



Nourishing Today  
Sustaining Tomorrow

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Denise Eblen, PhD  
Administrator  
Food Safety and Inspection Service  
United States Department of Agriculture  
Room 331-E Whitten Building  
1400 Independence Avenue SW  
Washington, DC 20250-0251

Docket Clerk  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
1400 Independence Avenue SW  
Mailstop 3782  
Room 6065  
Washington, DC 20250-3700

**Re – *Salmonella Framework for Raw Poultry Products* – Proposed Rule [Docket No. FSIS-2023-0028]; 89 Fed. Reg. 64678; (August 7, 2024).**

Dear Dr. Eblen:

The Meat Institute is the nation’s oldest and largest trade association representing packers and processors of the majority of U.S. beef, pork, lamb, veal, turkey, chicken, and processed meat products. The Meat Institute provides regulatory, scientific, legislative, public relations, and educational services to the meat and poultry packing and processing industry. Together, Meat Institute members produce the majority of U.S. beef, pork, lamb, and poultry products in the United States.

Consumer health and safety are the driving forces for our members in the production of meat and poultry products. *Salmonella* has been, and will continue to be, a high priority for the meat and poultry industry. Contrary to statements made by industry critics, packers and processors are not “asleep at the wheel,” but alert and focused on *Salmonella*; implementing intervention strategies and dedicating time and resources to identify new methods for control. The Meat Institute commends the Food Safety and Inspection Service (FSIS or the agency) and the Office of Food Safety for the continued efforts and openness to address *Salmonella*. The agency’s transparency in engaging all stakeholders early and throughout the process is a refreshing approach to inform policy. This open, on-going dialogue with diverse perspectives should be an example to all federal agencies on how to adopt meaningful policies with the best chance of achieving the intended effect. The Meat

Institute appreciates the opportunity to participate in public meetings and provide comments and looks forward to continued dialogue.

## **EXECUTIVE SUMMARY**

The Meat Institute appreciates the agency's commitment to addressing *Salmonella* in raw poultry products and the opportunity to comment on the proposed framework. While the proposal reflects well-intentioned efforts to enhance public health, significant concerns remain regarding its practicality, burdensome impacts, scientific validity, and alignment with established regulatory principles.

**Component Three:** The proposed determination to classify certain *Salmonella* levels and serotypes as adulterants is flawed. It lacks sufficient legal and scientific support and overlooks viable alternatives like performance standards, which have proven effective in reducing *Salmonella* prevalence in the past. The Meat Institute urges FSIS to prioritize data collection to inform product specific risk-based performance standards over final product standards. Existing case law and regulatory precedent do not support the classification of *Salmonella* as an adulterant in raw poultry products.

**Testing Accuracy and Timeline** – Testing methods for rapid *Salmonella* quantification testing methods, and specifically the one selected by FSIS, are inaccurate at low levels and unsuitable for determining compliance with a 10 CFU/g standard. Additionally, the impractical and aspirational timeline of at least 2-14 days for test results jeopardizes product shelf life, increasing food waste and costs. Accelerated validation and implementation of faster and more reliable testing methods are essential.

**Test and Hold** – The defined lot sizes are unworkable and unsupported. Such impractical lot sizes would create operational and logistical challenges with food security impacts from limited availability and increased costs. Clear guidance on manageable lotting practices would be urgently needed if the proposed final products standards were finalized. The agency grossly underestimates the burden of holding and diverting product that would be created with the proposed approach.

**Component Two:** The Meat Institute supports the integration of Statistical Process Control (SPC) monitoring as a critical tool for ensuring process consistency and verifying food safety measures. However, the proposed SPC requirements are overly prescriptive, lack clarity, and deviate from standard, accepted SPC principles, potentially hindering their effectiveness. FSIS should adopt a more flexible approach to SPC monitoring, emphasizing clear, practical guidance over regulation. The agency should refrain from requiring

standardized reporting or overly prescriptive corrective actions, which could stifle innovation and continuous improvement.

The Meat Institute supports a science-based, risk-driven, and achievable regulatory approach that emphasizes prevention, continuous improvement, and collaboration. FSIS should reconsider portions of the framework that could impose undue burdens on industry without delivering meaningful public health benefits and the Meat Institute stands ready to collaborate on developing effective, outcome-based, balanced policies to enhance food safety.

### COMPONENT THREE

#### *Proposed Final Product Standards*

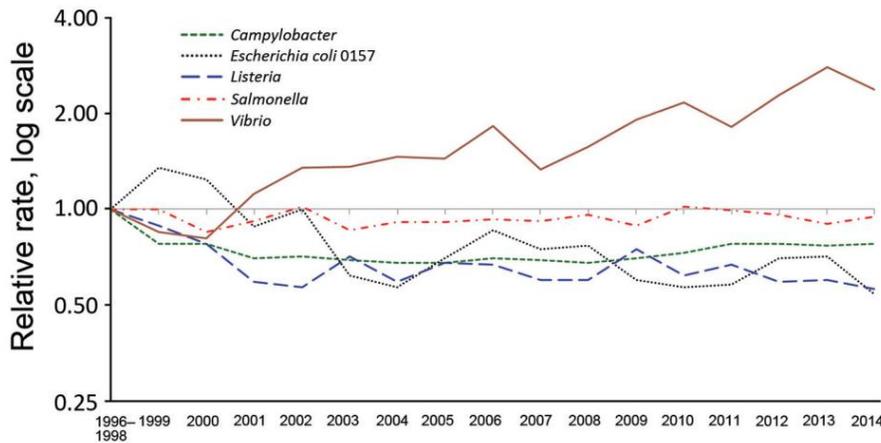
The Meat Institute supports an outcome-based and data-driven approach grounded in sound science and informed by a robust risk assessment. Unfortunately, the proposed determination that would establish final product standards misses the mark. Considering the legal vulnerabilities, risk assessment flaws, and viable alternative approaches, the agency should conduct a *Salmonella* level baseline and implement a performance standard instead of adopting the proposed final product standards. A performance standard approach would incentivize establishments to conduct *Salmonella* quantification testing to evaluate the establishment's status.

#### **The agency should re-examine the proposed final product standards and instead implement a risk-based performance standard approach.**

Microbiological testing of products can provide a minimal level of control at the end of a production process and is best used for verification. The industry cannot test its way to safe products. The safety of all product cannot be guaranteed, because only a small portion of product is tested. Before setting effective finished product testing standards, the agency needs to give ample time for attribution information to be collected and analyzed to determine if the current approach is effective. For example, when the agency declared *E. coli* O157:H7 (O157) an adulterant in 1994, a reduction in O157 illnesses was not seen until 1999 and 2000.<sup>1</sup> Similarly, here, not enough time may have occurred to determine whether current approaches are effective at reducing *Salmonella* related illnesses.

