

# SAFE FOOD COALITION

1620 I Street, NW, Suite 200, Washington, DC 20006 202-939-1010

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January 17, 2025

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

**Re: Proposed determination that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products contaminated with certain *Salmonella* levels and serotypes are adulterated within the meaning of the Poultry Products Inspection Act (Docket No. FSIS-2023-0028)**

Dear Dr. Esteban,

The undersigned members of the Safe Food Coalition appreciate the opportunity to submit these comments. As several of our groups indicated in our previous letter requesting an extension of the comment period on this rulemaking, we applaud USDA's Food Safety and Inspection Service (FSIS) for undertaking this important rulemaking process. By implementing long-needed reforms to limit the presence of dangerous *Salmonella* in poultry, anchored to enforceable finished product standards, this rulemaking will greatly improve public health and avert the tragedy of preventable foodborne illness for families across the country. More comprehensive standards, however, will better conform to the Poultry Products Inspection Act's (PPIA) adulteration provision, and achieve a greater public health benefit. In particular, we urge FSIS to define enforceable regulatory standards that prohibit poultry contaminated with harmful levels of *Salmonella* species generally, and to expand the list of targeted serotypes.

**Poultry producers are subjecting consumers to unreasonable foodborne illness risk.**

Today in the U.S., *Salmonella* contaminated chicken causes 195,634 illnesses and costs Americans \$6.9 billion each year.<sup>1</sup> This public health burden has changed little over the past two decades, despite revolutionary technological advances like whole genome sequencing, which have led to dramatic reductions in illness caused by pathogens in other foods. Indeed, reported *Salmonella* infections in CDC FoodNet sites have actually increased since 1996, when FSIS issued its Hazard Analysis and Critical Control Point Systems / Pathogen Reduction (HACCP/PR) final regulation for all meat and poultry plants.<sup>2</sup> This increase starkly contrasts with the experience in Europe, where

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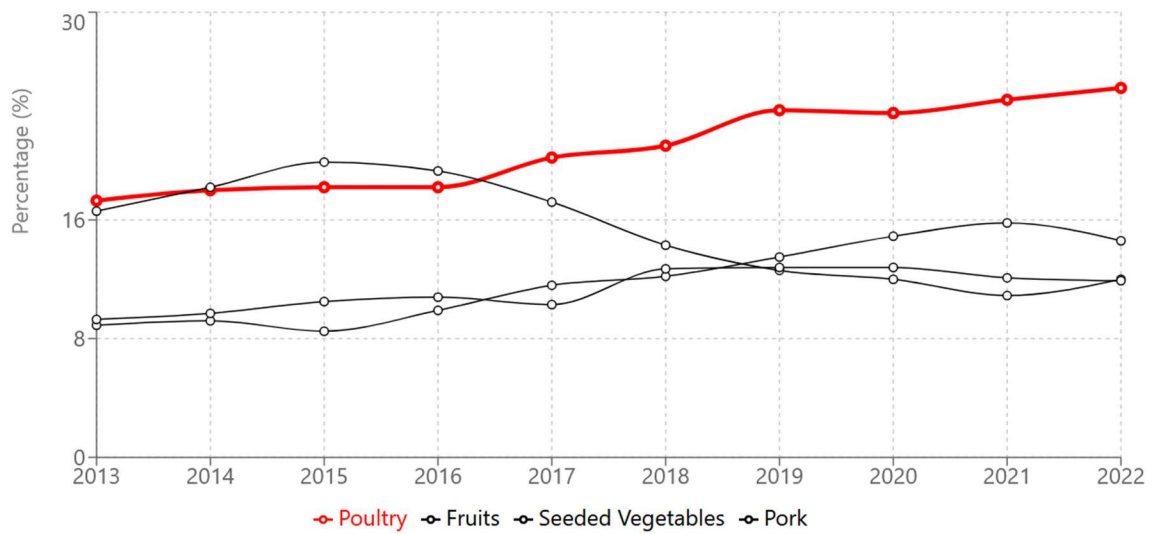
<sup>1</sup> Scharff, R. L. (2020). Food Attribution and Economic Cost Estimates for Meat- and Poultry-Related Illnesses. *Journal of Food Protection*, 83(6), 959–967. <https://doi.org/10.4315/JFP-19-548>

