## DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2025-0180]

Delayed Verification Sampling of Not Ready-to-Eat Breaded Stuffed Chicken Products

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Notice.

SUMMARY: FSIS is delaying the implementation of its verification activities related to Salmonella in not ready-to-eat (NRTE) breaded stuffed chicken product because of current testing method limitations. The current available test methods have accuracy limitations and have resulted in findings of false positives, especially at low levels of contamination.

**DATES:** FSIS will not begin sampling and testing NRTE breaded stuffed chicken or other verification activities related to that product on November 3, 2025.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

## SUPPLEMENTARY INFORMATION:

FSIS is the public health agency within the USDA responsible for ensuring that meat, poultry, and egg products are safe, wholesome, and properly labeled. In support of this mission, FSIS published a final determination in the **Federal** 

Register on May 1, 2024, declaring that NRTE breaded stuffed chicken products containing Salmonella at levels of 1 colony forming unit per gram (1 CFU/g) or higher are adulterated under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 453 (g) (1) and (3)) (89 FR 35033).

The final determination also announced FSIS' intention to implement sampling and testing of raw incoming chicken components used to produce NRTE breaded stuffed chicken products (88 FR 35033, 35050-35051). The testing program was initially set to begin on May 1, 2025. On April 11, 2025, FSIS extended the start date until November 3, 2025, to give the Agency additional time to finalize relevant guidance and instructions and to prepare laboratories for sampling and testing (90 FR 15433).

FSIS is now announcing a further delay in the implementation of verification sampling and testing and other verification activities for NRTE breaded stuffed chicken products. The available methods, including the reference method Most Probable Number (MPN) have accuracy limitations and have resulted in findings of false positives for Salmonella at 1 CFU/g; that is, there have been instances in which some product that in fact contains less than 1 CFU/g has tested positive.

Specifically, an evaluation study conducted by the Agricultural Research Service (ARS), tested source material for

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<sup>&</sup>lt;sup>1</sup> Schmidt, J. W., Wu, W., Harhay, D. M. & Wheeler, T. L., (2025) Identification of Chicken Component Samples Containing Salmonella Concentrations Greater Than or Equal to 1 CFU/g, Meat and Muscle Biology 9(1): 18993, 1-8. doi: https://doi.org/10.22175/mmb.18993.

NRTE breaded stuffed chicken, consistent with the sampling approach FSIS planned to use and found false positives. According to the study, under the specific method<sup>2</sup> FSIS planned to use, if a sample contains Salmonella at a concentration of 0.9 CFU/g, there is a 75% chance the method will report  $\geq$  1 CFU/g. If a sample is 0.5 CFU/g, there would still be a 40% chance the method would report  $\geq$  1 CFU/g. As a result, moving forward with the current testing method could lead to enforcement actions against products that are positive for Salmonella at less than 1 CFU/g and are, therefore, not adulterated based on the final determination published May 1, 2024 (89 FR 35033).

Applying a quantitative threshold (i.e., 1 CFU/g) for Salmonella in raw poultry is a regulatory approach the Agency has not taken before. FSIS has historically relied on presence or absence testing to verify whether product is adulterated based on pathogen testing (e.g., when testing ready-to-eat product for Listeria monocytogenes or Salmonella or applicable raw beef product for Shiga toxin-producing Escherichia coli).

Given the implications of enforcement based on a specific numerical threshold, FSIS needs additional time to reevaluate the testing program and determine its viability moving forward.

This delay reflects FSIS' commitment to ensuring that enforcement decisions are based on data that are not only

<sup>&</sup>lt;sup>2</sup>More information about the "Confidently Above Threshold" (CAT) method and the CAT method protocol (CAT-80) is available in the article in *Meat and Muscle Biology* at: https://doi.org/10.22175/mmb.18993.

scientifically valid, but also operationally reliable, reproducible, and fair. This delay also gives industry more time to implement controls to reduce *Salmonella* in source components used to produce NRTE breaded stuffed chicken.

At this time, FSIS is not establishing a new implementation date. The duration of the delay will depend largely on whether the Agency is able to refine the current method or develop and validate an alternative method that can be reliably applied in a regulatory context. FSIS will provide advance notice in the Federal Register before beginning verification sampling and testing activities.

## Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: https://www.fsis.usda.gov/federal-register.

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[FR Doc. 2025-21737 Filed: 12/1/2025 8:45 am; Publication Date: 12/2/2025]