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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2022–0013]

Salmonella Not Ready-To-Eat Breaded Stuffed Chicken Products

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

ACTION: Final determination and response to comments.

SUMMARY: FSIS is announcing its final determination that not ready-to-eat (NRTE) breaded stuffed chicken products that contain *Salmonella* at levels of 1 Colony Forming Unit per gram (hereinafter, “1 CFU/g”) or higher are adulterated within the meaning of the Poultry Products Inspection Act (PPIA). FSIS is also announcing that it intends to carry out verification procedures, including sampling and testing of the raw incoming chicken components used to produce NRTE breaded stuffed chicken products prior to stuffing and breading.

DATES: This final determination will be effective on May 1, 2025.

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I. Background

On April 28, 2023, FSIS published a proposed determination (88 FR 26249) in which the Agency tentatively declared that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels at or above 1 CFU/g present a significant public health concern. This proposed determination emphasized risks that are particular to these products, given their unique characteristics. Specifically, data from outbreak investigations, as well as consumer behavior research studies, show that common consumer preparation practices associated with these products may not destroy *Salmonella* that may be present in the product. Information from consumer behavior research discussed in the proposed determination (88 FR 26257) also shows that common consumer handling of NRTE breaded stuffed chicken products may contribute to cross-contamination. Further, the proposed determination noted that *Salmonella* has been associated with severe and debilitating human illness and available data suggest that the *Salmonella* infectious dose can be relatively low (88 FR 26261–26264). In addition, outbreak data cited in the proposed determination indicates that NRTE breaded stuffed chicken products have been consistently and disproportionately associated with *Salmonella* illness outbreaks over the years (88 FR 26252–26259). Based on the information discussed in the proposed determination, FSIS tentatively concluded that previous efforts to mitigate the public health concerns associated with these products, which primarily focused on

product labeling and outreach to inform consumers that these products are raw and how to prepare them safely, have failed to adequately ensure that consumer preparation of NRTE breaded stuffed chicken products will result in a product that does not contain *Salmonella* at levels sufficient to cause a high risk of human illness when consumed. As such, FSIS tentatively determined that the appropriate response to protect public health is to ensure that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels more likely to cause human illness are excluded from commerce (88 FR 26264).

FSIS specifically proposed to declare that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels of 1 CFU/g or above as adulterated under the PPIA. As discussed in the proposal, FSIS tentatively concluded that when present in NRTE breaded stuffed chicken products, *Salmonella* at 1 CFU/g or higher meets the definition of an “added substance” that “may render” them injurious to health pursuant to 21 U.S.C. 453(g)(1) (88 FR 26260–26261). The proposal further explained that FSIS also believes that NRTE breaded stuffed chicken products that contain *Salmonella* at 1 CFU/g or higher meets the more stringent “ordinarily injurious” standard under 21 U.S.C. 453(g)(1) (88 FR 26261). Moreover, the proposed determination tentatively concluded that such products are adulterated under 21 U.S.C. 453(g)(3) because their elevated risk of illness makes them “. . . unsound, unhealthful, unwholesome, or otherwise unfit for human food” (88 FR 26261).

After reviewing comments on the proposed determination, FSIS is finalizing the determination as proposed, with one exception. Based on public comments, FSIS has decided to modify the verification sampling location originally proposed to provide greater flexibility and reduce costs to industry. Specifically, instead of collecting samples after the establishment has completed all processes needed to prepare the chicken component to be stuffed and breaded to produce a final NRTE breaded stuffed chicken product, as was proposed, FSIS will collect verification samples on the raw incoming chicken components. FSIS is also clarifying that

establishments may incorporate raw chicken components sampled by FSIS into finished NRTE breaded stuffed chicken products so long as such products remain under the establishments' control pending test results. FSIS is also clarifying, as requested by commenters, that it does not intend to begin FSIS sampling and verification testing discussed in this determination until May 1, 2025. In addition, FSIS has considered the economic effects of this determination and has updated the final Cost Benefit Analysis (CBA) in response to public comments.

II. Summary of Comments and Responses

FSIS received 3,386 comments on the proposed determination from individuals, a laboratory services business, an association representing the entire food industry, research institutes associated with the meat and frozen foods industries, a society of meat industry professionals, an animal welfare advocacy organization, trade associations representing the poultry products industry, members of the meat and poultry industry, and consumer advocacy organizations.

A summary of issues raised by commenters and the Agency's responses follows.

A. FSIS' Legal Authority and Adulteration Under the PPIA

Comment: A trade association representing the poultry industry asserted that FSIS does not have Congressional authorization to take the actions discussed in the proposed determination. Poultry products trade associations, members of the poultry products industry, a society of meat industry professionals, and an institute representing the interests of the meat industry asserted that FSIS' determination that *Salmonella* is an added substance in NRTE breaded stuffed chicken pursuant to 21 U.S.C. 453(g)(1) is inconsistent with legal precedent, which holds that a substance is only "added" if it is artificially introduced by a person.¹ A poultry products trade association and an institute representing the meat industry asserted that FSIS does not have a legal basis to declare that any level of *Salmonella* ordinarily renders NRTE breaded stuffed chicken injurious to health under 21 U.S.C. 453(g)(1), given the courts have previously determined

that consumers prepare raw chicken in a manner that destroys *Salmonella*.²

On the other hand, consumer advocacy organizations agreed with the Agency's tentative conclusion that *Salmonella* is an added substance in NRTE breaded stuffed chicken and is thus subject to the "may render injurious" standard. The commenters also agreed with FSIS' tentative conclusion that NRTE breaded stuffed chicken products that contain *Salmonella* at 1 CFU/g or higher meet the more stringent "ordinarily injurious" standard, because ordinary consumer handling and preparation preserves levels in the end product that result in illness.

Response: The PPIA provides FSIS with the authority to regulate poultry to ensure that adulterated products do not enter commerce.³ Furthermore, Congress, at 21 U.S.C. 453(g)(1), declared two standards for determining whether a product is adulterated. First, if a substance is an "added substance" the product is adulterated if the substance may render the product injurious to health. Second, if the substance is not added, the product is adulterated if the quantity of such substance in or on the product ordinarily renders it injurious to health.

As discussed in the proposed determination (88 FR 26250–26251), this is not the first time that FSIS has exercised its authority to designate a foodborne pathogen as an adulterant in a raw product. In September 1994, FSIS stated that it considered raw ground beef contaminated with *Escherichia coli* O157:H7 (*E. coli* O157:H7) to be adulterated within the meaning of an identical adulteration provision in the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601(m)), and that the Agency was prepared to use the enforcement provisions of that statute to exclude adulterated product from commerce. At the same time, FSIS indicated that it would begin to sample raw ground beef at federally regulated establishments

and in commerce.⁴ Shortly after the 1994 decision, a group of supermarket and meat industry organizations filed suit in the U.S. District Court for the Western District of Texas to reverse FSIS' determination, arguing the Agency exceeded its statutory authority by declaring *E. coli* O157:H7 to be an adulterant under the FMIA. The court ruled in favor of FSIS.⁵ The Agency then updated its policy in 1999, declaring *E. coli* O157:H7 to also be an adulterant of intact beef cuts that are to be further processed into nonintact raw products before being distributed for consumption. In 2011, FSIS declared that six additional Shiga Toxin-Producing *Escherichia coli* (STEC) serogroups (O26, O45, O103, O111, O121, and O145) are adulterants of raw non-intact beef products and raw intact beef components intended to be used in these products.⁶

FSIS is now taking similar action, declaring *Salmonella* to be an adulterant in NRTE breaded stuffed chicken when present at levels at or above 1 CFU/g. FSIS based this decision on the best available science and data using similar criteria as in its 1994, 1999, and 2011 STEC policymaking. This determination, like the STEC determinations, is within the scope of the Agency's statutory authority.

The adulteration definition in 21 U.S.C. 453(g)(1) includes two standards for determining whether a product is adulterated. Under 21 U.S.C. 453(g)(1), if a substance is an "added substance" the product is adulterated if the substance "may render" the product injurious to health. If the substance is not added, the product is adulterated "if the quantity of such substance in or on" the product "ordinarily" renders it injurious to health.

FSIS has determined that when present in NRTE breaded stuffed chicken products, *Salmonella* at 1 CFU per gram or higher meets the definition of an "added substance" that "may render" these products injurious to health. As discussed in the proposed determination (88 FR 26260–26261) and herein, (processing can add *Salmonella* to previously uncontaminated NRTE breaded stuffed chicken components and may increase the occurrence of *Salmonella* throughout the finished product overall. As such, some portion of *Salmonella* present in the NRTE

¹ *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157 (5th Cir. 1980). *United States v. Coca Cola*, 241 U.S. 265 (1915).

² *Texas Food Industry Association v. Espy*, 870 F. Supp. 143, 149 (W.D. Tex. 1994). *American Public Health Association v. Butz*, 511 F.2d 331, 334 (D.C. Cir. 1974). *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432, 438–39 (5th Cir. 2001). 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").

³ 21 U.S.C. 451 and 452.

⁴ Michael R. Taylor, FSIS Administrator. September 29, 1994. "Change and Opportunity to Improve the Safety of the Food Supply." Speech to American Meat Institute Annual Convention, San Francisco, CA.

⁵ See *Texas Food Industry Association v. Espy*, 870 F. Supp. 143 (1994).

⁶ 76 FR 58157, Sept. 20, 2011.

breaded stuffed chicken products has been introduced by humans.

While no court has addressed whether *Salmonella* in processed poultry products is an “added substance” under the PPIA, FSIS’ determination that *Salmonella* at 1 CFU/g is an added substance in NRTE breaded stuffed chicken is consistent with the holding in *United States v. Anderson Seafoods* (622 F.2d 157 (1980)). The issue directly before the court in *U.S. v. Anderson Seafoods* was the meaning of the term “added substance” as used in an adulteration provision of the Federal Food, Drug, and Cosmetic Act (FFDCA), which, in relevant parts, is identical to the “added substance” provision in the PPIA.⁷ *U.S. v. Anderson Seafoods* involved hazardous levels of mercury in swordfish. Specifically, the issue before the court was whether all mercury in the fish should be considered an “added substance” under the adulteration provisions of the FFDCA and thus subject to the “may render injurious standard” when some mercury in swordfish occurs naturally and some is the result of man-made pollution. After considering the legislative history and relevant case law, the court found that the term “added,” as used in the FFDCA, means “artificially introduced, or attributable in some degree to the acts of man.”⁸ The court also held that the “may render it injurious to health” standard applies to the food, not to the added substance and, therefore, “where some portion of a toxin present in a food has been introduced by [humans], the entirety of that substance present in the food will be treated as an added substance.”¹⁰

As discussed in the proposed determination (88 FR 26260–26261) and herein, processing can add *Salmonella* to previously uncontaminated NRTE

breaded stuffed chicken components and may increase the occurrence of *Salmonella* throughout the finished product overall. As such, some portion of *Salmonella* present in the NRTE breaded stuffed chicken products has been introduced by man and, in accordance with the holding in *Anderson Seafoods*, all *Salmonella* in this product should be treated as an “added substance” and may be regulated under the PPIA’s “may render injurious” standard.

In addition, FSIS’ believes that *Salmonella* at 1 CFU/g in NRTE breaded stuffed chicken meets the more stringent “ordinarily injurious to health” standard for substances that are not added, satisfying the definition of “adulterated” under 21 U.S.C. 453(g)(1). This determination also does not conflict with legal precedent. The Agency recognizes that, historically, most foodborne pathogens, including *Salmonella*, have not been considered adulterants of raw and other NRTE meat and poultry based on the assumption that ordinary cooking is generally sufficient to destroy the pathogens.

However, NRTE breaded stuffed chicken products are NRTE multi-ingredient, further processed products that often contain multiple raw poultry source materials and are heat treated in a manner that typically imparts an RTE appearance. As noted in the proposed determination (88 FR 26249), consumer research, together with information gathered during outbreak investigations, clearly show that, because of these unique product characteristics, which make these products particularly risky, consumers often do not prepare these products properly, even when the products display adequate cooking instructions and statements on the label. FSIS is not aware of any court that has analyzed the status of *Salmonella* as an adulterant in NRTE breaded stuffed chicken products, giving due weight to the products’ unique characteristics, consumer behaviors, public health risks associated with these products, or the most recent science and data concerning *Salmonella* in NRTE breaded stuffed chicken products.

Comment: A group of consumer advocacy organizations agreed with FSIS’ position and reasoning in the proposed determination that *Salmonella* is an added substance pursuant to 21 U.S.C. 453(g)(1) in NRTE breaded stuffed chicken products. However, poultry products trade associations, members of the poultry products industry, a society of meat industry professionals, and an institute representing the interests of the meat industry disagreed with FSIS’

determination, arguing that *Salmonella* exists naturally in chicken, and provided studies that they assert show that *Salmonella* exists naturally in muscle tissue.^{11 12 13 14} These commenters also stated that FSIS did not adequately support its view that cross-contamination during further processing is responsible for the presence of *Salmonella* in chicken components used to create NRTE breaded stuffed chicken products.

Response: In the proposed determination, FSIS specifically evaluated whether *Salmonella* should be considered an added substance in NRTE breaded stuffed chicken (88 FR 26260–26261). Although FSIS agrees with the commenters that *Salmonella* naturally exists in certain parts of poultry before processing, such as the skin, livers, feather follicles, and bones, the Agency noted that *Salmonella* is not ordinarily found in the muscle tissue of healthy birds. NRTE breaded stuffed chicken products contain raw, comminuted chicken breast meat, trim, or whole chicken breast meat (*i.e.*, further processed chicken parts or comminuted chicken). FSIS sampling data has shown that further processed chicken parts (legs, breasts, and wings) and comminuted chicken have a higher occurrence of *Salmonella* positive results compared to carcasses.^{15 16}

As FSIS noted in the proposed determination (88 FR 26260), these sampling data indicate that, during processing, *Salmonella* that is regularly present in certain parts of the bird is added to the interior of edible poultry muscle tissue, where *Salmonella* is not ordinarily found. The proposed

¹¹ Rimet, C.S., Maurer, J.J., Pickler, L., Stabler, L., Johnson, K.K., Berghaus, R.D., . . . & Franca, M. (2019). *Salmonella* harborage sites in infected poultry that may contribute to contamination of ground meat. *Frontiers in Sustainable Food Systems*, 3, 2.

¹² 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).

¹³ 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).

¹⁴ 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).

¹⁵ Sampling Results for FSIS-Regulated Products. Available at: <https://www.fsis.usda.gov/science-data/sampling-program/sampling-results-fsis-regulated-products>.

¹⁶ USDA FSIS Annual Sampling Summary Report 2022. Available at: https://www.fsis.usda.gov/sites/default/files/media_file/documents/FY2022-Sampling-Summary-Report.pdf.

⁷ The definition in the FFDCA provides that “A food shall be deemed to be adulterated (a)(1) 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 food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health” (21 U.S.C. s 342(a)(1)).

⁸ While the PPIA defines the circumstances in which a poultry product may be adulterated, FSIS has referred to the FFDCA as a substantially similar statute to further elucidate the meaning that terms are given in a similar provision. See, e.g., FSIS final response to petition #12–02, *Petition to Require Labeling of All Ritually Slaughtered Meat and Poultry* (Jan 1, 2012) p. 2. Available at: <https://www.fsis.usda.gov/federal-register/petitions/petition-require-labeling-all-ritually-slaughtered-meat-and-poultry>.

⁹ *United States v. Anderson Seafoods, Inc* 622 F.2d 157, 160 (citing *United States v. Coca Cola*, 241 U.S. 265 (1915)).

