NATIONAL CHICKEN COUNCIL

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Mr. Paul Kiecker
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Office of Food Safety
Food Safety and Inspection Service
1400 Independence Ave SW
Washington, DC 20250-3700

Re: Docket No. FSIS-2022-0013: *Salmonella* in Not-Ready-To-Eat Breaded Stuffed Chicken Products

Dear Mr. Kiecker:

The National Chicken Council (NCC) appreciates the opportunity to provide comments regarding the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS or the Agency) proposed determination on *Salmonella* in Not-Ready-To-Eat (NRTE) breaded stuffed chicken products (the Proposed Determination).[1] NCC is the national, non-profit trade association that represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States.

A subset of our members produce NRTE breaded stuffed chicken products. These products are consumed safely nearly every time they are eaten, but we recognize their nature raises special considerations that merit additional attention. To that end, NCC has engaged with FSIS for decades to collaborate on scientifically valid and legally defensible approaches to this product category, and NCC remains committed to continued collaboration. The approach outlined in FSIS's Proposed Determination, however, suffers from significant legal and scientific infirmities and is unlikely to achieve meaningful public health impacts.

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

These comments first review key aspects regarding the long history of the industry's attempts to collaborate with FSIS on this product category, the positive track record for these products, and the current expert consensus on how best to further enhance the products' safety profile (Part I). These comments then discuss key concerns with FSIS's proposed approach:

- The Proposed Determination is premised on legally infirm conclusions that *Salmonella* would be considered an adulterant at a level at or above 1 CFU/g in raw poultry used in these products (Part II);
- The Proposed Determination is not supported by appropriate scientific data, which would make it an arbitrary and capricious Agency action (Part III);
- The Proposed Determination raises a major question requiring Congressional direction (Part IV);
- The Proposed Determination raises numerous scientific and technical issues that would have to be resolved before it could be implemented in an orderly and reasonable fashion (Part V);
- It is premature to issue the Proposed Determination in light of outstanding scientific questions and FSIS's pending *Salmonella* Framework review (Part VI);
- The Proposed Determination would impose economic burdens well in excess of those predicted in the Agency's analysis (Part VII).

Finally, these comments propose more appropriate and feasible alternative approaches that align with expert recommendations and can be readily implemented to further improve the safety profile of NRTE breaded stuffed chicken products (Part VIII).

I. NCC Has Long Pursued Constructive Approaches to Ensure NRTE Breaded Stuffed Chicken Products Are Safely Consumed, Which Have Resulted in Significant Public Health Outcomes

NCC and our member companies have worked for more than a decade to develop and refine best practices for these products, including labeling guidelines and intervention strategies, all of which are designed to ensure that consumers can prepare and consume these products safely. These efforts include obtaining source material from Category 1 establishments, testing source material, testing other product ingredients, updating cooking validations, revising labels to emphasize these products' raw nature and proper cooking, researching consumer understanding of labels, and even evaluating palatability and consumer acceptance of fully cooked versions of these products.

To complement these labeling interventions, industry has also implemented a multi-faceted approach at the processor level focusing on the continual reduction of *Salmonella* from farm to fork – implementing robust vaccination, biosecurity, sanitation, and other measures. In addition, FSIS has significantly tightened existing *Salmonella* standards over the past few years; introduced new performance standards for chicken parts; rolled out a new, scientifically driven, modernized poultry inspection system that allows for greater testing and analysis; released detailed guidance on controlling *Salmonella* through processing controls; and approved new interventions. These efforts have been extremely successful. Based off the most recent FSIS testing results, *Salmonella* prevalence on whole chicken carcasses is 3.4 percent and *Salmonella* prevalence on chicken parts is 6.9 percent across all broiler processing establishments.[2] These testing results are well below the *Salmonella* performance standards for both young chicken carcasses and

[2] FSIS, *Sampling Results for FSIS Regulated Products*, USDA (2023), https://www.fsis.usda.gov/science-data/sampling-program/sampling-results-fsis-regulated-products.

chicken parts. Currently over 90 percent of the industry is meeting or exceeding the performance standard for both young chicken carcasses and chicken parts.[3]

The combination of previous and ongoing industry efforts has resulted in a substantial reduction of foodborne illness outbreaks related to this product category. From 1998 through 2016, FSIS indicates that thirteen salmonellosis outbreaks related to NRTE breaded stuffed chicken products occurred, an average of one outbreak per year during that period. Thanks to industry investments in research and production, education initiatives, and improved labeling practices, only one outbreak linked to these products has occurred since 2016, an average of 0.14 outbreaks per year. In other words, due entirely to voluntary industry efforts, the frequency of outbreaks related to these products has been reduced sevenfold.[4]

In addition, raw chicken overall has only grown safer over the years. The incidence of salmonellosis in humans has remained relatively unchanged since 1996, despite the fact that Americans eat nearly 50 percent more chicken today than in 1996.[5] When consumption of chicken is taken into account, the incidence of salmonellosis in humans has decreased significantly over the last decade. These outcomes demonstrate that focused efforts can, and have had, significant public health benefits.

NCC members will continue to ensure NRTE breaded stuffed chicken products are produced, handled, and able to be consumed safely. For these efforts to be effective and sustainable, however, FSIS must reinforce them using its existing regulatory and public health tools to strengthen science-based practices and support risk assessments, rather than implementing untested policies with doubtful public health outcomes. In particular, NCC highlights and supports the recommendations from the National Advisory

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[3]FSIS, Salmonella *Verification Testing: June 26, 2022 through June 24, 2023*, USDA (2023), https://www.fsis.usda.gov/news-events/publications/salmonella-verification-testing-june-26-2022-through-june-24-2023.

[4] NCC questions FSIS's apparent reliance on outbreak frequency as the leading indicator of product risk, but the trend nevertheless is striking.

[5] In 1996, chicken consumption in the U.S. was 69.7 pounds per person. NCC, *Per Capita Consumption of Poultry and Livestock, 1965 to Forecast 2022, in Pounds*, NCC (2023), https://www.nationalchickencouncil.org/about-the-industry/statistics/per-capita-consumption-of-poultry-and-livestock-1965-to-estimated-2012-in-pounds/. In 2023, USDA estimates that Americans will consume 116.8 pounds of chicken per person. USDA, *World Agricultural Supply and Demand Estimates*, USDA (Jul. 2023), https://www.usda.gov/oce/commodity/wasde/wasde1222.pdf. Importantly, neither the Centers for Disease Control and Prevention's (CDC's) FoodNet Fast database, which displays select pathogens transmitted through food, nor the Interagency Food Safety Analytics Collaboration (IFSAC), account for consumption patterns of various food sources, including chicken. When the data from both FoodNet Fast and IFSAC are analyzed by per-pound consumption of chicken, the rate of salmonellosis associated with chicken is shown to have decreased over the past ten-plus years. This data further demonstrates that the robust public-health measures implemented by FSIS and the chicken industry over the past decade have been working. *See* CDC, *FoodNet Fast*, CDC.gov (2022), https://wwwn.cdc.gov/foodnetfast/; CDC, *Interagency Food Safety Analytics Collaboration (IFSAC)*, CDC.gov (2022), https://www.cdc.gov/foodsafety/ifsac/publications.html.

Committee on Meat and Poultry Inspection's (NACMPI's) 2021 report, which provided actions FSIS might take with respect to this product class.[6] The NACMPI recommendations to FSIS included:

- Re-verifying labeling and cooking instruction validation;
- Making this re-verification a periodic inspectional task in the Public Health Information System (PHIS);
- Updating guidance to industry on labeling best practices;
- Assessing illness outbreak information to determine whether other labeling factors, such as product images, might lead to consumer misidentification of the product;
- Reassessment of HACCP plans for establishments producing these products;
- Conducting targeted consumer outreach regarding these types of products;
- Adopting mandatory labeling requirements for these products, based on the NCC petition;
- Updating the compliance guideline on validating cooking instructions for these products; and
- Gathering additional data on how consumers understand and handle these products.[7]

This assessment reinforced the idea that FSIS can best improve public health outcomes for the NRTE breaded stuffed chicken product category by complementing and reinforcing existing industry activities.

NCC members want *every* eating occasion to be safe and have sought to collaborate with FSIS on additional steps industry can take to achieve this goal. For example, in 2009, the poultry industry engaged in a series of meetings with FSIS regarding industry best practices and ways to enhance oversight of NRTE breaded stuffed chicken products, culminating in a letter to FSIS Administrator Almanza in December of that year. That letter encouraged FSIS to take various actions, including requiring mandatory reassessment of the Hazard Analysis and Critical Control Point (HACCP) plans by establishments producing these products. In 2016, NCC petitioned FSIS to promulgate regulations for the labeling of these products to reinforce their raw nature and ensure consumers understand how to properly handle them.[8] NCC proposed specific regulatory language that included highly prominent warnings using a combination of graphics, words, and specific handling and cooking instructions.[9] Last year, NCC submitted an update to that petition that incorporated the latest learnings and reflected newer kitchen appliances available to consumers, such as air fryers.[10] FSIS has not responded substantively to our

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[6] FSIS, *National Advisory Committee on Meat and Poultry Inspection*, 86 Fed. Reg. 48115 (Aug. 27, 2021). NACMPI is comprised of leading food safety experts from across all stakeholder groups, including industry, consumer, and academic representatives.

[7] National Advisory Committee on Meat and Poultry Inspection, *Subcommittee II: Stuffed Not Ready-to-Eat Poultry Products*, USDA (Sept. 28, 2021), https://www.fsis.usda.gov/sites/default/files/media_file/2021-10/Subcommittee_II_Stuffed_Not_Read-to-Eat_Poultry_Products_9-28-21_final_Report.pdf.

[8] *National Chicken Council Petition to Establish Regulations for the Labeling and Validated Cooking Instructions for Not-Ready-to-Eat Stuffed Chicken Breast Products that Appear Ready-to-Eat*, FSIS Petition 16-03 (May 24, 2016), https://www.fsis.usda.gov/federal-register/petitions/establish-labeling-requirements-not-ready-eat-stuffed-chicken-products.

[9] *Id.*

[10] *National Chicken Council Petition to Establish Regulations for the Labeling and Validated Cooking Instructions for Not-Ready-to-Eat Stuffed Chicken Breast Products that Appear Ready-to-Eat: Petition*

original petition or to our update. NCC most recently wrote to FSIS on July 15, 2022, requesting the Agency take specific and comprehensive actions to address the labeling, manufacturing, and microbiological profiles for these products.[11] NCC likewise has not received a response to that outreach.

In short, FSIS's and industry's existing paradigm for approaching *Salmonella* control across the board has been effective. The Proposed Determination would abandon these approaches for legally infirm and technologically infeasible strategies with no clear supporting data. NCC encourages FSIS to continue using the latest science and industry-Agency collaborations to drive continued food safety and public health improvements.

II. *Salmonella* Is Not an Adulterant in Raw Poultry Under the Poultry Products Inspection Act

FSIS premises its proposal on two novel interpretations of the adulteration provision of the Poultry Products Inspection Act (PPIA): (1) *Salmonella* is an added poisonous or deleterious substance when present in a chicken component at or above 1 CFU/g, rendering the product adulterated under 21 U.S.C. § 453(g)(1); and (2) the presence of *Salmonella* in a chicken component above 1 CFU/g renders the product "unsound, unhealthful, or unwholesome, or otherwise unfit for food" under 21 U.S.C. § 453(g)(3). These legal theories lack merit and contradict established Agency and court precedent.

Under the PPIA, a product is adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health."[12] Thus, whether a pathogen renders a product adulterated depends on whether the substance is added to the product or occurs naturally (not added) in the product. For substances that are not added, the pathogen is an adulterant only if the substance is present in quantities that "ordinarily" render the product injurious to health. As FSIS has consistently recognized, *Salmonella* is not an adulterant in raw poultry because (1) *Salmonella* is not an added substance in raw poultry and (2) *Salmonella* is not present in levels that render chicken injurious to health because customary cooking practices destroy any *Salmonella* that may be present. FSIS has not provided new information in the record to support its change in this interpretation.

a. *Salmonella* is not an "added substance" under 21 U.S.C. § 453(g)(1)

FSIS premises its novel legal interpretation on the proposition that *Salmonella* is not present in the muscle tissue of chickens. This is scientifically incorrect, and it reads the "added substance" provision of the PPIA too broadly.

