September 27, 2024

Dr. Emilio Esteban
Under Secretary for Food Safety
U.S. Department of Agriculture
1400 Independence Ave SW
Washington, DC 20250

Re: Poultry Safety Rulemaking (Docket No. FSIS-2023-0028)

Dear Dr. Esteban,

Stop Foodborne Illness (STOP), Consumer Reports, the Consumer Federation of America, and the Institute for Food Safety and Nutrition Security at The George Washington University Milken Institute School of Public Health are writing to explain why we joined in the Poultry Safety Coalition's recent request for an extension of the comment period on USDA's *Salmonella* in poultry rulemaking. We urge you to grant a six month extension, and we outline here what we hope can be accomplished with that additional time.

First, however, we want to applaud and express sincere appreciation for this FSIS rulemaking initiative. It breaks critically important new ground by proposing the first legally enforceable finished product standards to limit the presence of dangerous *Salmonella* in poultry. This is a common sense but long overdue reform. You, Secretary Vilsack, Deputy Under Secretary Eskin, and the FSIS team deserve much credit for this breakthrough in food safety policy at USDA. Properly constructed, enforceable product standards will make a big difference for consumers and public health.

We joined in requesting an extension of the comment period because, as outlined below, we are concerned that the proposed rule is not sufficiently comprehensive and may by itself foreclose important reforms that we believe USDA should consider for inclusion in the final rule. Additional time is required for USDA to give notice to stakeholders regarding these alternatives and to solicit written comment and genuine public dialogue to produce the best possible rule.

Overview of Concerns

Control of *Salmonella* spp.

We support setting rigorous standards for certain serotypes of *Salmonella*, but we are concerned that the proposed rule lacks any regulatory standard for *Salmonella* spp. We agree that the current unenforceable *Salmonella* performance standards are obsolete, but we do not believe the solution is to dispense with all regulatory accountability for preventing contamination with *Salmonella* serotypes other than the ones subject to serotype-specific standards.

Rather, we believe an enforceable, quantitative *Salmonella* spp. standard that complements the serotype-specific standards is essential to fulfilling USDA's regulatory and public health

responsibility to hold poultry processors accountable for doing everything they reasonably can to reduce *Salmonella* illnesses.

The presence of a quantitative *Salmonella* spp. standard would incentivize companies to maintain comprehensive programs to broadly prevent *Salmonella* contamination in their operations. We know that illnesses are caused by serotypes other than the ones USDA proposes to target. A *Salmonella* spp. standard would help prevent them.

We are thus concerned that by targeting only certain types of *Salmonella* the proposed rule will not do enough to address dangerous contamination. Companies would be incentivized to vaccinate for the targeted serotypes and diminish their investment in the sanitary poultry production and processing programs needed to minimize dangerous forms of *Salmonella* contamination more broadly. This could be a step backward from the status quo.

We believe the right answer is a combination of a feasible quantitative standard for *Salmonella* spp. and the 1 cfu/g standard USDA proposed for targeted serotypes.

We believe that an enforceable *Salmonella* spp. standard set at 10 cfu/g (the level of detection of the quantitative PCR technology) is feasible, as evidenced by the data reported in Table 2 of the FSIS risk assessment document. For example, FSIS reports that 3.08% of chicken carcasses test positive for *Salmonella* spp., but only 1% of the positive samples are contaminated at a level of 10 cfu/g or more.

This means that well less than one-tenth of 1% of chicken carcasses are exceeding the 10 cfu/g level. This is a sign of progress in controlling contamination. It is also a demonstration of what is achievable under current good manufacturing practices and sanitation programs. We believe USDA's responsibility to consumers includes verification that current best practices for safely processing poultry are being consistently followed and holding companies accountable when they fail. A quantitative *Salmonella* spp. standard of 10 cfu/g would be a reasonable and feasible benchmark for success. We believe that products that don't meet such a benchmark should not receive the USDA mark of inspection.

The Poultry Products Inspection Act (PPIA) provides that the mark of inspection will be placed on products that FSIS finds <u>not</u> to be adulterated. The PPIA deems poultry adulterated if it is prepared or packed "under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." USDA should find through this rulemaking that poultry products found not to meet a reasonable benchmark for implementation of current GMPs with respect to *Salmonella* spp. are adulterated and/or do not satisfy the "not adulterated" standard for grant of the mark of inspection.

