UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

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)	)	Docket No. _____

CITIZEN PETITION

Submitted by:

Marler Clark LLP, PS, on behalf of:

Rick Schiller

Steven Romes

The Porter Family

Food & Water Watch

Consumer Federation of America

Consumer Reports

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January 19, 2020

FSIS Docket Clerk
United States Department of Agriculture
Food Safety and Inspection Service (FSIS)
Room 2534 South Building
1400 Independence Avenue, S.W.
Washington, DC 20250-3700

I. REQUESTED ACTIONS

A. Requested Actions in Brief

Marler Clark LLP, PS, on behalf of Rick Schiller, Steven Romes, the Porter Family, Food & Water Watch, Consumer Federation of America, and Consumer Reports (hereinafter, "Petitioners") are requesting that the Food Safety and Inspection Service (FSIS) declare the following outbreak serovars (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 (hereinafter, "Outbreak Serotypes" or "*Salmonella* Outbreak Serotypes").[1]

[1] Thirty of the thirty-one above-listed serotypes are from CDC's *Salmonella* Atlas. *See* *Salmonella* Atlas 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. As of December 30, 2019, the CDC has reported that this outbreak "appears to be over." *See* CDC Outbreak Investigation Notice with thirteen reported cases from eight states, nine hospitalization, and one death. *Available at* https://www.cdc.gov/salmonella/dublin-11-19/index.html. *S.* Dublin is further discussed below in the "Ordinarily Injurious 'Outbreak' Serotypes" section of the petition.

Each of these Outbreak Serotypes has a demonstrable history associated with either an illness outbreak or a product recall and is proven to be injurious to human health. Thus, Petitioners believe the above-listed serotypes constitute an imminent threat to public health necessitating prompt agency action.

We request that FSIS take this action through interpretive rulemaking on all thirty-one Outbreak Serotypes jointly or on each serotype individually (if FSIS concludes that one or more serotypes do not merit such treatment). Such an act furthers the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act's (PPIA) goals to protect the health and welfare of consumers by encouraging the meat and poultry industry to engage in more effective oversight measures and create and implement effective preventative measures. These same motives prompted a previous court to find interpretive rulemaking the proper avenue for the USDA to deem another harmful pathogen, *E. coli* O157:H7, an adulterant under the FMIA.[2] Given the compelling and immediate public health risks associated with *Salmonella* Outbreak Serotypes, we further request that FSIS grant this petition expedited review.

B. Issuance of an Interpretive Rule

Pursuant to 5 U.S.C. § 553(e), 9 C.F.R. § 392, and 7 C.F.R. § 1.28, we submit this petition requesting the administrator of FSIS to issue an interpretive rule declaring *Salmonella* Outbreak Serotypes to be adulterants within the meaning of the FMIA and the PPIA.

Both the FMIA[3] and the PPIA[4] expressly state that no person shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce any meat or poultry products that

[2] *Texas Food Industry Association, et. al., v. Mike Espy*, 870 F. Supp. 143 (1994).
[3] 21 U.S.C. § 610.
[4] 21 U.S.C. § 485(a)(2).

are capable of use as human food and that are adulterated at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation.

Further, the definitions of the term "adulterated" are identical in both the FMIA and PPIA. The relevant FMIA provision—21 U.S.C. § 601(m)(1)—states in pertinent part that a carcass, part thereof, meat, or meat food product is adulterated

> if it 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.

Similarly, the PPIA's provision—21 U.S.C. § 453(g)(1)—states that any poultry product[5] is considered adulterated

> if it 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.

Issuing a new interpretive rule that declares Outbreak Serotypes of *S. enterica* subspecies *enterica* adulterants within the meaning of the FMIA and PPIA will encourage increased monitoring efforts and better ensure the safety of the general public, as is required by the FMIA[6] and PPIA.[7] Demonstrable proof shows that such declarations produce positive results and are not merely symbolic gestures. In the wake of a major outbreak of *E. coli* O157:H7 illnesses, FSIS announced in 1994 that it would henceforth interpret the FMIA, specifically 21 U.S.C. §61(m)(1),

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[5] "Poultry product" is defined by 21 U.S.C. § 453(f), which states in relevant part, "mean[ing] any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof."

[6] As stated in the FMIA, "It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged." 21 U.S.C. § 602.

[7] The PPIA identically states that "It is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged." 21 U.S.C. § 451.

to declare *E. coli* O157:H7 an adulterant.[8] A few years later, the present Petitioners requested that FSIS declare all enterohemorrhagic Shiga toxin-producing serotypes of *E. coli* to be adulterants within the meaning of the FMIA.[9] FSIS announced it would do just that in 2012, officially declaring six additional strains of *E. coli*—O26, O45, O103, O111, O121, and O145—to be adulterants.[10] The 2012 declaration was based on the six strains' demonstrated threat to human health and to the U.S. food supply, as well as the fact that "illnesses due to *E. coli* serogroups other than O157:H7…outnumber[ed] those attributed to O157:H7."[11]

The effect of these declarations is unmistakable. Although it took time to implement the necessary changes and methodology ensuring compliance with FSIS's new declaration,[12] these heightened standards caused a predictable initial spike in reporting numbers, followed by a sharp decline in both recall events and reported illnesses (*see* Figure 1) as, presumably, the industry reacted positively to the heightened safety requirements. *See also Salmonella* and EHEC Illness Rates Document included with this petition as **Attachment A.**

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[8] "Timeline of Events Related to *E. coli* O157:H7." UNITED STATES DEPARTMENT OF AGRICULTURE, FOOD SAFETY INSPECTION SERVICE, (last modified Jun. 23, 2013) https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/updates-and-memos/timeline-of-events-related-to-e-coli-o157h7/e-coli-timeline.

[9] Citizen Petition Submitted by Marler Clark LLP, PS, October 5, 2009. *Available at* https://www.fsis.usda.gov/wps/wcm/connect/a99e6a71-372e-497f-858f-9af08dd7256c/Petition_Marler_100509.pdf?MOD=AJPERES

[10] "USDA Targeting Six Additional Strains of *E. coli* in Raw Beef Trim Starting Monday." UNITED STATES DEPARTMENT OF AGRICULTURE, FOOD SAFETY INSPECTION SERVICE, (May 31, 2012). https://www.usda.gov/media/press-releases/2012/05/31/usda-targeting-six-additional-strains-ecoli-raw-beef-trim-starting

[11] *Id.*

[12] "Timeline of Events Related to *E. coli* O157:H7." UNITED STATES DEPARTMENT OF AGRICULTURE, FOOD SAFETY INSPECTION SERVICE, (last modified Jun. 23, 2013) https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/updates-and-memos/timeline-of-events-related-to-e-coli-o157h7/e-coli-timeline.

