NATIONAL CHICKEN COUNCIL

1152 FIFTEENTH STREET NW, SUITE 430
WASHINGTON, DC 20005
PHONE: 202-296-2622

May 22, 2020

Submitted electronically via regulations.gov

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue SW
Mailstop 3758, Room 6065
Washington, DC 20250-3700

Re: Docket No. FSIS-2020-0007: Petition for an Interpretive Rule Declaring "Outbreak" Serotypes of *Salmonella enterica* subspecies *enterica* to be Adulterants

Dear Sir or Madam:

The National Chicken Council (NCC) appreciates the opportunity to provide comments on the Petition to the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS or the Agency) for an Interpretive Rule Declaring "Outbreak" Serotypes of *Salmonella enterica* subspecies *enterica* to be Adulterants Within the Meanings of 21 U.S.C. § 601(m)(1) and 21 U.S.C. § 453(g)(1) (the Petition).[1] NCC is the national, non-profit trade association that represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States. The Petition is wrong on the law and on policy, and NCC strongly opposes it.

NCC member companies are deeply committed to food safety. Chicken processors implement a wide variety of interventions to control and reduce *Salmonella* throughout the production process. In the past decade, *Salmonella* incident rates in chicken have been driven down dramatically, showing that this approach works. At a fundamental level, NCC believes that all regulatory actions related to food safety, including performance standards, must be lawful and based in sound science. The actions requested in the Petition are neither. Fundamentally, the law and well-established FSIS policy make clear that *Salmonella* is not an adulterant *per se* in raw meat and poultry, regardless of serotype.[2] Nor does sound science support cherry picking individual strains and treating them as adulterants.

---

[1] Petition for an Interpretive Rule Declaring "Outbreak" Serotypes of *Salmonella enterica* subspecies *enterica* to be Adulterants Within the Meanings of 21 U.S.C. § 601(m)(1) and 21 U.S.C. § 453(g)(1), Filed January 19, 2020, Docket No. FSIS-2020-0007, https://www.fsis.usda.gov/wps/wcm/connect/d2a7c76e-dda9-475d-bf35-4cb69f5fca24/20-01-marler-011920.pdf?MOD=AJPERES.

[2] These comments focus on the impact of the Petition on chicken production. To the extent FSIS finds these comments useful in considering the effects of the Petition on meat and other poultry, we encourage FSIS to do so.

Instead of wasting resources on unsound and impractical efforts to address individual strains, NCC encourages FSIS to continue following a broad-based approach of using data-driven and scientifically-sound parameters to drive down levels of all *Salmonella* throughout the production process. As the science advances, we recognize FSIS's approach will advance as well. However, any advancement should be grounded in data and science. This response provides further discussion on why NCC believes FSIS should decline to issue an interpretive rule declaring serotypes of *Salmonella* to be adulterants.

1. The potential inherent presence of *Salmonella* in poultry fails to meet the basic statutory requirements of the meaning of "adulterated," as it is not considered an "added substance."

The Poultry Products Inspection Act (PPIA) identifies the situations in which a food is considered adulterated. Among other situations, a food is adulterated if the poultry product "bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health."[3] Further, the PPIA defines a "poultry product" as "any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof."[4]

The second clause of subsection (g)(1) makes clear that an otherwise potentially deleterious substance that is inherently present in or on the food, such as a foodborne pathogen naturally carried by the bird, does not adulterate the food when present at levels that do not ordinarily render it injurious to health. First, it is well recognized that *Salmonella* is inherently present in poultry,[5] and thus is not an "added substance" under the definition. Second, the thousands of *Salmonella* serotypes do not ordinarily render a food injurious to health because normal cooking practices destroy the organism[6] and many *Salmonella* serotypes have little to no association with human illnesses.[7] *Salmonella* has never been considered a *per se* adulterant in raw poultry, dating back to the passage of the PPIA, and FSIS has been clear in its position.

The Petition tries to sidestep this conclusion by drawing artificial and legally untenable distinctions between parts of the chicken, asking FSIS to take the position that *Salmonella* naturally present in one part of a chicken carcass is nevertheless an "added substance" in another.[8] This sleight of hand would eviscerate the PPIA's distinction between naturally occurring and added substances, a distinction repeated in the FMIA, the Egg Products Inspection Act, and the Federal Food, Drug, and Cosmetics Act.[9] In essence, the Petition

---

[3] 21 U.S.C. § 453(g)(1) (emphasis added).