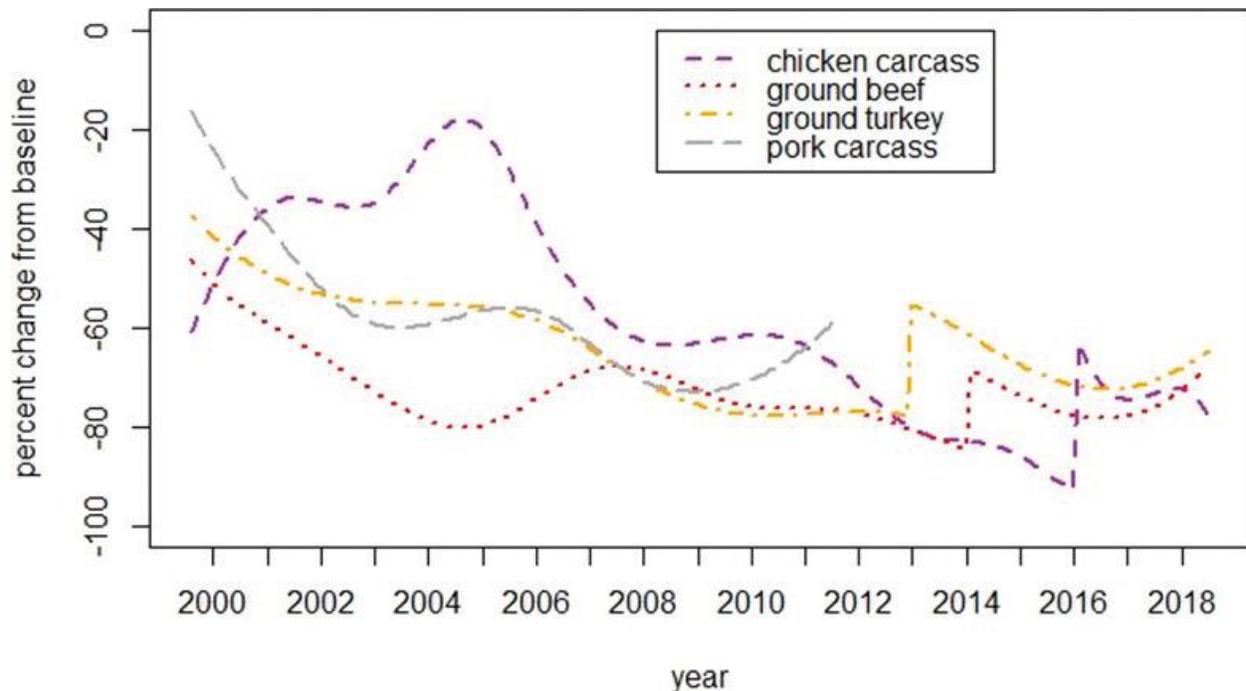
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<sup>1</sup> Henao, O. L., Jones, T. F., Vugia, D. J., Griffin, P. M., & Foodborne Diseases Active Surveillance Network (FoodNet) Workgroup (2015). Foodborne Diseases Active Surveillance Network-2 Decades of Achievements, 1996-2015. *Emerging infectious diseases*, 21(9), 1529–1536. <https://doi.org/10.3201/eid2109.150581>



**Figure 2.** Relative rates of culture-confirmed infections with *Campylobacter*, *Escherichia coli* O157, *Listeria*, *Salmonella*, *Vibrio*, and *Yersinia* compared with 1996–1998 rates, Foodborne Diseases Active Surveillance Network, United States, 1996–2014. The position of each line indicates the relative change in the incidence of that pathogen compared with 1996–1998. The actual incidences of these infections cannot be determined from this graph. Data for 2014 are preliminary.

Though many have argued that the previous *Salmonella* prevalence-based performance standards were ineffective, that is simply inaccurate. The previous performance standards achieved the intended goal: reducing the prevalence of *Salmonella* in poultry products. Peer reviewed data from FSIS show consistent reductions in *Salmonella* prevalence.<sup>2</sup> The only increase in prevalence followed changes in the laboratory methodology.



Unfortunately, the significant reduction in *Salmonella* prevalence did not seemingly lead to the desired public health outcome, but that does not mean that adapted

<sup>2</sup> Williams, M. S., Ebel, E. D., Saini, G., & Nyirabahizi, E. (2020). Changes in *Salmonella* contamination in meat and poultry since the introduction of the pathogen reduction and hazard analysis and critical control point rule. *Journal of food protection*, 83(10), 1707-1717.

performance standards could not. If the agency believes that reducing *Salmonella* level in poultry products will lead to reduced illnesses, then performance standards are a tried-and-true mechanism to achieve that goal. Performance standards can also be adjusted over time to drive continuous improvement.

There is also a misconception that performance standards are not “actionable.” Although a court ruled that FSIS does not have the authority to shut down processing facilities solely for failing performance standards, suspension is not the only enforcement tool in the toolbox.<sup>3</sup> In fact, the agency has historically used other tools to encourage establishments to reduce *Salmonella* prevalence and achieve a better performance standard category. Establishments in Category 3 status on performance standards are subject to increased oversight, which may include a Food Safety Assessment (FSA) by Enforcement, Investigations, Analysis, Officers (EIAO) assigned by the District Office (DO) and possible follow-up sampling. An EIAO can conduct a thorough assessment of the establishment food safety programs, especially as they relate to the control of *Salmonella*. EIAOs can assess sanitation, dressing practices, interventions, Good Manufacturing Practices (GMPs), facilities, sampling programs, *etc.* It is unlikely for an FSA to end with zero enforcement actions taken. At a minimum, FSAs typically result in noncompliance records (NRs) and further actions such as a Notice of Intended Enforcement or Notice of Suspension, where applicable. All those enforcement actions require documented corrective actions from the establishment, with escalating oversight responsibilities from FSIS depending on the action taken.

### **Poultry is not beef, and *Salmonella* is not *Escherichia coli* O157:H7.**

The agency must understand the significant differences between Shiga toxin-producing *Escherichia coli* (STEC)<sup>4</sup> in beef and *Salmonella* in poultry when considering its approach to regulatory oversight. The proposed framework repeatedly references lessons learned in the agency’s approach to STEC in beef, while seemingly ignoring fundamental differences between the species and pathogens.

1. Cattle are large, ruminant mammals. Chicken and turkeys are relatively small non-ruminant birds. The basic biology and pathophysiology of the species are significantly different.
2. Cattle and poultry slaughtering and processing are vastly different. To name but a few differences:
  - a. Cattle are slaughtered at a rate measured in carcasses per hour where poultry is much faster and measured per minute;

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<sup>3</sup> *Supreme Beef Processors, Inc. v. United States* (2001)

<sup>4</sup> STEC: Shiga toxin-producing *Escherichia coli* O157:H7 and serogroups O26, O45, O103, O111, O121, and O145

- b. Cattle carcasses are dehided to remove the hide where poultry carcasses are scalded to defeather the skin; and
  - c. Due to large carcass size, cattle carcasses are chilled in coolers and fabricated a day or more after slaughter. Poultry carcasses are chilled continuously from the slaughter line and move directly to processing within minutes.
3. Though cattle are carriers of STEC they do not get sick from STEC. It has long been shown that STEC reside on the exterior of the animal and in the gastrointestinal (GI) tract. Poultry can and do become sick from *Salmonella*, which led to the implementation of USDA's National Poultry Improvement Program. Even if birds do not become sick, they can carry *Salmonella* on the exterior of the bird, in the GI tract, **and** intrinsically in the bird. *Salmonella* is even transmissible to eggs and reside with the yolk, vitelline membrane, and albumen before the egg is even laid.
4. *Salmonella* and STEC are distinctive bacteria with diverse pathways that vary between and within cattle, swine, and poultry.

