS would require the plant to take appropriate actions.

CFA does not agree with this approach. If FSIS does not establish specific OCP standards for all plants to meet, consumers will have no assurances that poultry establishments are producing poultry in a uniform manner and adequately removing defected carcasses. Through a Freedom of Information Act request, Food & Water Watch found little consistency across a set of fourteen plants enrolled in the HIMP pilot program, and found wide variation in the number of defects missed from plant to plant. Food & Water Watch also found that company employees routinely miss many defects in poultry carcasses, especially dressing defects such as feathers, oil glands and trachea still on the carcass (OCP 4). Without establishing some basic standard for establishments to meet, that variation will continue and FSIS will not be able to adequately compare data across the industry to know whether defects are being appropriately removed in the industry as a whole. FSIS should at least set some minimum standard for OCP defects that establishments must meet in order to better assure that defective product is not reaching consumers at high rates.

**Establishment employees should be trained and certified**

A 2001 Government Accountability Office report on the HIMP pilot program criticized FSIS for not requiring that plant employees complete training before assuming carcass sorting activities. GAO also criticized the agency for not establishing a way to measure plant employee’s knowledge and competence.

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In its response to the GAO recommendations, FSIS acknowledges that proper training is important to be sure that establishment sorters are able to identify and address animal carcass defects, stating that “[t]raining of sorters is vitally important to ensure that sorting procedures are properly performed.” Yet in the next paragraph FSIS states that it will not propose specific, formalized sorter training. The agency provides no justification for its decision. By not requiring plant employees to undergo training, the agency is placing a further burden on FSIS inspectors to stop production lines and take regulatory actions to address problems with carcass defects going down the line. The proposed higher line speeds further increases that burden on inspectors, as they will be unlikely to spot all carcass defects, jeopardizing product safety and quality.

Currently, FSIS inspectors who conduct sorting activities in poultry plants receive formal training on identifying carcass defects and determining whether they are suitable for consumption. In addition, similar poultry slaughter programs in countries such as Australia and Canada which export poultry to the U.S. require plant employees to undergo classroom training, pass a competency test, and be certified. Furthermore, as a condition of equivalency determination, FSIS requires training and certification of plant sorters in these foreign poultry slaughter programs.

Since adequate training is clearly recognized as an essential requirement prior to employees conducting sorting activities, FSIS should require employee sorters to undergo specific training regarding carcass sorting activities. The training should be at least comparable to the training received by FSIS inspectors who currently conduct sorting activities, and plant sorters should be certified as having met the standards of the training prior to assuming any carcass sorting activities.

NIOSH data should be incorporated before moving forward
In its proposed rule, FSIS is proposing to allow a new maximum line speed for young chicken slaughter establishments of 175 birds per minute and 55 birds per minute for turkey slaughter establishments. FSIS maintains that the agency has very little data, if any, on how increased line speeds will impact worker safety. However, the public health literature has demonstrated that the speed of the line is one of the leading factors contributing to the injury rate of workers in meat and poultry plants.\(^\text{17}\) The prevalence of carpal tunnel syndrome has been shown to be higher in Latino poultry-processing workers than other Latino manual workers.\(^\text{18}\) Similar findings were found in a study on female poultry processing workers.\(^\text{19}\) Increased line speeds will undoubtedly place workers in poultry plants at greater risk of repetitive motion related injuries and musculoskeletal disorders.

The agency has asked the National Institute for Occupational Safety and Health (NIOSH) to evaluate the effects of line speeds by collecting data from five non-HIMP plants that have been granted line speed waivers under the Salmonella Initiative Program. The agency states that it

\(\text{17}\) Nebraska Appleseed, “The Speed Kills You.” October 2009.
will “consider the available data on employee effects collected from NIOSH activities when implementing any final rule resulting from this proposal.” CFA has learned from conversations with agency officials that only one plant had been enrolled in the NIOSH study and the study has yet to get underway. The NIOSH study is anticipated to run through next year, yet FSIS intends to implement its poultry slaughter proposal at the end of this year, meaning the agency will allow plants to increase their line speeds in the absence of NIOSH data to inform their decision.

In addition, CFA fails to see how FSIS will be able to make appropriate generalizations about the impact of increased line speeds on worker safety based on data from a single plant. A range of biases are introduced when one relies on data from a single case. Furthermore, activities conducted by plant employees in SIP plants are different than those conducted by workers in HIMP plants, so it is difficult to see what types of usable information NIOSH will gather in SIP plants that could be then applied to plants in the agency’s proposed poultry slaughter program. FSIS should not go forward with its proposal until it has the results of an expanded (beyond one plant) study by NIOSH on the effect on workers of increased line speeds and has incorporated those findings as well as evidence from the literature into its proposal.

**Poor-performing establishments should be dropped from the program**

FSIS indicates that its new poultry slaughter inspection program will be a voluntary program operating under a waiver through the Salmonella Initiative Program. By deciding to take part in this new poultry inspection program, plants will be granted certain benefits, such as the ability to increase their line speeds, which will likely provide plants with an economic advantage in the marketplace. FSIS officials have said that poor-performing plants will be addressed through the agency’s regular enforcement process.

CFA believes that only plants that perform well should be able to participate in a new voluntary program that provides them specific benefits. Poor-performing plants should not be “rewarded” for their poor performance by being allowed to take part in a program and increase their line speeds, which could further exacerbate performance and worker safety problems. If a plant in the new program repeatedly violates agency regulations or is unable to produce product that meets microbial performance standards, the plant should not be allowed to continue accruing the benefits of the program and should be returned to traditional inspection. The 2001 GAO report concurred, stating that “[c]ontinued participation in a modified inspection system should depend on the plants’ ability to maintain good performance.” FSIS should develop procedures for addressing how plants with repeated violations, repeated NRs, or microbial testing failures will be removed from the program and transitioned to traditional inspection. This approach would provide a very strong incentive for plants to maintain their processes and achieve acceptable levels of performance.

CFA appreciates the opportunity to provide comments on this proposal.

Sincerely,

Chris Waldrop  
Director, Food Policy Institute  
Consumer Federation of America