<u>Proposed Serotypes</u>

The selection of three serotypes (Enteritidis, Typhimurium, and I 4,[5],12:i) seems to have been driven largely by a risk assessment that we recognize is required by OMB. Such risk assessments can inform FSIS risk management decision making, such as identification of particularly concerning serotypes, but epidemiological data are also key for those purposes.

We believe the risk assessment FSIS used to select the three serotypes deserves more technical scrutiny and public comment because it incorporates a relatively novel virulence analysis and does not fully consider epidemiological data showing that comparable numbers of illnesses are caused by other serotypes not included in the FSIS proposal. Some 32 serotypes of *Salmonella* have been implicated in poultry-related outbreaks. We agree that USDA should target a subset of these for the serotype-specific element of its regulatory standards, but we do not understand why USDA chose the three it did and why it settled on only three when the Centers for Disease Control and Prevention (CDC) has also argued for including Infantis. We also note that Infantis, Blockley, Branderup, and Heidelberg were all associated with more chicken-related outbreak illnesses in the 2017-2021 period than I 4,[5],12:i:-.[1]

For these reasons, we are concerned that FSIS proposed to target only three serotypes. We are wondering whether the decision to limit the number to three was influenced by the fact that current PCR technology can conveniently handle only three serotypes. If so, we question this as a public health basis for decision making when gene sequencing technologies are already available to simultaneously analyze for many more *Salmonella* serotypes. We also believe the microbiological analytical industry can be relied on to innovate rapidly in response to emerging public health regulatory standards.

In addition to technical analyses, we consider it essential that USDA take full account of its broader statutory and public health responsibilities to provide incentives and accountability for processors to do everything they reasonably can to make poultry safe. Meeting that public health responsibility is what consumers reasonably expect of USDA.

Opportunity for Further Public Comment and Discussion

Control of *Salmonella* spp.

In its risk assessment, FSIS discussed the possibility of quantitative *Salmonella* spp. standards, but it did not invite comment on such standards as regulatory options. We request that FSIS take advantage of the extended comment period to clarify that a final rule may include a quantitative *Salmonella* spp. standard and invite stakeholders to comment on both the need for and the structuring of such a standard. FSIS will then have the option of adopting such a standard as a "logical outgrowth" of this rulemaking process if it chooses to do so.[2]

We ask FSIS to solicit comment on the following questions (or similar ones) related to quantitative *Salmonella* spp. limits:

1. What is the public health and regulatory rationale for a quantitative *Salmonella* spp. standard to complement serotype-specific standards?

[1] Katherine E. Marshall, et al, "An Approach to Describe *Salmonella* Serotypes of Concern for Outbreaks: Using Burden and Trajectory of Outbreak-related Illnesses Associated with Meat and Poultry," Journal of Food Protection Volume 87, Issue 9, September 2024 (Table 1).

[2] *See Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 160 (2007).

2. What is the appropriate quantitative level for such a standard?

3. What is the feasibility of meeting the standard?

4. What means exist for verifying compliance with the standard?

We also urge FSIS to convene one or more public stakeholder dialogue meetings that include FSIS leaders and staff, consumer and industry representatives, and independent experts to provide opportunity for genuine exchange among FSIS and its stakeholders on the issues related to a *Salmonella* spp. standard. Such meetings should be open to the public in conformance with APA requirements and be designed both to inform FSIS and build understanding among stakeholders on the key issues and possibilities for resolving them.

For an issue of such impact on consumers and on which USDA is breaking important new ground, we think USDA should provide a setting in which consumer voices can be heard alongside other industry and other stakeholders.

We think a six-month extension from November 7 provides reasonable time for FSIS to further consider the issue of *Salmonella* spp. standards and gain essential public input.

Proposed Serotypes

During the six-month extension, FSIS should provide further explanation and rationale for the three serotypes it selected and hold a public meeting to consider modifying the proposed serotypes, posing the following questions (or similar ones) for comment:

1. What alternative approaches should FSIS consider in selecting serotypes of public health concern to include in the rule?

2. Are there additional technological and public health considerations that should be weighed in determining the number of serotypes to include in the rule?

3. Should *Salmonella* Infantis or other serotypes be included in the rule?

4. FSIS has proposed updating the targeted serotypes every 3-5 years or more often as needed.

    a. Should there be a more frequent and routine review of the targeted serotypes?

    b. What changes in the production and processing environment should prompt the agency to consider updates to the standards?

    c. What public health data and analysis should be sought and applied to update the standards?

Questions and comments about the proposed serotypes could be managed partially in writing, but we also see a need for genuine discussion and dialogue in a public meeting dedicated to this issue.

Thank you for consideration of our requests.

Sincerely,

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