



United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW,
Washington, D.C.
20250

William D. Marler, Esq.
Marler Clark LLP PS
1012 First Avenue, Fifth Floor
Seattle, WA 98104-1008
bmarler@marlerclark.com

May 31, 2022

Dear Mr. Marler:

The Food Safety and Inspection Service (FSIS) has completed its review of the January 19, 2020, petition you submitted on behalf of Rick Schiller, Steven Romes, the Porter Family, Food & Water Watch, the Consumer Federation of America, and Consumer Reports.¹ The petition asks FSIS to declare thirty-one *Salmonella* serotypes to be adulterants of all meat and poultry products subject to the Federal Meat Inspection Act (FMIA)(21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA)(21 U.S.C. 453 *et seq.*) (hereinafter, “the Acts”), as it has done for certain strains of Shiga toxin-producing *E. coli* (STEC) in certain beef products.² According to the petition, this action is necessary because the Agency’s current efforts are ineffective at reducing human illness associated with *Salmonella*.

FSIS does not believe that there is sufficient data available at this time to support the sweeping actions requested in your petition. While the agency is denying your petition without prejudice, we are in the process, as announced³ in October 2021, of reevaluating our approach to controlling *Salmonella* in poultry. As part of this reevaluation, we are considering many of the points and arguments made in your petition.

In undertaking our *Salmonella* in poultry initiative, FSIS agrees that we need to rethink our existing strategy⁴ to further reduce instances of human salmonellosis associated with the products we regulate. Despite reductions in the prevalence of *Salmonella* contamination in meat and poultry products, FSIS-regulated products are linked to a significant portion of the approximately 1.35 million cases of salmonellosis that occur each year. We are focusing on poultry products

1 FSIS also reviewed 377 public comments submitted in response to the petition. Approximately 338 opposed the petition, 31 supported the petition, and 8 expressed no opinion or were outside the scope of the petition. Comments are available at:

<https://www.regulations.gov/document/FSIS-2020-0007-0001/comment>.

2 Please note that FSIS already considers ready-to-eat meat and poultry products containing *Salmonella* to be adulterated under the Acts.

3 United States Department of Agriculture. (October 19, 2021). USDA Launches New Effort to Reduce Salmonella Illness Linked to Poultry. <https://www.usda.gov/media/press-releases/2021/10/19/usda-launches-new-effort-reduce-salmonella-illnesses-linked-poultry>. See also Food Safety and Inspection Service. (December 2, 2021). Pilot Projects: Salmonella Control Strategies.

<https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/pilot>.

4 FSIS currently focuses on reducing the prevalence of *Salmonella* in raw meat and poultry products by using pathogen reduction performance standards to assess the food safety performance of slaughter and processing establishments. FSIS testing to assess establishment performance

because they are associated with nearly one quarter (23%) of all *Salmonella* infections.⁵

FSIS believes that an updated *Salmonella* strategy is necessary to reduce such illnesses. Towards that end, FSIS is actively gathering data and information necessary to support a revised strategy that we hope will be more effective. We hosted a [research and science roundtable](#)⁶ in February 2022 to solicit input from the scientific community on the scientific support for various strategies to control *Salmonella* in poultry. FSIS is also leveraging USDA's strong [research](#)⁷ capabilities and strengthening its partnership with the [Research, Education, and Economics](#)⁸ mission area to address data gaps and develop new laboratory methods to guide future *Salmonella* policy.

