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Food Safety and Inspection Service
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Ms. Sandra Eskin
Deputy Under Secretary for Food Safety
Office of Food Safety
Food Safety and Inspection Service
1400 Independence Ave SW
Washington, DC 20250-3700

Re: Docket No. FSIS-2022-0029: Proposed Framework for Controlling *Salmonella* in Poultry

Dear Ms. Eskin:

The National Chicken Council (NCC) appreciates the opportunity to provide comments regarding the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS or the Agency) Proposed Framework for controlling *Salmonella* in poultry. NCC is the national, non-profit trade association that represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States.

The Agency's Proposed *Salmonella* Framework raises several questions about numerous complex topics, including risk assessment and public health modeling, pathogenicity data, current and future laboratory testing technologies, detailed applications of highly technical Hazard Analysis and Critical Control Point (HACCP) systems, and legal and technical considerations, to name but a few. NCC member companies would be significantly impacted by the Agency's Proposed Framework, and NCC encourages the Agency to take a science-based, data-driven approach to impacting public health. However, as the Proposed Framework is not based on science, data, or the results of a risk assessment(s), it is challenging for the regulated industry to provide meaningful comments. Instead, we encourage the Agency to take a more measured approach and use robust data demonstrating true impact on public health when proposing sweeping regulatory changes.

The concerted efforts by both the broiler chicken industry and FSIS to drive down *Salmonella* rates have been enormously successful. Based off the most recent FSIS testing results¹, *Salmonella* prevalence on young chicken carcasses is 3.1% and *Salmonella* prevalence on chicken parts is 7.1% across all broiler processing establishments. These testing results are well below the *Salmonella*

¹FSIS, *Sampling Results for FSIS Regulated Products*, USDA.gov (2022), <https://www.fsis.usda.gov/science-data/sampling-program/sampling-results-fsis-regulated-products>.

performance standard for both young chicken carcasses and chicken parts. Coupled with performance standards, currently over 90% of the industry is meeting or exceeding the performance standard for both young chicken carcasses and chicken parts.² In just the past few years, FSIS has significantly tightened existing *Salmonella* standards; introduced new performance standards for chicken parts; rolled out a new, scientifically driven, modernized poultry inspection system that allows for greater testing and analysis; released detailed guidance on controlling *Salmonella* through processing controls; and approved numerous new interventions; among many other endeavors. FSIS has taken or is in the process of rolling out similar programs for other species. These actions are consistent with the science-based, data-driven actions NCC believes are beneficial to public health.

As with FSIS, food safety is a top priority for the broiler chicken industry, and we support changes in food safety regulations that are based on sound science, robust data, and are demonstrated to positively impact public health. For years the industry has implemented a multi-hurdle approach focused on the continual reduction of *Salmonella* from farm to fork – implementing robust vaccination, biosecurity, sanitation, and other effective measures.

In 1996, the CDC created FoodNet Fast to display data for select pathogens transmitted through food, including *Salmonella*.³ While the incidence of salmonellosis in humans has remained relatively unchanged since 1996, Americans eat significantly more chicken and chicken products today than in 1996. In 1996, chicken consumption in the U.S. was 69.7 pounds per person. In 2022, USDA estimates that Americans will consume 99.0 pounds of chicken per person.⁴ This reflects a 42% increase in chicken consumption over the past 26 years. Neither FoodNet Fast nor Interagency Food Safety Analytics Collaboration (IFSAC)⁵ takes into account consumption patterns of various food sources, including chicken. When the data from both FoodNet Fast and IFSAC are analyzed based on per-pound consumption of chicken, the rate of salmonellosis associated with chicken is shown to have decreased over the past ten-plus years. This data demonstrates that the robust public-health measures implemented by FSIS and the chicken industry over the past decade have been working.

In short, FSIS's existing framework for approaching *Salmonella* control has been working, and NCC encourages FSIS to continue using the latest science and industry-Agency collaborations to drive improvements in this framework. For example, as discussed in these comments, science-based changes such as transitioning to an enumeration-based performance standard would apply new technological and scientific developments to FSIS's proven approach and would drive continued food safety improvements.

The Proposed Framework would abandon these approaches for legally infirm and technologically infeasible strategies with no clear supporting data. While NCC appreciates FSIS's interest in thinking creatively about food safety, the Proposed Framework is not the right approach. First, the Proposed Framework appears premised on legally infirm conclusions that *Salmonella* may be considered an adulterant in raw poultry and that FSIS can mandate on-farm activities. Second, the Proposed Framework is presented nearly devoid of data, and it lacks specificity as to how the Agency plans to implement and enforce the proposed changes. Additionally, there appears to be a significant misunderstanding about how the broiler industry operates, the industry's supply chain structure, and current industry practices regarding the control of *Salmonella*. As written, the Proposed Framework threatens the economic viability of the entire poultry sector and threatens negative impacts on family

²Salmonella Verification Testing: October 31, 2021 through October 29, 2022, FSIS (2022), <https://www.fsis.usda.gov/news-events/publications/salmonella-verification-testing-october-31-2021-through-october-29-2022>.

³FoodNet Fast, Center for Disease Control (2022), <https://wwwn.cdc.gov/foodnetfast/>

⁴USDA, World Agricultural Supply and Demand Estimates (Dec. 9, 2022), <https://www.usda.gov/oce/commodity/wasde/wasde1222.pdf>.

⁵Center for Disease Control, *Interagency Food Safety Analytics Collaboration (IFSAC)*, CDC.gov (2022), <https://www.cdc.gov/foodsafety/ifsac/publications.html>

farmers, company employees, and consumers. The Proposed Framework would have negative impacts on both the availability of chicken and the cost of chicken to consumers of U.S. chicken around the world. Overall, the Proposed Framework appears to be moving away from long-standing HACCP-based principals that focus on identifying and controlling risk to a command and control, once-size-fits-all approach that could have significant negative public health outcomes.

These comments address overarching concerns regarding FSIS's statutory authority under the Poultry Products Inspection Act (PPIA) and the lack of supporting data presented with the Proposed Framework, provide feedback on each of the three Components, and finally address several cross-cutting issues raised in the Proposed Framework.

Salmonella Is Not an Adulterant Under the Poultry Products Inspection Act

Fundamentally, the Proposed Framework is legally infirm because *Salmonella* is not an adulterant in raw chicken under the PPIA.

Under the PPIA, a 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.”⁶ Thus, whether a pathogen renders a product adulterated depends on whether the substance is added to the product or occurs naturally in the product. For added substances, the pathogen is an adulterant only if the substance is present in quantities that “ordinarily” render the product injurious to health. As FSIS has consistently recognized, *Salmonella* is not an adulterant in raw poultry because (i) *Salmonella* is not an added substance in raw poultry and (ii) *Salmonella* is not present in levels that render chicken injurious to health because customary cooking practices destroy any *Salmonella* that may be present. FSIS has offered nothing to change this interpretation.

First, *Salmonella* is not an added substance because it occurs naturally within the chicken biome. *Salmonella* is not an avian pathogen, and it exists naturally as part of the microflora in and on chicken. *Salmonella* can exist in a chicken's skin, muscle tissue, and gut. Peer-reviewed literature establishes that healthy, asymptomatic birds are known to carry *Salmonella*.⁷ Researchers have also identified *Salmonella* in chicken neck skin, on the outer layer of skin, on feather follicles, connective tissue, and in drumstick muscle.⁸ Moreover, literature shows correlations between *Salmonella* loads on the farm or in birds and at various processing steps, reinforcing that *Salmonella* enters the process via the chickens themselves.⁹

⁶21 U.S.C. § 453(g)(1).

⁷See, e.g., Rigney, C. P., Salamone, B. P., Anandaraman, N., Rose, B. E., Umholtz, R. L., Ferris, K. E., et al. (2004). *Salmonella* serotypes in selected classes of food animal carcasses and raw ground products, January 1998 through December 2000. *J. Am. Vet. Med. Assoc.* 224, 524–530. doi: 10.2460/javma.2004.224.524; Nde, C. W., Mcevoy, J. M., Sherwood, J. S., and Logue, C. M. (2007). Cross contamination of turkey carcasses by *Salmonella* species during defeathering. *Poult. Sci.* 86, 162–167. doi: 10.1093/ps/86.1.162; Erol, I., Goncuoglu, M., Ayaz, N. D., Ellerbroek, L., Ormanci, F. S., and Kangal, O. I. (2013). Serotype distribution of *Salmonella* isolates from turkey ground meat and meat parts. *Biomed Res. Int.* 2013, 281591. doi: 10.1155/2013/281591.