These fundamental differences, among others, may be described in more detail where relevant in the subsequent comments.

**Salmonella does not meet the statutory definition of an adulterant in raw poultry products.**

The Poultry Products Inspection Act (PPIA or Act) broadly defines a “poultry product” as

...any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof,...<sup>5</sup>

The definition of “adulterated” in the PPIA provides a poultry product is adulterated

...if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health.<sup>6</sup> (Emphasis added)

or

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<sup>5</sup> 21 U.S.C. 453(f).

<sup>6</sup> 21 U.S.C. 453(g)(1).

...is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;...<sup>7</sup>

This definition establishes different standards for whether a poultry product is adulterated, depending on whether the substance is “added.” If the substance is “added” the easier to satisfy “may render ... injurious to health” standard applies. Conversely, if the substance is not added, or what many consider naturally occurring, the more difficult to meet “does not ordinarily render it injurious to health” standard applies. It also includes a highly ambiguous and seemingly “catch all” standard for products that are “unsound, unhealthful, unwholesome, or otherwise unfit.”<sup>8</sup>

### ***Salmonella* is not an added substance in raw poultry products.**

The justifications used to support STEC as an adulterant in raw ground beef do not apply for *Salmonella* in poultry. For example, it is well known that *Salmonella* and other bacteria exist on the exterior surface of live animals. In cattle, the exterior of the animal (*i.e.* the hide) is removed. The agency determined that STEC on cattle carcasses was “added,” because it was transferred from the hide during the dehiding process. In poultry, it is not feasible to remove the exterior; because birds do not have hides, so the exterior is cleaned, but the skin remains on the carcass and is part of many poultry products, including those proposed to be covered by the final product standards (*i.e.* carcasses, parts, ground products). Any *Salmonella* remaining on the carcass after cleaning is, therefore, not added.

*Salmonella* can also be intrinsic to poultry products, because poultry products consist of more than muscle tissue, *e.g.* livers, skin, bone, *etc.* *Salmonella* can exist on the exterior of the animal, harbor in feather follicles, and travel from the gastrointestinal tract of poultry to the bloodstream, theoretically providing a pathway for *Salmonella* to be distributed throughout the bird.<sup>9</sup> Though the agency

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<sup>7</sup> 21 U.S.C. 4153(g)(3).

<sup>8</sup> *Id.*

<sup>9</sup> Rimet C-S, Maurer JJ, Pickler L, Stabler L, Johnson KK, Berghaus RD, Villegas AM, Lee M and França M (2019) *Salmonella* Harborage Sites in Infected Poultry That May Contribute to Contamination of Ground Meat. *Front. Sustain. Food Syst.* 3:2. doi: 10.3389/fsufs.2019.00002. Accessed here: <https://www.frontiersin.org/articles/10.3389/fsufs.2019.00002/full#h8>

Chappell, L., Kaiser, P., Barrow, P., Jones, M. A., Johnston, C., & Wigley, P. (2009). The immunobiology of avian systemic salmonellosis. *Veterinary immunology and immunopathology*, 128(1-3), 53-59.

Dunkley, K. D., Callaway, T. R., Chalova, V. I., McReynolds, J. L., Hume, M. E., Dunkley, C. S., ... & Ricke, S. C. (2009). Foodborne *Salmonella* ecology in the avian gastrointestinal tract. *Anaerobe*, 15(1 - 2), 26-35.

Mastroeni, P., & Grant, A. J. (2011). Spread of *Salmonella* enterica in the body during systemic infection: unravelling host and pathogen determinants. *Expert reviews in molecular medicine*, 13, e12. Lutful Kabir, S. M. (2010). Avian colibacillosis and salmonellosis: a closer look at epidemiology, pathogenesis, diagnosis, control and public health concerns. *International journal of environmental research and public health*, 7(1), 89-114.

tries to ignore the science that *Salmonella* can be intrinsic to the entire bird, there is agreement that *Salmonella* can naturally be found in the skin and bones.<sup>10</sup> Yet, the agency ignores the fact that poultry skin and bones are inherently part of poultry products that would be subject to the final product standard. The case law provides that to be “added” a substance must be artificially introduced by a person. For example, in *United States v. Anderson Seafoods, Inc.*, the court explained that the

distinction between added and not-added substances comes from the “adulterated food” provisions of the original Food, Drug, and Cosmetic Act of 1906. The legislative history shows that “added” meant attributable to acts of man, and “not-added” meant attributable to events of nature. (Emphasis added)<sup>11</sup>

The Supreme Court drew the same distinction in *United States v. Coca Cola*.<sup>12</sup> Construing the “added . . . ingredient” provisions of the 1906 Act, the Court said

Congress, we think, referred to ingredients artificially introduced; these are described as “added.” The addition might be made to a natural food product or to a compound . . . we think that it was the intention of Congress that the artificial introduction of ingredients of a poisonous or deleterious character which might render the article injurious to health should cause the prohibition of the statute to attach.<sup>13</sup>

Interestingly, commenters on the draft framework cited *United States v. Anderson Seafoods, Inc.*, stating that *Salmonella* is an added substance because some *Salmonella* has been introduced by human intervention.<sup>14</sup> These commenters claim that potential cross-contamination of *Salmonella*, which was present on the animal before it arrived at the poultry establishment, during processing is equivalent to human intervention in the same way that pollution leads to mercury in fish. This argument is misguided and wrong. Man-made pollution is not comparable to naturally occurring bacteria. FSIS justifiably rejected the notion that *Salmonella* is an added substance in response to the first and second iterations of a petition submitted by the Center for Science in the Public Interest (CSPI), which argued antibiotic-resistant (ABR) *Salmonella* was an added substance.<sup>15</sup> In denying the CSPI petition the agency concluded ABR *Salmonella* was not an “added substance” because it was not artificially added by humans. The agency should maintain its

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<sup>10</sup> 89 *Fed. Reg.* 64705 (August 7, 2024)

<sup>11</sup> 622 F.2d 157, 160 (5th Cir. 1980).

<sup>12</sup> 241 U.S. 265, 36 S.Ct. 573, 60 L.Ed. 995 (1915).

<sup>13</sup> *Id.*

<sup>14</sup> 89 *Fed. Reg.* 64704 (August 7, 2024)

<sup>15</sup> See [letter](#) from Carmen Rottenberg, Acting Deputy Under Secretary, Office of Food Safety, to Laura MacCleery, Director Regulatory Affairs, Center for Science in the Public Interest, February 7, 2018.

traditional and scientifically accurate interpretation that *Salmonella* is not an added substance.

