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Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue SW
Mailstop 3758, Room 6065
Washington, DC 20250-3700

Re: Docket No. FSIS–2018–0044: Notice and Request for Comments on Changes to the *Campylobacter* Verification Testing Program: Revised Performance Standards for *Campylobacter* in Not-Ready-To-Eat Comminuted Chicken and Turkey and Related Agency Procedures

Dear Sir or Madam:

The National Chicken Council (NCC) appreciates the opportunity to provide comments on the Food Safety and Inspection Service (FSIS or the Agency) Notice and Request for Comments on Changes to the *Campylobacter* Verification Testing Program: Revised Performance Standards for *Campylobacter* in Not-Ready-To-Eat Comminuted Chicken and Turkey and Related Agency Procedures (the Notice).¹ NCC is the national, non-profit trade association that represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States.

NCC member companies are deeply committed to food safety. Chicken processors implement a wide variety of interventions to control and reduce *Salmonella* throughout the production continuum, and they take *Campylobacter* reduction just as seriously. NCC recognizes that developing performance standards is complex and raises numerous scientific and policy issues. Our collective scientific understanding of *Campylobacter* is limited and there are key research gaps that need to be addressed. Because so much remains to be learned about *Campylobacter*, industry needs appropriate time to adjust to the new performance standards once they are finalized and to continue to research and refine intervention strategies. We know that *Salmonella* and *Campylobacter* are very different bacteria and respond differently to reduction and control strategies, but many scientific gaps remain to be filled. Finally, at a fundamental level, NCC believes that all regulatory actions related to food safety, including performance standards, must have a demonstrable benefit to public health.

¹ 84 Fed. Reg. 38203 (Aug. 6, 2019) <https://www.govinfo.gov/content/pkg/FR-2019-08-06/pdf/2019-16765.pdf>.

Against that background, we are pleased to offer the following specific comments intended to help achieve an effective and fair implementation of the performance standards. Our comments address how the proposed performance standard was developed, implementation issues, and enforcement issues. In particular, we urge FSIS to tailor the *Campylobacter* performance standard to reflect differences in bird size, to adopt a single uniform effective date for all the *Campylobacter* standards under development, and not to post establishment-specific information without at least providing a meaningful opportunity for establishments to adjust to the new performance standard. We expand on these and other comments below.

Additional Information on the Development of the Performance Standards

Performance Standards Should Reflect Differences in Campylobacter Prevalence Based on Bird Size

NCC members' experience has been that bird age (and thus size) has a significant effect on rates of *Campylobacter* presence, with younger (and smaller) birds having higher rates.² Experience indicates that the age cut-off typically occurs between 8-9 weeks, with birds older than 8-9 weeks having significantly lower *Campylobacter* rates.³ It is our understanding that FSIS did not consider bird size or age when developing the proposed standard, nor is bird age or size mentioned in the Notice. We believe this omission significantly erodes the scientific support for the proposed *Campylobacter* standard and may negate any public health impacts the performance standard might have.

NCC believes that an effective performance standard must account for key criteria affecting *Campylobacter* rates, including bird size. NCC members' experience is that the difference between positive rates for large and small birds can be quite significant. By not taking this significant distinction into account, FSIS robs the performance standard of its usefulness as a comparative measure of establishment performance.

Fundamentally, performance standards are supposed to evaluate an establishment's performance relative to a baseline level reflective of how that and similar establishments were performing at a specific time. FSIS's stated goal is to encourage improvement relative to that baseline. For such a program to work, the baseline standard must be reasonably reflective of how similar establishments were performing – it has to allow for an apples-to-apples comparison. That need presumably is one reason why FSIS establishes separate performance standards for different species; it would make no sense to compare a chicken processing establishment's *Campylobacter* performance to a turkey processing establishment's performance. Likewise, because there is a significant difference between *Campylobacter* presence in younger and older birds, it makes little sense to compare the performance of an establishment processing 7-week-old birds to that of an establishment processing 10-week old birds. The establishment processing younger birds might improve its performance markedly and in keeping with FSIS's Health People 2020 goals, but because that establishment is processing birds that inherently are more likely to harbor *Campylobacter*, it might still find itself

² Han, Z., Pielsticker, C., et al. The Influence of Age on *Campylobacter jejuni* Infection in Chicken. Dev. Comp. Immunol. 2016, Sep;62:58-71; see also Northcutt, J.K., Berrang, M.E., et al. Effect of Broiler Age, Feed Withdrawal, and Transportation on Levels of Coliforms, *Campylobacter*, *Escherichia coli* and *Salmonella* on Carcasses Before and After Immersion Chilling. Poultry Science. 2003, Jan;82(1):169-73.