FSIS's rationale for proposing to treat *Salmonella* as an added substance in NRTE breaded stuffed chicken products comes down to its assertion that, "*Salmonella* is present in the gastrointestinal tract of live birds, and there is evidence that extraintestinal *Salmonella* exist in poultry skin, livers, bones, and

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Supplement, FSIS Petition 16-03, USDA (Feb. 25, 2022), https://www.fsis.usda.gov/sites/default/files/media_file/2022-02/16-03-NCC-Supplement-02252022.pdf.

[11] Letter from Dr. Ashley Peterson, Senior Vice President, Scientific and Regulatory Affairs, to Sandra Eskin, Deputy Under Secretary for Food Safety, Office of Food Safety, July 15, 2022. NCC has yet to receive a response to this letter.

[12] 21 U.S.C. § 453(g)(1).

bone marrow before processing," (scientific support cited), that "*Salmonella* is not, however, ordinarily found in the muscle tissue of healthy birds," (no scientific support cited), 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."[13] There are critical flaws in each aspect of this statement.

First, these statements are contradicted by scientific literature. *Salmonella* is not an avian pathogen, and it exists naturally as part of the microflora in and on chicken. *Salmonella* can exist in a chicken's skin, muscle tissue, and gut. Peer-reviewed literature establishes that healthy, asymptomatic birds are known to carry *Salmonella*.[14] To provide but a few examples:

- Testing was completed on six- and eight-week-old birds after defeathering but before processing to determine the rate of naturally occurring *Salmonella* in the liver/gallbladder, spleen, and ceca. *Salmonella* was found in 10% of livers/gallbladders, 15% of spleens, and 8% of cecum for six-week-old birds and in 51% of livers/gallbladders, 48% of spleens, and 65% of cecum for eight-week-old birds.[15]

- A study concluded that the relatively higher presence of *Salmonella* in shoulder joints (0.8%) in comparison to coxofemoral joints (0.4%) and tibiofemoral joints (0.2%) supports the assertion that the presence of *Salmonella* in joints is not the result of a systemic infection.[16]

- Three different studies found that the difference in the rate of *Salmonella* found on skin-off chicken breasts versus skin-on chicken breast was not significant.[17]

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[13] 88 Fed. Reg. 26249, 26260.

[14] *See, e.g.*, Columb P. Rigney, et al., Salmonella *serotypes in selected classes of food animal carcasses and raw ground products, January 1998 through December 2000*, 224(4) J. Am. Vet. Med. Ass'n 524–30 (Feb. 2004) available at https://avmajournals.avma.org/view/journals/javma/224/4/javma.2004.224.524.xml; C.W. Nde, et al., *Cross contamination of turkey carcasses by* Salmonella *species during defeathering*, 86(1) Poult. Sci. 162–67 (2007) available at https://www.sciencedirect.com/science/article/pii/S0032579119423882?via%3Dihub; Irfan Erol, et al., *Serotype distribution of* Salmonella *isolates from turkey ground meat and meat parts*, 3 Biomed Res. Int. (Jul. 2013) available at https://www.hindawi.com/journals/bmri/2013/281591/.

[15] N.A. Cox et al., *Recovery of* Campylobacter *and* Salmonella *Serovars From the Spleen, Liver and Gallbladder, and Ceca of Six-and Eight-Week-Old Commercial Broilers*, 16(4) J. Applied Poultry Res. 477-80 (Dec. 2007) available at https://www.sciencedirect.com/science/article/pii/S1056617119316228#cesec30:~:text=CONCLUSIONS%20AND%20APPLICATIONS,final%20food%20product.

[16] Ty Sexton et al., Salmonella *Contamination in Broiler Synovial Fluid: Are We Missing a Potential Reservoir?*, 81(9) J. Food Protection 1425-31 (Sept. 2018) available at https://www.sciencedirect.com/science/article/pii/S0362028X22086781#:~:text=Between%20production%20systems%20(Table,95%25%20CI%2C%200.01%20to%202.75%25).

[17] Angela Cook et al., Campylobacter, Salmonella, Listeria monocytogenes, *Verotoxigenic* Escherichia coli, *and* Escherichia coli *Prevalence, Enumeration, and Subtypes on Retail Chicken Breasts with and without Skin*, 75(1) J. Food Protection 34-40 (Jan. 2012) available at

- The anatomy of chickens is such that the dendritic cells that can move *Salmonella* in the bird's body can transfer *Salmonella* from the GI tract through the circulation system to muscle tissue resulting in the *Salmonella* in muscle tissue originating from an internal source.[18]

- In a study focused on examining how *Salmonella* moves through both the host bird and other birds in the processing line, the authors commented that "healthy asymptomatic birds are known to carry *Salmonella*." *Salmonella* was identified in chicken neck skin, on the outer layer of skin, on feather follicles, connective tissue, and in drumstick muscle.[19]

- A study of chicken breasts and thighs in retail establishments in Atlanta found *Salmonella* in skin-off chicken thighs at a rate of 12% of chicken breasts and 22% in chicken thighs.[20]

- An additional three studies identified *Salmonella* in the internal liver, spleens, bone marrow, neck skin, and ceca of chickens.[21]

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https://www.sciencedirect.com/science/article/pii/S0362028X23004337#s0071:~:text=When%20comparing%20the,skin%2Doff%20chicken. FSIS, *The Nationwide Microbiological Baseline Data Collection Program: Raw Chicken Parts Survey*, USDA (2012) available at https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Baseline_Data_Raw_Chicken_Parts.pdf#:~:text=FSIS%20conducted%20the%20Raw%20Chicken%20Parts%20Baseline%20Survey,that%20produce%20raw%20chicken%20parts%20under%20Federal%20Inspection. A. Pointon et al., *A Baseline Survey of the Microbiological Quality of Chicken Portions and Carcasses at Retail in Two Australian States (2005 to 2006)*, 71(6) J. Food Protection 1123-34 (Jun. 2008) available at https://www.sciencedirect.com/science/article/pii/S0362028X22065577.

[18] A. Leoni Swart & Michael Hensel, *Interactions of* Salmonella enterica *with dendritic cells*, 3(7) J Virulence 660-67 (Nov. 2012) available at https://www.tandfonline.com/doi/full/10.4161/viru.22761.

[19] Claire-Sophie Rimet et al., Salmonella *Harborage Sites in Infected Poultry That May Contribute to Contamination of Ground Meat*, 3 Front. Sustain. Food Syst. (Feb. 2019) available at https://www.frontiersin.org/articles/10.3389/fsufs.2019.00002/full#:~:text=Chicken%20neck%20skin,days%20of%20age.

[20] Husnu Sahan Guran et al., Salmonella *prevalence associated with chicken parts with and without skin from retail establishments in Atlanta metropolitan area, Georgia*, 73(B) Food Control 462-67 (Mar. 2017) available at https://www.sciencedirect.com/science/article/abs/pii/S0956713516304777?via%3Dihub#:~:text=Salmonella%20prevalence%20in%20the%20skin%20of%20skin%2Don%20breasts,transmission%20to%20consumers%20compared%20to%20skin%2Doff%20chicken%20parts.

[21] I. Kassem et al., *An evaluation of the effect of sodium bisulfate as a feed additive on* Salmonella enterica *serotype* Enteritidis *in experimentally infected broilers*, Poultry Sci. (Apr. 2012) available at https://www.semanticscholar.org/paper/An-evaluation-of-the-effect-of-sodium-bisulfate-as-Kassem-Sanad/44b30d0bcce6f9d7d1d339d5f27fee8b4cf8c121. Diezhang Wu et al., *Prevalence of* Salmonella *in Neck Skin and Bone of Chickens*, 77(7) J. Food Protection 1193-97 (Jul. 2014) available at https://www.sciencedirect.com/science/article/pii/S0362028X23063731#s0005:~:text=Overall%2C%2021.4%25%20(95,undetermined%20Salmonella%20status. Amie M. Jones-Ibarra et al., Salmonella *recovery from chicken bone marrow and cecal counts differ by pathogen challenge method*, 98(9) Poultry Sci. 4104-12 (Sept. 2019) available at https://www.sciencedirect.com/science/article/pii/S0032579119307035?via%3Dihub.

In the case of NRTE breaded stuffed chicken products *Salmonella* could also be inherent in other ingredients, such as vegetable components. In addition, not all NRTE breaded stuffed chicken products include skin.

Despite ignoring this well-established literature, FSIS nonetheless acknowledges that "*Salmonella* exist[s] in poultry skin, livers, bones, and bone marrow" but ignores that these are routinely consumed as part of a wide variety of chicken products.[22] These are all parts of most chicken products. Chicken skin and livers are consumed directly on a regular basis. Consumers regularly eat skin-on and bone-in whole birds or chicken parts. Chicken livers are routinely consumed in various applications. Any *Salmonella* that may be present in these products via the skin, bone, or livers is not added; it is inherently part of the product. Likewise, any skin that may be included in a comminuted product is an inherent part of that product – just like all other components of the product. The fact that the skin is mixed more uniformly in a comminuted product does not change that.

Second, FSIS's own parts sampling data reinforces that *Salmonella* is in fact ordinarily found in chicken muscle tissue. If most of the *Salmonella* present on a bird resided only on the skin, then there should be significantly lower prevalence of *Salmonella* on skinless parts compared to skin-on parts. In 2012, FSIS published a report on data collected through its Raw Chicken Parts Baseline Survey that addressed the specific question. As part of that survey, FSIS collected hundreds of samples from chicken parts with and without skin. After analyzing the data, FSIS "determined that no significant difference (p-value > 0.05) existed in the percent of *Salmonella* positive samples in parts, whether skin remained intact or was removed."[23] Notably, FSIS collected its samples for this study at the end of the production process, "after all antimicrobial interventions are completed."[24] If *Salmonella* were present on the skinless part only through cross contamination (e.g., a knife slicing through a piece of skin and transferring *Salmonella* from that small portion of the skin to the meat), then the transferred organism would likely be present on the surface only and at low levels such that it would be eliminated by the subsequent amicrobial interventions. The data showed the opposite.[25] In other words, *Salmonella* was just as likely to be present on a chicken part regardless of whether the part had skin or not.[26]

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[22] 88 Fed. Reg. 26249, 26260.

[23] FSIS, *The Nationwide Microbiological Baseline Data Collection Program: Raw Chicken Parts Baseline Survey (RCPBS)*, USDA at 5 (2012), https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Baseline_Data_Raw_Chicken_Parts.pdf.

[24] *Id.* at 6.

[25] Indeed, FSIS can point only to differences between FSIS sampling for whole birds and parts (disregarding the data comparing skin-on and skin-off parts) and speculation that cutting through skin or bones, or incorporating skin into comminuted product, cross contaminates chicken with an added substance that would not otherwise be present.

[26] Similarly, the position is inconsistent with FSIS's routine recommendation to cook chicken to an internal temperature of 165°F as measured with a meat thermometer in the thickest part of the product. This would be unnecessary if *Salmonella* were only a surface pathogen transferred by cross contamination during processing.

Third, FSIS provides no scientific support for the statement that cross contamination during further processing is responsible for the presence of *Salmonella* in the chicken components used to create NRTE breaded stuffed chicken products. Tellingly, FSIS cites speculative or inapplicable sources when discussing its cross-contamination theory.[27] The entirety of FSIS's support is as follows and is readily distinguished: FSIS performance standard sampling (footnote 76, but as explained above, this difference could be explained by exposing different portions of the bird, including cut muscle, to the rinsate); FSIS and Codex guidance on process control (footnotes 77, 78, 81-84, but these are more broadly focused on controlling *Salmonella* during processing and do not establish that chicken muscle tissue is otherwise free of *Salmonella* but for processing); research articles represented as establishing that *Salmonella* is found in feather follicles (footnote 79, this may demonstrate that *Salmonella* is found in feather follicles but does not establish absence of *Salmonella* in muscle tissue); and FSIS exploratory sampling results for comminuted poultry (footnote 82, but this data at most shows only how the type of source material correlates to prevalence, not that the product would otherwise be free of *Salmonella.* In fact, the data on comminuted source material made without skin-on or bone-in source material reinforces that *Salmonella* is present in this product even without skin or bone). FSIS is unable to cite a single scientific source to support its position that muscle tissue would be free of *Salmonella* but for further processing, even though this is an *essential* scientific proposition underpinning its new "added substance" theory for *Salmonella*. FSIS also disregards alternative explanations, such as the fact that breaking carcasses into parts exposes more surfaces (including the interior of the meat) to the sampling rinsate, which would make it more likely to identify *Salmonella* presence when sampling parts.