<sup>2</sup> See <https://www.cdc.gov/foodnetfast/>

*Salmonella* infections declined over 50% since reforms there targeted dangerous *Salmonella* serotypes, a “major success story.”<sup>3</sup>

While the overall rate of *Salmonella* illness in the U.S. population has changed little in recent decades, the proportion of illnesses attributable to poultry has grown. Chicken alone now accounts for more *Salmonella* infections each year than any other single food category. According to Interagency Food Safety Analytics Collaboration (IFSAC) reports, chicken’s contribution to *Salmonella* infections grew 89% between 2013 and 2022 (the latest year for which estimates are available).<sup>4</sup> The graph below shows the combined *Salmonella* illness burden of chicken and turkey poultry products, compared to other food categories over time.

**Salmonella Infections by Food Source (2013-2022)**



Source: Interagency Food Safety Analytics Collaboration Annual Reports on Foodborne Illness Source Attribution Estimates (2013-2022), available at: <https://www.cdc.gov/ifsac/php/data-research/annual-reports/>

<sup>3</sup> *Control of Salmonella*. European Commission. [https://food.ec.europa.eu/food-safety/biological-safety/food-borne-diseases-zoonoses/control-salmonella\\_en](https://food.ec.europa.eu/food-safety/biological-safety/food-borne-diseases-zoonoses/control-salmonella_en)

<sup>4</sup> See 2013, 2015, 2017, 2019, and 2021 reports available at: <https://www.cdc.gov/ifsac/php/annual-reports/index.html>

**The performance standard-based system of regulating *Salmonella* in poultry is dysfunctional.**

As awareness of the preventable harms caused by poultry has grown, so too has the consensus in favor of reform. In 2021, many of the undersigned consumer groups joined poultry industry experts, food safety researchers, and current and former state and federal regulators in the Coalition for Poultry Safety Reform, premised on the belief that the “current system for regulating poultry safety is broken.”<sup>5</sup> In 2022, the Coalition wrote to Deputy Under Secretary for Food Safety Sandra Eskin that “FSIS should adopt enforceable product standards” because the current *Salmonella* performance standards “are not enforceable, fail to identify the products that are highest risk, and fail to ensure food safety from farm to fork.”<sup>6</sup>

FSIS has labored under these unenforceable, poorly targeted, incomplete standards for over two decades. The 1996 HACCP regulation replaced requirements aimed at closely regulating the conditions of the slaughter process with a system that gave greater flexibility, measuring the success of sanitation controls according to their effectiveness in reducing *Salmonella* contamination on the end products. Since 2001, the “performance standards” designed to measure that control have suggested limits on how often an establishment’s product should test positive for *Salmonella*. Yet the standards merely “suggest” limits because, shortly after they were introduced and FSIS sought to enforce them, the industry successfully challenged the agency’s authority to require compliance in the court case of *Supreme Beef Processors, Inc. v. U.S. Dept. of Agriculture*.<sup>7</sup> The industry’s legal challenge to the standards’ enforceability has left FSIS with a performance-based regulatory system for which it cannot require the specified performance.

With no threat of enforcement, much of industry does not comply with the performance standards. According to recent data, 14.5%, 9.5%, 45.2%, and 25% of whole chicken, chicken parts, ground chicken, and ground turkey processing establishments, respectively, fall into “category 3,” those which “have exceeded the maximum allowable percent positive during the most recent completed 52-week moving window.”<sup>8</sup> The list of failing establishments includes such household names as Tyson, Foster Farms, Perdue, Butterball, and Cargill.<sup>9</sup>

The system’s dysfunctional character has come into focus periodically when an especially virulent *Salmonella* strain has caused a nationwide outbreak. As a work around, FSIS determined in 2012 that poultry products contaminated with *Salmonella* are considered adulterated if they are “associated with an illness outbreak.”<sup>10</sup> But the burden of proof required under this rule is absurdly

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<sup>5</sup> *The coalition for poultry safety reform welcomes the launch of a new USDA effort to reduce Salmonella illnesses associated with poultry products.* (2021, October 19). Center for Science in the Public Interest. <https://www.cspinet.org/news/coalition-poultry-safety-reform-welcomes-launch-new-usda-effort-reduce-salmonella-illnesses>

<sup>6</sup> Coalition for Poultry Safety Reform letter to FSIS Deputy Undersecretary for Food Safety Sandra Eskin. (Feb. 2, 2022), available at: [https://www.afdo.org/wp-content/uploads/2022/09/Letter-to-FSIS\\_-Clean\\_2\\_2\\_22.pdf](https://www.afdo.org/wp-content/uploads/2022/09/Letter-to-FSIS_-Clean_2_2_22.pdf) (emphasis added).

