

Consumer Federation of America

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Sandra Eskin Deputy Under Secretary for Food Safety Food Safety and Inspection Service U.S. Department of Agriculture Room: 201-W, Jamie Whitten Building

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Consumer Federation of America appreciates the opportunity to submit these comments on the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) Proposed Regulatory Framework to Reduce Salmonella Infections Linked to Poultry Products. The U.S. poultry inspection system is ineffective and inefficient. It is oriented around performance standards with little connection to public health, and the agency cannot enforce compliance with the standards. Poultry inspection reforms to reduce the burden of salmonellosis are long overdue. The Proposed Framework represents an important step forward after more than two decades of stalled progress.

The Proposed Framework appropriately leverages the agency's authority under the Poultry Products Inspection Act (PPIA) to prevent adulterated poultry products from entering commerce.¹ As we stated in our joint letter with industry, food safety scientists, and other members of the Coalition for Poultry Safety Reform, "FSIS should adopt enforceable <u>product</u> standards" to replace the current unenforceable performance standards for *Salmonella* in poultry.² The PPIA mandates that FSIS protect consumers from poultry contaminated with levels and types of *Salmonella* that "render it injurious to health."³ By carrying out this duty, the agency will necessarily align its regulatory oversight with public health objectives.

FSIS should set ambitious final product standards targeting the *Salmonella* serotypes that actually cause human illness. Outbreak data and challenge studies suggest that the infectious dose of the most pathogenic *Salmonella* serotypes rivals that of *E.coli* O157:H7, in some cases fewer than 10 organisms.⁴ These *Salmonella* often cause serious illness, and ordinary consumer handling practices result in infection. Accordingly, FSIS has the authority to set a zero-tolerance standard for highly pathogenic serotypes such as *Salmonella* Enteritidis and Typhimurium. In tandem with serotype

¹ Poultry Products Inspection Act. 21 U.S.C. § 451 et seq.

² Coalition for Poultry Safety Reform letter to FSIS Deputy Undersecretary for Food Safety Sandra Eskin. (Feb. 2, 2022), available at: <u>https://www.afdo.org/wp-content/uploads/2022/09/Letter-to-FSIS -Clean 2 2 22.pdf</u> (emphasis added).

³ 21 U.S.C. § 453(g).

⁴ See Teunis, "Dose response for Salmonella Typhimurium and Enteritidis and other nontyphoid enteric salmonellae," *Epidemics*, Volume 41 (2022), <u>https://doi.org/10.1016/j.epidem.2022.100653</u>.

specific zero-tolerance standards, the agency may also employ a quantitative *Salmonella* species standard, since illness risk increases with the overall levels of *Salmonella* contamination, and new *Salmonella* serotypes of concern may emerge faster than regulators can practically adjust the standards. However, standards targeting specific serotypes serve a critical function in motivating poultry producers to adopt interventions throughout the supply chain, including potential sources of contamination like breeder farms and feed mills, over which FSIS does not have direct regulatory authority.

Final product standards will anchor an effective regulatory regime, but to ensure widespread compliance, FSIS will need to prescribe parameters governing on-farm interventions and process control monitoring within establishments. These parameters, referred to in components one and two of the Proposed Framework, are necessary because testing to verify compliance with final product standards may only be possible at relatively low levels of sensitivity, at least initially. Given this "needle in a haystack" problem, testing alone will not spur the requisite investment in reducing *Salmonella* illness risk, particularly among industry bottom dwellers. The measures described in components one and two will also serve to generate data on effective interventions, and lay the foundation for ratcheting up final product standards to higher levels of protection.

Protections against *Salmonella* in poultry should continue to evolve, but the agency should act expeditiously now to develop and implement each of the components outlined in the Proposed Framework. New rules should be data driven, and informed by peer reviewed quantitative risk assessments currently underway for chicken and turkey. Nevertheless, some level of uncertainty surrounding the impact of an adulteration determination and related rule changes is inevitable. Despite that uncertainty, a strong evidence base currently supports greater investment in on-farm interventions to reduce *Salmonella* risk in poultry, greater oversight of the HACCP process to reduce *Salmonella* contamination risk, and the need for enforceable product standards to align food producers' incentives with consumer safety. FSIS should therefore resist the "stall tactics" commonly employed by defenders of the status quo and seize this opportunity of rare consensus around the need for reform to protect public health.