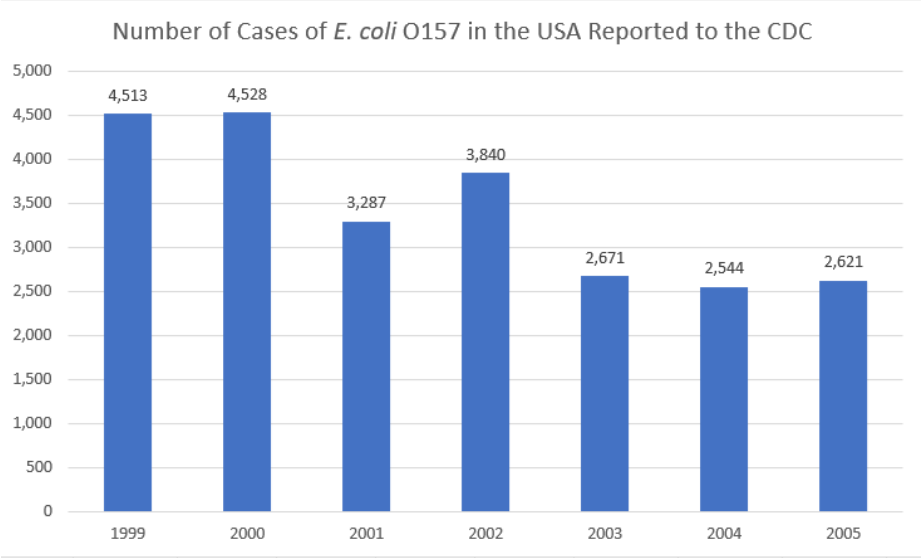

Figure 1

Meanwhile, reports of salmonellosis—which had been consistently higher than the reported numbers of both O157:H7 and STEC, generally—remained static during the same time. *See* Figures 2, 3, and 4.[13]

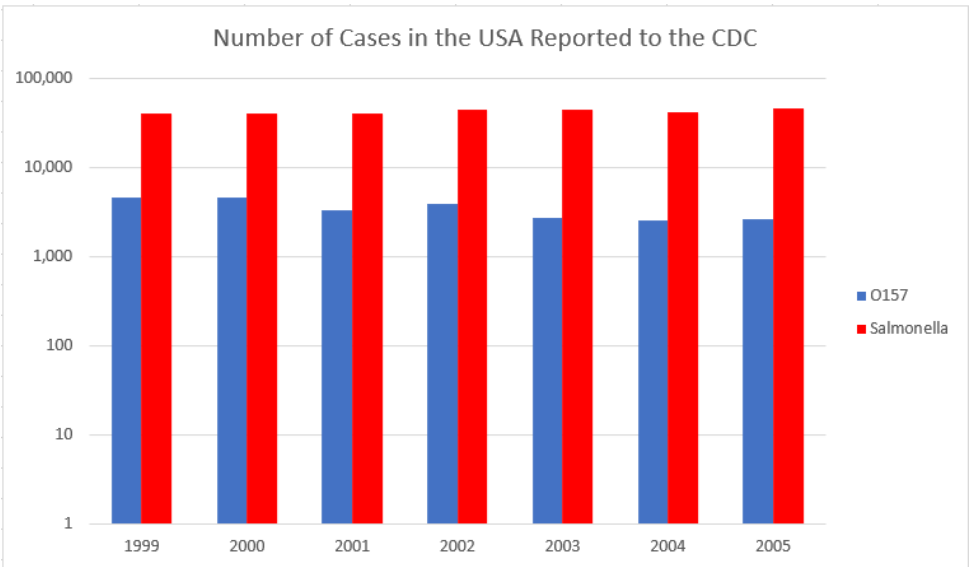

Figure 2

[13] Like Figure 1, *supra*, Figures 2-4 reflect the total illnesses reported without taking account of the implicated product.

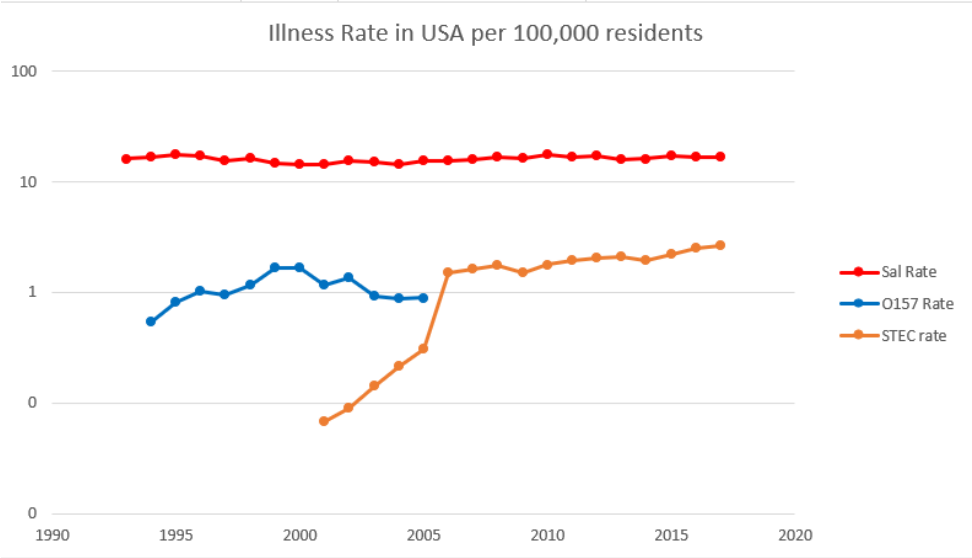

Figure 3

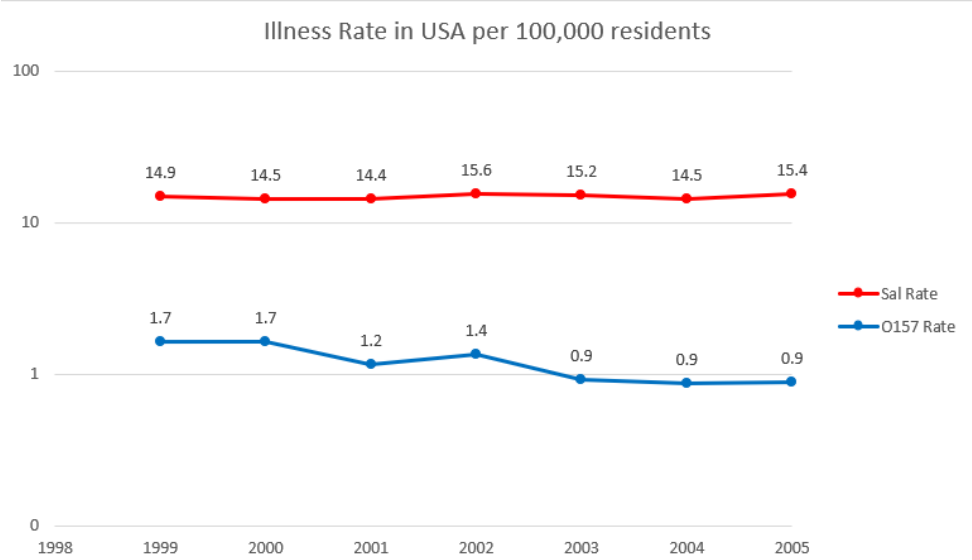

Figure 4

C. A Grant of Expedited Review

Because this petition requests action intended to enhance the public health by reducing food safety hazards, the Petitioners ask for expedited review. As stated in the FSIS petition procedures, 9 CFR § 392.8(a):

> A petition will receive expedited review by FSIS if the requested action is intended to enhance the public health by removing or reducing foodborne pathogens or other

potential food safety hazards that might be present in or on meat, poultry, or egg products.

This petition requests an interpretive rule that will prevent *Salmonella* Outbreak Serotypes from entering commerce, thus decreasing foodborne contamination. In accordance with 9 CFR § 392.8(b), the requested action is supported by scientific information that demonstrates that such an interpretive rule will reduce foodborne pathogens that are likely to be present in meat products. For these reasons, the Petitioners request FSIS to grant this petition expedited review.

