



NATIONAL CHICKEN COUNCIL

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SUBMITTED ELECTRONICALLY

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

Re: Docket No. FSIS-2011-0012; Modernization of Poultry Slaughter Inspection

Dear Sir or Madam:

The National Chicken Council (NCC) appreciates the opportunity to comment on the implementation of the Food Safety and Inspection Service's (FSIS') proposed rule, "Modernization of Poultry Slaughter Inspection," published in the *Federal Register* on January 27, 2012. ^{1/} NCC represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States. NCC's members would be directly affected by any changes to the poultry slaughter inspection system.

NCC and our members are committed to poultry production operations that ensure a safe, wholesome, and abundant supply of poultry products for both domestic and international markets, and the poultry slaughter inspection system plays an important role in this process. NCC supports a science-based, statistically validated, establishment-oriented approach to food safety and poultry slaughter inspection. In 1997, FSIS reported that studies by the National Academy of Sciences, the General Accounting Office (now, Government Accountability Office), and U.S. Department of Agriculture (USDA) "have established the need for fundamental change in the meat and poultry inspection program." ^{2/} To protect the public from foodborne illness better and more efficiently, these reports recommended that "FSIS should reduce its reliance on organoleptic inspection and shift to prevention-oriented inspection systems based on risk assessment." ^{3/} To this end, NCC supports efforts to modernize the poultry slaughter inspection system to reflect Hazard Analysis and Critical Control Point (HACCP) principles more closely by providing establishments more direct control over their operations and by focusing inspection on food-safety outcomes.

^{1/} 77 Fed. Reg. 4408 (Jan. 27, 2012).

^{2/} 62 Fed. Reg. 31553, 31557-58 (June 10, 1997).

^{3/} *Id.*

NCC supports USDA's desire to embrace scientifically-based inspection principles more fully, and appreciates the opportunity to provide comments to address some aspects of the proposed rule, including a lack of operational detail. The effectiveness of many of the concepts presented in the proposal depends significantly on how the agency implements the inspection system on a day-to-day basis. Without being provided details, we cannot fully evaluate and comment on how the proposed requirements would affect poultry slaughter operations and food safety. Despite these missing details, NCC cautiously supports modernizing the poultry slaughter inspection system to reflect a more individualized, scientifically based inspection approach, but cautions that a final rule must contain significant refinement and clarification. In this regard, NCC appreciates the agency granting our request for an extension of the comment period in order to fully document a few areas where refinement and clarification are needed.

The agency should work closely with industry stakeholders to ensure the rule is implemented in an appropriate manner. Unclear or inconsistent requirements, implementation procedures and timeframes, inspection, or enforcement will erase the efficiency gains anticipated by the agency. Moreover, the process of implementing the new inspection system will require extensive time, effort, and investment on behalf of chicken companies. Substantial capital will be required to make the necessary changes—from equipment to personnel—within each chicken processing facility that chooses to implement the new system; and production adjustments would be made only when the market demand increases.

These comments address various aspects of the proposed rule: Part I recommends necessary implementation procedures, Part II addresses the proposed sampling requirements, Part III recommends changes to the inspection process for RTC standards, Part IV explains why avian leukosis is not a condition of public health concern, Part V recommends special training regarding septicemic and toxemic conditions, Part VI explains why line speed should not be arbitrarily limited, Part VII addresses worker safety concerns; Part VIII requests clarification regarding online and offline antimicrobial use, Part IX addresses chilling requirements, and Part X addresses additional considerations.

I. Establishments Must be Given Flexible, Individualized Options for Implementing a Final Rule

The proposed rule neglects to address the significant costs of implementing the proposal, costs which will be significant for large companies and potentially insurmountable for small establishments. To implement the proposal effectively, establishments would need to develop training materials and fully train all their employees in the new system, with a special emphasis on training the employees who would be sorting carcasses. Establishments would also have to develop new recordkeeping requirements based on the new system and retrain or possibly hire new personnel to manage those recordkeeping systems. Implementing the new system would require significant capital investments: companies would need to retrofit facilities to provide new carcass inspector (CI) stands and rearrange lines and operations (including moving or replacing equipment) to accommodate the new inspection system. Moreover, without an understanding of

how the agency intends to implement the new system, companies are unable to begin making financial plans to address the capital investments, exacerbating potential costs. ^{4/}

Accordingly, an orderly implementation process will be essential for the success of any final rule modernizing poultry slaughter inspection. Our members' experience with previous inspection systems demonstrates that the initial success of a new inspection system relies on the training and experience of establishment and inspection personnel and close, clear, and consistent communication with and across the agency. Based on this experience, NCC recommends the agency task a small group of experts to resolve issues that arise during implementation, develop a structured implementation timeline whereby establishments prepare individualized implementation plans in coordination with their district offices, and establish a list of pre-approved implementation strategies to aid establishments in developing implementation plans. This approach would minimize cost and disruption to the industry and inspection, provide mutually beneficial training opportunities, and ensure a consistent approach to implementing the new system across the nation.

