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July 18, 2022

Sandra Eskin Deputy Under Secretary Office of Food Safety United States Department of Agriculture 1400 Independence Avenue, SW Washington, DC 20250

Re: Control of *Salmonella* in Not-Ready-To-Eat But Appears Ready-To-Eat Breaded and Stuffed Chicken Products

Dear Ms. Eskin,

I am writing on behalf of the National Chicken Council (NCC) to urge the Office of Food Safety and the Food Safety and Inspection Service (FSIS) to take actions to enhance control of *Salmonella* in not-ready-to-eat (NRTE) but appears ready-to-eat (RTE) breaded and stuffed chicken products.¹ NCC and our member companies share FSIS's commitment to controlling *Salmonella* during chicken processing and to reduce salmonellosis cases, and we recognize that addressing this specific product class is an important part of that commitment. We reviewed with great interest FSIS's recently announced *Cooperative Agreement on Salmonella Risk Assessments*,² which focused on the public health effects of various risk management options, and we were concerned that risk management options for NRTE but appears RTE breaded and stuffed chicken products were not specifically addressed in that announcement. We continue to urge FSIS to take several specific actions to help ensure these products are consumed safely. We summarize these actions in this letter, which we would like to discuss with your office further.

NCC is the national, non-profit trade association that represents poultry companies that produce and process more than 95 percent of the chicken marketed in the United States. A subset of our members produce various types of NRTE but appears RTE breaded and stuffed chicken products. These products are consumed safely nearly every time they are eaten, but we recognize their nature raises special considerations that merit additional attention. NCC and our member companies have worked for more than a decade to develop and refine best practices for these products, including labeling guidelines and intervention strategies, all of which are designed to ensure that consumers can prepare and consume these products safely. These efforts include obtaining source material from Category 1 establishments, testing source material, testing other product ingredients, revising labels to emphasize these products' raw nature and proper cooking, researching consumer understanding of labels, and even evaluating palatability and consumer acceptance of fully cooked versions of these products. The combination of previous and ongoing industry efforts has resulted in a substantial reduction of foodborne illness outbreaks related to this project occurred.

¹ For brevity, unless the context clearly indicates otherwise, references in this letter to "products" are to NRTE but appears RTE breaded and stuffed chicken products.

² FSIS Constituent Update, July 1, 2022, <u>https://www.fsis.usda.gov/news-events/news-press-</u>releases/constituent-update-july-1-2022.

Reflecting industry efforts and learnings from those experiences, there has been only one outbreak since 2015, demonstrating that focused efforts can and have had significant public health benefits. However, NCC members want every eating occasion to be safe, and we urge the Agency to collaborate with the companies producing these products to make them even safer.

Due to the nature of these products, NCC has long recognized that FSIS has an important role to play. For more than a decade, NCC has sought to collaborate with FSIS to reinforce strong food safety practices for these products. For example, in 2009, the poultry industry engaged in a series of meetings with FSIS regarding industry best practices and ways to enhance oversight of these products, culminating in a letter to Administrator Almanza in December of that year encouraging FSIS to take various actions, including mandatory reassessment of the Hazard Analysis and Critical Control Point (HACCP) plans by establishments producing these products. In 2016, NCC petitioned FSIS to promulgate regulations for the labeling of these products to reinforce their raw nature and ensure consumers understand how to properly handle them. NCC proposed specific regulatory language that included highly prominent warnings using a combination of graphics and words and specific handling and cooking instructions.³ Earlier this year, NCC submitted an update to our petition to incorporate the latest learnings and to incorporate newer kitchen appliances.⁴ FSIS never required the special HACCP plan reassessments, and FSIS has not responded substantively to our petition or to our update.

The industry has and will continue to ensure NRTE but appears RTE breaded and stuffed chicken products are produced, handled, and consumed safely. But it is imperative that FSIS use its available regulatory and public health tools to reinforce these efforts. Importantly, FSIS has already-existing regulatory tools that can help reinforce the use of science-based best practices and public health tools to help the industry and Agency better understand the specific risks for these products. We urge FSIS to use these tools.

NCC was pleased when FSIS last year asked the National Advisory Committee on Meat and Poultry Inspection (NACMPI) to advise on actions FSIS might take with respect to this product class.⁵ We viewed this as a welcomed step toward more direct involvement to reinforce efforts for this product class. The NACMPI subcommittee reported several recommendations to FSIS, including:

- Re-verifying labeling and cooking instruction validation;
- Making this re-verification a periodic inspectional task in the Public Health Information System (PHIS);
- Updating guidance to industry on labeling best practices;
- Assessing illness outbreak information to determine whether other labeling factors, such as product images, might lead to consumer mis-identification of the product;
- Reassessment of HACCP plans for establishments producing these products;
- Conducting targeted consumer outreach regarding these types of products;
- Adopting mandatory labeling requirements for these products, based on the NCC petition;

³ National Chicken Council, Petition to Establish Regulations for the Labeling and Validated Cooking Instructions for Not-Ready-to-Eat Stuffed Chicken Breast Products that Appear Ready-to-Eat (May 24, 2016), Petition 16-03, <u>https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/16-03-National-Chicken-Council.pdf</u>.

