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August 19, 2021

Ms. Sandra Eskin
Deputy Under Secretary for Food Safety
Food Safety and Inspection Service
331-E Jamie Whitten Federal Bldg.
1400 Independence Avenue, SW
Washington, D.C. 20250

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW
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Washington, D.C. 20250

Re: Requesting a Status Update on the Resolution of Docket No. FSIS-2020-0007; Document ID FSIS-2020-0007-0001 – 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).

Dear Ms. Eskin:

Marler Clark LLP, PS submits this letter requesting a status update relating to the above-referenced docket, Docket No. FSIS-2020-0007; Document ID FSIS-2020-0007-0001 – 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) (hereinafter "*Salmonella* Petition").

Over a year and a half ago, on January 19, 2020, Marler Clark submitted its *Salmonella* Petition on behalf of Rick Schiller, Steven Romes, the Porter family, Food & Water Watch, Consumer Federation of America, and Consumer Reports, requesting that FSIS declare the following "Outbreak Serotypes" to be *per se* adulterants in meat and poultry products:

> *Salmonella* Agona, Anatum, Berta, Blockely, Braenderup, Derby, Dublin, Enteritidis, Hadar, Heidelberg, I 4,[5],12:i:-, Infantis, Javiana, Litchfield, Mbandaka, Mississippi, Montevideo, Muenchen, Newport, Oranienburg, Panama,

Poona, Reading, Saintpaul, Sandiego, Schwarzengrund, Senftenberg, Stanley, Thompson, Typhi, and Typhimurium.[1]

FSIS posted the *Salmonella* Petition to its website shortly thereafter, and during the subsequent four-month comment period, the Petition garnered a total of 377 comments. On March 19, 2020, we wrote then-FSIS Administrator Paul Kiecker to reaffirm our request for an expedited review of the Petition. On June 5, 2020, we wrote former Under Secretary for Food Safety Mindy Brashears to supplement the Petition with additional and updated information, as well as to address some issues and criticism raised by comments submitted during the comment period, namely those generated using a template circulated by the Weston A. Price Foundation. A few months ago, on March 12, 2021, we again wrote Mr. Kiecker to request a status update relating to FSIS's response to and resolution of our Petition. Still, we have yet to receive a clear answer as to when or how our Petition will be addressed.

FSIS is required by the Administrative Procedure Act[2] and the courts[3] to, at the very least, respond to the merits of a petition for rulemaking. 5 U.S.C. §555(b), in particular, requires that "[w]ith due regard for the convenience and necessity of the parties…and within a reasonable time, each agency shall proceed to conclude a matter presented to it." It is also within the power of the courts to compel "unreasonably delayed" agency actions,[4] and, in determining whether unreasonable delay has occurred, courts are directed to consider, among other factors, whether human health and welfare are at stake as well as the nature and extent of the interests prejudiced by delay.[5]

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[1] Thirty of these 31 serotypes are from the Centers for Disease Control and Prevention's (CDC) *Salmonella* Atlas, which contains 42 years of laboratory-confirmed research. *See Salmonella* Atlas at https://www.cdc.gov/salmonella/reportspubs/salmonella-atlas/serotype-reports.html. The only exception, *Salmonella* Dublin, was added to Petitioners' list because it is a serotype of increasing public health concern that was recently involved in a foodborne illness outbreak linked to ground beef.

[2] In addition to 5 USC § 553(e)'s requirement that each agency "shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule," the Administrative Procedure Act also requires agencies to provide "prompt notice…of the denial in whole or in part of a written application, *petition*, or other request of an interested person made in connection with any agency proceeding,"5 USC §555(e).

[3] *Horne v. USDA*, 494 Fed. Appx. 774 (9th Cir. 2012) ("USDA responded to the Hornes' rulemaking petition—as it must under the Administrative Procedure Act"); *WWHT, Inc. v. F.C.C.*, 656 F.2d 807, 813 (D.C. Cir. 1981) ("an agency must receive and respond to petitions for rulemaking"); *Nat'l Parks Conserv. Ass'n v. Interior*, 794 F.Supp.2d 39, 44-45 (D.D.C. 2011) ("[A]n agency 'is required to at least definitively respond to . . . [a] petition—that is, to either deny or grant the petition.'"); *Families for Freedom v. Napolitano*, 628 F.Supp.2d 535,540 (S.D.N.Y 2009) (concluding the same and noting "DHS conceded this point at oral argument"); *but see Brown v. FBI*, 793 F.Supp.2d 368, 375 (D.C. Cir. 2011) (observing, in the context of reviewing petitioner's standing, that "the APA is less than crystal-clear on plaintiff's statutory right to a response," though simultaneously citing WWHT, "an agency must receive and respond"). *See also* Richard J. Pierce, Administrative Law Treatise 517 (5th ed. 2013) ("At a minimum, the right to petition for rulemaking entitles a petitioning party to a response to the merits of the petition.").

