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Re: *Salmonella* in Not-Ready-to-Eat Breaded Stuffed Chicken Products -- Proposed determination [Docket No. FSIS-2022-0013]; 88 *Fed. Reg.* 26249; (April 28, 2023)

Dear Ms. Edelstein:

The North American Meat Institute (NAMI or the Meat Institute) submits these comments concerning the above-referenced proposed determination to declare *Salmonella* an adulterant at levels of 1 colony forming unit per gram (CFU/g) in not-ready-to-eat (NRTE) breaded stuffed chicken products (proposed determination or proposal). The Meat Institute is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, poultry, and processed meat products and NAMI member companies account for more than 95 percent of United States output of these products. The Meat Institute provides regulatory, scientific, legislative, public relations, and educational services to the meat and poultry packing and processing industry.

The Meat Institute appreciates the opportunity to comment on the proposed determination. The proposal is a marked change from long-standing agency policy and legal precedent. Though some NAMI member companies will be directly impacted, because they produce NRTE breaded stuffed chicken products, all NAMI member companies have a vested interest in this proposed determination. There are several aspects of the proposal that warrant reconsideration and further examination by the agency.

DETERMINATION

Salmonella is inherent in poultry.

It is well understood that *Salmonella* are inherent in the microbiome of live healthy poultry.[1] In poultry, *Salmonella* infection is dependent on several factors including age, immune status, genetic susceptibility, environment, and stress.[2] When poultry are infected, *Salmonella* colonizes in the ceca and shed in feces for several weeks.[3] *Salmonella* is transmitted from healthy infected poultry to other animals via the fecal-oral route. After passing through the crop and stomach, *Salmonella* moves through the intestinal mucin layer and attaches to epithelial cells and invades the entire bird.[4] *Salmonella* is then taken up by sub-epithelial dendritic cells and macrophages and transported systemically via the bloodstream and lymphatic system throughout the entire bird, including the liver, spleen, bone marrow and other organ systems (ovary, oviduct, gizzard, yolk sac, and lungs).[5] Some *Salmonella* colonize the reproductive tracts of layers and enter the egg.[6] Further

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[1] 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. https://doi.org/10.1128/AEM.00598-11

[2] Barrow, P. A., Huggins, M. B., Lovell, M. A., & Simpson, J. M. (1987). Observations on the pathogenesis of experimental *Salmonella* typhimurium infection in chickens. Research in veterinary science, 42(2), 194-199.

Gast, R. K. (2013). Paratyphoid infections. Diseases of poultry, 10, 97-121.

[3] Gast, R. K., & Holt, P. S. (1998). Persistence of *Salmonella* enteritidis from one day of age until maturity in experimentally infected layer chickens. Poultry Science, 77(12), 1759-1762.

Gast, R. K. (2013). Paratyphoid infections. Diseases of poultry, 10, 97-121.

Phillips, R. A., & Opitz, H. M. (1995). Pathogenicity and persistence of *Salmonella* enteritidis and egg contamination in normal and infectious bursal disease virus-infected leghorn chicks. Avian diseases, 778-787.

[4] 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.

[5]Chappell, L., Kaiser, P., Barrow, P., Jones, M. A., Johnston, C., & Wigley, P. (2009). The immunobiology of avian systemic salmonellosis. Veterinary immunology and immunopathology, 128(1-3), 53-59.

Dunkley, K. D., Callaway, T. R., Chalova, V. I., McReynolds, J. L., Hume, M. E., Dunkley, C. S., ... & Ricke, S. C. (2009). Foodborne *Salmonella* ecology in the avian gastrointestinal tract. Anaerobe, 15(1-2), 26-35.

Mastroeni, P., & Grant, A. J. (2011). Spread of *Salmonella* enterica in the body during systemic infection: unravelling host and pathogen determinants. Expert reviews in molecular medicine, 13, e12.

Lutful Kabir, S. M. (2010). Avian colibacillosis and salmonellosis: a closer look at epidemiology, pathogenesis, diagnosis, control and public health concerns. International journal of environmental research and public health, 7(1), 89-114.