II. ABOUT THE PETITIONERS

Marler Clark LLP, PS, located in Seattle, Washington, is the nation's foremost law firm representing victims of foodborne illness. The Marler Clark attorneys spend the majority of their time working on food-related cases, representing victims of *Campylobacter*, *Escherichia coli* O157:H7, non-O157 Shiga toxin-producing *E. coli* (STEC), Hepatitis A, *Listeria*, *Norovirus*, *Salmonella*, and *Shigella* outbreaks across the country.

Rick Schiller is a man from San Jose, California who developed reactive arthritis and colonic diverticulitis after becoming infected by *Salmonella* Heidelberg during the 2013 Foster Farms poultry outbreak. He was one of 634 reported victims of the outbreak.

Steven Romes is a man from Gilbert, Arizona whose *Salmonella* Newport infection led to a chronic illness—Irritable Bowel Syndrome (IBS). He was one of the 400 reported victims of the 2018 JBS Tolleson beef outbreak.

Rose and Roger Porter, Jr. are a married couple from Rainier, Washington. In 2015, Rose, Roger, and their daughter Mikayla (who was 10 years old at the time) fell severely ill with *Salmonella* I 4,[5],12:i:- poisoning after consuming pork produced by Kapowsin Meats. The Porters are three of the 192 reported victims of the outbreak.

Food & Water Watch is a Washington, D.C.-based non-governmental organization which focuses on corporate and government accountability related to food, water, and corporate overreach. Food & Water Watch was the first U.S. national organization to call for a ban on fracking. In July 2006, the consumer advocacy group also released the names of poultry processors whose plants failed federal *Salmonella* standards, faulting the industry and regulators for not doing enough to reduce the foodborne pathogen. The organization has advocated for strengthening and enhancing the inspection program at FSIS.

The Consumer Federation of America is an association of non-profit consumer organizations founded in 1968 to advance consumer interests through research, education, and advocacy. The association promotes policies to strengthen and reform outdated meat and poultry inspection systems, such as enhanced testing requirements, stronger enforcement of safety standards, and steps to eliminate or minimize pathogens in meat and poultry products.

Consumer Reports is an independent, nonprofit membership organization that works side by side with consumers to create a fairer, safer, and healthier world. For 80 years, Consumer Reports has provided evidence-based product testing and ratings, rigorous research, hard-hitting investigative journalism, public education, and steadfast policy action on behalf of consumers' interests. Unconstrained by advertising or other commercial influences, Consumer Reports has exposed landmark public health and safety issues and strives to be a catalyst for pro-consumer changes in the marketplace. From championing responsible auto safety standards, to winning food and water protections, to enhancing healthcare quality, to fighting back against predatory lenders in the financial markets, Consumer Reports has always been on the front lines, raising the voices of consumers.

III. SOME BACKGROUND

Salmonella was first isolated in 1884 by bacteriologist Georg Gaffky.[14] *Salmonella* is a gram-negative, rod-shaped bacterium belonging to the *Enterobacteriaceae* family.

As of 2019, over 2,650 *Salmonella* serovars, many of which are pathogenic to humans, have been classified using the White-Kauffman-Le Minor scheme,.[15] *Salmonella* spp. can be subdivided into two broad species: *Salmonella enterica* and *Salmonella bongori*. The subspecies *enterica* encompasses 1,550 of the 2,650 serotypes, of which 99% can cause infections in humans and warm-blooded animals.[16]

S. enterica subsp. *enterica* serovars are a leading cause of foodborne-related hospitalizations and deaths in the United States. A third of the 1.35 million illnesses caused by *Salmonella* yearly are traced back to contaminated poultry and meat products.[17] *Salmonella*-poultry, *Salmonella*-beef, and *Salmonella*-pork are among the top 13 pathogen-food combinations.[18] Salmonellosis is responsible for approximately 26,500 hospitalizations and 420 deaths each year in the U.S.

In a recent surveillance report, the Centers for Disease Control and Prevention (CDC) listed *Salmonella* as one of the most common causes of large foodborne illness outbreaks in the United States.[19] Outbreaks occur when more than one person becomes ill from a common source.

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[14] The bacterium was later named after Dr. Daniel Salmon, although his assistant, Theobald Smith, was the one to isolate a new species of the bacterial genus (*Salmonella enterica*, formerly called *Salmonella cholerasuis*) in 1885.

[15] Ferrari, R. G., *et al*. (2019). Worldwide Epidemiology of *Salmonella* Serovars in Animal-Based Foods: A Meta-analysis. *Appl Environ Microbiol*. 85(14):1-56.

[16] For ease of reference and to avoid an implicit redundancy, nontyphoidal serotypes of *Salmonella enterica* subspecies *enterica* will be referred to as *S. enterica* or *Salmonella*.

[17] Hsi, D. J., E. D. Ebel, M. S. Williams, N. J. Golden, W. D. Schlosser. (2015). Comparing foodborne illness risks among meat commodities in the United States. *Food Control*. 54:353-359.

[18] Batz, M. B., S. Hoffman, J. G. Morris Jr. (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):1278-1291.

[19] Dewey-Mattia, D., K. Manikonda, A. J. Hall, M. E. Wise, S. J. Crowe. (2018). Surveillance for Foodborne Disease Outbreaks – United States, 2009-2015. *Surveillance Summaries*. 67(10):1-11.

Foodborne salmonellosis triggers approximately 130 outbreaks in the United States each year. Despite significant efforts to prevent *Salmonella* infections, rates of the foodborne disease are not declining. In fact, the number of infections has substantially grown since 2015.[20] The economic burden of invasive non-typhoidal *Salmonella* (NTS) infections is the most significant among the top 15 foodborne pathogens; salmonellosis is estimated to cost over $3.7 billion (and up to $11.4 billion) each year due to medical care, wage losses, and death.[21] Ninety percent of the burden, a staggering 3.3 billion dollars, is due to deaths.

Salmonellosis may cause 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.[22]

The dangers of *Salmonella* have been scientifically substantiated and documented for over a half century. The 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.[23] The report addressed cross-contamination, mishandling, and consumer incognizance long before this petition. The goal of this petition, and the interpretive rule it proposes, is to accomplish precisely what USDA-FSIS objectively seeks: reduced

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[20] Marder, E. P., *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. *Morbidity and Mortality Weekly Report (CDC)*. 66(15):397-403.

[21] Hoffman, S., B. Maculloch, M. Batz. (2015). Economic Burden of Major Foodborne Illnesses Acquired in the United States. *Economic Research Service*. Bulletin Number 140.

[22] Mead, P. S., *et al*. (2000). Food-Related Illness and Death in the United States. *J Environ Health*. 62(7):9-18.

[23] 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).

salmonellosis through better prevention and monitoring standards. The declaration that Outbreak Serotypes of *S. enterica* subsp. *enterica* are adulterants will be an essential catalyst to reaching this goal.

What follows is divided into three sections. The first states the grounds—both scientific and legal—for issuing the proposed interpretive rule. The second describes the stories of five victims affected by Outbreak Serotypes of *Salmonella*. The stories are followed by thorough discussions of the pathogen in the implicated food matrices. The third section concludes with a summary and request for action to resolve the explicit threat that Outbreak Serotypes represent to the United States food supply and to U.S. consumers.

IV. STATEMENT OF GROUNDS

A. Scientific Basis for the Regulation of *Salmonella* spp.

Animals used for human food consumption are major reservoirs of NTS serovars. Turkeys, chickens, pigs, and cows asymptomatically carry the pathogen and eventually shed it in their feces, thus delivering it to the environment. *Salmonella* is frequently transmitted to humans through the consumption of contaminated animal-based foods, namely poultry, beef, and pork.

