



As the voice of people affected by foodborne illness, we collaborate with partners in academia, the food industry, and government to prevent foodborne illness. We advocate for effective food safety policy and facilitate culture change to increase food safety.

Stop Foodborne Illness

November 22, 2024

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

Re: STOP Foodborne Illness Comment on Poultry Safety (Docket No. FSIS-2023-0028)

Dear Dr. Esteban,

On September 27, 2024, STOP Foodborne Illness (“STOP”) joined with other consumer and public interest groups in expressing our appreciation for [USDA’s August 7, 2024, proposal](#)¹ to set enforceable finished product standards for *Salmonella* in raw poultry.

We also requested an extension of the comment period to allow time for USDA consideration and stakeholder dialogue on a more inclusive approach to setting *Salmonella* standards that we think is essential to protect consumers. The public meetings that USDA is planning for December 3 and 5 are good first steps in that process.

In anticipation of those meetings, we explain here why, from the perspective of STOP and its constituents, a more inclusive approach to *Salmonella* standards is needed both to fulfill the statutory food safety mission Congress has given USDA and to meet the reasonable expectations of consumers. Poultry is one of the staples of the American diet. Consumers necessarily depend on USDA for its safety. More is needed for USDA to meet its obligation.

We focus in this comment on the proposed standards for chicken. The same concerns and arguments apply to turkey.

Summary

USDA’s August 7 *Salmonella* proposal represents an important milestone in setting enforceable safety standards and applying them where they matter to consumers: on poultry products themselves, rather than on the poultry processing establishments. Nevertheless, the rule is too narrow in its protections for consumers because it includes enforceable standards for just three of the many pathogenic serotypes of *Salmonella* and addresses only 43% of poultry-related *Salmonella* illnesses.

¹ USDA/FSIS, “*Salmonella* Framework for Raw Poultry Products,” 89 Federal Register 64678 *et seq.* (August 7, 2024).



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Under the USDA proposal, poultry companies would still be allowed to ship products contaminated with other dangerous *Salmonella* serotypes not covered by the proposal. While the rule would create powerful incentives for vaccination or other means to control the three types of *Salmonella* specified, it could lead to neglect of prevention programs covering *Salmonella* species generally. Chicken contaminated with dangerous serotypes, like Infantis and Heidelberg, could continue to flow into commerce bearing the USDA mark of inspection, no matter how high the level of contamination. Consumers would remain at significant, preventable risk.

STOP believes that USDA and poultry companies have a joint responsibility to consumers to do everything they reasonably can to make poultry safe. To fulfill its share of that responsibility and carry out its statutory mission, USDA should broaden its approach to setting enforceable standards. It should give real meaning to the mark of inspection by: (1) expanding enforceable standards for specific serotypes beyond the three it originally proposed, and (2) complementing serotype standards with an enforceable *Salmonella* species (“spp.”) standard that incentivizes continuing improvement in poultry safety practices.

STOP’s Role and Motivation

[STOP Foodborne Illness](#) is a consumer advocacy organization that works with illness victims and their families to support stronger food safety policies and practices in government and the food industry. STOP and its constituents were among those who [petitioned USDA](#) in January 2021 to initiate rulemaking to set enforceable standards for *Salmonella* in poultry and later joined with a consumer-industry-academic coalition [in a letter to the Secretary of Agriculture](#) calling on USDA to set enforceable finished product standards for *Salmonella* in poultry.

STOP seeks collaboration to improve food safety wherever possible with government, industry, academia, and other consumer groups. At the heart of STOP’s mission is building strong food safety cultures that motivate continuous improvement in government and industry programs. STOP’s [Alliance to Stop Foodborne Illness](#) pursues that goal through collaboration with 20 major food manufacturers, marketers, and associations.

STOP’s work is inspired by its constituents, including Amanda Craten and her son [Noah](#). As a two-year old toddler, Noah was one of many victims of the 2013 outbreak caused by *Salmonella* Heidelberg in chicken. This dangerous form of *Salmonella* wracked Noah’s small body with infection, resulting in a brain abscess that required surgery and caused permanent damage that Noah will struggle all his life to overcome.