[6] Gast R. K., Guard-Bouldin J., Holt P. S. 2004. Colonization of reproductive organs and internal contamination of eggs after experimental infection of laying hens with *Salmonella* Heidelberg and *Salmonella* Enteritidis. Avian Dis. 48:863–869

scientific evidence shows that *Salmonella* can colonize in the ceca, neck skin, tibiotarsus (leg bone), drumstick muscle and blood. Specifically, *Salmonella* was detected in internal tissues (muscle, bone, blood, liver, and spleen) within the first two weeks of infection, then intermittently in bone and muscle at later times.[7] While *Salmonella* abundance in muscle tissue was found in low ($<10^2$ CFU/g) abundance, it still falls above the proposed adulterant level.

A tremendous amount of research has been conducted demonstrating the complexity of *Salmonella* and how it infiltrates the body of healthy birds. Much of the research was supported and conducted by industry. The Foundation for Meat and Poultry Research and Education and industry will continue to aggressively pursue *Salmonella* research and seek solutions, because there is still much to learn about *Salmonella*. However, the science is clear on one aspect: *Salmonella* can be colonized and found in healthy birds throughout the entire body including blood, lymphatic system, digestive tract, muscle tissue, organs, and skin. Therefore, *Salmonella* is intrinsic to poultry products, including muscle.

<u>*Salmonella* is not an "added substance" in any poultry product.</u>

Under the PPIA a poultry product is "adulterated"

> if it bears or contains any poisonous or deleterious substance which <u>may render it injurious to health</u>; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article <u>does not ordinarily render it injurious to health</u>.[8] (Emphasis added)

This definition establishes different standards for whether a poultry product is adulterated, depending on whether the substance is "added."[9] If the substance is "added" the easier to satisfy "may render … injurious to health" standard applies. Conversely, if the substance is not added, or what many consider naturally occurring, the more difficult to meet "does not ordinarily render it injurious to health" standard applies.

Gast R. K., Guraya R., Guard-Bouldin J., Holt P. S. 2007. In vitro penetration of egg yolks by Salmonella Enteritidis and Salmonella Heidelberg strains during thirty-six-hour ambient temperature storage. Poult. Sci. 86:1431–1435

Gast R. K., Guraya R., Guard-Bouldin J., Holt P. S., Moore R. W. 2007. Colonization of specific regions of the reproductive tract and deposition at different locations inside eggs laid by hens infected with Salmonella Enteritidis or Salmonella Heidelberg. Avian Dis. 51:40–44

[7] 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.

[8] 21 U.S.C. 453(g)(1).

[9] Before determining whether a substance adulterates a product is whether the substance is "poisonous or deleterious."

The case law provides that to be "added" a substance must be artificially introduced by a person. For example, in *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157, 160 (5th Cir. 1980), the court explained that the

> distinction between added and not-added substances comes from the "adulterated food" provisions of the original Food, Drug, and Cosmetic Act of 1906. The legislative history shows that "added" meant attributable to acts of man, and "not-added" meant attributable to events of nature. (Emphasis added)

The Supreme Court drew the same distinction in *United States v. Coca Cola*, 241 U.S. 265, 36 S.Ct. 573, 60 L.Ed. 995 (1915). Construing the "added . . . ingredient" provisions of the 1906 Act, the Court said

> Congress, we think, referred to ingredients artificially introduced; these are described as "added." The addition might be made to a natural food product or to a compound . . . we think that it was the intention of Congress that the artificial introduction of ingredients of a poisonous or deleterious character which might render the article injurious to health should cause the prohibition of the statute to attach.

FSIS previously rejected the notion that *Salmonella* is an added substance in response to the first and second iterations of a petition submitted by the Center for Science in the Public Interest (CSPI), which argued antibiotic-resistant (ABR) *Salmonella* was an added substance.[10] In denying the CSPI petition the agency correctly concluded ABR *Salmonella* was not an "added substance" because it was not artificially added by humans. Scientific evidence demonstrates that *Salmonella* is inherent in poultry, corroborating the agency's earlier decision-making in responding to the petitions, that it is not an "added substance."

Whether the proposed determination meets the "ordinarily injurious" standard is unclear.