After an individual ingests a sufficient quantity of *Salmonella*-contaminated food, infectious organisms colonize the host's colon and ileum, traverse the intestinal mucus layer, and invade the intestinal epithelium. The invasion process, commonly known as bacterial-mediated endocytosis, comprises several steps.[24] The fimbriae and flagella of *Salmonella* organisms allow them to adhere to specific receptors on the intestinal epithelial cells. Bacterial attachment triggers profound cytoskeletal rearrangements in the host cell, inducing subsequent membrane ruffling. The resultant membranous ruffles then engulf the adherent bacteria.

[24] Ohl, M. E., S. I. Miller. (2001). *Salmonella*: A Model for Bacterial Pathogenesis. *Annu Rev Med*. 52:259-274.

Following invasion, *Salmonella* organisms multiply intracellularly and disseminate throughout the body, stimulating the release of various proinflammatory cytokines. An acute inflammatory response usually ensues shortly thereafter. This inflammatory reaction causes diarrhea and other gastrointestinal symptoms in human hosts.[25] Virulence markers and determinants encoded on the *Salmonella* pathogenicity islands SPI-1 and SPI-2 (*e.g.*, capsule, flagella, plasmids, type 3 secretion systems, and adhesion systems) play a crucial role in pathogenesis.[26]

Symptoms of salmonellosis typically occur within 12 to 72 hours of eating tainted food. In some cases, the infectious dose may be as low as one to 10 organisms.[27] Contaminated meat and poultry products generally do not look, smell, or taste any different than their uncontaminated counterparts. [28]

Salmonella bacteria are surprisingly hardy; numerous strains can survive desiccation, freezing, high cooking temperatures, and exposure to low pH (*e.g.*, during digestion).[29] *Salmonella* organisms are able to adapt to low-moisture environments and become more resistant to heat and other adverse conditions.[30] Additionally, certain pathogenic NTS strains have the ability to form biofilms, which greatly contributes to their resistance and persistence.[31] However, perhaps the most perplexing virulence factor associated with *Salmonella* is genomic plasticity.

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[25] Giannella, R. A. (1996). *Medical Microbiology: 4th edition*. Galveston: University of Texas Medical Branch at Galveston. Chapter 21 – *Salmonella*. Web.

[26] Jajere, S. M. (2019). A review of *Salmonella enterica* with particular focus on the pathogenicity and virulence factors, host specificity, and antimicrobial resistance including multidrug resistance. *Vet World*. 12(4):504-521.

[27] Jarvis, N. A., *et al*. (2016). An overview of *Salmonella* thermal destruction during food processing and preparation. *Food Control*. 68:280-290.

[28] "*Salmonella* Fact Sheet." *American Meat Association*, 2015.

[29] "*Salmonella* in the Pork Production Chain." *National Pork Board*, 2013.

[30] Kotzekidou, P. (1998). Microbial stability and fate of *Salmonella* Enteritidis in halva, a low-moisture confection. *J Food Prot*. 61:181-185.

[31] MacKenzie, K. D., M. B. Palmer, W. L. Koster, A. P. White. (2017). Examining the Link between Biofilm Formation and the Ability of Pathogenic *Salmonella* Strains to Colonize Multiple Host Species. *Front Vet Sci*. 4:138.

According to a recent report by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), highly virulent strains are virtually indistinguishable from non-virulent ones because "virulence markers for gastroenteritis are not serotype specific."[32] Nevertheless, certain serotypes of NTS (Heidelberg, Sandiego, Schwarzengrund, Panama, Poona, Oranienburg) are "more likely to escape the gastrointestinal tract and cause systemic disease." Moreover, according to the report, a few serotypes are "consistently associated with the greatest incidence of human disease," including *Salmonella enterica* serotypes Newport, Enteritidis, Javiana, Typhimurium, Infantis, Muenchen, and I 4,[5],12:i:-. These serotypes (and others) are thoroughly documented in CDC's *Salmonella* Atlas and are readily identifiable using Whole Genome Sequencing (WGS).[33]

Although the likelihood of an individual contracting salmonellosis is dependent on a variety of factors, including host susceptibility, concentration of the pathogen, amount of adulterated product consumed, nature of the food matrix, and virulence genes within the strain,[34] children are at the highest risk for *Salmonella* infection. Other at-risk populations include elderly persons, pregnant women, and immunocompromised individuals. Although the most characteristic manifestations of *Salmonella* infection are diarrhea and gastroenteritis, 5% of individuals affected by NTS—approximately 60,000 people every year—will develop bacteremia, a "serious and potentially fatal problem."[35] Bacteremia may result in the development of mycotic aneurysm, a

[32] National Advisory Committee on Microbiological Criteria for Foods. (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *J Food Prot.* 82(4):645-668.

[33] Arya, G., *et al*. (2017). Epidemiology, Pathogenesis, Genoserotyping, Antimicrobial Resistance, and Prevention and Control of Non-Typhoidal *Salmonella* Serovars. *Curr Clin Micro Rpt*. 4:43-53.

[34] Gurtler, J. B., M. P. Doyle, J. L. Kornacki. (2017). *Foodborne Pathogens – Virulence Factors and Host Susceptibility*. Springer International. Factors Affecting Variation in *Salmonella* Virulence (pages 151-167). Web.

[35] Hohmann, E. L. (2001). Nontyphoidal Salmonellosis. *Clin Infect Dis*. 32:263-269.

dangerous complication involving the abdominal aorta. The prognosis for this complication is grim, even with the most up-to-date forms of treatment.

Salmonella is not a timid bacterial illness; it can entail severe long-term consequences, the most prominent of which include IBS, osteomyelitis, and Reiter's Syndrome (*i.e.*, reactive arthritis). A 2010 health study on post-infectious IBS revealed that between 5% and 30% of persons who suffer from acute episodes of gastroenteritis "develop chronic gastrointestinal symptoms despite clearance of the inciting pathogens."[36] These GI symptoms include abdominal pain, bloating, cramping, gas, diarrhea, and constipation.

A certain percentage of ill individuals develop reactive arthritis as a result of their *Salmonella* infection.[37] Reactive arthritis is an immune response characterized by the inflammation of one or more joints. It can last for months or years and eventually lead to chronic arthritis, which

[36] Marshall, J. K., *et al*. (2010). Eight-year prognosis of post-infectious Irritable Bowel Syndrome following waterborne bacterial dysentery. *Gut*. 59(5):605-611.