The following provides further elaboration on why regulating *Salmonella* in poultry deserves urgent attention, why the current FSIS regulatory approach to controlling Salmonella in poultry is antiquated and dysfunctional, and why each of the components of the Proposed Framework are necessary, with final product standards anchoring a successful regulatory strategy.

The public health burden caused by Salmonella in poultry is unacceptable.

The U.S. Centers for Disease Control and Prevention estimates *Salmonella* bacteria cause some 1.35 million infections, 26,500 hospitalizations, and 420 deaths annually in the U.S., with most of these illnesses attributable to contaminated food.⁵ The Proposed Framework rightly emphasizes the lack of progress in reducing *Salmonella* infections. In particular, the Healthy People 2010 and 2020 targets were 6.8 and 11.4 *Salmonella* infections per 100,000 population, respectively, yet between 2010 and 2017, infection rates averaged 15.8 *Salmonella* infections per 100,000 population.

⁵ <u>https://www.cdc.gov/salmonella/index.html</u>

Poultry accounts for more *Salmonella* infections each year than any other food category, and in recent years, its contribution to illness appears to have grown. According to Interagency Food Safety Analytics Collaboration (IFSAC) reports, *Salmonella* infections attributable to poultry (most of which are attributable to chicken) have steadily risen from 17.3% of all infections (2013)⁶ to 18.2% (2015)⁷ to 20.2% (2017)⁸ to the 23% figure cited by the Proposed Framework and presented in the 2019 IFSAC report. This past November, a new IFSAC report bumped up the count for chicken by half a percentage point (from 16.8% to 17.3%).⁹ Preliminary modeling to inform the next IFSAC assessment suggests the tally may grow even higher as researchers use genetic sequencing to incorporate sporadic illnesses, and not just outbreak data, into their attribution estimates.¹⁰

The increasing burden of *Salmonella* illness caused by poultry is enormous. Popular perceptions tend to dismiss salmonellosis as a mild illness. But while many infections resolve after a temporary bout of diarrhea and gastroenteritis, an estimated 5% of victims develop life-threatening bloodstream infections (bacteremia).¹¹ These infections require antibiotics, to which emerging strains of *Salmonella* may be resistant. For example, a multi-drug resistant *Salmonella* Infantis strain associated with chicken, which had sickened an estimated 67,599 consumers as of 2021, contains genes known as extended-spectrum beta-lactamases (ESBLs), which are "are typically seen in healthcare-acquired infections and confer resistance to ceftriaxone and other [antibiotic] beta-lactamases." These antibiotics are typically used as treatments for *Salmonella* infections, "especially for children and bloodstream infections."¹² Even where initial symptoms are mild, salmonellosis often leads to long-term sequalae, including irritable bowel syndrome, osteomyelitis, and reactive arthritis. According to one study, between 5% and 30% of persons who suffer from acute episodes of gastroenteritis "develop chronic gastrointestinal symptoms despite clearance of the inciting pathogens."¹³

The FSIS regulatory approach to controlling Salmonella in poultry is antiquated and dysfunctional.

⁶ <u>https://www.cdc.gov/foodsafety/pdfs/IFSAC-2013FoodborneillnessSourceEstimates-508.pdf</u>

⁷ https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2015-report-TriAgency-508.pdf

⁸ https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2017-report-TriAgency-508-revised.pdf

⁹ <u>https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2020-report-TriAgency-508.pdf</u>. *Salmonella* illnesses attributable to turkey declined slightly during this period, perhaps a reflection of that industry's comparatively activist approach to addressing outbreak strains of the bacteria. *See, e.g.* Michael Grabell and Bernice Yeung, "When Dangerous Strains of Salmonella Hit, the Turkey Industry Responded Forcefully. The Chicken Industry? Not So Much," *ProPublica* (Dec. 29, 2021), <u>https://www.propublica.org/article/when-dangerous-strains-of-salmonella-hit-the-turkey-industry-responded-forcefully-the-chicken-industry-not-so-much</u>.