Since the science is clear that *Salmonella* is not "added," the question of adulteration hangs on whether the products would be "ordinarily injurious" to health if containing *Salmonella* at 1 CFU/g in the chicken component. The mere presence of *Salmonella* on poultry products does not render it injurious to health. Virulence, infectious dose, product characteristics, handling, preparation, and host susceptibility all play a role in pathogenicity. A simpler iteration of this concept is

[10] See letter from Carmen Rottenberg, Acting Deputy Under Secretary, Office of Food Safety, to Laura MacCleery, Director Regulatory Affairs, Center for Science in the Public Interest, February 7, 2018.

provided in *American Public Health Ass'n. v. Butz,* in which the court found the presence of *Salmonella* on not ready-to-eat meat and poultry does not render the product adulterated.[11] The two facets to consider in the "ordinarily injurious" question are the infectious dose of *Salmonella* and consumer preparation and handling practices.

Infectious Dose

Not all *Salmonella* are created equal. The infectious dose of *Salmonella* varies greatly from less than 100 to more than hundreds of thousands of cells, depending on virulence. The mere presence of certain serovars or even elevated levels of *Salmonella* on poultry products does not ordinarily render it injurious to health or result in illness without consideration of virulence. For example, the agency's own data on NRTE breaded stuffed chicken products show that more than a quarter of all *Salmonella* positives were *Salmonella* Kentucky and would not result in illness, especially at the level specified in the proposed determination, or even at 10 CFU/g.[12] Furthermore, recent infectious dose research has demonstrated the flaws in the evidence used in the proposed determination to set the level at 1 CFU/g. The original evidence used to support 1 CFU/g did not include data from challenge studies and, therefore, mishandled illness outcomes, resulting in missing susceptibility status and incomplete information on infectious dose. Recent research concluded the wider range of infectious doses for *Salmonella* and that previous research was very likely too conservative and that the infectious doses for many *Salmonella* are higher.[13] The proposed determination concluding that all *Salmonella* above 1 CFU/g should be considered an adulterant is misguided and not risk-based or public health focused.

Consumer Preparation and Handling

In *American Public Health Ass'n. v. Butz,* the court found the presence of *Salmonella* on not ready-to-eat meat and poultry does not render the product adulterated. There, the United States Court of Appeals for the D.C. Circuit said

> As the Department said in its August 18, 1971 letter "the American consumer knows that raw meat and poultry are not sterile and, if handled improperly, perhaps could cause illness." In other words, American housewives and cooks normally are not ignorant or stupid and their methods of preparing and cooking of food do not ordinarily result in salmonellosis.[14]

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[11] 511 F.2d 331, 334 (5th Cir. 1975).
[12] 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.
[13] Teunis, P. F. (2022). Dose response for Salmonella Typhimurium and Enteritidis and other nontyphoid enteric salmonellae. Epidemics, 41, 100653.
[14] 511 F.2d 331, 334 (5th Cir. 1975).

FSIS recognizes that the producers of these products have made substantial changes over time to educate consumers that these products are raw and how to properly handle and prepare them accordingly. The overall decreasing trend of outbreaks related to these products suggests the changes, such as enhanced labeling and validated cooking instructions, may have contributed to better preparation and handling by consumers. The agency should develop industry guidance on how to validate cooking instructions, which would be beneficial for many products, but especially so for these.

Agency data on consumer cooking and handling practices of NRTE breaded stuffed chicken products may demonstrate a continued lack of understanding unique to these products, despite clear labeling, that could form the basis of an argument that these products are "ordinarily injurious" from a consumer preparation and handling perspective. However, this argument hinges on the fact that the products may appear ready-to-eat due to heat treatment to set the batter. Therefore, the proposal should have been limited to products that may appear ready-to-eat, such as those products used in the agency's consumer studies. In fact, it was seemingly intended to be so limited.

> For example, an establishment may decide to reformulate their product so that the breading is no longer par-fried, such that the products may no longer appear RTE. This reformulation may also lead to the establishment relabeling this product to remove any ingredient associated with par-frying the products from the ingredients statement. Such products would no longer be classified as NRTE breaded stuffed chicken products in which the final product has been heat-treated only to set the batter or breading, which may impart a RTE appearance, and thus would not be subject to this proposed new policy.[15]

Also, the press release announcing the proposed determination stated that "breaded stuffed raw chicken products are pre-browned and may appear cooked, but the chicken is raw." This is true for some NRTE breaded stuffed chicken products, but not all. There are some NRTE breaded stuffed chicken products that are not pre-browned, making them clearly identifiable by a consumer as raw.[16] Products that can be easily identified as raw by consumers, such as those not pre-browned and sold in the meat case with other raw items, do not pose the same consumer handling risk as pre-browned products and should be excluded from a final determination.

