

July 27, 2023

Docket Clerk,
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).

To Whom it May Concern,

The undersigned groups respectfully submit these comments to the United States Department of Agriculture’s Food Safety and Inspection Service (FSIS) on the above-referenced proposed determination on *Salmonella* in Not-Ready-To-Eat (NRTE) Breaded Stuffed Chicken Products.¹

We support FSIS’s proposed determination that NRTE breaded stuffed chicken products that contain *Salmonella* at levels of 1 colony forming unit (CFU) per gram or higher are adulterated within the meaning of the Poultry Products Inspection Act (PPIA). The resulting final product standard will protect public health and the determination will assist the agency in formulating final product standards for *Salmonella* in other poultry products.

I. Background

Salmonellosis remains a key public health issue in the United States, sickening over 1.3 million people a year.² Despite efforts by FSIS and other public health agencies to reduce its incidence, the human salmonellosis rate has remained steady since 1996.³ Poultry products cause an estimated 23.2 percent of salmonellosis cases, more than any other FSIS-regulated product or any other category of food.⁴

Current USDA *Salmonella* regulations aim to reduce salmonellosis by assessing the effectiveness of an establishment’s *Salmonella* controls based on an allowed number of *Salmonella* positive product samples over a 52-week rolling window.⁵ A violation of these performance standards, which apply to whole carcasses, comminuted poultry, and parts, does not present sufficient cause, by itself, for FSIS to stop the establishment from producing poultry. Rather, failing establishments are subject to increased testing and food safety procedure

¹ *Salmonella* in Not-Ready-To-Eat Breaded Stuffed Chicken Products, 88 Fed. Reg. 26249. (April 28, 2023).

² *Salmonella*. Centers for Disease Control and Prevention. Updated July 13, 2023, 2022. Accessed July 18 2023. <https://www.cdc.gov/salmonella/index.html>.

³ Pathogen surveillance - *Salmonella*. Centers for Disease Control and Prevention. Updated June 28, 2023. Accessed July 18, 2023. <https://wwwn.cdc.gov/foodnetfast>.

⁴ Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2020 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes* and *Campylobacter* using multi-year outbreak surveillance data. Atlanta, GA and Washington D.C.: Centers for Disease Control and Prevention, Food and Drug Administration, Food Safety and Inspection Service; 2022. <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2020-report-TriAgency-508.pdf>

⁵ New Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule. 81 Fed. Reg. 7285. (February 2, 2016).

verification by FSIS inspectors.⁶ Product lots found to be contaminated are still allowed to be marketed. The performance standards also treat all *Salmonella* contamination equally,⁷ even though certain subtypes⁸ and amounts⁹ of *Salmonella* can be more harmful to public health than others.

In 2021, members of the undersigned groups petitioned USDA to reform its poultry *Salmonella* regulations due to the lack of progress in reducing human illnesses.¹⁰ The petition asked for enforceable final product standards that would disallow the sale to consumers of products with concerning types of *Salmonella* contamination, whether that be determined by the presence of specific *Salmonella* subtypes and/or the amount of *Salmonella*. The petition argued that final product standards would better motivate industry to control the most dangerous types of contamination and prevent products that are known to be particularly hazardous from reaching consumers.

Members of the undersigned groups also joined with leading industry members, food safety scientists, and regulators to form the Coalition for Poultry Safety Reform to push FSIS to modify its regulatory system to better address *Salmonella*.¹¹ Members of the Coalition agree that the current performance standards are not leading to the desired public health outcomes. The Coalition recommended that “FSIS should adopt enforceable product standards” to replace the current unenforceable performance standards for *Salmonella* in poultry.¹²

As detailed by FSIS in their explanation of the proposed determination, NRTE breaded and stuffed chicken products have been disproportionately associated with salmonellosis outbreaks associated with poultry compared to the amount of the products produced.¹³ These products are stuffed with ingredients like raw vegetables, butter, or other meats, heat-treated by producers to set the batter or breading on the exterior, and typically cooked from a frozen state by consumers.¹⁴ Outbreaks linked to NRTE breaded and stuffed chicken products represented five percent (14 total) of the chicken-associated outbreaks from 1998-2021 despite only accounting for 0.15 percent of the domestic chicken production.¹⁵

Past investigations and research indicate that the propensity of NRTE breaded and stuffed chicken products to sicken consumers stems from a high frequency of improper cooking practices like using microwaves (which is no longer recommended on labels) due, in part, to

⁶ Food Safety and Inspection Service. FSIS Directive 10,250.2 Performance Standards: *Salmonella* Verification Program for Raw Poultry Products. March 2, 2021. https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/10250.2_0.pdf

⁷ New Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule. 81 Fed. Reg. 7285. (February 2, 2016).