¹⁰ *United States v. Anderson Seafoods, Inc* 622 F.2d 157, 161.

determination cited several instances of how such cross-contamination could occur (88 FR 62260). For one, when poultry is cut, *Salmonella* in the skin and feather follicles can be exposed and spread during processing to previously uncontaminated product.^{17 18 19} Additionally, many NRTE breaded stuffed chicken products are made with comminuted chicken. Because of the nature of comminution, *Salmonella* contamination in chicken skin and bone can spread throughout an entire batch or lot through cross-contamination. FSIS sampling data show that ground and other raw comminuted chicken products that were produced using either bone-in or skin-on source materials were more likely to be contaminated with *Salmonella* than those fabricated from deboned, skinless source materials.²⁰ In addition, *Salmonella*-negative raw poultry parts and comminuted poultry may become cross-contaminated by contact with *Salmonella*-contaminated equipment or when they are commingled with *Salmonella*-positive products, such as when they are collected in combo bins for further processing.^{21 22} *Salmonella*-contaminated equipment used to incorporate the stuffed ingredients into the chicken component of NRTE breaded stuffed chicken products may also contribute to *Salmonella* contamination in these products. For these reasons, FSIS considers *Salmonella* an added substance in NRTE breaded and stuffed chicken products. It is important to note that the determination that *Salmonella* is an added substance in NRTE breaded and stuffed chicken products is based on the circumstances under which these particular products are fabricated and

processed and that FSIS has not made a determination about whether *Salmonella* is an added substance in any other raw poultry products. FSIS will address the status of *Salmonella* in other raw poultry products in a subsequent rulemaking proceeding after considering the comments received in that proceeding.

Industry commenters provided a study in which researchers tested poultry muscle tissue for the presence of *Salmonella*.²³ However, the study was not sensitive enough to draw the conclusion that *Salmonella* at 1 CFU/g or higher is ordinarily present in such tissue. In the study, 1-day old chicks were deliberately inoculated with highly pathogenic *Salmonella* before development of healthy gut microflora. Thus, the initial load of *Salmonella* in the tested birds was not necessarily representative of the pathogen levels ordinarily present in farm-raised poultry.²⁴ Moreover, the study had a very small sample size and, in the end, only one out of five muscle tissue samples collected from 42-day old birds were positive for the *Salmonella* serotypes tested.²⁵ Thus, this study does not serve as demonstrable evidence that *Salmonella* is ordinarily present in the muscle tissue of farm-raised poultry. In fact, the study concluded that the high prevalence of *Salmonella* in the skin of infected poultry significantly contributes to contamination of ground chicken and turkey and suggested that the exclusion of skin as a component of ground poultry may be the best option for reducing *Salmonella* contamination in ground poultry products. This finding, therefore, supports FSIS' position that, amongst other things, *Salmonella* contaminated chicken skin substantively contributes to the spread of the pathogen in NRTE breaded stuffed chicken products, including to

components that do not ordinarily contain *Salmonella*.

Industry also cites three other papers they say show that *Salmonella* prevalence is the same in skin-on and skin-off chicken.^{26 27 28} The commenters assert these studies prove that *Salmonella* naturally occurs in poultry muscle tissue. However, these papers show variable results for *Salmonella* detection in skin-off versus skin-on chicken.^{22–24} Two studies, Cook 2012 and Pointon 2008, showed similar rates of *Salmonella* between the skin-on and skin-off parts using a rinse sampling method. In contrast, the third study, Guran 2017, showed *Salmonella* presence in skin-on chicken parts was significantly higher than in the skin-off parts with 44.7% vs 12.3% positive for chicken breast and 40.9% vs 22.8% positive for chicken thighs when samples were mixed by stomaching.²³ The variable results from the studies discussed could be due to methodology differences. Researchers have noted that rinse sampling methods may not recover *Salmonella* that are firmly attached to the skin or trapped within skin folds and feather follicles, while vigorous mixing using a stomacher may release attached *Salmonella* therefore increasing detection.^{29 30} A study by Wu 2014 supports this, showing rinsed skin samples recovered significantly less *Salmonella* than skin that was stomached (2.3 vs. 20.7%).³¹

At an industry level, poultry skin is a known source of *Salmonella* contamination due to bacteria being trapped in the skin folds and feather follicles.³² These areas may not be accessible until they are disturbed

¹⁷ Kim J-W and Slavik MF. 1996.

Cetylpyridinium Chloride (CPC) treatment on poultry skin to reduce attached *Salmonella*. J. Food Prot. 59: 322–326.

¹⁸ Wu D, Alali WQ, Harrison MA, and Hofacre CL. 2014. Prevalence of *Salmonella* in neck skin and bone of chickens. J Food Prot. 77(7): 1193–1197.

¹⁹ FSIS Guidance for Controlling *Salmonella* in Raw Poultry (June 2021) pp. 59–60. Available at: <https://www.fsis.usda.gov/guidelines/2021-0005>.

²⁰ FSIS Guidance for Controlling *Salmonella* in Raw Poultry (June 2021) pp. 65–66, Table 4 FSIS exploratory sampling test results, raw comminuted chicken by source material composition (6/1/13–6/30/15, 2,688 samples. Available at: <https://www.fsis.usda.gov/guidelines/2021-0005>.

²¹ FSIS Guidance for Controlling *Salmonella* in Raw Poultry (June 2021) pp. 59. Available at: <https://www.fsis.usda.gov/guidelines/2021-0005>.

²² Codex Guideline for the Control of *Campylobacter* and *Salmonella* in Chicken Meat at https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FSCXG%2B78-2011%252FCXG_078e.pdf.

²³ Rimet, C.S., Maurer, J.J., Pickler, L., Stabler, L., Johnson, K.K., Berghaus, R.D., . . . & França, M. (2019). *Salmonella* harborage sites in infected poultry that may contribute to contamination of ground meat. *Frontiers in Sustainable Food Systems*, 3, 2.

²⁴ FSIS notes that—for farm raised birds—there are many options to eliminate or reduce the *Salmonella* contamination, including pre-harvest food safety control measures. Elimination efforts can include rearing and management practices, pre and probiotic use, antimicrobial therapy, and/or vaccination of birds. See, e.g., Foley, S.L., Nayak, R., Hanning, I.B., Johnson, T.J., Han, J., & Ricke, S.C. (2011). Population dynamics of *Salmonella enterica* serotypes in commercial egg and poultry production. *Applied and environmental microbiology*, 77(13), 4273–4279.

²⁵ Forty-two days is the approximate age when broilers are slaughtered. FSIS also notes that in the four weeks prior, only one sample in the study tested positive for either serotype and only after enrichment.

²⁶ 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).

²⁷ Husnu Sahar 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).

²⁸ 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).

²⁹ Wu D, Alali WQ, Harrison MA, and Hofacre CL. 2014. Prevalence of *Salmonella* in neck skin and bone of chickens. J Food Prot. 77(7): 1193–1197.

³⁰ Husnu Sahar 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).

³¹ Wu D, Alali WQ, Harrison MA, and Hofacre CL. 2014. Prevalence of *Salmonella* in neck skin and bone of chickens. J Food Prot. 77(7): 1193–1197.

³² FSIS Guidance for Controlling *Salmonella* in Raw Poultry (June 2021). Available at: <https://www.fsis.usda.gov/guidelines/2021-0005>.

during cutting or grinding. When this processing exposes and releases the pathogen, it can spread, resulting in higher contamination levels in the product. FSIS sampling data clearly indicates *Salmonella* poultry rates rise as poultry is further processed, from chicken carcasses at 4.14% to legs, breasts, wings at 7.62% to comminuted at 24.2%.³³ This is a pattern FSIS has observed yearly and based on more than 25,000 samples analyzed in FY2022 alone.³⁴

Comment: A few commenters, including trade associations representing the poultry products and frozen foods industries, asserted that the evidence cited in the proposed determination does not indicate that NRTE breaded stuffed chicken products contaminated with *Salmonella* are ordinarily injurious to health. First, they argued that the outbreak data cited does not indicate that the products have harmed a substantial amount of people. They also argued that outbreak investigations do not indicate that consumers ordinarily prepare NRTE breaded stuffed chicken in a manner that renders them unsafe to eat.

Response: NRTE breaded stuffed chicken products pose a substantive risk to public health. The data available show that NRTE breaded stuffed chicken products are inherently risky, given their unique characteristics, and have a disparate impact on public health. Specifically, as noted above and in the proposed determination (88 FR 26252), an analysis of all chicken associated outbreaks identified in the Centers for Disease Control and Prevention's (CDC) National Outbreak Reporting System (NORS)³⁵ or in the scientific literature from 1998–2020 found that, during this time, NRTE breaded stuffed chicken products accounted for less than 0.15 percent of the total domestic chicken supply yet represented approximately five percent of all chicken-associated *Salmonella* outbreaks in the United States. Specifically, although NRTE breaded stuffed chicken products make up a very small percentage of the total domestic

supply of chicken, they have been associated with 14 *Salmonella* outbreaks between 1998 and 2021, resulting in 195 reported illnesses and 41 reported hospitalizations (88 FR 26258–26259). The actual number of cases is likely higher than the number of reported cases.³⁶

As discussed in the proposed determination (88 FR 26263), *Salmonella* can cause bloody diarrhea, fever, abdominal cramps, nausea, and vomiting. In some instances, *Salmonella* enters the blood and makes its way to other areas of the body including, but not limited to, the heart, lung, bone, joints, and the central nervous system.³⁷ This can result in severe illness requiring hospitalizations and even death, especially in vulnerable populations, such as very young, elderly, and immunocompromised individuals. Even when *Salmonella* is no longer detectable in the body, prior *Salmonella* illness has also been associated with an increased risk in colon cancer and can cause debilitating, long-lasting conditions including inflammatory bowel disease, irritable bowel syndrome and reactive arthritis.³⁸

Comment: A few poultry products trade associations stated that the proposed determination did not explain or support why *Salmonella*, particularly at 1 CFU/g, would render a NRTE breaded stuffed chicken product adulterated under 21 U.S.C. 453(g)(3).

Response: Under 21 U.S.C. 601(m)(3) of the FMIA and 21 U.S.C. 453(g)(3) of the PPIA, a meat or poultry product is adulterated “if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.” Historically, FSIS has interpreted the phrase “is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food” as providing a separate basis for adulteration than consists of “any filthy, putrid, or decomposed substance.” Thus, meat or poultry products that FSIS has determined are “otherwise unfit for human food” within the meaning of 21 U.S.C. 601(m)(3) and 21 U.S.C. 453(g)(3) do not

also need to consist “in whole or in part of any filthy, putrid, or decomposed substance.” For example, when raw meat or poultry products are associated with an illness outbreak but contain pathogens that are not considered adulterants in raw products, FSIS has found products linked to the illness outbreak to be adulterated under 21 U.S.C. 601(m)(3) or 21 U.S.C. 453(g)(3) because they are “unsound, unhealthful, unwholesome or otherwise unfit for human food” (77 FR 72689). FSIS has also determined that certain materials from cattle as well as the carcasses of non-ambulatory disabled cattle are adulterated because they present a sufficient risk of exposing humans to the bovine spongiform encephalopathy agent such as to render them “unfit for human food” under 21 U.S.C. 601(m)(3) (69 FR 1862).

As discussed in the proposal (88 FR 26261), FSIS evaluated the available information on *Salmonella* associated with human illnesses, the *Salmonella* infectious dose, the severity of human illnesses caused by *Salmonella*, and consumer preparation practices associated with NRTE breaded stuffed chicken product as documented in outbreak investigations associated with these products and consumer behavior research studies. Based on this evaluation, FSIS concluded that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels of 1 CFU/g present a sufficiently serious risk of causing *Salmonella* illness. Thus, as discussed in the proposed rule, FSIS has determined that such products are adulterated as defined in 21 U.S.C. 453(g)(3) because their elevated risk of illness makes them “unhealthful, unwholesome, or otherwise unfit for human food” (82 FR 26261).

B. Need for the Proposed Action

Comment: Many commenters, including an animal welfare organization, two consumer advocacy groups, and several individuals, stated FSIS' proposed action is necessary to assure NRTE breaded stuffed chicken products are safe to eat. However, a few poultry products trade associations and an institute representing the meat industry asserted that the proposed determination is not necessary to protect public health. These commenters specifically asserted the rate of salmonellosis associated with all chicken products has decreased over the past ten years. They also stated that public health efforts by the industry and FSIS have already made NRTE breaded stuffed chicken products safe to eat.

Response: As discussed throughout the proposed determination (88 FR

³³ USDA FSIS Annual Sampling Summary Report 2022. Available at: https://www.fsis.usda.gov/sites/default/files/media_file/documents/FY2022-Sampling-Summary-Report.pdf

³⁴ Moreover, national prevalence data from chicken parts baseline sampling indicate that skin-on parts were more likely to be positive for *Salmonella* than parts without skin. See *The Nationwide Microbiological Baseline Data Collection Program: Raw Chicken Parts Survey* (2012), available at: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Baseline_Data_Raw_Chicken_Parts.pdf.

³⁵ CDC National Outbreak Reporting System available at: <https://www.cdc.gov/nors/index.html>.

³⁶ Scallan, et al. 2011; Mead, P.S., et al., Food related illnesses and deaths in the United States. *Emerging Infect Dis*, Oct1999. 5(5) p. 607–625.

³⁷ Batz, M.B., et al., Long-Term consequences of foodborne illness. *Infect Dis Clin North Am*, Sept 2013. 28(3) p. 599–661; Hohmann, E.L., Nontyphoidal Salmonellosis, *Clin Infect Dis*, Sept 2001. 32 p. 263–269; Heymann, D. *Salmonellosis*. *Control of Communicable Disease Manual*, 2021.

³⁸ Mughini-Gras, L. et al. Increased colon cancer risk after severe *Salmonella* infection. *PLoS ONE*, 2018. 13(1): p. 1–19. <https://doi.org/10.1371/journal.pone.0189721>.

26249), FSIS is specifically targeting *Salmonella* in NRTE breaded stuffed chicken products because their unique characteristics make them particularly risky, and they pose a disparate impact on consumers' health. There have been 14 recorded outbreaks associated with the consumption of NRTE breaded stuffed chicken products since 1998, with the latest outbreak occurring as recently as 2021. *Salmonella* outbreaks have been disproportionately associated with NRTE breaded stuffed chicken products. Specifically, an analysis of all chicken associated outbreaks identified in the CDC's NORS³⁹ and in the scientific literature from 1998–2020 found that, during this time, NRTE breaded stuffed chicken products accounted for less than 0.15 percent of the total domestic chicken supply yet represented approximately five percent of all chicken-associated outbreaks in the United States (88 FR 26252). Outbreaks associated with these products have continued to occur regularly despite updated labeling instructions, outreach, and other industry and Agency efforts to make the products safer and ensure consumers are aware of how to prepare them (88 FR 26259–26260). Moreover, data from outbreak investigations and consumer research discussed in the proposed determination show that many consumers continue to cook NRTE breaded stuffed chicken products in a manner that does not adequately destroy *Salmonella* in these products (88 FR 26252–26260).

C. Definition of NRTE Breaded Stuffed Chicken Products

Comment: Trade associations and institutes representing the meat and poultry foods industries asked FSIS to clarify what products are subject to this final determination and noted that it should not apply to frozen NRTE products that are not breaded or stuffed, or that appear raw. A trade association representing the poultry products industry specifically asserted that the determination should not include NRTE breaded stuffed chicken products intended for use by hotel, restaurant, or institutional consumers.