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[15] U.S. Department of Agriculture, Food Safety and Inspection Service, *Preliminary Cost-Benefit Analysis*
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[16] See example photos in the Addendum of NRTE breaded stuffed chicken products sold at retail that are not pre-browned and very clearly appear raw.

IMPLEMENTATION

The agency intends to test the chicken component for *Salmonella* at 1 CFU/g before it is used to produce the final NRTE breaded stuffed product. There are pros and cons to this plan and important aspects to consider.

A thorough scientific analysis of the proposed approach should be completed prior to implementation.

The Meat Institute appreciates the agency's preliminary study evaluating the safety of NRTE breaded and stuffed chicken products for *Salmonella*. However, the survey[17] was admittedly limited in sample size, and therefore statistical power, to support the results. A larger scope study that has more statistical power needs to be completed. In addition to the study being small, it did not use a consistent sample size or evaluate levels of *Salmonella*, making the comparison and interpretation of the results challenging.

Also, the laboratory methodology was inconsistent with the methods the agency intends to use to evaluate *Salmonella* in implementing a final determination. The study utilized retail samples of finished products, yet the proposal is to sample the chicken component only at the processing establishment. This is problematic as the agency has no data or historic knowledge on how chicken components relate to the finished product. A study needs to be done that looks at *Salmonella* using the same quantification method adopted by the agency at the proposed level utilizing the same component sampling approach as proposed. Given the study's limitations, it is pre-mature to state that NRTE breaded stuffed chicken products have a higher risk per serving than other raw chicken products. The agency, industry, and consumers are unable to determine any potential public health benefit from the proposed determination because the science has not been done. Before moving forward with any proposed determination, a thorough scientific study needs to be completed that uses consistent laboratory methodology and evaluates the *Salmonella* level in the chicken component as proposed by the agency.

Testing should be conducted where control can be applied.

The proposal states that samples of the chicken component would be taken prior to stuffing and breading at the establishment producing the NRTE breaded stuffed chicken product. There are logistical benefits to this approach, as there are few establishments producing these products, making it simple to focus sampling at those few establishments. However, the process is complex and there is much to

[17] 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.

consider when evaluating the best point in the process at which to test. The chicken component is not necessarily one raw material purchased from a single supplier. Processing establishments may utilize multiple raw materials from multiple suppliers and blend those with other ingredients to make the chicken component of the NRTE breaded stuffed chicken product. The formula for the chicken component is often unique and can only be utilized for that specific raw product, therefore, it cannot simply be diverted to another product stream, not even the fully cooked versions of stuffed chicken products.

Accordingly, some processing establishments have adopted a testing program to sample the incoming raw materials prior to blending them into the chicken component. This approach provides options for diverting those raw materials, but because many of these raw materials have a short shelf-life, samples are sometimes pulled at the supplying establishment so that results are available in a timely fashion. Sampling of the raw materials is logical, because the receiving establishment may not be in control of the process used to produce the raw material. To compare, testing of beef manufacturing trimmings intended for use in raw ground beef is conducted at the producing establishment, not the receiving establishment. In the ground beef example, the producing establishment is then responsible for holding the product during testing and diverting product as needed. To be clear, the Meat Institute is not suggesting FSIS sampling for this proposal should be conducted at the supplying establishment, only pointing out the pros and cons to different sampling locations. If the agency were to consider testing at the supplying establishment as an option in certain circumstances, intended use is key and the raw material must be clearly designated for use in NRTE breaded stuffed poultry products.

Though this is a robust option already utilized by some, testing all raw materials to be used to produce the chicken component may be overly burdensome for some. For these establishments, there may be limited options outside of testing the chicken component, but the agency must still recognize the inability for many to divert the product at this point in the process.

The agency should consider the entire process when determining its sampling plan, if any, for these products. Ideally, FSIS would allow flexibility in FSIS verification sampling plans based on the process of each impacted establishment and any support the establishment may have to employ the least disruptive process for their specific circumstances and supply chain. The agency should also consider sampling conducted by the establishment when determining the appropriate frequency for FSIS verification sampling, especially if establishment sampling is conducted through the Accredited Laboratory Program (ALP).