***Salmonella* does not ordinarily render raw poultry products injurious to health.**

The mere presence of certain serovars or levels of *Salmonella* on poultry products does not ordinarily render it injurious to health. Though the agency attempts to address virulence (by way of serovar) and level in its flawed risk assessment, the agency fails to account for product risk, handling, preparation, and individual infectious dose based on host condition, which all play a role in pathogenicity. A simpler iteration of this concept is provided in *American Public Health Ass'n. v. Butz*, in which the court found the presence of *Salmonella* on not ready-to-eat meat and poultry does not render the product adulterated.<sup>16</sup>

The agency seems to argue against that court decision and claim the average consumer is incapable of properly preparing raw poultry products. The proposal cites studies that demonstrate consumers do not follow specific preparation practices such as using a thermometer at all or properly, washing hands at certain steps in preparation or properly, among other practices. The agency, however, misinterprets the Act and court precedent by implying that because consumers sometimes fail to properly prepare raw poultry products *Salmonella* would ordinarily render the products injurious to health or be otherwise unhealthful or unwholesome.

In *Texas Food Association v. Espy* the court found that the presence of *E. coli* O157:H7 in raw ground beef rendered the product adulterated, because not “proper” cooking but “thorough” cooking is needed to render the product safe. In other words, consumers believe that cooking raw ground beef to medium rare is “proper” cooking based on preference, regardless of industry and agency recommendations. Some consumers intentionally undercook ground beef, which is why STEC is considered an adulterant in raw ground beef, as the agency has stated: “what many consumers consider to be **ordinary** cooking of ground beef does not destroy these pathogens (emphasis added).”<sup>17</sup> The same is not true for raw poultry. Consumers do not intentionally undercook poultry, but nobody is perfect. Chefs do not prepare medium rare chicken patties or fillets. Consumers know that poultry must be properly cooked, and though accidents happen, **ordinary** cooking of poultry is thoroughly cooked, not medium rare. Proper cooking of poultry products will render the product safe, therefore, *Salmonella* does not ordinarily render raw poultry products injurious to health or otherwise make them unhealthful or unwholesome.

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<sup>16</sup> 511 F.2d 331, 334 (5th Cir. 1975).

<sup>17</sup> FSIS Response to Petition 20-21 *Petition for Interpretive Rule Related to Certain Salmonella Serotypes* submitted by Marler Clark LLP PS

*Salmonella* does not meet the statutory threshold of an adulterant in raw poultry products.

Also, the consumer studies cited should have focused on outcome-based measures rather than idealized practices. Many of the studies fail to demonstrate whether the consumers' failures to follow the idealized practices rendered the product unsafe. For example, some consumers did not use a thermometer or did not use one correctly. Did the product still reach the desired internal temperature of 165°F? One of the studies showed no statistical difference between consumers who did or did not use a thermometer in achieving an end point of 165°F. 75% of consumers who did not use a thermometer still reached an end point of 165°F.<sup>18</sup> Would that not be deemed ordinary? For those 25% whose product did not reach 165°F, what temperature did it reach and how long was the product at that temperature? Was that time and temperature combination adequate to achieve lethality for *Salmonella*? Though consumer education should continue to stress proper use of a thermometer to ensure product reached the desired internal temperature of 165°F for poultry, the agency's own guidance states that lethality is achieved at lower temperatures.<sup>19</sup> Further consumer studies should focus on outcome and better evaluate the efficacy of consumer practices observed.

### **The agency fails to support its shift in policy.**

The agency has thrice denied petitions requesting the declaration of *Salmonella* as an adulterant in raw products. The justifications for each denial are specific to the petitioner's request, but some themes include:

1. *Salmonella* is not an added substance;
2. *Salmonella* is not an adulterant, because ordinary cooking and preparation of raw products are generally sufficient to destroy the pathogen; and
3. The probability of illness from *Salmonella* is a complex equation with variables outside of serovar and level.

The proposal largely relies on the same case law and data the agency determined did not support granting previous petitions to declare *Salmonella* an adulterant and does not provide sufficient justification to overturn the agency's long-held position that *Salmonella* is not an adulterant in raw meat and poultry products. In a post *Chevron*<sup>20</sup> world, it would be unwise to finalize the proposed final product standard for raw poultry products. Also, as discussed in subsequent sections, the agency relies on limited testing technologies still being developed, and recognizes methods are likely to change. Finalizing the impractical final product standard as proposed

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<sup>18</sup> 89 *Fed. Reg.* 64699 (August 7, 2024)

<sup>19</sup> *FSIS Cooking Guideline for Meat and Poultry Products* (Revised Appendix A) 2021

<sup>20</sup> Reference to the *Loper Bright Enterprises v. Raimondo* (2024) that overruled the principle of *Chevron* deference established in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* (1984)

in the face of unknown and changing technology would be unreasonable, an error in judgment, and arbitrary and capricious under the Administrative Procedure Act.

**Current *Salmonella* quantification technology is inaccurate at the level in the proposed final product standard.**

Industry and consumers alike rely on FSIS test results to inform food safety and public health decisions. Therefore, the accuracy of results is critical not only for the industry and consumers but also for FSIS to maintain its scientific integrity and reputation as a public health agency. The rapid quantification technologies available on the market, and specifically the one chosen by FSIS, are examples of remarkable tools and advancements made by modern microbiologists to improve food safety and public health. Many in industry use these tests to evaluate processes, product risk, incoming supply, and intended use; inform disposition decisions; or conduct research. However, tools such as these newer rapid *Salmonella* quantification technologies are only useful when applied appropriately. It is not appropriate to use these technologies to test for a highly specific level of a pathogen to determine whether a product is adulterated.

The rapid *Salmonella* quantification method used by FSIS does not provide an actual colony forming unit (CFU), which is what is stated in the proposed framework. Instead, these tools use calibration curves and advanced algorithms to estimate the concentration of *Salmonella* in a sample and do not provide a true CFU, as nothing is grown on a plate. Using these technologies to determine a specific adulterant level, where a CFU is stated, is an inappropriate use because the test cannot determine if a sample has a specific CFU level and meets the requirements outlined in proposed adulterant standard. Rather than providing a specific CFU, these rapid *Salmonella* quantification technologies provide an estimated range of potential CFU's within a statistically determined margin of error.

More egregious than misusing this technology, the research community has evaluated the accuracy of these technologies and found they are often inaccurate when attempting to determine a specific amount of *Salmonella* in a sample, especially when it is estimated below 100 CFU/g or ml and even more so around 10 CFU/g or ml.<sup>21</sup> Studies have shown these technologies have both “false positive” and “false negative” results at a rate well over the “gold standard” of quantification methods, most probable number (MPN).<sup>22</sup> The method specifically adopted by FSIS may be one of the more accurate rapid quantification methods available but is still

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<sup>21</sup> Schmidt, J. W., Carlson, A., Bosilevac, J. M., Harhay, D., Arthur, T. M., Brown, T., ... & Vipham, J. L. (2024). Evaluation of Methods for Identifying Poultry Wing Rinses With *Salmonella* Concentrations Greater Than or Equal to 10 CFU/mL. *Journal of Food Protection*, 87(11), 100362.

<sup>22</sup> *Id.*

only “correct” 86.1% of the time.<sup>23</sup> That is not a high enough confidence rate to determine whether product meets an adulteration standard.

