

Understanding the Implications of the New FSIS Requirement for *Salmonella* in Not-Ready-To-Eat (NRTE) Breaded Stuffed Chicken Products

Executive Summary

The United States Department of Agriculture's Food Safety and Inspection Service (FSIS) has undertaken broad efforts to reduce *Salmonella* in raw poultry in the United States. As part of this initiative, the agency has made a final determination establishing *Salmonella* as an *adulterant* when present in levels of one colony-forming unit per gram (cfu/g) or higher in NRTE breaded stuffed chicken products. Impacted food businesses must adhere to the final determination by May 1, 2025. [1] This article highlights compliance criteria and steps businesses can take to ensure they are ready before the compliance date arrives and continue to comply thereafter.



Introduction

Salmonella is a significant public health concern, reportedly responsible for over one million illnesses annually.[2] NRTE breaded stuffed chicken products accounted for 5% of all chicken related Salmonellosis outbreaks despite accounting for only 0.15% of the total domestic chicken product supply.[3] NRTE breaded stuffed chicken products have been identified as a specific risk for *Salmonella* contamination due to the raw ingredients, manufacturing processes and consumer preparation practices employed.

FSIS and its public health partners reviewed the data from the 14 outbreaks occurring from 1998 – 2021 and found that industry measures taken to correct and prevent *Salmonella* in NRTE breaded stuffed chicken products were ineffective. [4] Additional information reviewed, including, in part, infectious dose and severity of illness, lead the agency to conclude that *Salmonella* should be categorized as an adulterant, much like toxin-producing *E. coli* strains in ground beef. This re-characterization led to the current policy change limiting *Salmonella* to not more than 1 cfu/g in NRTE breaded stuffed chicken products since higher concentrations were a sufficiently serious risk to human health, rendering the food unfit for human consumption.

The FSIS Requirement

The FSIS requirement mandates that all manufacturers of NRTE breaded stuffed chicken products implement measures to address *Salmonella* contamination. Specifically, the requirement stipulates the implementation of process control measures during production, including validated cooking instructions and microbial testing protocols. Additionally, establishments are required to reassess their Hazard Analysis and Critical Control Points (HACCP) plans to incorporate specific measures for controlling *Salmonella*.

Implications for the Food Industry

The introduction of the FSIS requirement has significant implications for producers of NRTE breaded stuffed chicken products. Compliance with the new regulations may necessitate investments in additional or new equipment to support sanitation and cold storage needs, robust trainings and quality assurance protocols. Failure to comply could result in regulatory penalties, product recalls, and damage to brand reputation.

Potential Impact on Recall Activity

FSIS will conduct verification procedures for *Salmonella* in NRTE breaded stuffed chicken products. The Summary of Comments and Responses section of the final determination states they will also provide advance notice before they

collect a product sample for verification testing to give the establishment enough time to hold or control the sampled lot. A lot of chicken confirmed positive for *Salmonella* must be diverted for another use or destroyed and cannot enter commerce as a NRTE breaded stuffed chicken product. This testing and verification protocol is aimed at preventing illness (and recall) but is predicated on the food business having the proper controls in place to identify and hold product until test results have demonstrated that it meets the regulatory requirement for *Salmonella*.

Strategies for Compliance

Plan now to be ready. To comply with the new requirement, manufacturers of NRTE breaded stuffed chicken products must apply a comprehensive approach to food safety management including:

1. **HACCP Plan Reassessment:** The determination of *Salmonella* as an adulterant at 1cfu/g or higher is a change that requires HACCP reassessment. Additionally, changes to production processes would also require revalidation by the FSIS implementation date.
2. **Establish Sampling Plans and Control Measures:** Food businesses must have a thorough understanding of the testing practices implemented by FSIS onsite. They should also ensure that internal sampling and testing procedures are robust to detect *Salmonella* at concentrations of regulatory significance and have control measures in place to prevent the unintentional release of *Salmonella* positive product.
3. **Employee Training:** Comprehensive training should be provided to employees on food safety protocols, hygiene practices, and the importance of adhering to established procedures.
4. **Supplier Verification:** Stringent supplier verification processes should be enacted to ensure the quality and safety of raw materials and ingredients used in production.
5. **Documentation and Recordkeeping:** Documentation and records must be maintained for all food safety activities, including testing results, corrective actions, and HACCP plan revisions.
6. **Continuous Improvement:** Food safety practices should be continuously monitored and evaluated to identify areas for improvement; corrective actions should be implemented as necessary.



Conclusion

The new FSIS requirement represents a significant step towards enhancing food safety standards and protecting public health. The defining of the *Salmonella* adulteration level and verification procedures should decrease the number of illnesses associated with *Salmonella* in NRTE breaded stuffed chicken products thus protecting public health. While compliance with these regulations may present some challenges for the food industry, proactive measures can mitigate risks and ensure consumer confidence. By prioritizing food safety and implementing robust control measures, manufacturers can navigate regulatory requirements effectively while maintaining the integrity of their products.

The food industry should take this opportunity to review areas of opportunity in their businesses and ensure that measures enacted to enhance food safety and protect public health are demonstrated to be effective.

How RQA Can Help

RQA stands ready to assist clients with customized options to create, review and enhance existing programs, training and food safety measures. With our extensive expertise and personalized approach, RQA is committed to supporting your organization in navigating the complexities of the new FSIS requirement and maintaining the highest standards of food safety and compliance. Contact us today to learn more about how we can assist you in achieving your food safety goals.

[1] *Salmonella in Not Ready-To-Eat Breaded Stuffed Chicken Products* 88 FR 35033

[2] *Survey of Not Ready-to-Eat Breaded stuffed and Stuffed Chicken Products for Salmonella*. Prepared by Laboratory Quality Assurance, Response, and Coordination Staff (LQARCS), Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture. June 2023.

[3] *Salmonella in Not Ready-To-Eat Breaded Stuffed Chicken Products*, op cit.

[4] Ibid.