⁸See 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.

⁹See, e.g., Berghaus, R.D., Thayer, S.G., Law, B. F., Mild, R.M., Hofacre, C.L., and Singer, R.S. 2013. Enumeration of *Salmonella* and *Campylobacter* spp. in Environmental Farm Samples and Processing Plant Carcass Rinses from Commercial Broiler Chicken Flocks. *Applied and Environmental Microbiology.* 79:4106-4114; Volkova VV, Bailey RH, Rybolt ML, Dazo-Galarneau K, Hubbard SA, Magee D, Byrd JA, Wills RW. 2010. Inter-relationships of *Salmonella* status of flock and grow-out

The fact that *Salmonella* may be present in greater expected concentrations in some parts of a chicken than others is irrelevant to this analysis, as is the fact that *Salmonella*, as with any microbe, can be spread through cross-contact during processing. The PPIA asks only whether the organism is an added substance when determining if it is an adulterant. To view all pathogens that can be somehow spread among or within products as “added substances” would read out of existence the second prong of § 453(g)(1) and is simply inconsistent with the normal meaning of the term. Moreover, courts have been clear that an “added substance” refers to a substance not otherwise present in the food and added by man.¹⁰ As established, *Salmonella* occurs naturally within chickens. *Salmonella* is not an added substance in raw poultry, and thus it is an adulterant only if it “ordinarily” renders the product injurious to health.¹¹ It does not.

Salmonella does not “ordinarily” render raw chicken injurious to health. The PPIA establishes a very high standard to support a conclusion that a naturally occurring pathogen “ordinarily” renders a raw product adulterated. First, in the PPIA, Congress created a strong presumption against viewing a naturally occurring substance as an adulterant in raw products. Congress’s choice of language is striking: under the PPIA, added substances adulterate food if they “*may* render it injurious to health,” whereas a product with naturally present pathogens “*shall not* be considered adulterated” if the substance “does not ordinarily render it injurious.”¹² The statute thus sets up two very different standards. “May” could imply FSIS has a measure of discretion in evaluating added substances, but the statute sets a significantly higher bar for naturally occurring substances. FSIS is prohibited from considering a naturally occurring substance a pathogen (“*shall not* be considered adulterated”) unless it can meet the very high bar of proving that the substance would “ordinarily” render the product injurious to health. Reinforcing this high bar, in its statement of policy codified into the PPIA, Congress commanded that decisions such as product condemnation “shall be supported by scientific fact, information, or criteria.”¹³ By default, naturally occurring substances are not pathogens, and FSIS must go to great scientific lengths to establish otherwise.

Second, the plain meaning of “ordinarily” sets a very high bar. When a statute does not define a term – and the PPIA does not define “ordinarily injurious” – courts will consider its plain meaning with reference to its reasonable use, dictionary definitions, and its use in context.¹⁴ Multiple dictionary definitions contemporaneous with the passage of the PPIA show us what Congress meant when it used “ordinarily.” *Webster’s* 1953 edition defines “ordinarily” as “according to established rules or settled

environment at sequential segments in broiler production and processing. *Zoonoses Public Health* 57:463–475; Fluckey, WM, Sanchez MX, McKee SR, Smith D, Pendleton E, Brashears MM. 2003. Establishment of a microbiological profile for an air-chilling poultry operation in the United States. *J. Food Prot.* 66:272–279.

¹⁰See *United States v. Coca Cola*, 241 U.S. 265 (1915); *United States v. Anderson Seafoods, Inc.* 622 F.2d 157, 160 (5th Cir. 1980).

¹¹FSIS recognized that *Salmonella* is not an added substance in its recent 2022 denial of a petition requesting *Salmonella* be declared as an adulterant, noting that “FSIS has traditionally viewed *Salmonella* as ‘naturally occurring’ in food animals.” Letter from Rachel Edelstein to William D. Marler, Esq, at 3 (May 31, 2022). Although FSIS in that petition response noted it was considering reassessing its long-held view, the Agency still has provided no information to explain why *Salmonella*—which comes into plants on chicken skin and inside chickens, including in the muscle tissue—is not a substance naturally occurring in chickens. More established agency precedent reinforces that *Salmonella* is naturally occurring in raw chicken. See, e.g., Letter from Carmen Rottenberg, Acting Deputy Undersecretary, Office of Food Safety, to Laura MacCleery, Director, Center for Science in the Public Interest, at 1-2 (Feb. 07, 2018) (“We also disagree with your assertion that ABR *Salmonella* is an ‘added substance’ within the meaning of the adulteration provisions of the FMIA and PPIA.”).

¹²21 U.S.C. § 453(g)(1).

¹³21 U.S.C. § 452.

¹⁴*Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997).

method.”¹⁵ *Black’s Law Dictionary*, 1951 edition, defines the adverb by reference to “ordinary,” stating it means “regular” or “normal.”¹⁶ And *Oxford English Dictionary*, which examines the historical development of the term, defines it as “[b]elonging to the regular or usual order or course” or occurring in “regular custom or practice.”¹⁷ The term retains its meaning in modern parlance and as defined “usually; as a rule.”¹⁸ Thus, under the plain language of the PPIA, a naturally occurring substance can be considered an adulterant only if the substance “regularly” or “normally,” or through “regular or usual . . . course” or “regular custom or practice,” or “usually” or “as a rule” renders the product injurious to health.¹⁹ This simply is not the case.

As is well established, thorough cooking destroys *Salmonella*. Specifically, cooking raw chicken to an internal temperature of 165°F achieves a 7-log reduction in *Salmonella*.²⁰ In fact, even a slightly lower temperature still achieves instant lethality (162°F or 163°F, depending on the fat content), as can reaching yet-lower-still temperatures with sufficient dwell time, often of just a few seconds.²¹ Even in the event raw chicken were cooked at yet lower temperatures, there would be a substantial log-reduction in *Salmonella*.

Consumers customarily cook chicken in a manner that achieves thorough cooking and destroys *Salmonella*. Chicken is customarily cooked through. Consumers are regularly reminded to use a meat thermometer to cook chicken to an internal temperature of 165°F – including on the package itself – which achieves lethality. While NCC’s strong recommendation is that consumers use a meat thermometer, other less analytical ways to gauge “doneness”, such as cutting into the meat to see if it is visibly white and firm, are also highly likely to achieve lethality and certainly cannot be said to “usually” or “normally” result in the product being injurious to health. Chicken is not customarily cooked “rare” or “medium,” and waitstaff at restaurants do not ask patrons how they would like their chicken cooked because the default approach is to cook chicken all the way through. Certainly, it is not the case that due to handling and cooking practices, *Salmonella* in “regular custom or practices” causes the chicken to be injurious to health.

In this manner, *Salmonella* in raw chicken is fundamentally different than Shiga toxin producing *E. coli* (STECs) in raw non-intact beef. FSIS attempts to draw parallels between these product-pathogen pairs, but the analysis misses the key distinctions. In the Proposed Framework, FSIS attempts to reduce its 1994 decision declaring *E. coli* O157:H7 an adulterant in raw ground beef (and subsequent extension to STECs in raw non-intact beef) to a set of “criteria,” all of which appear equally weighted: association with human illness, low infectious dose, severity of human illness, and typical consumer cooking practices.²² However, that is not actually the approach FSIS took, nor is it the analysis courts performed when evaluating FSIS’s *E. coli* policy.

In fact, FSIS’s analysis turned *primarily* on whether *E. coli* was likely to be destroyed under customary cooking practices for raw ground beef. In explaining its policy on *E. coli* O157:H7, FSIS provided

¹⁵Webster’s New Twentieth Century Dictionary 1177 (1953).

¹⁶*Ordinary*, Black’s Law Dictionary (4th ed. 1951).