³ Cox, N.A., Richardson, L.J., et al. Recovery from *Campylobacter* and *Salmonella* Serovars from the Spleen, Liver and Gallbladder, and Ceca of Six- and Eight-Week-Old Commercial Broilers. 2007, J. Appl. Poultry. Res. 16:477–480.

above the performance standard, despite achieving the very type of reduction FSIS presumably wants.

As proposed, the performance standard would hold establishments that primarily process young birds to a more rigorous standard than other establishments, requiring them in effect to achieve more than a 50 percent reduction from a true young-bird average baseline rate to reach Category 1 status. As a result, young-bird establishments are not fairly rewarded for their efforts to reduce *Campylobacter*. This could lessen incentives to meet or exceed the performance standards. Moreover, it could result in arbitrary competitive disadvantages for young-bird establishments, which could remain classified as Category 2 or 3 establishments despite achieving significant reductions in *Campylobacter*. A single standard uniformly places small bird establishments at a competitive disadvantage by comparing them to establishments processing birds that have inherently lower levels of *Campylobacter*.

Instead, NCC recommends that FSIS evaluate baseline data based on bird age (bird size could provide a reasonable proxy for bird age for conventional broilers) and establish two separate performance standards—one for younger birds and one for older birds. This approach would ensure that establishments are evaluated fairly and would provide a more accurate measure of *Campylobacter* control.

NCC Requests Additional Information Regarding Data Used to Calculate the Performance Standards

The Notice provides a relatively succinct explanation of the sampling results and analysis used to develop the proposed performance standard. To better understand how the proposed standard was developed, NCC requests more details about the testing used to compute the standard, including information about the number and type of establishments where sampling occurred, how many samples were collected, bird age or size for the samples, sampling frequency, and date ranges, on an establishment-blinded basis. This information is important for understanding the proposed standard.

NCC Suggests FSIS Consider the Potential for an Enumerative Standard

NCC understands that the required infectious dose for *Campylobacter* is high (800–10⁶ ingested organisms are needed to produce illness in 10%–50% of persons).⁴ Because the threshold dose required for infection is high, NCC recommends that FSIS evaluate the potential for determining an enumerative standard. An enumerative standard targeting threshold levels of *Campylobacter* known to cause illness would allow for quantitative assessments that can further inform efficient, science-based decisions that effectively target public health at a meaningful way.

Implementation Recommendations

Unified Effective Date for All Campylobacter Performance Standards

We understand FSIS intends to also propose and request comments on revised pathogen reduction performance standards for *Campylobacter* in young chicken and turkey carcasses and in raw chicken parts. For administrative ease, NCC recommends that FSIS establish a uniform effective date for all *Campylobacter* performance standards in poultry establishments, keyed to a reasonable

⁴ Acheson, D., Allos, B.M. *Campylobacter jejuni* Infections: Update on Emerging Issues and Trends. Clinical Infectious Diseases, Volume 32, Issue 8, 15 April 2001, Pages 1201–1206.

period of time after the last *Campylobacter* performance standard is issued. FSIS could continue to collect samples, but establishments would not be formally categorized until after this effective date.

A unified effective date would greatly assist industry working to conform to the standards, especially for establishments that have more than one product subject to a *Campylobacter* performance standard. A uniform effective date will ensure an orderly transition; avoid confusion related to multiple effective dates for different products, and streamline implementation by field staff. It would also provide opportunity to work out any sampling implementation issues before formally evaluating establishments. A uniform effective date would also help provide a more complete picture of an establishment's *Campylobacter* control. For example, if an establishment were to fall slightly above the *Campylobacter* performance standard for comminuted product (thus falling in Category 3), it could be informative to know that the establishment is Category 1 for the other *Campylobacter* standards, as this could significantly affect what actions the establishment might consider taking in response. A uniform effective date would ensure that establishments and FSIS can look at a complete set of performance standards information when making decisions.

NCC recommends that the uniform effective date be set a reasonable period following the issuance of the last *Campylobacter* performance standard. It would be premature to speculate on what date to set given that the other *Campylobacter* performance standards have not even been proposed, much less finalized. But generally, this implementation period should be informed by FSIS and industry experience with the *Campylobacter* comminuted performance standard and with the *Salmonella* standards, and it should allow establishments a reasonable opportunity to evaluate their likely categorization, implement changes to their processes in response, and let those changes have a reasonable opportunity to be reflected in their categorization. Based on our industry's experience with the *Salmonella* performance standards, we anticipate the uniform effective date should be set for at least two years after the final *Campylobacter* performance standard is issued.