Test and hold programs are complex and difficult to implement.

No matter where sampling is conducted, test and hold programs are challenging to implement. It is most efficient to maintain a streamlined, minimal inventory and move through it quickly, meaning there generally is limited space to hold product. Learnings from the beef industry when *E. coli* O157:H7 (O157) was declared an adulterant in ground beef, indicate similar challenges that await manufacturers of NRTE breaded stuffed chicken products should FSIS finalize the proposal. The beef industry underwent a monumental shift to adopt test and hold procedures: expanding storage capacity, employing screening methodologies, and implementing hold systems to ensure product was retained pending test results.

In light of a final determination, establishments will have to reassess HACCP programs and may elect to conduct internal testing in addition to agency testing, which will further stress the process. Establishments will need time to implement test and hold programs, which may require capital expenditures for increased storage space, and evaluate a diversion plan for products that will have lost days of shelf life while awaiting test results, if diversion is even an option for the products. The details of these plans will hinge on the sampling plan FSIS will employ should it move forward with a final determination.

The proposal mentions that establishments would be able to divert product to a raw ground chicken product, but establishments will likely be hesitant to do so for many reasons. The product will have tested positive for *Salmonella*, and the sample will be sequenced and included in public health databases. Companies may not be comfortable with such product being released into commerce without undergoing a lethality step, generally resulting in a lower value product. Again, if the chicken component is sampled after raw materials and ingredients have been blended, it may not be able to be diverted. The formula is often not suited for other product streams. The blended component also often has a very short shelf-life. The proposal seems to imply that all establishments will hold the component awaiting results, but it is likely that establishments will need to take the risk of producing and holding the finished product, otherwise the component will be useless by the time test results are available. Disposal of finished products will be more costly, but the alternative may be not producing the product at all. This is further evidence for why the agency should consider sampling flexibility.

It is unclear how the agency will interpret downstream testing.

It is clear the agency intends to test the chicken component before it is used to make the NRTE breaded stuffed chicken product for its purposes, but it is reasonable to assume these products will also be sampled outside the FSIS sampling project implementing a final determination. O157 presence in ground beef is a clear line in the sand. The agency considers ground beef to be adulterated if O157 is present in any amount, at any point in the supply chain. However, with a limit-based

standard that is tested on the raw material and not the finished product, it is unclear how the agency will handle downstream test results from the finished product. One must assume testing will be conducted on the finished product at some point by customers, consumer advocacy organizations, state or local health authorities, or even FSIS during an outbreak investigation. At what level will those products be considered adulterated? Certainly 1 CFU/g would not make sense if that were the standard for the chicken raw material component alone. Though there are many benefits to testing raw materials prior to product formulation, the agency needs to clarify the public health actions it will take in response to finished product testing and address this aspect if it moves forward with a final determination. Samples of the finished product will include additional ingredients and are not solely representative of the raw chicken component the agency intends to set a product standard for. Negative test results from the raw chicken component must be considered when evaluating a further downstream positive result from a multi-ingredient product.

More research and data are needed to understand *Salmonella* in poultry systems to inform lotting practices.

It took industry years, if not decades, of research and in-plant studies to understand how *E. coli* O157:H7 moves through the slaughter and processing environment to fully support microbial independence of lots. Although much work has been done regarding *Salmonella*, that same level of understanding for *Salmonella* in poultry slaughter and processing has not been achieved. Given the lack of available information, it will be difficult for some establishments to demonstrate microbial independence of lots, outside of the default agency acceptance of a "clean-up to clean-up" approach, using the full overnight sanitation cleaning as the marker between lots. The sheer size of lot created by this approach would not be feasible through the supply chain and could have food waste and security implications, making it an unacceptable option.

As has been utilized to support lotting in other process, FSIS should support practices that establish microbiological independence of lots or batches of product when a representative sample is taken. Establishments can have confidence in test results that demonstrate the independence of lots if employing a statistically representative sampling procedure. With a level of certainty, establishments should be able to support that a lot is negative and independent of others. Any guidance the agency develops to assist establishments in determining microbial independence must allow for lotting narrower in scope than "clean-up to clean-up," such as through statistically representative sampling, and must be made available well in advance of a final determination, not simply before the effective date. Industry will need time to review the guidance and plan accordingly, as there will be a trickle effect through the supply chain.