<sup>7</sup> 275 F.3d 432, 440 (5th Cir. 2001).

<sup>8</sup> *Salmonella Verification Testing: October 29, 2023 through October 26, 2024.* (2024, November 20). Food Safety and Inspection Service. <http://www.fsis.usda.gov/news-events/publications/salmonella-verification-testing-october-29-2023-through-october-26-2024>

<sup>9</sup> *Id.* (data for October 29, 2023 through October 26, 2024).

<sup>10</sup> FSIS. HACCP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and Related Agency Verification Procedures Notice, 77 Fed. Reg. 72686-01 (Dec. 6, 2012),

high. Often, in order to meet this bar, regulators have determined that bacteria from an unopened package of poultry in a foodborne illness outbreak victim's refrigerator must match the isolates obtained from a case patient sample. But since few consumers happen to have such a specimen in their kitchen, FSIS has seldom invoked this largely irrelevant "product standard."<sup>11</sup>

### **The USDA mark of inspection demands meaningful final product standards.**

Notwithstanding many of their members' representations that FSIS poultry safety system "is broken," in recent public meetings, some industry trade group representatives have insisted that "prevalence based performance standards work," and that the agency should merely tweak them to flag poultry with high levels of *Salmonella* contamination.<sup>12</sup> But such an approach would only perpetuate, if not exacerbate, the ongoing failure to reduce *Salmonella* illnesses from poultry.

For one, under the *Supreme Beef* decision, so long as FSIS leaves in place "Salmonella's status as a non-adulterant," the agency has dubious legal authority to enforce a *Salmonella* performance standard based system, whether it measures establishments' "performance" based on how often samples test positive for the presence of *Salmonella* species, particular serotypes, or high loads of *Salmonella* contamination.<sup>13</sup> By contrast, product standards fall well within the agency's discretion. The PPIA requires that FSIS put its mark of inspection on poultry intended for sale in interstate commerce, signaling to consumers that a product is not "adulterated." FSIS can, and should, define poultry with dangerous *Salmonella* contamination as adulterated, following the model it used to ban *E.coli* O157:H7 from ground beef in the 1990s, a successful initiative that led to dramatic declines in illness from that pathogen in the years that followed.

Product standards directly address foodborne illness risk to consumers. And precisely because failure to comply with them results in costly recalls, they incentivize industry to invest in food safety, including by devising more accurate and rapid testing technologies. Industry trade group representatives have argued that a lack of sufficiently rapid and accurate testing will thwart product standards.<sup>14</sup> However, industry similarly questioned the feasibility of protecting consumers from beef products contaminated with *E.coli* O157:H7, even going so far as to sue FSIS after the agency issued its interpretive rule declaring *E.coli* O157:H7 an adulterant in raw ground beef. In that lawsuit, the industry plaintiffs alleged that "testing is prohibitively expensive and that the industry is already doing all it can to control the problem."<sup>15</sup> Just as FSIS' determination that *E.coli* O157:H7 is an

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<https://www.federalregister.gov/documents/2012/12/06/2012-29510/haccp-plan-reassessment-for-not-ready-to-eat-comminuted-poultry-products-and-related-agency>

<sup>11</sup> See, e.g. FSIS. "Jennie-O Turkey Store Sales, Inc. Recalls Raw Ground Turkey Products due to Possible Salmonella Reading Contamination," (Dec. 21, 2018), <https://www.fsis.usda.gov/recalls-alerts/jennie-o-turkey-store-sales-inc.-recalls-raw-ground-turkey-products-due-possible> (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-patient's home. The patient tested positive for Salmonella Reading and the samples from the case-patient and from the ground turkey are closely related genetically.")