⁸ Pathogen surveillance – *Salmonella*, culture confirmed, top 10. Centers for Disease Control and Prevention. Updated June 28, 2023. Accessed July 18, 2023. <https://wwwn.cdc.gov/foodnetfast>

⁹ Akil L, Ahmad HA. Quantitative risk assessment model of human salmonellosis resulting from consumption of broiler chicken. *Diseases*. 2019;7(1):19. Published 2019 Feb 7. doi:10.3390/diseases7010019

¹⁰ Petition to establish enforceable standards targeting *Salmonella* types of greatest public health concern while reducing all *Salmonella* and *Campylobacter* in poultry, and to require supply chain controls. January 25, 2021. <https://downloads.regulations.gov/FSIS-2021-0003-0001/content.pdf>

¹¹ The coalition for poultry safety reform welcomes the launch of a new USDA effort to reduce *Salmonella* illnesses associated with poultry products. Center for Science in the Public Interest. Updated October 19, 2021. Accessed December 6, 2022. <https://www.cspinet.org/news/coalition-poultry-safety-reform-welcomes-launch-new-usda-effort-reduce-salmonella-illnesses>

¹² Coalition for Poultry Safety Reform letter to FSIS Deputy Undersecretary for Food Safety Sandra Eskin. (Feb. 2, 2022), available at: https://www.afdo.org/wp-content/uploads/2022/09/Letter-to-FSIS-Clean_2_2_22.pdf

¹³ *Salmonella* in Not-Ready-To-Eat Breaded Stuffed Chicken Products, 88 Fed. Reg. 26249. (April 28, 2023).

¹⁴ *Ibid.*

¹⁵ *Ibid.*

consumer perceptions that they are not fully raw products.¹⁶ In outbreaks from 2006 to 2021, a median of 27% of people who became ill from these products thought they were sold fully cooked or did not know whether they were sold raw or fully cooked.¹⁷

Labels for these products have undergone several rounds of changes by industry and FSIS to increase consumer awareness of their raw nature and encourage proper cooking practices. For example, industry complied with an April 2006 FSIS guidance recommending improved labeling to such products to better emphasize that they are raw and instruct consumers in cooking.¹⁸ Despite these changes, a meal preparation experiment conducted by FSIS in 2020 showed that even when the labeling included recommended features (i.e., the word “raw” was prominently displayed with icons and instructions in proper cooking), over a quarter of participants did not understand the products were raw.¹⁹ 23% of those who were only provided the label before preparation failed to use a meat thermometer.²⁰

In addition to confusion about the rawness, the nature of the products themselves, such as being potentially thicker than other chicken products and containing multiple ingredients, could make them more difficult to cook thoroughly compared to other raw poultry products.²¹ Outbreak questionnaire data showed that some persons who knew the product was raw and followed the cooking instructions still became ill.²²

II. We Support the Described Final Product Standard for NRTE Breaded Stuffed Chicken Products

As discussed supra, we previously advocated for final product standards for all poultry products. The creation of an enforceable final product standard for NRTE breaded stuffed chicken products will be an important step that will better protect the public from these products.

In the proposed determination announcement, FSIS describes the deficiency of the current unenforceable performance standards in effectively protecting consumers from risk attributable to these products.²³ To date, implemented measures under this regulatory system have failed to adequately control such risks. For example, in 2014, FSIS instructed inspectors at plants producing NRTE breaded stuffed chicken products to verify that the plant personnel appropriately considered the microbial hazards associated with these products and had documentation to support their resulting corrective actions. In 2016, FSIS ensured that its inspection and data analysis system explicitly tracked the facilities that produced NRTE breaded stuffed chicken products. The agency then conducted risk evaluations at each plant and evaluated whether they had changed food safety production practices in response to recent outbreaks. Even

¹⁶ Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products, 88 Fed. Reg. 26249. (April 28, 2023).

