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**Re: Proposed Rule: Modernization of Poultry Slaughter Inspection
Federal Register / Vol. 77, No. 18 / January 27, 2012
9 CFR Parts 381 and 500
Docket No. FSOIS-2011-0012**

The Center for Foodborne Illness Research & Prevention (CFI) appreciates the opportunity to comment on USDA's proposed rule, Modernization of Poultry Slaughter Inspection. These are CFI's initial comments on the proposed rule and should not be considered complete.

Founded in 2006 to help America create innovative, science-based solutions for the food safety challenges of the 21st Century, CFI is a national, non-profit health organization dedicated to preventing foodborne illness by amplifying research, protecting its integrity, and translating it into evidence-informed public policies that provide better food protection for all Americans. CFI believes that federal, state and local government, as well as farmers; food processors, distributors and retailers; medical providers; educators; policy makers and consumers share the responsibility of building an environment that promotes food safety throughout the farm to fork continuum. No one sector can achieve this goal alone, so CFI is committed to collaboration in its efforts to improve food safety.

Background

According to the Centers for Disease Control and Prevention (CDC), foodborne illness is a serious public health issue that causes an estimated 48 million illnesses and 3,000 deaths each year in the United States alone.¹ Among the 31 known foodborne pathogens listed in CDC's FoodNet data, nontyphoidal *Salmonella* causes an estimated 1,000,000 cases each year in the United States, resulting in an estimated 19,000 hospitalizations and 380

¹ Scallan, Elaine; Robert M. Hoekstra, Frederick J. Angulo, Robert V. Tauxe, Marc-Alain Widdowson, Sharon L. Roy, Jeffery L. Jones, and Patricia M. Griffin. Foodborne Illness Acquired in the United States – Major Pathogens. *Emerging Infectious Diseases*, www.cdc.gov/eid; Vol. 17, No. 1, January 2011.

deaths.² Obviously, *Salmonella* causes significant morbidity and mortality, with disease severity ranging from mild/moderate diarrhea to death. In addition, *Salmonella* is one of the leading pathogens for triggering reactive arthritis (ReA), a painful condition that causes swollen joints, especially in the lower limbs.³ *Campylobacter*, another leading cause of foodborne illness in the United States, is listed as one of the top five foodborne pathogens, with an estimated 850,000 cases, 8,500 hospitalizations and 76 deaths each year.⁴ Like *Salmonella*, campylobacteriosis can cause longer-term health outcomes and accounts for about 40% of the 5,500 Guillain Barre syndrome (GBS) cases that occur each year in the United States.⁵

General Comments

Controlling and reducing *Salmonella* and *Campylobacter* in poultry products is feasible and desirable, but this is particularly important given the high rate of illness, hospitalizations and deaths that occur from these pathogens. Further, poultry is a common reservoir for these pathogens, so improving control during poultry production and processing should lead to reductions in the annual incidence of salmonellosis and campylobacteriosis in the United States.

USDA's proposed rule to modernize poultry slaughter inspection addresses a specific identified food safety challenge, i.e., the United States' inability to reduce the incidence of a leading foodborne illness pathogen, *Salmonella*, over the past ten years, as has been well documented by CDC's FoodNet data, 2000-2011. Therefore, while CFI agrees that poultry slaughter inspection should be modernized and applauds the Agency's for recognizing this need, CFI maintains that the current proposal needs more scrutiny before implementation of the proposed rule begins.

Process for Developing and Implementing the Proposed Rule

Transparency is critical in the development and implementation of major policy changes, such as the Modernization of Poultry Slaughter Inspection Rule. In fact, in the December, 2009 report entitled, "*Open Government: A Progress Report to the American People*," President Obama stated that openness will strengthen our country and improve the efficiency and effectiveness of our government.⁶ Unfortunately, large portions of the Modernization of Poultry Slaughter Inspection rule were developed without the benefit of a transparent process.

² CDC. 31 Pathogens causing U.S. illnesses, hospitalizations and deaths, 2000-2008. <http://www.cdc.gov/foodborneburden/>.

³ Townes, J.M., A.A. Deodhar, E.S. Laine et al. Reactive arthritides following culture-confirmed infections with bacterial enteric pathogens in Minnesota and Oregon: a population-based study. *Ann Rheum Dis.* 67:1689-97; 2008.