Response: As discussed in the proposed determination (88 FR 26252), FSIS specifically defines NRTE breaded stuffed chicken products as those NRTE products that are both breaded and stuffed, contain raw chicken components (e.g., comminuted chicken breast meat, trim, or whole chicken breast meat), and where the finished

product is heat-treated only to set the batter or breading on the exterior of the product, which may impart an RTE appearance. Only products that specifically meet this definition are subject to the 1 CFU/g or higher adulteration standard discussed in this final determination. As discussed in the proposed determination (88 FR 26266–26267) and herein, FSIS will also conduct verification sampling in federally regulated establishments that produce such products. Thus, this final determination does not apply to RTE products (e.g., fully cooked RTE chicken cordon bleu). In addition, NRTE products that are stuffed and breaded, but are not “par-fried,” “pre-browned,” or otherwise heat treated to only set the batter or breading, are not subject to this final determination.⁴⁰ This final determination also does not apply to NRTE stuffed products that are not breaded, such as turducken or whole stuffed chickens—nor to NRTE breaded products that are not stuffed, such as chicken nuggets. Under this determination, NRTE breaded stuffed chicken that contain *Salmonella* at or above 1 CFU/g will be considered adulterated even if intended for hotel, restaurant, or institutional use because, regardless of intended use, NRTE breaded stuffed chicken products have characteristics that can make effective cooking of these products more challenging, i.e., they may appear fully cooked, are typically cooked from a frozen state, and are thicker in diameter and have a different composition than other par-fried breaded products (82 FR 26252).

D. Food Emergency Response Network Survey

Comment: A few poultry product trade associations asserted that they did not have the time or information necessary to respond to the Food Emergency Response Network (FERN) Survey.⁴¹ Specifically, these commenters argued that the Agency published the FERN Survey during the proposed determination's comment period, leaving inadequate time for analysis and comment. They also asserted that FSIS never explained why this survey was relevant or how it supported the proposed determination.

A few poultry product trade associations and an institute

representing the meat industry also raised some specific issues with the FERN Survey. First, they noted that it did not utilize the laboratory or sampling methods discussed in the proposed determination. Second, these commenters stated that the samples were not weighted to reflect relative production volume, they were not geographically dispersed, and that no statistical analysis was performed on the base results. The commenters also stated that the study lacked statistical power, given minimal samples were collected over a short period of time.

Response: FSIS disagrees with the assertion that the Agency never explained why the FERN Survey was relevant or how it was used to inform the proposed determination. The proposed determination discussed the FERN Survey report in detail (88 FR 26265–26266). FSIS gave the public adequate time and information to respond to the FERN Survey report. After release of the FERN Survey report, FSIS extended the proposed determination's comment period to August 11, 2023, to give the public more time to review the materials and formulate comments. Furthermore, the survey's methodology and results—as well as FSIS' analysis—were discussed in detail in the proposed determination (88 FR 26265–26266), which published 105 days prior to the close of the comment period.^{42 43}

In regard to the specific issues with the FERN Survey raised by commenters, the FERN Survey report made clear that the data were derived from convenient sampling of eligible products available to the participating laboratories and that FSIS made no claims about the statistical significance of any differences observed⁴⁴ or about how this survey supports FSIS enumeration methodology. Indeed, FSIS explained that the survey was intended to collect information on the positive rate of *Salmonella* in NRTE breaded stuffed chicken purchased at retail and differences in testing strategies, which were intended to help inform the FSIS verification sampling plan resulting from this determination. The FERN Survey results indicate that the current FSIS testing methods are acceptable for these products because the FERN labs

⁴² FSIS Constituent Update—June 23, 2023. Available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-june-23-2023>.

⁴³ FSIS, *Survey of Not Ready-to-Eat Breaded and Stuffed Chicken Products for Salmonella*, Docket ID No FSIS–2022–0013–0015 (June 2023).

⁴⁴ Survey of Not Ready-to-Eat Breaded and Stuffed Chicken Products for *Salmonella* ([usda.gov](https://www.usda.gov)).

³⁹ CDC National Outbreak Reporting System available at: <https://www.cdc.gov/nors/index.html>.

⁴¹ FSIS, *Survey of Not Ready-to-Eat Breaded and Stuffed Chicken Products for Salmonella*, Docket ID No FSIS–2022–0013–0015 (June 2023).

tested samples using the validated methods. The survey was also conducted to help inform the FSIS sampling and verification testing resulting from this determination.

As explained in the proposed determination (88 FR 26265), the FERN Survey gathered data at retail to provide information about the *Salmonella*-positive rate of NRTE breaded stuffed chicken products. In the proposal, FSIS noted that when using FSIS methods and a larger test portion, the survey found that the 27 percent positive rate for *Salmonella* in NRTE breaded stuffed chicken products detected in retail samples is comparable to the 29 percent positive rate detected in FSIS sampling of comminuted chicken.⁴⁵ The Agency also noted that these rates are higher than the *Salmonella*-positive rates for other raw chicken products, which suggests that NRTE breaded stuffed chicken products and comminuted chicken have a higher risk than other raw chicken. However, as noted in the proposal, consumer preparation practices are more likely to mitigate the risk associated with comminuted or ground chicken because, unlike NRTE breaded stuffed chicken products, ground chicken clearly appears raw and is not typically cooked from a frozen state (88 FR 26265).

E. Outbreak Data

Comment: A poultry products trade association argued that FSIS placed too much emphasis on the duration of outbreaks associated with NRTE breaded stuffed chicken products to support its decision, noting that the length of an outbreak is not necessarily related to its severity. It also asserted that statements gathered during outbreak investigations are anecdotal and, thus, not adequate to support FSIS' conclusion that consumers do not safely prepare NRTE breaded stuffed chicken products. Moreover, the commenter noted that most of the outbreak investigations FSIS discussed were associated with outdated product labeling and used antiquated investigational methods.

Response: The outbreak data— together with the other evidence discussed in the proposed determination (88 FR 26249)—supports the conclusion that NRTE breaded stuffed chicken products are disproportionately associated with *Salmonella* illnesses compared to other raw poultry products and that, despite

industry and Agency efforts, consumers continue to prepare such products in a manner that does render them safe to eat. The outbreak investigation findings discussed in the proposed determination (88 FR 26252–26259) were not based on anecdotal evidence or antiquated investigational methods. The findings were based on exposure and food-history information gathered and analyzed by local, state, and Federal health partners, including the CDC. These investigations used accepted investigational practices at the time of the outbreak.

Although FSIS mentioned the length of such outbreaks in the proposed determination, the Agency judges the severity of such outbreaks on their overall public health impact, not the length of the outbreaks. As noted in the proposed determination, despite making up a very small percentage of the total domestic supply of chicken (88 FR 26252), NRTE breaded stuffed chicken products were associated with 14 *Salmonella* outbreaks between 1998 and 2021, resulting in 195 reported illnesses and 41 hospitalizations (88 FR 26258–26259).

F. *Salmonella* Framework

Comment: A poultry establishment and a poultry products trade association noted that FSIS has not finished its *Salmonella* Framework, which contemplates reviewing FSIS' comprehensive approach to *Salmonella* and that, considering this ongoing effort, it is premature to set specific standards for NRTE breaded stuffed chicken at this time. The commenters stated that pursuing a separate policy for NRTE breaded stuffed chicken products risks creating inconsistencies or redundant policies.

Response: The Agency is confident it can address the persistent *Salmonella* outbreaks caused by NRTE breaded stuffed chicken products, as stated in this notice, and also propose to address illness associated from *Salmonella* in raw poultry generally in a future proposed rule. This will not lead to inconsistent or redundant policies. FSIS develops food safety requirements based on pathogens, consumption data, and other food safety factors, which can vary depending on the product.

For the reasons discussed in the proposed determination, FSIS believes that NRTE breaded stuffed chicken products pose different exposure risks to consumers than other types of raw poultry products and are more likely to result in *Salmonella* outbreaks than other products; therefore, FSIS has determined to hold NRTE breaded stuffed chicken products to a more

stringent *Salmonella* adulteration standard than for other raw poultry products. FSIS is not delaying its efforts concerning this product. Consistent with this final determination, as the Agency develops the proposed *Salmonella* Framework,⁴⁶ it will consider measures that will be most effective in addressing the public health risks associated with other raw poultry products.

G. Wait for Additional Information

Comment: Poultry products trade associations, a poultry products establishment, and a society of meat industry professionals noted that FSIS needs to gather more information about *Salmonella* in NRTE breaded stuffed chicken products before finalizing this determination. Specifically, they stated that FSIS needs to gather more data on the frequency that products currently exceed the 1 CFU/g threshold, whether enforcing the 1 CFU/g standard would be feasible, and what impact the proposed determination would have on public health. The commenters further stated that FSIS needs more insight into which serotypes are most prevalent in these products, as well as better information regarding infectious dose and host susceptibility. The commenters said that FSIS should build a comprehensive microbiological baseline before moving forward and use that information to conduct a risk assessment.

Response: FSIS has sufficient information to finalize this determination. As discussed in the proposed determination (88 FR 26249), available data from outbreak investigations and consumer behavior research show that NRTE breaded stuffed chicken products contaminated with *Salmonella* pose a significant public health risk. As noted in the proposal, these data show that common consumer preparation practices associated with NRTE breaded stuffed chicken products may not destroy organisms that may be present in the product and may also contribute to cross contamination (88 FR 26264). The proposal also described available data that show *Salmonella* has been associated with severe and debilitating human illnesses and that the *Salmonella* infectious dose is relatively low (88 FR 26264). Thus, because *Salmonella* can survive ordinary handling and cooking practices for NRTE breaded stuffed chicken products,

⁴⁵ USDA Food Safety and Inspection Service Annual Sampling Report Fiscal Year 2021: https://www.fsis.usda.gov/sites/default/files/media_file/2022-02/FY2021-Sampling-Summary-Report.pdf.

⁴⁶ FSIS, Proposed Regulatory Framework to Reduce *Salmonella* Illnesses Attributable to Poultry, available <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/proposed>.

FSIS has determined that the appropriate response to protect public health is to ensure that products contaminated with *Salmonella* at levels more likely to cause human illness are excluded from commerce. As explained in the proposed determination, assuming a minimum of 0.5 log (68%) *Salmonella* reduction likely achieved with even partial cooking, considering a level of *Salmonella* at 1 CFU/g (assuming a typical 70–88 gram chicken component portion size) to adulterate product should significantly mitigate the risk of illness associated with NRTE breaded stuffed chicken products (88 FR 26263). Additionally, as discussed in the proposed determination, all *Salmonella* serotypes have the potential to cause illness, and the disparity in serotypes may be related to factors other than serotype-specific differences in human virulence. Thus, given the unique public health risk associated with NRTE breaded stuffed chicken products, FSIS has determined that any *Salmonella* at levels of 1 CFU/g or higher is an adulterant in these products. FSIS will continue to evaluate and, if necessary, refine its policies and standards related to the oversight of NRTE breaded stuffed chicken products as advances in science and technology related to pathogen levels, serotypes, and infectious dose become available.

FSIS typically performs baseline studies to estimate the national prevalence of bacteria of public health concern in situations where a large number of establishments produce a product and uniform verification sampling is performed. Here, a baseline study isn't warranted for NRTE breaded stuffed chicken products because there are currently only six federally regulated establishments producing such products. Due to the public health risk posed by the product type, which is supported by recurring *Salmonella* illness outbreaks, the Agency decided to move forward with the proposed determination.

H. Infectious Dose

Comment: Poultry products trade associations, a member of the poultry products industry, and a meat industry research institute asserted there were several deficiencies in the infectious dose data FSIS relied on to support its proposed determination that NRTE breaded stuffed chicken with 1 CFU/g *Salmonella* are adulterated. Specifically, the commenters stated that FSIS relied on a single dose-response study to support the 1 CFU/g proposed

determination.⁴⁷ Moreover, commenters asserted that this study (hereinafter, "Teunis 2010") contained insufficient and outdated data. The commenters, therefore, provided an updated study by the same author for FSIS' consideration (hereinafter, "Teunis 2022").⁴⁸ The commenters also suggested that *Salmonella* serotypes used in Teunis 2010 were not representative of the serotypes that caused NRTE breaded stuffed chicken product outbreaks or are found in raw chicken.

Response: The Agency considered Teunis 2022 along with the evidence already cited on infectious dose in the proposed determination. However, upon review, FSIS does not conclude that the updated dose-response model in Teunis 2022, in consideration with the other evidence previously cited, warrants a change in the proposed adulterant threshold of 1 CFU/g of *Salmonella* in NRTE breaded stuffed chicken products.

FSIS' 1 CFU/g determination was not based on a single study. FSIS cited seven *Salmonella* outbreak papers in the proposed determination where the infectious dose was found to be very low, *i.e.*, 10 or fewer *Salmonella* organisms. FSIS cited an additional nine papers noted in the proposed determination that found an infectious dose between 11 and 420 organisms resulted in human illness. Finally, FSIS cited an additional dose-response paper written by the World Health Organization (WHO) that supports *Salmonella* illness can result, on average, from small doses.⁴⁹

FSIS also did not rely on outdated data. Teunis 2022 specifically states the outbreak data analyzed in the study ". . . are the same that were used in a previous analysis," *i.e.*, Teunis 2010. In fact, most of the data from the human challenge feeding trials⁵⁰ used in Teunis 2022 were published in 1951, about 70 years before the publication of Teunis 2022. These data are scientifically debated. In these trials, healthy volunteers were fed *Salmonella*, but none of the strains used in Teunis 2022 had been isolated from a person

with salmonellosis.⁵¹ Some of the volunteers had been vaccinated for *Salmonella* typhoid and paratyphoid. Blaser and Newman summarize the issues as follows, "the ability to generalize about what happens in nature from the experimental data concerning the infective dose of salmonellae is limited by several factors, including choice of strains, repeated testing of the same subjects, failure to assess minimal infective doses, and use of too few volunteers at the lower dosages." FSIS also disagrees with the commenters' assertion that a transposition of an outbreak dose from 344 CFU to 3.44 CFU in Teunis 2010 was "significant" and, thus, evidence that FSIS' dose-response analysis was based on an outdated model. Teunis 2022 specifically states that "It was checked that correction of the dose changed the estimates of *Salmonella* Enteritidis infectivity and pathogenicity only by a minute amount, putting to rest concerns that quantitative risk assessments might have been caused to use an incorrect model."⁵²

The commenters also suggested that *Salmonella* serotypes used in Teunis 2010 are not representative of the serotypes that caused NRTE breaded stuffed chicken product outbreaks or are found in raw chicken. However, as stated in the proposed determination, all known NRTE breaded stuffed chicken product outbreaks have been Typhimurium, Heidelberg, I 4,[5],12:i:-, and Enteritidis. Teunis 2010 and Teunis 2022 used 48 outbreaks to estimate the *Salmonella* dose-response for all serotypes. Eighty-three percent of those outbreaks represent serotypes that have been associated with NRTE breaded stuffed chicken product outbreaks.

Lastly, as mentioned, the proposed determination cited an additional dose-response model, which was developed by the WHO Food and Agriculture Organization of the United Nations for risk assessments for *Salmonella* in eggs and broiler chickens.⁵³ Also using outbreaks, the model estimated a 13 percent chance of becoming ill if ingesting 100 organisms. Even at the level of 1 organism ingested, there was still a non-zero chance of illness (0.25%).