Further, to NCC's knowledge, FSIS has not even attempted to collect data to test its novel cross-contamination theory. However, NCC members have, and industry data demonstrates that *Salmonella* is not an environmental contaminant. NCC is aware that member companies have conducted experimental sampling to assess the potential for *Salmonella* cross-contamination through the environment. Those sampling efforts found virtually no *Salmonella* on processing equipment, reinforcing that *Salmonella* is not being spread through environmental cross-contamination.

Fourth, the fact that *Salmonella* may be present in different concentrations in some parts of a chicken compared to others is irrelevant to this analysis, as is the fact that *Salmonella,* like any other microbe, can be spread through cross-contact during processing. The PPIA asks only whether the organism is an added substance when determining if it is an adulterant. To view all pathogens that can be somehow spread among or within products as "added substances" would read out of existence the second prong of § 453(g)(1) and is inconsistent with the normal meaning of the term. Well-established canons of statutory interpretation require that all words in a statute be given meaning, and that includes the "inherent

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[27] It is telling that under the Proposed Determination, the Agency would at most recognize that "*Salmonella* is not . . . *ordinarily* found in the muscle tissue of healthy birds." 88 Fed. Reg. 26249, 26260 (emphasis added). This view implicitly recognizes that *Salmonella* is present at some frequency in the muscle tissue of healthy birds (otherwise, FSIS would not have had to qualify its statement with the term "ordinarily"). Even under FSIS's proposed view, whatever *Salmonella* was present in the muscle tissue originally could not be considered an added substance because it was in that tissue all along. This would create the situation of needing to establish whether individual cells or colonies of *Salmonella* originated from the muscle tissue or were added to that muscle tissue via cross-contamination during processing or by adding skin to the muscle tissue. This is a scientifically impossible task, yet one that would be legally necessary to determine whether the specific *Salmonella* detected was an added or inherent substance before invoking FSIS's statutory authority.

substance" clause of Section 453(g)(1). Moreover, courts have been clear that an "added substance" refers to a substance not otherwise present in the food and added by man.[28]

In sum, the Proposed Determination would lead to absurd results and inconsistencies that must be resolved. FSIS's support for its "added substance" theory is not only highly speculative but is also directly contradicted by the published literature. *Salmonella* occurs naturally within chickens and is not an added substance in raw poultry. Because significant evidence shows *Salmonella* does not "ordinarily" render the product injurious to health (see discussion below), it cannot properly be classified as an adulterant.[29]

b. FSIS has not established that *Salmonella* present at greater than 1 CFU/g "ordinarily" renders NRTE breaded stuffed chicken products injurious to health

Salmonella does not "ordinarily" render NRTE breaded stuffed chicken products injurious to health, and FSIS has not established that its proposed 1 CFU/g threshold meets this legal standard.

The PPIA establishes a very high standard to support a conclusion that a naturally occurring pathogen "ordinarily" renders a raw product adulterated. First, in the PPIA, Congress created a strong presumption against viewing a naturally occurring substance as an adulterant in raw products: under the PPIA, added substances adulterate food if they "*may* render it injurious to health," whereas a product with naturally present pathogens "*shall not* be considered adulterated" if the substance "does not ordinarily render it injurious."[30] The statute thus sets up two very different standards. While the use of "may" in the statute could imply FSIS has a measure of discretion in evaluating *added* substances, FSIS is prohibited from considering a *naturally occurring* substance an adulterant ("*shall not* be considered adulterated") unless it can meet the very high bar of proving that the substance would "ordinarily" render the product injurious to health. Reinforcing this high bar, in its statement of policy codified into the PPIA, Congress commanded that decisions such as product condemnation "shall be supported by scientific fact, information, or criteria."[31] By default, naturally occurring substances are not adulterants, and FSIS must go to great scientific lengths to establish otherwise. FSIS, in fact, has no "scientific fact, information or criteria," to proceed with the Proposed Determination that *Salmonella* is an added substance.

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[28] *See United States v. Coca Cola*, 241 U.S. 265 (1915).

[29] FSIS recognized that *Salmonella* is not an added substance in its recent 2022 denial of a petition requesting *Salmonella* be declared as an adulterant, noting that "FSIS has traditionally viewed *Salmonella* as 'naturally occurring' in food animals." Letter from Rachel Edelstein to William D. Marler, Esq, at 3 (May 31, 2022). Although FSIS in its petition response noted it was considering reassessing its long-held view, the Agency still has provided no information to explain why *Salmonella*—which comes into plants on chicken skin and inside chickens, including in the muscle tissue—is not a substance naturally occurring in chickens. More established Agency precedent reinforces that *Salmonella* is naturally occurring in raw chicken. *See, e.g.*, Letter from Carmen Rottenberg, Acting Deputy Undersecretary, Office of Food Safety, to Laura MacCleery, Director, Center for Science in the Public Interest, at 1-2 (Feb. 7, 2018) ("We also disagree with your assertion that ABR *Salmonella* is an 'added substance' within the meaning of the adulteration provisions of the FMIA and PPIA.").

[30] 21 U.S.C. § 453(g)(1).

[31] 21 U.S.C. § 452.

Second, the plain meaning of "ordinarily" sets a very high bar. When a statute does not define a term – and the PPIA does not define "ordinarily injurious" – courts will consider its plain meaning with reference to its reasonable use, dictionary definitions, and its use in context.[32] Multiple dictionary definitions contemporaneous with the passage of the PPIA show us what Congress meant when it used "ordinarily." *Webster's* 1953 edition defines "ordinarily" as "according to established rules or settled method."[33] *Black's Law Dictionary*, 1951 edition, defines the adverb by reference to "ordinary," stating it means "regular" or "normal."[34] And *Oxford English Dictionary*, which examines the historical development of the term, defines it as "[b]elonging to the regular or usual order or course" or occurring in "regular custom or practice."[35] The term retains its meaning in modern parlance and as defined "usually; as a rule."[36] Thus, under the plain language of the PPIA, a naturally occurring substance can be considered an adulterant only if the substance "regularly" or "normally," or through "regular or usual . . . course" or "regular custom or practice," or "usually" or "as a rule" renders the product injurious to health.[37] This simply is not the case for *Salmonella* in NRTE breaded stuffed chicken products.

As is well established, thorough cooking destroys *Salmonella*. Specifically, cooking raw chicken to an internal temperature of 165°F achieves a 7-log reduction in *Salmonella*.[38] In fact, even a slightly lower temperature still achieves instant lethality (162°F or 163°F, depending on the fat content), as can reaching yet-lower-still temperatures with sufficient dwell time, often of just a few seconds.[39] Even in the event raw chicken were cooked at yet lower temperatures in the center of the meat, there would still be a substantial log-reduction in *Salmonella*, decreasing the overall microbial load on the product.

Consumers customarily cook all raw chicken, including NRTE breaded stuffed chicken products in a manner that achieves thorough cooking and destroys *Salmonella*. Consumers are regularly reminded to use a meat thermometer to cook chicken to an internal temperature of 165°F – including on the package itself – which achieves lethality. NCC's strong recommendation is that consumers use a meat thermometer. Chicken is not customarily cooked "rare" or "medium," and waitstaff at restaurants do not ask patrons how they would like their chicken cooked because the default approach is to cook chicken all the way through. This same approach applies to NRTE breaded stuffed chicken products. *Salmonella* in

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[32] *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997).

[33] *Ordinarily*, Webster's New Twentieth Century Dictionary, 1177 (1953).

[34] *Ordinary*, Black's Law Dictionary (4th ed., 1951).

[35] *Ordinary*, Oxford English Dictionary (2d ed., 1989).

[36] *Ordinarily*, Webster's New World College Dictionary (4th ed., 2010).

[37] The legislative history behind comparable language in the Federal Food, Drug, and Cosmetic Act reinforces this interpretation. In one debate, members stated "ordinarily injurious" meant "that people—substantial numbers of people—must actually be harmed by the product before it can be restricted in any way. This provision . . . puts the burden of proof on the FDA." 120 Cong. Rec. 36007 (1974) (Statement of Rep. Peter Kyros).

[38] FSIS, *FSIS Cooking Guidelines for Meat and Poultry Products (Revised Appendix A)*, "Table 3," USDA at 37 (2021), https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf.

[39] *Id.*

"regular custom or practices" does not make these products injurious to health because of ordinary handling and cooking practices.

In light of this well-established precedent, FSIS has not established that *Salmonella* present at greater than 1 CFU/g "ordinarily" renders NRTE breaded stuffed chicken products injurious to health. FSIS cites in essence two main points: a consumer handling study and a paper with a dose-response model for *Salmonella* illness. Neither these, nor ancillary points included in the Proposed Determination, meets the PPIA's high standard.

i. 2020 Consumer Research Study

FSIS's 2020 consumer handling research project does not support the proposition that consumers mishandle NRTE breaded stuffed chicken products. First, FSIS attempts to draw conclusions from the research on a topic it was not intended to evaluate. The study had two main objectives: (1) evaluate food thermometer use, and (2) evaluate "whether participants adhered to other recommended food safety practices throughout the meal preparation."[40] The study was accordingly designed to focus observational efforts on evaluating thermometer use and meal preparation practices. The study also included a post-observation interview that collected additional information, but the study was not designed to maximize the value and reliability of those interview questions. For example, the study did not include a true control group against which to evaluate perceptions of the particular product evaluated.[41] The study thus has no way to determine critical factors, such as whether consumer perceptions of the tested product differed in any material way from perceptions of other raw products, how consumers understood the term "raw," and even whether perceptions of the product as being raw, cooked, or fully cooked affected behavior. Further, the study was only a single-location study, and thus it is not clear whether its results can be extrapolated to consumers in different geographies.

Even taking into account these and other limitations, the study does not support the proposition that consumers customarily mishandle these products. For example, only 11 percent of participants thought the NRTE breaded stuffed chicken product they were presented with was fully cooked. The study generated no data to indicate whether these consumers actually mishandled the product based on this perception. Moreover, 99% percent of the consumers reported having read the label, and the study does not provide enough information to understand whether this very small minority of consumers still thought this way after reading the instructions. More importantly, the overwhelming majority of consumers recognized the product was, in fact, not fully cooked, reinforcing that customary practice is to handle these products accordingly. The study also reinforced several other important points about consumer handling:

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[40] S. C. Cates, et al., *Food Safety Consumer Research Project: Meal Preparation Experiment on Raw Stuffed Chicken Breasts*, RTI Project No. 0215472, ES-1-2 (Sept. 23, 2020), https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/fscrp-yr3-nrte-final-report.pdf.

[41] The "control" group used was a separate group that did not view an instructional food safety video. This is not a valid control group for purposes of assessing consumer understanding of the product as participants' assignment had nothing to do with whether the product would be perceived as raw or cooked. This reflects that the focus of the study was on something very different than what FSIS is trying to use it for.

- 99 percent of participants reported reading the cooking instructions (and the remaining 1 percent had answers that were unclear or unavailable).[42]
- 77 to 88 percent of participants across the "control" and intervention groups (with no statistical difference) reported using a meat thermometer, and most even checked both chicken breasts, even though the cooking instructions did not specifically say to do so (the study had participants prepare a two-pack of products).[43]
- Even among the small minority of participants who did not use a meat thermometer, the next most common way to determine doneness was time, which is based on the labeled cooking instructions that have been validated to achieve lethality.
- The study cites existing literature "report[ing] no significant risk for cross-contamination posed by the handling of frozen products themselves given that no liquid matrix is associated with these facts."[44]

The study's findings are especially important because, as recognized by the researchers, "[p]revious research suggests that self-reported data collected through surveys on consumers' food safety practices may be unreliable because consumers tend to overreport their behavior," and that "[b]ecause of this limitation, observation is often a preferred approach for collecting information on consumers' food safety practices."[45] Therefore, the directly observed behavior, which entailed participants reading and following the cooking instructions, using the oven, and using meat thermometers, is important for understanding how consumers customarily handle these products. The researchers concluded that "most participants followed their normal behavior in the test kitchen regarding preparation method," reinforcing that the overwhelming majority of consumers handle these products safely.