FSIS has asked the National Advisory Committee on Microbiological Criteria for Food (NACMCF), an independent federal advisory committee, to look into how the Agency can build on the latest science to improve its approach to *Salmonella* control.⁹ FSIS is also conducting a risk assessment for *Salmonella* subtypes in poultry products associated with foodborne illness.¹⁰ Some of FSIS' other activities in this area include exploring more efficient methods to enumerate pathogens in samples, detect virulence factors in pathogens for potential risk ranking, and investigate new pathogen characterization methods.¹¹

Turning to the arguments raised in your petition, you contend that *Salmonella* should be considered an adulterant because it is an "added substance" and "may render injurious" a food contaminated with it. Alternatively, assuming *Salmonella* is "naturally occurring," you contend that it is "ordinarily injurious" in all meat and poultry products regulated by FSIS. At this time, FSIS cannot justify issuing the broad interpretive rule that you request, which would declare that all *Salmonella* are "added substances" in all products. Moreover, FSIS is not persuaded by your argument that the court's interpretation of the Federal Food, Drug, and Cosmetic Act (FFDCA) in *Anderson Seafoods*¹² applies to *Salmonella* in products regulated by FSIS. The *Anderson Seafoods* case differs in several material respects from the subject matter of the petition.

under these standards, the posting of establishment-specific FSIS test results, and the posting of the categorization of individual establishments subject to the standards incentivize establishments to take actions to reduce *Salmonella* in their products. See Ollinger, M., Wilkus, J. Hrdlicka, M., & Bovay, J. (May 2017). Public Disclosure of Tests for Salmonella: The Effects on Food Safety Performance in Chicken Slaughter Establishments (ERR-231). U.S. Department of Agriculture, Economic Research Service. In addition, when establishments do not meet the performance standards, FSIS conducts follow-up testing and other verification activities at the establishment (e.g., public health risk evaluations or food safety assessments) to verify whether the establishment's food safety system is effectively addressing microbial hazards.

⁵ The Interagency Food Safety Analytics Collaboration. (October 2021). Foodborne illness source attribution estimates for 2019 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States. <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf>.

⁶ Food Safety and Inspection Service. (February 15, 2022). Science in Poultry: Research and Science Roundtable.

<https://www.fsis.usda.gov/news-events/events-meetings/salmonella-poultry-research-and-science-roundtable>.

⁷ Food Safety and Inspection Service. (June 24, 2021). FSIS Food Safety Research Priorities and Studies. <https://www.fsis.usda.gov/science-data/research-priorities#:~:text=FSIS%20Data%20Gaps%20%20%20Study%20Title.may%20survi%20...%20%209%20more%20rows%20?msclkid=f7030eaea6c411ec9e91f63d1dde98ff>.

⁸ United States Department of Agriculture. Research, Education, and Economics.

<https://www.ree.usda.gov/#:~:text=The%20Research%2C%20Education%2C%20and%20Economics%20%28REE%29%20mission%20area%20youth%20through%20integrated%20research%2C%20analysis%2C%20and%20education.?msclkid=261bd671a6c411eca6c1c87daae90cd>.

⁹ Food Safety and Inspection Service. (May 2, 2022). 2021-2023 National Advisory Committee on Microbiological Criteria For Foods: FSIS Charge: Enhancing Salmonella Control in Poultry Products. <https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021>.

¹⁰ Food Safety and Inspection Service. (February 4, 2022). Constituent Update: "Reminder: FSIS Seeks Proposals for *Salmonella* Risk Assessments." <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-february-25-2022>.

¹¹ General Services Administration. (February 22, 2022). USDA Solicitation: Salmonella Enumeration Instruments, Reagents, and Kits. <https://sam.gov/opp/318089ba37714e4f9f20337014c145f1/view>.

¹² United States v. Anderson Seafoods, Inc., 622 F.2d 157 (5th Cir. 1980).

While FSIS has traditionally viewed *Salmonella* as “naturally occurring” in food animals, we are reassessing this interpretation as part of our *Salmonella* in poultry initiative and considering whether *Salmonella* should be considered an adulterant in any poultry products. In this consideration, we are relying on the factors we identified when we declared seven STEC strains (O157:H7, O26, O45, O103, O111, O121, and O145) to be adulterants in many non-intact raw beef products and intact source materials for raw ground beef.^{13,14} This determination was based on, among other considerations, the fact that, for these strains, the infectious dose is low.¹⁵ Moreover, ground beef contaminated with these STEC strains may cause serious, potentially life-threatening, illness.¹⁶ In addition, what many consumers consider to be ordinary cooking of ground beef does not destroy these pathogens.^{17,18}