Although NCC believes that a uniform compliance date will lead to a much more orderly implementation of the *Campylobacter* performance standards, should FSIS determine that one is not practical, NCC would recommend that establishments not be formally categorized under the comminuted standard until at least two years after the finalized comminuted standard is published in the *Federal Register*. This time would be necessary to work out implementation issues and to provide establishments an opportunity to evaluate their own performance and make any needed changes to their processes.

Category Calculations Should be Based on Samples Collected After the Performance Standard Is Finalized

The purpose of the performance standards is to evaluate an establishment's performance relative to the standard established by FSIS. Therefore, it is not appropriate to use for that evaluation samples collected before the final performance standard is announced because those samples do not reflect performance influenced by the performance standard. Simply put, establishments would not know what standard to aim for and would not know whether they should be taking steps to change their performance.

Accordingly, when the Agency begins evaluating establishments under the final performance standard(s), NCC requests FSIS reset all establishments' moving windows so that the first sample in each moving window was collected after the final standards were announced and became effective. (If FSIS were to adopt our recommendation of a uniform compliance date set at least two years after publication of the last of the *Campylobacter* performance standards, this would largely be a moot issue.) Resetting the moving windows ensures that establishments are evaluated based on data collected after they knew what performance standard to target. Use of historical data would

inevitably place some establishments in inaccurate categories not truly reflective of their current performance.

FSIS Should Issue the Updated Campylobacter Compliance Guideline Prior to Finalizing the Campylobacter Performance Standards

In 2015, FSIS published its most recent Draft Compliance Guideline for Controlling *Salmonella* and *Campylobacter* in Raw Poultry.⁵ In 2019, FSIS indicated it was in the process of updating the compliance guide, with the expectation the Agency was going to develop two separate guidelines – one for *Salmonella* and one for *Campylobacter*. NCC has provided extensive comments on the guideline and believes that separate guidelines would be most effective.

It would be inappropriate to issue a final performance standard before providing guidance on effective *Campylobacter* controls. Therefore, NCC urges FSIS to complete and issue the updated *Campylobacter* Compliance Guideline before finalizing the *Campylobacter* performance standards.

NCC Discourages Posting Establishment-Specific Information

FSIS states in the Notice that it will announce its timing for publicly posting establishment-specific *Campylobacter* information at the same time FSIS finalizes the *Campylobacter* standard for comminuted chicken.⁶ NCC discourages posting establishment-specific information and does not believe that doing so makes a meaningful impact on public health. However, should FSIS decide to publicly release establishment-specific *Campylobacter* performance standards category information, NCC strongly urges FSIS to (1) not post establishment-specific information until at least one year following the uniform effective date, and (2) evaluate before posting whether performance standard sampling has been conducted properly across establishments and whether current categorizations industry-wide are fairly reflective of real-world contemporaneous establishment performance. If FSIS does not use a uniform effective date, we would still recommend waiting until one year after the effective date of the last *Campylobacter* standard to publish so that the public is provided a full picture of an establishment's *Campylobacter* performance, rather than seeing information on a piecemeal basis.

Experience with the updated *Salmonella* performance standards has shown that it can take a significant length of time to work out sampling and other implementation issues and that it can also take long periods of time for an establishment's moving window to accurately reflect changes made to the establishment's food safety system. Therefore, while NCC continues to question the public health benefit of posting establishment-specific performance standards information, if this information is posted, it will be critical to make sure it is fair and accurate first.

Clarification that Mechanically Separated Chicken is Not Covered

NCC does not believe that the data collected or public health considerations warrant applying the proposed performance standards to mechanically separate chicken or turkey. Mechanically separated chicken is sold to commercial users for cooking in inspected establishments, and a performance standard for mechanically separated chicken will not provide meaningful health benefits. NCC requests that the Agency clarify that the standard applies to ground chicken and turkey products only and that it does not apply to mechanically separated chicken or turkey.

⁵ DRAFT FSIS Compliance Guideline For Controlling *Salmonella* and *Campylobacter* in Raw Poultry, Dec. 2015.

⁶ 84 Fed. Reg. 38209.

FSIS Should Apply the S-1 Adjusted Percent Positive Calculation Used for Salmonella to Campylobacter Performance Standard Calculations

Under the *Salmonella* performance standards, FSIS interprets results within a moving window comprising fewer than 52 samples (i.e., 10 to 51) by establishing a number of positive samples(s) such that $(s-1)/n < p \leq s/n$, where p is the maximum percent positive that would meet the performance standards and n is the number of samples in the moving window.⁷ In essence, if a sample set has fewer than 52 samples, FSIS drops one positive result when computing the percent positive rate for that establishment. While NCC continues to have concerns about the appropriateness of using only 52 (or fewer) samples to categorize an establishment, this approach provides some flexibility to account for variations in sampling frequencies and the inherent challenges of smaller sample sizes.

