

# MARLER CLARK

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November 11, 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  
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**Re: Requesting a Definitive Response to 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 definitive and prompt response 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”).

As stated in our August 19, 2021 letter, nearly two years have elapsed since the submission of our *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.<sup>1</sup>

Since then we have yet to receive a clear response as to when or how FSIS intends to address our Petition.

FSIS is required by the Administrative Procedure Act<sup>2</sup> and the courts<sup>3</sup> to, at the very least, respond to the merits of a petition for rulemaking. 5 U.S.C. §555(b) 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,<sup>4</sup> 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.<sup>5</sup>

As you know, human health and welfare are certainly at stake, and time is of the essence in ensuring that illnesses and deaths caused by *Salmonella* are prevented. By the close of 2021, *Salmonella* will have resulted in an estimated 1.35 million illnesses, 26,500 hospitalizations, and 420 deaths, and 130 outbreaks,<sup>6</sup> and cost a staggering 4.14 billion dollars.<sup>7</sup>

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<sup>1</sup> 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.

<sup>2</sup> 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).

<sup>3</sup> *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.”).

<sup>4</sup> *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”).

<sup>5</sup> *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);

<sup>6</sup> “*Salmonella* Homepage.” CDC, 2021.

<sup>7</sup> “Cost Estimates of Foodborne Illnesses.” ERS, 2021. <https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses/>

While we support FSIS's recent efforts to gather information about strategies to reduce the significant public health burden associated with *Salmonella*—most recently, with USDA's announcement of its plans to explore new approaches for addressing *Salmonella* in poultry—it is evident that FSIS needs better tools to handle this ongoing public health crisis. As explained in PBS Frontline's "The Trouble with Chicken"<sup>8</sup> in May 2015, and most recently, in ProPublica's October 29, 2021 article "America's Food Safety System Failed to Stop a *Salmonella* Epidemic. It's Still Making People Sick,"<sup>9</sup> despite the undisputed scientific evidence linking sickened individuals to contaminated food products, FSIS appears not to have the ability to protect the public from *Salmonella* based on its current enforcement regime and regulatory authority.

Our petition seeks to provide FSIS with such authority; it gives the agency the tools it needs to combat outbreaks such as the 2014 Foster Farms *Salmonella* Heidelberg outbreak and the 2018 *Salmonella* Infantis outbreak. Those two serotypes are listed among the 31 "outbreak" serotypes that we requested be deemed adulterants.

More specifically, our petition provides FSIS with a clear avenue for regaining control over the *Salmonella* problem: granting our petition and declaring "outbreak" serotypes, such as *S. Heidelberg* and *S. Infantis*, to be adulterants in meat and poultry, as was successfully done in 1994 when FSIS declared *E. coli* O157 an adulterant, and later in 2012, when FSIS declared the "Big Six" strains of non-O157 STEC *E. coli* adulterants in raw beef trim<sup>10</sup>.

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 grant our Petition. If we do not receive a definitive response within 180 days, we will assume that you have denied our petition and proceed with judicial remedies.

Very truly yours,



William D. Marler

cc: Mary Porretta, Petitions Manager  
Matthew Michael, Director, Regulations Development Staff  
Terri Nintemann, Deputy Administrator  
Food & Water Watch

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<sup>8</sup> See PBS Frontline's Season 2015: Episode 18, released May 12, 2015: "The Trouble with Chicken" at <https://www.pbs.org/wgbh/frontline/film/trouble-with-chicken/>

<sup>9</sup> See ProPublica's October 29, 2021, article: "America's Food Safety System Failed to Stop a *Salmonella* Epidemic. It's Still Making People Sick." at <https://www.propublica.org/article/salmonella-chicken-usda-food-safety>

<sup>10</sup> See <https://www.usda.gov/media/press-releases/2012/05/31/usda-targeting-six-additional-strains-ecoli-raw-beef-trim-starting>

Consumer Federation of America  
Consumer Reports  
Rick Schiller  
Steven Romes  
The Porter family