⁴⁷ Teunis P.F. et al., Dose-response modeling of *Salmonella* using outbreak data, 144(2) Int. J. Food Microbiol 243–9 (2010).

⁴⁸ Peter F.M. Teunis, Dose response for *Salmonella* Typhimurium and Enteritidis and other nontyphoid enteric salmonellae, 41 Epidemics (2022).

⁴⁹ World Health Organization, Risk assessment of *Salmonella* in eggs and broiler chickens, March 25, 2002. Available at: <https://www.who.int/publications/i/item/9291562293>.

⁵⁰ McCullough, N.B., Wesley Eisele, C., 1951a. Experimental human salmonellosis. I. Pathogenicity of strains of *Salmonella meleagridis* and *Salmonella anatum* obtained from spray-dried whole egg. J. Infect. Dis. 88, 278–289; McCullough, N.B.,

⁵¹ Blaser, M.J. and L.S. Newman, *A Review of Human Salmonellosis .1. Infective Dose*. Reviews of Infectious Diseases, 1982. 4(6): p. 1096–1106.

⁵² Peter F.M. Teunis, Dose response for *Salmonella* Typhimurium and Enteritidis and other nontyphoid enteric salmonellae, 41 Epidemics (2022).

⁵³ World Health Organization, Risk assessment of *Salmonella* in eggs and broiler chickens, March 25, 2002. Available at: <https://www.who.int/publications/i/item/9291562293>.

Comment: Industry members, poultry products trade associations, and a meat industry research institute said FSIS should establish a new adulteration threshold equal to or higher than 10 CFU/g for NRTE breaded stuffed chicken products. These commenters noted that the FERN Survey and FSIS data on NRTE breaded stuffed chicken products show that more than a quarter of all *Salmonella* positives were *Salmonella* Kentucky, which they claimed would not result in illness at 1 CFU/g.⁵⁴ A poultry products trade association also suggested FSIS based its adulteration threshold on the infectious dose for *Salmonella* Enteritidis, given it was the serotype most commonly associated with NRTE breaded stuffed chicken outbreaks documented in the proposed determination. Specifically, the trade association stated that FSIS should base its threshold on the median dose of *Salmonella* Enteritidis that is predicted to have a 50% probability of causing illness, which was reported as 3,360 CFU. The comment asserted that assuming that the average chicken component of an NRTE breaded stuffed chicken product is 70–88 grams as noted in the proposal, this provides a range of 38–48 CFU/g in NRTE breaded stuffed chicken products.

Response: FSIS is finalizing the 1 CFU/g threshold as described in the proposed determination because outbreaks associated with products have continued to occur regularly despite updated labeling instructions, outreach, and other industry and Agency efforts to make the products safer. FSIS is not establishing a higher adulteration threshold of 10 CFU/g or greater based on the dose at which 50% of individuals exposed to 3,360 CFU of *Salmonella* Enteritidis are predicted to become ill. Use of such a metric where half (50%) of individuals exposed could become ill is not acceptable for a public health regulatory program aimed at reducing the risk posed by NRTE breaded stuffed chicken products, which are habitually undercooked by consumers. *Salmonella* Enteritidis is not the only serotype of concern in NRTE breaded stuffed chicken product, nor it is representative of the infectious dose of all *Salmonella* serotypes. For example, Teunis 2022 states Infantis is predicted to have an InfD_{50} of 0.7 CFU and InfD_{01} 0.01 CFU. Infantis is also predicted to have an

InfD_{50} of 1 CFU and an InfD_{01} of 0.07 CFU. All four measures of infection and illness would be below the proposed 1 CFU/g adulteration threshold. Using the InfD_{01} , Teunis 2022 supports the limit of 1 CFU/g for Enteritidis, Typhimurium, and Infantis.

FSIS is not only concerned about *Salmonella* Enteritidis and Infantis, but numerous serotypes that have been shown to be in NRTE breaded stuffed chicken product. As discussed below, FSIS determined numerous serotypes were of concern based on three data sources: (1) verification sampling of raw comminuted chicken (a major component of NRTE breaded stuffed chicken), (2) outbreak associated investigated sampling of NRTE breaded stuffed chicken products, and (3) the recent FERN survey of NRTE breaded stuffed chicken at retail.

First, using FSIS raw poultry sampling verification datasets for comminuted chicken from 2015 to CYQ3 2021,⁵⁵ FSIS serotyped 2,921 *Salmonella* positives and 58 unique serotypes. FSIS found the following five most frequent serotypes in the following rank order from most to least: Infantis, Enteritidis, Kentucky, Typhimurium, and Schwarzengrund. Since NRTE breaded stuffed chicken products can be made by grinding intact chicken, with trim and chicken skin, these comminuted verification data suggest these serotypes are found in NRTE breaded stuffed chicken products. The second data source was a 2015, FSIS investigative sampling of NRTE breaded stuffed chicken comminuted source components, finished products, and the processing environment from two NRTE establishments associated with an outbreak.⁵⁶ Among the 1,433 samples, 518 were positive for *Salmonella*, a 36% positive rate. FSIS found the following serotypes in the following rank order from most to least: Kentucky, Typhimurium, Infantis, Enteritidis, Heidelberg, Schwarzengrund, I 4,[5],12:i:-, Montevideo, Mbandaka, and Muenchen indicating virulent *Salmonella* serotypes can be directly found in NRTE breaded stuffed chicken products. Lastly, in the FERN Survey, NRTE breaded stuffed chicken products were purchased at retail from July 1, 2022, to September 30, 2022. In total, 58 of the 487 samples, 12%, were positive for *Salmonella*. Fifty-three were serotyped finding Infantis, Enteritidis,

Kentucky, and Typhimurium, in that order of frequency.

As FSIS acknowledged in the proposed determination, not all *Salmonella* serotypes (e.g., *Salmonella* Kentucky), are equally likely to cause illness (88 FR 26262). However, all *Salmonella* serotypes, including *Salmonella* Kentucky, have the ability to invade, replicate, and survive in human host cells, resulting in potentially fatal disease,⁵⁷ and the disparity among serotypes may be related to factors other than serotype-specific differences in human virulence.⁵⁸ With *Salmonella*, higher virulence is associated with enhanced ability to survive and grow in the gut or to attach to and invade human cells, which is driven by changes to several mechanisms, including mobile genetic elements and resident genes as well as variations in gene sequence and expression. In an August 2018 report, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) was unable to find evidence in the literature for any determinant that correlated with high virulence in human foodborne disease.⁵⁹ NACMCF noted that a few *Salmonella* serotypes are consistently associated with the greatest incidence of human disease. However, this disparity among serotypes may be related to survival in animal hosts or during food harvesting and processing rather than serotype-specific differences in human virulence.

Comment: A meat industry research institute and industry member asserted that current support for the 1 CFU/g standard is based, in part, on data that include products whose characteristics are not the same as raw chicken. According to the commenters, FSIS cited studies/data associated with cheese, chocolate, and dressings, which are all RTE products of high fat content, and have known *Salmonella* protective characteristics during digestion. They noted that high fat content protects *Salmonella* against gastric acidity resulting in a reduction of dose-response curve with a low infectious

⁵⁷ Shu-Kee Eng, Priyia Pusparajah, NurulSyakima Ab Mutalib, Hooi-Leng Ser, Kok-Gan Chan & Learn-Han Lee (2015) *Salmonella*: A review on pathogenesis, epidemiology and antibiotic resistance, *Frontiers in Life Science*, 8:3,

⁵⁸ FSIS decision to declare all *Salmonella* at certain levels as an adulterant was also based on a review of the current state of laboratory technology (88 FR 26262).

⁵⁹ NACMCF (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *Journal of Food Protection* 82(4): 645–668.

⁵⁴ Laboratory Quality Assurance, Response, and Coordination Staff (LQARCS) Office of Public Health Science Food Safety and Inspection Service U.S. Department of Agriculture. Survey of Not Ready-to-Eat Breaded and Stuffed Chicken Products for *Salmonella*. June 2023.

⁵⁵ <https://www.fsis.usda.gov/news-events/publications/raw-poultry-sampling>.

⁵⁶ <https://www.fsis.usda.gov/news-events/publications/raw-poultry-sampling>.

dose.^{60 61 62 63} They argued that raw chicken, unlike these other products, provides increased heat lethality, is expected to be heated, and is lower in fat and not emulsified.

Response: FSIS does not agree with the assertion that the dose-response models, including Teunis 2010, Teunis 2022, and the WHO Risk assessment of *Salmonella* in eggs and broiler chickens, are not applicable to chicken-specific outcomes. The commenters indicated that many of the outbreaks used in the dose-response models reported low doses for high-fat products (some reported in the range of 10¹). Looking at the outbreaks used in the *Salmonella* Enteritidis dose-response model,⁶⁴ there are many outbreaks that are presumably high-fat but are also high dose. For example, (food vehicle and dose (CFU)) Hollandaise 4.48 × 10⁴, Macaroni salad 4.40 × 10⁴, Scallop/cream 1.00 × 10⁶, Yam/soup 1.94 × 10⁶, Bavarois (Bavarian ice-cream) 1.01 × 10⁵, Ice cream 3.84 × 10⁶, Tiramisu 1.29 × 10⁸, Cake 6.06 × 10⁵, Mayonnaise 5.57 × 10⁴. These outbreak doses range from about 10,000 to 100,000,000 organisms. Further, the commenter suggested that the chicken matrix is low-fat and the only ingredient of concern. NRTE breaded stuffed chicken products can be made from comminuted (ground) chicken where high-fat chicken skin may be combined and comminuted with skinless, boneless chicken. Additionally, NRTE breaded stuffed chicken products include high-fat ingredients, such as cheese, cream, butter, and ham, that could act to encourage pathogen survival.

FSIS agrees that very few of the outbreaks used in any of the dose-response models mentioned in the public comments or the proposed determination are specifically associated with an outbreak where the contaminated ingredient was determined to be chicken. However,

⁶⁰ Naschimento, et al., (2012) Inactivation of *Salmonella* during cocoa roasting and chocolate conching. *International Journal of Food Microbiology* 159 (3):225. 718–727.

⁶¹ Krapf, Tamara, and Corinne Gantenbein-Demarchi. "Thermal inactivation of *Salmonella* spp. during conching." *LWT-Food Science and Technology* 43, no. 4 (2010): 720–723.

⁶² Podolak, Richard, Elena Enache, Warren Stone, Darryl G. Black, and Philip H. Elliott. "Sources and risk factors for contamination, survival, persistence, and heat resistance of *Salmonella* in low-moisture foods." *Journal of food protection* 73, no. 10 (2010): 1919–1936.

⁶³ D'aoust, J.Y. "Salmonella and the chocolate industry. A review." *Journal of Food Protection* 40, no. 10 (1977).

⁶⁴ Peter F.M. Teunis, Dose response for *Salmonella* Typhimurium and Enteritidis and other nontyphoid enteric salmonellae, 41 *Epidemics* (2022).

there are several outbreaks used in the dose-response models that are based on animal products. These include beef, chicken, egg, prawn, scallop, and octopus. The commenters did not provide an explanation for how the lack of chicken outbreaks would impact the dose-response except to imply it would not be representative. However, dose-response models describe pathogens and are rarely, if ever, specific to the transmission pathway.

I. Virulence

Comment: A poultry industry commenter stated that FSIS needs to gather more information on *Salmonella* virulence.

Response: As discussed in the proposed determination (88 FR 26262), the basis for *Salmonella* virulence is not fully understood. Many virulence factors have been identified that contribute to *Salmonella* pathogenicity. The interactions of these factors and the resulting strain virulence and pathogenicity has not been completely elucidated, but single genes and pathogenicity islands have been identified as key virulence traits. However, there is currently no agreed-upon definition of virulence genes presence/absence profile that can reliably predict severity of disease.⁶⁵ FSIS, as discussed in the proposed determination (88 FR 26262), is working to better understand *Salmonella* characteristics, including virulence, and actively engages in and encourages research in this area. As science and laboratory technologies advance, FSIS will continue to use the most innovative and sensitive methods available to protect public health.

J. Consumer Behavior

Comment: Poultry products trade associations and a meat industry research institute argued that consumers prepare raw chicken in a manner that destroys *Salmonella* and, thus, *Salmonella* cannot be considered an adulterant in products that include raw poultry components. One poultry products trade association also specifically asserted that FSIS cannot take the action discussed in the proposed determination because it has not proved that consumers must cook NRTE breaded stuffed chicken products to a temperature higher than other raw poultry products in order to effectively kill *Salmonella*. A poultry products

trade association also asserted that the 2020 consumer study⁶⁶ and the 2022 CDC Appliance Report⁶⁷ cited in the proposed determination do not prove that consumers mishandle or use the incorrect appliances to prepare NRTE breaded stuffed chicken products. The commenter also noted that FSIS' analysis of consumer behavior pertaining to food thermometer use relied on an outdated paper explicitly focused on *microwavable* products from 1998–2006.⁶⁸

Response: FSIS disagrees. As FSIS noted in the proposed determination (88 FR 26252), there are special considerations to take into account with these particular products that are relevant to consumer cooking practices. For one, unlike most raw poultry products, NRTE breaded stuffed chicken products often appear fully cooked and, thus, some consumers may only reheat the product for aesthetic or palatability purposes rather than subject it to cooking sufficient to kill pathogenic bacteria. Second, consumers typically cook NRTE breaded stuffed chicken from a frozen state, which increases the risk that the products will not reach an internal temperature needed to destroy *Salmonella* organisms that may be in the product. Third, NRTE breaded stuffed chicken products have a thicker diameter and a different composition than most other raw chicken products that are not stuffed, including other par-fried breaded products, which can make effective cooking of NRTE breaded stuffed chicken more challenging. In addition, it may be difficult for a consumer to determine an accurate internal temperature of these products because they contain multiple ingredients, such as cheese and vegetables, that may cook at different rates. FSIS has recommended in the past that consumers check the temperature at multiple locations throughout the product using a food thermometer, but this is not always practical or accurate.

As discussed in the proposed determination (88 FR 26252–26259),

⁶⁶ 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).

⁶⁷ Marshall, K.E., Canning, M., Ablan, M., Crawford T.N., Robyn, M. Appliances Used by Consumers to Prepare Frozen Stuffed Chicken Products-United States, May–July 2022. *Morb Mortal Wkly Rep* Dec 2,2022; 71(48):1511–1516. Available at: <http://dx.doi.org/10.15585/mmwr.mm7148a2>.

⁶⁸ Smith, K.E., Medus, C., Meyer, S.D., Boxrud, J.D., Leano, F., Hedburg, C., Elfering, K., Braymen, C., Bender, J.B., Danila, R.N. 2008. Outbreaks of Salmonellosis in Minnesota (1998 through 2006) Associated with Frozen, Microwaveable, Breaded Stuffed Chicken Products. *Journal of Food Protection*. 71(10): 2153–2160.

⁶⁵ NACMCF (2022). Response to questions Posed by FSIS: Enhancing *Salmonella* Control in Poultry Products. Available at: https://www.fsis.usda.gov/sites/default/files/media_file/documents/NACMCF_Salmonella-Poultry_Response_for_Committee_Review.pdf.

outbreak investigations indicate that, despite industry and Agency efforts, consumers' cooking practices continue to be insufficient to destroy *Salmonella* in NRTE breaded stuffed chicken products and, as such, they continue to have a disparate impact on public health. Despite industry updates to labeling and Agency outreach on the safe preparation of NRTE breaded stuffed chicken products, outbreak investigations consistently indicate that case patients erroneously believed these products were precooked, did not ordinarily use food thermometers to check the internal temperature of the product, and used a microwave or other unsuitable appliance to cook the products. Moreover, many case patients became ill even when they used an oven to prepare the product.