¹⁷*Ordinary*, Oxford English Dictionary (2d ed., 1989).

¹⁸*Ordinarily*, Webster’s New World College Dictionary (4th ed., 2010).

¹⁹The legislative history behind comparable language in the Federal Food, Drug, and Cosmetic Act reinforces this interpretation. In one debate, members stated “ordinarily injurious” meant “that people—substantial numbers of people—must actually be harmed by the product before it can be restricted in any way. This provision . . . puts the burden of proof on the FDA.” 120 Cong. Rec. 36007 (1974) (Statement of Rep. Peter Kyros).

²⁰FSIS, *FSIS Cooking Guidelines for Meat and Poultry Products (Revised Appendix A)*, Table 3, USDA.gov (2021), https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf.

²¹FSIS, *FSIS Cooking Guidelines for Meat and Poultry Products (Revised Appendix A)*, Table 3, USDA.gov (2021), https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf.

²²Proposed *Salmonella* Framework at 10.

background on the risks of *E. coli* O157:H7 but then expressly tied *E. coli* O157:H7's status as an adulterant to cooking practices: "Raw ground beef products present a significant public health risk because they are frequently consumed after preparation (e.g., cooking hamburger to a rare or medium rare state) that does not destroy *E. coli* O157:H7 organisms that have been introduced below the product's surface."²³ If that were not clear enough, FSIS continued, "the Agency believes that the status under the FMIA of beef products contaminated with *E. coli* O157:H7 must depend on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed."²⁴ Cooking practices were expressly the dispositive factor. This is reinforced by the fact that FSIS determined that intact cuts of beef, when contaminated with the exact same *E. coli* O157:H7, were not adulterated because "[i]ntact steaks and roasts and other intact cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with *E. coli* O157:H7."²⁵ FSIS again cited to customary cooking practices as the dispositive point in its 2011 *Federal Register* notice declaring several other STECs to similarly be adulterants in raw non-intact beef.²⁶ Thus, rather than being a four-factor analysis as presented in the Proposed Framework, there is only question: whether the customary cooking practices would ordinarily render the product injurious to health.

Courts recognize this distinction as pivotal. In upholding FSIS's *E. coli* O157:H7 sampling program, and in a case that fundamentally turned on whether *E. coli* O157:H7 could properly be considered an adulterant in raw ground beef, the District Court for the Western District of Texas focused on whether the cooking practices that most Americans considered "proper" for ground beef were sufficiently "thorough" as to destroy *E. coli* O157:H7:

However, unlike other pathogens, it is not "proper" cooking but "thorough" cooking that is necessary to protect consumers from *E. Coli*. The evidence submitted by Defendants indicates that many Americans consider ground beef to be properly cooked rare, medium rare, or medium. The evidence also indicated that *E. Coli* contaminated ground beef cooked in such a manner may cause serious physical problems, including death. Therefore, *E. Coli* is a substance that renders "injurious to health" what many Americans believe to be properly cooked ground beef.²⁷

In *Texas Food Industry Association*, just as in FSIS's explanation, the entire analysis turned on whether customary consumer cooking practices were sufficient. Under the court's reasoning, had what consumers understood to be "proper" cooking been adequate to destroy *E. coli* O157:H7 in hamburgers, then the substance would not have been an adulterant (just as it is still not an adulterant on raw intact beef).

But raw chicken is handled very differently than ground beef. Consumers do not customarily consider it "proper" to cook a medium rare chicken breast. Even ground chicken products such as chicken burgers or meatballs are customarily cooked through, not served rare. What consumers consider to be the "proper" or "customary" method is also a method that cooks chicken "thoroughly."²⁸

²³FSIS, *Beef Products Contaminated with Escherichia Coli O157:H7*, 64 Fed. Reg. 2803, 2803 (Jan. 19, 1999) (emphasis added).

²⁴Id (emphasis added).

²⁵Id at 2804 (emphasis added).

²⁶FSIS, *Siga Toxin-Producing Escherichia coli in Certain Raw Beef Products*, 76 Fed. Reg. 58157, 58158 (Sept. 20, 2011).

²⁷*Texas Food Industry Ass'n v. Espy*, 870 F. Supp. 143, 149 (W.D. Tex., 1994).

²⁸Other critical distinctions exist between STECs in raw non-intact beef and *Salmonella* in raw poultry. For example, *E. coli* typically enters the cattle slaughter process through cross contamination with fecal matter on the outside of the hide, which can get transferred to the meat if sanitary practices are not observed. By contrast, *Salmonella* actually enters in the chicken, including in edible parts of the chicken.

Courts have likewise recognized this distinction. The Fifth Circuit recognized that “*Salmonella* [is] present in a substantial proportion of meat and poultry products” and “is not an adulterant *per se*” because “normal cooking practices for meat and poultry destroy the *Salmonella* organism.”²⁹ The D.C. Circuit reached a similar conclusion in *American Public Health Ass’n v. Butz*, holding “the presence of salmonellae on meat does not constitute adulteration” and that “American housewives and cooks are not ignorant or stupid and their methods of preparing and cooking of food do not ordinarily result in salmonellosis.”³⁰ In other words, existing circuit precedent indicates the mere “presence of *Salmonella* in meat products,” without more, does not support USDA regulation under § 453(g)(1).³¹

FSIS, too, has long and consistently recognized that *Salmonella* is not an adulterant in raw poultry. For example, as recently as this year, FSIS denied a petition requesting FSIS declare certain *Salmonella* strains to be adulterants in raw poultry. In 2018, FSIS denied a different petition making a similar request to declare certain *Salmonella* strains as an adulterant in raw meat and poultry. In its 2016 *Federal Register* notice announcing new *Salmonella* performance standards for poultry, FSIS clearly explained, “*Salmonella* is not an adulterant in NRTE poultry products.”³² In 2014, FSIS rejected a petition to declare antibiotic resistant *Salmonella* an adulterant, stating “we are not aware of any data to suggest that consumers consider ground poultry . . . to be properly cooked when rare, medium rare, or medium.”³³ Crucially, USDA has never argued that *Salmonella* is an adulterant under § 453(g)(1). Instead, it has argued the opposite in litigation and policy documents. For example, in the *Supreme Beef* case on the enforceability of *Salmonella* performance standards, the court noted, “The USDA agrees in this case that *Salmonella* is not a[n] . . . adulterant.”³⁴

In light of this long and consistent history, and even if the PPIA were to permit such an interpretation, FSIS would be hard-pressed to provide a rationale that its change in policy was not arbitrary and capricious or that an abrupt change in position was warranted by the record.³⁵ As it stands, FSIS has presented no data to support a conclusion that *Salmonella* in raw chicken “ordinarily” or “usually” renders chicken injurious to healthy under customary cooking practices.

Finally, the Proposed Framework would entail creating new substantive requirements affecting the rights of NCC member companies, which would make it a legislative rule, and would require amending or creating multiple regulations. If FSIS were to pursue the Proposed Framework, the Administrative Procedure Act would require FSIS to engage in a substantial amount of notice-and-comment rulemaking, which would require FSIS to develop and make available for public comment a record

No amount of process control or sanitary dressing can prevent its being in the product because it starts out in the product.

²⁹*Supreme Beef Processors, Inc. v. U.S. Dep’t of Agric.*, 275 F.3d 432, 438–39 (5th Cir. 2001).

³⁰*American Public Health Ass’n v. Butz*, 511 F.2d 331, 334 (D.C.Cir.1974).

³¹See also, e.g., *Starr Surplus Lines Ins. Co. v. Mountaire Farms Inc.*, 920 F.3d 111, 117 (1st Cir. 2019) (“[T]he mere fact of the FSIS-orchestrated recall does not give rise to the plausible inference that the type of salmonella found . . . could not be eliminated by proper cooking.”); *Craten v. Foster Poultry Farms Inc.*, 305 F. Supp. 3d 1051, 1058 (D. Ariz. 2018) (observing that existing case law “suggests Salmonella is not an adulterant” and rejecting several state law tort claims because Salmonella “is killed through proper cooking, which is how raw chicken products are intended to be used”).