[37] In 2011, Marler Clark represented 74-year-old Bernice Mager, a woman from Port Washington, New York who contracted a mycotic (infectious) abdominal aortic aneurysm after consuming scrambled eggs contaminated with *Salmonella* Enteritidis. Bernice was one of 3,578 victims of the 2010 Wright Egg County outbreak, which prompted a nationwide recall of over 380 million shell eggs. What Bernice initially thought might be a bad case of the flu nearly took her life. After returning from a trip to Boston, Massachusetts, Bernice developed nausea and extreme diarrhea. Over the next several days, Bernice's symptoms continued to worsen. She experienced severe chest pains and shortness of breath. After undergoing a cardiac catheterization procedure, Bernice was discharged from the emergency room for the first time. Unfortunately, this would turn out to be one of many hospital visits. A few days later, Bernice became increasingly disoriented and began shaking uncontrollably. She returned to the hospital, where she was diagnosed with symptoms of a mild stroke and an altered mental status. During an overnight stay at the hospital, Bernice experienced so much agitation that she required wrist restraints and powerful sedatives. She experienced numerous episodes of delirium, tongue biting, incontinency, and confusion which doctors thought might be due to seizure activity. Eventually, Bernice was diagnosed with an aortic aneurysm—a potentially fatal area of damage to the wall of the largest blood vessel in the body as it runs through the abdomen. She was informed that she had to have an emergency surgery with a 20% chance of survival. On August 16, 2010, Bernice underwent an open aortic resection with reconstruction using cadaver graft. In the days following her surgery, Bernice experienced significant weight loss and groin pain, but she was happy to be alive. At this point, her medical bills totaled over $200,000. Bernice never fully recovered from her illness. As a result of her *Salmonella* infection, her aorta has been permanently compromised. She is required to have a CT scan at least four times a year to ensure that the infection does not reappear. Bernice still feels weak and suffers from pain in her chest and thighs. She will never be able to live the independent and active lifestyle she had previously been accustomed to.

is highly difficult to treat. Persons with reactive arthritis may develop focal and/or urinary tract infections.

In adopting a zero-tolerance policy for a pathogen, it is appropriate to consider the worst of the impacts on those most susceptible to serious injury or death. Although the frequency of *Listeria monocytogenes* infections is comparatively low, the fact that such infections, when they do occur, cause serious and deadly consequences, including fetal deaths, has been accepted by both FDA and USDA as justification for a zero-tolerance policy for this pathogen, despite the fact that it is unusual for the pathogen to cause serious infection or injury to most healthy adults.[38]

B. Legal Basis for Declaring Outbreak Serotypes of *Salmonella* Adulterants Under the FMIA

The FMIA does not require the USDA to engage in substantive rulemaking as a predicate to interpreting the Act to deem a particular substance an adulterant.[39] Pursuant to the Administrative Procedures Act (APA), 5 U.S.C. § 553(b)(3)(A), agencies may issue "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice" without the notice and comment procedures required for proposed rulemaking. In 1994, for instance, several supermarket and meat industry organizations sought an injunction against the USDA, attempting to prevent the agency from declaring *E. coli* O157:H7 an adulterant, and barring it from implementing an *E. coli* sampling program.[40] Addressing the Petitioners' claims, the court was careful to distinguish interpretive rules from substantive rules by stating that interpretive rules do not create new law, instead they are "statements as to what the administrative officer thinks the regulation means."[41]

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[38] Archer, D.L. (2018). The evolution of FDA's policy on *Listeria monocytogenes* in ready-to-eat foods in the United States. *Current Opinion in Food Science*. 20:64-68.

[39] *Texas Food Industry Association, et. al., v. Mike Espy* 870 F. Supp. 143, 147 (1994).

[40] See *Id.*

[41] *Id.* at 147.

To determine whether the 1994 declaration of *E. coli* O157:H7 as an adulterant was an interpretive rule, the *Espy* court relied on criteria established in *American Mining Congress v. Mine Safety & Health Administration,*[42] which stated:

> Accordingly, insofar as our cases can be reconciled at all, we think it almost exclusively on the bases of whether the purported interpretive rule has "legal effect," which in turn is best ascertained by asking (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. If the answer to any of these questions is affirmative, we have a [substantive], not an interpretive rule.[43]

Applying these criteria, the court held that the declaration of *E. coli* O157:H7 as an adulterant was within the USDA's interpretive rulemaking powers, and thus, did not require notice and comment procedures.

The legal process to issue an interpretive rule declaring the aforementioned *Salmonella* Outbreak Serotypes[44] to be adulterants in meat and poultry products under the FMIA is identical to the process utilized by the USDA in the 1994 *E. coli* O157:H7 declaration. As with the rule upheld in *Espy*, the interpretive rule proposed in this Petition fits well within the *American Mining Congress* criteria. First, as reaffirmed in *Espy,* because the FMIA does not require the USDA to engage in substantive rulemaking to determine whether a particular substance is an adulterant, the agency has "the discretion to proceed through case-by-case adjudication and interpretive orders, rather than through the rulemaking process."[45] Second, the request in this petition does not require

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[42] *American Mining Congress v. Mine Safety & Health Administration* 302 U.S. App. D.C. 38, 995 F.2d 1106 (D.C. Cir. 1993).

[43] *Id.* at 1112.

[44] *S.* 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.

[45] *Texas Food Industry Association, et. al., v. Mike Espy* 870 F. Supp. 143, 147 (1994).

FSIS to publish the rule in the Code of Federal Regulations, or invoke its general legislative authority. Finally, the proposed interpretive rule does not amend a prior legislative rule. Thus, all of the *American Mining Congress* criteria are met.

Other legal concerns raised by opponents in *Espy*, namely, that the requested action would be arbitrary and capricious and that the FMIA does not grant the USDA authority to declare non-O157 STEC—or in this case, *Salmonella* Outbreak Serotypes—adulterants, would also be unfounded. First, as stated in *Espy*, the USDA may properly declare substances to be adulterants with the intended purpose of spurring industry to create and implement preventative measures.[46] Similarly, the purpose here is to encourage the meat and poultry industry to engage in more effective oversight measures in order to prevent *Salmonella* outbreaks. Second, despite a court acknowledgement over thirty years ago, based on the agreement of the parties, that *Salmonella* is not an adulterant *per se*,[47] the aforementioned *Salmonella* Outbreak Serotypes are properly declared to be adulterants in both poultry and meat products given that:

(1) the bacteria, despite its presence in some areas of the animal, is not naturally present in the final products[48] governed by the FMIA and PPIA and meant for sale and consumption to the public, thereby making it an added substance in those products;

(2) Outbreak Serotypes' extensive history of association with outbreak-linked products regulated by the USDA-FSIS clearly demonstrates that they also ordinarily render those products injurious to human health;

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[46] *Id.* at 148.

[47] A ruling that, given the wealth of scientific data detailing the prevalence and toxicity of *Salmonella*, is now controversial, to say the least.

[48] "Final Products," as used here, entails "parts"—*i.e.* legs, breasts, wings—but more specifically applies to the muscle tissue traditionally sought after for consumption by consumers. As discussed in more detail in sections V(A)(ii) and (V)(B)(iii), *infra*, *Salmonella*'s presence on muscle tissue, whether by spoilage or pathogenic, is a result of contamination because these parts have been shown to be sterile prior to their exposure to processing and reprocessing methods.

(3) USDA-FSIS has and currently recognizes Outbreak Serotypes as adulterants, but only after contaminated products are proven to cause illness, a practice purely reactionary and directly contrary to its assigned duties to protect the health and welfare of American consumers under 21 U.S.C. § 451 and 21 U.S.C. § 602;

(4) recent scientific studies have proven that *Salmonella* is a far more resilient bacteria than traditionally believed;

(5) the prevalence and severity of cross-contamination among consumers, professionals, and FSIS-inspected establishments has been revealed to be far more pervasive than previously recognized; and

(6) consumer education on proper cooking and sanitation, unaccompanied by additional regulatory measures, has proven to be wholly ineffective at preventing *Salmonella* illnesses and outbreaks.

In sum, as established by both the USDA and prior judicial decisions, the interpretative rule proposed in this petition has clear legal precedent and does not violate APA procedures.