A. The Agency Must Develop a Centralized Group to Coordinate Implementation and Policy

Experience with implementing previous inspection systems has demonstrated the importance of consistent, centralized policy for new inspection systems and underscored that quick and clear channels of communication to centralized decision makers are vital. We accordingly recommend the agency establish a small, centralized group of decision makers with expertise in the new system to address the questions that will inevitably arise as a new inspection system is implemented. This group would function as a sort of "operational hotline" to address questions from plants and inspectors about practices and methods of implementing the new program. The group should be small enough to ensure consistent advice is given in a timely manner and should be in regular contact as the new inspection system is implemented. These individuals ideally would have theoretical or practical experience operating in the processing environment.

This operational hotline group would greatly facilitate implementation by providing real-time answers to implementation and operational questions, ensuring all involved are properly focused on their respective roles in ensuring product safety. Questions will inevitably arise that require quick, consistent decisions. In many instances, these questions require immediate resolution and can be conveyed through discussion much more easily than through drawn-out written inquiries, making live communication critical. A representative from this designated group would field an inquiry from plant or inspection personnel (or sometimes a joint inquiry from both), ask any follow-up questions necessary to understand the issue fully, and then explain how the agency intends the new inspection system to work in that situation, addressing any follow-up questions

^{4/} Although NCC believes the proposed system, with modifications recommended in these comments, would result in a cost savings to the industry, the agency, and consumers if properly implemented, we question the agency's estimate that the proposed rule would save industry \$258.9 million annually. FSIS appears to base its estimates on several unrealistic assumptions about how many plants will choose to or are capable of operating at the higher line speeds and fails to take into account overall consumer demand when estimating industry-wide output. Nonetheless, the benefits to food safety and overall efficiencies to be gained are worth the cost and investment.

in the process. Designating a small group of experts to address these questions from plants as well as inspectors, the agency would foster immediacy and consistency in the agency's responses.

Although it serves a useful purpose, the current AskFSIS system would not be appropriate for addressing these inquiries. The time required to prepare and generalize a written response through the AskFSIS system would detract significantly from the consistency and finality of an agency decision for specific implementation or operational questions. Instead, the group of experts comprising this operational hotline could document inquiries and their responses, periodically compare notes, and document through the AskFSIS system (after the fact) answers to commonly asked questions that may be of general interest to stakeholders. The operational hotline should remain the front-line resource for operational questions.

Centralizing and coordinating implementation and operational questions in this manner would greatly facilitate compliance and preempt questions and disputes about the new system's implementation, saving the agency and industry time and money and ensuring food safety as the new program is implemented.

B. Establishments Should Develop Individualized Implementation Plans

Establishments will approach the new system from varying levels of familiarity and preparedness for compliance with the new requirements. To enable each establishment to implement the new system in the best manner possible, establishments can develop individualized implementation plans, which can be shared with district offices to facilitate agency planning and resource allocation. These plans should be plant-specific and allow for considerable flexibility from plant to plant. A recently built plant operating under numerous waivers may be in a position to implement the new system in one fell swoop, while another plant may want to take a phased-in approach, implementing the new system on a single "shake-down" line or implementing only some features at a time.

At the same time, district offices will have to coordinate changes in inspector coverage based on the new system and the implementation timeline and will have to anticipate and allocate funds for training and other implementation-related expenses. Ensuring district offices are informed throughout the implementation process would help minimize these costs and ensure adequate resources are made available for food safety throughout the implementation process.

After a final rule is made available and establishments can begin analyzing the new requirements and planning for the necessary capital expenditures to comply with the new inspection system, establishments should be provided a significant transition period whereby they may continue operating under their current inspection systems and develop and make available to the agency implementation plans for the new system. A plan would indicate when the establishment would begin implementing the new system, how long implementation would be expected to take, and how the establishment anticipates implementing the system. The agency would have a set period of time to comment on the plans, after which establishments would begin making the necessary financial, facility, and personnel arrangements to prepare for implementation. Understandably, these plans would be subject to continual reevaluation throughout the implementation process to

take into account changing conditions, but they would provide the agency and the district offices useful information to structure inspection and implementation resources.

Following this system would enable establishments to develop implementation plans specific to their operations and districts to anticipate and direct resources appropriately while ensuring the new system is implemented in a smooth and measured fashion. Moreover, permitting different establishments to develop their own implementation procedures would give the agency valuable feedback as it observes the new systems gradually come online. Similarly, companies with multiple plants can refine their systems in one establishment before rolling the new program out to the other plants, and even single-plant companies could assign one line or shift as an initial shake-down shift so the company and its employees can gain appropriate experience before implementing the program plant-wide. In all, this system would greatly facilitate the transition into the new inspection program.

Importantly, implementation decisions need to be driven by establishments, which are in the best position to understand what resources are required to implement the new system in their plants. Given the significant, plant-specific implementation costs discussed earlier—capital investments, personnel hiring and training, equipment changes, and facility renovations—a one-size-fits-all approach would not be appropriate. Nor would it be appropriate to open the new inspection system to only a small subset of the poultry industry at a time, creating competitive imbalances and preventing some establishments from implementing a system designed to be more protective of food safety.