[4] 21 U.S.C. § 453(f).

[5] *See Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432, 438-39 (5th Cir. 2001). Indeed, the Petition repeatedly states how bacterial loads are internal to the chickens, e.g., "the GI tracts of poultry often harbor the largest bacterial loads." Petition, pg. 26.

[6] *Id. at* 439.

[7] *See Centers for Disease Control and Prevention, Serotypes and the Importance of Serotyping Salmonella*: "More than 2,500 serotypes have been described for *Salmonella*; but, because they are rare, scientists know very little about most of them. Less than 100 serotypes account for most human infections" (Feb. 21, 2020) https://www.cdc.gov/salmonella/reportspubs/salmonella-atlas/serotyping-importance.html.

[8] The Petition states that "the bacteria, despite its presence in some areas of the animal, is not naturally present in the final products governed by the FMIA and PPIA and meant for sale and consumption to the public, thereby making it an added substance in those products." Petition, pg. 18 (emphasis added).

[9] Indeed, Courts have interpreted similar language in the Federal Food, Drug & Cosmetic Act (FFDCA) under the same standard, and have held that "added" substances must not be naturally occurring but artificially introduced by a person. *See, e.g.*, *U.S. v. Anderson Seafoods, Inc*., 622 F.2d 157, 160 (5th Cir. 1980) (explaining the "distinction between added and not-added substances comes from the

concedes *Salmonella* "presence in some areas of the animal,"[10] yet it would have FSIS focus its inquiry only on whether the *Salmonella* was initially present in the specific portion of the chicken being marketed as the final product. The Petition would define those "final products" as specific parts (i.e., legs, breasts, wings) containing the muscle tissue, and asserts that these parts would be "sterile" but for processing.[11] The Petition's rationale essentially requires arbitrarily subdividing the chicken until a portion can be found without *Salmonella*, and then considering any *Salmonella* from another portion of that same bird to be "added." This approach is not supported by law or science.

The Petition conveniently overlooks numerous other portions of a chicken sought out by consumers, such as skin, bone-in parts, whole birds, livers, giblets, and feet, which are not whole muscle pieces. In doing so, the Petition would impose an entirely arbitrary standard. Further, the PPIA does not support selectively subdividing a chicken carcass into discrete parts when evaluating added substances. The PPIA's definition of "adulteration" applies to "poultry products."[12] As noted above, a "poultry product" in turn is defined broadly as "any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof."[13] This definition must be read to include all components. *Salmonella* can be naturally present in live chickens when they arrive at processing facilities, and it can remain present in the chicken carcass and any parts subsequently derived from that carcass. What happens to the bacteria during processing is irrelevant for determining whether it is "added" under 21 U.S.C. § 453(g)(1). If *Salmonella* is naturally present in chickens, by definition it is not "added."

Salmonella's inherent potential presence in poultry products means it cannot be an "added substance," and it therefore is not considered an adulterant because it does not ordinarily render the product injurious to health.

2. The Petition flies in the face of longstanding FSIS policy and court decisions.

The Petition requests a procedurally improper change to longstanding and unequivocal Agency policy that would contradict court cases dating back decades.

FSIS has for years expressly and consistently articulated its policy that *Salmonella* is not an adulterant in raw meat or poultry. This policy has been articulated in numerous Agency actions on which FSIS sought and responded to public comment through dockets announced in the *Federal Register*.

A few recent examples underscore just how established FSIS's position is: In a 2016 *Federal Register* Notice announcing it would begin assessing whether establishments met the pathogen reduction performance standards in raw chicken parts and not-ready-to-eat (NRTE) chicken and turkey products, FSIS stated, "*Salmonella* is not an adulterant in NRTE poultry products. Therefore, a positive test result for *Salmonella* in imported NRTE poultry product sampled by FSIS import inspection personnel would not result in regulatory control actions at port-of-entry (i.e., refused entry of the product)."[14] In FSIS Notice 21-19 on actions to take in raw poultry establishments exceeding *Salmonella* performance standards, FSIS stated it

---

'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."); *see also U.S. v. Forty Barrels & Twenty Kegs of Coca-Cola*, 241 U.S. 265, 284 (1916) (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").