V. IMPACT ON CONSUMERS

What follows are just a few of the personal stories associated with *Salmonella enterica* outbreaks. These stories are presented on behalf of the Petitioners to give a small insight into the significant harm that results from *Salmonella*-contaminated products. The victims' stories are followed by discussions of *Salmonella* in the implicated food products.

C. Poultry Products

i. Rick Schiller, *Salmonella* Heidelberg, 2013

Rick Schiller was one of hundreds of persons sickened in the March 2013 *Salmonella* Heidelberg outbreak linked to poultry distributed by Foster Farms. The outbreak spanned over a

year and sickened 634 people in 29 states and Puerto Rico. On September 27, 2013, Rick was diagnosed with gastroenteritis, yet did not seek medical treatment as he was convinced that he was suffering from a mild case of food poisoning. Rick could not have been more wrong.

On Saturday night, September 28, 2013, Rick went to bed early, hoping to feel better in the morning. When he woke up the next day, his right knee was painful, reddened, and warm to the touch. On Sunday night, Rick went to bed with his right leg propped up and an ice pack on his knee. In the middle of the night, he was awakened by a sharp pain. When he pulled back the covers, he was startled by the sight of his own body—his right leg was dark purple and swollen to about three times its normal size. Rick's fiancé immediately dialed for an ambulance, but Rick thought it would be faster to have her drive him to the emergency room. However, this was no easy feat. Rick recalls the agonizing experience:

> I couldn't get my leg into the car because it wouldn't bend. I leaned over into the driver seat and [my fiancé] had to force my leg into the car. It was excruciating. At the hospital, it took five people to help get me out of the car into the ER. As soon as I got in there, they pumped me full of morphine for the pain, then they put Novocaine in my leg and attempted to tap the knee. The first needle they stuck in didn't work, so they got out a bigger one. They pulled on the syringe and "meat-like" stuff came out. It was excruciating, even on the morphine.

Rick was in so much pain that he felt like he might die. After being admitted to the hospital, Rick took out his cell phone, snapped a photograph of himself, and proceeded to draft a Last Will and Testament on his phone.

During his time at the Kaiser San Jose Medical Center, Rick developed a very high fever and recalls an unpleasant memory of being covered head-to-toe with ice packs. He continued to have pain all over the right side of his body. Both his right leg and right arm were painful. His right eye would crust up and his right ear had intermittently muffled sound.

The following day, doctors ran blood work, and performed an arthrocentesis, a duplex Doppler sonography, and an MRCP (magnetic resonance cholangiopancreatography) on Rick. On October 2, he was diagnosed with colitis—localized *Salmonella* infection—and arthritis of the right knee, and he was discharged from the hospital.

On October 15, Rick returned to the Kaiser Medical Center for a follow-up. He was seen by Orod Khaghani, MD, who informed him that his gastroenteritis and *Salmonella* colitis were resolved; however, Rick was diagnosed with reactive arthritis. A few days later, Pradipta Ghosh, MD, performed X-rays on Rick's lower extremities and diagnosed him with bone spurring and mild joint space loss, consistent with mild osteoarthritis.

Four months after his *Salmonella* infection, Rick returned to Dr. Khaghani, unfortunately having relapsed with lower left quadrant abdominal pain. He also complained of decreased appetite and loose stools. Dr. Khaghani confirmed his initial diagnosis of reactive arthritis and informed Rick that he was suffering from diverticulitis of the colon. At this point, Rick's medical bills and estimated wage loss totaled nearly $15,000.

Rick's reactive arthritis remains symptomatic to this day. He feels as if his "entire right side is now weaker than [his] left." He constantly worries about his health and feels as if he never fully recovered from his systemic illness. He notices generalized fatigue and is no longer able to do the "handyman" work that he once enjoyed.

According to CDC, the multistate outbreak in which Rick was involved lasted from March 1, 2013 to July 11, 2014. FSIS was first notified of the *Salmonella* outbreak as early as June 2013.[49] By September 2013, FSIS officials had determined that Foster Farms' chicken was behind the outbreak, yet they were powerless and unable to force a recall of the tainted poultry until July

[49] "Frequently Asked Questions – *Salmonella* Outbreak Linked to Chicken Products Produced at Three Foster Farms Facilities." *United States Department of Agriculture*, 2013.

2014.[50] While FSIS can certainly request an establishment to recall a product in commerce, the agency indicated that it did not request a recall because "despite its efforts to identify the product causing the illness, no data were available that enabled its investigators to pinpoint the types of contaminated chicken products—for example, chicken breasts, whole chickens, or ground chicken—or production dates or lots."[51] During these seventeen long months, at least 240 victims were hospitalized, and despite significant epidemiological, microbiological, and traceback evidence linking the illnesses to a common production,[52] Foster Farms was allowed to continue producing and selling potentially tainted chicken.[53] In September of 2013, during a USDA-FSIS in-facility testing for *Salmonella* at three Foster Farms production plants in California and Washington, FSIS determined that sanitary conditions at the facilities were so poor that they posed a "serious ongoing threat to public health." The subsequent letters written by FSIS to Ron Foster (Foster Farms' chief executive) cited "fecal material on carcasses" and findings of poor sanitary dressing practices, insanitary food contact surfaces, insanitary non-food contact surfaces, and direct product contamination.

ii. ***Salmonella*** **and Poultry – The Adulterant's Public Health Threat in Production**

Each year, a quarter of all foodborne illnesses, hospitalizations, and outbreaks are traced back to poultry products. Poultry has been identified as the primary human health factor[54] and transmission route of foodborne *Salmonella*. In 2018 alone, outbreak serotypes of *Salmonella* traced back to various chicken and turkey products caused four multistate outbreaks, leading to

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[50] "California Firm Recalls Chicken Products Due to Possible *Salmonella* Heidelberg Contamination." *United States Department of Agriculture*, 2014.

[51] "Weaknesses in FSIS's *Salmonella* Regulation." *The Pew Charitable Trusts*, 2013.

[52] *Id.* at 7.

[53] Centers for Disease Control and Prevention (2014). Multistate Outbreak of Multidrug-Resistant *Salmonella* Heidelberg Infections Linked to Foster Farms Brand Chicken (Final Update).

[54] Akil, L., H. A. Ahmad. (2019). Quantitative Risk Assessment Model of Human Salmonellosis Resulting from Consumption of Broiler Chicken. *Diseases*. 7(1):19.

four deaths.[55] In August of 2011, Cargill recalled 36 million pounds of ground turkey products due to *Salmonella* Heidelberg contamination, which led to a death in California. That same year, Jennie-O-Turkey recalled 55,000 pounds of turkey burgers due to contamination by drug-resistant *Salmonella*.

Salmonella exists in 42.9% of chicken meat and 10.3% of turkey flesh.[56] The infectious dose of the pathogen is relatively low even in healthy individuals; it usually ranges from 10^6 to 10^8 CFU in chicken products.[57] Eighty percent of chicken is sold into parts (legs, breasts, and wings) and chicken parts largely outnumber carcasses. Parts are twice as likely than chicken carcasses to be contaminated with *Salmonella*.[58]

The gastrointestinal tracts of domestic fowls, including chickens, turkeys, geese, and ducks, are the primary reservoirs of NTS serovars; however, *Salmonella* is not ordinarily found in or on the muscle tissue of these animals. Several decades of scientific research and opinion have shown that the muscle tissue of normal healthy animals is sterile.[59] Thus, when found on poultry end products, salmonellae are "added substances" subject to 21 U.S.C. § 453(g)(1); they must only meet the "may be injurious" criterion to be deemed adulterants (rather than the more rigorous criterion of "ordinarily injurious").