Further, FSIS disagrees with commenters' assertions that the consumer research cited in the proposed determination was flawed or did not indicate that a significant percentage of consumers customarily mishandle NRTE breaded stuffed chicken products despite reading the manufacturer's labeling and instructions. As commenters noted, the proposed determination cited a 2008 report published in the *Journal of Food Protection*. FSIS appropriately cited this report to describe four separate salmonellosis outbreaks associated with NRTE breaded stuffed chicken that occurred between 1998–2006, related investigative findings, and the subsequent actions taken in response.⁶⁹ The report indicated that most consumers sickened in a 1998 outbreak reported using a microwave to prepare the product, and no consumers reported using a food thermometer. In response, the company responsible for the outbreak updated the preparation instructions on its product labeling. Then, in 2005, the report indicated that another outbreak occurred. Again, the manufacturer responsible for the outbreak updated its labeling instructions. FSIS also issued a public health alert to remind consumers that frozen meat and poultry products must be fully cooked before they are consumed. According to the report, following these additional communications with consumers and labeling changes by the manufacturers, two additional outbreaks occurred in the 2005–2006 timeframe. Again, most

of the case patients used a microwave oven to cook the products and none of the case patients took the internal temperature of the product after cooking it. FSIS, therefore, issued another public health alert, emphasizing that consumers must cook NRTE breaded stuffed chicken products to 165 °F. FSIS sent a letter to an establishment involved in one of the outbreaks recommending they enhance and validate the cooking instructions to ensure that they address the intended use by the consumer.⁷⁰ FSIS then posted the letter online as guidance to all industry and requested that all such establishments update their labeling to include a statement such as “Uncooked: For Safety, Must be Cooked to an Internal Temperature of 165 degrees F as Measured by Use of a Thermometer.” As discussed in the proposed determination, despite these efforts, consumers continued to prepare NRTE breaded stuffed chicken products in a manner that did not adequately destroy *Salmonella*, resulting in several more outbreaks and subsequent unsuccessful efforts to update labeling instructions and educate the public on how to properly cook such products (88 FR 26252–26259).

In addition to analyzing outbreak data, FSIS discussed the results of two consumer behavior studies that helped inform its determination that a significant percentage of consumers do not customarily cook NRTE breaded stuffed chicken products in a manner that adequately destroys *Salmonella*. In the 2020 Meal Preparation Experiment cited in the proposed determination (88 FR 26257),⁷¹ FSIS contracted with RTI International and North Carolina State University to conduct five separate iterations of a meal preparation study to evaluate consumer food handling behaviors in a test kitchen. The third iteration of the study specifically examined participants' meal preparation related to NRTE breaded stuffed chicken products. Half of the participants were assigned to a control group, whereas the other half was assigned to a treatment group. Amongst other things, the study found that consumers may confuse frozen NRTE breaded stuffed chicken products with RTE products. Specifically, the study concluded that even though 99% of all participants

read the manufacturer's instructions for NRTE breaded stuffed chicken products, nearly a quarter reported they were not sure if the products were raw or fully cooked, twenty-two percent reported they were unaware that the product was raw, and eleven percent of the participants incorrectly believed the product was fully cooked. The study also found that a significant number of participants did not use food thermometers to check that the NRTE breaded stuffed chicken product reached a safe internal temperature of 165 °F, with some using other methods to determine doneness such as time, visual cues, and touch. Thirty-eight percent of participants also self-reported not using their food thermometer at home to check that NRTE breaded stuffed chicken products were properly cooked. Moreover, the study observed that a significant number of participants did not adequately wash their hands during meat preparation. The study concluded that these issues were likely attributable to participants preparing a NRTE breaded stuffed chicken product rather than raw, unfrozen poultry that is not breaded and stuffed. This indicates that the appearance of NRTE breaded stuffed chicken products and the fact that they are typically cooked from a frozen state may contribute to *Salmonella* cross-contamination in the home.

The proposed determination also discussed the results of a 2022 survey that collected information from thousands of participants from May 31–July 6, 2022, to determine the demographic characteristics of persons who prepare NRTE breaded stuffed chicken products and the appliances they use to prepare them.⁷² Even though NRTE breaded stuffed chicken product labels typically instruct consumers to cook the product in an oven and specifically warns against the use of a microwave, 54 percent of participants reported that they prepared these products using appliances other than, or in addition to, ovens.⁷³ Specifically, 30 percent reported preparing the products using air fryers, 29 percent reported using microwaves, approximately 14 percent reported using toaster ovens, and approximately 4 percent reported using another appliance. Economic and other factors might affect certain groups'

⁶⁹ Smith, K.E., Medus, C., Meyer, S.D., Boxrud, J.D., Leano, F., Hedburg, C., Elfering, K., Braymen, C., Bender, J.B., Danila, R.N. 2008. Outbreaks of Salmonellosis in Minnesota (1998 through 2006) Associated with Frozen, Microwaveable, Breaded Stuffed Chicken Products. *Journal of Food Protection*. 71(10): 2153–2160.

⁷⁰ Letter to industry about the safe handling labeling of uncooked, breaded, boneless poultry products (March 2006) at: <https://www.fsis.usda.gov/guidelines/2006-0007>.

⁷¹ Final Report: Food Safety Consumer Research Project: Meal Preparation Experiment on Raw Stuffed Chicken Breasts (September 23, 2020) at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/fsrpp-yr3-nrte-final-report.pdf.

⁷² Marshall, K.E., Canning, M., Ablan, M., Crawford T.N., Robyn, M. Appliances Used by Consumers to Prepare Frozen Stuffed Chicken Products-United States, May–July 2022. *Morb Mortal Wkly Rep* Dec 2, 2022; 71(48):1511–1516. Available at: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7148a2.htm>.

⁷³ Participants in the study were allowed to choose more than one cooking option.

access to recommended cooking appliances and, thereby, the customary manner in which these groups cook NRTE breaded stuffed chicken products.

FSIS also disagrees that, in order to finalize the proposed determination, it must show that consumers must cook NRTE breaded stuffed chicken products to a temperature higher than other raw poultry products in order to effectively kill *Salmonella*. As noted in the proposed determination, the status of NRTE breaded stuffed chicken products contaminated with *Salmonella* must depend on whether there is adequate assurance that consumer handling of the product will result in a product that does not contain *Salmonella* at levels sufficient to cause human illness when consumed (64 FR 2803). The evidence cited in the proposed determination, including the consumer research cited above, shows consumers routinely do not fully cook NRTE breaded stuffed chicken nor do they routinely use a food thermometer to test the internal temperature of the product and, thus, has concluded that the appropriate response to protect public health is to ensure that products contaminated with *Salmonella* at levels sufficient to cause human illness (1 CFU/g) are excluded from commerce.

K. Laboratory Methods

Comment: Poultry products trade associations, a meat products research institute, a member of the poultry products industry, a trade group representing the frozen foods industry, and a society of meat industry professionals raised some issues regarding the laboratory methods FSIS intends to implement. Generally, they stated that *Salmonella* enumeration testing technology is still under development, that current methods are limited, and that FSIS needs to ensure that its methods are validated prior to implementation of this determination. Specifically, they noted that available *Salmonella* enumeration methods are not currently validated for NRTE breaded stuffed chicken products or at a detection level of 1 CFU/g. A poultry products trade association and an industry member also asserted that there is a margin of variability inherent in the available laboratory methods and asked for clarity on how FSIS would account for this. An industry member also asked FSIS to use polymerase chain reaction (PCR)-based limit of detection testing, until quantification methods are improved and validated.

Response: FSIS laboratories performed a thorough verification of validated methods by independent organizations. FSIS' current qPCR

method is validated for 1 CFU/g in NRTE breaded stuffed chicken.⁷⁴ The Most Probable Number (MPN) method is another enumeration technique that FSIS has adopted.⁷⁵ FSIS intends to routinely evaluate new methods of *Salmonella* quantification, as they become available, that provide both accuracy and fitness for a high-throughput laboratory environment.

Comment: To expedite test results, a poultry products trade association requested that the Agency consider conducting the quantitative assay concurrently with the assay being conducted to screen the sample for the general presence of *Salmonella*, not based on that assay. The commenters also asked for clarity on if quantitative and general detection results will be obtained from the same homogenized sample to avoid conflicting results that could arise if using different analytical sample portions due to factors such as the nonhomogeneous distribution of *Salmonella*.

Response: FSIS intends to use the same homogenized sample for the quantitative and detection screen protocols. Enumeration results will be reported on the same day. For samples that are potential positives, an additional 3 days may be necessary for a confirmed positive or negative result. These timeframes and methods may change as FSIS incorporates new laboratory technologies into its sampling and verification testing.

Comment: A poultry products trade group stated that *Salmonella* levels in finished product are typically less than 1 CFU/g but that the levels in samples may grow beyond the 1 CFU/g threshold during transport of the sample to Federal laboratories. The commenters asked the Agency to account for this phenomenon in its final determination, given even a slight difference in results may have a negative impact on industry.

Response: Current FSIS procedures ensure the temperature of the *Salmonella* samples to be 15 °C or less upon receipt at the field service laboratories.⁷⁶ The laboratories will discard samples that arrive at a temperature above 15 °C.⁷⁷ This upper temperature limit is intended to prevent

the outgrowth of competitors that could affect pathogen recovery in the lab. These limits also ensure that growth during shipment does not occur. While 15 °C is the upper allowable limit, samples received at the laboratory typically do not approach that temperature. USDA studies have shown no significant difference in the levels of *Salmonella* in ground beef samples if kept at refrigerator temperatures for 24–48 hours (Narang et al, 2005).

Comment: A commercial laboratory suggested that FSIS consider using third-party laboratories that are part of the Accredited Laboratory Program (ALP) when including laboratories that will be assisting the Agency. Further, a member of the poultry products industry stated that FSIS should utilize industry analytical data from ALP on the levels of *Salmonella* to conduct their verification, to assist small and very small processors.

Response: Currently, FSIS labs analyze all samples that FSIS inspectors collect to verify that product is wholesome and not adulterated. Also, FSIS labs currently have the capacity to conduct verification sampling and testing of NRTE breaded stuffed chicken products. Thus, at this time, FSIS intends to collect all samples and use its own labs for verification testing conducted under this final determination.

L. Verification Sampling

Comment: Poultry products trade associations, industry members, and a meat industry research institute asked FSIS to consider sampling earlier in the NRTE breaded stuffed chicken product production process to give establishments more flexibility to divert failed product for other uses. Specifically, commenters asked FSIS to consider conducting sampling on the raw incoming chicken components used to produce NRTE breaded stuffed chicken, prior to those materials being comminuted and combined. They indicated that, if FSIS finalized the sampling location as discussed in the proposed determination, establishments would have less flexibility to divert product exceeding the 1 CFU/g adulteration threshold, given the chicken components, once processed and prepared for breeding and stuffing, have a short shelf life and a unique formulation that can only be utilized to produce NRTE breaded stuffed chicken products. Thus, the commenters asserted that sampling at the location discussed in the proposed determination would lead to substantial food waste and lost product costs.

⁷⁴ BioMerieux GENE-UP QUANT *Salmonella*, AOAC Performance Tested MethodsSM Certification Number 082104 is the current validation.

⁷⁵ See <https://www.fsis.usda.gov/news-events/publications/microbiology-laboratory-guidebook>.

⁷⁶ USDA FSIS MLG 1.01 FSIS Laboratory System Introduction, Method Performance Expectations, and Sample Handling for Microbiology, available at https://www.fsis.usda.gov/sites/default/files/media_file/2022-03/MLG_1.01.pdf.

⁷⁷ FSIS Directive 10250.1, *Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products*.

Response: In the proposed determination (88 FR 26249), FSIS proposed to collect verification samples after the establishment has completed all processes needed to prepare the chicken component to be stuffed and breaded to produce final NRTE breaded stuffed chicken products. However, FSIS agrees with commenters that sampling earlier in the production process may provide some establishments with additional flexibility to divert sampled source products for other uses, thereby reducing food waste, lost product costs, and establishment operations changes due to the collection event. As such, FSIS will collect verification samples from incoming raw poultry source materials at the establishment producing the NRTE breaded stuffed chicken prior to breading and stuffing at an appropriate point in the establishment's process. In assessing the suitability of the sampling location at any individual establishment, FSIS will take into account the establishments' production process and the Agency's ability to collect the sample safely and effectively. Any *Salmonella* detected in NRTE breaded stuffed chicken source materials will be enumerated and source materials that exceed 1 CFU/g of *Salmonella* must be diverted for other uses.

Comment: A poultry products trade association asked for clarity on whether the *Salmonella* adulteration threshold for NRTE breaded stuffed chicken products applies only to the chicken components tested by FSIS or to the finished product itself. The commenter also asked for clarity on whether establishments may complete the production of NRTE breaded stuffed chicken products while awaiting sampling results, so long as such products remain under establishment control and are not released into commerce. Further, the commenter asked FSIS to provide that establishments may divert raw chicken source material confirmed positive for *Salmonella* at 1 CFU/g for uses other than the production of NRTE breaded stuffed chicken products.

Response: Under this determination, all finished NRTE breaded stuffed chicken products that are contaminated with *Salmonella* at 1 CFU/g or greater are adulterated within the meaning of 21 U.S.C. 453(g)(1) and 21 U.S.C. 453(g)(3). This adulteration standard applies to finished NRTE breaded stuffed chicken products, not the raw incoming chicken components tested by FSIS. Tested chicken components and those components represented by the sampled lot before incorporation into

NRTE-BSC products would not be considered adulterated for certain other uses if confirmed positive for 1 CFU/g or greater of *Salmonella*. Thus, establishments may divert such raw material components to another appropriate application (e.g., breaded nugget or fully cooked products). Chicken components subject to sampling and verification testing and confirmed positive for 1 CFU/g or greater of *Salmonella* would be ineligible for use in NRTE breaded stuffed chicken products under 9 CFR 417.2(c)(3).

In the proposed determination (88 FR 26266), FSIS stated that, pending test results, establishments should not incorporate sampled lots into finished NRTE breaded stuffed chicken products. However, in response to public comments, FSIS is clarifying that this statement was only meant to apply to sampled lots incorporated into NRTE breaded stuffed chicken products released into commerce. Establishments that produce NRTE breaded stuffed chicken may, at their discretion, incorporate sampled lots into finished NRTE breaded stuffed chicken products, so long as those finished products remain under establishment control awaiting acceptable test results.

Comment: A poultry products trade association and a meat industry research institute noted that, upon entering commerce, NRTE breaded stuffed chicken may be subject to additional testing by state or local health authorities, customers, consumer advocacy organizations, or even FSIS and other Federal partners. The commenters asked for clarity on how FSIS would interpret such downstream testing and what public health actions it would take if such testing showed that finished NRTE breaded stuffed chicken products in commerce contain *Salmonella* at 1 CFU/g or greater.

Response: Under this determination, all finished NRTE breaded stuffed chicken products that are contaminated with *Salmonella* at 1 CFU/g or greater are adulterated within the meaning of 21 U.S.C. 453(g)(1) and 21 U.S.C. 453(g)(3). If FSIS receives test results from a third party (e.g., a state health department, advocacy organization, or consumer), the Agency will address those results in accordance with FSIS Directive 10,000.1, *Policy on Use of Results for Non-FSIS Laboratories*. Assuming the test results are deemed acceptable, FSIS may use the results to inform Agency action, such as detaining the product or initiating a recall.