To prevent other [tragedies like this](#), reform of USDA’s poultry safety system is badly needed and long overdue. *Salmonella* in poultry is one of the [leading contributors to foodborne illness](#) in the United States, which makes it all the more difficult to explain to families like Noah’s why current and proposed USDA policies leave companies legally free to ship, with USDA’s imprimatur, raw



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poultry that is contaminated with dangerous forms of *Salmonella* known to cause illness, including Heidelberg.

That's why STOP applauds USDA for recognizing the safety of poultry as [one of its top priorities](#). And it's why STOP is committed to supporting USDA in getting it right. Opportunities for significant reform in USDA's food safety policies do not come often.

The Promise USDA's Mark of Inspection Makes to Consumers

When consumers go to the meat case in the grocery store, they see something they don't see anywhere else in the store. They see the USDA "mark of inspection" affirming that the product has been inspected by USDA and passed for sale to consumers under the uniquely comprehensive food safety mandate of USDA's meat and poultry inspection laws.

Under the Poultry Products Inspection Act (PPIA), USDA has issued extensive regulations directing virtually all aspects of how poultry processors manage their operations for food safety, including sanitation to prevent contamination with harmful bacteria.² USDA inspectors examine *every* chicken and turkey carcass passing through slaughter plants and inspect *every* processing plant every day. Based on this, the mark of inspection is affixed to the product label.

What is it reasonable for consumers to expect from USDA's comprehensive system of regulation? We believe the PPIA itself answers that question.

When Congress enacted the PPIA in 1957, the official congressional findings underpinning the new law expressed the law's strong consumer protection intent:

"It is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, *not adulterated*, and properly marked, labeled and packaged."³

Congress further declared that the failure to prevent adulteration and provide this food safety protection would cause "injury to consumers." Based on the intent of Congress and USDA's comprehensive oversight of poultry production, we believe *consumers have every right and reason to expect a credible assurance of safety based on prevention of conditions that can put consumers at risk*.

² 9 CFR Parts 412-442.

³ 21 USC 451.



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To fulfill its consumer protection intent and provide this assurance, Congress established a *de facto* pre-market approval system for poultry based on USDA making the finding, as a condition for granting the mark of inspection, that every poultry product it inspects is *not* adulterated. This is different from the burden of proof USDA bears if it seeks to stop sale to consumers of poultry that is already in the market. To pass inspection, the responsibility of processors is to present for inspection poultry products that are *not* adulterated, and USDA has extensive legal authority to define the conditions under which processors have met that responsibility.

USDA's Legal Authority

Congress enacted in the PPIA three distinct definitions of adulteration under which USDA is empowered to decide that the safety of poultry has been adequately assured. All relate to *preventing* the possibility of harm to consumers.

One definition addresses contamination of poultry with harmful substances, like pathogenic bacteria, and deems poultry “adulterated” and thus unlawful if it is contaminated at a level that “may render it injurious to health.”⁴ USDA properly invoked this prevention-oriented “may render” language in its August 7 proposal as the basis for proposing enforceable standards for specific serotypes of *Salmonella* that have been linked to outbreaks of illness in the past and may be in the future.

The second adulteration definition on which USDA has relied is even more sweeping in its consumer protection and preventive intent. It declares poultry adulterated if for any reason it is “unsound, unhealthful, unwholesome, or otherwise unfit for food.”⁵ In May 2024, USDA cited both this and the first definition in its final determination that breaded stuffed chicken products are adulterated if they contain 1 cfu/g or more of *Salmonella*, regardless of serotype.⁶ USDA cites both the first and second definitions as the basis for its proposed serotype-specific standards.

USDA did not invoke in its August 7 proposal a third definition of “adulteration” in the PPIA, which relates to the sanitary conditions under which poultry has been produced. However, this definition provides important authority as well. The PPIA deems poultry adulterated and thus unlawful if it is produced “under insanitary conditions....whereby it *may have been rendered injurious to health*” [*emphasis added*].⁷ By clarifying in its recent proposals that *Salmonella* is an adulterant in raw poultry, USDA may now establish a quantitative standard for *Salmonella* spp. as an objective basis for verifying the processor’s success in preventing insanitary conditions that “may” render poultry injurious to health.