⁴ CDC. 31 Pathogens causing U.S. illnesses, hospitalizations and deaths, 2000-2008. <http://www.cdc.gov/foodborneburden/>.

⁵ Frenzen, P. Economic cost of Guillain-Barre Syndrome in the United States. *Neurology.* 71:14-20, 2008.

⁶ Obama, Barack. http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment/

FSIS failed to provide important stakeholders with appropriate opportunities to investigate and discuss, in a public forum, the proposed changes in poultry inspection. At the very least, prior to the Federal Register posting of this proposed rule, the National Advisory Committee for Meat and Poultry Inspection (NACMPI) should have had been consulted – in fact, failure to do so constituted an avoidance of NACMPI’s charter.⁷ CFI appreciates the effort FSIS took to provide NACMPI members with an opportunity to provide comments during a special March 21, 2012 teleconference, but that effort did not result in a formal set of recommendations from the attending NACMPI members, even though public recommendations on proposed USDA proposals are generally an important part of NACMPI deliberations. Further, given the substantial changes that have been proposed, FSIS should have held (or should hold in the future) a public meeting to discuss the proposed changes. In fact, CFI signed and delivered a letter from Safe Food Coalition members to Secretary Hagen, dated April 13, 2012, asking for such a meeting.

If any of these public forums had been engaged, these venues could have helped to:

- 1) Examine the scientific literature – especially the studies documented by the Nordic countries where *Salmonella* control has been achieved – to better understand current control options.
- 2) Examine the merits (including the cost-benefits) that increased microbiological testing could have in reducing *Salmonella* and *Campylobacter* in poultry products.
- 3) Develop recommendations about verifying and adopting innovations for all aspects of poultry slaughter and pre-requisite programs (including on-farm flock testing, to be done before contaminated birds are presented for slaughter).

Unfortunately, FSIS did not vet the proposed changes using an appropriate process and, as a result, it is difficult for important stakeholders, including CFI, to support the current proposal as written. ***At this point in time, CFI recommends that FSIS asks NACMCF or NAS to thoroughly examine the issues listed above, as well as other inspection concerns, and make recommendations based on their findings.***

Use of the Best Available Science and Risk Assessments

CFI has long advocated for the implementation of a risk-based food safety system that is rooted in the best available science and data. FSIS has based the proposed rule largely on a risk assessment that evaluates the public health impact of reassigning online inspectors to

⁷ NACMPI Charter: http://www.fsis.usda.gov/about/NACMPI_Charter/index.asp; renewed 7/25/2007.

Charter renews the NACMPI in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. The Secretary is required to consult with an advisory committee or committees authorized under section 301(a) (4) of the FMIA (21 U.S.C. 661(a) (4)) to carry out the responsibilities imposed by sections 7(c), 24, 205, 301(a) (3), and 301(c) of the FMIA (21 U.S.C. 607(c), 624, 645, 661(a) (3), and 661(c)), and authorized under section 5(s) (4) of the PPIA (21 U.S.C. 454 (a) (4)) to carry out the responsibilities imposed by sections 5(a) (3), 5(c), 8(b), and 11(e) of the PPIA (21 U.S.C. 454(a) (3), 454(c), 457(b), and 460(e)).

offline activities. While CFI applauds the use of risk assessments to more effectively allocate our limited resources to ensure the biggest public health impact, the risk assessment does not support the breadth of changes proposed by FSIS and does not support the assertion that these changes will result in a public health benefit.

First, the risk assessment used in support of the proposed changes has not undergone appropriate peer review. The original 2005 risk assessment was peer-reviewed and significant deficiencies were found. In subsequent years, the 2005 risk assessment was revised twice to address some of its deficiencies, but the revised assessments have not been peer reviewed, so it is difficult to assess if the revisions fully addressed the original deficiencies. *FSIS should have the revised risk assessment and any additional risk assessments peer reviewed before moving forward with the implementation of the proposed rule.*

Second, the risk assessment evaluates the public health impact of reassigning online inspectors to offline activities. The changes in the proposed rule are much more extensive with online inspectors being either reassigned to offline activities or eliminated. Further, the proposed rule allows for significant increases in line speed that were not considered in the risk assessment. FSIS has inappropriately generalized the results of the risk assessment and assumed that similar results would be seen if all these changes were to be put into place. *FSIS should conduct new risk assessments to evaluate the public health impact of implementing these additional risk management changes.*