C. The Agency Should Pre-Approve a List of Implementation Strategies

Establishments should be encouraged to develop their own plant-specific implementation strategies specific to their operations. Permitting different establishments to develop their own implementation procedures would give the agency valuable feedback as it observes the new systems gradually come online. Similarly, companies with multiple plants could refine their systems in one establishment before rolling the new program out to the other plants, and even single-plant companies could assign one line or shift as an initial shake-down shift so the company and its employees could gain appropriate experience before implementing the program plant-wide.

To streamline this process, we recommend the agency develop a list of pre-approved implementation strategies. These strategies could readily be published in an FSIS Notice. Establishments should be encouraged to mix strategies from this list and strategies developed on their own to develop a full implementation plan. This list could be updated as new practices identified during implementation prove to be successful, enabling other plants to improve and streamline the implementation process. We provide a list of strategies the agency should approve, and we suspect the agency's experience would suggest additional useful strategies. ^{5/}

^{5/} We recognize some of these strategies are either allowed under current regulations or possible with a waiver. For consistency, we believe it would be useful for the agency to list all implementation strategies together, as we do here.

- Implement components of the new slaughter system, such as OCP checks instead of FPS checks, early. The agency already grants waivers for these types of changes. Using pre-implementation waivers would reduce the number of changes occurring concurrently.
- Establish a fast-track system for approving waivers related to the implementation of the new inspection system.
- Allow plants, after the final rule's effective date, to implement the new inspection system on one line of a multi-line plant, using that line as a "shake-down" line for letting establishment personnel gain experience in the new system while operating the remaining lines under the previous inspection system. The agency would be free to rotate inspectors through this line too to expose multiple inspectors to the new system. All poultry on the "shake-down" line would of course have to pass inspection under the proposed system. All lines would eventually transition to the new system.
- Permit plants to transition one shift at a time to the new system. Similar to the previous option, this approach would let establishments gain experience with the new system while still running the bulk of their operations under the previous systems.
- Allow establishments to rotate personnel through the presentation or inspector's helper position for training purposes. Establishment personnel would benefit from first-hand experience observing inspectors.
- Establish a marking system for birds condemned under the current systems for training purposes. Condemned birds with the reason for condemnation indicated could be examined to train establishment sorters.
- Approve the use of online salvage programs for conditions such as airsacculitis so plants can develop methods to deal with these issues under the new system.
- Allow establishments under the current systems to remove whole-bird condemned carcasses (*i.e.*, carcasses condemned for septicemic or toxemic conditions) from the line before inspection and include these condemned birds in the official Lot Tally totals. This approach would effectively let establishments train in their carcass sorting procedures while knowing that an inspector will still inspect and sort any birds that are missed during this initial training.
- Permit establishments to begin discarding or separating giblets from the carcasses before inspection to let plants develop the giblet harvest systems they will use under the new inspection system.

These options would provide establishments significant flexibility in deciding how best to implement the new inspection system. Importantly, each option is geared toward letting establishments (and the agency) gain familiarity with the new system without jeopardizing food safety or an establishment's overall operations. These approaches would greatly streamline the transition to the new system.

II. Sampling Requirements Should Follow HACCP Principles and Be Backed By Clear Agency Rationales

A. Establishments Should Be Afforded Maximum Flexibility in Selecting Sampling Locations

In keeping with HACCP principles, which emphasize developing safety procedures in keeping with the processes specific to each establishment, 6/ each establishment needs maximum flexibility in selecting the number and site of sampling locations to demonstrate process control for that particular establishment's processes. Conversely, prescriptively requiring an arbitrary number and location of sampling locations may not reflect actual conditions at a given establishment. Sampling programs must be scientifically based and statistically valid, which can be accomplished only through establishment-specific sampling programs.

Some establishments may elect to use two sampling locations, whereas others may develop ways to monitor process control using a single location. Similarly, sampling before and after the chiller may be appropriate in one establishment whereas another may receive more useful information by placing all sampling locations either before or after the chiller. Providing establishments this degree of process flexibility is not only consistent with HACCP principles, which envision individualized processing and safety plans, but also fosters the "industry innovations in operations and processing" the agency hopes to achieve in the new inspection system by enabling processors to develop new methods for demonstrating process control through sampling. 7/ It would not be appropriate, however, for the agency to require a third sampling location at rehang, and the agency appropriately opted not to include this requirement in the proposed rule. Three mandatory sampling locations is overly prescriptive, burdensome, and would not further food safety. Moreover, other regulatory requirements already require scientific validation of HACCP plans.

If the agency elects to maintain a proscriptive approach to sampling at the pre- and post-chill location, NCC recommends the agency clarify that establishments would have the flexibility to select where before and after the chiller this sampling would occur. Although such an approach would lack the appropriate flexibility described above, providing establishments some flexibility in selecting sample locations would still provide better, although perhaps less optimal, sampling information. Sampling only at points immediately pre- and post-chill, though, in many instances would not provide an establishment meaningful information specific to its particular operations and would not be an appropriate approach to sampling.