¹⁷ Ford L, Buuck S, Eisenstein T, et al. Salmonella Outbreaks Associated with Not Ready-to-Eat Breaded, Stuffed Chicken Products — United States, 1998–2022. *MMWR Morb Mortal Wkly Rep* 2023;72:484–487. DOI: <http://dx.doi.org/10.15585/mmwr.mm7218a2>

¹⁸ Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products, 88 Fed. Reg. 26249. (April 28, 2023).

¹⁹ Final Report: Food Safety Consumer Research Project: Meal Preparation Experiment on Raw Stuffed Chicken Breasts. Food Safety and Inspection Service. September 23, 2023. https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/fscrp-yr3-nrte-final-report.pdf

²⁰ *Ibid.*

²¹ *Ibid.*

²² Ford L, Buuck S, Eisenstein T, et al. Salmonella Outbreaks Associated with Not Ready-to-Eat Breaded, Stuffed Chicken Products — United States, 1998–2022. *MMWR Morb Mortal Wkly Rep* 2023;72:484–487. DOI: <http://dx.doi.org/10.15585/mmwr.mm7218a2>

²³ Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products, 88 Fed. Reg. 26249. (April 28, 2023).

with these industry-focused regulatory actions, in addition to the aforementioned labelling changes, outbreaks tied to these products occurred in 2008-9 (four outbreaks), 2013, 2014, 2015 (two outbreaks), 2016, and 2021.

There is recent evidence that a final product standard may have substantial benefits for public health. Canada implemented a system of standards covering breaded chicken products in 2019, though their regulations covered a different segment of the breaded products market (non-intact products like chicken nuggets).²⁴ The regulations require either specific processes that substantially reduce *Salmonella* loads (which would make them ready-to-eat products) or testing of the incoming chicken mixture or the raw final products with zero tolerance for *Salmonella* detection. While it is hard to determine causation from population foodborne illness data, the resulting decline in disease rates is a promising sign of the regulation's potential impact: in 2019, the incidence of illness caused by *Salmonella* Enteritidis, the serotype implicated in 89% of 2015-2019 outbreaks associated with breaded products in the country, was 33% lower than it was during 2015–2018 and 7% lower than during the baseline years 2010–2014.^{25,26}

We support the FSIS's tentative determination that these products would be adulterated if they contain above 1 CFU per gram. The threshold is supported by available dose-response studies and risk analysis. A previously published model that incorporated extensive historical outbreak data from all products indicated 36 CFU is an infectious dose for 50% of those exposed.²⁷ FSIS also estimated that partial cooking eliminates an estimated 68% of *Salmonella*.²⁸ A 70-88g serving size, which FSIS derived based on product formulations, would therefore result in an overall exposure per serving of 22-28 CFU if the NRTE product contained 1 CFU per gram prior to cooking, below the median infectious dose estimated from outbreak data.²⁹ Thus, a threshold of 1 CFU per gram should eliminate a substantial proportion of illnesses.

FSIS also ensured that the technology was available to test for this threshold in production conditions, estimating that negative results would be routinely available within 48 hours of sample shipment.³⁰ Testing timeframes could be further improved soon with new testing technology, such as expanded FSIS capabilities resulting from a 2022 agency quantification testing contract with the diagnostic testing company bioMérieux.³¹

A FSIS final product standard may also have greater benefit for people with low incomes. The labeling of NRTE breaded stuffed chicken products typically includes instructions to cook the product in an oven and no longer markets them as microwavable, a cooking practice that can lead to uneven cooking that does not thoroughly kill *Salmonella*.³² In 2022, CDC released study results detailing the demographics of people who prepare NRTE breaded stuffed chicken

²⁴ Government of Canada. *Salmonella control options in frozen raw breaded chicken products*. Updated April 1, 2019. Accessed July 7, 2023. <https://inspection.canada.ca/preventive-controls/meat/salmonella-in-frozen-raw-breaded-chicken/eng/1531254524193/1531254524999>