10 Petition, pg. 18.

11 Petition, pg. 18, fn 48.

12 21 U.S.C. § 453(g).

13 21 U.S.C. § 453(f).

14 81 Fed. Reg. 7285, 7297 (Feb. 11, 2016).

"does not consider raw poultry containing *Salmonella* to be adulterated as defined by 21 USC 453(g)(1) unless other circumstances make the product adulterated. Establishments are not required to segregate or hold product when the establishment exceeds a *Salmonella* performance standard."[15] In a 2012 FSIS final policy statement on not applying the mark of inspection pending certain test results, FSIS stated that "the policy would not cover raw meat or poultry products tested for *Salmonella* or other pathogens that FSIS has not designated as adulterants in those products."[16] In its response to comments on changes to the *Salmonella* verification sampling program, FSIS stated unequivocally that "*Salmonella* is not an adulterant in raw meat products."[17] And in FSIS Notice 46-19 on analysis for *Salmonella* of all imported beef, FSIS stated it "does not consider *Salmonella* an adulterant in raw meat products. Therefore, a positive test result for *Salmonella* in imported raw beef and veal products, sampled by FSIS inspection program personnel (IPP), does not require a regulatory control action to be taken."[18]

Further, Courts have consistently recognized FSIS's position and have held that *Salmonella* is not an adulterant. For example, in *American Public Health Association (APHA) v. Butz*, the Federal Circuit Court of Appeals for the DC Circuit explained that the "term 'adulterated' is defined by the statute, 21 U.S.C. § 601(m), and we think that the presence of salmonellae in meat does not constitute adulteration within this definition. The definition is directed at poisonous or deleterious additives and filthy, putrid or decomposed substances *but not at substances such as salmonellae which may be inherent in the meat.*"[19] Likewise, the court in *Supreme Beef Processors, Inc. v. USDA*, recognized that "*Salmonella*, present in a substantial proportion of meat and poultry products, is not an adulterant *per se*, meaning its presence does not require the USDA to refuse to stamp such meat 'inspected and passed.' This is because normal cooking practices for meat and poultry destroy the *Salmonella* organism, and therefore the presence of *Salmonella* in meat products does not render them 'injurious to health' for purposes of § 601(m)(1). *Salmonella*-infected beef is thus routinely labeled 'inspected and passed' by USDA inspectors and is legal to sell to the consumer."[20]

The Petition thus flies in the face of established Agency policy backed by court precedent. Nothing has changed about the nature of *Salmonella* – it has long been inherent in chickens' microflora, it has long been recognized as a foodborne pathogen, and proper cooking practices continue to destroy it. There is no basis for the Agency to change its longstanding position, and reversing its position through an interpretive rule in response to this petition would be arbitrary.

3. Ongoing FSIS actions continue to drive down *Salmonella* rates in a manner not recognized in the Petition.

The Petition comes in the midst of a concerted effort by FSIS to drive down *Salmonella* rates, an effort that has met with enormous success. Over the past 10 years, for example, *Salmonella* prevalence on whole broilers has dropped by almost 68% across all broiler processing establishments. In just the past few years, FSIS has significantly tightened existing *Salmonella* standards; introduced new performance standards for chicken parts; rolled out a new, scientifically driven modernized poultry inspection system that allows for greater testing and analysis; released detailed guidance on controlling *Salmonella* through processing controls; and approved numerous new interventions; among many other endeavors. FSIS has taken or is in the process of rolling out similar programs for other species. These actions are consistent with the science-based actions NCC believes are beneficial to the public.

---

15 FSIS Notice 21-19 - Actions To Take In Raw Poultry Establishments Exceeding Salmonella Performance Standards (July 12, 2019).

16 77 Fed. Reg. 73401, 76404 (Dec. 10, 2012).

17 79 Fed. Reg. 32436 (June 5, 2014).

18 FSIS Notice 46-19 - Analysis for Salmonella of All Imported Beef (Including Veal) Products Sampled for Shiga Toxin-Producing Escherichia Coli (Nov. 7, 2019).

19 *APHA v. Butz*, 511 F.2d 331, 334 (DC Cir. 1974) (*emphasis added*).

