

August 11, 2023

Dr. José Emilio Esteban

Under Secretary for Food Safety

U.S. Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue SW

Washington, DC 20250–3700

RE: Comment on Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products (Docket No. FSIS-2022-0013).

Dear Under Secretary Esteban,

Consumer Federation of America appreciates the opportunity to submit these comments on the United States Department of Agriculture’s Food Safety and Inspection Service’s (FSIS’) above-referenced proposed determination on *Salmonella* in Not-Ready-To-Eat (NRTE) Breaded Stuffed Chicken Products. As we indicated in our joint comments with Center for Science in the Public Interest, Stop Foodborne Illness, Center for Foodborne Illness Research and Prevention, Marler Clark LLP PS, and Consumer Reports, these final product standards will protect public health and represent a critical step towards formulating final product standards for *Salmonella* in a broader range of poultry products. CFA writes separately here to note that the law and facts support a more stringent standard than the 1 colony forming unit of *Salmonella* per gram of product sample (1 CFU/g) proposed by FSIS.

 Several factors support a more stringent standard. First, as FSIS has pointed out, large numbers of consumers—22% in the studies conducted by North Carolina State University at the behest of FSIS—are not aware that these products contain raw chicken, resulting in common occurrences of mishandling and undercooking. Second, the relationship between the number of *Salmonella* organisms consumed and the probability of illness is uncertain, and data from several outbreaks indicate that products in compliance with FSIS’ proposed standard may still expose consumers to an infectious dose of *Salmonella*. Finally, *Salmonella* bacteria continue to grow after a product has left the establishment, particularly when not kept cold, and so a margin of safety is appropriate. These factors support setting the standard for *Salmonella* in NRTE breaded stuffed chicken products below 1 CFU/gram, and ideally at zero, or below detectable amounts.

 The legal basis for taking such action is well established. The Poultry Products Inspection Act forbids the sale in interstate commerce of poultry products that have not been inspected by FSIS. Poultry products can only pass inspection and bear the USDA mark of inspection if they are not “adulterated.” As noted in our joint comments, USDA has never taken the position that *Salmonella* is “naturally occurring” and FSIS’ determination in this rulemaking that *Salmonella* is an “added substance” in NRTE breaded stuffed chicken products is well-supported. Accordingly, a NRTE breaded stuffed chicken product must not contain “any poisonous or deleterious substance which may render it injurious to health.” 21 U.S.C. 453 (g)(1).

The evidence cited in FSIS’ rule makes clear that any *Salmonella* contamination, not just *Salmonella* contamination exceeding the proposed standard of 1 CFU/gram, will render these products adulterated. In particular, the proposed rule cites five studies of foodborne outbreaks that “have shown that *Salmonella* can cause illness from exposure of 10 or fewer organisms per person,” and notes that, in general, the outbreak studies “suggest that exposure to a small number of *Salmonella* organisms can result in foodborne illness.” Nevertheless, FSIS concludes that “*Salmonella*, at a concentration lower than 1 CFU per gram, would not ordinarily render this type of NRTE commodity injurious to health or make them unwholesome, unhealthful or otherwise unfit for human food.”

 In support of this conclusion, FSIS reasons that “the average chicken portion in a NRTE breaded stuffed chicken product is approximately 70–88 grams,” “that most consumers will cook NRTE breaded stuffed chicken products to some degree, resulting in mitigation of the exposure to the pathogen,” and that “the average *Salmonella* median illness dose was 36 CFU,” in a 2010 study of outbreak data (Teunis et al).[[1]](#footnote-1) In other words, outbreak data indicates that 50% of a given population is likely to become ill from ingesting 36 CFU of *Salmonella*, and because compliance with a 1 CFU/gram standard will prevent NRTE breaded stuffed chicken products from delivering a dose of *Salmonella* in excess of this median illness dose—assuming consumers at least partially cook them and maintain them under appropriate conditions prior to cooking—products meeting that standard will not be considered adulterated.