³²FSIS, *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, 7297 (Feb. 11, 2016).

³³Letter from Daniel Engeljohn, Assistant Adm’r, Off. of Pol’y & Program Dev., USDA, to Sarah Klein, Food Safety Program (July 31, 2014).

³⁴*Supreme Beef*, 275 F.3d at 439 n.21.

³⁵See *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 34 (1983).

comprehensively addressing the numerous factual and scientific issues raised by the Proposed Framework.

Fundamentally, FSIS has provided no explanation for making an abrupt change in its approach to *Salmonella* in raw poultry, as it would be required to do. Under the plain language of the PPIA and long-standing caselaw, FSIS cannot compile a scientific basis for declaring *Salmonella* an adulterant in raw poultry. Accordingly, the Proposed Framework stands on infirm legal footing. We urge FSIS to instead pursue alternative approaches for which it has authority, such as revamped *Salmonella* performance standards, as explained elsewhere in these comments.

The Proposed Framework Lacks Adequate Supporting Data

As a public health agency, FSIS has long promoted the use of sound science-based decision-making, which by definition must be based on, and driven by, scientific data. FSIS has presented no data to suggest a change in policy is needed or to support the proposals or assumptions in the Proposed Framework. This is regrettable, as without supporting data, the Proposed Framework appears almost entirely speculative. The complete lack of data makes it impossible to provide meaningful feedback on key areas, such as whether the data calls for a change in policy, whether the Proposed Framework is supported by the data, and whether the specific elements of the Proposed Framework were developed appropriately in light of that data. NCC firmly believes that it is imperative that public health decisions and policy follow the data, not the other way around.

Data Issues Related to the Proposed Framework

FSIS must first develop data and conduct risk assessments and use that data to determine what, if any, policy changes are called for. There are a number of key missing data elements. For example:

- There is no data to support the idea that *Salmonella* levels on incoming flocks overwhelm food safety systems or would need to be monitored.
- There is not data to demonstrate that setting a finished product standard would have public health impacts, or what standard to even set.
- There is no data to suggest that additional testing during the process beyond what is already done would be impactful.
- We understand that FSIS has not even begun the two risk assessments, which would presumably provide useful insight to use in developing policy proposals.

In effect, the Proposed Framework seems to reflect a presumption that the proposed changes would be effective and has asked stakeholders to rebut that presumption. This applies the policy development process backwards.

Moreover, without data or details, it is impossible to provide meaningful feedback on the proposal. For example, stakeholders have no ability to assess whether the data supports the proposed actions or whether the actions are appropriate in light of the data. The Proposed Framework is devoid of virtually all key details, raising many questions and leaving just as many unanswered. To take but one example, FSIS has not explained why it has contemplated proposing a 1 CFU/g finished product standard, especially given that FSIS testing has a limit of detection (LOD) at 10 CFU/g and cannot accurately enumerate at the 1 CFU/g level and that FSIS has not begun two risk assessments seemingly designed to address this exact question.

What little data FSIS has referenced contains significant flaws:

- CDC’s National Outbreak Reporting System, or NORs, is a web-based platform that launched in 2009.³⁶ It is used by local, state, and territorial health departments in the United States to report all waterborne and foodborne disease outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission to CDC. From 2009 to 2020, NORs reported 15,344 poultry-related *Salmonella* illnesses, which represents 29.3% of all *Salmonella* illnesses (there were 52,374 total *Salmonella* illnesses reported from 2009 to 2020). Critically, however, that figure lumps together illness from both live poultry (e.g., handling a backyard flock) and consumption of poultry. Separating out the live-poultry exposures yields a very different result. 8,475 of the 15,344 poultry-related illnesses were attributed to live poultry – for example, handling chicks or interacting with backyard flocks – and not related to chicken consumption at all. Chicken consumption accounts for 5,076 cases in the NORS data, which represent 9.7% of all salmonellosis cases in the U.S. from 2009 to 2020. While the industry is committed to driving this number down further, failing to properly distinguish foodborne illness and the more-prevalent live-bird exposures significantly overstates the effect of chicken consumption on illness burden in the NORs data.
- The IFSAC report makes clear several important limitations: The illness estimates “should not be interpreted as suggesting that all foods in a category are equally likely to transmit pathogens.” The authors also urge “caution” in “comparing estimates across years” as the percentages reflect a relative contribution to illness burden, which means a category could see its actual illness contribution decrease yet its relative percentage increase if other categories dropped even further. The authors expressly “advise using these results with other scientific data for decision-making.”³⁷ The IFSAC report alone cannot drive scientifically based policy. Further, the illness contribution attributed to chicken is statistically indistinguishable from that of fruits, seeded vegetables, and pork and is followed very closely by “other produce.”³⁸ This statistical parity between product categories suggests that a coordinated approach applying measured strategies against all of these categories would have a much greater public health impact than merely singling out one category without addressing the other.
- As previously mentioned, salmonellosis incident rates attributed to chicken have decreased over the last decade when per-capita chicken consumption patterns are considered. Changes in consumption patterns are critical for assessing foodborne illness and must be considered to properly evaluate changes in illness rates or the significance of source attribution.
- If FoodNet Fast, NORS, and IFSAC data were reflective of consumption patterns of chicken over time, the overall burden of illness attributed to chicken would actually have decreased.
- FSIS has also left unaddressed whether the Proposed Framework would make an impact on the Healthy People 2030 goals, and if so, what impact would be anticipated and how it would be determined.

³⁶Center for Disease Control, *National Outbreak Reporting System*, Center for Disease Control, CDC.gov (2019), <https://www.cdc.gov/nors/index.html>.

³⁷The Interagency Food Safety Analytics Collaboration, *Foodborne illness source attribution estimates from 2020 for Salmonella, Escherichia coli O157, and Listeria monocytogenes using multi-year outbreak surveillance data, United States*, at 12 (Nov. 2022), <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2020-report-TriAgency-508.pdf>.

³⁸The Interagency Food Safety Analytics Collaboration, *Foodborne illness source attribution estimates from 2020 for Salmonella, Escherichia coli O157, and Listeria monocytogenes using multi-year outbreak surveillance data, United States*, at 8 (Nov. 2022), <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2020-report-TriAgency-508.pdf>.

In light of these substantial data gaps, it is essential that FSIS prioritize generating and making publicly-available key data before continuing further in this process. The Agency is currently working towards the development of two quantitative risk assessments – one focused on *Salmonella* in chicken and the other focused on *Salmonella* in turkey. In the July 1, 2022, *Constituent Update*, FSIS announced that it has signed a cooperative agreement with the University of Maryland’s Joint Institute for Food Safety and Applied Nutrition (JIFSAN) in partnership with EpiX Analytics to help in the Agency’s data collection effort for these risk assessments. NCC has engaged with JIFSAN routinely since July 2022 to understand this group’s approach to data collection, the specific data needs, and how NCC and our member companies can aid in this process. Unfortunately, FSIS only provided the JIFSAN team three months to work with trade associations like NCC to understand data needs, develop a platform by which data could be shared, and fully understand the goals of the Agency. This timeline has proven to be insufficient as we are approaching the end of 2022 and this group, in conjunction with several trade associations, industry representatives, and FSIS, has still not been able to execute the intended data collection effort.

Although the process has not progressed as quickly as FSIS seemed to expect, NCC believes that the approach to formalize two risk assessments is appropriate. Moreover, we support the risk management questions that the risk assessments intend to address including:

1. What public health impact (change in illnesses, hospitalizations, and deaths) is achieved by eliminating a proportion of chicken (or turkey) at receiving contaminated with specific levels of *Salmonella* and/or specific *Salmonella* subtypes?
2. What is the public health impact (change in illnesses, hospitalizations, and deaths) achieved by eliminating final product contaminated with specific levels of *Salmonella* and/or specific *Salmonella* subtypes?
3. What is the public health impact of monitoring/enforcing process control from re-hang to post-chill? Monitoring could include analytes such as Enterobacteriaceae, Aerobic Plate Count, or other indicator organisms, analysis could include presence/absence or levels and the monitoring could also include variability of actual result versus expected result, log reduction, absolute sample result, or other individual establishment specific criteria.
4. What is the public health impact of implementing combinations of the risk management options listed above?