Comment: To minimize product storage costs, a poultry products trade association asserted that FSIS should

provide establishments with enumeration results as soon as they are available, without waiting for serotype or WGS information.

Response: FSIS will transmit test results to establishments as soon as possible and will not withhold such results while awaiting other information. FSIS intends to use the LIMS-Direct system and Biological Information Transfer Email System (BITES) messages to alert establishments and Office of Field Operations personnel prior to the confirmed positive and WGS or serotyping steps of the analysis.

Comment: Poultry products trade associations, a poultry products industry member, and a meat industry research institute requested clarity on how production lots would be defined for purposes of FSIS' verification and sampling program.

Response: Establishments are responsible for defining a production lot. Establishments should ensure that there is a scientifically supportable basis for their lotting practices to ensure microbiological independence. To create independence between production lots, establishments need to consider the way in which the hazard is likely to be introduced to the process, such as from the addition of chicken skin, and during handling and processing of chicken parts, and grinding of chicken trim that may be used in the production of NRTE breaded stuffed chicken products. When applicable and available, FSIS and establishment microbial sampling, as well as the lotting of received source materials must also be considered and support the establishments product lot definition. A production lot can be defined by the establishment in several ways. FSIS does not consider "clean-up to clean-up" alone as a supportable basis for distinguishing one portion of raw chicken production from another portion of production. Establishments may decide to use a robust, statistically based sampling program, one or more processing interventions that have been validated to limit or control *Salmonella*, or other scientifically supportable process to define the lot.⁷⁸

M. Implementation Date

Comment: A meat industry research institute stated that the Agency must allow a reasonable timeframe to implement the final determination. The commenter noted that establishments

⁷⁸ For additional information on lotting see the *FSIS Guideline for Holding and Controlling Meat, Poultry, and Egg Products Pending FSIS Test Results*. Available at: <https://www.fsis.usda.gov/policy/fsis-guidelines>.

will need to adjust and put processes in place to hold product during testing and divert positive product. Moreover, according to the commenter, establishments may need to weigh the costs of these processes to determine whether continued production of these types of products is viable. According to the commenter, an effective date one year from the publication of a final determination would be reasonable.

Response: FSIS agrees that industry will need a reasonable amount of time to adjust to this determination. As such, this final determination will not be effective until 12 months after publication of this final determination. Also, FSIS inspection verification sampling will be implemented 12 months after publication of this final determination.

N. Cost Benefit Analysis

Comment: Poultry products trade associations, a meat industry research institute, and a member of the poultry products industry, asserted that storage costs under the proposal would be greater than anticipated in the proposed determination; however, they did not provide any costs estimates to support their assertion. Specifically, the commenters argued that some establishments do not have enough storage capacity to hold products awaiting test results and would, thus, have to purchase off-site storage. Further, commenters stated that the proposed determination did not adequately account for transportation or labor costs, associated with moving product to and from off-site storage facilities. Commenters also asserted that FSIS test results are likely to take longer than estimated in the proposed determination's CBA and that test and hold requirements will reduce shelf life for these products.

Response: FSIS disagrees that the anticipated costs for cold storage will be greater than estimated in the proposed determination. FSIS requires that establishments maintain control of sampled product pending FSIS verification testing results so that product does not enter commerce, while allowing establishments the flexibility of determining where to hold product as well as deciding whether to divert product into other uses. Additionally, as mentioned above, establishments will be able to complete the production process using sampled product, provided they maintain control of any finished products and do not release them into commerce, pending acceptable test results. This will likely reduce an establishment's need for cold storage capacity. To be conservative,

FSIS' preliminary cost benefit analysis (CBA; 88 FR 26267) accounted for cold storage costs assuming every lot would be sampled and held. The final CBA assumes FSIS would sample up to 5 lots per establishment per month. The preliminary CBA also assumed that sampling would take place right before the chicken component was stuffed and formed into a NRTE breaded stuffed chicken product. However, as discussed above, FSIS has updated the sampling location to give establishments greater flexibility to divert products for other uses and otherwise reduce operating costs. Given FSIS' assumed lower sampling frequency, greater flexibility in sampling location and establishments' ability to divert components or products, FSIS does not expect establishments to have challenges holding or controlling FSIS sampled product or have additional labor or transportation issues. Moreover, FSIS does not believe the quality or shelf-life of NRTE breaded stuffed chicken products would be impacted during cold storage while industry awaits FSIS sampling results because these products are frozen. In response to comments, FSIS updated the final CBA by conservatively using the higher estimate for frozen cold storage costs instead of the refrigerated cold storage costs used in the preliminary CBA.

FSIS also does not foresee an issue with cold storage capacity. Cold storage construction in the United States has increased since 2020 to meet higher refrigeration demands. According to the U.S. Bureau of Labor Statistics, the number of private refrigerated warehouse facilities increased by 7.5 percent from 2020 to 2021 and an additional 6.8 percent from 2021 to 2022.⁷⁹ This increase compares to an average annual growth rate of 2.5 percent per year from 2013 to 2020.⁸⁰ With the increase in the number of cold storage establishments, FSIS does not expect the cold storage availability to impact the establishments' ability to store lots of product when FSIS collects a sample. For a conservative estimate, the Agency assumed that all costs of storing product for the sampled lots are due to this final determination; however, establishments may already store the chicken components for NRTE

⁷⁹ Bureau of Labor Statistics. Number of Establishments in Private NAICS 49312 Refrigerated warehousing and storage for All establishment sizes in U.S. TOTAL, NSA. Annual totals from 2013 to 2022. Accessed on September 27, 2023.

⁸⁰ Bureau of Labor Statistics. Number of Establishments in Private NAICS 49312 Refrigerated warehousing and storage for All establishment sizes in U.S. TOTAL, NSA. Annual totals from 2013 to 2022. Accessed on September 27, 2023.

breaded stuffed chicken products in their facilities or in an off-site location for a certain amount of time.

FSIS is confident in its estimated sampling timeframes. In the final determination, FSIS estimates all product sampled and tested by FSIS will be held for 2 days pending screening and enumeration results. At the 1 CFU/g limit, FSIS estimates that about 97 percent of product could be released after two days. Receiving the enumeration results within two days will help industry make more timely decisions about their product and save on cold storage and lost product costs.

Comment: A poultry products trade association and meat industry research institute stated that there are issues with FSIS' analysis of costs in the proposed determination associated with diverted or destroyed product. Specifically, these commenters noted that there is not a market for raw chicken components that are already formulated for use in NRTE breaded stuffed chicken products and, thus, establishments producing raw poultry products cannot readily divert such products for other uses.

Response: FSIS proposed an inspection verification sampling program for *Salmonella* in NRTE breaded stuffed chicken products in which the Agency would collect a sample from the chicken component of NRTE breaded stuffed chicken product prior to breading and stuffing, but after the establishment had completed all the processes needed to prepare the chicken to be stuffed and breaded. However, in the final determination, and based on public comment, FSIS decided to modify the verification sampling location by collecting verification samples on the incoming chicken components. This change may provide establishments with additional flexibility and allow them to divert chicken components more readily.

Comment: A poultry products trade association and meat industry research institute noted that many establishments would be hesitant to divert *Salmonella*-positive product for other NRTE purposes. According to the commenters, to avoid potential liability, many establishments may cook the affected product or employ some other lethality step, resulting in a lower value product. The commenters also asserted that many establishments would need to incorporate sampled lots into finished NRTE breaded stuffed chicken products to avoid spoilage.

Response: FSIS accounts for the lost value in the CBA by assuming diverted chicken components would lose 2/3 of their market value. Alternatively, the establishment is not required to divert

product because FSIS collected a sample and thus, may choose to continue to produce NRTE breaded stuffed chicken and hold the finished product pending verification, which FSIS also included in its estimates for cold storage costs. NRTE breaded stuffed chicken finished product produced from chicken components that FSIS detects to contain *Salmonella* at levels of 1 CFU/g or higher are considered adulterated; however, establishments may be able to fully cook these finished products to achieve lethality resulting in a ready-to-eat product.

Comment: Industry asked FSIS to clarify how it estimated lot sizes in the proposed determination's CBA and noted that the lot sizes may be larger than estimated in the preliminary CBA.

Response: The lot size estimates used in the preliminary CBA were an assumption based on the Agency's data on annual production volumes at these establishments. The preliminary CBA assumed establishments producing at least 1 million pounds of NRTE breaded stuffed chicken annually were high volume establishments with 10,000-pound lots. This assumption was based on examples from the 2013 FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results.⁸¹ The preliminary CBA assumed establishments producing less than 1 million pounds of NRTE breaded stuffed chicken annually were low-volume establishments with 1,000-pound lots. This assumption was based on production data from FSIS' Public Health Information System. FSIS requested comments on these assumptions but did not receive specific comments on lot size for these products. However, in responses to the comments that the lot sizes may be larger, the final CBA has been updated to consider a day's production as a lot at both high and low volume establishments. This is a conservative estimate because the lot sizes may be smaller than a day's production. Establishments ultimately define and support their lot sizes.

Comment: A meat industry research institute and a poultry products industry member stated that FSIS' CBA should have accounted for different employee types to estimate sampling or HACCP plan reassessment labor costs. The same commenters stated that a food safety, quality assurance, or a laboratory employee are more likely to conduct sampling. They stated that

establishments typically do not use line personnel to conduct sampling and, thus, would need to hire additional personnel to conduct tasks associated with sampling and testing. Another commenter suggested that FSIS should better account for the wages of an "experienced production employee" in estimating the labor costs of HACCP plan reassessment.

Response: In response to comments, the final CBA has been updated to include that sample collection is conducted by food scientists and technologists. In addition, the final CBA has been updated to include wage ranges for all the wage estimates to account for the variability in wage rates within the professions. FSIS maintains the assumption that establishments would use and train current employees to implement any new or additional sampling in response to this final determination. While the CBA conservatively assumed every establishment would begin or increase sampling in response to this new policy, some establishments already have robust sampling procedures in place and may not make any changes to their sampling in response to the final determination, while other establishments may choose not to conduct any sampling. Additionally, the Agency did not receive any information on the number of additional employees an establishment would hire in response to this final determination.

Comment: Poultry product trade associations, a member of the poultry products industry, and a meat industry research institute stated that FSIS' CBA underestimated miscellaneous costs associated with the proposed determination, such as testing by industry, employee training, applying new *Salmonella* interventions, changing production processes, and validating new production methods and cooking instructions. These commenters also stated that the CBA underestimated the market price of NRTE breaded stuffed chicken products and, specifically, failed to adjust the price for inflation.

Response: FSIS disagrees that miscellaneous costs are underestimated. FSIS included the cost of HACCP reassessment in the CBA for all establishments producing NRTE breaded stuffed chicken products. Sanitation procedures are a prerequisite to HACCP and according to 9 CFR 416.1, "Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that

product is not adulterated."⁸² Any sanitation issues should be addressed as a condition for the establishment's grant of inspection. Any costs associated with sanitation will not be a result of the new policy.

FSIS did not include the cost of validating cooking instructions in the CBA because industry has already made the recommended changes after the 2015–2016 outbreaks. Any expenses establishments incur to validate cooking instructions or update labels are outside the scope of the policy.

FSIS updated the final CBA to 2022 dollars and used the 2022 average price of chicken breast to represent the price of chicken components for NRTE breaded stuffed chicken product. To be conservative, FSIS used the retail price of boneless chicken breast, which is the premium chicken component utilized in these products.

Comment: Poultry product trade associations, a member of the poultry product industry, and a meat industry research institute noted that sampling and testing alone does not change pathogen loads. Thus, according to commenters, the CBA should assume that establishments will bear the costs of updating their processes to control *Salmonella*.

Response: The final determination and FSIS inspection verification of the adequacy of the HACCP system to control the *Salmonella* hazard, will require industry to use effective methods to control *Salmonella* in NRTE breaded stuffed chicken products regardless of whether FSIS collects an inspection verification sample. FSIS included the cost for establishment-led sampling and testing in the CBA. Establishment-led sampling is an establishment HACCP validation and verification activity that would allow for establishments to support the adequacy of their HACCP system to control the *Salmonella* hazard at one or more steps in the process and verify that they are producing NRTE breaded stuffed chicken products with less than 1 CFU/g *Salmonella*.

Establishments may implement additional interventions to reduce the pathogen loads on their chicken component, but since FSIS did not receive specific comments on the interventions that establishments would use to reduce the *Salmonella* levels on the product, the cost of interventions are not included in the total cost estimate. Though the cost of interventions is not

⁸¹ FSIS Compliance Guideline: Controlling Meat and Poultry Products. Pending FSIS Test Results. 2013. https://www.fsis.usda.gov/sites/default/files/media_file/2021-09/FSIS-GD-2013-0003.pdf. Accessed on: November 9, 2023.

⁸² National Archives. Code of Federal Regulations. Part 416.1 Sanitation Rules: General Rules. Accessed on October 11, 2023: <https://www.ecfr.gov/current/title-9/chapter-III/subchapter-E/part-416>.

included in the CBA, establishments would only adopt new interventions if the new interventions and the cost to implement interventions is more beneficial than diverting or destroying product. Any new interventions used should offset the cost of diverted or destroyed product already accounted for in the CBA.

Comment: A poultry products trade association stated that the benefits of the proposed determination would need to be greater than estimated to achieve the breakeven effect noted in FSIS' CBA, as costs were underestimated. According to the commenter, the use of the Grocery Manufacturers Association (GMA) data does not address the specific nature of recalls for this product class, and the CBA should account for every recall and not every outbreak. The commenter also argued that since trends show the number of outbreaks in these products has decreased over the years, industry may already be implementing interventions and trending toward less outbreaks through voluntary actions.

Response: FSIS disagrees that costs are underestimated and that benefits need to be higher for the final breakeven analysis. FSIS also disagrees that the GMA report¹⁰⁶ is not in scope for NRTE breaded stuffed chicken products. The GMA report is based on survey results from 36 companies and nearly 91 percent of respondents came from the food and beverage industry. FSIS used this report to determine the average impact of a recall on industry. The cost of recalls in NRTE breaded stuffed chicken products would be similar to the cost of recalls averaged over other food products represented in the GMA report.

While the number of outbreaks has slowed slightly in recent years, outbreaks are still occurring regularly, and we have no reason to believe that there would be a downward trend absent this new policy. The most recent 2021 outbreak resulted in more hospitalizations than any of the 14 other NRTE breaded stuffed chicken product outbreaks, with 36 illnesses, and 12 hospitalizations (88 FR 26258–26259). *Salmonella* outbreaks have been disproportionately associated with NRTE breaded stuffed chicken products, which account for less than 0.15 percent of the total domestic chicken supply yet represented approximately five percent of all chicken-associated outbreaks in the United States (88 FR 26252). Based on the available data, FSIS believes that a downward trend in *Salmonella* outbreaks and illnesses from NRTE breaded stuffed chicken can only be achieved by a policy change. The new policy is expected to cause industry to

use more effective methods to control for *Salmonella* in NRTE breaded stuffed chicken products, including diverting, or destroying chicken components with *Salmonella* levels at or over the 1 CFU/g limit.

O. Additional Action

Comment: One individual stated that, in addition to the actions discussed in the proposed determination, FSIS should incentivize establishments to only implement validated control programs in their HACCP Systems.

Response: FSIS regulations at 9 CFR 417.4(a) require that every establishment validate their HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis and verify that the plan is being effectively implemented. Therefore, establishments are currently required to implement control programs into their HACCP Systems that are validated. FSIS has published guidance for industry on how to validate their HACCP Systems.⁸³

Comment: In addition to the actions discussed in the proposed determination, a consumer advocacy organization suggested that FSIS create final product standards for all poultry products contaminated with *Salmonella*.

