September 10, 2021

Sandra Eskin
Deputy Under Secretary for Food Safety
1400 Independence Ave. S.W.
Washington, D.C. 20250

RE: Comments on the KPI Pre-decisional Draft

Dear Deputy Under Secretary Eskin,

The Center for Science in the Public Interest, the Consumer Federation of America, Consumer Reports, and Stop Foodborne Illness thank you for providing the opportunity to comment on the pre-decisional draft of the pathogen reduction Key Performance Indicator (KPI). The agency is proposing to better track the *Salmonella* serotypes on poultry after slaughter that are most associated with human illnesses and measure changes to these serotypes' prevalence on poultry products over time.

We are encouraged that the United States Department of Agriculture Food Safety and Inspection Service (FSIS) is taking steps to look more closely at the poultry food safety system. The U.S. failed to make progress towards the Healthy People 2010 and 2020 *Salmonella* foodborne illness rate reduction goals, indicating that the current FSIS system is not working to adequately protect public health.[1,2,3] If the agency aims to achieve the Healthy People 2030 targets, it must take a new approach.

There is a broad stakeholder and scientific evidence consensus that some types of *Salmonella* are more detrimental to public health than others and that regulatory change is needed to assure that resources are appropriately prioritized. The undersigned groups and victims of foodborne illness presented the evidence of this consensus in January to FSIS in a petition asking the agency to revamp its poultry food safety regulations and "…create modernized, enforceable, finished product standards for *Salmonella* types of greatest public health concern..."[4] In July, leading food safety scientists published an op-ed in *The Hill* asking for poultry regulation updates.[5] This month, leading poultry industry members, food safety advocates, and scientists requested a meeting with Secretary Vilsack to discuss needed poultry food safety reforms that would include standards that are enforceable and "…flexible enough to adapt to emerging evidence and the latest science," which should include identifying and prioritizing dangerous serotypes.[6]

FSIS's proposal to begin monitoring the most important serotypes for public health is a step in the right direction. Creating a system to monitor these priority serotypes and to assess the impact that FSIS regulations and industry changes have on their prevalence will better track public health protection.

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[1] Healthy People 2020 Objective FS-1.4: Reduce Infections Caused by Salmonella Species Transmitted Commonly Through Food. U.S. Department of Health and Human Services. Updated August 27, 2021. Accessed September 10, 2021. https://www.healthypeople.gov/2020/topics-objectives/topic/food-safety/objectives

[2] Healthy People 2030 Objective FS-04: Reduce infections caused by Salmonella. U.S. Department of Health and Human Services. Accessed September 10, 2021. https://health.gov/healthypeople/objectives-and-data/browse-objectives/foodborne-illness/reduce-infections-caused-salmonella-fs-04

[3] National Center for Health Statistics. Healthy People 2010 Final Review. Hyattsville, MD. 2012. https://www.cdc.gov/nchs/data/hpdata2010/hp2010_final_review.pdf

[4] Petition to Establish Enforceable Standards Targeting Salmonella Types of Greatest Public Health Concern while Reducing all Salmonella and Campylobacter in Poultry, and to Require Supply Chain Controls. January 25, 2021. https://downloads.regulations.gov/FSIS-2021-0003-0001/content.pdf

[5] Hedberg C, Morris JG, Wiedmann M. Unhealthy Diet? Food Safety Regulations Need Updating. *The Hill.* July 15,2021. Accessed September 10, 2021. https://thehill.com/opinion/healthcare/563160-scientists-call-for-changes-to-food-safety-regulation-in-poultry?rl=1

[6] Letter to Thomas J. Vilsack: Poultry Food Safety Improvements. September 2, 2021. https://cspinet.org/sites/default/files/attachment/Vilsack%20Poultry%20Meeting%20Request%20Letter_0.pdf

While we applaud the efforts to set reduction targets based on the proposed KPI, we encourage the agency to be more ambitious in its approach and to ensure that the KPI and the target reductions are calibrated towards helping achieve the best public health success.

To that end, we have comments on the following key areas:

1. Reduction Targets

Reduction targets that FSIS sets can inform regulatory strategies that will drive the needed reductions in *Salmonella* illnesses in people. It is therefore critical that the targets in the KPI proposal be public health oriented and aligned with the Healthy People 2030 goal. FSIS did this in the past when the agency considered the reductions in poultry needed to meet the Healthy People 2020 goals in developing the performance standards for *Salmonella* and *Campylobacter* in not-ready-to-eat comminuted chicken and turkey products and raw chicken parts.[7]

The proposal, however, has reduction targets for the priority serotypes in *Salmonella* verification samples of only a 1% change from baseline for FY 2022 and 2023, and 2% for FY 2024-2026. According to the proposal, these serotypes commonly associated with human illness are only estimated to be 4.53% of the total number of *Salmonella* verification samples. That will equate to a total reduction of less than 0.36%, or 7.9% of 4.53%, in 5 years. FSIS did not specify how these targets were decided upon and how they will effectively contribute to achieving the Healthy People 2030 goal of reducing illnesses by 25%.[8]

Moreover, prior cases indicate that poultry industry efforts can substantially reduce the prevalence of specific serotypes. *Salmonella* Heidelberg and Typhimurium illness rates per 100,000 people in FoodNet Fast decreased 93% and 72% from 1996 to 2019.[9] This decrease was in part due to actions by the poultry industry specifically targeting these serotypes, including sourcing Heidelberg-free flocks, vaccinations, and interventions on chicken parts at processing.[10] We petitioned for needed FSIS regulatory modernization for poultry food safety based in part on this potential for substantial reductions. The agency should consider closely this potential as it looks to improve poultry food safety. The drastic decrease in illnesses indicates that more substantial decreases in *Salmonella* than those targets in the draft KPI are possible, assuming that the illness rates are correlated to verification sample rates.