Third, the risk assessment relies heavily on the data collected through the HIMP program and the microbiological verification testing programs. However, since these programs are not representative of all poultry establishments, data collected through these programs are not generalizable. Since the HIMP program was voluntary and required poultry establishments to meet additional requirements, participating establishments could be viewed as high performers with regard to food safety. While these establishments may have been able to achieve significant reductions under the HIMP model, it is unclear if all establishments could achieve the same results. Similarly, the microbiological verification testing programs were not designed to estimate the incidence of foodborne pathogens in meat and poultry products, nor were they designed to evaluate trends over time. Despite these limitations, the risk assessment has used this data to evaluate the public health impact of reassigning online inspectors to offline activities and has concluded that there is a public health benefit to doing so. *FSIS should conduct a pilot study in a representative sample of poultry establishments to ensure that there is a public health benefit before implementing the proposed rule in all poultry establishments.*

Finally, the risk assessment defines a public health benefit to be no increase in the incidence of human cases of *Salmonella* or *Campylobacter*. However, it is hard to argue that no increase in the number of illnesses is a public health benefit. *FSIS should define a public health benefit to be a decrease in the incidence of human illness and demonstrate that the proposed changes are likely to result in this public health benefit.*

CFI strongly feels that the process employed by FSIS as well as the problems with the risk assessment used as the foundation for the new rule are significant barriers to support of the Modernization of Poultry Slaughter Inspection proposed rule. CFI recommends that FSIS appropriately address these overarching problems before implementing the proposed rule.

Specific Comments

In addition to the overarching problems outlined above, CFI has several comments on some of the specific changes proposed in the new rule.

- 1. For all facilities operating under the new proposed rule, FSIS will allow pre-sorting activities, by facility personnel, prior to inspection by a FSIS on-line carcass inspector (CI).**

CFI believes that pre-sorting of carcasses by facility personnel can be beneficial for increasing the efficiency of FSIS' CI performance. However, CFI is very concerned that the deficiencies in the pre-sorting requirements of the proposed rule could result in more contaminated birds entering the chiller, thereby allowing more cross contamination of product to occur, which in turn, could result in more contaminated product reaching retail outlets and consumers.

The proposed rule does not provide sufficient requirements for training and/or enforcement of pre-sorting activities to ensure food safety. In its Federal Register Notice (p. 4419), FSIS acknowledges the importance of training sorters and indicates that FSIS will take action if there is documentation showing a lack of training. However, this response is certainly reactive at best and, given the difficulty in proving such a deficiency, it may prove to be impossible to verify "lack of training" of facility personnel sorters as a factor in poor performance.

CFI recommends that training for facility sorters become another prerequisite program, similar to FSIS' sanitation requirement, which requires all facility personnel to complete a training program. Further, CFI believes that it is inconsistent for FSIS to demand training for foreign slaughtering facilities so that they can meet U.S. equivalency standards,⁸ but not require U.S. domestic facilities to provide the same level of training. In addition, CFI recommends that FSIS set expectations for the type and extent of pre-sorting activities to be conducted. These requirements should be based on the best available science and a risk assessment should be conducted to verify that they will improve public health.

⁸ New Zealand submission to USDA on July 16, 2011, stating that New Zealand company employees performing non-food safety related inspection tasks will be required to obtain a National Certificate in Animal Product Examination in Other Consumer Protections (Level 3) from the New Zealand Qualifications Authority (NZQA) in accordance with standards approved by the Ministry of Agriculture and Forestry (MAF). Operators are required to provide evidence of this certification prior to beginning their inspection tasks. Operators are required to keep a documentation of these certifications and make them available for verification by the official inspector.

2. For all facilities operating under the new proposed rule, FSIS will reduce the number of on-line carcass inspectors (CI) to one per line and increase the number of off-line food safety activities.

CFI is concerned that the proposed rule has not investigated the impact that reclassifying *and eliminating inspectors* at poultry slaughter establishments will have on public health and poultry worker safety. This proposed rule is rooted in the 2005 Risk Assessment that only addressed the impact of moving CIs to off-line inspection activities; whereas, the current proposal provides that current CIs working in poultry slaughter facilities will be either moved to off-line inspection activities or eliminated from poultry slaughter inspection and reassigned other work within the Agency.