20 *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432, 438-39 (5th Cir. 2001).

These steps are having a significant impact on *Salmonella* prevalence but are not reflected in the Petition. In fact, these actions have significantly changed the current scientific data regarding *Salmonella*, and these and similar actions promise further improvements in *Salmonella* performance industrywide. These actions and their impact on *Salmonella* data are ill-reflected in the Petition and, in fact, undermine the dire picture the Petition paints. They certainly reinforce that the Petition is not based on current facts and data, much less the likely continued reduction in prevalence as FSIS continues to implement its *Salmonella* reduction strategy.

Moreover, FSIS's actions are focused on continuing to drive down *Salmonella* rates for all serotypes, not just ones that in the past have been associated with identified outbreaks. The Agency's current approach is much more comprehensive and effective in reducing the overall *Salmonella* risk than the Petition's backwards-looking approach of focusing only on strains that have been associated with identified outbreaks.

4. The Petition's focus for serotype-specific testing is impractical and will not achieve the Petition's stated objectives.

The Petition's request to identify only certain *Salmonella* serotypes as adulterants in poultry would result in tremendous confusion and uncertainty with no meaningful food safety benefit. There are no serotype-specific interventions for *Salmonella*, and there are no practical or reliable ways to rapidly identify serotypes in-plant, much less to have a high degree of confidence that all serotypes present in a flock have been identified. Moreover, it is not practical or reasonable for the Agency to take a post-hoc approach to adulteration by delineating and identifying 31 serotypes of *Salmonella* to be considered adulterants while recognizing the other roughly 2,500 serotypes as not adulterating product.

Poultry processing plants operate under the assumption that any incoming flock could have a high load of *Salmonella* and implement a full complement of interventions to reduce and control *Salmonella* throughout the production process. Plants do not turn specific controls on or off flock by flock, as the goal is to reduce any *Salmonella* that may be present. Even if there were validated serotype-specific interventions available, there is no testing method available that would provide rapid serotype results and a high degree of confidence that all serotypes in the flock had been identified. Instead, plants would be forced to produce product, perhaps conduct representative sampling that by definition would be incomplete, and simply hope that one of the Petition's outbreak strains was not later found in the product. As a result, companies would be exposed to widespread risk based on entirely arbitrary situations with no meaningful way to affect the outcome, and with no benefit to public health.

Such a regulatory system would be arbitrary and capricious. Controlling specific serotypes would be practically impossible, the framework established in the Petition would not keep the Petition's serotypes out of product, and it would do nothing to affect overall *Salmonella* levels. If anything, the confusion caused by the Petition could result in consumers developing misplaced beliefs about the safety of raw chicken.

5. *Salmonella* can be controlled through proper handling and cooking.

The Petition suggests that *Salmonella* presents a serious hazard to public health because it cannot be controlled through proper handling and cooking. That is simply not true. It is well established that proper handling and cooking of chicken achieves lethality.[21] Moreover, customary consumer practice is to cook chicken thoroughly. Chicken is not consumed "rare." Appropriate labeling and safe handling instructions reinforce appropriate cooking practices.

---

[21] *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432, 439 (5th Cir. 2001) (normal cooking practices for meat and poultry destroy the *Salmonella* organism" (citing *APHA v. Butz*, 511 F.2d 331, 332 and 334 (1974), "Proper cooking destroys salmonellae," "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")).

6. The petition cites largely anecdotal evidence, which is not scientifically reliable or appropriate to support Agency action.

The Petition is rife with anecdotal evidence detailing several individuals' experiences with *Salmonellosis*. Anecdotal statements, however, do not provide scientifically reliable evidence necessary to support rulemaking or reverse long-standing Agency positions through interpretative rules. Moreover, the handful of specific case studies does not discuss other underlying factors, patient history, or other potential causes for the ultimate outcomes. It would be wholly inappropriate to support regulatory action based on anecdotal evidence and individual stories. The data in fact show that *Salmonella* prevalence has been a steady decline due to concerted efforts by FSIS and the industry to enhance *Salmonella* controls.

Conclusion

NCC appreciates the opportunity to provide comment on the Petition. Please feel free to contact us with any questions regarding the above comments. Thank you for your consideration.

Respectfully submitted,

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