<sup>12</sup> See Meeting Transcript, FSIS public meeting re Product Standards and the Salmonella Framework for Raw Poultry Products (Dec. 3, 2024), p.7 (Testimony of Ashley Peterson, National Chicken Council), available at: <https://www.fsis.usda.gov/shared/audio/transcript-12-3-24-Public-Meeting-Product-Standards-Salmonella-Framework-Raw-Poultry-Products.pdf> ["Meeting transcript"]

<sup>13</sup> 275 F.3d 432, 441.

<sup>14</sup> See Meeting Transcript *supra* note 12.

<sup>15</sup> *Texas Food Indus. Ass'n v. Espy*, 870 F. Supp. 143, 148 (W.D. Tex. 1994).

adulterant spurred the market to supply affordable, rapid testing for that pathogen, so too will FSIS' adulteration determination for dangerous *Salmonella* lead to innovation in testing for particular loads and serotypes of the bacteria.

### **FSIS has more than sufficient data to act now.**

This rule addresses a glaring externality in industrial poultry production. In a perfect world, each poultry processor would have to answer for every person sickened by its products. But this feedback loop is largely absent. According to CDC researchers, for every laboratory-confirmed *Salmonella* infection, over 29 cases go unreported.<sup>16</sup> Among those with a confirmed case, few identify the food vehicle that caused the infection; onset of symptoms may not occur until days, in some cases nearly a week, after exposure.<sup>17</sup> As a result, so long as a company's products do not cause an outbreak, few economic repercussions follow from investing as little as possible in food safety and reducing dangerous *Salmonella* contamination.

At some point, the cost of reducing food safety risk in poultry exceeds what consumers would be willing to pay for safer product. But there is no reason to believe, and no evidence to suggest, that we are anywhere near that point. To the contrary, a vast literature now indicates that FSIS has ample justification to step in to level the playing field. Two peer reviewed risk assessments support this proposal, along with a peer reviewed risk profile, both informed by extensive FSIS sampling data and literature review. The National Advisory Committee on Microbiological Criteria in Foods (NACMF) has deliberated and published a report detailing the abundant evidence in support of reforms.<sup>18</sup> And the agency has allowed more than 160 days of comment on the rule.

FSIS should continue to gather quality data, independently and through the companies it regulates, to understand *Salmonella* contamination in poultry as well as possible. But the promise of future insights should not deter the agency from acting now on the information it has to protect consumers from a significant market failure.

### **Product standards should target both highly virulent serotypes and harmful levels of contamination with *Salmonella* spp.**

The proposed rule defines as adulterated chicken or turkey products that “contain any type of *Salmonella* at or above 10 colony forming units/per milliliter or gram . . . **and** contain any detectable level of at least one of the *Salmonella* serotypes of public health significance identified for that commodity.”<sup>19</sup> This proposed standard creates incentives for companies to target the specified serotypes with interventions such as vaccines, which FSIS may not have authority to otherwise require. Insofar as companies cannot eradicate the specified strains, or rapidly test for them, the proposed standard creates incentives to adopt interventions such as in-plant anti-microbial treatments to drive down overall *Salmonella* levels below 10 CFU/g. But product that does not

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<sup>16</sup> *Individual Salmonella Serotypes Reports*. (2020, February 14). Centers for Disease Control and Prevention. [https://archive.cdc.gov/www\\_cdc\\_gov/salmonella/reportspubs/salmonella-atlas/serotype-reports.html](https://archive.cdc.gov/www_cdc_gov/salmonella/reportspubs/salmonella-atlas/serotype-reports.html)

<sup>17</sup> *Salmonella infection*. (2022, April 29). Mayo Clinic. <https://www.mayoclinic.org/diseases-conditions/salmonella/symptoms-causes/syc-20355329>

<sup>18</sup> Response to Questions Posed by the Food Safety and Inspection Service: Enhancing Salmonella Control in Poultry Products. (2024). *Journal of Food Protection*, 87(2), 100168. <https://doi.org/10.1016/j.jfp.2023.100168>

<sup>19</sup> *Salmonella Framework for Raw Poultry Products*. (2024, August 7). Regulations.Gov. <https://www.regulations.gov/document/FSIS-2023-0028-0007> (emphasis added)

contain one of the specified serotypes is not considered adulterated, no matter how high the *Salmonella* load.