⁴ National Chicken Council, Petition to Establish Regulations for the Labeling and Validated Cooking Instructions for Not-Ready-to-Eat Stuffed Chicken Breast Products that Appear Ready-to-Eat (Feb. 25, 2022), Petition 16-03, <u>https://www.fsis.usda.gov/sites/default/files/media_file/2022-02/16-03-NCC-Supplement-02252022.pdf</u>.

⁵ FSIS, *National Advisory Committee on Meat and Poultry Inspection*, 86 Fed. Reg. 48115 (Aug. 27, 2021).

- Publishing a compliance guideline on validating cooking instructions for these products; and
- Gathering additional data on how consumers understand and handle these products.⁶

The NACMPI subcommittee did not reach a consensus on whether FSIS should consider additional sampling for these products, and the subcommittee recommended against requiring that these products be required to be RTE. FSIS has not publicly responded to these recommendations.

NCC again urges FSIS to uses its existing regulatory tools to reinforce a consistent approach toward these products, verify science-based best practices are being followed, and help improve our collective understanding of risk factors for these products. Importantly, FSIS can draw on existing regulatory tools and policies to take steps now that will have an impact on public health. Specifically, NCC urges to take the following actions:

- 1. Act on NCC's updated 2022 labeling petition (Petition 16-03). Our 2022 petition updated our 2016 petition and requests that FSIS (i) define this product category; (ii) require the term "raw" be included in the product name and appear prominently in several other specific places on the label; (iii) require a prominent statement that the product must be cooked to 165°F measured by a meat thermometer; (iv) require a prominent front-of-pack "raw chicken" icon that includes instructions to oven bake and not to microwave the product; (v) require labels to include detailed validated cooking instructions; and (vi) publish a compliance guide on validating cooking instructions for these products. This petition reflects our latest understanding of best practices for labeling these products, and a codified regulation would ensure uniformity across all such products sold in the United States, would enhance consumer familiarity and reinforce proper handling practices, and would provide FSIS with a clear mechanism for enforcing labeling requirements and for conducting in-plant verification activities. This action would also be consistent with NACMPI's recommendation. We urge FSIS to act on our petition.
- 2. **Conduct a baseline study on** *Salmonella* **levels in source material.** FSIS policy has long recognized the value of conducting comprehensive baseline studies to support regulatory decision-making and to drive performance improvements. FSIS has never conducted a baseline study to understand what levels of *Salmonella* may be in the source material used to create these products. We encourage FSIS to initiate such a baseline study promptly. Importantly, because FSIS has long recognized that decreases in *Salmonella* prevalence do not correlate to decreases in human salmonellosis rates,⁷ we recommend that FSIS conduct a baseline study focused on quantifying the level of *Salmonella* present in source material rather than determining only presence or absence. This is especially opportune in light of FSIS's recent announcement that it has selected a non-enrichment quantification system for *Salmonella* for use in FSIS laboratories,⁸ and FSIS's commitment to gathering data as part of a science-based approach to informing *Salmonella* policy.⁹ Conducting this baseline would provide FSIS and the industry with a clearer

⁶ National Advisory Committee on Meat and Poultry Inspection, Subcommittee II: Stuffed Not Readyto-Eat Poultry Products (Sept. 28, 2021), <u>https://www.fsis.usda.gov/sites/default/files/media_file/2021-</u> 10/Subcommittee_II_Stuffed_Not_Read-to-Eat_Poultry_Products_9-28-21_final_Report.pdf.

⁷ *E.g.*, FSIS, *Salmonella* By the Numbers (June 29, 2022) ("FSIS testing data show that Salmonella contamination on poultry has been going down, but this has not translated into a reduction in human illnesses."), <u>https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/salmonella.</u>

⁸ FSIS, *Constituent Update* (July 8, 2022).

⁹ FSIS, USDA Launches New Effort to Reduce Salmonella Illnesses Linked to Poultry (Oct. 19, 2021), https://www.usda.gov/media/press-releases/2021/10/19/usda-launches-new-effort-reduce-salmonella-illnesseslinked-poultry.

understanding of *Salmonella* levels on source material and would help inform policy and intervention strategies. Without good baseline data, it would be difficult for FSIS to determine what other actions might be appropriate and to measure success for these products.