Bacteria in and on muscle tissue, whether spoilage or pathogenic, are a result of contamination. Contamination generally occurs during slaughter and dressing of animal

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[55] "Reports of *Salmonella* Outbreak Investigations from 2018." *Centers for Disease Control and Prevention*, 2018.

[56] Tegegne, F. M. (2019). Epidemiology of *Salmonella* and its serotypes in human, food animals, foods of animal origin, animal feed and environment. *J Food Nutr Health*. 2(1):7-14.

[57] Akil, L., H. A. Ahmad. (2019). Quantitative Risk Assessment Model of Human Salmonellosis Resulting from Consumption of Broiler Chicken. *Diseases*. 7(1):19.

[58] Ebel, E. D., M. S. Williams, B. Tameru. (2019). Relatedness of *Salmonella* contamination frequency on chicken carcasses and parts when processed in the same establishment. *Food Control*. 100:198-203

[59] Gill, C. O. (1979). A Review: Intrinsic Bacteria in Meat. *J Appl Bacteriol*. 47:367-378.

carcasses[60] and certainly results in a product that "may be injurious" to human health. Studies consistently show that a vast majority of carcass contamination results from fecal cross-contamination from ruptured intestinal or cloacal contents, skin, or feathers of domestic fowls.[61]

A variety of processing methods have been proven to contaminate poultry parts previously uncontaminated with bacteria and exacerbate the spread of pathogens in poultry. After poultry carcasses are submerged in hot water,[62] their feathers are "picked," or removed. The feather removal process greatly contributes to the microbial count of the final product. Large poultry processing plants use mechanical pickers with rubber "fingers" to assist in the defeathering process. During the plucking process, the picker fingers inadvertently press on the abdomen of the animals, pushing out fecal matter and ingesta in the process. The leaked gastrointestinal content often harbors large bacterial loads and may cross-contaminate birds or slaughter equipment that previously had low or undetectable levels of *Salmonella*.

Contaminated slaughter equipment is highly hazardous; it can spread pathogens from a single carcass to thousands of others. Several studies have shown the severity of in-plant cross-contamination. In a 2001 study on broiler breast skin samples, one of 120 samples tested positive for another foodborne pathogen, *Campylobacter*, before defeathering, while 95 of 120 were positive post-defeathering.[63] Another study demonstrated that 75% of liver end products and 50% of carcasses from chicken processing plants contained *Campylobacter*.[64]

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[60] Elmossalami, E., N. Wassef. (1971). Penetration of some Microorganisms in Meat. *Zbl Vet Med*. 18:329-336.

[61] Rouger, A., O. Tresse, M. Zagorec. (2017). Bacterial Contaminants of Poultry Meat: Sources, Species and Dynamics. *Microorganisms*. 5(3):50.

[62] While a scalding process is often implemented to reduce microbial loads in chickens, any benefit conveyed by that process is negated by the procedure it facilitates: the feather removal process.

[63] Berrang, M. E., R. J. Buhr, J. A. Cason, J. A. Dickens. (2001). Broiler Carcass Contamination with *Campylobacter* from Feces during Defeathering. *J Food Prot*. 64(12):2063-2066.

[64] Oosterom, J., S. Notermans, H. Karman, G. B. Engels. (1983). Origin and Prevalence of Campylobacter jejuni in Poultry Processing. *J Food Prot*. 46(4):339-344.

It is worth noting that methods of reducing contamination during processing are not fictional or unfeasible, as research reveals a seemingly effective way of preventing cross-contamination. In one study, the cloacae of chicken carcasses were plugged and sutured shut prior to scalding so that the gastrointestinal content of the birds could not leach out during defeathering. After undergoing the scalding process, breast skin samples were taken before and after plucking. Prior to defeathering, 1 of 120 samples was positive for *Campylobacter*. After defeathering, 0 of 120 plugged carcasses were positive for this pathogenic contaminant.[65] These results demonstrate that when fecal matter and ingesta do not leak out of poultry carcasses, cross-contamination is significantly reduced.

Another stage in the processing line where *Salmonella* is introduced to previously sterile poultry parts is when the animals go through an evisceration step in which their internal organs are removed. During the evisceration process, the gastrointestinal tract of poultry may be damaged, resulting in contaminated carcasses.[66] Since the GI tracts of poultry often harbor the largest bacterial loads, the evisceration process is the most common source of fecal cross-contamination.[67] A paper by Rasschaert *et al*. revealed the pernicious consequences of the evisceration process. In the study, 13% of broiler flocks were originally colonized with *Salmonella*. After the slaughter process, 55% of the carcasses were contaminated.[68] In the same study, 69% of breeder and layer flocks were initially colonized in the GI tract, yet after slaughter, carcasses of all flocks were contaminated.

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[65] Berrang, M. E., R. J. Buhr, J. A. Cason, J. A. Dickens. (2001). Broiler Carcass Contamination with *Campylobacter* from Feces during Defeathering. *J Food Prot*. 64(12):2063-2066.

[66] Rasschaert, G., *et al*. (2008). Contamination of Carcasses with *Salmonella* during Poultry Slaughter. *J Food Prot*. 71(1):146-152.

[67] National Advisory Committee on Microbiological Criteria for Foods. (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *J Food Prot*. 82(4):645-668.

[68] Rasschaert, G., *et al*. (2008). Contamination of Carcasses with *Salmonella* during Poultry Slaughter. *J Food Prot*. 71(1):146-152.

Currently, USDA-FSIS attempts to counteract the known hazards associated with the processing methods described above by imposing a zero-tolerance policy for visible fecal material, ingesta, or milk on carcasses and parts at the time of inspection.[69] Under this standard, in-facility FSIS inspectors are required to perform carcass-by-carcass visual checks for defects and "contamination" at slaughter establishments around the country. However, studies have shown that the absence of visible gastrointestinal contamination (VGC) is not a reliable indicator that pathogens are not present. The lack of VGC on carcasses does not indicate that gastrointestinal contamination or pathogenic microorganisms such as *Campylobacter* or *Salmonella* are not present. Microbial contamination is invisible, therefore, the visual inspection food safety standards enforced by FSIS are highly ineffective. The results of a 2015 study by Giombelli *et al*. indicated that, in some cases, chickens with no VGC contain higher microbial loads than chickens with VGC.[70] In the study, *Salmonella* and *Campylobacter* were found on carcasses with and without VGC.

The current processing methods not only spread *Salmonella* to previously sterile poultry parts, but also encourage entrenchment of the bacteria in those parts, making it even harder to effectively eliminate the bacteria after a product's contamination. Raw poultry skin contains microcracks, microfolds, and feather follicles that facilitate bacterial attachment and colonization.[71] *Salmonella* can become entrapped in these crevices and persist during poultry

[69] Per 9 CFR § 310.18(a).

[70] Giombelli, A., *et al*. (2015). High pressure spray with water shows similar efficiency to trimming in controlling microorganisms on poultry carcasses. *Poult Sci*. 94:2589-2595.