Failure to achieve illness reduction targets over the past decade has proven that the status quo is not working when it comes to poultry safety. In developing targets for the coming decade, FSIS must be more ambitious, and think not about what is readily achievable under the current, failed regulatory environment, but what can and should be achieved with new regulatory standards that are aligned with public health goals. We know that substantial reduction effects are possible when industry is motivated to target specific serotypes, and that regulations have the potential to provide that motivation.

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[7] 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. February 2, 2016. https://www.federalregister.gov/documents/2016/02/11/2016-02586/new-performance-standards-for-salmonella-and-campylobacter-in-not-ready-to-eat-comminuted-chicken

[8] Healthy People 2030 Objective FS-04: Reduce infections caused by Salmonella. U.S. Department of Health and Human Services. Accessed September 10, 2021. https://health.gov/healthypeople/objectives-and-data/browse-objectives/foodborne-illness/reduce-infections-caused-salmonella-fs-04

[9] Tauxe R. Public Health Challenge of Salmonellosis in the 21st Century. Presentation at: Salmonella: State of the Science; September 22, 2020; virtual.https://www.fsis.usda.gov/sites/default/files/media_file/2020-12/salmonella-public-meeting-presentation-09222020.pdf

[10] Ibid.

We therefore ask that the agency set its goals higher. Specifically, we urge the agency to use achieving the Healthy People 2030 *Salmonella* illness reduction goal as an intermediate success point, and work backwards from that target to determine what reductions in priority serotypes are needed to achieve it.

2. Explicitly Connecting Poultry *Salmonella* Reductions to Public Health Measures

The primary goal of programs that aim to reduce *Salmonella* in poultry is reducing illnesses in people. Thus, the top indicator of the success of a *Salmonella* reduction program is a measured reduction in human illnesses. As previously mentioned, helping to achieve the Healthy People 2030's *Salmonella* illness reduction goal should be the initial target for FSIS.

The proposed KPI lacks a method to explicitly measure human illnesses over time as they relate to poultry products. It only includes monitoring reductions of the priority serotypes in poultry verification samples, but not explicitly reporting changes in human illness levels potentially due to changes in these serotypes in poultry. In addition, the draft proposes redetermining the priority serotypes every year for the baseline and monitoring the prevalence changes in poultry samples only as an aggregate count of the priority serotypes and not by individual serotype. This method may obscure identifying illness reduction trends and regulatory and industry measures that may have been most effective if they were serotype-specific. While the aggregate count is an important indicator, individual serotype counts should also be reported, understanding the potential limitations of analyzing smaller datasets.

FoodNet Fast data, which FSIS proposes to use to determine serotypes that should be included in the baseline, includes *Salmonella* serotypes for all culture-confirmed samples and could be used to make a more explicit public health connection.[11] While there are limitations in directly connecting FSIS *Salmonella* verification data with FoodNet Fast data, that should not stop FSIS from proposing a manner to best do this or utilize other datasets. FSIS should also explore setting baselines and targets in the public health data as well as in the poultry verification sample data.

3. The Baseline Denominator

The draft has the total number of poultry verification samples analyzed as the denominator for the baseline calculation of the priority serotype prevalence. Thus, the baseline will account for two types of qualitative *Salmonella* reduction: reduction in the total number of *Salmonella* positives and reduction in the serotypes most associated with human illness. For example, a 1% reduction in *Salmonella* total may be evenly distributed across serotypes. Thus, a 1% change in this baseline may not reflect targeted reductions in the priority serotypes that are most damaging to public health.

For the intended trend analysis, the primary number of interest may be the proportion of positive Salmonella samples that are serotypes commonly associated with human illness. This baseline calculation would help account for targeted reductions in priority serotypes separately from reductions in *Salmonella* overall, which we support FSIS moving away from prioritizing with this KPI.

For public health policy purposes, both baselines may be relevant. Both should be reported by FSIS, and potentially reduction targets should be set for each.

[11] FoodNet Fast: Pathogen Surveillance. Updated June 19,2020. Accessed September 10, 2021. https://wwwn.cdc.gov/foodnetfast/

4. Measuring the quantity of *Salmonella* on poultry products

The current KPI proposal focuses on measuring reductions in the percent of samples positive for serotypes of *Salmonella* commonly associated with human illness but does include a proposal to take into account enumerating the amount of *Salmonella* present on products and reducing this as well. Because the potential for infection increases with dose, assessing the amount of *Salmonella* present on products is an important indicator of risk.[12] We therefore encourage FSIS to explore how to develop a means to quantify the amount of *Salmonella* on products and develop a KPI for this quantification, in addition to measuring the prevalence of the priority serotypes.

5. Motivation for Industry Change

While developing a KPI is an important part of revamping the poultry food safety system, it is only a measurement tool. Alone, a KPI does not provide motivation for stakeholders to work towards meeting *Salmonella* reduction targets. More concrete changes are needed, including creating enforceable *Salmonella* standards that will introduce more accountability in the system.

Thank you for reviewing our comments. We look forward to working with the agency in the future on poultry food safety system changes.

Sincerely,

Mitzi D. Baum
Chief Executive Officer
Stop Foodborne Illness

Thomas Gremillion
Director of Food Policy
Consumer Federation of America

James Kincheloe
Food Safety Campaign Manager
Center for Science in the Public Interest

Brian Ronholm
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Consumer Reports

[12] Akil L, Ahmad HA. Quantitative Risk Assessment Model of Human Salmonellosis Resulting from Consumption of Broiler Chicken. Diseases. 2019;7(1):19. Published 2019 Feb 7. doi:10.3390/diseases7010019