

SAFE FOOD COALITION

1620 I Street, NW, Suite 200, Washington, DC 20006 202-939-1010

August 27, 2018

The Honorable George “Sonny” Perdue III
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

RE: Protecting consumers from *Campylobacter* in chicken

Dear Secretary Perdue:

The undersigned members of the Safe Food Coalition write to encourage you to take swift action to protect consumers from poultry contaminated with *Campylobacter*. In 2017, public health authorities documented more illness from *Campylobacter* than from any other foodborne pathogen. Yet recently, we learned that a change in the Food Safety Inspection Service’s (FSIS) sampling methodology, designed to better detect *Salmonella* in verification testing of poultry carcasses and parts, has had the unintended effect of significantly reducing the sensitivity of the agency’s *Campylobacter* testing. This change exacerbated the already low sensitivity of the agency’s “direct plating” *Campylobacter* testing, a quality that led many of our groups to recommend against adopting the procedure when FSIS proposed new *Campylobacter* performance standards in 2015. FSIS officials have assured us that they intend to address this problem by revising the testing methodology and developing new performance standards, and they have indicated that the agency will suspend existing testing against *Campylobacter* performance standards in the interim. We applaud the commitment to developing new standards, however, we question the agency’s decision to suspend testing in the interim, particularly if it means consumers would endure a prolonged period without a system in place to identify and mitigate excessive levels of *Campylobacter* contamination.

We therefore urge you to take immediate action to:

- Announce a firm deadline—ideally within six months—by which FSIS will develop and implement effective, enrichment-based testing and performance standards for *Campylobacter*.
- Leave in place existing testing and *Campylobacter* performance standards unless the new standards can be implemented within 6 months. These standards are particularly important for comminuted chicken, which has not been affected by the changes in sampling methodology and for which fully one-third of processing plants are “failing” the current standard.

- Consider interim sampling measures—in particular taking separate samples for *Salmonella* and *Campylobacter* tests with appropriate buffered peptone water (BPW) solutions—to ensure that the current tests for poultry parts and carcasses are meaningful.
- Immediately begin publishing plants’ *Campylobacter* compliance status on the FSIS website.

FSIS has a critical role to play in protecting consumers from *Campylobacter*. Most *Campylobacter* infections originate with the handling and consumption of raw poultry. The bacterium sickens an estimated 1.3 million people every year, with many patients developing life-threatening bloodstream infections, long-term consequences including irritable bowel syndrome and arthritis, or even paralysis. Yet the cases are rarely part of a recognized outbreak.¹ As a result, food producers associated with these infections often remain unaware, and unaccountable. Without effective agency action, the problem could get worse. In 2017, not only did *Campylobacter* cause more documented illnesses than any other foodborne pathogen, the incidence of infections from *Campylobacter* rose 10%, as compared to 2014-2016.²

These numbers underscore the challenge facing FSIS in reaching its stated goal to “reduce illness from *Campylobacter* by about 33 percent.”³ The agency announced that objective on January 26, 2015, when it proposed new pathogen reduction performance standards for *Salmonella* and *Campylobacter* bacteria in poultry.⁴ In the proposal, FSIS explained that it conducted baseline surveys in 2012 to estimate the percent of various poultry products that tested positive for *Campylobacter*.⁵ It then developed performance standards that it projected would achieve illness reductions consistent with the Healthy People 2020 goals.

FSIS explained in its proposal that it developed the new performance standards for *Campylobacter* in comminuted poultry using a “direct plating” laboratory method of analysis on relatively small samples, but that in the upcoming fiscal year, the agency would be “concurrently analyzing” some larger samples “using an enrichment method of analysis.” That analysis would “allow FSIS to determine whether the pathogen reduction performance standards for *Campylobacter* in NRTE

¹ Centers for Disease Control and Prevention, *Campylobacter* (Campylobacteriosis), <https://www.cdc.gov/campylobacter/faq.html> (last visited Aug. 27, 2018).

² Marder, MPH EP, Griffin PM, Cieslak PR, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006–2017. *MMWR Morb Mortal Wkly Rep* 2018;67:324–328. DOI: <http://dx.doi.org/10.15585/mmwr.mm6711a3>

³ Food Safety and Inspection Service. “Changes to the Salmonella and Campylobacter Verification Testing Program: Proposed Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Related Agency Verification Procedures and Other Changes to Agency Sampling,” 80 *Fed. Reg.* 3940, 3942 (Jan. 26, 2015), available at: <https://www.federalregister.gov/documents/2015/01/26/2015-01323/changes-to-the-salmonella-and-campylobacter-verification-testing-program-proposed-performance> [hereinafter “proposed performance standards”]