For consistency with calculations under the *Salmonella* performance standards, NCC recommends that the Agency confirm it will continue to use the s-1 adjusted percent positive for the *Campylobacter* performance standards. Moreover, for establishments where 9 or less samples are collected, the window should not be categorized.

Potential Enforcement Issues

FSIS Should Continue to Reiterate that Performance Standards Are Not Enforceable Regulations

Ever since the *Supreme Beef* case invalidated binding performance standards (which were later formally repealed), the fundamental premise behind the chicken performance standards has been that they are nonbinding tools used to help evaluate an establishment's overall performance against an industry average baseline. Although this framework is well established, NCC believes that it continues to be important for FSIS to reiterate that the performance standards are nonbinding, both in internal communications to field staff and in external communications to stakeholders and the general public. Effectively communicating this framework can avoid significant confusion at the plant level and with the general public, especially given the amount of information that FSIS now releases publicly. NCC encourages FSIS to continue emphasizing to Inspection Program Personnel that enforcement action may not be taken on the basis of an establishment's failure to meet a performance standard and to incorporate into public communications an explanation that the performance standards are not binding regulations and are but one of many pieces of information that can be used to evaluate an establishment's process control.

Guidance on How to Prioritize Performance Standards

As FSIS develops more performance standards for additional pathogen/product combinations, the likelihood increases that establishments will find themselves in Category 1 or 2 for some or most pathogen/product combinations, but in Category 3 for another. While NCC members strive to control *Salmonella* and *Campylobacter* for all products they produce, it is possible that some pathogen/product combinations may have a greater public health impact than others, and those should be prioritized. And in any event, an establishment understandably may be wary about changing interventions that are effectively controlling *Salmonella* and *Campylobacter* for most of the products they produce.

⁷ See, e.g., 81 Fed. Reg. 7285, 7286 (Feb. 11, 2016); see also FSIS Presentation: FSIS Salmonella Categorization Process for Raw Chicken Parts and Comminuted Poultry Products, <https://www.fsis.usda.gov/wps/wcm/connect/f059169f-5cb3-4ae5-9388-7de79b9fa217/Salmonella-Categorization-Webinar061318.pdf?MOD=AJPERES>.

This issue is exacerbated by the fact that interventions are not universally effective for both *Salmonella* and *Campylobacter*. Indeed, experience has shown that some interventions that work for *Salmonella* do not work (or do not work as well) for *Campylobacter*, and vice versa. The organisms have different ideal growth conditions, and in theory an intervention or condition that is effective in reducing one organism could be conducive for another. Given these realities, NCC is very concerned about the possibility of a see-saw effect, where an establishment is pressured to make changes to its process to address performance for one pathogen/product combination and begins to perform worse for another pathogen/product combination due to the change.

NCC urges FSIS to tailor its policy, establishment evaluations, and instructions to field staff to avoid this type of see-saw effect. It would be particularly helpful to establishments for FSIS to clearly explain in guidance how it intends to weigh performance under the different performance standards when evaluating establishment performance so that establishments may prioritize appropriately. Two helpful considerations may be the relative volume of different types of products subject to different performance standards and the types of end uses and users for which product is intended.

Clarification is Needed Around the Role of PHREs and FSAs, and HACCP Plan Re-Assessments

Similarly to the concerns indicated above, NCC requests guidance from the Agency on how FSIS will approach evaluating establishments that fall into differing Categories for *Salmonella* and *Campylobacter*. For example, NCC does not believe it would be appropriate for an establishment to automatically receive a Public Health Risk Evaluation (PHRE) or Food Safety Assessment (FSA) if Category 3 for *Campylobacter* if the same establishment is in Category 1 or Category 2 for *Salmonella* for whole birds or parts because the overall food safety control program should be considered, not just one measure. PHREs and FSAs are more appropriately used when there are trends in noncompliance or public health regulations, recalls or outbreaks, or production of adulterated product that poses a public health risk. Categorization based on *Campylobacter* results alone should not be enough to trigger a PHRE, especially in the case where overall control is demonstrated. Likewise, it would not be appropriate to automatically require a reassessment of Hazard Analysis and Critical Control Point (HACCP) plans based solely on *Campylobacter* performance standards, as changes could negatively impact *Salmonella* control.

Conclusion

NCC appreciates the opportunity to provide comment on the performance standards for *Campylobacter*. Please feel free to contact us with any questions regarding the above comments. Thank you for your consideration.

Respectfully submitted,



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