To adequately protect consumers, limits could apply to products contaminated with *Salmonella*, regardless of whether they contain “high virulence” strains. According to the agency’s risk assessment, the probability of illness from eating poultry parts contaminated with 100 or 10 cfu/g of “low virulence” *Salmonella* is comparable to the risk associated with eating the same products contaminated with 10 or 1 cfu/g, respectively, of “high virulence” *Salmonella*.<sup>20</sup> In other words, *Salmonella* spp. generally, regardless of serotype, can quickly become an unreasonable public health risk. FSIS could protect consumers from that risk by designating a protective limit on *Salmonella* spp. contamination, while applying a lower threshold to define as “adulterated” products contaminated with “high virulence” strains of *Salmonella*.

### **FSIS should expand the list of targeted serotypes**

The agency correctly seeks to target the most dangerous *Salmonella* variants. Less than 100 of the 2,500 *Salmonella* serotypes identified by scientists cause most cases of salmonellosis in people.<sup>21</sup> The current regulatory system’s failure to differentiate between high and low virulence *Salmonella*, with the rare exception of a widespread outbreak, creates perverse incentives to adopt interventions that may actually work against reducing salmonellosis risk, such as by vaccinating birds against *S. Kentucky*,<sup>22</sup> a common but largely innocuous serotype.<sup>23</sup> The agency’s efforts to designate virulence on the basis of genetic factors, rather than serotype alone, is an ambitious and worthy undertaking, which should contribute to further refinements in poultry product standards as the science linking human illness risk to particular genetic factors continues to evolve. For now, however, FSIS has translated a genetic virulence analysis into a designation of three “high virulence” serotypes, and the process has resulted in significant gaps.

According to the proposed rule, CDC has estimated that the serotypes of public health significance represent only 66 percent of outbreaks and 68 percent of outbreak-associated illnesses in the past five years.<sup>24</sup> These serotypes omit *Salmonella* *Infantis*, whose human illness burden has grown rapidly in recent years, both in the United States and abroad.<sup>25</sup> According to CDC’s latest

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<sup>20</sup> *Quantitative Risk Assessment for Salmonella in Raw Chicken and Raw Chicken Products*. July 2024. Food Safety and Inspection Service, United States Department of Agriculture, p. 88, Table 29.

[https://www.fsis.usda.gov/sites/default/files/media\\_file/documents/Chicken\\_SRA\\_July2024.pdf](https://www.fsis.usda.gov/sites/default/files/media_file/documents/Chicken_SRA_July2024.pdf)

<sup>21</sup> *Get the Facts about Salmonella*. (2023, October 26). U.S. Food and Drug Administration; FDA.

<https://www.fda.gov/animal-veterinary/animal-health-literacy/get-facts-about-salmonella>

<sup>22</sup> Redweik, G. A. J., Stromberg, Z. R., Van Goor, A., & Mellata, M. (2020). Protection against avian pathogenic *Escherichia coli* and *Salmonella Kentucky* exhibited in chickens given both probiotics and live *Salmonella* vaccine. *Poultry Science*, 99(2), 752–762. <https://doi.org/10.1016/j.psj.2019.10.038>

<sup>23</sup> Kim, M., Barnett-Neefs, C., Chavez, R. A., Kealey, E., Wiedmann, M., & Stasiewicz, M. J. (2024). Risk Assessment Predicts Most of the Salmonellosis Risk in Raw Chicken Parts is Concentrated in Those Few Products with High Levels of High-Virulence Serotypes of *Salmonella*. *Journal of Food Protection*, 87(7), 100304. <https://doi.org/10.1016/j.jfp.2024.100304>

<sup>24</sup> *Salmonella Framework for Raw Poultry Products*. (2024, August 7). Regulations.Gov. <https://www.regulations.gov/document/FSIS-2023-0028-0007>