Far from establishing that consumers routinely mishandle NRTE breaded stuffed chicken products, the 2020 study reinforces that consumers do in fact handle these products appropriately and that customary cooking practices render these products safe to eat.

ii. 2010 Study and the 1 CFU/g Proposed Threshold

Although science and law establish that no amount of *Salmonella* would "ordinarily" render NRTE breaded stuffed chicken products injurious to health, science also does not support the proposed 1 CFU/g threshold. FSIS appears to base the proposed threshold on a single paper – a 2010 study that proffered a

[42] Cates at 3-9.

[43] *Id*. at ES-2.

[44] *Id*. at 1-2 (citing Schaffner, D. W., & Schaffner, K. M., *Management of risk of microbial cross-contamination from uncooked frozen hamburgers by alcohol-based hand sanitizer*, 70(1) J. Food Protection 109–113 (2007) available at https://doi.org/10.4315/0362-028X-70.1.109).

[45] *Id*. at ES-1–2 (citing Redmond, E. C., & Griffith, C. J., *Consumer food handling in the home: A review of food safety studies*, 66(1) J. Food Protection 130–161. (2003) available at https://doi.org/10.4315/0362-028X-66.1.130).

dose-response model using data from 2002 and earlier.[46] Much has changed since then, including the views of the study's lead author.

In a 2022 paper published in the journal *Epidemics*, the author of the 2010 study referred back to the 2010 study relied on by FSIS, explaining that "the analysis had several shortcomings: censored doses and unknown susceptibility status of hosts were not handled adequately and challenge studies were not included."[47] The earlier study did not include the results of challenge studies, and "[m]issing information was not handled optimally."[48] "Due to these shortcomings," explained the author of the 2010 study, it was necessary to revisit the earlier study "to correct the above issues."[49] Among the "shortcomings" corrected in the 2022 study was a significant transposition in the data for one of the outbreaks, in which the mean infectious dose in one of the studied outbreaks was errantly reported as 3.44 CFU instead of 344 CFU, a one-hundred-fold difference.[50] FSIS thus based its dose-response analysis on an outdated model.

Further, this dose-response model, whether in its 2010 or 2022 form, is not obviously applicable to chicken-specific *Salmonella* risks. The author notes that matrix considerations such as lipid content can affect the likelihood of illness.[51] For example, foods with high fat content and low water activity can result in more heat resistance of *Salmonella*, and high fat content protects *Salmonella* against gastric acidity.[52] But these factors are not controlled for in the model. In fact, the model draws on data from salmonellosis outbreaks associated with high-fat products such as chocolate, cheese, ice cream, peanut products, and cake. Many of the reported doses for these high-fat products are low (some reported in the range of 10^1), skewing the results of the dose-response model downward. Chicken, by contrast, is a much leaner product, and the matrix effects seen in higher-fat foods would not be present. Notably, none of the outbreak data included in the author's model (either in the 2010 or 2022 paper) includes NRTE breaded stuffed chicken products, or even products that were clearly raw chicken. In fact, only two outbreaks in the entire data set might have been associated with chicken; the outbreak vehicle is listed as "chicken/eggs/rice."[53] Nor does FSIS account for the fact that the dose-response model includes a wide variety of *Salmonella* serotypes, many of which are not associated with NRTE breaded stuffed chicken

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[46] 88 Fed. Reg. at 26262 n.97 (citing Teunis P.F. et al., *Dose-response modeling of* Salmonella *using outbreak data*, 144(2) Int. J. Food Microbiol 243–9 (2010) available at https://www.sciencedirect.com/science/article/abs/pii/S0168160510005519?via%3Dihub).

[47] Peter F.M. Teunis, *Dose response for* Salmonella *Typhimurium and Enteriditis and other nontyphoid enteric salmonellae*, 41 Epidemics (2022) available at https://www.sciencedirect.com/science/article/pii/S1755436522000937?via%3Dihub.

[48] *Id.* at 5.

[49] *Id.* at 1.

[50] *Id.* at 2.

[51] *Id.* at 5.

[52] D'aoust, J. Y., Salmonella *and the Chocolate Industry. A Review.*, 40(10) J. Food Protection 718-727 (Oct. 1977) available at https://www.sciencedirect.com/science/article/pii/S0362028X23033653?via%3Dihub.

[53] *See* Teunis, *Dose response for* Salmonella *Typhimurium and Enteriditis and other nontyphoid enteric salmonellae* at 7.

product outbreaks or even raw chicken. In all, these critical points call into question the accuracy of the dose-response model for NRTE breaded stuffed chicken products.

The Proposed Determination notably omits any reference to the author's more recent 2022 paper, his criticisms of his own 2010 work, the author's updated model, or how FSIS controlled for the issues the author identified with the earlier paper. The Proposed Determination is relying on the very definition of outdated science to support the proposed 1 CFU/g threshold.

Although NCC believes that a proper application of § 453(g)(1) obviates any need to determine a threshold level for *Salmonella* in these products and that this model is not necessarily appropriate to analyze this particular product, a more appropriate application of this dose-response model would point to a standard at or above 10 CFU/g. The outbreak data reviewed by FSIS points to *Salmonella* Enteritidis as the serotype most commonly involved in outbreaks associated with NRTE breaded stuffed chicken products. Absent a robust baseline analysis to determine which serotypes are actually present in these products, and at what levels (discussed further below), this information provides an imperfect indication of which serotype(s) to target in modeling. Using the updated 2022 model, for *Salmonella* Enteritidis, the median dose that is predicted to have a 50% probability of causing illness was reported as 3.36×10^3 CFU, or 3360 CFU.[54] Using FSIS's statement that the average chicken component in an NRTE breaded stuffed chicken product is 70-88 grams, this provides a range of 38-48 CFU/g. This range would be much more consistent with other studies in the literature. A target at or above 10 CFU/g would have the potential to have significant public health benefits. Furthermore, this concentration is a realistic limit of detection given limitations of the assays used to quantify *Salmonella* in complex matrices.

iii. 2022 CDC Appliance Report

FSIS also references a 2022 report from the Centers for Disease Control and Prevention (CDC), which has several limitations.[55] The 2022 CDC report consisted only of an online survey. As the 2020 consumer research study reinforced, direct observation is a much more reliable means for evaluating how consumers actually behave. CDC acknowledges as much in its 2022 report, noting that responses were self-reported and subject to recall and social bias.[56] Moreover, CDC's questionnaire did not specifically ask about raw products, it asked about "frozen stuffed chicken products" in general. The authors seem to write this off by noting that "some consumers might be unaware that these products are usually raw." But this is a speculative attempt to get around a fundamental flaw with the study design, and it stands directly in conflict with the observations from FSIS's 2020 consumer behavior study. It would be entirely appropriate for a consumer handling a precooked stuffed product to use a different cooking appliance than for a raw product. Worse, FSIS completely overlooks this limitation in the Proposed Determination, misconstruing the 2022 CDC report as "describ[ing] the demographic characteristics of persons who prepare NRTE breaded stuffed chicken products and which appliances they use to prepare them."[57] But this is not correct; the CDC report said nothing about consumer handling of raw product in particular and

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[54] Teunis, *Dose response for* Salmonella *Typhimurium and Enteriditis and other nontyphoid enteric salmonellae* at 4, table 2.

[55] *See* Katherine E. Marshall, et al., *Appliances Used by Consumers to Prepare Frozen Stuffed Chicken Products – United States, May–July 2022*, 71(48) Morb. & Mortal Weekly Rep. 1511-1516 (Dec 2, 2022) available at http://dx.doi.org/10.15585/mmwr.mm7148a2.

[56] *Id.*

[57] 88 Fed. Reg. at 26257.

"did not include questions about whether cooking instructions were noticed or followed."[58] The 2022 CDC report also suffers from the same risks as all surveys based only on self-reported responses, such as respondents not understanding the questions or answering in a way that does not actually reflect their practice. The study does not show that consumers select the incorrect appliances for NRTE breaded stuffed chicken products, nor does it address whether consumers read and understand product labels. The study simply was not designed to provide those answers, and it is inappropriate for FSIS to interpret the CDC report as saying anything about customary consumer practices with respect to NRTE breaded stuffed chicken products. It certainly is insufficient to support such a broad and novel change to federal food safety policy.

Even with these significant limitations, the CDC report still concluded that 82.7 percent of consumers self-reported using an oven to prepare frozen stuffed chicken products.[59] To the extent that consumers have interest in or might consider using other appliances, such as toaster ovens and air fryers, NCC's 2022 supplement to its 2016 petition specifically requested that FSIS establish requirements for validating cooking instructions for other appliances if desired. As discussed in Section I, there are other ways to address concerns with other kitchen appliances that align with current industry initiatives.

Finally, FSIS appears to allude to the fact that some consumers do not own ovens as a reason to adopt a dramatic change in *Salmonella* policy for NRTE breaded stuffed chicken products. FSIS should not establish a policy based on ownership of specific appliances nor should policy dictate which appliances consumers should own. Doing so is clearly arbitrary and capricious, as discussed below.

iv. Statements from past outbreak investigations

FSIS reviews at considerable length the history of foodborne illness outbreaks associated with NRTE breaded stuffed chicken products. For some, but not all, of these investigations, FSIS cites occasional statements that a consumer had mishandled the product, prepared it using a microwave, or did not understand the product was raw. None of these statements provide proper support for the Proposed Determination.

For one, the statements FSIS references reflect an extremely small number of consumers spread over many decades. The PPIA does not require that products be handled perfectly by every consumer; rather, the statute and courts look to customary practice. The fact that a small number of individuals have, over more than two decades, reported mishandling product in no way establishes that this is the customary practice. If anything, the dearth of such statements reinforces the opposite – that consumers by and large handle this product properly. Moreover, industry-implemented labeling changes have clearly helped aid in proper handling of the product by consumers. This is reflective of the fact that there has only been one outbreak associated with these products since 2016. FSIS cannot simply assume these few statements over 25 years reflect broad consumer trends today.

[58] Marshall, et al., *Appliances Used by Consumers to Prepare Frozen Stuffed Chicken*, at 1515. Indeed, it is entirely possible that responses about appliance use reflect answers from consumers who were thinking about fully cooked products, which are routinely (and safely) cooked using appliances such as microwaves or air fryers.

[59] Again, this is *all* frozen stuffed products, not only raw products.

Moreover, as FSIS's 2020 consumer research study recognizes, interview statements about handling practices are not nearly as reliable as observational data. Scattered statements made after the fact in the context of an outbreak should be viewed accordingly.

FSIS also appears to misinterpret certain aspects of outbreaks in the public health context. For example, FSIS notes that NRTE breaded stuffed chicken products are typically stored in the freezer and consumed over time, such that "*Salmonella* illness outbreaks associated with these products tend to persist for several months, even when implicated products represent a few days of production," and that "the long, recurring history and ongoing nature of *Salmonella* illness outbreaks associated with" these products raises public health concerns.[60] FSIS appears to be confusing the *length* of an outbreak with the *severity* of an outbreak. An outbreak in which two case patients are identified each month for five months has the same public health impact as one in which ten case patients are identified in one month, and less public health impact than one involving 20 case patients in one month. If anything, the fact that NRTE breaded stuffed chicken products are kept in freezers and consumed over time means that, in the unfortunate and unlikely event a food safety problem is identified, it is more likely that consumers can be made aware of the problem before consuming the product. FSIS's focus on the duration of outbreaks is misplaced and does not support the proposed action.

c. FSIS's reliance on *E. coli* precedent is misplaced and misapplied

FSIS's reasoning for the Proposed Determination appears heavily tied to its precedent for *E. coli*. This reliance is misplaced and misapplied.