²⁵ Government of Canada. National Enteric Surveillance Program (NESP): annual summary 2019. Guelph, Canada: Government of Canada, Public Health Agency of Canada; 2020. https://publications.gc.ca/collections/collection_2021/aspc-phac/HP37-15-2019-eng.pdf

²⁶ Ford L, Buuck S, Eisenstein T, et al. *Salmonella Outbreaks Associated with Not Ready-to-Eat Breaded, Stuffed Chicken Products — United States, 1998–2022*. *MMWR Morb Mortal Wkly Rep* 2023;72:484–487. DOI: <http://dx.doi.org/10.15585/mmwr.mm7218a2>

²⁷ Teunis PF, Kasuga F, Fazil A, Ogdén ID, Rotariu O, Strachan NJ. Dose-response modeling of *Salmonella* using outbreak data. *Int J Food Microbiol*. 2010;144(2):243-249. doi:10.1016/j.ijfoodmicro.2010.09.026

²⁸ *Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products*, 88 Fed. Reg. 26249. (April 28, 2023).

²⁹ *Ibid.*

³⁰ *Ibid.*

³¹ *Ibid.*

³² *Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products*, 88 Fed. Reg. 26249. (April 28, 2023).

products and the appliances they use to prepare them.³³ The study showed that 54% reported using appliances or devices other than or in addition to ovens. The researchers found that oven use was lower among respondents with lower household income and those who lived in mobile or portable homes.

III. We Support the FSIS Determination that *Salmonella* is an “Added Substance”

FSIS relies in part on PPIA 21 U.S.C. 453(g)(1), in setting the proposed standard. Classifying *Salmonella* as an “added substance” or “naturally occurring” is important in determining when a product is “adulterated” within the meaning of (g)(1) because that provision requires a higher likelihood of harm for substances that are “not an added substance” (i.e., “naturally occurring”), than for added substances. Specifically, whereas a poultry product may be considered adulterated if “it bears or contains any poisonous or deleterious substance which may render it injurious to health;” in the case of a naturally occurring substance, the standard requires that the “quantity of such substance” must “ordinarily render it injurious to health.”³⁴

In the proposed determination, the agency summarized its position on *Salmonella* as an “Added Substance” as follows:

FSIS has traditionally viewed *Salmonella* as ‘naturally occurring’ in food animals. However ... FSIS has reassessed whether *Salmonella* should be considered as a ‘naturally occurring’ substance in NRTE breaded stuffed chicken products. Based on this assessment, the Agency has tentatively concluded that for these specific products, *Salmonella* is an added substance within the meaning of 21 U.S.C. 453(g)(1) of the [Poultry Products Inspection Act (PPIA)]. This tentative determination is limited to *Salmonella* in NRTE breaded stuffed chicken products. FSIS will reassess its traditional view of *Salmonella* as ‘naturally occurring’ in other poultry products in the near future as it develops a new strategy to control *Salmonella* in poultry products.³⁵

FSIS has proposed that *Salmonella* is an added substance in NRTE breaded stuffed poultry products, based on the fact that it is not normally found in the muscle tissue of healthy birds, and that “[f]urther processing presents various opportunities in which *Salmonella* that is present in certain parts of the bird may be added to interior edible muscle where *Salmonella* is not ordinarily found.”³⁶ The agency also cites data showing that further processed chicken parts and comminuted chicken have a higher incidence of *Salmonella* compared to carcasses, most likely because of cross-contamination. These facts provide compelling support for declaring that *Salmonella* is indeed “added” to these products by human intervention.

We agree with the agency that *Salmonella* is an added substance. In addition, since the agency has suggested that this determination reconsiders a prior interpretation of the statute, we urge the agency to clarify that its prior interpretation was not considered in any public deliberative process.

³³ Marshall KE, Canning M, Ablan M, Crawford TN, Robyn M. Appliances Used by Consumers to Prepare Frozen Stuffed Chicken Products — United States, May–July 2022. MMWR Morb Mortal Wkly Rep 2022;71:1511–1516. DOI: <http://dx.doi.org/10.15585/mmwr.mm7148a2>

³⁴ 21 U.S.C. 453 (g)(1).