As stated in the July 1, 2022, *Constituent Update*, “These risk management questions reflect the information needed to evaluate and compare the public health benefits of policy options for controlling *Salmonella* in poultry.” The Agency went on to state that the risk assessments would undergo an independent peer review and be released publicly once completed. To reiterate, NCC fully supports the completion of and the independent peer review of both risk assessments. NCC believes that it is imperative that any policy changes rely on the results of the risk assessments and without that information, it is impossible to understand what regulatory changes, if any, would impact public health. It also makes it very challenging for the regulated industry to provide meaningful comments with this information lacking, and the Agency has not disclosed their sources of data used to develop the Proposed Framework. Without the completion, peer review, and publication of the two risk assessments, the Agency risks operating without the benefit of a robust record, undermining informed decision making.

Finally, there are two national advisory committees whose recommendations may influence the content of the Proposed Framework: the National Advisory Committee on the Microbiological Criteria for Foods (NACMCF) and the National Advisory Committee on Meat and Poultry Inspection (NACMPI). Charges of both advisory committees include a focus on *Salmonella* in poultry among other topics. We encourage FSIS to update its thinking on the Proposed Framework in light of many of the recommendations by these advisory committees.

Data Recommendations

Given the critical role data plays in public health decisions, NCC provides the following data recommendations:

1. Complete the two risk assessment studies, submit them for peer review, and release them for public review once complete.
2. Use the risk assessment results to inform further development of the Proposed Framework.
3. Provide the public a detailed report with the data, information, and scientific analysis supporting the key elements of the Proposed Framework and provide an opportunity for public comment on the Proposed Framework based on the report.
4. Consider key NACMCF and NACMPI recommendations as they may apply to the Proposed Framework.
5. Hold technical meetings with stakeholders to discuss in detail the changes and complications that would be raised by any aspect of the Proposed Framework being contemplated. These should be made part of the administrative record in any subsequent rulemaking, and they should be held before any rulemaking is initiated to facilitate open dialogue.

Feedback on Component 1 – Incoming Flock Testing

NCC has significant concerns that Component 1 of the Proposed Framework exceeds FSIS's authorities, is not supported by data, would be impractical, and is unnecessary. We suggest alternative approaches that will better achieve FSIS's objectives within the confines of law and reality.

Component 1 would have FSIS mandate on-farm testing, impose an incoming flock *Salmonella* standard, seemingly provide FSIS inspectors with the ability to dictate which flocks may or may not enter an establishment, and force establishments to view *Salmonella* as a hazard reasonably likely to occur (RLTO) at receiving. None of these actions are appropriate, and they risk significantly undermining existing policy and systems.

FSIS Lacks Authority to Regulate Farms

First, FSIS lacks jurisdiction to mandate on-farm testing, although Component 1 would do just that. The PPIA is clear that FSIS's authority begins at the official establishment. FSIS's primary slaughter-related inspectional authorities are expressly limited to operations in official establishments:

- Ante mortem inspection: “[T]he Secretary shall, where and to the extent considered by him necessary, cause to be made by inspectors ante mortem inspection of poultry **in each official establishment** processing poultry or poultry products. . . .”³⁹
- Post-mortem inspection: “The Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors post mortem inspection of the carcass of each bird processed . . . in each **official establishment** processing such poultry or poultry products”⁴⁰
- Sanitary practices: “Each **official establishment** slaughtering poultry or processing poultry products . . . or otherwise subject to inspection under this chapter shall have such premises, facilities, and equipment, and be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purposes of preventing the entry into . . . commerce, of poultry products which are adulterated.”⁴¹

³⁹21 U.S.C. § 455(a).

⁴⁰21 U.S.C. § 455(b).

⁴¹21 U.S.C. § 456(a).

- General compliance: “No **establishment** processing poultry or poultry products for commerce otherwise subject to this chapter shall process any poultry or poultry product except in compliance with the requirements of this chapter.”⁴²

It is telling that even ante mortem inspection, which is inspection of live birds, must occur at the official establishment. Had Congress wished for FSIS to be able to oversee farms, Congress could have given that authority to FSIS. Instead, Congress specifically limited FSIS’s inspectional and oversight activities to official establishments, even for the inspection of live birds. FSIS has long agreed with this limitation. For example, in the final rule implementing HACCP, FSIS expressly recognized that “FSIS does not intend nor is FSIS authorized, to mandate production practices on the farm.”⁴³ Thus, not only does the statute specifically limit FSIS’s authority to official establishments (and further distribution therefrom), but FSIS also expressly recognizes this limitation in its foundational rulemaking for the very HACCP framework that FSIS proposes using to regulate activity on farms.

By establishing *Salmonella* thresholds for incoming flocks, FSIS would require that farms take actions to prevent *Salmonella* levels on flocks from exceeding the incoming threshold level. Farms would have to figure out how to monitor *Salmonella* levels and would be required to take actions to bring levels to within FSIS’s target, otherwise the flocks are of essentially no economic value. FSIS is very clear about its intent. Component 1 is entitled, “Requiring incoming flocks be tested for *Salmonella* before entering an establishment.”⁴⁴ This testing would have to occur on farms, and by the plain language of the Proposed Framework would happen before reaching the establishment. In other words, FSIS would be “mandating production practices on the farms,” which FSIS has long recognized it may not do. Positioning the threshold merely as a receiving criteria that applies to the official establishment does not help because the only way to ensure a flock meets the incoming criteria is to require a farm to take various actions to ensure the threshold is met. No matter how FSIS phrases the threshold, the application of a threshold would require farms take actions, which FSIS may not do. FSIS cannot achieve through an indirect regulation what it lacks authority to do directly.

Further, setting a *Salmonella* threshold for incoming flocks necessarily implies that *Salmonella* above the threshold (1) renders the incoming birds adulterated and (2) that the purported adulteration cannot be corrected through processing. The only explanation for prohibiting entry of flocks that test above a certain *Salmonella* threshold is that the flocks would somehow irreparably adulterate any finished product that would be produced from them. FSIS would have no basis to arbitrarily restrict the use of flocks otherwise. But as explained above, *Salmonella* does not render raw poultry adulterated, and FSIS has presented no evidence to change this longstanding conclusion. Moreover, by categorically prohibiting entry, FSIS is indicating there is no means for an establishment to correct the purported adulteration, otherwise under HACCP principles the establishment could accept and process the product to correct the issue. FSIS has presented no evidence to indicate that flocks with *Salmonella* above a certain threshold are *per se* adulterated, much less somehow irreparably so.

Additional Issues Pertaining to Component 1

Even setting aside FSIS’s lack of authority to regulate on-farm activities, Component 1 suffers from numerous other issues. First, FSIS has presented no data to demonstrate that an incoming threshold is necessary for an establishment to maintain process control and sufficiently reduce *Salmonella* during processing; no information to explain how a threshold would be determined or what data FSIS or an establishment would use to do so; no data to establish that on-farm *Salmonella* sampling several weeks before a flock is processed correlates in a reliable way to actual incoming *Salmonella* loads at the beginning of processing; no data to demonstrate that reducing incoming loads would achieve any particular public health impact; and no data to demonstrate that incoming loads require measuring for

⁴²21 U.S.C. § 459(a).

⁴³61 Fed. Reg. 38806, 38810 (July 25, 1996).

⁴⁴*Salmonella* Framework at 5 (emphasis added).

HACCP systems to operate as designed. Without data to support such a substantial policy shift, the Agency cannot justify its approach, nor can stakeholders meaningfully provide informed feedback on whether the approach is justified by or consistent with the data. Science-based policymaking must start with data.

Second, a mandatory receiving threshold would be fundamentally inconsistent with HACCP principles. Under HACCP, establishments, not inspectors, make decisions about how to execute their food safety systems. FSIS's role is to verify that the HACCP system is designed and scientifically supported in accordance with FSIS regulations and that the establishment is implementing the HACCP plan as intended. FSIS's role decidedly is not to tell an establishment which flocks may be processed, and which may not. Component 1 would wind back the food safety clock a quarter century and reimpose a long-abandoned command and control approach to poultry processing.