⁴ 21 USC 453(g)(1).

⁵ 21 USC 453(g)(3).

⁶ USDA/FSIS, “Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products,” 89 Fed. Reg. 35033 (May 1, 2024)

⁷ 21 USC 453(g)(4).



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In sum, USDA has the legal tools and the congressional mandate to provide consumers a credible assurance of safety based on prevention of conditions that can put consumers at risk.

Consumers expect and deserve that. It's the promise made by the mark of inspection.

Delivering on the Promise by Including a *Salmonella* spp. Standard

Following are public health and policy reasons for establishing a quantitative *Salmonella* spp. standard as part of a comprehensive strategy to fulfill the prevention purpose of the PPIA.

Value of Serotype-Specific Standards and Limits of Risk Assessment

The need and rationale for an enforceable *Salmonella* spp. standard flows from USDA's proposal to set enforceable standards for three serotypes, namely, in the case of chicken, Enteritidis, Typhimurium, and I 4,[5],12:i. These proposed product standards mark an important shift away from today's unenforceable *Salmonella* "performance standards" for facilities and toward enforceable product standards that determine whether USDA can grant the mark of inspection and allow the sale of raw poultry.

An important benefit of serotype-specific standards is that they focus industry prevention and USDA verification efforts on the types of *Salmonella* that contribute most to the burden of illness. This is in keeping with the public health principle and necessity to target and prevent known risks and to verify success.

Limiting the proposed standards to three serotypes, however, does not provide the breadth of consumer protection Congress intended. According to the data USDA cites in Table 12 of USDA's Risk Profile, the three serotypes USDA proposed to cover – Enteritidis, Typhimurium, and I 4,[5],12:I – account for only 43% of chicken-related *Salmonella* illnesses and hospitalizations associated with chicken carcasses and parts.⁸ The USDA proposal to limit its standards to these three serotypes thus overlooks a majority of the illnesses that epidemiological studies attribute to *Salmonella* in chicken.

This limited coverage seems based almost entirely on risk assessments cited by USDA.⁹ STOP respects the role risk assessment can play in understanding the differing impacts of specific serotypes

⁸ FSIS/USDA, "Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry" (July 2024), https://www.fsis.usda.gov/sites/default/files/media_file/documents/Risk_Profile_for_Pathogenic_Salmonella_Subtypes_in_Poultry.pdf.

⁹ FSIS/USDA, "Quantitative Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products" (July 2024), https://www.fsis.usda.gov/sites/default/files/media_file/documents/Chicken_SRA_July2024.pdf.



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on the total burden of illnesses associated with *Salmonella* in chicken. We also understand that Executive Order 12866 requires USDA to submit significant proposed rules to the White House Office of Management and Budget for review of the proposal's risks and benefits. Risk assessment can inform that review, but USDA's heavy reliance on risk assessment to limit its proposal to three serotypes is not legally required and conflicts with the consumer protection intent and prevention mandate expressed by Congress in the PPIA.

In setting its standards for *Salmonella*, USDA should reframe its approach in keeping with the mandates and authorities of the PPIA and sound public health policy. It should recognize the inherent inability of current risk assessment data and methods to fully and accurately assess the risks and benefits of possible changes to regulations. USDA should include all relevant data sources and methods in its analysis, especially epidemiologic data on the estimated number of illnesses caused by various *Salmonella* serotypes and the estimated proportion of each linked to poultry.

Most importantly, USDA should prioritize its statutory and public health responsibility to prevent "injury to consumers" from more than a select few of the illness-causing serotypes.

Why a *Salmonella* spp. Standard is Needed and Feasible

Complementing a broader set of serotype-specific standards with an enforceable *Salmonella* spp. standard is both necessary to achieve the consumer protection objective of the PPIA and feasible.

