



Food Safety and Inspection Service  
U.S. DEPARTMENT OF AGRICULTURE

# Proposed Regulatory Framework to Reduce *Salmonella* Illnesses Attributable to Poultry



# Introduction

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The Food Safety and Inspection Service (FSIS) is considering a regulatory framework for a new strategy to control *Salmonella* in poultry products and more effectively reduce foodborne *Salmonella* infections linked to these products. The framework under consideration has been shaped by months of information-gathering and discussions with a wide range of stakeholders, researchers, and scientists.

At the same time, FSIS is gathering scientific evidence relevant to the approaches presented in this framework. The [National Advisory Committee on Microbiological Criteria for Foods \(NACMCF\)](#) has been charged with providing guidance on what types of microbiological criteria FSIS might use to better prevent *Salmonella* infections associated with poultry products. FSIS is also completing a risk profile for pathogenic *Salmonella* subtypes in poultry and is collaborating on [quantitative risk assessments](#) for *Salmonella* in chicken and turkey that will address key risk management questions associated with this framework. FSIS also [expanded its exploratory sampling program for young chicken carcasses](#) to generate microbial data to help inform future policies and is transitioning from using presence-based tests to [tests that quantify the amount of all \*Salmonella\* cells](#).

While awaiting results from these activities, FSIS is sharing this framework to identify the key elements that the Agency is currently considering as part of a new regulatory strategy. FSIS is soliciting feedback from stakeholders on all of the elements of the framework—both at a public meeting and in written comments submitted to the meeting docket in the *Federal Register*—before moving forward with any proposed changes to regulations or other actions.



# Background

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FSIS is the public health agency in U.S. Department of Agriculture (USDA) whose mission is to ensure that meat, poultry, and egg products are safe, wholesome, and properly labeled. As a public health agency, we continually review and optimize our policies and practices to best protect consumers from foodborne illness. For example, past illness outbreaks, such as those caused by Shiga toxin-producing *E. coli* (STEC) in beef and *Listeria monocytogenes* in ready-to-eat products, have prompted the Agency to respond with regulations and policies that resulted in substantial decreases in human illnesses due to those pathogens.

However, while FSIS has had a goal of reducing *Salmonella* infections linked to poultry products for some time, we have not seen the same level of success with our current approach. FSIS has used the U.S. Department of Health and Human Services' [Healthy People](#)<sup>1</sup> target to set pathogen reduction goals over the past few decades, but the 2010 and 2020 Healthy People targets for a reduction in *Salmonella* infections from all sources were not met.<sup>2</sup> The Healthy People 2030 target is to reduce *Salmonella* infections to national case rate of no more than 11.5 per 100,000 consumers per year. To reach the 2030 target, illnesses must be reduced by 25%. Although this target is for *Salmonella* infections from all sources, FSIS has adopted the same target and aims to reduce *Salmonella* infections linked to FSIS-regulated products by 25%.

Despite FSIS sampling data showing reductions in *Salmonella* contamination in poultry products, our current approach to *Salmonella* has not led to a demonstrable reduction in *Salmonella* infections. For example, during the five-year period from 2017 to 2021, the number of chicken samples in which FSIS detected *Salmonella* decreased by more than 50%. However, the estimated rate of human *Salmonella* infections from all sources has remained consistent over the last two decades, with an estimated 1.35 million infections in the U.S. each year. The [most recent report from the Interagency Food Safety Analytics Collaboration](#) estimates that over 23% of foodborne *Salmonella* illnesses are attributable to poultry consumption—almost 17% from chicken and over 6% from turkey.

<sup>1</sup>The Healthy People initiative guides national health promotion and disease prevention efforts to improve the health of the nation. Led by the U.S. Department of Health and Human Services (HHS), Healthy People has identified, for every decade since 1980, science-based objectives with targets to monitor progress and motivate and focus action.

<sup>2</sup>The Healthy People 2010 and 2020 targets were 6.8 and 11.4 *Salmonella* infections per 100,000 population, respectively. Between 2010 and 2017, infection rates averaged 15.8 *Salmonella* infections per 100,000 population.



# FSIS' Proposed Framework

## Testing For:

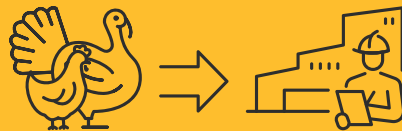
● *Salmonella*

● Indicator organisms

This document outlines the regulatory framework under consideration for a new strategy that we anticipate should reduce the number of *Salmonella* infections linked to poultry consumption. The framework consists of three components that, together, support a comprehensive approach to controlling *Salmonella* in poultry.