Salmonella in raw chicken is fundamentally different than Shiga toxin producing *E. coli* (STEC) in raw non-intact beef. FSIS attempts to draw parallels between these product-pathogen pairs, but the analysis misses the key distinctions. In the Proposed Determination, FSIS attempts to reduce its 1994 decision declaring *E. coli* O157:H7 an adulterant in raw ground beef (and subsequent extension to STEC in raw non-intact beef) to a set of "criteria," all of which appear equally weighted: association with human illness, low infectious dose, severity of human illness, and typical consumer cooking practices.[61] However, that is not actually the approach FSIS took at the time, nor is it the analysis courts performed when evaluating FSIS's *E. coli* policy.

In fact, FSIS's analysis turned *primarily* on whether *E. coli* was likely to be destroyed under customary cooking practices for raw ground beef. In explaining its policy on *E. coli* O157:H7, FSIS provided background on the risks of *E. coli* O157:H7 but then expressly tied *E. coli* O157:H7's status as an adulterant to cooking practices: "Raw ground beef products present a significant public health risk *because* they are frequently consumed after preparation (*e.g.*, cooking hamburger to a rare or medium rare state) that does not destroy *E. coli* O157:H7 organisms that have been introduced below the product's surface."[62] If that were not clear enough, FSIS continued, "the Agency believes that the status under the FMIA of beef products contaminated with *E. coli* O157:H7 *must depend* on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when

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[60] 88 Fed. Reg. at 26263.

[61] *E.g.*, 88 Fed. Reg. at 26250.

[62] FSIS, *Beef Products Contaminated with* Escherichia Coli *O157:H7*, 64 Fed. Reg. 2803, 2803 (Jan. 19, 1999) (emphasis added).

consumed."[63] Cooking practices were expressly the dispositive factor. This is reinforced by the fact that FSIS determined that intact cuts of beef, when contaminated with the exact same *E. coli* O157:H7, were not adulterated because "[i]ntact steaks and roasts and other intact cuts of muscle with surface contamination are customarily cooked in a manner than ensures that these products are not contaminated with *E. coli* O157:H7."[64] FSIS again cited to customary cooking practices as the dispositive point in its 2011 *Federal Register* notice declaring several other STECs to similarly be adulterants in raw non-intact beef.[65] Thus, rather than being a multi-factor analysis as presented in the Proposed Determination, FSIS must answer only one question: whether the customary cooking practices would ordinarily render the product injurious to health.

Courts recognize this distinction as pivotal. In upholding FSIS's *E. coli* O157:H7 sampling program, and in a case that fundamentally turned on whether *E. coli* O157:H7 could properly be considered an adulterant in raw ground beef, the District Court for the Western District of Texas in *Texas Food Industry Association v. Espy* focused on whether the cooking practices that most Americans considered "proper" for ground beef were sufficiently "thorough" as to destroy *E. coli* O157:H7:

> However, unlike other pathogens, it is not "proper" cooking but "thorough" cooking that is necessary to protect consumers from *E. Coli*. The evidence submitted by [USDA] indicated that many Americans consider ground beef to be properly cooked rare, medium rare, or medium. The evidence also indicated that *E. Coli* contaminated ground beef cooked in such a manner may cause serious physical problems, including death. Therefore, *E. Coli* is a substance that renders "injurious to health" what many Americans believe to be properly cooked ground beef.[66]

In *Texas Food Industry Association*, just as in FSIS's explanation of its *E. coli* O157:H7 policy, the analysis turned on whether customary consumer cooking practices were sufficient. Under the court's reasoning, if what consumers understood to be "proper" cooking had been adequate to destroy *E. coli* O157:H7 in hamburgers, then the substance would not have been an adulterant (just as it is still not an adulterant on raw intact beef). In contrast to ground beef, consumers do not customarily consider it "proper" to cook chicken breast medium rare, for example, regardless of what product format that chicken breast is in. Even ground chicken products such as chicken burgers or meatballs are customarily cooked through, not prepared rare. What consumers consider to be the "proper" or "customary" method is also a method that cooks chicken "thoroughly."[67]

Courts have likewise recognized this distinction. The Fifth Circuit in *Supreme Beef Processors, Inc. v. USDA* recognized that "*Salmonella* [is] present in a substantial proportion of meat and poultry products"

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[63] *Id.* (emphasis added).

[64] *Id.* at 2804 (emphasis added).

[65] FSIS, *Siga Toxin-Producing* Escherichia coli *in Certain Raw Beef Products*, 76 Fed. Reg. 58157, 58158 (Sept. 20, 2011).

[66] *Texas Food Industry Association v. Espy*, 870 F. Supp. 143, 149 (W.D. Tex. 1994).

[67] Other critical distinctions exist between STECs in raw non-intact beef and *Salmonella* in raw poultry. For example, *E. coli* typically enters the cattle slaughter process through cross contamination with fecal matter on the outside of the hide, which can get transferred to the meat if sanitary practices are not observed. By contract, *Salmonella* actually enters in the chicken, including edible parts of the chicken. No amount of process control or sanitary dressing can prevent its being in the product because it starts out in the product.

and "is not an adulterant *per se*" because "normal cooking practices for meat and poultry destroy the *Salmonella* organism."[68] The D.C. Circuit reached a similar conclusion in *American Public Health Association v. Butz*, holding "the presence of salmonellae on meat does not constitute adulteration" and that "American housewives and cooks are not ignorant or stupid and their methods of preparing and cooking of food do not ordinarily result in salmonellosis."[69] In other words, existing court precedent indicates the mere "presence of *Salmonella* in meat products," without more, does not support FSIS regulation under § 453(g)(1).[70]

FSIS, too, has long and consistently recognized that *Salmonella* is not an adulterant in any raw poultry. For example, as recently as last year, FSIS denied a petition requesting FSIS declare certain *Salmonella* strains to be adulterants in raw poultry. In 2018, FSIS denied a different petition making a similar request to declare certain *Salmonella* strains as an adulterant in raw meat and poultry. In its 2016 *Federal Register* notice announcing new *Salmonella* performance standards for poultry, FSIS clearly explained, "*Salmonella* is not an adulterant in NRTE poultry products."[71] In 2014, FSIS rejected a petition to declare antibiotic resistant *Salmonella* an adulterant, stating "we are not aware of any data to suggest that consumers consider ground poultry . . . to be properly cooked when rare, medium rare, or medium."[72] Crucially, USDA has never argued that *Salmonella* is an adulterant under § 453(g)(1). Instead, it has argued the opposite in litigation and policy documents. For example, in the *Supreme Beef* case on the enforceability of *Salmonella* performance standards, the court noted, "The USDA agrees in this case that *Salmonella* is not a[n] . . . adulterant."[73] FSIS has not identified any evidence in the Proposed Determination that would support a change in this position.

d. FSIS has not established that *Salmonella* presence at above 1 CFU/g renders the product "unsound, unhealthful, or unwholesome, or otherwise unfit for food."

Throughout the Proposed Determination, FSIS includes a statement that NRTE breaded stuffed chicken products with *Salmonella* above 1 CFU/g would also be adulterated under 9 U.S.C. § 453(g)(3) because *Salmonella* at above that threshold renders the product "unsound, unhealthful, or wholesome, or otherwise unfit for food." FSIS never explains why this would be the case, and this statement appears to be an

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[68] *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432, 438–39 (5th Cir. 2001).

[69] *American Public Health Association v. Butz*, 511 F.2d 331, 334 (D.C. Cir. 1974).

[70] *See also, e.g., Starr Surplus Lines Ins. Co. v. Mountaire Farms Inc.*, 920 F.3d 111, 117 (1st Cir. 2019) ("[T]he mere fact of the FSIS-orchestrated recall does not give rise to the plausible inference that the type of salmonella found . . . could not be eliminated by proper cooking."); *Craten v. Foster Poultry Farms Inc.*, 305 F. Supp.3d 1051, 1058 (D. Ariz. 2018) (observing that existing case law "suggests *Salmonella* is not an adulterant" and rejecting several state law tort claims because *Salmonella* "is killed through proper cooking, which is how raw chicken products are intended to be used").

[71] FSIS, *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, 7297 (Feb. 11, 2016).

[72] Letter from Daniel Engeljohn, Assistant Adm'r, Off. of Pol'y & Program Dev., USDA, to Sarah Klein, Food Safety Program (July 31, 2014).

[73] *Supreme Beef*, 275 F.3d at 439 n.21.

effort to buttress FSIS's legal support with a second statutory provision. FSIS appears, though, to take one of two positions: either (1) situations that trigger Section 453(g)(1) also automatically trigger Section 453(g)(3), or (2) Section 453(g)(3) is a sort of catchall provision that encompasses any situation not specifically captured by the other adulteration provisions of Section 453(g). Neither is correct.

First, Section 453(g)(3) is not just duplicative of the other adulteration provisions. Congress organized Section 453(g) into clear categories encompassing different ways in which products are considered adulterated. Section 453(g)(1) encompasses the situations in which substances added to or inherent in the products render the products adulterated, Section 453(g)(2) covers food additives, Section 453(g)(4) covers manufacturing conditions, and so on. A situation could trigger multiple adulteration provisions, but each violation would have to be established independently. FSIS provides no explanation as to why the presence of *Salmonella* in NRTE breaded stuffed chicken products at greater than 1 CFU/g causes those products to be unfit for food.

Second, and more importantly, Section 453(g)(3) is not a general catch-all provision giving FSIS authority to find a product to be adulterated whenever the Agency is unable to invoke one of the other adulteration provisions. Congress specifically addressed in Section 453(g)(1) the situations in which pathogens render a food adulterated. In doing so, Congress established a very specific framework with different standards applying to added and inherent substances. It would have made no sense for Congress to create such a precise set of standards for added and inherent substances in one subsection only to give in another subsection USDA carte-blanche authority to disregard those distinctions. Congress did not write the PPIA to allow USDA to use Section 453(g)(3) to make an organism an adulterant when USDA was not able to do so under Section 453(g)(1).

III. The Proposed Determination Is Unsupported by FSIS's Record, Rendering It Arbitrary and Capricious

Under the Administrative Procedure Act (APA), Agency actions may be invalidated when they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[74] Courts have held that Agency action is "arbitrary and capricious" when the Agency has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[75] In determining whether an Agency action is arbitrary and capricious, courts review the information available in the administrative record.

FSIS has proposed a drastic change to longstanding Agency policy and based its new position on speculative statements, inadequate (and often contradictory) scientific support, and outdated data. Any of these infirmities are enough to render the Proposed Determination arbitrary and capricious.[76]

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[74] 5 U.S.C. § 706(2)(A).

[75] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

[76] *See id.* at 34.

a. The Basis of the Proposed Determination Suffers from Lack of Relevant and Recent Supporting Data

As discussed in Section II above, which is incorporated by reference here, the Proposed Determination is rife with unsupported and speculative statements, which in many cases are contradicted by the record and/or by scientific literature. To briefly recap key points:

- The premise that *Salmonella* is not found in chicken muscle tissue is contradicted by the scientific literature;
- FSIS provides no data to support its speculative cross-contamination theory, which is contradicted by industry testing data;
- The leading studies cited by FSIS to support its statements about consumer handling of these products either contradict FSIS's assertions or simply do not address what FSIS says they do;
- The sole dose-response study cited to support the proposed 1 CFU/g threshold was criticized by its own author, relies on outdated data, and does not account for the specific features of chicken as a food matrix; and
- FSIS cannot extrapolate from a handful of anecdotal statements collected during outbreak investigations over 25 years to determine consumer handling of these products.

In addition to these serious issues with the record, FSIS relies heavily on old and inapplicable data. FSIS does not explain how this data reflects the current situation, and in some cases, the data is likely outdated due to progress in testing technologies.

For example, FSIS relies heavily on the fact that there have been 14 outbreak investigations related to NRTE breaded stuffed chicken products over the past 25 years. Most of these reflect dated product labeling and were based on less precise investigational methods. Of the 14 outbreak investigations reported in the Proposed Determination, only one occurred in the past half decade, and most occurred more than thirteen years ago. One occurred 25 years ago. The years since have seen significant changes in how NRTE breaded stuffed chicken products are sourced, processed (including enhanced interventions such as phage, inhibitors, and antimicrobials), and labeled, as well as in how outbreaks are investigated and attributed. Importantly, around 2006, the industry implemented voluntary labeling to better inform consumers of the raw nature of these products, including instructions not to microwave the products. Outbreaks based on improper handling before these changes were implemented are not relevant for evaluating the current public health impact.