Response: This determination is only concerned with *Salmonella* in NRTE breaded stuffed chicken products. The recommendation is, thus, outside the scope of the proposed determination. FSIS intends to address issues related to *Salmonella* illnesses associated with other raw poultry products separately through the *Salmonella* Framework Initiative.⁸⁴

Comment: One animal welfare organization noted that stress can cause or exacerbate *Salmonella* infections in live poultry and, thereby, increase contamination in final products. Thus, in addition to the actions discussed in the proposed determination, the commenter asked FSIS to consider strategies to minimize the time poultry spend awaiting slaughter, protect live poultry from severe environmental conditions during holding, ensure stun baths are designed to prevent pre-stun shocks, and otherwise minimize stress, bruising, and injury to birds during transport.

⁸³ FSIS Compliance Guideline: HACCP Systems Validation. April 2015. Available at: https://www.fsis.usda.gov/sites/default/files/import/HACCP_Systems_Validation.pdf.

⁸⁴ FSIS, Proposed Regulatory Framework to Reduce *Salmonella* Illnesses Attributable to Poultry, available <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/proposed>.

Response: The final determination is concerned with *Salmonella* in NRTE breaded stuffed chicken products and specifically, establishing an adulteration threshold, and inspection verification of the new policy. Thus, the commenters' suggestions are not within the scope of this action. However, FSIS guidance specifically addresses best practices to control *Salmonella* prior to and during slaughter and processing.⁸⁵ FSIS inspection program personnel (IPP) also routinely verify that poultry establishments operate in accordance with Good Commercial Practices, which includes the employment of humane methods of handling and slaughtering.⁸⁶

Comment: An industry member asked FSIS to partner with the U.S. Food and Drug Administration (FDA) to implement the 1 CFU/g standard for other RTE items such as peanut butter, lettuce, tomatoes, and other goods that have been linked to *Salmonella* outbreaks so there is a consistent standard for all such products.⁸⁷ Another industry member recommended that FSIS partner with universities to develop education programs aimed at ensuring that robust statistical process control systems are implemented at establishments. The commenter also asked FSIS to work with the USDA Animal and Plant Health Inspection Service to promote vaccine approval, and with other Federal partners to develop more widespread salmonellosis risk assessments.

Response: Recommendations, petitions, and comments on non-FSIS-regulated food products should be directed to FDA. FSIS regularly partners with Federal and State health partners and academia to address issues pertaining to *Salmonella* in FSIS-regulated products. FSIS will continue these partnerships to ensure food safety and further consumer protections.

Comment: A poultry products trade association and an industry member stated that FSIS should amend 9 CFR 381.173 and 381.174 to prohibit mechanically separated chicken (MSC) from being used as a component of NRTE breaded stuffed chicken products.

⁸⁵ FSIS Guideline for Controlling *Salmonella* in Raw Poultry. June 2021. Available at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-07/FSIS-GD-2021-0005.pdf.

⁸⁶ FSIS Directive 6110.1, *Verification of Poultry Good Commercial Practices*, available at: <https://www.fsis.usda.gov/policy/fsis-directives/6110.1>.

⁸⁷ Foodborne illness source attribution estimates for 2019 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States. The Interagency Food Safety Analytics Collaboration (IFSAC); October 2021.

Response: At this time, FSIS does not believe that 9 CFR 381.173 and 381.174 need to be revised because, under this determination, all source material received and used to produce NRTE breaded stuffed chicken must be considered in the establishment's hazard analysis to support the *Salmonella* hazard control required and intended by the HACCP system. Any raw chicken components establishments use to produce NRTE breaded stuffed chicken, including MSC, will be subject to FSIS' food safety inspection verification. MSC must also appear in the ingredients statement.

P. Alternatives to the Proposed Action

Comment: In lieu of the proposed action, a poultry products trade association and an industry member stated that FSIS should take the actions described in the 2022 supplement to the National Chicken Council's 2016 petition⁸⁸ and otherwise focus on improved labeling for NRTE breaded stuffed chicken products.

Response: As discussed throughout the proposed determination and above, over the years, establishments have repeatedly updated their NRTE breaded stuffed chicken product labeling practices in response to reoccurring illness outbreaks caused by these products in an attempt to reduce future instances of salmonellosis. However, these attempts have been unsuccessful. Thus, FSIS does not believe codifying special labeling requirements for NRTE breaded stuffed chicken products is likely to address the *Salmonella* concerns related to these types of products.

Comment: In lieu of the proposed action, a poultry products trade association stated that FSIS should, amongst other actions, require all NRTE breaded stuffed chicken to reassess their HACCP plan, noting that FSIS has taken similar approaches in the past.

Response: HACCP system regulations require that every establishment reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the underlying hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)). This final determination that *Salmonella* at levels of 1 CFU/g or higher is an adulterant in NRTE breaded stuffed chicken products constitutes such a change. Thus, all establishments that

produce NRTE breaded stuffed chicken products must reassess their HACCP plans. Establishments that make changes to their production process as a result of their reassessment would also need to re-validate their HACCP plans. FSIS will issue instructions to IPP in establishments that produce NRTE breaded stuffed chicken products to verify that these establishments have completed their reassessment before the effective date of this final determination. That said, FSIS does not believe that a HACCP reassessment, in the absence of a change in policy, is likely to be a sufficient option to address the *Salmonella* concerns related to these types of products. As discussed in the proposed determination, FSIS believes the appropriate response to protect public health is to ensure that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels sufficient to cause human illness are excluded from commerce.

Comment: In lieu of the proposed action, a poultry products trade association and meat industry research institute suggested that FSIS, amongst other things, develop guidance for processing NRTE breaded stuffed chicken products to reinforce best practices and help small establishments.

Response: FSIS currently has several applicable industry guidance resources available. FSIS has, for example, published industry guidance on NRTE breaded stuffed chicken product labeling⁸⁹ and industry guidance for controlling *Salmonella* in raw poultry to assist establishments that slaughter or process raw poultry products to prevent and minimize the risk of *Salmonella* in their operations.⁹⁰ These documents contain best practices and recommendations for industry to consider in their food safety system(s). FSIS will continue to publish and revise relevant guidance, as needed. However, FSIS does not believe that new or updated guidance, in the absence of a change in policy, is likely to be a sufficient option to address the *Salmonella* concerns related to these types of products.

Comment: In lieu of the proposed action, a poultry products trade association stated that FSIS should, amongst other things, conduct food safety assessments (FSAs) at

establishments producing NRTE breaded stuffed chicken products to verify that food safety systems are being implemented properly for these products. The commenter also noted that these FSAs could also help identify best food safety practices for producing such products.

Response: FSIS does not believe that conducting FSAs, in lieu of this final determination, would sufficiently address the *Salmonella* concerns related to these types of products.

FSIS assigns and conducts Public Health Risk Evaluations (PHREs) as described in FSIS Directive 5100.4⁹¹ using both for-cause and routine risk-based PHRE criteria. PHREs are an analysis of establishment performance and use risk-based criteria to determine if FSIS will conduct an FSA. FSAs, as described in FSIS Directive 5100.1,⁹² are conducted to assess an establishment's food safety system and verify that meat, poultry, or egg products are safe, wholesome, and produced in accordance with FSIS statutory and regulatory requirements. FSIS will continue to conduct PHREs and FSAs following the criteria described in these FSIS Directives at establishments that produce NRTE breaded stuffed chicken products.

Comment: A poultry products trade association and a trade association representing the frozen food industry stated that FSIS should implement the recommendations outlined in NACMPI's 2021 report.⁹³

Response: As discussed in the proposed determination (88 FR 26259), the report provided several recommendations that primarily focus on the labeling of NRTE breaded stuffed chicken products. Specifically, the subcommittee recommended that FSIS re-verify that companies continue to voluntarily label NRTE breaded stuffed chicken products as raw in several places on the label and that labels of these products include validated cooking instructions. The subcommittee also recommended that FSIS update the 2006 labeling guidance to warn consumers not to use microwaves and air fryers if validated instructions are not provided for these methods and to cook the product to a minimum of

⁹¹ FSIS Directive 5100.4, *Public Health Risk Evaluation Methodology*, available at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-08/5100.4.pdf.

⁹² FSIS Directive 5100.1, *Public Health Risk Evaluation Methodology*, available at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-08/5100.1.pdf.

⁹³ National Advisory Committee on Meat and Poultry Inspection, Subcommittee II: Stuffed Not Ready-to-Eat Poultry Products, USDA (Sept. 28, 2021).

⁸⁸ FSIS Petition 16-03, *Establish Labeling Requirements for Not-Ready-To-Eat Stuffed Chicken Products*. Originally submitted on May 24, 2016. Supplemented on February 25, 2022. Available at: <https://www.fsis.usda.gov/federal-register/petitions/establish-labeling-requirements-not-ready-to-eat-stuffed-chicken-products>.

⁸⁹ FSIS Labeling Policy Guidance: Uncooked, Breaded, Boneless Poultry Products. Available at: https://www.fsis.usda.gov/sites/default/files/import/Labeling_Policy_Guidance_Uncooked_Breaded_Boneless_Poultry_Products.pdf.

⁹⁰ FSIS Guideline for Controlling *Salmonella* in Raw Poultry. June 2021. Available at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-07/FSIS-GD-2021-0005.pdf.

165 °F as measured using a food thermometer. The subcommittee further recommended that FSIS add label verification for these products as a recurring task for inspectors and review labels from the 2021 outbreak. In addition, the subcommittee recommended that FSIS require establishments that produce these products to reassess their HACCP plans in light of the outbreaks and encouraged FSIS to conduct targeted consumer outreach regarding these types of products, including creating an FSIS web page highlighting NRTE breaded stuffed chicken products. The subcommittee also recommended that FSIS establish requirements for the labeling of NRTE breaded stuffed chicken products and publish industry guidance explaining how to validate cooking instructions for such products.

In light of the 2021 *Salmonella* outbreak and earlier outbreaks associated with these products, the Agency concluded and shared with NACMPI in 2023 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. Therefore, FSIS concluded that public health measures that focus primarily on product labeling and consumer handling practices have not been effective in preventing additional foodborne illnesses associated with NRTE breaded stuffed chicken products.

III. Implementation

A. HACCP Reassessment

FSIS' regulations require that every establishment reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the underlying hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)). This final determination that *Salmonella* at levels of 1 CFU/g or higher is an adulterant in NRTE breaded stuffed chicken products constitutes such a change. Thus, as discussed in the proposed determination (88 FR 26264), FSIS is announcing that all establishments that produce Heat Treated but Not Fully Cooked—Not Shelf Stable NRTE breaded stuffed chicken products must reassess their HACCP plans; establishments can reassess as part of their annual reassessment if their annual reassessment occurs before the effective date. Establishments that make changes to their production process as a result of their reassessment would also need to

revalidate their HACCP plans. Prior to the effective date of this final determination, FSIS will issue instructions to IPP in establishments that produce NRTE breaded stuffed chicken products to verify that these establishments have completed their reassessment. Establishments must complete the reassessment and revalidate their HACCP plans by May 1 2025.

B. Implementation and Status of Laboratory Methods

As explained in the proposed determination (88 FR 26264–26266), FSIS will implement routine sampling and verification testing for *Salmonella* in NRTE breaded stuffed chicken products. In the proposed determination (88 FR 26264), FSIS stated that it would collect samples from the chicken component of a NRTE breaded stuffed chicken product prior to breading and stuffing after the establishment had completed all the processes needed to prepare the chicken to be stuffed and breaded. However, in response to public comments, FSIS has decided to modify the proposed verification sampling location to give establishments greater flexibility to divert source components for other appropriate uses and, thereby, lower lost product costs. Therefore, instead of collecting verification samples after the establishment has completed all processes needed to prepare the chicken component to be stuffed and breaded to produce a final NRTE breaded stuffed chicken product, as was proposed, FSIS will collect verification samples on the raw incoming chicken components used to produce NRTE breaded stuffed chicken product. In implementing sampling and verification testing for these products, FSIS will consider the production process at each impacted establishment and the Agency's ability to collect samples safely and effectively.

FSIS intends to perform, evaluate, determine, and report whole genome sequencing (WGS), serotype, levels, and antimicrobial resistance (AMR) profile for *Salmonella* isolates identified.⁹⁴ As noted in the proposed determination (88 FR 26262), FSIS intends to continuously evaluate and, if necessary, refine the status of *Salmonella* as an adulterant in NRTE breaded stuffed chicken products

⁹⁴ This information would be reported as with any test result. Inspectors would get result through the Public Health Information System (PHIS). FSIS would report out through Laboratory Information Management System (LIMS) Direct for industry as well as the result would be in the new PHIS sample result history report. The results would also be in public release data sets that the Agency does quarterly. The WGS data would also be uploaded to NCBI as are other *Salmonella* isolates.

as advances in science and technology related to pathogen levels, serotypes, virulence genes, and product matrices become available. FSIS will likewise refine its sampling and verification testing for these products, as needed.

The detection and isolation methodology for *Salmonella* is described in chapter 4.14, of the FSIS Microbiology Laboratory Guidebook (MLG).⁹⁵ When sampling the raw incoming chicken components of NRTE breaded stuffed chicken products under this final determination, FSIS will collect one pound of the selected incoming chicken component from the establishment to analyze 325 grams per test for *Salmonella*. Samples will be initially screened, post-enrichment, for the presence or absence of *Salmonella*. Samples that screen negative will be reported as “negative.” For samples that screen positive, FSIS will then analyze *Salmonella* levels. Potential positives that screen positive for *Salmonella* presence and contain levels ≥ 1 CFU/g will then be analyzed using selective and differential culture-based media to identify the presumptive positive samples. Presumptive positives will then be confirmed by molecular-based mass spectrometric identification. A sample is only considered a “confirmed positive” for *Salmonella* after completion of both cultural and confirmatory testing. If any chicken component is “confirmed positive” with *Salmonella* levels of 1 CFU/g or higher, the entire sampled lot will need to be diverted to a use other than NRTE breaded stuffed chicken products. Any NRTE breaded stuffed chicken products that contain a chicken component from a sampled lot confirmed positive with *Salmonella* levels of 1 CFU/g or higher prior to stuffing and breading will be considered adulterated and excluded from commerce.

FSIS estimates that negative results will routinely be available within two days of sample collection, assuming overnight sample transit to the laboratory coupled with an overnight sample enrichment followed by screening and quantification at the laboratory. Enumeration is conducted from the same sample as screen testing and both results will be reported on the same day. For samples that are potential positives, an additional 3 days may be necessary for a confirmed positive or negative result. These timeframes and methods may change as FSIS incorporates new laboratory

⁹⁵ FSIS Microbiology Laboratory Guidebook available at: <https://www.fsis.usda.gov/news-events/publications/microbiology-laboratory-guidebook>.

technologies into its sampling and verification testing.⁹⁶

FSIS does not intend to begin the sampling and verification testing discussed in this final determination until May 1, 2025. This should give establishments enough time to adjust their relevant procedures and processes to facilitate such sampling and testing.

C. Sampled Lot

When FSIS tests a product for adulterants, the Agency withholds its determination as to whether product is not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received.⁹⁷ Under this policy, establishments must maintain control of products tested for adulterants to ensure that the products do not enter commerce while waiting for receipt of the test results. Thus, when FSIS samples raw incoming chicken components intended for use in NRTE breaded stuffed chicken products, establishments will need to control and maintain the integrity of the sampled chicken components (*i.e.*, the sampled lots) pending the availability of test results. As noted above, establishments may incorporate sampled lots into finished NRTE breaded stuffed chicken products, so long as those finished products remain under establishment control awaiting test results.