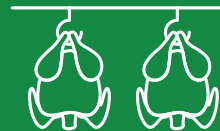
### The three components are:

#### COMPONENT 1



Requiring incoming flocks be tested for *Salmonella* before entering an establishment

#### COMPONENT 2



Enhancing establishment process control monitoring and FSIS verification

#### COMPONENT 3



Implementing an enforceable final product standard

\*Under this proposed framework, testing for *Salmonella* would also occur during the same steps in production as testing for indicator organisms.



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# Component 1: Requiring incoming flocks be tested for *Salmonella* before entering an establishment

## Testing For:

- *Salmonella*
- Indicator organisms

FSIS is considering requiring establishments to characterize *Salmonella* as a hazard reasonably likely to occur at receiving and that incoming flocks be tested for *Salmonella* before entering an establishment. Under this approach, the flock would have to meet a predetermined target for *Salmonella* at receiving, which may be industry-wide or establishment-specific, and the establishment must demonstrate that its subsequent process will be effective in reducing *Salmonella* so that the product will meet the final product standard.

## COMPONENT 1



## COMPONENT 2



## COMPONENT 3



## Component 1: Requiring incoming flocks be tested for *Salmonella* before entering an establishment (continued)

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*Salmonella* enters an establishment in and on the birds. The goal of this component is to incentivize use of preharvest interventions that reduce the level of incoming *Salmonella* contamination or mitigate the risk of a particular serotype entering the establishment.

FSIS is currently evaluating whether *Salmonella* is a hazard reasonably likely to occur at receiving and if establishments must, therefore, address *Salmonella* at receiving as part of their Hazard Analysis and Critical Control Point (HACCP) plans. HACCP, which is FSIS' prevention-based approach to food safety, requires that an establishment's hazard analysis include food safety hazards that can occur before, during, and after entry into the establishment. *Salmonella* is a significant microbial hazard in raw poultry and for this reason, FSIS is contemplating a requirement that all establishments monitor *Salmonella* levels or serotypes in incoming flocks. Establishments would be expected to have procedures in place to address the incoming *Salmonella* levels.

This component of the framework under consideration would also require that each flock received at the establishment is accompanied with documentation demonstrating that the birds were tested for *Salmonella* before slaughter and documenting the *Salmonella* levels or serotypes. FSIS would use periodic *Salmonella* testing at rehang to verify this documentation.

Additionally, the agency is considering that if a flock's documented *Salmonella* load does not meet the predetermined target at receiving, then the establishment could implement corrective actions and additional interventions necessary to reduce the *Salmonella* load and meet the final product standard, such as processing a more contaminated flock at the end of the day ("logistical slaughter"). This assessment could be based on the documented ability of an establishment's processes to consistently decrease the *Salmonella* load.

Under this approach, FSIS does not intend to require industry to adopt any specific pre-harvest interventions but would allow flexibility for industry to adopt the practices that are most effective at controlling *Salmonella* in each particular operation. Establishments would be encouraged to work with their suppliers and contractors to ensure they are implementing best practices in reducing the *Salmonella* hazard in breeding facilities, hatcheries, grow out, and throughout transport.



# Component 2: Enhanced Establishment Process Control Monitoring and FSIS Verification

## Testing For:

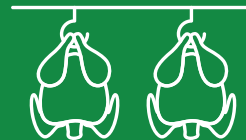
- *Salmonella*
- Indicator organisms

To ensure that poultry slaughter establishments are effectively controlling *Salmonella* throughout their operations, FSIS may propose to modify its current regulations to prescribe enhanced establishment monitoring procedures, including revised locations for multipoint sampling and use of a statistical approach to process control.

### COMPONENT 1



### COMPONENT 2



### COMPONENT 3



\*Under this proposed framework, testing for *Salmonella* would also occur during the same steps in production as testing for indicator organisms.



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## Component 2: Enhanced Establishment Process Control Monitoring and FSIS Verification (continued)

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The second component of this proposed framework builds on HACCP, FSIS' prevention-based approach to food safety. To ensure pathogen control throughout slaughter and processing operations, FSIS may modify the existing requirements for indicator organism testing for process control and establish additional parameters to better define the required analysis of the data. As part of the proposal, establishments may be required to test for indicator organisms (e.g., aerobic plate count [APC], Enterobacteriaceae). FSIS would consider production volume when determining the frequency that establishments must collect samples.

FSIS is considering the following modifications to the regulations related to preventing contamination throughout establishment operations:

**Changes in location for multipoint sampling:** FSIS may propose requiring that the pre-chill location at which establishments must conduct sampling for indicator organisms should be at rehang. The requirement to sample at post-chill would remain unchanged. Specifying that establishments will sample at rehang would standardize the paired microbial data generated by establishments and enable FSIS to improve instructions to FSIS in-plant personnel on how to verify establishments' process control.