A *Salmonella* spp. standard would serve three important purposes:

- Fill the gap in public health and consumer protection. USDA can't fulfill its PPIA mandate by leaving over half of the *Salmonella* illnesses associated with poultry unaddressed and consumers vulnerable to foreseeable but preventable injury. An enforceable *Salmonella* spp. standard would fill that gap by creating regulatory accountability and incentive for processors to comprehensively minimize *Salmonella* contamination.
- Avoid a counter-productive incentive for processors to de-emphasize comprehensive *Salmonella* prevention programs. If regulatory accountability is limited to three or some other limited number of serotypes, processors will have a strong incentive to target only those serotypes. The cost-conscious poultry industry would have no better regulatory incentive than it has today to invest in maintaining and continuously improving comprehensive *Salmonella* prevention programs.
- Give the mark of inspection meaning as an assurance of safety. Consumers do not expect perfection or zero risk but they reasonably see the mark of inspection as an assurance that USDA and the poultry industry are doing everything they reasonably can to make poultry



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safe. By establishing more comprehensive accountability for prevention via a *Salmonella* spp. standard, USDA can deliver on that promise with regard to this leading cause of foodborne illness.

USDA's past actions and sampling data demonstrate that a rigorous standard for *Salmonella* spp. is both needed and feasible.

In May 2024, USDA finalized its determination that the presence of any type of *Salmonella* in breaded, stuffed chicken at or above 1 cfu/g adulterates the product. It found that this level poses "a serious public health concern" based in part on the low infectious dose of *Salmonella*. The fundamental feasibility of this standard was not seriously challenged by industry, and USDA explained how its verification sampling would be adjusted to avoid implementation of the standard disrupting the operations of the processing facility. Given USDA's decision that a 1 cfu/g *Salmonella* spp. standard is needed and feasible for breaded stuffed chicken, the Department bears a substantial burden to explain why such a standard is not needed and feasible to protect consumers from *Salmonella* contamination of other poultry products.

The data on the prevalence and levels of *Salmonella* in poultry that USDA presented in its August 7 proposal in Table 3 confirm the feasibility of a 1 cfu/g standard.¹⁰ FSIS reports that 3.08% of chicken carcasses test positive for *Salmonella* spp., but only 9% of the positive samples are contaminated at a level of 1 cfu/g or more. This means that well less than one-third of 1% (0.28%) of sampled chicken carcasses are exceeding the 1 cfu/g level. The percentage of chicken parts testing positive for *Salmonella* at or above 1 cfu/g is even smaller (0.13%). The percentage for comminuted chicken is 3%.

These numbers are a sign of progress in controlling *Salmonella* in chicken processing. They are also a demonstration of what is achievable under current good manufacturing practices and sanitation programs. This makes 1 cfu/g a reasonable benchmark for a processor's success in meeting its statutory obligation to offer for inspection poultry products that are not adulterated and thus merit the mark of inspection.

STOP urges USDA to engage stakeholders in dialogue on the need for a *Salmonella* spp. standard and how best to structure and implement it in conjunction with serotype-specific standards. The goal should be *Salmonella* standards that maximize consumer protection, incentivize continuing innovation, and provide accountability for processors doing everything they reasonably can to make poultry safe.

Such a standard is needed to protect consumers. It's feasible. And it's what consumers want.

¹⁰ 89 Fed. Reg. at 64701.



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In a [2021 poll of registered voters](#) that surveyed Republicans, Democrats, and Independents, 87% said they were aware of *Salmonella* illnesses due to contaminated poultry. And, on a broadly bipartisan basis, 86% favored USDA adopting enforceable poultry product standards to protect against *Salmonella* illnesses caused by contaminated poultry.

America Can Afford Safe Poultry

A senior USDA official recently said publicly that USDA must balance food safety protection with concerns about industry and consumer costs and consumer access to food (food security) as affected by food waste. STOP agrees that the feasibility of implementation of new rules is a legitimate factor for USDA to consider, but the PPIA does not contemplate USDA subjectively balancing harm to the health of consumers and cost to industry or impact on food access.

Moreover, STOP is unaware of any example of food safety reform at either USDA or the Food Administration that has actually had the impacts of concern to the USDA official. And the possibility of such impacts is not borne out by the facts of poultry safety regulation.

Regulatory Cost and Benefit

Like all food companies, poultry processors have varying degrees of market incentives to invest in food safety practices. Also as a result of past USDA regulatory requirements, poultry companies have in place significant physical capital and human resources dedicated to food safety. Thus, as is commonly the case, the incremental cost of food safety regulatory improvements for poultry is small in relation to the potential benefits to consumers and the health system.