FSIS IPP will give establishments that produce NRTE breaded stuffed chicken product advance notice before they collect a product sample for verification testing to give the establishment enough time to hold or control the sampled lot. Establishments are responsible for providing a supportable basis for defining the sampled lot. For sampling

⁹⁶ For example, on July 8, 2022, FSIS announced that it had awarded a contract to bioMérieux to incorporate its non-enrichment quantification system for *Salmonella*, 'GENE-UP™ QUANT *Salmonella*,' into the Agency's laboratory system. The Agency evaluated commercially available quantification systems and determined that this technology is the most appropriate for use in the high throughput FSIS laboratory environment. FSIS stated that in the future, the Agency would announce when the method is available and when it will be implemented in all three FSIS food testing laboratories. FSIS also stated that it plans to extend pathogen quantification technology to sample types other than raw poultry rinses in the future (see FSIS Constituent Update, Jul 8, 2022, *FSIS to include Salmonella Quantification in Raw Poultry Rinse Samples*. Available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-july-8-2022#:~:text=Salmonella%20quantification%20is%20a%20significant%20step%20in%20FSIS%20regulatory%20sample%20C%20not%20solely%20its%20presence%20or%20absence>).

⁹⁷ *Not Applying the Mark of Inspection Pending Certain Test Results*, 77 FR 73401, December 10, 2012.

purposes, production lots should be defined such that they are microbiologically independent. Microbiological independence is documented by separation, (*e.g.*, physical, temporal, or by sanitation intervention), that clearly delineates the end of one production lot and the beginning of the next. The microbiological results from one test are independent of prior or later lots. In other words, if a chicken component sample collected prior to stuffing and breading tests positive for *Salmonella* at a level of 1 CFU/g or higher, products from other chicken component lots should not be implicated if the lots are microbiologically independent.

Generally, FSIS recommends that establishments develop and implement in-plant sampling plans that define production lots or sub-lots that are microbiologically independent of other production lots or sub-lots. Production lots that are so identified may bear distinctive markings on the shipping cartons. FSIS has issued guidance to help establishments comply with the requirement that product that FSIS has tested for adulterants does not enter commerce until test results become available.⁹⁸ FSIS intends to update the guidance to add NRTE breaded stuffed chicken products. In addition to providing guidance on adequate control measures establishments can implement for products tested for adulterants, the document also includes guidance on how establishments can define a product lot in order to determine the amount of product that must be controlled pending test results. Before implementation, FSIS will update the guidance to cover sampling and verification testing for *Salmonella* in the selected raw incoming chicken components intended for use in NRTE breaded stuffed chicken products.

D. State Programs and Foreign Government Programs

States that have their own poultry inspection programs for poultry products produced and transported solely within the State are required to have mandatory ante-mortem and post-mortem inspection, reinspection, and sanitation requirements that are at least equal to those in the PPIA (21 U.S.C. 454(a)(1)). In accordance with this final determination, these States will need to adopt sampling procedures and testing methods to detect *Salmonella* at 1 CFU/g or above in the chicken

⁹⁸ FSIS Compliance Guideline: Controlling Meat and Poultry Product Pending FSIS Test Results (2013) at: <https://www.fsis.usda.gov/guidelines/2013-0003>.

component in NRTE breaded stuffed chicken products that are at least equal to FSIS' procedures and testing methods for State-inspected establishments that produce these products.⁹⁹ Any State participating in a Cooperative Interstate Shipment Program will need to adopt FSIS' sampling procedures and testing methods to detect *Salmonella* at 1 CFU/g or above in NRTE breaded stuffed chicken products in selected establishments that produce these products for shipment in interstate commerce that are the "same as" those utilized by FSIS (21 U.S.C. 472).

Foreign countries that are eligible to export poultry products to the United States must apply inspection, sanitation, and other standards that are equivalent to those that FSIS applies to those products (21 U.S.C. 466). At this time, no foreign countries export NRTE breaded stuffed chicken products to the United States. As discussed in the proposed determination (88 FR 26267), in evaluating a foreign country's poultry products inspection system to determine the country's eligibility to export NRTE breaded stuffed chicken products to the United States, FSIS would consider whether the sampling procedures and testing methods the country uses to detect *Salmonella* at 1 CFU/g in these products are equivalent to those that FSIS uses.

IV. Anticipated Costs and Benefits of This Final Determination

FSIS has considered the economic effects of this determination and has updated the final CBA in response to public comments. In the final CBA, FSIS updated the estimated costs and benefits for the final policy from those published in the preliminary CBA from 2021 to 2022 dollars. Also, in response to public comments, FSIS updated the assumed lot size for FSIS and industry sampling, included a range of wages, updated the assumed type of employee that will conduct establishment led sampling, and updated the assumptions used to estimate cold storage time and costs. With input from the Centers for Disease Control and Prevention (CDC), the Agency included an under-reporting multiplier of 25.5 to estimate the actual number of *Salmonella* illnesses associated with outbreaks from NRTE breaded stuffed chicken products.^{100 101}

⁹⁹ FSIS is not aware of any State-inspected establishments that produce NRTE stuffed chicken products.

¹⁰⁰ Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, Griffin PM. Foodborne illness acquired in the United States—major pathogens pdf icon [PDF—9 pages]. *Emerging Infectious Diseases*. 2011;17(1):7–15: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3375761/>.

In the final determination, the Agency also includes an estimated opportunity cost for the Agency to implement the new sampling and testing program and updated the impact on small businesses analysis.¹⁰² The full analysis is available at: <https://www.regulations.gov/docket/FSIS-2022-0013/document>.

Summary of Estimated Costs and Benefits

The final determination is expected to impact six domestic establishments and cost industry at least \$5.29 million annually, assuming a 7 percent discount rate over a ten-year period. These costs are associated with HACCP plan reassessments, holding sampled chicken components or finished products in storage awaiting FSIS test results, the costs associated with developing and implementing an establishment-conducted sampling program and destroying or diverting the chicken components of NRTE breaded stuffed chicken with *Salmonella* levels at or over the 1 CFU/g limit. Industry may also incur other costs associated with their individual responses to this policy, including applying interventions, training, product reformulation and label changes, and subsequent HACCP plan validation. However, based on public comments, the Agency does not expect establishments to make these changes. If establishments were to implement these additional changes, then we would expect both additional costs and benefits. The Agency would incur an opportunity cost of \$0.02 million associated with sampling and testing for *Salmonella*. FSIS will be able to shift existing resources as necessary to conduct sampling, testing, and associated FSAs to implement the final determination. The estimated total cost for this policy is \$5.31 million: \$5.29 million in costs to industry and \$0.02 million in opportunity costs for FSIS, assuming a 7 percent discount rate over a 10-year period.

The estimated benefits for this policy are derived from preventing outbreak-

¹⁰¹ FSIS used the under-reporting multiplier of 25.5 estimated in Scallan et al. for a group of pathogens for which only outbreak data were available to approximate the total number of cases for NRTE stuffed chicken products. FSIS used this under-reporting multiplier as only outbreak data is available for NRTE stuffed chicken products.

¹⁰² As noted by the Office of Management and Budget in the Circular No. A-4 published on November 9, 2023. Opportunity costs “is the cost attributable to a regulation if an agency will be performing enforcement activities or otherwise using resources in connection with that regulation, even if the agency’s budget is not increasing.” <https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf>. Accessed on 02/15/2024.

related recalls.¹⁰³ Each prevented outbreak-related recall has an estimated benefit of \$34.99 million (\$1.42 million in health benefits + \$33.57 million in industry benefits). Between 2006 and 2021 there was one outbreak every 1.36 years on average (15 years ÷ 11 outbreaks). Total benefits will exceed total costs if the new policy prevents at least 1 outbreak-related recall every 6.6 years (\$34.99 million ÷ \$5.31million).¹⁰⁴ Though the policy may not prevent every possible outbreak-related recall, the Agency expects it will prevent at least 1 every 6.6 years.

Without this policy, there is a higher risk of *Salmonella* illnesses from NRTE breaded stuffed chicken products. When only considering health benefits, the policy would break-even if 1,134 illnesses were avoided annually (\$5.31 million ÷ \$4,682).¹⁰⁵ The smallest number of cases associated with an outbreak from NRTE breaded stuffed chicken products occurred in 2009, with 2 reported cases, which represents an estimated 51 cases and a cost burden of \$0.24 million, when applying the under-reporting multiplier of 25.5.¹⁰⁶ The largest number of reported cases associated with outbreaks occurred between 2008–2009, with 47 reported cases, which represents 1,199 estimated cases and a cost burden of \$5.6 million, when applying the under-reporting multiplier.^{107 108} Despite proper labeling, the most recent outbreak in 2021 occurred with 36 reported cases, which represents 918 estimated cases and a cost burden of \$4.3 million. In the final determination, FSIS is declaring NRTE breaded stuffed chicken products that contain *Salmonella* at levels of 1 CFU/g or higher adulterated. FSIS intends to carry out verification

¹⁰³ Though each reported outbreak between 2006 and 2021 did not result in a recall, FSIS assumes there is a risk of recall with each possible *Salmonella* outbreak.

¹⁰⁴ Numbers may not add up due to rounding.

¹⁰⁵ Number rounded to the nearest whole number.

¹⁰⁶ Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, Griffin PM. Foodborne illness acquired in the United States—major pathogens pdf icon [PDF—9 pages]. *Emerging Infectious Diseases*. 2011;17(1):7–15: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3375761/>.

¹⁰⁷ Food Safety and Inspection Service, USDA. *Salmonella* in Not Ready-To-Eat Breaded Stuffed Chicken Products. Final Determination. Docket No. FSIS-2022-0013, available at: <https://www.regulations.gov/docket/FSIS-2022-0013>.

¹⁰⁸ The FSIS estimate for the cost of *Salmonella*-related illness \$4,682 per case, (2022 dollars) was developed using the USDA, Economic Research Service, Cost Estimates of Foodborne Illness *Salmonella* (October 2014) updated for inflation. <https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses/>. The cost model accounts for medical costs (including hospitalizations), premature death and productivity loss. Numbers may not calculate due to rounding.

procedures, including sampling and testing of the raw incoming chicken components used to produce NRTE breaded stuffed chicken products, to verify that producing establishments do not produce adulterated products. This determination, and the associated FSIS verification procedures, should decrease the number of illnesses associated with *Salmonella* in NRTE breaded stuffed chicken products.

Impact on Small Businesses

In the CBA, FSIS defines high-volume establishments as establishments that produce at least 1 million pounds of NRTE breaded stuffed chicken products annually and low-volume establishments as establishments that produce less than 1 million pounds annually. Using these categories, three of the six establishments that produce NRTE stuffed chicken products were classified as high-volume, and three establishments as low volume. All three of the low-volume establishments are HACCP size small or very small.¹⁰⁹ FSIS expects the cost burden of this determination on low-volume establishments would be under 4.2 percent of the estimated revenue from NRTE stuffed chicken for these three establishments. Establishments are not required to develop and implement their own sampling programs in response to this determination. If establishments chose to avoid these voluntary costs, the final determination is estimated to cost low-volume establishments about 1.9 percent of estimated revenue from NRTE breaded stuffed chicken products produced at these three establishments. In addition, nearly 90 percent of production at two of the three low-volume establishments is product other than NRTE breaded stuffed chicken. Thus, the impact of this final determination would represent a smaller percentage of these establishments’ overall total revenue. Further, once the policy is implemented, FSIS does not intend to begin the FSIS sampling and the verification testing discussed in the final determination until 12 months after the date of publication in the **Federal Register**. A small business would have this time to prepare for changes, lowering the burden. Finally, establishments needing monetary assistance with this new policy may be able to take advantage of the grants and financial options available to small

¹⁰⁹ Under the HACCP size definitions, large establishments have 500 or more employees, small establishments have between 10 and 499 employees, and very small establishments have less than 10 employees or less than \$2.5 million in annual revenue. 61 FR 38806.

establishments, reducing potential burden. More information on these loans and grants can be found on the FSIS website.¹¹⁰

V. USDA Non-Discrimination Statement

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (e.g., Braille, large print, audiotope, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720-2600 (voice and TTY).

To file a program discrimination complaint, a complainant should complete a Form AD-3027, USDA Program Discrimination Complaint Form, which can be obtained online at <https://www.usda.gov/forms/electronicforms>, from any USDA office, by calling (866) 632-9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD-3027 form or letter must be submitted to USDA by:

(1) *Mail*: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410;

(2) *Fax*: (833) 256-1665 or (202) 690-7442; or

(3) *Email*: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

¹¹⁰ Grants and Financial Options, USDA FSIS <https://www.fsis.usda.gov/inspection/apply-grant-inspection/grants-financial-options>.

VI. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>. FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Paul Kiecker,
Administrator.

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DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket ID: NRCS-2024-0007]

Urban Agriculture and Innovative Production Advisory Committee

AGENCY: Natural Resources Conservation Service, United States Department of Agriculture.

ACTION: Notice to solicit nominees.

SUMMARY: The Department of Agriculture's (USDA) Office of Urban Agriculture and Innovative Production (OUAIP) is seeking nominations for individuals to serve on the Urban Agriculture and Innovative Production Advisory Committee (UAIPAC). The UAIPAC advises the Secretary of Agriculture on the development of policies and outreach relating to urban, indoor, and other emerging agricultural production practices. The 12 members appointed by the Secretary of Agriculture are expected to serve a 3-year term. The nomination period

includes four vacancies, including the: urban producer representative; higher education or extension program representative; business and economic development representative; and representative with related experience in urban, indoor, and other emerging agriculture production practices.

DATES: USDA will consider nominations received via email or postmarked by July 1, 2024.

ADDRESSES: Please send nominations via email to: UrbanAgricultureFederalAdvisoryCommittee@usda.gov. Email is the preferred method for sending nominations; alternatively, nominations can be mailed to Brian Guse, Director of the Office of Urban Agriculture and Innovative Production, Department of Agriculture, 1400 Independence Avenue SW, Room 4083, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Markus Holliday, Coordinator, Office of Urban Agriculture and Innovative Production; telephone: (301) 974-1287; email: UrbanAgricultureFederalAdvisoryCommittee@usda.gov.

Individuals who require alternative means for communication may contact the USDA TARGET Center at (202) 720-2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay service (both voice and text telephone users can initiate this call from any telephone).

SUPPLEMENTARY INFORMATION:

UAIPAC Overview and Membership

Section 222 of the Department of Agriculture Reorganization Act of 1994, as amended, by section 12302 of the 2018 Farm Bill (7 U.S.C. 6923; Pub. L. 115-334), directed the Secretary of Agriculture to establish an "Urban Agriculture and Innovative Production Advisory Committee" to advise the Secretary on any aspect of section 222, including the development of policies and outreach relating to urban, indoor, and other emerging agricultural production practices as well as identify any barriers to urban agriculture. UAIPAC will host public meetings to deliberate on recommendations from the Secretary of Agriculture. These recommendations provide advice to the Secretary on supporting urban agriculture and innovative production through USDA's programs and services. For additional background and member information visit the UAIPAC website at <https://www.usda.gov/partnerships/federal-advisory-committee-urban-ag>.

The UAIPAC consists of 12 members including:

- 4 representatives who are agriculture producers including 2 individuals who are located in an urban