¹⁰ Rose, E., H. Carleton, J. Pettingill, B. Tolar, R. Lindsey, M. Batz, M. Bazaco, J. Chen, E. Click, Z. Cui, A. Lauer, M. Simmons, B. Tameru, G. Tillmann, and B. Bruce. 2022. Source attribution of Salmonella using whole genome sequencing and random forest. p. 105. In, International Symposium on Salmonella and Salmonella and Salmonellosis, St. Malo, France.

¹¹ Hohmann, E. L. (2001). Nontyphoidal Salmonellosis. *Clin Infect Dis.* 32:263-269.

¹² Presentation of Louise Francois Watkins, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, to Consumer Groups. "Multidrug Resistant Salmonella Infantis (REPJFX01) Linked to Chicken: Update." (Dec. 6, 2021).

¹³ Marshall, J. K., et al. (2010). Eight-year prognosis of post-infectious Irritable Bowel Syndrome following waterborne bacterial dysentery. Gut. 59(5):605-611.

The significant, and worsening, public health burden of *Salmonella* in poultry cries out for better consumer protections. Under the current system, poultry products contaminated with *Salmonella* are only considered adulterated if they are "associated with an illness outbreak."¹⁴ Public health officials must find an unopened package of product in a foodborne illness outbreak victim's refrigerator, and match the *Salmonella* strains in the package to isolates obtained from a case patient sample, before FSIS will take action to pull the offending product off the market. These "product standards," to the extent that label applies, are reactive to foodborne illness caused by *Salmonella*. They come into force after people get sick, rather than preventing illness in the first place, and FSIS has only rarely invoked them to declare a *Salmonella* contaminated product "adulterated."¹⁵

Rather than product standards, performance standards drive the current regulatory regime. At most establishments, FSIS inspectors sample product on a weekly basis to verify compliance with the standards for a given product category. If an establishment producing poultry parts, for example, has more than 15.4% of parts samples test positive for *Salmonella* over a 52-week period, it fails the performance standard.¹⁶ This system has failed to protect consumers both because *Salmonella* prevalence appears to correlate poorly with public health outcomes, and because FSIS cannot enforce the performance standards.

Lack of enforcement authority has dealt a crippling blow to the FSIS poultry inspection regime. In 1994, FSIS declared *E. coli* O157:H7 an adulterant in raw ground beef. The declaration marked a momentous shift towards regulating meat and poultry on the basis of microbiological contamination, rather than on traditional organoleptic carcass inspection, or "poke and sniff" as some critics refer to it. In 1996, FSIS issued its Hazard Analysis and Critical Control Point Systems / Pathogen Reduction (HACCP/PR) final regulation for all meat and poultry plants. The rule set standards for microbiological contamination in poultry plants, and gave establishments discretion to determine the HACCP systems that would allow them to meet those standards. The HACCP/PR rule moved away from "command and control" rules dictating what food safety interventions must apply in processing plants, towards a system in which companies would have more flexibility to innovate in order to meet the performance standards, at least in theory.

But the regulatory system contemplated by the HACCP/PR rule never fully emerged. Incentives for compliance are the driving force in any performance based regulatory system. Yet

¹⁴ FSIS. HAACP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and Related Agency Verification Procedures Notice, 77 Fed. Reg. 72686-01 (Dec. 6, 2012),

https://www.federalregister.gov/documents/2012/12/06/2012-

^{29510/}haccp-plan-reassessment-for-not-ready-to-eat-comminuted-poultry-products-and-related-agency. ¹⁵ See, e.g. FSIS. "Jennie-O Turkey Store Sales, Inc. Recalls Raw Ground Turkey Products due to Possible Salmonella Reading Contamination," (Dec. 21, 2018), <u>https://www.fsis.usda.gov/recalls-alerts/jennie-o-turkey-store-sales-inc.-</u> <u>recalls-raw-ground-turkey-products-due-possible</u> (explaining that the agency was "conducting traceback activities for a sample of Jennie-O brand ground turkey in an intact, unopened package from a case-patients home. The patient tested positive for Salmonella Reading and the samples from the case-patient and from the ground turkey are closely related genetically.").