Before FSIS implements this proposed rule, the Agency needs to initiate a new risk assessment to evaluate the public health and worker safety impact that elimination, as well as reclassification, of poultry inspectors will have on FSIS inspected plants. Further, FSIS needs to determine if the eleven off-line inspection procedures (p. 4415-16) can be conducted in a timely and effective manner given the inspection personnel on hand. Based on the results of these studies, the poultry proposal should include language regarding the number of full-time VIs and CIs needed in a poultry slaughter facility when operating under this new rule. CFI also strongly recommends that production volume, along with other risk factors, be used to determine the number of inspectors needed at each facility, and that the number of inspectors, assigned to a facility, be reviewed routinely based on the history/performance of the plant.

3. For facilities operating under the new proposed rule, FSIS will be allowed a maximum line speed of 175 birds/minute.

CFI is concerned that FSIS has not conducted studies or a risk assessment on line speeds to verify public health and worker safety concerns. Currently, there is a study being conducted by the Occupational Safety and Health Administration (OSHA) to assess worker safety issues in poultry plants and at the very least, the implementation of this proposed rule should be delayed until after this study is completed.

In addition, one major organization and university has already published comments to the proposed Modernization of Poultry Inspection Slaughter rule and recommend not implementing this proposed rule's maximum lines speeds, due to the health issues related to worker safety.⁹ Both the American Public Health Association and Duke University maintain that worker exposure to rapid line speed and awkward postures, coupled with high levels of force, could impact worker safety and result in long-term health issues for poultry workers. Again, the findings of these studies indicate that there is a need to revise the proposed rule's maximum line speed.

⁹ See comments on the Modernized Poultry Slaughter Inspection proposed rule from the American Public Health Association (5/31/2012) and Duke University Medical Center (4/09/2012).

4. For facilities operating under the new proposed rule, FSIS will replace Finished Product Standards with Ready-to-Cook standards, with the stipulation that each facility must maintain written records showing that the facility has met the requirements for Ready-to-Cook.

CFI agrees with that written records describing how a facility meets standards is very beneficial. Written procedures help facilities to identify hazards and develop strategic plans to improve food safety. This, in turn, leads to adopting and implementing a more preventive food safety system.

At this point, CFI does not believe that it has enough information on the differences between the two sets of standards (Finished Product Standards and Ready-to-Cook standards) to make a specific comment. CFI would welcome more information and discussion on this topic.

5. For facilities operating under the new proposed rule, FSIS will require facilities to conduct two microbial testing points, one pre-chiller and one post-chiller.

Microbiological testing is a critical tool for verifying that food safety risk management interventions are effectively preventing microbial contamination of meat and poultry products. However, microbiological test results are only as good as the sensitivity of the tests and the sampling plans used to collect the data. Ideally, microbiological testing would be conducted throughout the farm-to-fork food chain using very sensitive and rapid tests, combined with a sampling plan that provides a high degree of confidence to detect contamination if it is present. Therefore, CFI supports the decision to increase the number of microbial testing points. However, CFI is concerned with the following portions of the proposed rule's testing guidance:

- a. The intention to not identify any required indicator pathogen as a standard;
- b. The omission, on FSIS' part, to set a microbial testing frequency per line per shift.

In response to the first point, CFI believes that not specifying *Salmonella* or *Campylobacter* (or both) as indicator pathogens, when both are commonly found in poultry, is a major concern.. Modern scientific research shows that *Salmonella* contamination can be controlled in poultry production and slaughter.¹⁰ Furthermore, according to various sources, the private marketplace does **not** provide strong incentives to control foodborne pathogens.¹¹ Industry needs federal standards that are enforced in order to provide the optimal health protection for American consumers.¹²

¹⁰ Wegener H.C., Hald T., Wong D.L.F., Madsen M., Korsgaard H., Bager F., et al. (2003). Salmonella control programs in Denmark. *Emerging Infectious Diseases*, 9(7), 774-780. <http://www.cdc.gov/ncidod/EID/vol9no7/03-0024.htm>. Roberts, T. (2005) Economic Incentives, Public Policies, and Private Strategies to Control Foodborne Pathogens. *Choices*, 2nd Quarter 20(2). <http://www.choicesmagazine.org/2005-2/safety/2005-2-01.htm>.

¹¹ Golan, E., Roberts, T., Salay, E., Caswell, J., Ollinger, M., & Moore, D. (2004). Food safety innovation in the United States: Economic theory and empirical evidence from the meat industry (Agricultural Economic Report No.

As to the second point, CFI is concerned that microbial testing frequency per line per shift needs to be specified to assure that sufficient testing for pathogens is achieved. Both *Salmonella* and *Campylobacter* testing protocols are needed, since both are public health hazards. CFI believes that federal standards for *Salmonella* and *Campylobacter* control, along with well-defined microbial testing frequencies, will give industry the needed economic incentives to adopt and develop preventive innovations and control solutions aimed at public health goals.

CFI recommends that FSIS:

- Adopt *Salmonella* and/or *Campylobacter* (preferably both) as required indicator pathogens for poultry slaughter facilities to help reduce the prevalence of disease;
- Clarify the number and frequency of microbial samples to be collected by both FSIS and industry, based on the volume of product and other risk factors.

6. The proposed rule rescinds the 1996 PR/HACCP Performance Standards (codified) for young chicken broilers with the new *Salmonella* and *Campylobacter* standards, based on FSIS' 2008 and 2009 baseline studies, for chilled carcasses.

While CFI supports revising the *Salmonella* and *Campylobacter* performance standards for chilled carcasses using the most recent and best available information, we are very concerned that the proposed rule does not contain a provision for amending or codifying the new standards.

In 2008, FSIS developed a new standard (Categories I, II and III) for meat and poultry facilities and began posting testing results of deficient Category II and III facilities on FSIS' website. Further, in 2008 and 2009, FSIS conducted new baseline studies for young chickens and young turkeys and, in 2010, announced new performance standards for chilled chicken and turkey carcasses based on these studies. In their announcement, FSIS stated that, in the near future, these new standards would replace the codified, but non-enforceable, PR/HACCP performance standards.

The *Salmonella* performance standards, as set forth in the 1996 PR/HACCP final rule, have not been enforceable since the 2001 *Supreme Beef* ruling. This ruling and the subsequent restrictions placed on FSIS have made it very difficult for the United States to control the prevalence of *Salmonella*. Given this 2001 Court ruling, CFI is concerned about rescinding a codified standard in favor of a non-codified standard. Using a non-codified standard

AER831). Washington, DC: United States Department of Agriculture Economic Research Service.
<http://www.ers.usda.gov/publications/AER831/>.

¹² Akerlof, G. (1970). The market for "lemons": Quality uncertainty and the market mechanism. *Quarterly Journal of Economics*, 84(3), 488-500. Metcalf, S. (1995). The economic foundations of technology policy: Equilibrium and evolutionary perspectives. In Paul Stoneman (Ed.), *Handbook of the Economics of Innovation and Technological Change* (pp. 410-512). Oxford, UK: Blackwell Publishers Ltd.

assumes that the non-codified standard will continue into the future and will be consistently applied, yet there is no basis for making this assumption. Future administrations and/or agency policies could overturn non-codified policies.

CFI recommends that FSIS take all the necessary steps to codify the new *Salmonella* and *Campylobacter* standards, even as the Agency strives to improve and/or codify standards for other dangerous foodborne pathogens. The lack of a provision for amending or codifying *Salmonella* and *Campylobacter* performance standards is a major barrier to supporting the proposed rule.

Conclusion

CFI appreciates the challenges facing the United States with regard to food safety and the prevention of foodborne illness. We understand that a new approach to poultry slaughter inspection needs to be developed if we hope to better control *Salmonella* and *Campylobacter* infections in our American populations. However, having said that, CFI is concerned that the current proposal has significant design and implementation shortcomings. We have tried to provide comments that will lead to better decisions and more sustainable outcomes.

CFI is committed to working with FSIS to minimize foodborne illness through more effective food safety management, including the development of appropriate regulation. We appreciate this opportunity to comment on the Modernization of Poultry Slaughter Inspection proposed rule, and we look forward to continuing our dialog with the Agency on important food safety issues.

Respectfully submitted,

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