If the agency is going to make the biggest policy change since 1996 and declare raw poultry products adulterated if they contain certain serovars of *Salmonella* and *Salmonella* at or above 10 CFU/g or ml, the method must actually measure what FSIS proposed (a CFU) and be accurate, for the sake of public health and the agency’s own scientific credibility.

**The proposed framework is not estimated to make a meaningful public health impact.**

As previously stated, the Meat Institute supports an outcome-based and data-driven approach to *Salmonella* that is grounded in sound science and informed by a robust risk assessment. However, the proposal is not outcome-based because according to the agency’s risk assessment it is not expected to result in a meaningful public health improvement or achieve the Healthy People 2030 goals, even though that goal is the intent of the framework.<sup>24</sup> There are an estimated 125,115 chicken-associated and 42,669 turkey-associated foodborne Salmonellosis cases each year. The Agency’s goal is a 25% reduction in chicken and turkey associated Salmonellosis cases. FSIS’s approach would need to prevent 31,279 cases associated with chicken and 10,667 cases associated with turkey to meet that goal. The agency’s risk assessment estimates that the proposed framework would not come anywhere close and would achieve virtually no perceptible change in public health outcomes. Specifically, FSIS estimates that using the proposed 10 CFU/g or mL level in combination with at least one serotype of public health significance would only prevent 765 illnesses total, with 240 cases amounting to a 0.19% reduction for chicken and 525 cases amounting to a 0.19% reduction for turkey. Even taking a more aggressive approach of 10 CFU/g or mL level without selecting for serotype, the agency only estimates a reduction of 1,000 cases for chicken, a 0.80% reduction, and 2,100 for turkey, a 4.92% reduction.<sup>25</sup> Neither approach would move the needle on foodborne illnesses attributed to chicken and turkey consumption, much less overall Salmonellosis rates.<sup>26</sup>

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<sup>23</sup> Schmidt, J. W., Carlson, A., Bosilevac, J. M., Harhay, D., Arthur, T. M., Brown, T., ... & Vipham, J. L. (2024). Evaluation of Methods for Identifying Poultry Wing Rinses With *Salmonella* Concentrations Greater Than or Equal to 10 CFU/mL. *Journal of Food Protection*, 87(11), 100362.

<sup>24</sup> 89 *Fed. Reg.* 64683 (August 7, 2024)

<sup>25</sup> 89 *Fed. Reg.* 64739 (August 7, 2024), tbl.34. The first estimate is what FSIS defines as its “low” estimate for prevented illnesses, and the second is what FSIS defines as its “medium” estimate. FSIS’s “high” estimate is still vanishingly small, but it should not be considered because FSIS arrives at it by adding together the number of illnesses that its risk assessment suggested would be avoided for each chicken product category, even though the Agency specifically recognizes that because of the way the risk assessment was conducted, the numbers cannot be added in this manner.

<sup>26</sup> Given FSIS’s estimate of 1.3 million annual Salmonellosis cases, even under the more bullish scenario, the Proposed Framework would change annual total Salmonellosis cases by only 0.20%.

Further muddying the waters, the agency's estimates of annual illnesses prevented have extraordinarily wide credible intervals. The agency assessed different threshold levels from 0.03 CFU/g or mL to 100, broken down by commodity (chicken carcasses, parts, comminuted, and comminuted turkey). For example, for a threshold of 10 CFU/g for comminuted chicken, only around 1000 illnesses are expected to be prevented, but that estimate is not precise. The 95% credible interval for this estimate ranges from 400 to 19,000; meaning, the actual number of illnesses prevented could be as low as 400. The wide intervals around these estimates can likely be attributed to too few and inconsistent data, which supports that FSIS needs to conduct a quantified *Salmonella*. This baseline could easily be achieved by implementing this approach as a performance standard to gather more information to determine potential future approaches.

**The agency needs to model the actual proposed final product standards to ensure it is an effective public health approach.**

As previously discussed, the proposed adulterant standard is a combination of both level and serotype. This is similar to what the Meat Institute and other stakeholders have advocated for: a risk-based approach looking at a combination of level and virulence. However, if the agency is going to claim that the proposed final product standard will make “meaningful” advancements in public health and the Healthy People 2030 goals, the proposed approach must be modeled and demonstrate the expected public health benefit. Rather than FSIS doing its due diligence, the agency modeled selecting three serotypes and the 10 CFU/g or ml level separately. Meaning that, while the risk assessments were generally well designed and executed from a scientific and methodological perspective, the results do not reflect the potential public health benefit of the proposed final product standards. By modeling the segregation of product positive for the three serotypes in question and the segregation of product at or above 10 CFU/g or ml, the agency is likely inflating the estimated public health benefit from implementing the proposed adulterant definition. To add insult to injury, the over inflated estimated public health benefit is highly uncertain or at the worst minimal, as estimates have extraordinarily wide error margins. This radical proposed change, which may provide little to no public health benefit at a tremendous burden for industry must be reconsidered and resources should be dedicated to investigating more effective solutions.

**The proposed final product standards are overly burdensome with potential food security implications**

***The *Salmonella* testing timeline is wildly impractical.***

The proposed *Salmonella* final product standards have an extraordinarily impractical testing timeline, with questionably accurate results available 2-14 days after sampling, if not longer. Drawing from experience, various factors can cause

delays in test results, rendering the agency's estimated timeline more aspirational than realistic. Test method accuracy aside, in the best-case scenario establishments will have a result back within two days, if the sample is negative. While the agency may think this is reasonable, for many establishments it is anything but. Product will lose precious shelf-life days while being held pending sample results, disrupting the supply chain even when results are negative. Though shelf-life is variable by product and establishment, a good estimate for the shelf-life of tray-packed fresh poultry is 15 days. Many retailers have shelf-life expectations for their suppliers, such as requiring that products are received within five days of slaughter or with at least 10 days of shelf-life remaining. Based on this shelf-life estimate, even in the best-case scenario, which is more idealistic than realistic, a two day wait for sample results gives establishments only three days to get product on shelves. A more realistic timeline exacerbates the situation and minimizes the options for the product. Product without sufficient shelf life to meet customer requirements will need to be diverted, likely to rendering or disposal.

Further compounding the challenges, the timeline for results with the agency's chosen serotyping method is at least 14 days. Product would be out of shelf life and potentially spoiling in storage if establishments waited for serotyping results. The agency referenced that more rapid serotyping technologies may be selected by the agency in the future, but those methods must still be developed, vetted by researchers and industry, and officially selected and validated by FSIS. It is premature to designate specific serotypes in a final product standard when the only commercially available serotyping method takes an estimated 14 days to results. The testing methodology used by the agency must be substantially quicker. Additionally, although FSIS intends to exclude vaccine-strain positives from the final product standard, the product would likely be out of shelf-life before results are available, which may inadvertently disincentivize vaccine programs.