A third mandatory location could cause confusion as establishments and inspectors struggle to make sense of data that do not necessarily reflect the overall process. If, for example, a processor's primary interventions occur between the second and third sampling locations, data from a rehang location would not provide any meaningful information and risk interjecting noise into the process evaluation.

6/ See 61 Fed. Reg. 38806, 38814 (Jul. 25, 1996).

7/ See 77 Fed. Reg. at 4408 (Jan. 27, 2012).

Sampling must be designed to demonstrate process control, ^{8/} which necessarily entails designing a sampling program specific to an individual establishment's programs and processes. The proposed rule appropriately does not specify specific sampling frequencies, instead requiring that "sampling frequency be adequate to monitor the effectiveness of the establishment's process control for enteric pathogens." ^{9/} We do not agree, though, with the agency's tentative view that production volume, the source of flocks, and slaughter and dressing processes are appropriate factors to consider when determining sampling frequencies. ^{10/} HACCP requires that establishments maintain process control while operating within the parameters of their HACCP plans; the way process control is demonstrated does not vary with the operations being conducted. Scientifically based sampling frequency thus depends on the programs and procedures established in an establishment's HACCP plan, not already-accounted for variables like volume or flock source.

We therefore recommend the agency craft the final rule to provide establishments maximum flexibility to develop sampling plans—including the number, location, and frequency of sampling—that appropriately let the establishment demonstrate process control based on its own operations.

B. Establishments Should Be Permitted To Choose An Indicator Organism Appropriate to Each Establishment's Operations

NCC and its members recognize the importance of selecting an appropriate indicator organism that enables accurate and efficient testing for conditions of interest. For years, industry has tested for generic *E. coli*, per agency regulations, as an indicator organism for microbiological conditions. We agree with removing the mandatory generic *E. coli* testing requirement as *E. coli* testing is not appropriately used for regulatory purposes. In eliminating mandatory generic *E. coli* testing, the agency suggests that generic *E. coli* testing is rarely an appropriate indicator organism, ^{11/} which may cause confusion as establishments and inspectors try to implement the proposal that establishments test for the "microbiological organisms [that] will best help [establishments] monitor the effectiveness of [their] process control procedures." ^{12/} Specifically, the agency's explanation indicates that establishments may select any indicator organism appropriate to their operations. We recommend the agency clarify that, while it is eliminating the mandatory generic *E. coli* testing, generic *E. coli* remains an appropriate indicator organism that establishments may demonstrate can effectively be used to monitor

^{8/} *Id.* at 4428. At times in the preamble to the proposed rule and in the *Federal Register* document announcing the extension of the comment period, 77 Fed. Reg. 24873 (Apr. 26, 2012), the agency discusses fecal contamination in a way that could be read to suggest the agency sees a correlation between fecal material and microbiological loads. *See, e.g.*, 77 Fed. Reg. at 24874 ("We have no evidence to show that ingesta carries the same microbes as fecal contamination."). While fecal material may be a source of microbial contamination, there is no correlation between visible fecal material and microbial loads. Microbial loads can originate from various sources, which underscores the importance of using scientifically based sampling procedures to monitor overall process control.

^{9/} 77 Fed. Reg. at 4428.

^{10/} *See id.*

^{11/} *See, e.g., id.* at 4427.

^{12/} *Id.* at 4428.

process control. Indeed, establishments should be permitted to use any indicator they can demonstrate effective through a statistically validated process.

III. RTC Standards Should be Applied at a Location of the Establishment's Choosing and Should Follow Established Standards

Consistent with enabling establishments to develop and maintain their own operations, a final rule must provide establishments the flexibility to decide where in the production process to check the product against the ready-to-cook (RTC) standards using the other consumer protection (OCP) standards. Because an establishment may apply additional processes—especially processes targeting RTC criteria and other quality issues—at various locations after the chiller, it is not appropriate for the carcass inspector (CI) to inspect for RTC criteria before the chiller. As the agency recognizes in the proposal, RTC criteria address quality, not food safety, issues. ^{13/} There is thus no food safety concern associated with birds that may not yet meet the RTC standard entering the chiller; a bird with bruising, for example, will not “contaminate” other birds in the chiller. Accordingly, there is no public health rationale for requiring carcasses meet the RTC criteria before entering the chiller, and the CI should not be distracted from inspecting for food safety issues with the additional task of checking for RTC criteria.

NCC generally agrees with FSIS that establishments should “have the flexibility to design and implement measures to address OCP defects that are best suited to their operations,” ^{14/} which is consistent with the thrust of the proposed rule and HACCP principles. The establishment is in the best position to determine where in its process it considers its product ready for the consumer, and thus when the RTC standards should be applied. Plants typically rely on very strict customer standards, and many establishments may find it most efficient to verify products meet RTC standards at the same time they verify they meet customer criteria. We recommend FSIS thus explicitly approve an establishment's setting the RTC check at any location of the establishment's choosing, up to and including the point of packaging, and permit establishments to develop their own OCP criteria depending on the specific product.