⁴ See *id.*

⁵ See *id.* at 3941 citing FSIS. Nationwide Microbiological Baseline Data Collection Programs: Raw Chicken Parts Baseline Survey (Jan. 2012), http://www.fsis.usda.gov/wps/wcm/connect/a9837fc8-0109-4041-bd0c-729924a79201/Baseline_Data_Raw_Chicken_Parts.pdf?MOD=AJPERES

[not-ready-to-eat] comminuted chicken and turkey should be revised from the above proposed standards to standards based on an enrichment method.”⁶

Commenting on the proposed standards, several consumer advocacy groups requested that FSIS base its *Campylobacter* performance standards on results from tests using the more sensitive enrichment-based testing methods, instead of direct plating.⁷ FSIS acknowledged that its analysis of the two testing methods revealed that direct plating failed to identify some 75-80% of the samples flagged as *Campylobacter*-positive by enrichment testing. Nevertheless, the agency declined to define the standard against an enrichment-based test. According to the Federal Register notice finalizing the new standards:

“FSIS developed the pathogen reduction performance standards for *Campylobacter* using a direct plating laboratory method of analysis with a 1 mL test portion. Therefore, FSIS will proceed with assessing establishment performance relative to those standards based on the 1 mL portion size.”⁸

FSIS further announced in that final notice that it would begin assessing whether establishments met the new pathogen reduction performance standards on May 11, 2016.

On July 1, 2016, however, FSIS adopted the change in sampling methodology previously referenced. Specifically, inspectors began using a new neutralizing buffered peptone water (nBPW) to reduce the effect of potential carryover of antimicrobial interventions in carcass and parts testing.⁹ The change came on the heels of USDA researchers discovering that carryover from the antimicrobials that poultry plants spray on their products “may create false negative results” in *Salmonella* testing.¹⁰

⁶ *Id.* at 3944.

⁷ See, e.g. Comments of Consumers Union on FSIS Proposed Performance Standards, Docket No. FSIS-2014-0023, (May 26, 2015), https://consumersunion.org/wp-content/uploads/2015/06/Salm.Campy_Std_poultry.FSIS_5.26.15.pdf (recommending that performance standard be based on enrichment because it is “the most sensitive test.”); Comments of Consumers Union on U.S. Department of Agriculture Food Safety Inspection Service’s Proposed Rule: Discontinuation of the Qualitative (30 mL) *Campylobacter* Analysis for Young Chickens. Docket No. FSIS-2013-0037, <http://www.regulations.gov/#!documentDetail;D=FSIS-2013-0037-0002> (predicting that reliance on the direct plate method alone “will give suboptimal detection rates and the false impression that process controls are adequate when they may not be.”). Comments of The Pew Charitable Trusts, FSIS Proposed Performance Standards, Docket No. FSIS-2014-0023 (May 21, 2015) (recommending “switching to the enrichment-based method immediately” because it is “more sensitive,” “has already been validated,” and “the routine use of the non-enrichment based method would not provide any measurable benefits over the enrichment-based method.”).

⁸ FSIS. “New Performance Standards for Salmonella and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule,” 81 *Fed. Reg.* 7285 (Feb. 11, 2016), available at: <https://www.federalregister.gov/d/2016-02586/p-110> [hereinafter “Final Performance Standards”]

⁹ FSIS. Notice 41-16 “New Neutralizing Buffered Peptone Water to Replace Current Buffered Peptone Water for Poultry Verification Sampling.” (June 8, 2016), <https://www.fsis.usda.gov/wps/wcm/connect/2cb982e0-625c-483f-9f50-6f24bc660f33/41-16.pdf?MOD=AJPERES> (“This notice provides instructions to inspection program personnel (IPP) on use of the new neutralizing buffer for verification sampling of young chicken and turkey carcasses and chicken parts starting July 1, 2016.”).

¹⁰ See Press release of Consumer Federation of America. “New Department of Agriculture Research Indicates Antimicrobials Conceal Salmonella.” (May 17, 2016), https://consumerfed.org/press_release/new-department-of-agriculture-research-indicates-antimicrobials-conceal-salmonella/

But while the nBPW helped to improve the sensitivity of *Salmonella* testing, FSIS now reports that it “adversely impacts *Campylobacter* recovery,” resulting in lower detection rates due to “false negative” testing results.¹¹ In response, the agency has suggested it will suspend all testing using the direct plating method, and propose revised *Campylobacter* performance standards based on the enrichment testing method in a Federal Register notice at a date uncertain.¹²

Protecting Consumers

We support the expeditious development of new *Campylobacter* performance standards that incorporate a more sensitive, enrichment method of testing. Consumer groups requested that the enrichment method be used during the initial rulemaking, and its benefits have only been further highlighted by the agency’s more recent data. Indeed, in a recent presentation to stakeholders, the agency presented analysis, based on thousands of test results, that leaves no question that the direct plating method creates an unacceptable number of “false negatives.”¹³ Direct plating tests of 2000 chicken carcasses, for example, identified positives in just 1% of samples, while enrichment revealed that at least 17% were actually contaminated. The results for direct plating of chicken parts and comminuted chicken were similar, detecting 2% versus 16% and 3% versus 11%, respectively. To ensure that FSIS adopts more effective standards and verification testing in a timely fashion, we urge you to establish an aggressive timetable for achieving the needed performance standard and testing revisions.