Just as importantly, FSIS's ability to identify and attribute outbreaks has undergone seismic changes during this period. Only a few of the outbreaks have occurred since FSIS began using whole genome sequencing (WGS) in the mid-2010s. Some even predate FSIS's use of pulsed-field gel electrophoresis (PFGE) starting in the mid-2000s. It is not even clear how many of the outbreaks FSIS cites would even be considered linked to these product under modern epidemiological standards. It is especially telling that even as FSIS's ability to detect and attribute outbreaks improved substantially around 2015, the number and frequency of outbreaks associated with NRTE breaded stuffed chicken products dropped significantly. Viewed in total, the data associated with older testing technologies must be discounted when evaluating the current public health profile for these products, and FSIS's reliance on old outbreaks is questionable.

FSIS also cites outdated research. For example, FSIS cites a 2008 paper explicitly focused on *microwavable* products from 1998-2006 when talking about food thermometer use, even though labeling

instructions have changed since then.[77] Citations to this paper appear repeatedly throughout FSIS's discussions, but research focused on consumer behavior from 15 to 25 years ago is simply not relevant.

Even more modern data references are inappropriate. For example, although not cited in the *Federal Register* notice, FSIS added to the rulemaking docket a June 2023 paper entitled, *Survey of Not Ready-to-Eat Breaded and Stuffed Chicken Products for Salmonella*.[78] This paper was published to the docket on June 27, 2023, about two-thirds of the way through the comment period. While the results of the study are referenced in the Proposed Determination, FSIS has provided no explanation of its relevance or whether or how FSIS is using it to support its thinking behind the Proposed Determination. We therefore are unable to adequately comment on the study and to what extent it is informing FSIS's policymaking. We nonetheless have several comments on the inappropriateness of relying on this study for any policymaking. First, FSIS acknowledges that this is a "non-scientific study" and that its focus is to "determine the presence of *Salmonella* in these products."[79] The samples are not weighted to reflect relative production volume, they are not geographically dispersed, multiple sample methods were used (with highly varying results between methods), and no statistical analysis was performed on the base results. Second, the study uses multiple laboratory methods and sample sizes, and FSIS concludes that those differing methods and sample sizes significantly affect the sample results. Third, the study evaluated prevalence, not levels or quantity, of *Salmonella*, and so it is unclear how confirming that *Salmonella* is present on raw products informs the 1 CFU/g threshold in the Agency's proposal. Fourth, the study involved testing of the finished product, whereas FSIS has proposed a standard to be applied to only the chicken component of the product; the study could be picking up *Salmonella* present from other ingredients. These reasons alone are enough to set it aside for policy development purposes.

This paper also raises another significant issue, discussed further below: FSIS has never conducted any sort of targeted sampling for this product category, including enumerative sampling for *Salmonella*. Doing so should be a critical prerequisite to developing policy based on science.

b. FSIS has proposed a threshold standard to which it cannot reliably test

FSIS has proposed an adulteration threshold that it cannot reliably test against. FSIS has adopted in the Microbiology Laboratory Guidebook one test method that is capable of enumerating *Salmonella* in raw poultry.[80] Based on publicly available information, this test method is accredited to enumerate *Salmonella* based on a limit of detection of 10 CFU/g without enrichment.[81] To the best of NCC's understanding, FSIS would need to use a non-accredited process to enrich samples and convert the results

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[77] 88 Fed. Reg. at 26249, n.16.

[78] FSIS, *Survey of Not Ready-to-Eat Breaded and Stuffed Chicken Products for Salmonella*, Docket ID No. FSIS-2022-0013-0015 (June 2023), https://www.fsis.usda.gov/sites/default/files/media_file/documents/NRTE_Survey_Sampling_for_Salmonella_Report_05252023.pdf.

[79] *Id.* at 3.**Error! Hyperlink reference not valid.**

[80] FSIS, *Microbiology Laboratory Guidebook*: *4.14 Sample Salmonella Enumeration Procedure (Poultry Rinsates and Raw Poultry)* USDA at 18 (2023), https://www.fsis.usda.gov/sites/default/files/media_file/documents/MLG-4.14.pdf.

[81] NCC takes no position in these comments regarding the usefulness of this test when used within in its accredited parameters or for non-regulatory purposes.

back to values reflective of the original quantity of *Salmonella* present in the sample. This process presumably would inject a margin of variability into the final result, but FSIS has not discussed how it would accommodate this variation in its verification sampling. We have serious concerns about the appropriateness of such an approach, and FSIS has provided inadequate information for the industry to understand and assess how the Agency would account for issues related to the test method.

Moreover, forcing an enrichment process significantly increases the necessary time to receive a test result. This in turn increases the burdens posed by test and hold programs, including cold storage cost and availability, logistics costs, lost raw material shelf life, and others.

c. The history shows continued improvement in the public health profile for these products

Contrary to what FSIS suggests throughout the Proposed Determination, there has been a marked and continued improvement in the public health profile for NRTE breaded stuffed chicken products. As explained in Part I, the current approach has been working and undermines the lack of justification for such a drastic change.

FSIS goes to considerable length reviewing 14 outbreak investigations over the past quarter century. Importantly, five of those outbreaks did not result in a recall or public health alert, suggesting that FSIS was unable to conclusively identify the source and calling into question their relevance to the Proposed Determination. Even taking FSIS's list at face value, though, shows how effective voluntary industry actions have been in controlling health risks for NRTE breaded stuffed chicken products.

FSIS has identified 14 outbreaks associated with NRTE breaded stuffed chicken products. Of those, 57 percent occurred more than ten years ago. And 93 percent occurred more than seven years ago. Only a single outbreak associated with these products has occurred in the past seven years. This trend exists despite drastic improvements in laboratory testing and outbreak detection. So even though it is many more times likely that outbreaks would be detected over the past seven years, we have seen dramatically fewer. This alone reinforces that the current approach is working. If *Salmonella* did not render these products ordinarily injurious to health ten years ago, the data show it certainly does not now.

FSIS appears to be heavily motivated by the 2021 outbreak, citing to this outbreak often in the Proposed Determination and in its Preliminary Cost-Benefit Analysis to justify the need for urgent and drastic action.[82] From 1998 through 2016, there was on average one outbreak per year associated with this product category. Since 2016, there has been an average of 0.14 outbreaks per year, or one outbreak every seven years. This is a seven-fold decrease. If all FSIS- and FDA-regulated product categories achieved a similar reduction in outbreaks, the overall impact on public health would be immense.

IV. The Proposed Determination Raises a Major Question Requiring Congressional Direction

The Proposed Determination would mark a seismic and unprecedented shift in how FSIS regulates raw poultry. As recently explained by the Supreme Court in *West Virginia v. EPA*, in certain cases of

[82] 88 Fed. Reg. at 26259 ("In light of the 2021 Salmonella outbreak and earlier outbreaks associated with these products, the Agency has concluded that the recommendations, which focus primarily on product labeling and consumer handling practices, are unlikely to be effective in preventing additional foodborne illnesses associated with NRTE breaded stuffed chicken products.").

"economic and political significance," an agency must demonstrate "clear congressional authorization" to exercise its powers.[83] This proposal would see FSIS upend a more than fifty-year-old approach to how it regulates raw poultry, and FSIS's approach to NRTE breaded stuffed chicken products could have significant collateral consequences in law and policy but also the communities where these products are produced. Moreover, throughout the proposal, FSIS notes the uncertain or speculative nature of its decision and significant scientific gaps. This proposal presents the very definition of a major question requiring Congressional direction.

V. The Proposed Determination Raises Numerous Other Practical and Scientific Issues Without Clear Resolution

The Proposed Determination also raises numerous practical, technical, and scientific issues that would have to be resolved before the proposal could be implemented, and it is unclear whether some are even resolvable. The nature of these issues in many ways reinforces the speculative and premature nature of FSIS's proposal.

a. Verification testing

FSIS proposes to conduct verification testing to support its Proposed Determination. Although NCC believes the proposal should not be pursued further, we have several comments on this point.

FSIS should provide flexibility in the location for FSIS sampling. FSIS indicates it would take the sample after formation of the raw chicken. Many processors would be unable to divert impacted product at this stage, leading to substantial food waste if raw material were to exceed the threshold. If the establishment is able to support an alternate location, such as incoming raw chicken material, we urge FSIS to adopt that sampling location.[84]

FSIS specifically requested comment on whether it should conduct verification sampling on finished product. FSIS should not sample finished product. Sampling incoming raw materials would provide establishments some ability to divert or otherwise salvage raw materials that fail the standard. FSIS should consider the costs associated with such diversion in the cost-benefit analysis. A finished NRTE stuffed breaded chicken product has a different formulation than the limited range of these products that are sold fully cooked. Therefore, finished products cannot be salvaged or remediated, and sampling them would result in food waste. NCC would also encourage FSIS to make clear that any standard applies only

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[83] *West Virginia v. EPA*, 142 S. Ct. 2587, 2613–14 (2022) (explaining that in certain cases of "economic and political significance," an agency must demonstrate "clear congressional authorization" to exercise its powers); *see also Nat'l Fed'n Ind. Business v. OSHA*, 142 S. Ct. 661 (2022) (per curiam) (rejecting the Occupational Safety and Health Administration's claims of regulatory authority regarding emergency temporary standards imposing COVID-19 vaccination and testing requirements on a large portion of the national workforce); *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485 (2021) (per curiam) (rejecting the CDC's claims of regulatory authority regarding a nationwide eviction moratorium).

[84] FSIS notes that, "Under this proposal, such lots could be diverted for use in a fully cooked poultry product or for use in another raw poultry product, such as ground chicken, in which consumer preparation is more likely to mitigate the risk." 88 Fed. Reg. at 26266. While NCC agrees that this would be a permissible action based on FSIS's rationale in the Proposed Determination, NCC questions whether FSIS should actively encourage establishments to divert product that FSIS views as presenting a public health risk to a raw ground application.

to the chicken component and that one cannot determine a noncompliance merely by testing finished product, because other ingredients could contribute *Salmonella* to the product.

FSIS should also clarify that its standard applies to the release of the finished product. In the proposal, FSIS states that, "under this proposed FSIS verification sampling, establishments would be required to control the chicken component product sampled by FSIS and not incorporate it into NRTE breaded stuffed chicken products pending the test results."[85] Specifically, FSIS should clarify that any raw material failing this or any other standard is not itself adulterated, but rather any NRTE breaded stuffed chicken product made using it would be. Establishments should be free to divert any raw material at the time of testing to another appropriate application without that raw material or the other product being considered adulterated.

If the establishment chooses to use the FSIS sampled raw material to make a finished NRTE breaded stuffed chicken product, FSIS would be expected to require establishments to control any finished product made using the tested chicken components pending the test results. To the extent an establishment may wish to complete manufacturing (e.g., because it is not feasible for it to hold the raw material), it should be allowed to do so, so long as the finished product remains under company control.

NCC agrees that FSIS should provide establishments enumeration results as soon as they are available, without waiting for serotype or WGS information, to minimize product hold times. That said, the verification sampling as proposed would still place establishments in the difficult position of needing to decide whether to release products before they have received all testing information or whether to hold product or raw material for several more weeks to receive all testing information. This would place an unfair financial and risk management burden on establishments.

Finally, it is unclear how FSIS would approach verification sampling, both in terms of frequency, the number of samples collected, and how the final level would be determined. For example, would FSIS collect multiple samples and use an average or composite result to determine the level for the product represented by that sample? These and other considerations are critical parts of the Proposed Determination and deferring them to later policy development presents an incomplete version of FSIS's proposal for comment.

b. Lotting

FSIS's proposal raised significant questions about how raw material lots would be defined. FSIS has maintained the position that industry processes and antimicrobial interventions are effective when used according to scientific support. For this reason, FSIS has allowed industry to use test results from their own sampling programs in conjunction with other food safety program data to demonstrate microbiological independence between lots. FSIS needs to clarify that the Agency will accept results from establishment testing programs to demonstrate that each negatively tested lot is microbiologically independent from other lots. FSIS should also clarify that the Agency will accept an establishment's negative test results in the event an outside sample is taken of the finished product. Testing of finished product would not be representative of the raw chicken component that is the subject of the Proposed Determination.