³⁵ *Salmonella* in Not-Ready-To-Eat Breaded Stuffed Chicken Products, 88 Fed. Reg. 26249, 26251 (April 28, 2023).

³⁶ *Ibid.* at 26260.

The Supreme Court, under the well-known *Chevron* doctrine, will defer to reasonable agency interpretations of an ambiguous statute.³⁷ And while the court has clearly stated that “[a]n initial agency interpretation is not instantly carved in stone,”³⁸ some cases have suggested that a revised interpretation is subject to less deference.³⁹ Moreover, the level of formality with which an agency considers its interpretation can affect how much deference the interpretation is granted by the courts.⁴⁰ In light of these principles, we urge FSIS to clarify that its prior “traditional” interpretation was not informed by a public deliberative process, and that it is now providing a reasoned analysis of the issue on the public record for the first time.

The “added substances” language was adopted into the PPIA when that statute was passed in 1957, after the language had already been incorporated into the standard for adulteration in the Federal Meat Inspection Act of 1906 (FMIA) and Food, Drug, and Cosmetics Act of 1938 (FDCA). Early cases interpreting the phrase did not suggest the federal government took the view that *Salmonella* was “naturally occurring” in poultry products: if anything, the opposite was true. For example, a 1977 review of cases by the FDA⁴¹ identified a case, *United States v 1200 Cans, Pasteurized Whole Eggs*,⁴² in which the parties stipulated that *Salmonella* in frozen eggs, then an FDA-regulated product⁴³ was, in fact an “added poisonous or deleterious substance.” The district court affirmed that position in the opinion on that case, stating “[a]n infected chicken generally contaminates an egg with this *Salmonella* on the outside only... The presence of *Salmonella* in frozen eggs is a deleterious and poisonous additive which is dangerous to health within the meaning of 21 U.S.C. § 342(a)(1).”⁴⁴

Later, the USDA Secretary Earl Butz was sued by the American Public Health Association to require changes to the label for raw poultry. The court in *Butz* took the opportunity to state, in *dicta* famously criticized for its misogynistic phrasing in addition to its lack of factual support, that “American housewives and cooks normally are not ignorant or stupid and their methods of preparing and cooking of food do not ordinarily result in salmonellosis.”⁴⁵ While it may be indirectly inferred from its phrasing that the court believed the “ordinarily injurious” standard applied, USDA’s own statutory interpretation was not considered, as the issue of whether *Salmonella* is an “added substance” under (g)(1) was not necessary to resolve that case.

In 1995, USDA proposed new regulations establishing performance standards for *Salmonella* in raw poultry. The rulemaking did not directly consider whether *Salmonella* was an “added substance” within the meaning of 453(g)(1).⁴⁶ Notably, in promulgating these standards, the agency also considered whether “to determine, based on risk assessments, the levels of specific pathogens on raw meat and poultry products that do not pose a significant risk of illness and

³⁷ *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984).

³⁸ *Ibid.*; see also *Rust v Sullivan*, 500 U.S. 173, 184 (1991)(upholding a changed interpretation of the Public Health Service Act where the new interpretation was amply justified by reasoned analysis); *Smiley v. Citibank (South Dakota), N. A.*, 517 U.S. 735 (1996)(“the mere fact that an agency interpretation contradicts a prior agency position is not fatal”).

³⁹ *INS v. Cardoza-Fonseca*, 480 U.S. 421, 448 (1987).

⁴⁰ See *United States v. Mead*, 533 U.S. 218 (2001); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

⁴¹ *Poisonous or Deleterious Substances*. 42 Fed. Reg. 52814, 52814, (Sep. 30, 1977).

⁴² 393 F.Supp. 131 (N.D. Ga. 1972).

⁴³ The court in *1200 Cans* noted that jurisdiction over the safety of frozen egg products was poised to transfer in June of 1972 to FSIS, where it remains today.

⁴⁴ 393 F.Supp. at 135.

⁴⁵ *American Public Health Ass’n v Butz*. 511 F.2d 331 (D.C. Cir. 1974).