<sup>25</sup> Mattock, J., Chattaway, M. A., Hartman, H., Dallman, T. J., Smith, A. M., Keddy, K., Petrovska, L., Manners, E. J., Duze, S. T., Smouse, S., Tau, N., Timme, R., Baker, D. J., Mather, A. E., Wain, J., & Langridge, G. C. (2024). A One Health Perspective on *Salmonella enterica* Serovar *Infantis*, an Emerging Human Multidrug-Resistant Pathogen. *Emerging Infectious Diseases*, 30(4). <https://doi.org/10.3201/eid3004.231031>

estimates, *S. Infantis* was the second-ranking serotype in causing salmonellosis outbreaks linked to chicken between 2017 and 2021.<sup>26</sup> A single strain of multidrug-resistant *Salmonella* *Infantis*, denominated REPJFX01, has caused at least 11 outbreaks and 3,442 reported illnesses since it was first detected in 2012.<sup>27</sup> The strain is widespread in the chicken industry, and alone causes an estimate “11,000-17,000 illnesses per year,” according to internal CDC estimates.<sup>28</sup> The list of “high virulence” serotypes includes other questionable omissions, such as *Salmonella* Heidelberg, which was responsible for one of the largest *Salmonella* outbreaks linked to chicken in recent memory.<sup>29</sup>

During the public meetings, some commenters questioned whether FSIS placed undue emphasis on earlier outbreak data in designating its “high virulence” serotypes. Other commenters pointed out that the agency’s methodology for “clustering serotypes by virulence gene markers” may have allowed some more virulent serotypes, particularly *S. Enteritidis*, to drive the results and inappropriately exclude *S. Infantis*, while including other, less harmful serotypes whose genomes more closely resemble that of *Enteritidis*. Agency officials, in turn, indicated during one public meeting that questions of feasibility related to testing and vaccinations may have influenced the choice of serotypes designated as “high virulence.”<sup>30</sup>

In the final rule, FSIS should continue to designate certain serotypes as “high virulence,” with more stringent final product standards applying to products contaminated with those strains. However, the agency should more fully explain the factors that account for its choice of “high virulence” serotypes, and expand the list of these serotypes to cover a larger proportion illnesses caused by *Salmonella* in chicken and turkey. Finally, given the alarming growth of *S. Infantis* infections among humans and its widespread colonization of chicken flocks, the agency should reconsider its exclusion of that serotype from the standards applicable to chicken.

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<sup>26</sup> *BEAM Dashboard*. (2024, November 19). Centers for Disease Control. <https://www.cdc.gov/nceid/dfwed/BEAM-dashboard.html>

<sup>27</sup> *Data Summary: Persistent Strain of Salmonella Infantis (REPJFX01)*. (2024, December 16). Centers for Disease Control. <https://www.cdc.gov/salmonella/php/data-research/repjfx01.html>

<sup>28</sup> Simon, B. Y., Michael Grabell, Irena Hwang, Mollie. (2021, October 29). *America’s Food Safety System Failed to Stop a Salmonella Epidemic. It’s Still Making People Sick*. ProPublica. <https://www.propublica.org/article/salmonella-chicken-usda-food-safety>

<sup>29</sup> Gieraltowski, L., Higa, J., Peralta, V., Green, A., Schwensohn, C., Rosen, H., Libby, T., Kissler, B., Marsden-Haug, N., Booth, H., Kimura, A., Grass, J., Bicknese, A., Tolar, B., Defibaugh-Chávez, S., Williams, I., Wise, M., & Team, S. H. I. (2016). National Outbreak of Multidrug Resistant *Salmonella* Heidelberg Infections Linked to a Single Poultry Company. *PLOS ONE*, 11(9), e0162369. <https://doi.org/10.1371/journal.pone.0162369>

<sup>30</sup> See “Reducing Salmonella in Poultry Meeting Summary,” George Washington University Milken Institute, School of Public Health (October 30, 2024).

## Conclusion

Consumer confidence in food safety has declined significantly in recent years, reaching a ten-year low according to the International Food Information Council, which surveys consumers each year.<sup>31</sup> Concerns about microbiological contamination have risen against a backdrop of high-profile outbreaks, and general distrust in the food regulatory system. FSIS has an important opportunity to restore trust with this rulemaking, adopting reforms supported by both industry leaders and public health advocates. The agency should act expeditiously to take full advantage of this opportunity.

Sincerely,

Center for Food Safety  
Center for Science in the Public Interest  
Consumer Federation of America  
Consumer Reports  
Food & Water Watch  
Government Accountability Project  
Institute for Food Safety and Nutrition Security  
National Consumers League  
Stop Foodborne Illness

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<sup>31</sup> *Consumer Confidence In Food Safety On The Decline: Unpacking Concerns Over Ingredients & Trust*. (2024, September 19). International Food Information Council. <https://ific.org/media-information/press-releases/food-safety/>