Further, FSIS has not addressed other critical questions, such as: How would FSIS approach a situation in which production of raw source material from a supplying establishment is sent to multiple further

[85] 88 Fed. Reg. at 26266.

processors, some or all of whom produce NRTE breaded stuffed chicken products? Again, FSIS should clarify that if an establishment has testing results to show the product met the standard, FSIS should accept those results. It is essential that FSIS recognize and accept establishment test results to conclusively demonstrate that a product lot meets the standard (unless there is contradictory FSIS verification sampling for that specific production lot, however that would be defined).

c. Inadequate test and hold capacity

NCC anticipates that establishments will implement comprehensive and costly testing schemes to ensure they comply with any proposed standard. Presumably, establishments will test and hold raw materials pending test results. This would in effect result in *all* raw material or finished NRTE breaded stuffed chicken products being subjected to a multi-day hold process. Moreover, based on the timelines described in the Proposed Determination, FSIS verification sampling could require extended hold times of one or more weeks for the sampled materials. This presents numerous practical and logistical challenges.

First, implementing a hold time for the fresh raw materials risks compromising product quality and artificially shortens raw material shelf life. The fresh raw materials are raw products, and they have finite shelf lives as raw or work-in-progress (WIP) materials. The raw chicken component will have undergone multiple processing steps before being ready for use in an NRTE breaded stuffed chicken product. These steps will vary by product and process, but they could include harvesting and processing the whole bird, chilling the whole carcass, breaking the carcass into parts, deboning, subsequent storage, and shipment, and for comminuted raw materials, collection and shipment of source material to a grinding operation, again followed by subsequent shipment and storage. The raw materials must then be shipped to the establishment producing the NRTE breaded stuffed chicken product, processed at that establishment to prepare it for stuffing and breading, and then breaded product and frozen. All told, a raw chicken component would have a typical useful working shelf life maximum of 10 days, and by the time it is ready for use in a NRTE breaded stuffed chicken product, 5-7 days may have been used, leaving a margin of only 3-5 days. Injecting a forced WIP hold period of 14 days (based on FSIS's testing timeline) risks seriously compromising product quality and the ability to use raw materials in these products. In many instances, the only alternative may be to simply discard the product, leading to substantial food waste of a high quality and affordable protein source. Even under a best-case-scenario expedited industry testing program, the slightest delay could destroy the raw material's usefulness.

Further, the establishments that produce these products may not have sufficient onsite or off-site cold storage to hold a week's worth of raw material or finished product. There may be limited offsite cold storage capacity convenient to these plants, and the attendant labor, transportation, and cold-storage fees would significantly inflate the price of these products, to consumers' detriment. Moreover, we understand FSIS is currently assessing its *Salmonella* policy for raw poultry more broadly. If that policy were to also require or encourage industrywide testing, it would likely require cold-storage capacity beyond what exists, further driving up costs, bottlenecking supply chains, and exacerbating the cold storage problems presented by the Proposed Determination.[86]

[86] This is one reason it is premature to issue the Proposed Determination while FSIS is concurrently looking at its *Salmonella* policy more broadly, as discussed further below.

As discussed, establishments would likely choose to conduct their own testing to ensure their raw materials would meet FSIS' standard, even though that is not strictly required.[87] FSIS is aware of this likelihood through its long experience with the beef industry. This could lead to concerns regarding raw material supply as producers of this product may elect to not sell the material to producers of NRTE breaded stuffed chicken. In addition, the testing may overwhelm lab capacity, leading to testing delays (exacerbating cold storage and shelf-life problems) and increasing costs. These problems would become exponentially worse were FSIS to develop a *Salmonella* policy for raw poultry broadly that would also encourage this type of testing.

FSIS does not appear to have meaningfully considered these challenges in its Proposed Determination or in its cost-benefit analysis.

d. Additional Scoping Considerations for the Proposed Determination

NCC has several additional comments on the specifics of the Proposed Determination, recognizing that NCC does not believe the Proposed Determination is necessary or legally appropriate in the first place:

- NCC does not support extending the Proposed Determination to any other products beyond those specific NRTE breaded stuffed chicken products that are the source of the discussion. This would include not extending the proposed policy to other breaded chicken products, such as chicken nuggets or patties. Many of these products are sold to foodservice (i.e., QSR) that operate under the Food Code and maintain validated cooking processes and are overseen by the health department.

- NCC does not believe that the Proposed Determination, if pursued further, should be applied to NRTE breaded stuffed chicken products intended for use by hotel, restaurant, or institutional (HRI) consumers. Foodservice operators receive extensive food safety training and are familiar with how to safely prepare various products, and their operations are overseen by state and local health departments. None of the consumer perception information or outbreak investigation information presented by FSIS is relevant to HRI consumers. In fact, NCC is not aware of any foodborne illness outbreaks associated with foodservice or institutional preparation of NRTE breaded stuffed products. There is no rationale for imposing the Proposed Determination on product intended for HRI use. Adopting the NCC petition is adequate for these customers.

- FSIS's rationale also does not support extending the Proposed Determination to stuffed products that appear raw (either in the retail case with other raw chicken products or frozen and pre-packaged). FSIS's rationale turns heavily on the cooked visual appearance of breaded stuffed products. If the product maintains its raw appearance, there would be no reason under FSIS's rationale to expect consumers to treat the product differently than any other raw chicken product.

- FSIS implies at various points that mechanically separated chicken (MSC) is being used as source material in NRTE breaded stuffed chicken products.[88] NCC does not believe this to be the case. The NCC members producing NRTE breaded stuffed chicken products do not use MSC as source material. As explained further below in NCC's alternative proposal, NCC would support a

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[87] FSIS's blithe dismissal of these and other costs being incurred by establishments only "if it were in their economic best interest" is addressed further below.

[88] *See, e.g.*, 88 Fed. Reg. at 26260.

requirement that MSC not be permitted for use in these products. Importantly, any potential risks associated with MSC can be readily controlled through such a requirement, without the need to impose any sort of standard for NRTE breaded stuffed chicken products.

VI. Addressing NRTE Breaded Stuffed Chicken Products Is Premature in Light of FSIS's Proposed *Salmonella* Framework

FSIS earlier announced its *Salmonella* Framework, through which the Agency has expressed interest in reviewing its policy toward *Salmonella* in raw poultry more broadly.[89] That framework contemplates reviewing FSIS's approach to *Salmonella* across the board in raw poultry products. In light of that ongoing effort, it is premature to set specific standards for a specific product category as FSIS has not determined the specific product/products that are most likely to be a risk for consumers. FSIS's focus on this particular category in absence of data to support its risk is a questionable use of scarce public resources in light of FSIS's efforts on *Salmonella* more broadly.

Worse, pursuing a separate policy for NRTE breaded stuffed chicken products risks creating inconsistencies or redundant requirements. For example, how would FSIS reconcile any final approach for NRTE breaded stuffed chicken products with one taken under the Framework? What if those standards conflicted or were inconsistent? Would FSIS have to repropose a new, conforming standard for NRTE breaded stuffed chicken products?

Moreover, FSIS suggests throughout the Proposed Determination that it has gotten out ahead of the data. In many instances, FSIS references the speculative nature of its theories and significant data gaps. One significant data gap is that FSIS lacks any sort of insight into the microbiological profile of the products it is targeting for regulation. FSIS has never conducted baseline sampling on either NRTE breaded stuffed chicken products or the raw materials used to produce those products. FSIS is unable to determine at what frequency products currently exceed the proposed 1 CFU/g threshold and whether imposing such a threshold is (1) feasible, (2) would have any impact on the microbiological profile of these products, or (3) would have any measurable impact on public health. FSIS even lacks insight into which serotypes are most prevalent in these products. The most detailed data FSIS has appears to be the recently released "non-scientific" study of *Salmonella* prevalence from NRTE breaded stuffed chicken products purchased at retail, but as discussed above, that study is by design not appropriate for determining current *Salmonella* levels on the raw materials or informing policies.

We encourage FSIS take a more measured, scientifically driven approach to these products. Rather than relying on piecemeal findings from decades-old outbreaks and dated research papers focused on microwavable products, NCC encourages FSIS to conduct the baseline quantification sampling necessary to understand the microbiological profile of the raw chicken materials used in these products and that would be a necessary step for determining what (if any) levels or quantity of *Salmonella* would actually render these products ordinarily injurious to health.

Moreover, a comprehensive microbiological baseline would enable FSIS and industry to develop a much more focused, nuanced, and effective approach for managing the safety profile of these products, one that in all likelihood would not require the drastic and unprecedented steps of declaring *Salmonella* an adulterant in these products. For example, an appropriate baseline might reveal that only certain raw

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[89] FSIS, *Proposed Regulatory Framework to Reduce* Salmonella *Illnesses Attributable to Poultry*, USDA (Oct. 14, 2022), https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/proposed.

materials pose the greatest risk in these products, and establishments could use that information to voluntarily update their food safety programs to avoid the use of those materials, or to require targeted interventions for them. But without a baseline, the Agency and industry are blind to these types of insights, and FSIS's proposal is speculative at best.

VII. FSIS's Cost-Benefit Analysis Dramatically Understates the Economic Costs of the Proposed Determination

FSIS dramatically underestimates the costs and overstates the potential economic benefits of the proposal. Early on, the cost-benefit analysis includes a telling statement: after noting a decrease in overall production of NRTE breaded stuffed chicken products from 2107 through 2021, FSIS remarks that "[t]his sharp decline in production indicates that establishments may *already* be moving away from producing NRTE breaded stuffed chicken products."[90] The use of "already" shows that FSIS either expects or desires establishments to move away from producing this product. But FSIS fails to account for *any* of the economic costs that would follow from further "moving away" from this product class, including lost jobs, possible plant closures, loss of business viability, bankruptcies or liquidation of businesses, and the increased cost and decreased choice for consumers.

In late 2022 NCC surveyed member companies who produce NRTE breaded stuffed chicken products. This survey provides more updated information than FSIS relied on in its cost-benefit analysis. Based on NCC's survey, on an annual basis, these companies produce over 75 million pounds of finished NRTE breaded stuffed chicken product, which equates to almost 193 million servings. It is estimated that this volume of finished product has an annualized value of almost $284 million dollars. If *Salmonella* were declared an adulterant in these products, it could undermine the commercial viability of these products.

a. Inaccuracies Permeate the Cost-Benefit Analysis

There are a number of issues in FSIS's cost assessment that cumulatively call into question the results. For example:

- FSIS significantly under-estimates the retail price of NRTE breaded stuffed products. FSIS estimates the average retail price of these products is $3.45 per pound, but based on the citation, that price appears to actually be the 2021 average retail price of a boneless chicken breast based on Bureau of Labor Statistics data.[91] As value-added products, NRTE breaded stuffed products retail for more than boneless chicken breasts. Economy-wide inflation also means that 2021 prices are unlikely to reflect current prices. Based on NCC's understanding of the retail market, these products tend to retail for a price of approximately $7.20 to $9.60 per pound. This causes FSIS's computation of lost product to be off by a factor of two to three, even under FSIS's assumptions.

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[90] FSIS, *Preliminary Cost-Benefit Analysis:* Salmonella *in Certain Not-Ready-To-Eat Breaded Stuffed Chicken Products*, Docket ID FSIS-2022-0013-0015, 8 (2022), https://www.fsis.usda.gov/sites/default/files/media_file/documents/NRTE_Stuffed_Chicken_CBA_FSIS-2022-0013.pdf (emphasis added).

[91] Complicating stakeholders' ability to review the cost-benefit analysis, the report identified in the footnote appears to be for a different year, as the data FSIS cites cannot be found in it. *See* FSIS, *Preliminary Cost Analysis* at 26 n.50.