**The suggested lot sizes in the risk assessments and proposal are unrealistic and unsupported.**

The lot sizes proposed in the *Salmonella* framework are defined as one flock for carcasses and one day of production for both parts and comminuted products, unless an establishment can justify a smaller lot, which the agency has not provided guidance. While all establishments will likely struggle to support lotting practices, small establishments will be especially disadvantaged. In other words, the "ask" for many establishments is to hold everything produced in one day. In fact, depending how it is defined, a flock could represent a portion of an establishment's production for a day or span multiple days of production. A common industry definition for flock is a farm, which may have multiple barns and tens of thousands of birds that would take multiple days to process, which was not developed with the proposed framework in mind. These unworkable lot definitions encompass vast quantities of product, creating logistical challenges for test and hold programs, all hinging on the result of one sample.

The agency fails to support that testing a single sample from such a large lot accurately represents the contamination levels across the entire lot, undermining the reliability of results. It is unreasonable and scientifically unsupportable to assume that the rinsate of a single bird represents a lot that may consist of tens of thousands of birds, especially given that FSIS estimated high-volume establishment flock sizes range from 16,000 to 79,000 birds.<sup>27</sup> The agency must validate its sampling to ensure it is representative of the lot, which the agency defines as a flock or entire day of production potentially consisting of tens of thousands of pounds of product.<sup>28</sup>

Additionally, the framework provides no guidance or flexibility on reducing lot sizes to a more manageable scale. Smaller, more practical lot sizes could make test and hold programs more feasible and encourage industry testing, but the lack of direction from FSIS leaves the industry in a state of uncertainty and operational risk. The agency points to existing guidance on lotting practices, but that guidance is specific to STEC in raw beef and *Listeria* in RTE foods, neither of which are appropriate analogs to *Salmonella* in raw poultry. Clear guidance on acceptable lotting practices specific to *Salmonella* in raw poultry is essential for a final product standard to be workable.

**The proposal's test and hold burden is excessive, if not insurmountable.**

Few, if any, poultry establishments are currently capable of holding anywhere close to an entire day's production. Many facilities ship products within hours of live birds arriving at the establishment, with relatively no storage space for finished products. Some establishments are land-locked and unable to add storage capacity, which will force them to utilize outside storage at steep costs. Those with access to land to add storage capacity face a substantial capital expense. Even the alternative option of using refrigerated trailers for additional storage comes at a significant cost.<sup>29</sup>

If the agency moves forward with the proposed final product standard, establishments will need ample time and resources to implement test and hold programs. At a minimum, the agency must allow flexibility in establishment programs, such as allowing for tested product to move under hold with sufficient controls to an outside warehouse or further processor until test results are available. Unfortunately, most establishments will have to focus time and

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<sup>27</sup> Food Safety and Inspection Service. (2024). *Quantitative risk assessment for Salmonella in raw chicken and raw chicken products*. United States Department of Agriculture. Page 223

<sup>28</sup> Malone, T., Schaefer, K. A., & Thompson, J. (2025, January 2). *Economic analysis of FSIS Salmonella controls*. Prepared for the Meat Institute, National Chicken Council, and National Turkey Federation.

<sup>29</sup> *Id.*

resources on managing test and hold programs that could be better utilized on research and efforts to better understand and control *Salmonella*.

**The burden of compliance will likely come at a cost to consumers and jeopardize food security.**

Protein is essential for health and nutrition. Poultry is a staple in the American diet and often the protein of choice for many families because it is nutritious and affordable. If the proposal were finalized as written, millions of pounds of product every month would need to be held pending FSIS sample results. At a minimum, products will lose shelf life, increasing the amount of product wasted at the retail or consumer level, and at least some products and associated packaging will be diverted to rendering or landfill before reaching retailers. Availability and cost will be impacted,<sup>30</sup> which will be especially difficult for consumers when food prices are at an all-time high.

**The disposition options for products must be expanded and clear.**

The agency seems to only recognize one option for products that fail the proposed final product standards: fully cooked product. However, that is a limited option, at best. Few establishments are equipped to internally process raw and fully cooked poultry items and would have to find another establishment within a reasonable distance willing to buy the raw materials, given the limited market for fully cooked poultry products. Also, the raw product would need to be the right specification for the end product and many are not marketable as a fully cooked item, e.g. drumsticks. Especially true for chicken products, certain establishments are designed to slaughter and/or process only certain sizes of birds. Not all sizes are appropriate for all types of further processed products.

In reality, many poultry products would need to be diverted to rendering if not landfill. The option to divert products to rendering will be limited, based on the location of rendering sites and capacity. Not to mention, certain products like tray-packed or otherwise retail packaged poultry products will likely not be accepted by renderers. Generally, rendering systems are not designed to remove packaging and the labor cost of unpackaging the products negates the value. If it is possible to unpackage the product, then the packaging will still be diverted to landfill even if the product is able to be rendered. The landfill will be the only option in some scenarios, with its own complications, costs, and impacts.<sup>31</sup>

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<sup>30</sup> Malone, T., Schaefer, K. A., & Thompson, J. (2025, January 2). *Economic analysis of FSIS Salmonella controls*. Prepared for the Meat Institute, National Chicken Council, and National Turkey Federation.

<sup>31</sup> *Id.*

As the proposed final product standard is, in part, level based, the agency should consider validated processes outside fully cooked processing for products that do not meet the standard, such as high-pressure pasteurization and irradiation. These options are not applicable for all products and capacity is limited but, if establishments can provide sufficient support that such interventions would result in a reduction that ensures product met the final product standard, the agency should accept these alternatives. Industry and FSIS field personnel will need guidance on the agency's expectations of support for these alternatives. Will the agency expect verification testing? If so, at what frequency? Will the receiving establishment need to provide a letter of guarantee back to the shipping establishment once the product is treated? Also, the agency should clarify its expectations for demonstrating control of product that does not meet the final product standard if shipped for further processing, treatment, rendering, or disposal.

### **FSIS must update its sample receiving criteria.**

Historically the agency has only evaluated industry based on prevalence-based criteria. A sample with multiple logs of bacteria and a sample with low levels of bacteria at the highly sensitive level of detection amount have the same result: positive. Now, for the first time, FSIS is proposing to evaluate a specific quantifiable level or amount of bacteria present. While this approach is designed to target higher risk product that contains more *Salmonella*, FSIS' sample handling criteria can negate this intention entirely. The scientific literature consistently supports that *Salmonella* can grow under a wide range of environmental conditions, including low temperatures. Based on the current FSIS sample discard criteria,<sup>32</sup> the agency only discards samples over 15°C (59°F). While *Salmonella* growth is significantly slower at and below 15°C compared to its optimal growth temperature, it still consistently grows.<sup>33</sup> *Salmonella* grows at temperatures below 15°C and is documented to grow as low as 5°C.<sup>34</sup> Using a conservative modeling scenario (starting point of 1 CFU and 0.5 g/dL of salt) within 48 hours at 10°C, the USDA Pathogen Modeling Program shows that *Salmonella* could grow more than one log. At 15°C the same program estimates growth between 1.80 logs and 6.18 logs with the average at 3.62 logs within 48 hours. When implementing any quantifiable metric, whether as a performance standard or a final product standard, it is imperative that FSIS adjust their sample handling procedures to require incoming samples be discarded at over 5°C. Procedures that allow samples to be accepted

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<sup>32</sup> MLG 1.03 Laboratory System Introduction, Method Performance Expectations, and Sample Handling for Microbiology

<sup>33</sup> Mackey, B. M., Roberts, T. A., Mansfield, J., & Farkas, G. (1980). Growth of *Salmonella* on chilled meat. *Epidemiology & Infection*, 85(1), 115-124.