¹⁶ New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule. 81 Fed. Reg. 7285. February 2, 2016. <u>https://www.federalregister.gov/documents/2016/02/11/2016-02586/new-performance-standards-for-salmonella-and-campylobacter-in-not-ready-to-eat-comminuted-chicken</u>

when FSIS tried to shut down a Texas facility, Supreme Beef Processors, which had repeatedly failed to meet the *Salmonella* performance standards, the agency's new inspection system did not stand up to legal scrutiny. The federal Fifth Circuit Court of Appeals ruled that FSIS lacked the authority to take enforcement action against an establishment solely because it failed to meet microbiological standards.¹⁷ This left FSIS with a performance-based regulatory system for which it could not require the specified performance.

Not surprisingly, a sizeable proportion of meat and poultry establishments have failed to comply with *Salmonella* performance standards in the two decades following the *Supreme Beef* decision. At this point, however, the available evidence indicates that even universal compliance with the existing *Salmonella* performance standards for poultry would not adequately protect consumers.

That is because in addition to being unenforceable, the performance standards are only loosely tied to preventing human illness. As FSIS has made clear, not all *Salmonella* contamination is equal. Some serotypes and strains are much more likely to cause human illness than others. And higher loads of *Salmonella* are much more likely to cause human illness than lower loads. The existing performance standards create an incentive for establishments to eradicate all types of *Salmonella* from most production lots. But the prevalence-based standards make no distinction for poultry contaminated with multi-drug resistant *Salmonella* Infantis, or for poultry contaminated with tens of thousands of *Salmonella* cells per gram. In this sense, the existing standards are not "risk-based" and may explain the increasing attribution of *Salmonella* infections to poultry, even as compliance with *Salmonella* performance standards has grown.

Final product standards must anchor a successful regulatory strategy.

Due to the *Supreme Beef* decision, FSIS cannot effectively protect consumers from *Salmonella* in poultry through a performance standard based system. By replacing prevalence-based performance standards with standards that target dangerous serotypes, or high loads of *Salmonella*, the agency could align the standards more closely with public health objectives. However, the problem of enforcing compliance with the standards would remain. For the past two decades, FSIS has pursued a failed strategy of responding to incompliance with the performance standards by deploying additional inspectors and testing, conducting "Food Safety Assessments," and otherwise investing taxpayer dollars into oversight of companies unwilling to invest their own resources into food safety. Arguably, FSIS could take a more aggressive approach to shutting down establishments that repeatedly fail to meet performance standards, but the agency has interpreted its authority to preclude such an approach.¹⁸

By contrast, the legal basis for enforcing product standards is straightforward. The PPIA forbids the sale in interstate commerce of poultry products that have not been inspected by FSIS. Poultry products can only pass inspection and bear the USDA mark of inspection if they are not "adulterated." As CFA and its advocacy partners explained in our 2020 petition requesting an interpretive rule declaring "outbreak" serotypes of *Salmonella* to be adulterants, *Salmonella* on poultry products is an "added substance" because it does not naturally occur in or on muscle tissue of healthy chickens and turkeys, but rather ends up there as a result of cross-contamination from the

¹⁷ Supreme Beef Processors, Inc. v. U.S. Dept. of Agriculture, 275 F.3d 432, 440 (5th Cir. 2001).