Third, Component 1's proposed requirement that establishments declare *Salmonella* as a hazard RLTO at receiving is inconsistent with HACCP principles. Under HACCP, the establishment – not FSIS – is required to conduct its own hazard analysis, identify those hazards that are RLTO in the process, and implement Critical Control Points (CCPs) accordingly. If *Salmonella* were a hazard RLTO at receiving, it is unclear what step would be the CCP and how an establishment would be expected to validate that CCP.

Fourth, Component 1 is likewise inconsistent with established FSIS inspectional approaches because FSIS cannot verify the testing. FSIS typically must be able to verify the data used by an establishment to support its food safety system, but it is unclear how FSIS would verify incoming flock testing that occurred on a farm several weeks before a flock arrived at the establishment. FSIS's proposal to conduct verification testing at rehang is not appropriate for verifying on-farm testing. Several weeks would have passed from the time an on-farm sample was collected and FSIS's rehang sampling, and the microflora would be expected to change during this time. On-farm data would likely be collected by drag or boot swabs, which is a very different sampling process than taking a rehang sample. More importantly, however, is that fact that there is inconclusive evidence as to what method of on-farm testing actually yields repeatable and defensible results. Additionally, different enumeration technologies could yield different results and different confidence intervals. Moreover, between the time of on-farm testing and rehang sampling, the birds or carcasses will have undergone multiple interventions and processing interventions that affect *Salmonella* load. Even the Agency's own instructions in the Raw Chicken Parts Sampling Program require IPP to sample eligible chicken parts after the last intervention is applied.⁴⁵ Simply put, rehang samples would not correlate with on-farm samples, nor has FSIS provided any data to demonstrate otherwise.

Fifth, pre-harvest sampling would impose significant burden across the entire industry. NCC estimates that between 260,000 and 300,000 flocks were required to reach USDA's estimate for chickens processed in 2021. That would require collecting and testing between 260,000 and 300,000 samples annually, in rural locations, to comply with the proposal, and that is assuming each flock requires only one test. This would impose a substantial cost, pose unnecessary biosecurity risks, and overwhelm existing laboratory capacity and supply availability.

Sixth, challenges would also complicate FSIS verification sampling. For example, FSIS would have to collect a large number of samples to obtain a statistically reliable measure of the *Salmonella* level of a flock – one hot rehang sample would not suffice. It is doubtful FSIS has the sampling or laboratory capacity for this. It is also not clear how FSIS would handle outliers. For example, would the flock be evaluated by the average load or by the highest result, and how would FSIS obtain enough samples to have a sufficiently narrow confidence interval around the result? And even if FSIS could obtain this

⁴⁵FSIS, *Raw Chicken Parts Sampling Program*, USDA.gov (2021), https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/10250.1-Raw-Chicken-Parts-Sampling-Program.pdf.

information, how would FSIS be able to meaningfully compare it to on-farm sampling conducted weeks earlier, using different sampling and possibly test methods, and reflecting birds before they had undergone various processing steps?

Seventh, it is unclear how FSIS would handle the inherent delay in receiving results for its verification testing, which, especially for enumeration, could take a significant amount of time until results are obtained. The flock would likely have been processed, the resulting products shipped, and perhaps even consumed well before FSIS received its verification results. But if the purpose of rehang sampling is to verify the establishment is properly conducting on-farm sampling and meeting the Agency's pre-determined threshold at live receiving, several serious logistical and practical problems arise. If FSIS is framing the proposed live receiving threshold as an acceptance criterion, with the implication being that a flock whose verification sampling exceeds the threshold should be rejected, then typically the establishment would be expected to hold the flock pending the results of FSIS's verification sampling. But holding an entire flock's worth of production every time FSIS conducted verification sampling would be extraordinarily burdensome and in effect impossible for most establishments. But if the establishment were allowed to ship the product before FSIS received the rehang verification results, it is unclear how the establishment would be able to implement corrective action. And it is entirely unclear how FSIS would view a situation in which the FSIS rehang verification sample was above the live receiving "threshold" yet the product from that flock met an enforceable finished product standard.

Additional logistical and practical problems abound. For example:

- It is unclear at what time period a flock would be required to be tested, how that would be determined, whether it would vary for different bird types, housing conditions, farm location, and market weight of the flock, among many other compounding factors.
- It is unclear what test method should be used for on-farm testing, as different methods might yield different types of results.
- Mandating such a high volume of on-farm testing could pose significant logistical difficulties in getting supplies and samples, especially to and from remote rural areas.
- It is entirely unclear what on-farm testing strategies would best reflect the load (or, if used, serotypes) actually entering the plant. Substantial industry testing has shown this is very difficult to do, and FSIS has provided no data on this point.
- How would issues such as testing delays, lost samples, equivocal results, or lab error resulting in a flock not having an on-farm test result be handled? A flock cannot be held past its target catch date without risking serious bird welfare issues.

FSIS has not addressed what would happen to a flock that tested above threshold. FSIS's contemplated policy could have catastrophic bird welfare outcomes and could result in flocks being needlessly held, delayed, diverted, or euthanized. Likewise, the proposal risks imposing substantial financial losses on the family farmers who raise the majority of broiler chickens and now might be left with flocks that cannot be brought to market and processed.

At bottom, FSIS's contemplated proposal would introduce a tremendous number of challenges and would be inconsistent with established HACCP principles. The reality is that the industry already implements numerous preharvest intervention strategies to reduce *Salmonella* loads coming into establishments, and they have done so even though they are not required to. For example, robust preharvest *Salmonella* control strategies are widely implemented across the industry to include programs in the hatchery, feed mill, breeder house, and broiler house. These programs include, but are not limited to:

- Biosecurity programs
- Equipment sanitation
- Feed treatment

- Litter treatment
- Water sanitation programs
- Feeding of prebiotics and probiotics
- Rodent/insect control
- Cleanout programs
- Vaccinations

The industry is already taking significant steps to address *Salmonella* in preharvest. Component 1 would contribute nothing but would impose considerable cost and complication. If FSIS's objective is to enhance process control and drive down finished product *Salmonella* levels, a much more direct and efficient approach would be to consider an enumerated performance standard for finished products and allow establishments to innovate and design their systems as appropriate to meet that target.

Component 1 Recommendations

In light of the substantial legal, scientific, and practical considerations associated with Component 1, NCC recommends the following:

1. FSIS should not establish incoming flock thresholds.
2. If FSIS wants to better understand process control throughout the process, from live receiving to pack-out, FSIS should engage in more extensive exploratory rehang sampling programs and use that data, along with FSIS data from other sampling points, to analyze process control throughout processing and to inform risk assessment modeling.
3. As discussed further below, FSIS should instead consider an enumerative performance standard after a baseline and qualitative risk assessment is performed. Establishments should be provided the flexibility to design science-based systems specific to their operations to meet that standard.

Feedback on Component 2 – In-Process Testing

NCC is concerned that Component 2 would be too prescriptive and could stifle food safety innovation. Component 2 would require establishments to conduct in-process testing at specified points using certain indicator organisms. Establishments already conduct extensive in-process testing, and a command-and-control-style approach dictating testing at certain points would be counterproductive.

As with other elements of the Proposed Framework, FSIS has provided no data to explain why Component 2 is needed, what benefits Component 2 would have on food safety outcomes, or how the testing locations, frequencies, or target organisms would be selected, among others. Without this information, it is impossible to thoroughly evaluate options, offer meaningful feedback, or understand whether the Agency's proposal is a reasonable response to the data. As with the other Components, it is critical that FSIS first develop and make available its data and then make decisions based on that data in a transparent manner.

As discussed above, HACCP principles dictate that establishments, not FSIS, are to develop and implement their food safety plans, including any process control monitoring strategies. Chicken processors do this, and processors collect substantial volumes of data throughout their processes. It is inappropriate to dictate specifically where an establishment must sample, how frequently it must sample, and what it must sample for. Doing so risks stifling innovation. An overly rigid sampling framework will hinder innovation and technology development by creating outsized focus on specific points and specific target organisms. Instead, plants should be encouraged to innovate by testing at the appropriate point for their systems, which in turn will provide more data and more impetus to drive technological improvements. A rigid framework also risks punishing companies whose food safety systems are better monitored using different testing protocols than called for under FSIS's one-size-fits-

all approach. Such a company would be forced to choose between incurring the cost of additional sampling or implementing FSIS's less-effective approach. Similarly, a rigid framework risks diverting limited company resources away from the most effective sampling points to meet the regulatory sampling requirements. None of these outcomes promote food safety.