<sup>34</sup> Matches, J. R., & Liston, J. (1968). Low temperature growth of *Salmonella*. *Journal of Food Science*, 33(6), 641-645.

Matches, J. R., & Liston, J. (1972). Effect of pH on low temperature growth of *Salmonella*. *Journal of Food Protection*, 35(1), 49-52.

and analyzed for *Salmonella* level over 5°C run the high likelihood of not being representative of the product that was sampled and unnecessarily failing the proposed final product standard.

**Downstream testing will cause significant disruptions.**

Testing poultry products downstream from the slaughter establishment presents significant challenges because *Salmonella* can grow during storage and transit. The same product that may have initially met the proposed final product standards could later fail the same standard a step or two further down the supply chain. Factors such as time, temperature, and handling conditions during transportation and distribution can influence bacterial growth, even if the product tested and passed the proposed standard at slaughter. Given that the agency intends to test at further processors, among other parties that may test product, FSIS should strongly consider how to appropriately assess product downstream that may have been subject to inadequate refrigeration or delays in shipping. Downstream testing may not accurately reflect the conditions at the originating establishment. Establishments should not be penalized for factors beyond their control.

FSIS cites a reduction in the number of recalls as a benefit to the proposal, but the reverse is the more likely scenario, especially given the low number of recalls for *Salmonella* in poultry in recent years. Establishing a final product standard will lead to increased testing by the agency and other parties. Positives from downstream testing will likely lead to recalls, as the product may no longer be under the producing establishment's control.

**Additional questions require clarification.**

1. If an establishment utilizes off-site interventions, such as high-pressure processing or irradiation, how will FSIS manage sampling those products? Ostensibly, the products should be sampled once all interventions are completed. Will the agency sample products after off-site interventions are applied?
2. How will the agency address sample results for multi-ingredient products? *Salmonella* is commonly associated with other food products, such as spices.
3. Has the agency considered that some raw poultry products are formulated with antimicrobials to inhibit bacterial growth, such as dried vinegar? FSIS should consider whether these products warrant different policy, such as the agency's *Listeria* approach.
4. What is the agency's expectation for documentation to demonstrate that products are intended for full lethality at a further processor to exempt those products from sampling?
5. If a supplying establishment and receiving establishment are sister establishments owned by the same company, will the agency consider testing

sampling at only one location? The current proposal would allow for the same product to be sampled at both locations.

## **COMPONENT TWO**

### ***Enhanced Establishment Process Control Monitoring***

Statistical process control is a widely adopted and trusted approach to verifying any process. Industry has long-utilized SPC and the Meat Institute supports such data-driven approaches. The agency is wise to focus on process control but should be careful not to take a narrow view. Though a safe harbor option for small establishments is welcome and needed, the most effective SPC programs are tailored to individual processes and a standardized SPC approach would unnecessarily limit individual establishments from considering new and innovative ways to assess process control. The agency assumes the proposed SPC requirements would have a limited impact on industry because there are existing regulations requiring microbial monitoring. However, the proposed regulations go far beyond the existing requirements, are overly prescriptive, and may inadvertently hinder continuous improvement.

### **The proposed regulations do not reflect true statistical process control and corrective action requirements are overly prescriptive.**

The proposed regulations and draft guidance are unclear and little to no clarification is provided in the preamble to the proposal. Some clarification was provided during the public meetings, but that feedback was inconsistent. It seems the agency's expectations are not aligned with normal application of SPC. The proposal outlines that microbial monitoring programs (MMPs) must incorporate at least three criteria: an expected microbial reduction between two arbitrary points; quantitative consistency for individual results and variation over time; and qualitative consistency of MMP compared with other monitoring results.

SPC is a method of analysis to monitor, control, and improve processes by identifying patterns and trends that may indicate deviations from normal operations. Only part one of these criteria is applicable to SPC: quantitative consistency over time. An SPC program based on measuring the reduction in microbial counts between two points in a process would be set up to evaluate the mean reduction of the process and a normal range of results outside that mean. All data will contain outliers and SPC is designed to help determine whether something is an isolated incident or a concerning trend. Unfortunately, the proposed regulations seemingly expect establishments to react to single instances outside of a predetermined range. True SPC evaluates trends, not single instances.

This concept is especially important when considering that the microbial SPC monitoring proposed is focused on log reductions of APC between two points. Not

all logs are created equal. A 3-log reduction when starting with 7 log CFU/g (a difference measured in millions of CFUs) is substantially different than a 3-log reduction when starting with 4 log CFU/g (a difference measured in thousands of CFUs). The microbial reduction potential of a process is also not necessarily a linear relationship. If one day an establishment's incoming load is 7 log CFU/g and the next day 4 log CFU/g, the same process may be able to reduce the 7 log CFU/g to 3.5 log CFU/g but only reduce the 4 log CFU/g to 3 log CFU/g. It may be more appropriate for establishments to design an SPC program that measures a percent reduction between two points instead of a log reduction.

The following regulations should simply read:

9 CFR 381.65(g)

- (3) Microbial Organism and Methods. Establishments must analyze monitoring samples for microbial organisms that are quantifiably detectable in their slaughter process and that will generate microbial monitoring data that is adequate to monitor their ability to maintain process control for enteric pathogens.
  - (i) The establishments' sample collection method must be appropriate for the product sampled, the microbial organism monitored, and the laboratory method used to analyze the samples.
  - (iii) The establishment's microbial sampling results must be generated by validated laboratory analyses and methods.
- (4) Microbial Monitoring Criteria. The establishment must use appropriate statistical methods to compare microbial monitoring data against predefined quantitative limits adequate to gauge its ability to maintain process control.
- (5) Corrective Actions. The establishment must implement written corrective actions when microbial monitoring results deviate from predefined quantitative limits.

Other aspects of the proposed regulations are confusing, overly prescriptive, and beyond the scope of SPC. For example, proposed regulation 381.65(g)(5)(ii) would require establishments to implement corrective actions when microbial SPC monitoring results differ from other monitoring results for the same process. This implies a correlation or causation relationship between two different monitoring programs that may not exist. SPC is not designed to be compared with data for other programs, though a prudent establishment will consider all monitoring when evaluating its food safety program. It makes no sense to expect corrective actions simply because two different monitoring programs had different results. Additionally, FSIS states in the proposal that process variability can be caused by chance or assignable causes yet the agency expects a corrective action and root cause assessment for a single result outside the normal range. The specific language requiring a root cause assessment is more prescriptive than the HACCP regulations and should be abandoned.

**SPC records should not be included in pre-shipment review.**

Pre-shipment review must be conducted prior to products entering commerce and is intended to review records that directly monitor food safety hazards. The agency has consistently conveyed through policy and guidance that the distinction between records required for pre-shipment review hinges on whether the results inform if products are adulterated. The agency's preferred indicator, APC, does not directly correlate to food safety or inform whether product is adulterated.<sup>35</sup> In many instances, pathogen-negative samples have high indicator organism counts and pathogen-positive samples have low indicator organism levels.<sup>36</sup> Research demonstrates relationships between indicator organisms and *Salmonella* in some areas of the establishment, while in others, it does not, and when there is a relationship, the strength of the correlation is usually low.<sup>37</sup> Instead, establishments use microbial SPC monitoring as a verification tool to inform the greater food safety program.