- FSIS uses cost data from a 2015 study but inflation-adjusts it only to 2021 dollars. Given the unprecedented overall inflation in 2021, 2022, and now in 2023, this decision alone dramatically understates the costs of the proposal.
- FSIS makes inappropriate assumptions about the labor costs of various activities. For example, FSIS assumes that an "experienced production employee" spends a number of hours to conduct a HACCP plan reassessment (which would be required under the Proposed Determination), but then chooses the 2021 "average hourly wage" for a production employee, picking $15.39. HACCP plans are technically complex documents. At least one "experienced" employee would be required to conduct this task. An experienced employee would be paid on the higher end of the wage curve; the "average" wage understates this. Typically, this would be an experienced, highly skilled employee in a regulatory or food safety department, not general production, who would likely command a higher wage than an average production employee.
- In calculating cold-storage costs, FSIS erroneously assumes that creating cold-storage capacity would cost a plant (even a small establishment) the same as it would cost to purchase offsite cold-storage capacity, which ignores the significant returns to scale achievable by third-party sites.
- The cold-storage estimates also ignore transportation and labor costs to pack sampled product, transport it to and from cold storage, and unpack it.
- The cold-storage estimates also assume an overly optimistic sampling result timeframe. Although FSIS estimates that only two days of cold-storage are needed for a negative sample, this represents an unlikely best-case scenario in which a plant is able to sample product early in the day, get that sample to a lab for setup during that same business day, for the lab to have capacity to immediately process the sample, and get the results in time to retrieve product from cold storage and use it the day the result is received. In reality, samples will often need to go out at the end of a day or the next day, sometimes labs are not available nearby, and lab testing capacity is a nationwide issue. Most negative results would take more than two days to receive.
- FSIS did not consider the cost to establishments of employee time and resources required for establishment sampling to ensure compliance with the Proposed Determination.
- FSIS did not consider the cost of re-validating cooking instructions and updating product labels as necessary.

Errors like these permeate the cost-benefit analysis and accumulate to dramatically understate the compliance costs. FSIS also appears dismissive of any costs that establishments might incur to manage their processes or businesses in light of the Proposed Determination, noting for example that establishments "[t]o varying degrees . . . may also incur costs associated with their individual responses to this policy,"[92] but not trying to quantify any of those costs.

b. The Projected Benefits are Unrealistic

Moreover, the projected benefits of the proposal are questionable. FSIS frames the benefits in terms of outbreak avoidance. Specifically, FSIS predicts that its proposal would be cost-neutral if it were to avoid one outbreak about every six years. NCC agrees that avoiding foodborne illness and foodborne illness outbreaks has significant economic, societal, and personal value. NCC member companies take steps to do this every day. However, there are several critical flaws with FSIS's analysis.

First, because FSIS has drastically underestimated the costs of the Proposed Determination, the benefit would have to be much greater to achieve FSIS's desired breakeven effect.

[92] *E.g.*, 88 Fed. Reg. at 26267.

Second, FSIS's use of the Grocery Manufacturers Association outbreak cost report is misplaced. That report does not address the specific nature of recalls for this product class, and FSIS also erroneously counts every outbreak, rather than every recall, when calculating the extent of purported recall avoidance costs. FSIS should calculate recall avoidance costs based only on actual recall frequency or use a probability-based discount factor when assessing the recall-avoidance costs associated with an outbreak.

Third, and perhaps more importantly, FSIS has failed to credibly take into account the likelihood of its proposal having the desired outcome. As recent trends show, the frequency of foodborne illness outbreaks associated with NRTE breaded stuffed chicken products has dropped precipitously in the past seven years, without FSIS's intervention. It is highly likely that the industry has already achieved through voluntary action what FSIS proposes to achieve. FSIS therefore is likely to experience the diminishing marginal effects of "chasing zero." If foodborne illness outbreaks for these products are already occurring at a rate of 0.14 outbreaks per year, or one outbreak every 84 months, it is questionable how easily or effectively the Proposed Determination could drive that rate down further and achieve its desired breakeven goal. The Proposed Determination would have to drive the current foodborne illness outbreak rate for these products down even further, to somewhere on the order of 0.07 outbreaks every year, or one outbreak every 168 months (or every 14 years), even using something close to FSIS's predicted cost and benefit figures. This is a laudable but unrealistically optimistic goal, and one that is not likely to be achievable for any food category under any circumstances.

VIII. FSIS Should Pursue an Alternative Approach to Better and More Efficiently Achieve Its Public Health Objectives

One key trend that emerges from FSIS's discussion of outbreaks in the Proposed Determination is that outbreaks have occurred for NRTE breaded stuffed chicken products in recent years at a dramatically lower rate than in years past. This is no accident. Rather, it reflects concerted efforts by the NCC members who produce these products to continually improve these products' food safety profile. This experience demonstrates the value and effectiveness of intelligent, focused, science-based food safety initiatives, all of which can and have been achieved without a single change to Agency regulations or policy. This collaborative approach has worked, and it can continue to improve the public health profile of these products. We see no reason to abandon what works in favor of unprecedented policy changes.

NCC firmly believes that food safety initiatives work best when they reflect collaboration between the industry and FSIS. That is why NCC wrote to Deputy Under Secretary Sandra Eskin on July 15, 2022, requesting the Agency take specific and comprehensive actions to address the labeling, manufacturing, and microbiological profiles for these products.[93] NCC is concerned by the lack of a response to our 2022 letter, as well as FSIS's failure to act on our 2016 petition for rulemaking and 2022 supplement. NCC's requests reflect prevailing expert recommendations and years of experience from those involved firsthand with these products, and they would be expected to advance FSIS's public health objectives for this product category. Our recommendations remain valid and continue to reflect and go beyond expert recommendations. We encourage FSIS to instead adopt this proposed approach.

Working with the food safety professionals from our member companies, and drawing on the expert NACMPI recommendations, NCC has developed a set of proposed steps that are robust, data-driven, and

[93] Letter from Dr. Ashley Peterson, Senior Vice President, Scientific and Regulatory Affairs, to Sandra Eskin, Deputy Under Secretary for Food Safety, Office of Food Safety, July 15, 2022. NCC has yet to receive a response to this letter.

likely to continue improving the public health profile of these products. Specifically, NCC urges FSIS to take the following actions:

Act on NCC's updated 2022 labeling petition (Petition 16-03). Our 2022 petition updated our 2016 petition and requests that FSIS (1) define this product category; (2) require the term "raw" be included in the product name and appear prominently in several other specific places on the label; (3) require a prominent statement that the product must be cooked to 165°F measured by a meat thermometer; (4) require a prominent front-of-pack "raw chicken" icon that includes instructions to oven bake and not to microwave the product; (5) require labels to include detailed validated cooking instructions; and (6) publish a compliance guide on validating cooking instructions for these products. This petition reflects our latest understanding of best practices for labeling these products. A codified regulation would ensure uniformity across all such products sold in the United States, enhance consumer familiarity and reinforce proper handling practices, and provide FSIS with a clear mechanism for enforcing labeling requirements and for conducting in-plant verification activities. This action would also be consistent with NACMPI's recommendation. We urge FSIS to act on our petition.

Conduct a baseline study on *Salmonella* levels in source material. FSIS policy has long recognized the value of conducting comprehensive baseline studies to support regulatory decision-making and to drive performance improvements. FSIS has never conducted a baseline study to understand what levels of *Salmonella* may be in the source material used to create these products. We encourage FSIS to initiate such a baseline study promptly. Importantly, because FSIS has long recognized that decreases in *Salmonella* prevalence do not correlate to decreases in human salmonellosis rates,[94] we recommend that FSIS conduct a baseline study focused on quantifying the level of *Salmonella* present in source material rather than determining only presence or absence. Conducting this baseline would provide FSIS and the industry with a clearer understanding of *Salmonella* levels on source material and would help inform policy and intervention strategies. Without good baseline data, it would be difficult for FSIS to determine what other actions might be appropriate and to measure success for these products.

Conduct a risk assessment based on the *Salmonella* levels baseline study. One particularly valuable use for quantified *Salmonella* baseline data is that it would provide FSIS the ability to conduct a public health risk assessment to better understand how the amount of *Salmonella* in source material may affect public health outcomes. This type of a risk assessment would help FSIS develop science-based policies, and it could help establishments develop best practices for their processes and to make better informed decisions about incoming source materials.

Develop a compliance guideline for processing NRTE breaded stuffed chicken products. Although the industry has long worked to develop best practices, an FSIS compliance guideline would provide significant value by reinforcing the best practices and highlighting their importance in an establishment's food safety system. A compliance guideline might address topics such as source material control and selection, processing interventions, cooking validation, labeling, and packaging. It would also be particularly helpful for the small and very small establishments that produce this product and may lack the technical resources to conduct their food safety research.

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[94] *E.g.*, FSIS, Salmonella *By the Numbers*, USDA (June 29, 2022), https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/salmonella ("FSIS testing data show that Salmonella contamination on poultry has been going down, but this has not translated into a reduction in human illnesses.").

Require HACCP plan reassessments for NRTE breaded stuffed chicken products. Although HACCP plans are reassessed annually, an additional focused reassessment would ensure establishments are considering the latest information when designing and implementing their HACCP plans. FSIS has taken similar approaches in the past. For example, in 2012, FSIS instructed establishments producing NRTE comminuted poultry products to reassess their HACCP plans based on updated information related to several foodborne illness outbreaks from prior years.[95] FSIS should take a similar approach for NRTE breaded and stuffed chicken products and call for establishments producing these products to reassess their HACCP plans in light of experiences since 2016 and the FSIS After Action Report[96] recently published regarding the one post-2016 outbreak. Reassessments could also be recommended based on the results of the baseline study discussed above. This step would ensure that establishments have appropriate processes in place to render *Salmonella* a hazard not reasonably likely to occur or establish a critical control point to address the potential hazard. Reassessment might, for example, identify opportunities for additional interventions, enhanced labeling practices, or some other step; or, a reassessment might provide an establishment (and FSIS) additional confidence that its systems are in fact well designed based on the latest information. FSIS could verify this reassessment once or could verify programs on a periodic basis through existing HAV/PHIS instructions. This approach is also consistent with the NACMPI recommendations.

Conduct targeted food safety assessments (FSAs) at plants producing NRTE breaded and stuffed products. FSAs are rigorous inspectional tools that let FSIS conduct an in-depth review of specific aspects of an establishment's food safety system. Through targeted FSAs, FSIS can verify that food safety systems are being implemented properly for these products and could help surface additional best practices. From surveying member companies producing these products, NCC understands that FSIS last conducted an FSA focused on these products last decade.

Follow through on the remaining NACMPI recommendations. In addition to the specific points raised here, we encourage FSIS to also follow through on the other NACMPI recommendations, which include analyzing labeling features and targeted consumer outreach that could promote better consumer understanding of these products. It is critical that consumers be provided the information to safely handle these products, and NACMPI has identified several important strategies that would reinforce the petitioned-for labeling requirements.

Prevent the use of MSC in NRTE breaded stuffed chicken products. NCC does not believe that MSC is appropriate for NRTE breaded stuffed chicken products. Although NCC members do not use MSC to produce NRTE breaded stuffed chicken products, we encourage FSIS to take steps to ensure this practice is followed universally. FSIS has multiple options available, but perhaps the simplest would be to amend the regulations governing mechanically separated poultry at 9 C.F.R. §§ 381.173–74 to prohibit the use of MSC in NRTE breaded stuffed chicken products.

Importantly, all of these steps would have an immediate impact on the safety profile of these products, and in turn on public health. These steps would likely require only modest expenditure of Agency resources and rely on and are consistent with existing Agency policies and authorities. FSIS could begin

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[95] FSIS, *HACCP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and Related Agency Verification Procedures*, 77 Fed. Reg. 72686 (Dec. 6, 2012).

[96] FSIS, Salmonella Enteritidis Outbreak Linked to Frozen, Raw, Breaded, Stuffed Chicken Products, USDA (Nov. 2022), https://www.fsis.usda.gov/sites/default/files/media_file/2022-04/FSIS-After-Action-Review-2021-07.pdf.

many or all of these steps immediately, or to the extent additional financial resources are needed, as soon as the next fiscal year, and NCC would stand ready to assist FSIS in implementing these steps.

IX. Conclusion

NCC appreciates the opportunity to provide comment on the Proposed Determination. NCC recognizes that NRTE breaded stuffed chicken products raise special considerations, and the NCC member companies that produce these products have long sought to collaborate with FSIS to ensure these products are prepared and enjoyed safely. However, NCC feels strongly that the Proposed Determination would take the wrong approach, from a legal, scientific, and practical standpoint. Instead, NCC urges FSIS to pursue the recommendations that both NACMPI and NCC have put forward, as detailed in these comments.

Thank you for your consideration, and please do not hesitate to contact us with any questions.

Respectfully submitted,

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