¹⁸ See, e.g., 81 Fed. Reg. 7285, supra note 15.

gastrointestinal tract during the slaughter and dressing of carcasses, specifically during defeathering and evisceration. But regardless of whether FSIS considers the *Salmonella* serotypes most associated with human illness to be an "added substance," they are "adulterants" because they also "ordinarily render" contaminated poultry products injurious to health.¹⁹ The same rationale applies to high loads of *Salmonella*.

During the public meeting that FSIS held earlier this year, some stakeholders raised objections to final product standards on the basis that poultry processing plants do not have the capacity to hold product while awaiting test results, or do not have a viable means of diverting product deemed adulterated to cooking or some other "kill step." While FSIS must assess these concerns and any other costs and benefits associated with regulatory action, the agency should keep in mind that industry similarly questioned the feasibility of protecting consumers from beef products contaminated with E.coli O157:H7. In the lawsuit challenging the agency's interpretive rule declaring E.coli O157:H7 an adulterant in raw ground beef, industry plaintiffs alleged that "testing is prohibitively expensive and that the industry is already doing all it can to control the problem."²⁰ FSIS (and the federal court) rejected that argument then, and the agency should do so again now. There is good reason to believe that testing technology and industry best practices will quickly evolve following a declaration of dangerous Salmonella serotypes and loads as adulterants in poultry. Indeed, tests are already available that accurately quantify Salmonella in less than four hours, enabling "same-shift" decisions.²¹ The market will provide even more rapid tests, capable of detecting the presence of particular Salmonella serotypes in ever smaller quantities, if FSIS policy indicates a need for them.

Again, final product standards should include standards targeting the specific serotypes that cause human illness. Most poultry-associated salmonellosis in the US is associated with just a few serotypes, i.e. Enteritidis, Typhimurium, 4,5,12:i:-, Infantis, and Heidelberg, which correspond to any even smaller number of "serogroups," for which a single vaccine may provide inoculation. Successful efforts to reduce contamination of specific serotypes, both in the United States and abroad, support tailoring the regulatory strategy to reduce the occurrence of these pathogens, rather than *Salmonella* species writ large.²² To best protect public health, FSIS should declare the 31 serotypes identified in our 2020 petition to be adulterants. However, should the agency choose to narrow its focus, a recent study by the European Food Safety Authority (EFSA) concluded that "S. Enteritidis, S. Typhimurium (including monophasic variants) and S. Infantis" should continue to be targeted in breeding flocks "based on their occurrence in populations of G. gallus and in humans."²³

 ¹⁹ Marler Clark et al. Petition for an Interpretive Rule Declaring 'Outbreak' Serotypes of Salmonella enterica subspecies enterica to be Adulterants Within the Meanings of 21 U.S.C. § 601(m)(1) and 21 U.S.C. § 453(g)(1), (Jan. 22, 2020), available at: <u>https://www.regulations.gov/document/FSIS-2020-0007-0001</u>

²⁰ Texas Food Indus. Ass'n v. Espy, 870 F. Supp. 143, 148 (W.D. Tex. 1994).

²¹ See, e.g. <u>https://www.biomerieux-industry.com/en-us/products/gene-up-quant-salmonella</u>

²² See, e.g. O'Brien, S. J. 2013. The "decline and fall" of nontyphoidal Salmonella in the United Kingdom. Clin 2468 Infect Dis. 56:705-710 (describing the precipitous decline of *Salmonella* Enteriditis infections in the United Kingdom during the 1990s and concluding that "the temporal relationship between vaccination programs and the reduction in human disease is compelling and suggests that these programs have made a major contribution to improving public health.".

²³ EFSA Panel on Biological Hazards, K. Koutsoumanis, A. Allende, A. Alvarez-Ordonez, D. Bolton, S.

Notably, FSIS cannot directly regulate breeding flocks or any other part of the poultry supply chain upstream of the slaughterhouse. Yet the experience in the European Union and elsewhere make clear that "pre-harvest" interventions targeting the most dangerous *Salmonella* serotypes can play an essential role in reducing foodborne illness. In addition to vaccines, interventions to keep dangerous *Salmonella* serotypes out of breeder flocks should play a role in protecting public health. In particular, destroying grandparent or "elite" breeder flocks contaminated with a dangerous *Salmonella* serotype may be necessary to prevent vertical transmission of *Salmonella* to potentially hundreds of thousands of offspring.²⁴ Serotype specific final product standards will create the incentives for both poultry processors and the upstream entities that supply them to invest more in protecting consumers.