The current *Salmonella* adulterant level of 1 CFU/g is not supportable.

As previously discussed, not all *Salmonella* are created equal and as a result, the infectious dose of *Salmonella* varies greatly from < 100 to more than hundreds of thousands of cells. Risk assessments demonstrate a public health improvement at 10 CFU/g. A level of 10 CFU/g would also sort out potentially higher risk product and allow the focus to be on product that has greater potential for causing illness. Additionally, the agency inappropriately relied on research conducted on chocolate and cheese outbreaks to determine the infectious dose and therefore level of 1 CFU/g.[18] Foods with low water activity (0.3 to 0.5) and high fat content (>20%) like chocolate, have more heat resistance of *Salmonella*. Additionally, food with high fat content protects the *Salmonella* against gastric acidity, resulting in a reduction of dose–response curve with a low infectious dose.[19] While the Meat Institute strongly questions the legal and scientific basis for *Salmonella* to be deemed an adulterant in NRTE breaded stuffed chicken products, any program the agency adopts should not be based on a level of 1 CFU/g. Should the agency elect to move forward, it should consider using 10 CFU/g instead.

The accuracy and reliability of the agency's testing program is essential. The agency's decision to classify *Salmonella* as an adulterant in NRTE breaded stuffed chicken products makes the testing protocols even more important. Although the agency went through a rigorous process to determine the method it would use to quantify *Salmonella*, adjustments need to be made to the proposed determination to ensure the accuracy of *Salmonella* quantification results. The validated quantification curve goes down to 1 CFU/g. Any *Salmonella* quantification method adopted by the agency should have a curve validated at, above, and **below** the desired level of detection, in this case 1 CFU/g, to ensure confidence in the results. Since the curve is only validated down to 1 CFU/g, and not around 1 CFU/g, the agency should modify the proposed determination above 1 CFU/g. Not only is the agency's chosen testing method currently more reliable, accurate, and repeatable at 10 CFU/g than 1 CFU/g, this approach is risk-focused, allowing the industry to concentrate on product that is most likely to cause illness.

Industry will need ample time to implement a final determination.

If the agency finalizes a determination that *Salmonella* is an adulterant in certain NRTE breaded stuffed chicken products, the agency must allow a reasonable timeframe for implementation. The supply chain will need to adjust and put

[18] do Nascimento, M. D. S., Brum, D. M., Pena, P. O., Berto, M. I., & Efraim, P. (2012). Inactivation of *Salmonella* during cocoa roasting and chocolate conching. International Journal of Food Microbiology, 159(3), 225-229.

[19] D'aoust, J. Y. "Salmonella and the chocolate industry. A review." Journal of Food Protection 40.10 (1977): 718-727.

Krapf, T., & Gantenbein-Demarchi, C. (2010). Thermal inactivation of Salmonella spp. during conching. LWT-Food Science and Technology, 43(4), 720-723.

processes in place to hold product during testing and divert positive product. Companies may need to weigh the costs of these processes to determine whether continued production of these types of products is viable. These decisions will hinge on the details of a final determination and cannot be fully mapped out until that is known. For these reasons, an effective date one year from the publication of a final determination would be reasonable. An effective date earlier than six months from the publication of a final determination would be inappropriate and overly burdensome.

COST BENEFIT ANALYSIS

The cold storage cost estimate is incomplete.

The agency used data on the cost of cold storage, assuming the storage space was available. The estimate intends to account for capital expenditure costs to expand storage capacity, but the estimated cost, though adjusted for 2021 inflation, falls short. Establishments without the capital or physical space on-site to expand storage will have to be outsourced. However, that assumes they can find third party storage space. Cold storage availability in the U.S. continues to be sparse, physical space being only one part of the equation. Transportation lag, labor availability, increased market demand for fresh products, and other factors all continue to contribute to a strain on cold storage availability. Factors can also be regional. Transportation cost plays a significant role and this cost of moving product to and from outside cold storage is not addressed in the cost benefit analysis (CBA). The agency should also adjust its estimate to add a day to the holding time. The agency estimated negative results would be available within 48 hours of shipment of the samples and an additional 2-4 days for confirmation, but the realistic timeframe seen by industry between the day the sample is taken and when sample results are reported back to the establishment is typically at least a day longer.