Moreover, FSIS seems to contemplate requiring all establishments to follow the same process control methodologies, or perhaps requiring all establishments to meet the same process control standard. This would be inappropriate. Each establishment must be free to monitor process control as appropriate for their systems. FSIS has provided no data to show that it is appropriate or even feasible to evaluate all establishments using the same standard, especially if establishments have different line configurations or intervention strategies relative to FSIS-mandated sampling points. Without more information about what FSIS means by "requiring establishments to use the same statistical process-control method," it is difficult to provide specific feedback, but establishments need the ability to design their testing programs to reflect their processes, and they should be evaluated on their ability to implement their plans successfully, not against a rigid benchmark that might not reflect their operations. FSIS's science-based changes implemented through the New Poultry Inspection System created the opportunity for greater science-based decision-making by enhancing establishments' flexibility and promoting more science-based verification activities by FSIS. Mandating that establishments follow fixed sampling plans would be a step backward from this more modernized approach. Instead, FSIS should be encouraging establishments to innovate and implement tailored food safety systems.

Component 2 Recommendations

In light of these concerns, NCC makes the following recommendations:

1. Consider specifying where, when, and how FSIS will collect process control verification samples, and let establishments develop their own individual sampling plans as appropriate for their operations. This approach would provide FSIS a consistent frame of reference but leave establishments free to design their processes as they determine will best promote food safety.
2. Use FSIS verification sampling results to feed into risk assessment modeling to better understand process control considerations.
3. Encourage individualized sampling plans and strategies for establishments.
4. Encourage plants to utilize Statistical Process Control (SPC) by providing detailed guidance on options for application and key locations. This could be particularly helpful for small and very small establishments and could be developed in conjunction with the appropriate academic institution.

Feedback on Component 3 – Enforceable Final Product Standard

NCC strongly opposes setting an enforceable finished product standard for raw chicken. Such a standard would be legally infirm since FSIS has provided no data to demonstrate why any standard, much less the contemplated 1 CFU/g threshold, is scientifically appropriate. Regardless of how implemented, an enforceable finished product standard would impose substantial logistical and technical challenges on the industry.

FSIS Lacks Legal Authority to Implement a Finished Product Standard for Raw Chicken

FSIS lacks statutory authority to establish an enforceable finished product standard for *Salmonella*. For a threshold-based finished product standard to be legally enforceable, FSIS would have to determine, through scientific data, that the substance is not an added substance, and that the substance would "ordinarily render [the product] injurious to health" at levels above the threshold. Otherwise, the product would not be adulterated and there would be no legal mechanism FSIS could use to enforce the standard. As explained above, *Salmonella* is not an adulterant in raw chicken, a position consistently reflected in decades of Agency policy and court decisions.

Such a cavalier proposed change to Agency policy is especially alarming because FSIS has provided absolutely no data to support its proposal. FSIS has provided no data, in the context of the Proposed Framework or otherwise, to support a conclusion that *Salmonella* above any threshold level would “ordinarily render” raw chicken injurious to health, much less the 1 CFU/g threshold contemplated in the Proposed Framework. Nor is NCC aware of any.

NCC is gravely concerned that FSIS has abandoned science-based decision-making in Component 3. Sound science-based policymaking requires first developing data and then developing policies in light of that data. In the Proposed Framework, FSIS has gone about its decision-making backwards. FSIS appears to have a desired outcome in mind and has asked for data to support it. The 1 CFU/g threshold previewed in the Proposed Framework appears entirely arbitrary. If anything, it appears simply to be set as close to zero as possible without actually creating a zero-tolerance standard.

FSIS has not explained why an enforceable product standard is appropriate, why it should be set at 1 CFU/g, or why it should apply uniformly to all raw poultry regardless of differing commercial and consumer applications and known differences in *Salmonella* levels in different types of poultry.

Just as troubling, the Proposed Framework suggests FSIS is not interested in developing data to test its proposed threshold. For example, FSIS has indicated it does not intend to conduct a baseline enumeration survey, which would make it impossible to assess the current level of *Salmonella* present on raw poultry and to determine the public impacts of this or any other change. We question how FSIS can be confident that 1 CFU/g is an appropriate threshold for a finished product standard when FSIS does not even know what levels are actually present on finished products today. Moreover, FSIS has indicated it is conducting two risk assessments, but we understand the data collection analysis to begin those risk assessments has not even begun. We fail to understand why FSIS would, knowing that it is conducting risk assessments to provide information addressing this very point, nonetheless move forward and propose a specific finished product threshold at this point. The appropriate approach would be to conduct the risk assessments, conduct a baseline, gather and analyze any additional data needed, and only then determine whether a finished product standard might be appropriate and, if so, how to develop such a standard.

Moreover, while a risk assessment is essential for projecting the likely effect of different proposed standards on public health and product risks, for a risk assessment to provide value, the risk must be accurately identified, analyzed, and evaluated. A risk assessment is but one component of the broader science-based decision-making process. To determine the level of risk mitigation that would have a meaningful impact on public health, the Agency must implement a comprehensive risk analysis strategy, which must include three components: the risk assessment itself, risk communication, and risk management. Moreover, a risk assessment cannot itself determine whether a product is adulterated. That standard is established in the PPIA, which as discussed above requires demonstrating that a naturally occurring substance renders the product “ordinarily” injurious to health.

Finally, we understand that FSIS may be considering applying a potential finished product standard differently depending on the size of the establishment. If the finished product standard is an adulteration standard – which is the only way it could be enforceable – the PPIA provides no such flexibility. Under the PPIA, if a product is adulterated, the product is adulterated regardless of the size of the establishment involved.

At bottom, the PPIA’s adulteration standard for naturally occurring substances requires a very clear scientific analysis: the substance has to “ordinarily” render the product injurious to health at the threshold level. Otherwise, by law, the product is not adulterated. FSIS has not provided any information to support such a determination. And without such information, it is impossible to meaningfully critique the contemplated approach.

Component 3 Raises Myriad Unresolved Issues

Beyond the grave legal concerns, Component 3 raises numerous other complex issues that remain unaddressed. For example, the necessary testing technology simply does not exist. FSIS's assumption that testing technology with sufficient throughput, sensitivity, and speed will materialize simply because FSIS wills it is arbitrary. In fact, FSIS's own newly approved testing technology has a LOD of *Salmonella* at 10 CFU/g, so it is unclear how FSIS would even evaluate compliance with the contemplated 1 CFU/g standard. Moreover, the fact that FSIS is unable to accurately quantify *Salmonella* at 1 CFU/g with its method casts considerable doubt on how FSIS developed this proposed standard.

Moreover, raw chicken is a highly perishable product with a short shelf life, and supply chains are not set up to hold substantial quantities of raw chicken. But an enforceable finished product standard would require testing and holding of enormous quantities of raw chicken until results are received. There simply is not enough cold storage in the country to accomplish this, and a widescale test and hold program would significantly degrade product shelf life and quality. Companies may be forced to destroy product or divert it to the cooking market, which accounts for only a modest amount of chicken production and would quickly find both demand and processing capacity outstripped. FSIS's policy threatens to constrict the supply of raw chicken, which in turn risks driving up food inflation and heightening food insecurity for America's most vulnerable families.

Likewise, an "enforceable" final product standard implies that FSIS would request a recall if a product were found to exceed the standard, and it is entirely unclear how lotting would be determined when establishing the scope of a recall. For example: Would lots be defined on a flock-by-flock basis? What about other flocks processed earlier or later that day? Would all chicken that contacted the same chiller water be included in recall? How would rework and hang-backs be handled? If parts of a day's production were sent to a different use, would all products from that day or flock be implicated? If a specific part, such as thighs, exceeded the standard, would that also affect other parts made from that flock, such as breasts? What if some types of parts exceed the standard but others do not? All of these questions, and many more, would require careful, considered analysis. NCC is extremely concerned that under the Proposed Framework, a single test result could cause the recall of an extremely large amount of product. There are much better ways to focus efforts on driving down levels of *Salmonella* without raising these extremely complicated issues.