On-farm, "pre-harvest" interventions are critical to protecting public health and should be integrated into HACCP plans.

While final product standards will create important incentives for food safety interventions on-farm, FSIS should reinforce these incentives by requiring establishments to characterize *Salmonella* as a hazard reasonably likely to occur at receiving. Researchers have noted that "poultry and poultry meat can become contaminated with *Salmonella* during the entire poultry production chain, that is from the breeder farm, production farm, transportation, slaughterhouse, and retail."²⁵ Just two companies, Aviagen and Cobb-Vantress, a wholly owned subsidiary of Tyson Foods, dominate the poultry breeding industry. These two firms provide virtually all of the breeding stock to the otherwise vertically integrated chicken companies, or "integrators," the largest 10 of which accounted for 79 percent of the chicken produced in the United States in 2015.²⁶ Because *Salmonella* bacteria is vertically transmitted from breeding stock to the "broilers" raised for food, even the most rigorous food safety program at the integrator level may prove ineffective. According to one recent study of genetic data from *Salmonella* isolates gathered from poultry and case patients around the globe, *Salmonella* contamination appears to arise "from centralized origins at the pinnacle of poultry production."²⁷

To address the threat posed by *Salmonella* contamination on the farm, in 2003, the European Union pioneered a serotype-based approach to Salmonella control with European Commission Regulation No. 2160/2003. The rule directed the European Food Safety Authority (EFSA) to identify the Salmonella serotypes, or "serovars," most detrimental to public health, and to define

²⁶ Gary Thornton, "Top 10 US chicken producers grow in new directions,"

https://www.wattagnet.com/articles/25893-top---us-chicken-producers-grow-in-new-directions ²⁷ Li, S. et al. *supra* note 24.

Bover-Cid, M. Chemaly, A. De Cesare, L. Herman, F. Hilbert, R. Lindqvist, M. Nauta, L. Peixe, G. Ru, M. Simmons, P. Skandamis, E. Suffredini, J. Dewulf, T. Hald, V. Michel, T. Niskanen, A. Ricci, E. Snary, F. Boelaert, W. Messens, and R. Davies. 2019. Salmonella control in poultry flocks and its public health impact. *EFSA Journal*. 17:e05596.

²⁴ See Li, S., He, Y., Mann, D.A. et al. Global spread of Salmonella Enteritidis via centralized sourcing and international trade of poultry breeding stocks. Nat Commun 12, 5109 (2021). <u>https://doi.org/10.1038/s41467-021-</u> 25319-7

²⁵ H. Zeng, K. De Reu, S. Gabriël, W. Mattheus, L. De Zutter, G. Rasschaert, Salmonella prevalence and persistence in industrialized poultry slaughterhouses, *Poultry Science*, Volume 100, Issue 4, 2021, 100991, ISSN 0032-5791, https://doi.org/10.1016/j.psj.2021.01.014.

targets for each member state to achieve in reducing their prevalence.²⁸ This regulatory initiative coincided with a dramatic decline in *Salmonella* infections. That decline has since leveled off, but as alluded to above, a 2019 EFSA review endorsed a continued requirement to control levels of certain *Salmonella* serovars on-farm.

Many U.S. poultry processors have already adopted practices to reduce *Salmonella* contamination on the farm. One recent survey of broiler farm managers and poultry veterinarians found that a majority of respondents reported using drinking water management, litter management, and feed practices aimed at reducing *Salmonella* and *Campylobacter* colonization. And many of these operations already test for *Salmonella* on the farm. Of the survey respondents, 33% of the poultry veterinarians and 56% of the broiler farm managers responded that on-farm microbiological tests are conducted to detect *Salmonella* in the flocks. At the same time, the survey "revealed gaps" in respondents' understanding of poultry pathogens, and found that many farms were neglecting best practices for reducing pathogen contamination, such as cleaning catching and transportation equipment between flocks.²⁹ The requirements described in Component 1 of the Proposed Framework will bring greater scrutiny to farms that do not adopt best practices for controlling *Salmonella*.

More prescriptive standards are necessary to ensure that HACCP plans adequately control *Salmonella*.

Many establishments will respond to rigorous, health-based product standards with innovation and greater investments in food safety. For those that do not, however, reliance on testing finished product alone to verify compliance with the new standards will lead to haphazard and incomplete protections for consumers. More prescriptive HACCP regulations will help to ensure higher rates of compliance, at lower cost.

In 2015, CFA issued a report entitled "The Promise and Problems of HACCP: A Review of USDA's Approach to Meat and Poultry Safety."³⁰ The report's top recommendation, echoing similar recommendations from the Government Accountability Office and USDA's Office of Inspector General, is that FSIS develop a better mechanism to ensure the adequacy of HACCP plans. As the report explains, the agency lacks an effective mechanism for ensuring that HACCP plans are adequate. Even where FSIS conducts a Food Safety Assessment or Hazard Analysis Verification procedure in response to evidence of a deficient HACCP plan (e.g. failure to meet performance standards), the agency does not specify what corrective or enforcement measures should be taken when deficiencies are found.

By specifying a standardized statistical method to measure the efficacy of microbial controls in establishments, FSIS will give inspectors a valuable tool to head off "process control" problems

²⁸ Messens W, Vivas-Alegre L, Bashir S, Amore G, Romero-Barrios P, Hugas M. 2013. Estimating the public health impact of setting targets at the European level for the reduction of zoonotic Salmonella in certain poultry populations. Int J Environ Res Public Health 10:4836–4850. doi:10.3390/ijerph10104836.

²⁹ Hwang and Singer. "Survey of the U.S. Broiler Industry Regarding Pre- and Postharvest Interventions Targeted To Mitigate Campylobacter Contamination on Broiler Chicken Products."

³⁰ Consumer Federation of America. "The Promise and Problems of HACCP: A Review of USDA's Approach to Meat and Poultry Safety," available at: <u>https://consumerfed.org/pdfs/150424_CFA-HACCP_report.pdf</u>

before they lead to an illness outbreak. Indeed, a better definition of "process control" is needed beyond just the context of regulating *Salmonella* in poultry. In recent years, the agency has granted line speed and other waivers to meat and poultry establishments on the condition that they "maintain process control," but struggled to articulate what that condition means. Parameters around process control will also harmonize the agency's regulations with requirements of major retailers, such as Walmart, which for years now have specified parameters for poultry suppliers to demonstrate "process control," such as scientific validations of interventions "between pre-scald to post-chill that will consistently produce, at a minimum, a cumulative 4-log reduction of *Salmonella*."³¹

Conclusion

The public health burden of *Salmonella* illness from poultry in the United States today is not inevitable. It is a market failure. Were poultry companies responsible for the medical bills, sick leave pay, compensation for pain and suffering, and all of the other costs associated with each case of salmonellosis attributable to their products, they would dedicate more resources to prevent these illnesses, including on the farm. But despite advances in whole genome sequencing and other surveillance technologies, the vast majority of *Salmonella* infections still cannot be traced back to a specific food, and so the poultry companies need not internalize the full costs associated with their production practices. This creates an unlevel playing field for companies that want to protect their customers from illness. The reforms outlined in the Proposed Framework have the potential to correct this market failure, and FSIS should act expeditiously to develop and implement them.

Sincerely,

Thomas Gremillion Director of Food Policy Consumer Federation of America

³¹ Walmart, Commodity Specific Requirements, available at: <u>https://one.walmart.com/content/food-</u> safety/en_us/food-safety-requirements/unlabeled-or-exclusive-products/u-s--grown-and-supplier-imported1.html