- 3. **Conduct a risk assessment based on the** *Salmonella* **levels baseline study.** One particularly valuable use for quantified *Salmonella* baseline data is that it would provide FSIS the ability to conduct a public health risk assessment to better understand how the amount of *Salmonella* in source material may affect public health outcomes. This type of a risk assessment would help FSIS develop science-based policies, and it could help establishments develop best practices for their processes and to make better informed decisions about incoming source materials. Even if this cannot be included in the recently announced cooperative agreement on *Salmonella* risk assessments, we encourage FSIS to prioritize this action using existing Agency resources and expertise.
- 4. **Develop a compliance guideline for processing NRTE but appears RTE breaded and stuffed chicken products.** Although the industry has long worked to develop best practices, an FSIS compliance guideline would provide significant value by reinforcing the best practices and highlighting their importance in an establishment's food safety system. A compliance guideline might address topics such as source material control and selection, processing interventions, labeling, and packaging.
- 5. Require HACCP plan reassessments for NRTE but appears RTE breaded and stuffed chicken products. We are aware of Agency concerns based on past foodborne illness outbreaks associated with these products, and NCC members likewise want every eating occasion to be safe. Although there has only been one reported multistate outbreak associated with these products in the past seven years,¹⁰ and HACCP plans are reassessed annually, an additional focused reassessment would ensure establishments are considering the latest information when designing and implementing their HACCP plans. FSIS has taken similar approaches in the past. For example, in 2012, FSIS instructed establishments producing NRTE comminuted poultry products to reassess their HACCP plans based on updated information related to several foodborne illness outbreaks from prior years.¹¹ FSIS could take a similar approach for NRTE but appears RTE breaded and stuffed chicken products and call for establishments producing these products to again reassess their HACCP plans in light of experiences since 2015 and the FSIS After Action Report¹² recently published regarding the one post-2015 outbreak. Reassessments could also be requested based on the results of the baseline study discussed above. This step would ensure that establishments have appropriate processes in place to render Salmonella a hazard not reasonably likely to occur or else a critical control point to address the potential hazard. Reassessment might, for example, identify opportunities for additional interventions, enhanced labeling practices, or some other step; or a reassessment might provide an establishment (and FSIS) additional confidence that its systems are in fact well designed based on the latest information. FSIS could verify this reassessment once or could verify programs on a periodic basis through existing HAV/PHIS instructions. This approach is also consistent with the NACMPI recommendations.

¹⁰ FSIS, *Outbreak Investigation After Action Review, Report 2021-07,* https://www.fsis.usda.gov/sites/default/files/media_file/2022-04/FSIS-After-Action-Review-2021-07.pdf.

¹¹ FSIS, HACCP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and Related Agency Verification Procedures, 77 Fed. Reg. 72686 (Dec. 6, 2012).

- 6. Conduct targeted food safety assessments (FSAs) at plants producing NRTE but appears RTE breaded and stuffed products. FSAs are rigorous inspectional tools that let FSIS conduct an in-depth review of specific aspects of an establishment's food safety system. Through targeted FSAs, FSIS can verify that food safety systems are being implemented properly for these products and could help surface additional best practices.
- 7. Follow through on the remaining NACMPI recommendations. In addition to the specific points raised here, we encourage FSIS to also follow through on the other NACMPI recommendations, which include analyzing labeling features and targeted consumer outreach that could promote better consumer understanding of these products. It is critical that consumers be provided the information to safely handle these products, and NACMPI has identified several important strategies that would reinforce the petitioned-for labeling requirements.

Importantly, all these steps would have an immediate impact on the safety profile of these products, and in turn on public health. These steps would likely require only modest expenditure of Agency resources and rely on and are consistent with existing Agency policies and authorities. FSIS could begin many or all of these steps immediately, or to the extent additional financial resources are needed, as soon as the next fiscal year.

In sum, NCC remains confident that NRTE but appears RTE breaded and stuffed chicken products can be prepared and consumed safely. The NCC member companies that make these products remain committed to continuing their efforts to further enhance the safety of these products, demonstrated by a significant decline in outbreak occurrences over the past 7 years. But NCC believes that timely FSIS action to reinforce these approaches, drive consistency, and develop better data would have an extremely beneficial impact on public health. NCC stands ready to support FSIS in the steps mentioned above.

Given the importance of this issue to both our members and the Agency, we would like to request a meeting with your office to discuss these requests further. We would be pleased to follow up with your office to coordinate such a meeting.

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

Sincerely,

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Ashley B. Peterson, PhD Senior Vice President, Scientific and Regulatory Affairs National Chicken Council