Establishments also face significant market incentives to ensure their products meet exacting customer criteria, which are often much more stringent than the agency's minimum wholesomeness RTC standards. To avoid costly contractual penalties, establishments would closely ensure their products meet the RTC standards, and FSIS offline inspection can verify product is in fact wholesome. Moreover, offline inspectors would be able to directly observe carcasses and would have access to OCP monitoring records; if an inspector observes an establishment not following its OCP plan or failing to meet its standards, the inspector should alert the IIC.

This approach would allow the CI to closely focus on true food safety issues, more accurately reflect modern practices, and leverage naturally occurring market incentives to ensure product meets the RTC criteria efficiently.

^{13/} *Id.* at 4422–23.

^{14/} *Id.* at 4423.

IV. Avian Leukosis Does Not Require Condemning Whole Carcasses or Specialized Inspection

The proposed avian leukosis check serves no meaningful public health purpose and should be eliminated to streamline the proposed rule. Similarly, avian leukosis does not warrant condemning whole carcasses and is properly treated as a trimmable condition under a modern inspection system. Specifically, avian leukosis should be treated as an OCP-1 trimmable condition, consistent with the way the agency treats all other avian diseases that render part of the bird unwholesome. Doing so would further the agency's intent to implement a sound, science-based inspection system.

When avian leukosis inspection procedures were developed, the etiology of leukosis was largely unknown. Scientists now understand that leukosis is caused by two different types of viruses: a herpes virus known as Marek's Disease and a group of endogenous retroviruses (located within the chromosome) known as the Avian Leukosis Complex. Marek's Disease is typically associated with younger birds, while Avian Leukosis Complex affects birds closer to maturity (age 16 weeks or older). Modern treatment and flock handling practices, though, have effectively eliminated these diseases in commercial poultry operations. Nearly all birds are vaccinated against Marek's Disease as embryos or chicks, and the disease prevalence has been effectively eliminated from commercial flocks. ^{15/} Avian Leukosis Complex is a genetic virus and has been virtually eliminated through careful flock breeding practices. The agency's own data supports the conclusion that avian leukosis is a "rare manifestation" in broilers. ^{16/} Even as early as 1984, according to the agency's data, avian leukosis was present in only 0.017 percent of young chickens slaughtered. ^{17/} That number is lower today.

Moreover, as the agency recognizes, avian leukosis "is not transmissible to humans" and "does not present a human health concern," ^{18/} a fact the agency has acknowledged since at least 1997. ^{19/} The viruses that cause leukosis are species-specific and cannot be transmitted to humans. The National Institutes of Health (NIH) has declared that neither virus "is associated with disease in healthy adult humans." ^{20/} Comprehensive literature reviews of Marek's Disease ^{21/} and Avian Leukosis Complex ^{22/} have also concluded that neither diseases presents any apparent risk to public health.

^{15/} The proposed rule recognizes this practice. *Id.* at 4422.

^{16/} *Id.* at 4421.

^{17/} *Id.* at 4422.

^{18/} *Id.* at 4421-22.

^{19/} See 62 Fed. Reg. 31553, (June 10, 1997) ("Aesthetic conditions with no known food safety concerns include leukosis, other tumors, and airsacculitis.").

^{20/} National Institutes of Health, NIH Guidelines for Research Involving Recombinant DNA Molecules 44, app'x B.V (Oct. 2011).

^{21/} H.G. Purchase and R.L. Witter, *Public Health Concerns From Human Exposure to Oncogenic Avian Herpesvirus*, 189 J. Am. Vet. Med. Ass'n 1430 (1986).

^{22/} E.S. Johnson, *Poultry Oncogenic Retroviruses and Humans*, 18 Cancer Detection & Prevention 9 (1994).

Checking flocks specifically for avian leukosis and treating the condition as a whole-bird condemnable condition thus reflect outdated inspectional approaches and are not scientifically sound given modern flock management practices and an evolved scientific understanding of leukosis. A scientifically based inspection system treats avian leukosis consistent with any other trimmable condition. Establishments would still be required to remove any visible lesions, regardless of whether they are associated with leukosis or another condition. ^{23/} Building a separate inspection station, inspecting the first 300 birds of each flock for avian leukosis, and condemning whole carcasses due to potential signs of leukosis, however, imposes an unnecessary burden on establishments and inspectors with no corresponding public health benefit.

V. Ensuring Establishment Carcass Sorters and Inspectors Understand and Apply the Same Criteria for Identifying Septicemic and Toxemic Conditions Is Crucial for Smoothly Implementing NPIS

NCC supports the agency's efforts to clarify the division of responsibilities between inspectors, who should monitor operations, and establishment employees, who should actually conduct those operations. Placing the responsibility of initially sorting carcasses on establishments is an important and necessary step in properly delineating those roles. Establishments are well positioned to sort carcasses effectively and the proposed change provides establishments flexibility and control to run their operations properly. The initial success of the proposed rule, though, could turn heavily on establishment sorters and agency inspectors demonstrating a common understanding and application of condemnable septicemic and toxemic conditions.

Given the subjective nature of visually identifying septicemic and toxemic conditions, we recommend the agency provide detailed training and guidance on what conditions require the carcass be condemned. ^{24/} This training should ensure uniform standards are applied regardless of the inspector or district. Interactive training involving both establishment representatives and inspectors would help ensure all apply the same standard, as would providing clear examples to follow.

Training also provides an opportunity to revisit, refine, and refocus inspection for septicemic and toxemic conditions in a way more reflective of actual public health risks. Septicemia is generally recognized as a "systemic disease associated with the presence and persistence of pathogenic microorganisms or their toxins in the blood." ^{25/} Toxemia is defined as "any condition resulting from the spread of toxins or toxic bacterial products by the bloodstream." ^{26/} Poultry inspection is appropriately concerned only with septicemic or toxemic conditions that present a foodborne risk to public health, which are few in number. In the preamble to the proposal, though, the

^{23/} Indeed, the white spots on livers associated with leukosis can be caused by numerous other conditions. Industry experience is that testing the few birds that are condemned for leukosis shows the birds actually had a different, trimmable condition.

^{24/} Other important implementation issues are discussed elsewhere in these comments.

^{25/} Dorland's Illustrated Medical Dictionary 1718 (31st ed., 2007).

^{26/} *Id.* at 1968.

agency provides an overly broad, ungrounded characterization of the risk posed by septicemic or toxemic conditions: “Carcasses that exhibit septicemic and toxemic conditions are likely to contain infectious agents, such as bacteria, virus, rickettsia, fungus, protozoa, or helminth organisms, which can be transmitted to humans. For this reason, they present a food safety risk if they are permitted to enter the chiller.” 27/ This assessment is not scientifically sound.

A review of zoonotic diseases between chickens and humans caused by the infectious agents identified by the agency reveals the only real hazards are posed by enteric bacteria such as *Salmonella* and *Campylobacter*. 28/ *Salmonella* and *Campylobacter*, though, are typically not pathogenic in poultry and thus do no illicit lesions and would not be identified in an inspection for septicemia or toxemia. 29/ The infectious agents noted by the agency are either common diseases infecting both man and poultry but not transmissible between the two species, exotic diseases that are closely monitored in the field to prevent affected birds from reaching the plant, or contracted through contact with dry aerosolized fecal material, which is unlikely to occur in the processing environment. Therefore, the statement that carcasses identified during inspection as septicemic or toxemic are “likely to contain” the infectious agents noted, “which can be transmitted to humans,” is not scientifically sound. Pathogenic diseases that can be transmitted from poultry to humans are very rare, especially in light of highly effective disease eradication and monitoring programs in the United States. A carcass condemned for septicemia or toxemia is not likely to contain an infectious agent of public health concern.

The agency should use this opportunity to refocus inspection for septicemia and toxemia using scientifically sound principles, otherwise this disposition risks becoming a catch-all category for any “different-looking” birds, and the inspection system loses a significant amount of the scientific rigor that is necessary to properly protect public health.

Additionally, districts should monitor the number of carcasses condemned by inspectors for septicemic or toxemic conditions by establishment, date, shift, and inspector to identify situations in which standards are not being applied consistently so training resources can be efficiently brought to bear. Similarly, the efficient implementation of the rule requires establishing a clear chain of communication between the establishment and the agency for quickly, decisively, and constructively addressing situations of disparate or inconsistent application of septicemic or toxemic standards. Clear and transparent communication regarding these conditions will greatly facilitate the transition to the new system.

27/ 77 Fed. Reg. 4408, 4421.

28/ See Pan American Health Organization, *Zoonoses and Communicable Diseases Common to Man and Animals* (3rd ed. 2001).

29/ Indeed, these pathogens are addressed through an establishment’s hazard analysis and prerequisite programs.

VI. Line Speeds Should Be Established Based on the Individual Establishment's Ability to Process and Present Birds for Inspection

A. A Set Line Speed Is Unnecessarily Prescriptive

NCC appreciates the agency's recognition that line speeds should not be based on arbitrary numbers, but rather should reflect the ability of plants to maintain process control while ensuring inspection of each carcass. In keeping with this approach, the agency should remove the 175 birds-per-minute line speed limit and instead let establishments run at line speeds at which they can maintain process control while allowing for inspection of each carcass.

This approach would better align with the agency's determination that establishments should exercise more direct control over their operations. Line speeds affect processing operations in a number of ways. Regulations aside, line speed is often dictated by the equipment an establishment is using. When considering capital investments, an establishment will consider what line speed the contemplated equipment would permit, and limits on line speeds would limit future investment decisions. Line speeds also affect how many employees an establishment will hire and how those employees will be trained. For example, to increase line speed, an establishment could hire additional carcass sorters, ensuring each carcass sorter handles a manageable number of carcasses that feed into the faster production line. Lastly, line speeds directly affect food safety. Establishments design operations and interventions around targeted line speeds. Because line speeds dictate how long carcasses will be exposed to certain temperatures and how long it will take them to reach specific interventions, an establishment's pathogen modeling may be dependent on maintaining a specific target line speed, with slower speeds increasing ambient temperature exposures. Moreover, flexible, uncapped line speeds allow for innovative approaches to process design, equipment development, and, when appropriate, inspection techniques. Given how line speeds permeate an establishment's decision making and process design, HACCP principles dictate that establishments have responsibility for selecting a line speed appropriate to their operations.