Also, at best, numerical results for APC are not available for two days after sampling and product is generally slotted to ship the same day it is produced. Establishments that need to ship samples for analysis might not get results for three or more days. Microbial monitoring for SPC is valuable, but it simply cannot be used to make real-time decisions, such as dispositioning product. It is not feasible or logical to include SPC records in a pre-shipment record review. The results do not indicate food safety and are not available for days after production. The agency must abandon this thought process and instead review microbial SPC monitoring during other verification activities, as has long been done for the existing process control verification sampling FSIS requires for all species.

**SPC data cannot and must not be compared between establishments.**

The Meat Institute is wary of the agency's attempt to standardize microbial SPC monitoring across establishments and require establishments to regularly submit their results. Again, the best SPC programs are unique to the establishment and thus generally not comparable between establishments. The central collection of establishment monitoring data implies comparisons that either the agency intends to do, or others might be tempted to do, if such data were made available. SPC is almost always done using indicator organism data, which is generally not comparable, because not all establishments use the same indicator and the limits for each establishment are variable.

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<sup>35</sup> 89 *Fed. Reg.* 64711 (in reference to "Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products" from the National Advisory Committee on Microbiological Criteria for Foods)

<sup>36</sup> Vargas, D. A., De Villena, J. F., Larios, V., Bueno López, R., Chávez-Velado, D. R., Casas, D. E., ... & Sanchez-Plata, M. X. (2023). Data-Mining Poultry Processing Bio-Mapping Counts of Pathogens and Indicator Organisms for Food Safety Management Decision Making. *Foods*, 12(4), 898.

<sup>37</sup> *Id.*

The agency has previously wisely adopted less prescriptive regulations around process control in poultry that allow establishments to choose an indicator organism and FSIS should continue that approach. Even if two establishments use the same indicator organism, SPC data is still difficult, if not impossible, to compare. For example, if two establishments use APC for an indicator and the incoming load for the first establishment is 7 log CFU/g and the second is 4 log CFU/g, and both achieve a 3-log reduction through their process, the end result is seemingly very different though the reduction was similar. Another example would be for the first establishment to have 5-log reduction and the second a 2-log. The end results may seem similar, but end results should not be evaluated without the context of the starting point. The agency's attempts to standardize process control data and collect establishment data is ill-advised, a waste of agency resources, and unlikely to yield more insights because there are simply too many variables. Requiring standardization of SPC may even negate the benefit of SPC for some establishments because a one size fits all approach rarely fits all.

Additionally, the agency would need to provide a secure portal and assurances of data integrity and security for establishments to regularly submit data. Would the data be accessible through Freedom of Information Act requests? If so, the data could easily be misunderstood by requestors. If not, what assurances can the agency provide that it will not be unintentionally released? The agency also assumes that uploading data into a system would be easy. Unfortunately, that is rarely the case. At a minimum it will require all establishments to consistently format the data for submission. Time and labor will be spent preparing and submitting the data rather than meaningful food safety tasks. The agency should not standardize and require establishments to regularly submit SPC data, given there is no public health benefit and local FSIS inspection personnel, who better understand the specific establishment's processes, have the authority to review this information regularly.

**Guidance on SPC is welcome and needed but must be clear.**

Guidance and support for establishments on how to implement and verify SPC programs is a logical use of agency time and resources that would benefit industry. Companies with resources and staff expertise can more easily utilize SPC. Other companies are limited to the "safe harbor" options in regulation (possibly without the expertise to gain insight from the information) or paying for outside consulting: neither is ideal. A more robust, yet still simple enough to implement, "safe harbor" for some establishments, along with guidance on how to build on that foundation, assess results, and reevaluate, could prove valuable. A guidance document is likely the correct vehicle, but the guidance provided with the proposal is unclear and does not reflect true SPC, as discussed regarding the regulations. Guidance documents are beneficial in that they can be updated relatively easily to incorporate new information and do not carry the "weight" of regulation; such that companies with

resources and expertise have the flexibility to adopt unique programs. The Meat Institute welcomes the opportunity to work with the agency and other industry trade associations to develop relevant guidance that will benefit the industry, specifically small and very small establishments.

## COMPONENT ONE

### *Preharvest Measures*

Preharvest food safety measures can be excellent tools as a part of the food safety continuum. That said, preharvest food safety tools are often inconsistent in their perceived benefit and are only effective within specific systems and scenarios. Logically thinking, less *Salmonella* walking into establishments should result in less *Salmonella* in final product, but while establishments would certainly welcome less pathogens on incoming animals, preharvest tools do not always deliver on what they promise. Producers can implement some preharvest food safety tools and lower pathogen levels on farm; however, stress during transport or interactions with other animals, can increase pathogens loads. More research is needed on the consistency and effectiveness of preharvest food safety tools on finished products. Again, while meat and poultry companies would welcome less *Salmonella* walking into their establishments, preharvest food safety measures must prove to be worthwhile investments for livestock producers and poultry growers that demonstrate lower pathogen levels on final products. As a result, requiring establishments to characterize *Salmonella* as a hazard reasonably likely to occur at receiving is unreasonable, unnecessary, and will likely provide little to no food safety benefit. Rather than attempt to regulate *Salmonella* out of live animals, the agency should push leadership at USDA to rigorously invest research dollars into meaningful and consistent preharvest food safety tools.

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The Meat Institute appreciates FSIS's commitment to reducing *Salmonella*-related illnesses and improving food safety. While the proposed framework demonstrates a focus on public health, several aspects require refinement to ensure practicality, scientific integrity, and alignment with regulatory standards. By pivoting to performance standards, providing clear guidance, and adopting a collaborative, science-based approach, FSIS can achieve meaningful progress without imposing unnecessary burdens on industry. Additionally, the Meat Institute is wary of the potential for portions of the proposed framework to be finalized sooner than others. The different portions, though seemingly distinct, were designed as a strategic approach that works together. It is important for all stakeholders to consider the framework as a whole and how the portions fit to address *Salmonella*. The Meat Institute appreciates the opportunity to provide these comments and looks forward to continued dialogue and collaboration to enhance food safety while maintaining feasibility and consumer trust. Please contact us if you have questions about these

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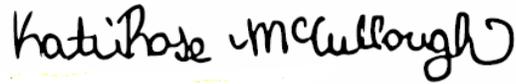
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comments or anything else regarding this matter. Thank you for your consideration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Casey Lynn Gallimore', with a stylized, cursive script.

Casey Lynn Gallimore  
Senior Director, Regulatory Policy

A handwritten signature in black ink, appearing to read 'KatieRose McCullough', with a cursive script.

KatieRose McCullough, PhD, MPH  
Senior Director, Science and Public Health

Cc: Sandra Eskin  
Julie Anna Potts  
Mark Dopp  
Nicole Johnson-Hoffman