**Use of statistical process control:** FSIS is also considering requiring that establishments use a standardized statistical approach to process control. Requiring establishments to use the same statistical process-control method will standardize the microbial data definition of process control at a particular establishment and ensure that establishments generate and monitor data that lead to supportable results. A standard definition of process control would also enable FSIS in-plant personnel to identify and take consistent action if an establishment fails to identify or respond to loss of process control.





# Component 3: Enforceable Final Product Standard

## Testing For:

- *Salmonella*
- Indicator organisms

FSIS is assessing whether certain levels or types of *Salmonella* on raw poultry product present an elevated risk of causing human illness such that they should be considered adulterants. As a result, the Agency is considering implementing a final product standard or standards to ensure that product contaminated with *Salmonella* that is likely to make people sick is not sold to consumers.

### COMPONENT 1



### COMPONENT 2



### COMPONENT 3



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## Component 3: Enforceable Final Product Standard (continued)


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To protect public health, FSIS regulations should prevent product with high levels of contamination and/or specific serotypes from entering commerce. This goal would be accomplished by declaring *Salmonella* an adulterant. In doing so, FSIS would rely on criteria that were applied to STECs. These criteria are: consideration of serotypes associated with human illness; low infectious dose; severity of human illnesses; and typical consumer cooking practices.

Consistent with its approach to determining the status of certain STECs as adulterants in specific raw beef products, FSIS is considering whether there are specific *Salmonella* and raw poultry product pairs that have characteristics that distinguish them from other raw poultry products contaminated with *Salmonella*, such that *Salmonella* at certain levels and/or types of *Salmonella* should be considered as an adulterant when present in that specific raw poultry product. For example, FSIS will soon be releasing a proposal that *Salmonella* meets the criteria to be considered an adulterant in not-ready-to-eat (NRTE) breaded and stuffed raw chicken products, an action that will allow the Agency to better protect public health<sup>1</sup>.

At the same time, FSIS is exploring if a single product standard for *Salmonella* in all raw poultry products may be appropriate. From a consumer's perspective, exposure to a quantity and/or serotype of *Salmonella* likely to make them sick is a key risk factor for illness that may be consistent across product types. In developing a final product standard, FSIS would evaluate existing scientific support, stakeholder feedback, and access to test results to support timely identification of *Salmonella* serotypes or pathogenicity factors. FSIS could also take into account documentation presented with a flock and make a regulatory distinction between vaccinated flocks and non-vaccinated flocks in the context of a final product standard. In light of existing testing technology, the Agency is considering initially developing an enforceable final product standard based on quantification rather than a "zero-tolerance" standard for *Salmonella*.

This final product standard would promote *Salmonella* reduction by establishments and incentivize upstream practices that reduce *Salmonella*, including on-farm and transportation practices. As noted above, the interventions at slaughter and processing must demonstrate that they are capable of achieving the final product standard.

<sup>1</sup>FSIS [will soon release a proposed notice of determination](#)  declaring that NRTE breaded and stuffed raw chicken products that contain *Salmonella* at levels of 1 colony forming unit (CFU) per gram or higher are adulterated.



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## Component 3: Enforceable Final Product Standard (continued)

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FSIS is authorized to use any enforcement tools, up to and including retention to control product and suspension of inspection services, to address continued failures of the food safety system. Establishments would be able to further process the adulterated product to render it safe and wholesome or send it to another inspected establishment for further processing.

If an enforceable final product standard is ultimately finalized and implemented, FSIS is considering sunsetting the current *Salmonella* performances standards, including the moving window-approach to sampling and categorization of establishments.



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# Cross-cutting Issues

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## Testing for *Salmonella*

FSIS<sup>1</sup> goal is to use the most widely accessible, cost-effective, and rapid laboratory technology to determine as precisely as possible if a product is contaminated with *Salmonella* at a level and/or with a serotype more likely to cause human illness. FSIS is transitioning from using presence-based tests to tests that quantify<sup>1</sup> the amount of all *Salmonella* cells, because more highly contaminated product is more likely to cause human illness. Presently, quantification is the most practical testing technology that meets the above criteria, and that FSIS can rely on to help inform regulatory decision-making.

FSIS is considering targeting the serotypes of *Salmonella* found in poultry that are most likely to cause human illness. There are over 2,500 *Salmonella* serotypes, but current scientific evidence suggests that less than one hundred *Salmonella* serotypes are associated with human illness. After analyzing recent data on human illness from the Centers of Disease Control and Prevention and FSIS sampling results from chicken and turkey products, the Agency has decided to focus at this time on three serotypes: Enteritidis, Typhimurium, and Infantis<sup>2</sup>, which together cause 33% of all *Salmonella* illnesses. However, there are currently no available and affordable rapid tests to identify specific serotypes.