Lastly, the agency indicates worker safety is a factor in determining the appropriate line speed. ^{30/} NCC's members agree that worker safety must be considered when establishing a line speed, and establishments take into account worker safety as part of their commitment to ensuring safe workplaces, establishing appropriate limits on line speeds and other operating parameters to ensure a safe work environment. Importantly, though, worker safety and food safety represent different concerns influenced by different factors and are most appropriately addressed separately to ensure each receives the attention and focus it deserves.

Many establishments have operated under waivers or inspection systems permitting higher line speeds for years, establishing employee safety records demonstrating the safety of higher line speeds for establishment employees. NCC and its members take seriously the safety of workers in the broiler chicken industry, and we are confident the increased line speeds allowed under the proposed rule have been demonstrated to be safe for workers. Our members take employee

^{30/} 77 Fed. Reg. at 4423-24.

safety very seriously, and we welcome a continued dialogue with federal and state worker-safety organizations.

B. The Agency Should Draw on Established Procedures to Address Line Speed During Inspection

NCC recommends the agency adopt the procedures used in existing inspection systems as the model for responding to line speed concerns during inspection. These procedures emphasize the importance of statistical analysis and the relation of the CI to the establishment's CCPs.

The proposed system should expressly incorporate statistical analysis as the primary method of determining whether an establishment is maintaining process control at the current line speed. Individual observations or statistically untested observed trends are not adequate indicators. As in existing systems, line-speed adjustments and other regulatory actions are not appropriate unless a system wide review by the IIC indicates a systemic noncompliance. Determining system wide compliance requires analyzing the establishment's overall processing plan and interventions.

FSIS thus should explicitly incorporate well-tested procedures into the final rule. These procedures have a demonstrated history of efficiently identifying and addressing systemic issues, which is a driving factor behind HACCP systems. CIs should be instructed to stop the line only to remove a food safety defect after the final control for that defect, and regulatory action should be taken only after further analysis indicates a systemic problem. CIs should be instructed not to stop the line or otherwise interrupt the production process for OCP defects. Moreover, it would not be appropriate to order line-speed reductions unilaterally. Rather, line-speed should be one of many tools available to establishments to use to bring their processes back under control.

VII. NCC is Confident That Modernizing the Poultry Inspection System Will Not Endanger Our Members' Workforces

NCC and our member companies take seriously the health and safety of our workers. We are confident the increased line speeds allowed under the proposed rule have been demonstrated over many years to be safe for workers in the broiler chicken industry.

A recent survey of broiler establishments participating in the agency's pilot project show, for both Total Recordable Injury Rates and Days Away, Restricted, or Transferred (DART) Rates, that these plants are as safe for workers as plants that operate under traditional inspection. In fact, the data indicate that there is no statistical difference between plants involved in the HIMP pilot project and traditional inspected facilities with regards to Total Recordable Injury Rates and DART Rates. Specifically, in 2009 and 2010, Total Recordable Injury Rates in establishments participating in the pilot project were 5.6 and 5.3, respectively. Industry average for Total Recordable Injury Rates was 6.1 and 5.5 in 2009 and 2010, respectively. In 2009 and 2010, DART rates in establishments participating in the pilot project were 3.4 and 3.9, respectively. Industry average for DART rates was 4.0 and 3.9 in 2009 and 2010, respectively.

As a result, NCC is confident that modernizing the poultry inspection system will not endanger our members' workforces. Whether plants are operating in the HIMP pilot project or under traditional inspection, the chicken industry continues to improve its record for the health and wellness of its workforce, decreasing its injury and illness rate 74 percent since 1994.

VIII. Approved Antimicrobials Must Be Made Widely Available for Both Online and Offline Reprocessing

NCC and its members applaud FSIS's decision to eliminate the need for repetitive individualized waivers and instead authorize antimicrobials for use by all establishments in online and offline reprocessing. In doing so, we recommend the agency eliminate the outdated distinction between online and offline reprocessing, instead relying on establishments to justify the appropriate use of safe and suitable antimicrobials in their HACCP plans.

Establishments already must validate their processes, including the antimicrobials used in reprocessing; a formalistic FSIS distinction serves no meaningful purpose and only risks confusing issues and deterring innovation. Moreover, limiting uses of certain antimicrobials to online or offline reprocessing overlooks the fact that all chicken must meet the same standards. Relying on individual plant validations would reflect a more scientifically sound approach. To the extent the agency has concerns about the appropriateness of particular antimicrobials for certain applications, the agency can limit the conditions of use for the antimicrobial when listing the antimicrobial as safe and suitable for use in poultry products. The instances in which the agency identifies a scientific basis for limiting the use of an antimicrobial to online or offline reprocessing would presumably be rare.