Regarding your arguments related to dose response, serotypes and virulence factors, we are reviewing the most up-to-date science to determine whether any *Salmonella* serotypes have a uniformly, relatively low infectious dose. As your petition acknowledges, the likelihood of an individual contracting salmonellosis is dependent on a variety of factors. Studies indicate that, in addition to serotype, the probability of illness associated with the dose of a pathogen may be influenced by variables including host factors and the food matrix.¹⁹

Regarding *Salmonella* virulence factors, they are not as well understood as for STEC strains. Therefore, FSIS does not concur with the petitioners’ position that all of the identified serotypes in your petition necessarily represent strains with higher virulence in all meat and poultry products.

Finally, we want to address two other points in your petition. First, although the petition refers to the identified serotypes as “Outbreak Serotypes,” not all are associated with human illness outbreaks caused by FSIS-regulated products. FSIS researched outbreaks associated with FSIS-regulated products using CDC’s Foodborne Disease Outbreak Surveillance System (FDOSS; 1998–2018), CDC’s [outbreak web postings](#)²⁰ (2006–2020), PubMed, and other online resources. FSIS did not identify any confirmed or suspected outbreaks associated with FSIS-regulated products from *Salmonella* serotypes Litchfield, Mississippi, and Poona. Therefore, FSIS would not characterize these strains as “Outbreak Serotypes” in FSIS-regulated products.

Second, the petition discusses FSIS’ decision to allow certain poultry establishments to increase line speed; it also addresses instances of inhumane handling and recalls associated with foreign

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

14 Beef Products Contaminated with *Escherichia Coli* O157:H7, 64 FR 2803 (Jan. 19, 1999). *see also* Shiga-Toxin-Producing *Escherichia coli* in Certain Raw Beef Products,” 76 FR 58157 (Sept. 20, 2011).

15 Shiga-Toxin-Producing *Escherichia coli* in Certain Raw Beef Products, 76 FR 58157, 58158 (Sept. 20, 2011).

16 *Id.*

17 FSIS Fact Sheet: *Ground Beef and Food Safety*. <https://www.fsis.usda.gov/food-safety/safe-food-handling-and-preparation/meat/ground-beef-and-food-safety#:~:text=To%20keep%20bacterial%20levels%20low,Other%20bacteria%20cause%20spoilage>.

18 Food & Drug Administration. (2011). *2010 Food Safety Survey: Key Findings and Topline Frequency Report*.

<https://www.fda.gov/food/cfsan-consumer-behavior-research/2010-food-safety-survey-key-findings-and-topline-frequency-report>.

19 *E.g.*, Blaser, M. J., & Newman, L. S. (1982). A review of human salmonellosis: I. Infective dose. *Rev Infect Dis.* 4:1096-106. *see also*, Doyle, M. P., & Beuchat, L. R. (2007). *Food Microbiology: Fundamentals and Frontiers*. ASM Press, Washington, D.C. *see also* Lehmacher, A., Bockemuhl, J., & Aleksic, S. (1995). Nationwide outbreak of human salmonellosis in Germany due to contaminated paprika and paprika-powdered potato chips. *Epidemiol Infect.* 115:501-11.

20 Centers for Disease Control and Prevention. (April 5, 2022). List of Selected Multistate Foodborne Outbreak Investigations. <https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html>.

Mr. Marler
Page 4

material contamination. This information is not relevant to whether the identified serotypes meet the criteria for adulterant status.

In conclusion, because our denial is without prejudice, you can submit a revised petition that contains additional information to support the requested or other action. Of course, we welcome your comments on any proposed rulemakings or other policy changes we will be issuing as part of our *Salmonella* in poultry initiative.

Sincerely,

A handwritten signature in black ink that reads "Rachel A. Edelstein". The signature is written in a cursive, flowing style.

Rachel Edelstein
Assistant Administrator
Office of Policy and Program Development