FSIS has also provided no information on how it would expect establishments to test entire production lots of raw chicken in a statistically meaningful way. Raw chicken is not like raw non-intact beef, where lots can be limited to specific source materials and tested individually. Raw chicken production lots are very large, and *Salmonella* is unlikely to be uniformly distributed in a lot. As a result, it would be necessary to collect a tremendous number of samples to have confidence that the result is representative of the entire production lot. A single sample would be wholly inadequate. It is unclear if FSIS has the laboratory resources to adequately sample and analyze finished products lots, and it would impose considerable costs on establishments to do so. Moreover, raw poultry cannot be lotted in a way to limit lot size for finished product testing, and there would be no way to form lots conducive to a finished product test and hold program. We are also concerned about establishments that implement a less than daily (LTD) sanitation program and how those establishments would be expected to lot product. For example, due to time and difficulty involved, some establishments do not completely empty their chiller systems daily and instead have validated LTD sanitation programs in conjunction with FSIS. This facilitates efficient operations and protects the environment by reducing water and chemical use. The environmental impact and resources associated with losing a LTD sanitation program would be significant and must be considered.

Further, to the extent the Agency were considering applying a finished product standard differently based on establishment size or conducting sampling for small or very small establishments, it is unclear

how the Agency would take the necessary number of samples and still have remaining lab capacity to complete any verification sampling.

In practice, a standard like that contemplated in Component 3 would impose substantial cost on the industry, would divert tremendous amounts of raw chicken to less-demanded cooking applications (and would overwhelm the already saturated market for cooked chicken as well as capacity to cook it), and ultimately would mean less chicken at higher costs for consumers.

Component 3 Recommendations

NCC strongly opposed Component 3. FSIS lacks statutory authority to implement it, and the proposal raises numerous insurmountable technical issues. Instead, NCC recommends the following for enhancing *Salmonella* control in raw poultry finished products:

1. Conduct an enumerative baseline for *Salmonella* in raw poultry, focusing on different parts and perhaps different end-use applications or differences between slaughter and further processing facilities. Develop robust enumeration data for different parts.
2. Use enumerative baseline data to inform a risk assessment model.
3. Develop an enumerative performance standard to replace the current presence-based performance standard that is focused on specific parts.
4. Enhance labeling and consumer education. NCC has petitioned FSIS multiple times for more robust and modern labeling for certain types of raw poultry, which FSIS has yet to act on.

In particular, NCC believes that an enumerative performance standard would advance FSIS's public health goals in a much simpler and easier-to-implement manner. History has shown that chicken processors will make changes to meet voluntary performance standards. A properly constructed enumerative performance standard would achieve the same objective of driving down levels of *Salmonella* on finished product raw poultry, but with a number of benefits over the proposed Component 3. An enumerative performance standard provides the Agency and establishments with greater flexibility; can be implemented quickly without the need to rely on a novel application of the adulteration standard; is more responsive to existing supply chains and distribution practices; would not require new rapid testing technologies or complex test and hold programs (but the existence of the program would provide demand to spur testing innovation anyway); and would generate valuable long-term data about *Salmonella* levels on finished product. We strongly encourage FSIS to explore this pathway instead of the proposed Component 3, and NCC stands ready to collaborate with FSIS on this approach.

Cross-Cutting Considerations

NCC has feedback on several cross-cutting considerations related to the Proposed Framework.

Developing a Robust Data-Sharing Mechanism is a Critical Prerequisite Step

Throughout our comments, we have expressed concern about the lack of data and scientific analysis supporting the Proposed Framework. Chicken processors collected substantial quantities of data, dwarfing that collected by FSIS through verification and exploratory sampling. For more than a decade, NCC has sought a mechanism to facilitate aggregate data sharing with FSIS. NCC members are interested in developing an appropriate data-sharing process. In particular, NCC urges FSIS to develop a data-sharing framework that is consistent with the Freedom of Information Act exemption (b)(3), either with FSIS or a sister agency within USDA.⁴⁶ This data would provide FSIS with substantially more insight into food safety systems throughout the industry and would facilitate policy development and risk assessment modeling.

⁴⁶5 U.S.C. § 552(b)(3).

Serotype and Virulence-Based Testing is Not Practical with Current Technology

NCC supports efforts to enhance cutting-edge technologies to better understand *Salmonella* risks. Advanced testing technologies such as serotype-specific testing and virulence-based testing show great promise but, as FSIS recognized in the Proposed Framework, will require additional development before they can be used widely and effectively in everyday food processing operations. We encourage FSIS to support the continued development of and innovation with these technologies, but they are not quick, affordable, or available enough to be used widely in food processing operations. Moreover, we encourage FSIS to support further research on virulence factors and how they may impact public health.

The Proposal Risks Significant Disruption to the Industry and Threatens Food Prices for Consumers

Many aspects of the Proposed Framework threaten to drive up costs and cut availability of chicken. This would be an extremely unfortunate outcome, especially in light of recent record across-the-board inflation and the continuing food insecurity afflicting millions of American families. Chicken is American's most affordable and most consumed protein. It is nutritious and versatile, and it is a staple protein for many, and critically for those families trying to make the most out of every food dollar. Moreover, chicken makes up a significant portion of food bank donations and purchases for federal and state nutrition assistance programs. Aspects of the Proposed Framework threaten to undermine chicken availability.

For example, Component 1 would seem to contemplate entire flocks being turned away from plants before they are even processed. This would have devastating animal welfare implications, and it would reduce the supply of chicken in the market, in turn driving up costs. Likewise, a finished product standard would likely cause substantial amounts of product to be diverted to cooking operations. However, there is limited use and demand for precooked chicken, and that demand is largely saturated. Moreover, there is limited capacity to actually produce cooked chicken. Combined, these factors mean that much of the chicken that FSIS likely anticipates would be diverted to cooking operations would simply be destroyed, again reducing the supply of chicken and driving up costs. It would be most unfortunate for FSIS to choose this moment to worsen food insecurity and to drive up consumer food prices.

Further, the family farmers who raise most of the broiler chickens processed in the United States would be put at great financial risk if FSIS were to subject the marketability of the flocks they raise to a live receiving threshold. It is entirely unclear how FSIS anticipates the threshold affecting farmers, and this change could inject tremendous uncertainty into what has long been a prosperous way to deploy farming capital.

Conclusion

NCC appreciates the opportunity to provide comment on FSIS's Proposed *Salmonella* Framework. NCC member companies share FSIS's goal of reducing *Salmonella* levels on raw chicken and, ultimately, driving down salmonellosis cases. The chicken industry has made tremendous advances in reducing *Salmonella* presence, and the industry continues to drive down *Salmonella*. However, NCC has serious concerns about many aspects of the Proposed Framework. The Proposed Framework contemplates actions that exceed FSIS's statutory authority, that would be extremely difficult and perhaps impossible to implement, and that are not consistent with modern food safety approaches. Moreover, the lack of supporting information and data makes it extremely difficult to meaningfully evaluate and provide feedback on the Proposed Framework. NCC is concerned that policy appears to be getting ahead of the science.

NCC urges FSIS to instead pursue the recommendations made in these comments. The Agency should continue to work closely with all stakeholders through hosting technical meetings prior to the issuance of a proposed rule to ensure the ability for two-way dialogue and the development of the best approach forward based. These recommendations – in particular, conducting additional data gathering and analysis, developing an appropriate industry-agency data sharing protocol, and developing an enumerated performance standard – would significantly advance public health objectives while avoiding many of the complications, uncertainties, and costs raised by the Proposed Framework.

Please feel free to contact us with any questions regarding the above request. Thank you for your consideration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ashley B. Peterson". The signature is fluid and cursive, with the first name being the most prominent.

Ashley B. Peterson, Ph.D.
Senior Vice President, Scientific and Regulatory Affairs
National Chicken Council