IX. The Proposed Chilling Regulations Are Appropriate with Minor Revisions

NCC supports the agency's decision to permit establishments to validate their own chilling processes while still retaining the current chilling processes as a validated safe harbor. This approach is consistent with the agency's desire to follow a more scientifically based approach to food safety. To facilitate compliance and encourage innovative chilling processes, the agency should provide guidance on how establishments should validate new chilling processes. ^{31/} The agency should also reiterate in the final rule the established safe harbor provisions.

We also recommend the agency clarify the definition of air chilled poultry to accommodate reasonable applications of antimicrobials using small amounts of water. These applications are not designed to affect cooling or moisture pick-up, but a hypertechnical reading of the proposed regulation might prohibit their use. The proposal would permit only antimicrobial applications that do "not result in any pick-up of water or moisture and . . . [do] not assist the chilling processing by lowering the product temperature." ^{32/}

^{31/} We recognize the agency recently released guidance on HACCP validation. *See* HACCP Systems Validation, 77 Fed. Reg. 27135 (May 9, 2012). In implementing the proposed new inspection system, we recommend the agency review its existing and any draft guidance to ensure establishments validating systems under the new inspection system clearly understand expectations and the validation process.

^{32/} *Id.* at 4453-54 (proposed §381.66(e)).

Antimicrobial mists are often applied during air chilling for pathogen control. Some of the misted water drips off the carcass, but some minute amount likely evaporates, which would technically cool the product by a trivial amount, while another small amount might remain on the carcass. In no cases would the pick-up for cooling effect be significant, but the rule should be revised to clarify that such a use would comply with regulations. Specifically, the agency should revise proposed § 381.66(e) to permit antimicrobial applications applied with water if the water is used for a short duration and does not materially contribute to the chilling process or result in a material amount of water pick-up. This change would align the proposal with industry practice currently permitted by the agency.

X. Additional Issues Require Clarification or Revision for an Effective Inspection System

A. The Agency Should Provide Safe Harbor Guidance for Industry

To facilitate compliance, the agency should issue guidance or identify procedures that establishments may use as safe harbors in processing to ensure they comply with the new inspection requirements. Just as the agency has indicated it would establish the existing chilling time and temperature parameters as a safe harbor, the agency should identify current regulations or established practices (that would be eliminated or replaced by the proposed rule) that provide operational safe harbors for establishments under the proposed system. Establishing these procedures would facilitate compliance, ensure food safety, and eliminate duplication of efforts as plants needlessly validate well-established agency procedures. These safe harbors would likely significantly reduce the burdens on small and very small establishments wishing to operate under the new system.

B. Facility Requirements Should Permit Flexible Applications

Adapting to the proposed system may pose logistical challenges for some establishments based on their plant sizes or layouts. For example, some establishments may have interventions directly before the chiller, or some facilities may not have room for the proposed CI station in that location. In recognition of these potential logistical issues, we recommend the agency develop a special hardship process to accommodate establishments that would have to incur unreasonably substantial capital costs to implement the proposed system. Possible options include temporarily placing the CI at a different location agreeable to the establishment and the district or creating a long-term phase-in plan for establishments that simply cannot make the necessary changes in time.

The agency should also eliminate the requirement for a “trough or other similar drainage facility” extending beneath the conveyor at all places where processing occurs, in proposed § 381.36(c)(4), and instead rely on establishments’ general obligations to maintain sanitary conditions to address drainage issues. This change would be consistent with the general HACCP principles embraced throughout the proposal.

Conclusion

It is the goal and primary focus of the chicken industry and FSIS alike to provide consumers with safe, high quality, and wholesome chicken. NCC supports FSIS's efforts to modernize the poultry slaughter inspection system, which has been called for by National Academy of Sciences, the General Accounting Office and the agency. We and our members believe a statistically valid, scientifically based approach to food safety and processing will improve food safety and better protect public health.

NCC and our member companies also take seriously the health and safety of our workers. We are confident the increased line speeds allowed under the proposed rule have been demonstrated over several years to be safe for workers in the broiler chicken industry. Under the proposal, FSIS will remain in its oversight role, and FSIS inspectors will still be in every plant, looking at each carcass to ensure the safety of chicken products and providing them with the USDA seal of approval for wholesomeness. The proposed inspection system will better protect the public from foodborne illnesses by reducing reliance on old-fashioned visual and sensory inspection and moving to prevention-oriented inspection systems based on actual risk to consumers.

NCC and our members believe the proposal's success depends on making additional clarifications to the proposal and in illustrating how the rule would be implemented. In making these changes, the agency should adhere strictly to HACCP principles and enable establishments to make individualized processing and implementation decisions—decisions that will ensure food safety is best ensured in each individual situation. The changes described above are designed to ensure an efficient transition to an even safer and more effective slaughter system.

Please do not hesitate to contact us if we may be of further assistance. Thank you for your consideration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ashley B. Peterson". The signature is fluid and cursive, with the first name being the most prominent.

Dr. Ashley B. Peterson
Vice President, Science and Technology