The Regulatory Impact Analysis (RIA) that USDA¹¹ conducted for its *Salmonella* proposal estimated the aggregate annual cost of compliance by industry to range from \$3.31 million to \$32.25 million. The USDA analysis also said that the estimated economic cost of chicken-related *Salmonella* illnesses to individuals and society is \$2.8 billion.

For sake of argument, if we take USDA's high-end cost estimate and double it to \$65 million for STOP's more inclusive *Salmonella* standards, and then very conservatively assume that our preferred standard eliminates only 10% of the economic burden of illness, the ratio of societal benefit to cost would still be greater than 4 to 1.

Food Costs

As is typically the case with new food safety rules, the impact on food costs of new measures to strengthen prevention of poultry-related *Salmonella* illnesses would be negligible. USDA says that

¹¹ 89 Fed. Reg. at 64722 *et seq.*



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43 billion pounds of chicken are produced annually in the United States. Conservatively assuming \$65 million in compliance costs, as outlined above, the average cost per pound would be less than two-tenths of one cent per pound (\$0.0015). This is unlikely to have any detectable effect on consumer costs.

Food Waste and Food Security

Under enforceable finished product standards for raw chicken, lots that are found through testing to fail the standard would need to be diverted to a cooked use or be disposed of in some other way. Based on USDA's data, and conservatively assuming that all of the chicken exceeding a 1 cfu/g *Salmonella* spp. standard is disposed of rather than being diverted to cooking, less than one-third of 1% (0.28%) of chicken carcasses and even less (0.13%) of chicken parts would be removed from commerce. This is insignificant compared to USDA's Economic Research Service estimate that [22% of all poultry produced in the United States is wasted](#).

Food security is a real problem for low income consumers, but the problem is not caused by efforts to make poultry safer.

For these reasons, STOP is concerned about the suggestion that USDA's *Salmonella* standards must balance food costs and food security concerns against health risks to consumers.

We are further concerned that the balancing of these factors was not discussed in the *Federal Register* publication of USDA's proposed new standards, even though they seem to have influenced what USDA proposed. Without fair notice of the basis for USDA's decision, the public is unable to provide informed comment. If USDA is going to consider and balance such non-statutory factors, it needs to explain the legal, policy, and factual basis for that balancing.

Concern for Low Volume Poultry Processors

STOP recognizes that low-volume poultry processors can face different challenges in implementing new requirements. STOP thus supports USDA providing these smaller companies whatever technical assistance, regulatory flexibility, and subsidies they need to feasibly produce safe poultry.

Low-volume firms account for a tiny fraction of the country's chicken supply (0.08% of carcasses and 0.1% of parts).¹² In the interest of consumer protection and public health, regulatory provisions that are necessary and feasible for larger facilities should not be compromised based on what may not be feasible for low-volume operators.

¹² RIA, Tables 20 and 22, 89 Fed. Reg. at 64730 and 64731.



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Conclusion

Since the 1992-1993 Jack-in-the Box outbreak, USDA has been on a long journey when it comes to reducing pathogenic bacteria in raw meat and poultry. USDA has moved from its pre-Jack-in-the-Box stance of disclaiming responsibility for minimizing such contamination and the illnesses it causes to today's recognition that preventing illnesses from pathogenic bacteria is central to USDA's food safety mission and its aspiration to be a public health agency.¹³ To fulfill that mission and aspiration – and meet legitimate consumer expectations – USDA should return to its statutory roots and reframe its approach around the public health principle of prevention. This is how consumers can have the protection Congress intended. In the long run, providing a credible assurance of safety will benefit not only consumers but poultry processors and the food system at large.

Sincerely,

Mitzi D. Baum
CEO
STOP Foodborne Illness

¹³ From the USDA website: “Food Safety and Inspection Service (FSIS) is the USDA public health agency responsible for protecting the public’s health by ensuring the safety of meat, poultry, and egg products.”
<https://www.usda.gov/our-agency/about-usda/mission-areas>