⁴⁶ *Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems*. 60 Fed. Reg. 6774 (Feb. 3, 1995).

prohibit distribution of products exceeding such levels.” The agency decided to forgo this approach, not from any concern that it lacked legal authority, but due to “large gaps in the scientific knowledge required to determine the levels of specific pathogens that do and do not pose a hazard.”⁴⁷ This suggests that the agency believed at the time that such standards were legally feasible, if not yet supported by adequate science.

Most recently, USDA commented on the adulteration standard in responding to three regulatory petitions submitted by consumer advocates, including members of the undersigned groups.^{48,49,50} Two of these petitions, submitted by Center for Science in the Public Interest (CSPI), asked USDA to declare specific strains of antibiotic-resistant *Salmonella* to be adulterants on the ground that the genes conferring antibiotic resistance were “added” through human intervention. USDA rejected these petitions because the line between “resistant” *Salmonella* and susceptible variants was unclear.⁵¹ These responses by the agency, delivered as letters to the petitioner outside the context of a rulemaking, were narrowly focused on whether a meaningful distinction between *Salmonella* and ABR *Salmonella* could be made, and did not offer a reasoned opinion on whether *Salmonella* in general was an “added substance.”⁵²

A third letter was published by FSIS in 2022 in response to a petition submitted by Bill Marler two years previously.⁵³ In that petition, FSIS stated “[w]hile FSIS has traditionally viewed *Salmonella* as ‘naturally occurring’ in food animals, we are reassessing this interpretation as part of our *Salmonella* in poultry initiative and considering whether *Salmonella* should be considered an adulterant in any poultry products.” However, the sources above establish that the reasoning for that view was never provided on the public record.

Therefore, the agency is now, for the first time, directly applying its expertise to consider, in a public deliberative process, the question of whether *Salmonella* is an “added substance” under the PPIA. We urge the agency to clarify this point when it issues its final determination, as it will help to illustrate why the current decision should be afforded full judicial deference.

IV. We Agree with the Conclusion that Products Failing the Proposed Standard Meet the “Ordinarily Injurious” Standard

Because *Salmonella* is an added substance in NRTE Breaded Stuffed Chicken, the proposed determination does not require the agency to find that *Salmonella* contamination will “ordinarily

⁴⁷ Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems. 60 Fed. Reg. 6774 (Feb. 3, 1995).

⁴⁸ Petition Submitted by Center for Science in the Public Interest. May 25, 2011 <https://www.fsis.usda.gov/policy/petitions/petition-submitted-center-science-public-interest-0>. Accessed August 9, 2023.

⁴⁹ Request for an Interpretive Rule Declaring Certain Antibiotic-Resistant Strains of *Salmonella* to Be Adulterants. October 21, 2014. <https://www.fsis.usda.gov/federal-register/petitions/request-interpretive-rule-declaring-certain-antibiotic-resistant-strains> . Accessed August 9, 2023.

⁵⁰ Petition for Interpretive Rule Related to Certain *Salmonella* Serotypes. January 19, 2020. <https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-salmonella-serotypes>. Accessed August 9, 2023.

⁵¹ https://www.fsis.usda.gov/sites/default/files/media_file/documents/11-06-FSIS-Final-Response-07312014.pdf (“the available data do not clearly support the legal distinction between *Salmonella* and ABR *Salmonella* under the FMIA and PPIA that is suggested in the petition.”)

⁵² While USDA stated in its 2018 response that “*Salmonella* is not considered a per se adulterant of raw meat and raw poultry because ordinary cooking and preparation of these products are generally sufficient to destroy the pathogen,” this agency did not provide any deliberation or rationale as to why *Salmonella*, overall, is an “added substance.” 14-06 FSIS Final Response. (Feb 7, 2018).

https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/FSIS-response-CSPI-020718.pdf . Accessed August 9, 2023.