Testing does not eliminate *Salmonella*.

The CBA includes contradictory thought processes:

> In response to the proposed new policy, some establishments may make additional changes to their production processes to control for *Salmonella*. These changes may include applying interventions, training, product reformulation and label changes, and subsequent HACCP plan validation. FSIS is not requiring establishments to make these additional changes to

> their processes. Establishments would only incur these additional costs if it were in their economic best interest.[20]

Here the agency implies that establishments will only implement additional controls if they choose. However, testing does not eliminate *Salmonella*, as understood in the underlying basis for HACCP: you cannot test your way to food safety after product is produced. Testing is simply a tool to monitor a process where controls are in place to effectively eliminate or reduce the hazard. The agency adopts this more accurate mentality later.

> The proposed policy would cause industry to use more effective methods to control for *Salmonella* in NRTE breaded stuffed chicken products.[21]

The agency should assume that all affected establishments will bear the cost of making changes to their processes, either at their establishment or as a requirement for suppliers, which should be reflected in the CBA. Testing for O157 did not reduce illnesses associated with ground beef. Credit for that result goes to the implementation of interventions and controls throughout the process to reduce the likelihood of O157 presence in ground beef. The same will be true for *Salmonella* in NRTE breaded stuffed chicken products. However, there are many differences between *Salmonella* and O157 and ground beef and poultry, making the elimination and reduction of *Salmonella* in these products much more complicated.

Additional feedback on the cost benefit analysis.

- The final CBA will depend heavily on the guidance provided by FSIS for lotting. The Meat Institute would like to understand how the agency came to the assumption that "the lot size at high-volume or low-volume establishments would be 10,000 or 1,000 pounds, respectively."[22] Industry will need to assess lotting practices once the guidance is available and get back to the agency with additional feedback on the impact on the CBA. The agency has also never done enumerated *Salmonella* testing on the chicken components used for NRTE breaded stuffed chicken products. Therefore, it is impossible to truly understand the impact of the proposal.

- The estimate should have accounted for a food safety, quality assurance, or laboratory employee to conduct sampling. It is unlikely that establishments will use production personnel to conduct sampling.

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[20] U.S. Department of Agriculture, Food Safety and Inspection Service, *Preliminary Cost-Benefit Analysis Salmonella in Certain Not-Ready-To-Eat Breaded Stuffed Chicken Products,* Page 4
[21] U.S. Department of Agriculture, Food Safety and Inspection Service, *Preliminary Cost-Benefit Analysis Salmonella in Certain Not-Ready-To-Eat Breaded Stuffed Chicken Products,* Page 8
[22] U.S. Department of Agriculture, Food Safety and Inspection Service, *Preliminary Cost-Benefit Analysis*
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- The agency is wise to solicit comment on possible costs industry may incur on product that is screened positive for *Salmonella* but then found to be below the 1 CFU/g threshold. Some establishments may elect to divert any product that tests positive, regardless of whether it is over the 1 CFU/g threshold, especially knowing that the sample will be sequenced and that sequence will be publicly available.

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The proposal is not supported by science or legal precedent, fails to adequately support public health improvement, and relies on a flawed cost benefit analysis. FSIS specifically requests comment on whether there are alternative bases for determining adulteration of these products or support for an alternative adulteration threshold. The agency should consider whether certain *Salmonella* of public health significance at 10 CFU/g in the chicken component destined for a pre-browned NRTE breaded stuffed chicken product that may appear ready-to-eat would render the product "ordinarily injurious." Given the complexities of the process and the gaps in understanding of virulence factors, the agency should also consider entirely alternative approaches for addressing *Salmonella* in raw materials or components used for these products that may provide a better public health outcome. Industry would welcome further discussion on alternative approaches. The Meat Institute appreciates the opportunity to provide these comments and requests the agency consider the points discussed in making any final determination. Please contact us if you have questions about these comments or anything else regarding this matter. Thank you for your consideration.

Respectfully submitted,

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Addendum: