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**Re: 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 Dr. Brashears:

Marler Clark LLP, PS submits these comments regarding 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) (“*Salmonella* Petition”).

We are writing to supplement the *Salmonella* Petition with additional and updated information, as well as addressing some issues and criticisms raised by other comments. Of course, it is not possible to address all such issues and criticisms in detail. Thus, what follows attempts to address such issues and criticisms in a collective fashion, identifying a few comments as representative examples. By identifying specific comments, it is not intended that these are the only comments here addressed, or that we believe are incorrect or unsupported by fact.

## **Background**

In the above-referenced Petition, we requested—on behalf of Rick Schiller, Steven Romes, the Porter Family, Food & Water Watch, Consumer Federation of America, and Consumer Reports—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, Poonna, Reading, Saintpaul, Sandiego, Schwarzengrund, Senftenberg, Stanley, Thompson, Typhi, and Typhimurium.<sup>1</sup>

## **Not “Slight” – Outbreak Serotypes Pose Serious Risks**

*Salmonella* is the leading bacterial cause of foodborne illness in the United States, resulting in an estimated 1.35 million illnesses, 26,500 hospitalizations, 420 deaths, and 130 outbreaks each year.<sup>2,3</sup> While estimates vary, *Salmonella* is believed to have a low infectious dose, requiring fewer than 100 CFUs to cause infection.<sup>4</sup> Food is the major source for salmonellosis with a significant proportion being attributed to poultry, eggs, beef, and pork.<sup>5</sup> The estimated cost of *Salmonella* illnesses associated with meat and poultry products is estimated to be between \$2.7B and \$6.5B annually.<sup>6</sup>

Salmonellosis is responsible for a number of disease syndromes, the most common of which is gastroenteritis (i.e. diarrhea, fever, abdominal cramps, vomiting). Infection by *Salmonella* can also lead to severe dehydration, bacteremia, reactive arthritis, cardiovascular complications, as well as long-term sequelae, including chronic arthritis and post-infectious IBS. For every diagnosed and reported case of *Salmonella*, scientists estimate that 38 similar cases go unreported.<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> “*Salmonella* Homepage.” CDC, 2019.

<sup>3</sup> Laufer AS, *et al.* (2015). Outbreaks of *Salmonella* Infections Attributed to Beef – United States, 1973-2011. *Epidemiol Infect.* 143(9):2003-13.

<sup>4</sup> Teunis PFM, *et al.* (2010). Dose-response modeling of *Salmonella* using outbreak data. *Int J Food Microbiol.* 144:243-9.

<sup>5</sup> Batz MB, Hoffman S, Morris Jr. JG. (2012). Ranking the disease burden of 14 pathogens in food sources in the United States using attribution data from outbreak investigations and expert elicitation. *J Food Prot.* 75(7):1278-91.

<sup>6</sup> Scharff RL. (2020). Food Attribution and Economic Cost Estimates for Meat and Poultry Related Illnesses. *J Food Prot.* 83(6):959-67.

<sup>7</sup> Mead PS, *et al.* (2000). Food-Related Illness and Death in the United States. *J Environ Health.* 62(7):9-18.

Despite significant efforts to prevent *Salmonella* infections, rates of the foodborne disease have not declined. In fact, studies show that the number of infections has substantially grown since 2015.<sup>8</sup>

The dangers of *Salmonella* have been scientifically substantiated and documented for over half a century. In 1969, the National Academy of Sciences (NAS) investigated the nature of the U.S. “*Salmonella* Problem” and made recommendations to the USDA to mitigate the contributing factors.<sup>9</sup> The report addressed cross-contamination, hazardous slaughtering practices, and consumer mishandling and miseducation. The following year, a USDA committee evaluated the 1969 NAS report and, in 1970, published “A Review of the NAS-NRC Report.” The USDA committee agreed with every NAS recommendation except the one recommending one Agency “to coordinate training or act as a single authority.”<sup>10</sup> Moreover, a 1974 General Accountability Office (GAO) Report to Congress discussed the “hazard to public health from raw meat and poultry products contaminated with *Salmonella*” and urged USDA to improve its safeguards.<sup>11</sup>

The need and scientific basis for taking a modernized, public health approach to poultry safety was recently documented in the 2019 report of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) regarding *Salmonella* control strategies in poultry.<sup>12</sup> The report specifically recommended as key opportunities to reduce *Salmonella* and prevent illness across the farm-to table spectrum: (1) serotype-specific pre-harvest controls, (2) strict process controls in slaughter establishments, and (3) identification and development of “approaches that exclude serotypes of greatest public health concern from raw poultry products.”<sup>13</sup>

Each of the above-referenced Outbreak Serotypes has a demonstrable history associated with either an illness outbreak or a product recall and has been proven to be injurious to human health.

### **Identification by Serotype – A Practical Method**

A limited number of serovars are responsible for the vast majority of outbreaks and cases of human foodborne illness. The ten most prevalent *Salmonella* serotypes—Enteritidis, Newport, Typhimurium, Javiana, I 4,[5],12:i:-, Infantis, Muenchen, Montevideo, Braenderup, and

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<sup>8</sup> Marder EP, *et al.* (2017). Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food and the Effect of Increasing Use of Culture-Independent Diagnostic Tests on Surveillance – Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2013-2016. *MMWR Morb Mortal Wkly Rep.* 66(15):397-403.

<sup>9</sup> Foster EM, *et al.* *An Evaluation of the Salmonella Problem.* Washington D.C.: National Academy of Sciences, 1969. Web (Google eBook).

<sup>10</sup> “A Review of the NAS-NRC Report.” Microbiological Subgroup of the USDA Food Safety Committee, 1970.

<sup>11</sup> Anon., 1974a. “Salmonellae in raw meat and poultry – An assessment of the problem.” GAO Report to the Congress. Comptroller General of the United States, Washington D.C., Publication No. B-154031(2).

<sup>12</sup> NACMCF. (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *J Food Prot.* 82(4):645-68.

<sup>13</sup> *Id.* at 661-3.

Thompson—are responsible for nearly 60% of all nontyphoidal *Salmonella*-associated human illnesses.<sup>14</sup> Additionally, 41% of *Salmonella*-related human disease is caused by the top three serovars—Enteritidis (16.8%), Newport (10.1%), and Typhimurium (14.5%). Several fewer common serotypes are known for their ability to escape the GI tract and cause dangerous systemic diseases, including *S. Heidelberg*, *S. Oranienburg*, *S. Panama*, *S. Poona*, *S. San Diego*, and *S. Schwarzengrund*.<sup>15</sup>

Modern methods of serotyping have revolutionized the way scientists go about tracking and identifying strains of bacteria. Whole genome sequencing (WGS) can clearly define foodborne illness outbreaks and has enabled scientists to identify pathogenic strains with a high degree of specificity, regardless of serotype, antibiotic resistance, or virulence genes. The high discriminatory power of WGS has allowed scientists and public health officials to link seemingly isolated cases of *Salmonella* to a single common source.

Moreover, the above-mentioned NACMCF report states that it is difficult to identify pathogenicity based on genes and that identifying by serotype is superior.<sup>16</sup> APHIS uses serotyping,<sup>17</sup> <sup>18</sup> as does FSIS for Shiga-toxin positive *Escherichia coli* (STEC).<sup>19</sup> For *Listeria monocytogenes*, FSIS relies on species only and in some cases, on genus.<sup>20</sup>

Our colleagues at Stop Foodborne Illness, Center for Science in the Public Interest (CSPI), and Center for Foodborne Illness Research and Prevention (CFI) have expressed their support of our Petition<sup>21</sup> and proposed innovative and feasible methods of testing and process controls, including, but not limited to, replacing the current *Salmonella* standards with serotype-specific *Salmonella* standards.

### **“Just Cook it” Does Not Cut it**

Although consumers—for the most part—are aware that meat and poultry contain germs, that undercooked meat and poultry items can make people sick, and that cross-contamination can be dangerous,<sup>22</sup> studies have shown time and time again that consumers, restaurant managers, and chefs alike do not know how to handle and cook meat adequately.

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<sup>14</sup> “National Enteric Disease Surveillance: *Salmonella* Annual Report, 2016.” CDC, 2016.

<sup>15</sup> NACMCF. (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *J Food Prot.* 82(4):645-68.

<sup>16</sup> *Id.* at 646-8.

<sup>17</sup> “National Veterinary Services Laboratories *Salmonella* Serotyping Proficiency Test Summary.” USDA-APHIS, 2012.

<sup>18</sup> “Monitoring *Salmonella* in Humans & Cattle.” USDA-APHIS, 1994.

<sup>19</sup> “Detection, Isolation and Identification of Top Seven Shiga Toxin-Producing *Escherichia coli* (STECs) from Meat Products and Carcass and Environmental Sponges.” USDA-FSIS, 2018.

<sup>20</sup> “FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products.” USDA-FSIS, 2014.

<sup>21</sup> See Comments to the Petition, available at: <https://beta.regulations.gov/document/FSIS-2020-0007-0001>.

<sup>22</sup> “2016 Food Safety Survey Report.” FDA, 2016.

In one study, consumers with and without food safety training exposed themselves to potential foodborne illness, even when they were knowingly being recorded.<sup>23</sup> Another study exposed the food handling practices of restaurant managers across the country.<sup>24</sup> Many of the managers who were interviewed (65%) indicated that they had been working in the food service industry for over 15 years. Despite their experience, the managers being interviewed expressed that they “[do not] always measure the final cook temperature of hamburgers with a thermometer” (77%) or “never measure the final cook temperatures of hamburgers” (49%). In fact, personnel at over 80% of the restaurants in the study determined doneness of hamburgers using subjective measures. Fifty-one percent of restaurant managers “always or often checked doneness by the color of the inside of the hamburger,” 61% “always or often checked the doneness by the external appearance of the hamburger,” and 37% “always or often checked doneness by the feel or texture of the hamburger.” Subjective measures, however, including texture and color indicators, have been proven ineffective and unreliable.

Additionally, during the course of research, two or more risky handling practices were observed in over half of the restaurants being surveyed. In 62% of the restaurants, food preparers did not wash their hands between handling raw beef and ready-to-eat or cooked beef products. In 42% of restaurants, the same utensils (without rinsing or sanitizing between uses) or gloved hands (without a glove change) were used on both raw and cooked ground beef. In 40% of restaurants, workers wiped their hands-on aprons or wiping cloths immediately after handling raw meat.

Safe handling to prevent cross contamination is critical, but difficult to attain. Cross-contamination frequently occurs—even in federally inspected establishments.<sup>25</sup> And unfortunately, many home kitchens are not as well-designed as federally regulated establishments or restaurant kitchens; in fact, many home kitchens are cluttered and crowded. As a result, preventing cross-contamination is difficult, even for educated consumers.<sup>26</sup>

### **Education in Lieu of Regulatory Action?**

We believe that consumer education is important and should be maintained. However, although consumer education has accomplished much, we believe that it has not accomplished

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<sup>23</sup> Phang HS, Bruhn CM. (2011). Burger Preparation: What Consumers Say and Do in the Home. *J Food Prot.* 74(10):1708-16.

<sup>24</sup> Bogard AK, et al. (2013). Ground Beef Handling and Cooking Practices in Restaurants in Eight States. *J Food Prot.* 76(12):2132-40.

<sup>25</sup> See Marler Clark Petition, p. 47.

<sup>26</sup> Here are a few recent citations of scientific papers on consumer handling, one of which you co-authored, that indicate that the past four decades of USDA food safety education have been less than adequate: (1) Irlbeck EG, Akers C, Brashears MM. (2009). A Content Analysis of Food Safety Measures on Television's Food Network. *Food Prot Trends.* 29(1):16-20; (2) Duong M, et al. (2020). An Observational Study of Thermometer Use by Consumers when Preparing Ground Turkey Patties. *J Food Prot.* <https://doi.org/10.4315/JFP-19-594>; (3) Moore CJ, Sweet CL, Harrison JA, Franck KL. (2019). Validating Responses to a Food Safety Survey with Observations of Food Preparation Behaviors Among Limited Resource Populations. *Food Prot Trends.* 39(6):449-60; (4) Maughan C, Chambers, IV E, Godwin S. (2017). Food Safety Behaviors Observed in Celebrity Chefs Across a Variety of Programs. *J Public Health (Oxf).* 39(1):105–12; (5) Sneed J, et al. (2015). Consumer Food Handling Practices Lead to Cross-contamination. *Food Prot Trends.* 35(1):36-46.

enough. Ideally, an educated and competent consumer population could eliminate the need for many regulatory programs, including the *Salmonella* Performance Standard, the STEC programs, and the requirement for cooking STEC-positive lots in FSIS establishments. However, despite the educational efforts of FSIS, FDA, NIFA, the meat and poultry industry, and consumer groups, consumer education on proper cooking and sanitation, unaccompanied by additional regulatory measures, has proven to be ineffective at preventing *Salmonella* illnesses and outbreaks.

As indicated in the Petition,<sup>27</sup> a 2014 Pew Charitable Trusts report—involving then-Vice President of Corporate Food Safety for Cargill and then-Senior Vice President of Food Safety and Quality Assurance for Tyson Foods—detailed that, “while there has been some progress, meat and poultry products remain significant vehicles for foodborne illnesses in the United States” and “the inspection system developed more than 100 years ago does not employ the most science-based means to protect consumers from pathogenic contamination.”<sup>28</sup> Additionally, the report specified that “many critics of the current meat and poultry oversight system believe that [the laws currently in place] are the major obstacles to significant reductions in foodborne disease linked to meat and poultry because they are outdated and inflexible.”

By banning recurring serotypes in meat and poultry products, FSIS will take a significant leap forward in ensuring the safety of American consumers.

### **Salmonella as an "Added Substance"**

As nearly every knowledgeable person would readily concede, the decision to declare a substance an adulterant under 21 U.S.C. § 601(m)(1) and 21 U.S.C. § 453(g)(1) involves a need to decide whether, legally speaking, the substance in question is “added.” The commenters that argued (or simply asserted) that *Salmonella* is not, and cannot be, an “added substance” did so on two grounds: one supposedly factual and the other primarily legal. But the arguments offered are misinformed at best and intentionally misleading at worst.

The factual argument rests entirely on the assertion that **some** *Salmonella* that ends up as a contaminant of meat and poultry originates in the lymph nodes and thus is not added. But even if this were true (and it is only partly), there is no support for the idea that a substance cannot be declared an adulterant unless one hundred percent of contamination is attributable to an additive process. Those making the lymph node argument concede that nearly all such contamination is a result of an additive process. It also remains indisputably a fact that process controls, regulatory interventions, and other mechanisms can eliminate the presence of *Salmonella* in poultry.<sup>29</sup> In sum, if the lymph node argument was to be dispositive here, then there is no reason that the USDA was also incorrect in declaring *E. coli* O157:H7 as an adulterant.

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<sup>27</sup> See Marler Clark Petition, pp. 41-2.

<sup>28</sup> “Recommendations to Modernize the Meat and Poultry Oversight System in the United States – Developed by the Meat and Poultry Dialogue Group.” Meridian Institute, 2017.

<sup>29</sup> See, e.g., Wegener H, *et al.* (2003). *Salmonella* Control Programs in Denmark. *Emerg Infect Dis.* 9(7):774-80; Neches R. “How Denmark Eradicated *Salmonella* in Poultry” (Apr. 2, 2014), <http://microbe.net/2014/04/02/how-denmark-eradicated-salmonella-in-poultry/>; Ledstrup M, “No More *Salmonella* in Danish Poultry” (Jul. 3, 2012), <http://sciencenordic.com/no-more-salmonella-danish-poultry>.

With regard to the legal argument that *Salmonella* cannot be declared an adulterant, the comment submitted by North America Meat Institute (NAMI)<sup>30</sup> is both representative of many identical arguments made by others, but also representative of the willingness to misrepresent. First, contrary to what NAMI argues, there is no judicial consensus on the legal question of what constitutes an “added substance” within the meaning of the FMIA and PPIA. Instead, as the NAMI letter clearly demonstrates, most case law on the question involves the Food, Drug, and Cosmetic Act (FDCA) and FDA regulations promulgated under that Act. The FDA’s most extensive discussion of the question can be found in its responses to comments submitted prior to its adoption of the final rule on “regulating food contaminants and naturally occurring poisonous or deleterious substances in food.”<sup>31</sup> As explained by the Agency, whether a substance was “added” rested on whether it was “naturally occurring” or “intrinsic part of” the food in question.

But this explanation and approach, which the court called a “rather extreme position,” was largely rejected in *United States v. Anderson Seafoods, Inc.*, which held that, to be an “added substance,” its presence must at least in part be attributable to “acts of man.”<sup>32</sup> In so holding, the court granted no deference to the Agency’s interpretation, focusing instead on legislative history and the plain language of the Act to affirm that added “means artificially introduced, or attributable to the acts or intervention of man.” More importantly for the question raised by the Petition, the *Anderson* court—upon which NAMI primarily relies—stated the following:

Since the purpose of the “may render injurious” standard was to facilitate regulation of food adulterated by acts of man, **we think that it should apply to all of a toxic substance present in a food when any of that substance is shown to have been introduced by man.** Anderson argues that this reading of the statute would result “in the anomalous situation where a substance in a food can be 90 percent natural and 10 percent added if the entire substance is considered as added.” There is no anomaly, however, in such a situation. The Act’s “may render it injurious to health” standard is to be applied to the food, not to the added substance. The food would not be considered adulterated under our view unless the 10 percent increment creates or increases a potentiality of injury to health. If the increment does create or increase such a potentiality, then, because the increment that triggered the potentiality was introduced by man, the Food and Drug Administration ought to be able to regulate it under the standard designed to apply to adulterations of food caused by man.<sup>33</sup>

In other words, not only does the right to regulate not require that all of the contamination be attributable to human agency, the amount so required can be of a small percentage so long as the total amount of contamination is injurious. And there is simply no question that this reasoning applies to *Salmonella* in meat and poultry, even if some level of the pathogen being present is not attributable to human agency.

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<sup>30</sup> See Comments to the Petition, available at: <https://beta.regulations.gov/document/FSIS-2020-0007-0001>.

<sup>31</sup> 21 CFR Part 109 and 509; 42 Fed. Reg. 52814 (Sept. 30, 1977).

<sup>32</sup> 662 F.2d 157, 160 (5th Cir. 1980) affirming 447 F. Supp. 1151 (N.D. Fla 1978) (emphasis added).

<sup>33</sup> *Id.* at 161 (emphases added).

Not long after *Anderson* was decided, the D.C. Federal Circuit Court, which is often considered the highest of the circuit courts when it comes to regulatory issues, applied the rule and reasoning in *Anderson Seafoods* to hold that *Salmonella* in shrimp was an “added substance” because its presence “can result from human acts and can frequently be attributable to insanitary processing procedures.”<sup>34</sup> The court also noted that other countries “routinely export *Salmonella*-free shrimp to the United States,”<sup>35</sup> thus showing that it was feasible to provide shrimp that was not contaminated, just as it is feasible to provide uncontaminated meat and poultry. Finally, the court rejected the argument that the presence of *Salmonella* did not satisfy the “may render injurious” requirement because “many people do not cook shrimp properly, or like the patrons of Japanese restaurants, eat it raw.”<sup>36</sup>

In addition to addressing the questions about how to meet the “added substance” and “may render injurious” requirements, the court in *Continental Seafoods* rejected the argument that FDA had no authority to declare *Salmonella* an adulterant under any circumstances because that question had been fully decided already in *American Public Health Authority (APHA) v. Butz*.<sup>37</sup> The argument rested on the statement in the APHA decision where that court stated that if *Salmonella* was considered to be “inherent in meat,” then the “presence of salmonella [sic] in meat does not constitute adulteration within the [Act’s] definition.”<sup>38</sup> Calling this statement “dictum,” the court in *Continental Seafoods* pointed out that the APHA decision was made at a time when “microscopic examinations” of meat was not occurring and the court had not addressed the issue of whether *Salmonella* may be “added” to meat, assuming instead (based on the agreement of the parties) that the bacteria were inherent to the meat.<sup>39</sup>

Given that this reading of the APHA decision is certainly correct, it does not follow that the effect of the decision has ceased. APHA v. Butz continues to be cited by courts and parties for the proposition that *Salmonella* does not, and cannot, meet the definition of “adulterated” under the Act whether it be the FMIA or FDCA, the definition in both being exactly the same. For example, *Supreme Beef Processors, Inc. v. USDA*<sup>40</sup> famously cites APHA v. Butz as having held that “*Salmonella*...is not an adulterant per se.” But at the same time, it notes that “USDA agrees

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<sup>34</sup> *Continental Seafoods, Inc. v. Schweiker*, 674 F.2d 38, 43 (D.C. Cir. 1982). It also bears emphasizing that the court in *Continental Seafoods* rested its decision in large part on the prior decision of the U.S. Supreme Court in *United States v. Coca Cola*. *Id.* citing 241 U.S. 265, 282-83, 36 S. Ct. 573, 578-79, 60 L. Ed. 995 (1915). In its public comment, NAMI misrepresents the holding in *Coca Cola*, omitting what the court in *Continental Seafoods* clearly points out, namely:

Determining that man must appear on the stage before a substance is an added one does not determine the size of the role he must play before it is. The dichotomy in § 342(a)(1) is between two clear cases that bracket the present case. The Act considers added things such as lead in coloring agents or caffeine in Coca Cola. It considers not-added things like oxalic acid in rhubarb or caffeine in coffee. The Act did not contemplate, however, the perhaps rare problem of a toxin, part of which occurs “natural,” and part of which results from human acts.

*Continental Seafoods*, 674 F. 2d at 160-61. Thus, again, courts that have addressed the issue hold that only some part of the added contamination must be attributable to human agency, not all of the contamination.

<sup>35</sup> *Id.* at 43 n. 17.

<sup>36</sup> *Id.* at 44.

<sup>37</sup> 511 F. 2d 331 (D.C. Cir. 1974).

<sup>38</sup> *Id.* at 334.

<sup>39</sup> *Continental*, 674 F.2d at 41-42.

<sup>40</sup> 275 F.3d 432, 438 and n. 21 (5th Cir. 2001).

in this case that *Salmonella* is not an adulterant per se.”<sup>41</sup> As a result, the issue of whether *Salmonella* is not an adulterant per se was not before the court in *Supreme Beef* and it is incorrect to state that *Supreme Beef* contained any such holding. That said, there is still much that is relevant and helpful in the *Supreme Beef* decision.

Interestingly, the *Supreme Beef* court then goes on to comment on a related decision under the FDCA to explain why the result in that decision (i.e. a required step in making smoked salmon that was intended to combat germination, outgrowth, and multiplication, but not eliminate, botulinum spores) was not “in tension” with its holding on “insanitary conditions.”<sup>42</sup> Specifically, the *Supreme Beef* court explained:

While this may appear to conflict with our determination that pre-existing characteristics of raw materials before they are “prepared, packed or held” are not within the regulatory reach of § 601(m)(4), the regulations at issue in Nova Scotia did not attempt to control the levels of *Clostridium botulinum* spores in incoming fish, as the performance standard does to *Salmonella* in incoming raw meat. Instead, the regulations in Nova Scotia required the use of certain heating and salination procedures to inhibit growth of the spores.<sup>43</sup>

This explanation again makes clear that the *Supreme Beef* ruling solely interpreted § 601(m)(4), and not § 601(m)(1).

There is also an analogous case decided at around the same time as *Supreme Beef*—*United States v. Blue Ribbon Smoked Fish, Inc.*<sup>44</sup> In this case, the court upheld the treatment of *Listeria* as an adulterant based on the food in question being a ready-to-eat food intended for human consumption because it was shown that “any quantity” of *Listeria* was unsafe for humans and it was not a substance that could “not be avoided by good manufacturing practices.”<sup>45</sup> Moreover, in this case, it was undisputed that the presence of *Listeria* on finished product and in the facility was the result of an inadequate HACCP plan and other insanitary conditions that, by themselves, rendered the product “adulterated” under a different provision of the Act. As such, the fact that the contamination was the result of “intervening acts” that spread or increased the presence of *Listeria* indicates that it was these acts that caused the *Listeria* to be an “added” substance injurious to health.

Like the *Salmonella* deemed an adulterant on shrimp in *Continental Seafoods*, the presence of the pathogen is attributable to preharvest and harvest conditions that, if controlled, would prevent the contamination from occurring. Moreover, the idea that any court has ruled that the USDA lacks the authority to declare *Salmonella* to be an adulterant is mere fiction and fiction of the most self-serving kind. Accordingly, the legal and factual arguments to the contrary should be disregarded in favor of those arguments plainly supporting the adulterant declaration.

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<sup>41</sup> *Id.* at n. 21.

<sup>42</sup> *See United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977).

<sup>43</sup> 275 F.3d at 441-42.

<sup>44</sup> 179 F. Supp. 2d 30 (E.D. N.Y. 2001).

<sup>45</sup> *Id.* at 48-49 (quotation omitted).

### **Regulatory Action Worked for *E. coli* O157:H7**

Following the tragic 1993 Jack in the Box *E. coli* O157:H7 outbreak that killed four children, Michael Taylor, then-current FSIS Administrator, announced that *E. coli* O157:H7 would be deemed an adulterant in ground beef, thus requiring additional testing by meat packers. After the ban took effect and reforms followed, Marler Clark's legal cases involving victims sickened by *E. coli* in meat—which previously accounted for 90 percent of the firm's caseload—dwindled to less than five percent.<sup>46</sup> As detailed in the Petition, the heightened standards also caused a sharp decline in both recall events and reported illnesses.<sup>47</sup> Furthermore, when the USDA implemented the HACCP/Pathogen Reduction Rule in 1996, a subsequent economic analysis estimated that compliance with the regulations raised a plant's costs of production less than one cent per pound.<sup>48</sup>

In the case of *Texas Food Industry Association v. Espy*, the court found that “*E. coli* O157:H7 fits the definition of an adulterant under the Federal Meat Inspection Act” and cited “relatively low infectious dose,” “serious illness conditions,” and survival in “what many consumers consider to be proper cooking of ground beef products” as reasons for the change.<sup>49</sup> The dangers of *Salmonella*, still, were ignored even though the above-cited reasons also apply to Outbreak Serotypes of *Salmonella*.

### **Another Concern: Recurring Phrases Within Comments**

Upon inspection of the comments to the Petition,<sup>50</sup> we quickly noticed a troubling pattern—certain phrases and sentences were used repeatedly in many of the comments. Using the “Search” tool, we determined that 197 of the 377 comments (52%) contained the phrase “USDA should reject this petition”; 201 of 377 (53%) contained “consolidating our meat supply in the hands of large-scale operations”; 179 of 377 (47%) contained the sentence “While salmonella [sic] is a serious problem, this very broad, zero-tolerance approach is not the answer”; and 191 of 377 (51%) contained the sentence “Many of these strains pose only slight risks, yet the testing requirements that would result from classifying them as adulterants could put small-scale processors out of business.” We ultimately determined that these recurring phrases stemmed from a template posted online and sent around by the Weston A. Price Foundation.<sup>51</sup> Thus, it is likely that many of the commenters using this template did not read the Petition in its entirety, but instead, merely copied and pasted Weston Price's template to comment in objection of our Petition.

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<sup>46</sup> That, despite *ad hominen* attacks to the contrary, is in no small part the point of this Petition.

<sup>47</sup> See Marler Clark Petition, pp. 5-7.

<sup>48</sup> Ollinger M, Moore D, Chandran R. “Meat and Poultry Plants’ Food Safety Investments: Survey Findings, USDA/ERS Technical Bulletin No. 1911” (May 2004) at p. 37 (emphasis added) (noting that “ERS survey data suggest that the PR/HACCP rule has raised beef and poultry slaughter plant costs by about one-third of 1 cent per pound.”).

<sup>49</sup> 870 F. Supp. 143. United States District Court, W.D. Texas, Austin Division (1994).

<sup>50</sup> See Comments to Docket No. FSIS-2020-0007, available at: <https://beta.regulations.gov/document/FSIS-2020-0007-0001/comment>.

<sup>51</sup> See “Tell USDA to Reject Zero Tolerance Policy,” available at: <https://www.westonaprice.org/tell-usda-to-reject-zero-tolerance-policy/>; See **Attachment 1** for Weston Price's e-mail template.

## Conclusion

In conclusion, we believe that the food industry has a moral responsibility to produce the safest food possible for consumers. Food safety is not one party's responsibility; rather, it is a shared responsibility among all stakeholders. The collaboration of regulators, the food industry, and science is the best means to enhance public health through pathogen management and elimination.

When analyzing the rates of foodborne illnesses over the past decades, it is important to remember that we have made significant advances and now have better detection tools and reporting methods for foodborne illnesses. As a result of these significant advances, all of which are further demonstrated by the numerous scientific studies cited in the Petition, USDA has much more evidence now on which to base a decision to declare *Salmonella* an adulterant—especially as related to the first petition filed by CSPI,<sup>52</sup> where a shortage of solid data made more sense as a reason to deny that first petition.

Finally, it has been proven time and time again that more stringent regulations are effective. For example, in September 2015, the annual prevalence of *Salmonella* on chicken parts was about 24 percent. In 2016, FSIS published a Federal Register Notice finalizing the chicken parts performance standard for *Salmonella*. Currently, using annual data for September 2019, the *Salmonella* prevalence on chicken parts has decreased to about 9 percent. This is a statistically significant decrease following the finalization of the chicken parts performance standard. Similarly, the additional regulations implemented in the wake of the 1993 Jack in the Box *E. coli* outbreak have led to a sharp decline in both recall events and reported illnesses.

Very truly yours,



William D. Marler

cc: Mary Porretta, Petitions Manager  
Paul Kiecker, Administrator  
Matthew Michael, Director  
Food & Water Watch  
Consumer Federation of America  
Consumer Reports  
Rick Schiller  
Steven Romes  
The Porter family

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<sup>52</sup> “Petition for an Interpretive Rule Declaring Specific Strains of Antibiotic-Resistant *Salmonella* in Ground Meat and Poultry to be Adulterants.” CSPI, 2011.