While FSIS aims to test for *Salmonella* serotypes to more accurately identify the products that are most likely to cause human illness, the ultimate goal is to identify the specific pathogenicity factors that make certain *Salmonella* within the same or different serotypes more likely to cause human illness. The technology to detect specific pathogenicity factors is not yet available; however, as the science and testing technology evolve to reliably identify serotypes and pathogenicity factors, FSIS expects to revise its testing requirements and, as appropriate, update the final product standard(s), to incorporate these developments.



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<sup>1</sup>On August 8, 2022, [FSIS laboratories began using quantification for Salmonella in raw poultry rinses](#). FSIS also plans to extend pathogen quantification technology to other samples.

<sup>2</sup>FSIS has developed an annual [Key Performance Indicator \(KPI\) related to the three Salmonella serotypes](#) (Enteritidis, Typhimurium, and Infantis) to help evaluate its success in meeting the performance objective. The KPI is the reduction in the proportion of poultry samples that are positive for the three *Salmonella* serotypes, including the rate of reduction, as compared to the baseline (the recent four years of FSIS sampling data).

## Cross-cutting Issues (continued)

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In addition to FSIS in-plant personnel, establishments would also test for *Salmonella* at rehang under this proposed framework. FSIS would require that samples are tested for *Salmonella* by a laboratory that is using methods equivalent to FSIS laboratory methods and that is accredited to ISO/IEC standard 17025:2017 or by the FSIS Accredited Laboratory Program.

### Small and Very Small Establishments

FSIS understands that low volume producing establishments have resource constraints that differ from those of larger volume, vertically integrated poultry establishments. To help alleviate the resource burden on small and very small establishments, FSIS is considering how to account for production volume and other additional options, as appropriate, to factor establishment size into our proposal. For example, if an establishment has a low production volume, then FSIS could instead collect and test the samples at rehang and post-chill to verify process control. FSIS will also consider if small and very small establishments require more time to meet regulatory requirements, necessitating a phased rollout of new requirements. Ultimately, FSIS standards and regulatory requirements will apply to all establishments, regardless of size.

### Data Sharing

In addition to the current requirement of establishments making sampling data available to FSIS in-plant personnel for review, FSIS is considering developing a process for establishments that are performing their own sampling and testing for *Salmonella* and indicator organisms at rehang and post-chill to regularly share this data with FSIS electronically. This data would allow FSIS scientists to develop tools and processes that aid FSIS in-plant personnel and establishments in monitoring trends and identifying food safety issues, allow for prioritization of FSIS resources, enhance the continual evaluation and refinement of FSIS systems and procedures, and support future policy development.



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## Looking Forward

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We know that there is no single solution to a complex problem like *Salmonella* contamination in poultry, so we need a comprehensive strategy with components that work together to reduce human illness. The Agency is confident that a new regulatory strategy based on this framework would help to reduce *Salmonella* illnesses associated with poultry and move us closer to the Healthy People 2030 goal.

FSIS will continue to seek stakeholder input on this proposed framework. The Agency will aim to be methodical and transparent in our approach as we move towards implementing a final strategy. We will publish a proposed notice of determination to declare *Salmonella* an adulterant in NRTE breaded and stuffed chicken products in 2022, and we intend to publish additional proposed rules and policies implementing this strategy in 2023, with the goal of finalizing any rules by mid-2024.



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## Reference Links

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National Advisory Committee on Microbiological Criteria for Foods (NACMCF): <https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021>

Constituent Update - July 1, 2022: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-july-1-2022>

Revised Young Chicken Carcass Exploratory Sampling Program: <https://www.fsis.usda.gov/policy/fsis-notice/44-22>

Constituent Update - August 5, 2022: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-august-5-2022-0>

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Healthy People: <https://health.gov/healthypeople>

Foodborne illness source attribution estimates for 2019 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States: <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf>

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[Footnote] USDA Announces Action to Declare Salmonella an Adulterant in Breaded Stuffed Raw Chicken Products: <https://www.usda.gov/media/press-releases/2022/08/01/usda-announces-action-declare-salmonella-adulterant-breaded-stuffed>

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[Footnote] USDA Announces Action to Declare Salmonella an Adulterant in Breaded Stuffed Raw Chicken Products: <https://www.usda.gov/media/press-releases/2022/08/01/usda-announces-action-declare-salmonella-adulterant-breaded-stuffed>

[Footnote] FY 2022-2026 Food Safety Key Performance Indicator: [https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/salmonella-0#:~:text=A%20key%20performance%20indicator%20\(KPI\),%202022%2D2026%20Strategic%20Plan.](https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/salmonella-0#:~:text=A%20key%20performance%20indicator%20(KPI),%202022%2D2026%20Strategic%20Plan.)