In the meantime, we question the need for suspending the existing performance standards and verification testing, despite their flaws. While FSIS has indicated that a new standard can be established relatively swiftly, the agency has not set a specific timeline for doing so.¹⁴ In addition, the current *Campylobacter* standard relies on a 52-week moving window approach requiring data collection over the course of a year in order to categorize an establishment. If the new standard relies on a similar 52-week window, this will add an additional year during which FSIS would not be categorizing establishments or reporting out the results of *Campylobacter* verification testing to the public.

Unfortunately, the current performance standards are not superfluous. Fully one-third (7 out of 21) of plants producing comminuted chicken are “failing” to meet current *Campylobacter* standards, according to FSIS aggregate data.¹⁵ A greater proportion of plants are meeting or exceeding the standards for parts and carcasses, perhaps because of the nBPW’s impact on testing of those products. Even so, FSIS data indicates that some 30 out of 223 plants were either category 2 or 3 for parts testing for *Campylobacter* and 8 out of 191 plants were category 2 or 3 for the carcass testing in the

¹¹ FSIS Presentation to Consumer Stakeholders. “Revising *Campylobacter* Testing Using Enrichment.” Aug. 16, 2018.

¹² *Id.*

¹³ *Id.* at 5 (indicating that direct plating testing resulted in *Campylobacter*-positive results for 1% of 2000 chicken carcass samples, while enrichment resulted in 17%. For 1800 samples of chicken parts, the results were 2% and 16%, respectively.

¹⁴ Ingrid Mezo. “USDA to release new *Campylobacter* standards soon, top officials say.” *Food Chemical News*, (Aug. 20, 2018), <https://iegpolicy.agribusinessintelligence.informa.com/PL217383/USDA-to-release-new-Campylobacter-standards-soon-top-officials-say>

¹⁵ FSIS. “Aggregate Salmonella & *Campylobacter* Categorization of Raw Chicken Parts, NRTE Comminuted Poultry, Young Chicken Carcass and Young Turkey Carcass Establishments Using Moving Windows: Reporting period May 7, 2017 to July 28, 2018,” available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program/aggregate-data> (last visited Aug. 24, 2018).

period May 7, 2017 to July 28, 2018. Clearly, FSIS has detected high rates of *Campylobacter* at many establishments even using tests with low sensitivity. It is vital that this testing continue to allow FSIS to continue working towards its goal of reducing *Campylobacter* contamination rates in poultry, and in turn reducing foodborne illness. Suspending verification testing would remove an important incentive for these plants to invest in better food safety controls.

Rather than suspend testing, we encourage the agency to consider interim means to improve the accuracy of the direct plating testing on parts and carcasses as the agency works to develop a new performance standard. This could include collecting separate samples for *Campylobacter* and *Salmonella* testing, and using alternative buffering solutions for each, in order to avoid the negative impact of the nBPW on *Campylobacter* detection.

We also urge you to put an end to the agency's indefinite moratorium on web-posting *Campylobacter* category data. FSIS announced these new performance standards some two-and-a-half years ago. In that Federal Register notice, the agency committed to begin publicizing "*Salmonella* and *Campylobacter* category status based on sample results from May 2015 . . . to the present," as early as May 11, 2016.¹⁶ FSIS continues to post individual plants' *Salmonella* category status, but not establishment-specific data on *Campylobacter* contamination. As FSIS made clear in proposing these standards, "the Agency's policy of web-posting establishments' process control performance has stimulated improvement in industry performance."¹⁷ Nothing in the agency's Federal Register notice suggests that this rationale does not apply to plants' performance in controlling *Campylobacter*, nor are we aware of any reason why it would not. The current test results, despite their limitations, should guide buyers and the public that value food safety, and help the market to operate more efficiently in creating incentives for higher quality, safer products.

We would appreciate the opportunity to meet with you and your staff to discuss these requests.

Sincerely,

Center for Foodborne Illness Research & Prevention

Center for Science in the Public Interest

Consumer Federation of America

Consumers Union

Food & Water Watch

National Consumers League

Stop Foodborne Illness

The Pew Charitable Trusts

¹⁶ FSIS. Final Performance Standards, 80 *Fed. Reg.* 7288.

¹⁷ FSIS. Proposed Performance Standards, 80 *Fed. Reg.* 3947-48.