[4] *In re. Natural Resources Defense Council*, 645 F.3d 400, 406 (D.C. Cir. 2011) (applying 5 USC § 555(b) to an FDA citizen's petition); *Fund for Animals v. Norton*, 294 F.Supp.2d 92, 112 (D.C. Cir. 2003) (applying 5 USC §§555(b) and 706(1) to review agency delay in responding to a petition); *Nat'l Parks Conserv. Ass'n v. Interior*, 794 F.Supp.2d 39, 44-45 (D.D.C. 2011) citing 5 USC §§553(e), 555(b), and concluding "an agency is required to at least definitively respond to…[a] petition").

[5] *Telecommunications Research & Action Center (TRAC) v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984); *Shinnecock Indian Nation v. Kempthorne*, 2008 U.S. Dist. LEXIS 75826 (E.D.N.Y. 2008) (following *TRAC*);

While we support FSIS's efforts to gather information about strategies to reduce the significant public health burden associated with *Salmonella*, including through recent public meetings such as FSIS's September 22, 2020, "*Salmonella*-State of Science" seminar, the country's stalled progress on reducing salmonellosis demands bold action, far beyond the measures included in the agency's "Roadmap to Reducing *Salmonella*." *Salmonella* is the leading bacterial cause of foodborne illness in the United States, resulting in an estimated 1.35 million illnesses, 26,500 hospitalizations, and 420 deaths, and 130 outbreaks each year[6] [7] and unfortunately, the burden on consumers shows no signs of letting up. In 2021, USDA's Economic Research Service (ERS) estimated the cost of *Salmonella* illnesses alone to be a staggering 4.14 billion dollars.[8]

According to Foodborne Diseases Active Surveillance Network (FoodNet), the incidence of salmonellosis was 14.46 cases per 100,000 people in 1996 across FoodNet sites. As of 2019, it was 17.12.[9] New culture-independent diagnostic testing (CIDTs) may account for some of the increase, but CDC researchers have made clear that "identification of infections that might not have been detected before adoption of CIDTs cannot explain this overall lack of progress."[10] CDC researchers further estimate that for every diagnosed and reported case of *Salmonella* infection, another 29 go unreported.[11] Foods regulated by FSIS substantially contribute to this public health burden; according to the Interagency Food Safety Analytics Collaboration, over a third of salmonellosis cases can be attributed to chicken (14.0%), pork (10.3%), beef (6.4%), and turkey (6.2%).

Designing *Salmonella* performance standard to more closely align with the goal of reducing foodborne illness is fundamental to improving food safety. Currently, *Salmonella* performance standards measure how well an establishment is reducing the frequency with which its products test positive for contamination by any *Salmonella* species. FSIS verification testing may identify virulent strains of *Salmonella* that are linked to currently ongoing outbreaks, but the product nevertheless can go into commerce so long as the establishment has a sufficient number of "negative" samples and is otherwise meeting the rules designed to show that its plant conditions are not "insanitary." This indirect approach is not working.

To protect the public, FSIS needs to acknowledge that certain *Salmonella* serotypes pose an unacceptable risk to consumers and make rules to keep adulterated products contaminated by these serotypes off the shelves. Accordingly, we again invite you to respond favorably to our Petition.

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6 "*Salmonella* Homepage." CDC, 2021.

7 Laufer AS, *et al.* (2015). Outbreaks of *Salmonella* Infections Attributed to Beef – United States, 1973-2011. *Epidemiol Infect.* 143(9):2003-13.

8 "Cost Estimates of Foodborne Illnesses." ERS, 2021. https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses/

9 *See* FoodNet Fast at https://wwwn.cdc.gov/foodnetfast/.

10 Tack DM, *et al.* (2020). Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food – Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016-2019. *MMWR.* 69(17):509-514.

11 Scallan E, *et al*. (2011). Foodborne Illness Acquired in the United States–Major Pathogens. *Emerg Infect Dis*. 17(1):7-15.

Very truly yours,

William D. Marler

cc: Mary Porretta, Petitions Manager
Matthew Michael, Director, Regulations Development Staff
Terri Nintemann, Deputy Administrator
Food & Water Watch
Consumer Federation of America
Consumer Reports
Rick Schiller
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The Porter family