⁵³ 20-01 FSIS Final Response (May 31, 2022). https://www.fsis.usda.gov/sites/default/files/media_file/2022-06/20-01-Final-Response-05312022.pdf. Accessed August 9, 2023.

render [the products] injurious to health.” However, the agency did include such a finding in a footnote to the proposed rule, stating:

FSIS also believes that NRTE breaded stuffed chicken products that contain *Salmonella* at 1 CFU per gram or higher meet the more stringent ‘ordinarily injurious’ standard for substances that are not added because ordinary consumer handling and preparation, as reported in outbreak investigations and consumer research, may not reduce *Salmonella* to levels that do not result in illness and may also contribute to cross-contamination when these products are prepared in the home.⁵⁴

We agree with this finding. As FSIS stated in the proposed determination, because such products may appear cooked, some consumers may only reheat the product for aesthetic or palatability reasons, rather than cooking to a time and temperature sufficient to kill pathogenic bacteria. In addition, as described above, the nature of the products makes it difficult for consumers to cook them thoroughly. These difficulties have led to repeated outbreaks despite efforts to promote consumer education through updates to labeling.

For these reasons, we agree with FSIS that NRTE breaded stuffed chicken products that contain *Salmonella* at 1 CFU per gram or higher meet the more stringent “ordinarily injurious” standard, because ordinary consumer handling and preparation preserves levels in the end product that result in illness.

V. We Support the Determination That *Salmonella* Above 1 CFU per Gram Renders NRTE Breaded Stuffed Chicken Unwholesome, Unhealthful, or Otherwise Unfit for Human Food

In addition to considering NRTE breaded stuffed chicken products under 21 U.S.C. 453(g)(1), FSIS has also tentatively declared NRTE breaded stuffed chicken products that are contaminated with *Salmonella* at levels of 1 CFU per gram or above to be adulterated within the meaning of 21 U.S.C. 453(g)(3) because such products present a sufficiently serious risk of causing human *Salmonella* illnesses such as to make them unhealthful, unwholesome, or otherwise unfit for human food. As the agency notes in the proposed determination, the same (g)(3) provision formed the basis of the agency’s conclusion, issued in 2012, that products linked to an outbreak are considered adulterated.⁵⁵

We agree with the agency that because *Salmonella* can survive ordinary handling and cooking practices for NRTE breaded stuffed chicken products, products contaminated with *Salmonella* at levels sufficient to cause human illness are “unhealthful, unwholesome, or otherwise unfit for human food” and should be excluded from commerce.

VI. FSIS Should Continue to Be Flexible in Evaluating its Final Product Standards as Science and Technology Advances

The scientific understanding of and technology to test for *Salmonella* is changing, and we support FSIS explicitly stating that it will “continue to evaluate and, if necessary, refine its

⁵⁴ *Salmonella* in Not-Ready-To-Eat Breaded Stuffed Chicken Products, 88 Fed. Reg. 26249. (April 28, 2023).

⁵⁵ *Ibid.*

proposed determination on the status of *Salmonella* as an adulterant in NRTE breaded stuffed chicken products as advances in science and technology related to pathogen levels, serotypes, and infectious dose become available.”⁵⁶

We emphasize the importance of this flexible stance. We expect that this proposal and the potential upcoming FSIS regulatory reforms described in the agency’s recently published Framework on Poultry Safety Reform⁵⁷ will motivate advances in science and diagnostic testing technology that will pave the way for future regulatory advances, and FSIS should be prepared to adjust its approach in response to these changes. For example, with testing technology that allows for rapid serotyping and whole genome sequencing, it may become possible to pinpoint the most virulent and infectious serotypes or genetic variants of *Salmonella*, allowing FSIS to develop more stringent standards for these types. We may find in the coming years that a specific *Salmonella* subtype causes illnesses at a lower dose (which future technology could test for at ease) and is especially prevalent in these products, leading to a need to adjust the standards.

VI. Conclusion

The proposed determination and the resulting standard are laudable steps by the agency in working to ensure the safety of consumers. We support the standard as proposed and urge the agency to consider adjustments as science and technology evolve in the future. We also look forward to working with the agency to develop additional poultry final product standards.

Sincerely,

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⁵⁶ *Salmonella* in Not-Ready-To-Eat Breaded Stuffed Chicken Products, 88 Fed. Reg. 26249. (April 28, 2023).

⁵⁷ Food Safety and Inspection Service. Proposed Regulatory Framework to Reduce Salmonella Illnesses Attributable to Poultry. Updated October 14, 2022. Accessed July 7, 2023. <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/proposed>