This rationale raises two sets of concerns. First, foods contaminated with an amount of *Salmonella* just under the median illness dose will, by definition, cause nearly half of those who eat them to become ill. Indeed, according to Teunis et al., the median infection dose—the “infection ID50” or “number of organisms that need to be ingested to cause a 50% probability of infection,” as opposed to “illness,” is just 7 CFUs.[[2]](#footnote-2) This is significant in part because asymptomatic individuals infected with *Salmonella* may transmit illness to others.[[3]](#footnote-3) Even accepting, however, the propriety of exposing consumers to the median illness dose of *Salmonella*, a 1 CFU / gram standard will likely result in higher levels of exposure. Just as many consumers will cook the product in such a way as to reduce its bacterial load, many others may fail to keep the product adequately refrigerated, or otherwise mistakenly handle it in a way as to *increase* the bacterial load, under the mistaken impression that the product is already cooked, and thus effectively sterile.

As noted in the FSIS proposed rule, improved product labels have not succeeded in preventing widespread consumer confusion about the raw nature of these products.[[4]](#footnote-4) Facing similar confusion related to a slightly different category of NRTE breaded chicken products, Canadian health authorities announced new regulations in 2018 that now require processors to reduce *Salmonella* below detectable levels in these products.[[5]](#footnote-5) In the year following the announcement, the incidence of non-typhoidal *Salmonella* in Canadaplunged 19.6% compared with the previous 5 years, while cases increased in the U.S.[[6]](#footnote-6) A similar “zero tolerance” policy in the U.S. for *Salmonella* in NRTE stuffed and breaded chicken products would more fully protect consumers, and potentially achieve similarly outsized effects.

We appreciate the agency’s consideration of these comments.

 Sincerely,

 Thomas Gremillion

 Director of Food Policy

 Consumer Federation of America

1. Teunis P.F., et al., Dose-response modeling of Salmonella using outbreak data. Int J Food Microbiol, 2010. 144(2): p. 243–9. [↑](#footnote-ref-1)
2. *Id.* at 247. [↑](#footnote-ref-2)
3. *See, e.g.,* Steere AC, Hall WJ 3rd, Wells JG, Craven PJ, Leotsakis N, Farmer JJ 3rd, Gangarosa EJ. Person-to-person spread of Salmonella typhimurium after a hospital common-source outbreak. Lancet. 1975 Feb 8;1(7902):319-22. doi: 10.1016/s0140-6736(75)91221-0. PMID: 46457. [↑](#footnote-ref-3)
4. *See* Ford et al. “Salmonella Outbreaks Associated with Not Ready-to-Eat Breaded, Stuffed Chicken Products — United States, 1998–2022,” *Morbidity and Mortality Weekly Report* (May 5, 2023), *available at*: <https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7218a2-H.pdf> (noting that up to 75% of case patients in some outbreaks linked to NRTE breaded, stuffed chicken products, reported erroneously believing the products were cooked, even after the widespread adoption of labeling practices initiated to identify the products as raw and warn against preparing them in a microwave oven). [↑](#footnote-ref-4)
5. Morton VK, Kearney A, Coleman S, et al. Outbreaks of Salmonella illness associated with frozen raw breaded chicken products in Canada, 2015–2019. Epidemiol Infect 2019;147:e254. PMID:31436145 https://doi.

org/10.1017/S0950268819001432 [↑](#footnote-ref-5)
6. *See* Glass-Kaastra, *et al.* “Estimated Reduction in the Burden of Nontyphoidal Salmonella Illness in Canada Circa 2019.” FOODBORNE PATHOGENS AND DISEASE Volume 19, Number 11, 2022. DOI: 10.1089/fpd.2022.0045 (“hypothesizing that the zero tolerance rules for NRTE chicken products “are likely at least partially responsible for the decline in the [non-typhoidal *Salmonella*] incidence rate observed in Canada in 2019.”). [↑](#footnote-ref-6)