[71] Mohamed, H. M. H., H. H. S. Abdel-Naeem. (2018). Enhancing the bactericidal efficacy of lactic acid against *Salmonella* Typhimurium attached to chicken skin by sodium dodecyl sulphate addition. *LWT – Food Science and Technology*. 87:464-469.

processing. Attached bacteria are difficult to remove and can be protected from microbial interventions.[72]

USDA permits the reprocessing of contaminated carcasses by combinations of trimming, vacuuming, and washing.[73] These reprocessing interventions, however, have proven to be highly ineffective. A study by Blankenship *et al*. replicated the classic methods of trimming, vacuuming, and washing with bactericidal chemicals (20 ppm of chlorine) used in the poultry industry.[74] Post-intervention, the reprocessed chickens had the same prevalence of *Salmonella* as the control chickens.[75] Another method commonly used in the food industry is the whole carcass rinse method. In 1987, Lillard showed that, although a gradual reduction in bacteria occurs after 10 rinses of broiler carcass skin, 10^4 CFU of *Enterobacteriaceae* can still be detected after 40 rinses.[76]

Although both processing and reprocessing methods are inadequate, FSIS recently published new guidelines that allow slaughter establishments to increase their poultry production line speeds to 175 birds per minute (bpm) if plant operators meet certain requirements. Increasing line speeds to 175 bpm would require a single federal inspector to inspect three carcasses per second—an impossible task. Although microbial contamination remains invisible to the naked eye, the new speeds are likely to increase the stress, fatigue, and potential for injury of poultry plant workers. Workers in the poultry industry are already at risk for chronic pain disorders, severe

[72] Kim, K. Y., J. F. Frank, S. E. Craven. (1996). Three-dimensional visualization of *Salmonella* attachment to poultry skin using confocal scanning laser microscopy. *Lett Appl Microbiol*. 22(4):280-282.

[73] Per 9 CFR § 381.91(b).

[74] Blankenship, L. C., *et al*. (1993). Broiler Carcass Reprocessing, A Further Evaluation. *J Food Prot.* 56(11):983-985.

[75] Both the reprocessed carcasses (with VGC) and those not reprocessed, or "conventionally processed," (without VGC) contained similar amounts of non-visible fecal material.

[76] Lillard, H. S. (1988). Comparison of Sampling Methods and Implications for Bacterial Decontamination of Poultry Carcasses by Rinsing. *J Food Prot.* 51(5):405-408.

injuries, and unsafe chemical exposures.[77] Driving line speeds up will exacerbate these risks and will undoubtedly lead to an increase in human errors that further compromises food safety.

iii. *Salmonella* and Poultry – The Adulterant's Public Health Threat in Cross Contamination

Poultry products contaminated with Outbreak Serotypes of *Salmonella* represent serious hazards to public health. These risks are aggravated by the fact that consumers do not know how to properly handle chicken to avoid cross-contamination.[78] A recent survey of consumers has revealed an alarming trend in at-home food handling practices: 98% of Hispanic participants, 93% of African American participants, 91% of Asian participants, and 82% of Caucasian participants reported washing whole poultry prior to cooking it.[79] Similar trends were observed for small cuts of poultry: 100% of Hispanics, 95% of African Americans, 91% of Asians, and 84% of Caucasians indicated that they wash small cuts of poultry. Numerous studies reported similar figures; a 2015 survey indicated that 70% of American consumers wash or rinse raw poultry before cooking it.[80] Washing whole carcasses and cuts of poultry is an unsafe practice because contaminated droplets of water can disperse up to 50 centimeters in front and 70 centimeters to either side of a sink in which poultry is washed. The splashing of contaminated aerosols may transfer pathogens to other foods and food contact surfaces. *Salmonella* can persist on kitchen surfaces for extensive periods of time and lead to cross-contamination. A study by Kosa *et al*. also revealed that over half of Americans believe that it is uncommon to acquire a foodborne illness in a home setting.[81] Yet, the

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[77] "Inspection Guidance for Poultry Slaughtering and Poultry Processing Establishments." *United States Department of Labor*, 2015.

[78] Oosterom, J., S. Notermans, H. Karman, G. B. Engels. (1983). Origin and Prevalence of Campylobacter jejuni in Poultry Processing. *J Food Prot*. 46(4):339-344.

[79] Henley, S. C., S. E. Stein, J. J. Quinlan. (2015). Characterization of raw egg and poultry handling practices among minority consumers. *Brit Food J*. 117(12):3064-3075.

[80] Kosa, K. M., S. C. Cates, S. Bradley, E. Chambers IV, S. Godwin. (2015). Consumer-Reported Handling of Raw Poultry Products at Home: Results from a National Survey. *J Food Prot*. 78(1):180-186.

[81] See *Id.*

complete opposite is true; food safety experts estimate that the home is the primary location where outbreaks occur. Furthermore, the study shows that only 17% of participants know how to store poultry correctly (*i.e.*, "in a plastic bag or sealed container on the bottom shelf of the refrigerator").

Another significant food safety concern is that a vast majority of consumers do not know how to properly cook chicken to reduce microbial contamination. Researchers estimate that only 19-20% of people use a thermometer to check the temperature of chicken while it is being cooked and to verify the internal temperature of the final product.[82] As little as 12% of people use a thermometer to measure the internal temperature of smaller cuts of poultry and ground poultry.[83] A recently published review paper that encompasses eighty-five prior studies concluded that many participants believe that using a thermometer while cooking chicken is not necessary.[84] Four barriers were identified for respondents in this category: "(i) preference for alternative techniques, (ii) mainstream media and food professionals seldom serve as role models and often negate the need for food thermometers, (iii) limited awareness of potential health issues associated with current practices, and (iv) limited knowledge and awareness related to thermometer usage for specific food groups." Using a food thermometer is the only reliable method to ensure that any foodborne pathogen is destroyed. Therefore, verifying the internal temperature of all chicken products is, in fact, a necessity, but a measure that is too often ignored.

Numerous people use visual cues to determine whether the chicken they are preparing is thoroughly cooked and ready to be consumed. However, studies show that participants often mistakenly believe that chicken is thoroughly cooked when, in fact, it is improperly cooked or

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[82] Henley, S. C., S. E. Stein, J. J. Quinlan. (2015). Characterization of raw egg and poultry handling practices among minority consumers. *Brit Food J*. 117(12):3064-3075.

[83] Kosa, K. M., S. C. Cates, S. Bradley, E. Chambers IV, S. Godwin. (2015). Consumer-Reported Handling of Raw Poultry Products at Home: Results from a National Survey. *J Food Prot.* 78(1):180-186.

[84] Feng, Y., C. M. Bruhn. (2019). Motivators and barriers to cooking and refrigerator thermometer use among consumers and food workers: A review. *J Food Prot*. 82:128-150.

even raw. In one study, 70% of chicken pieces that were judged by consumers as "done" had not reached safe internal cooking temperatures.[85] Jarvis *et al*. showed that participants incorrectly label raw breaded chicken pieces as "fully cooked" whenever a golden outer color is observed.[86]

In 2009, a group of researchers sought to determine whether consumer intent translates into actual safe food handling behavior. Study results indicated that, not only was there a clear discrepancy between observational and self-reported data, but every participant, without exception, implemented unsafe food handling practices.[87] While nearly 20% of participants reported using a thermometer, only 7% were observed doing so correctly. Two individuals failed to remove protective casings prior to taking internal temperature readings.

Although poultry products are not ordinarily eaten raw or "pink," *Salmonella* outbreaks remain a significant concern—even in thoroughly cooked poultry products—due to the risk of cross-contamination. The incidence of *Salmonella* cross-contamination in poultry products has been recognized for nearly sixty years. A 1960 paper titled "The *Salmonella* Problem" acknowledged that "the improper handling of food" is a contributing factor "in most outbreaks of salmonellosis."[88] In 1963, Kampelmacher wrote, "In contrast to red meat, raw poultry is not consumed or prepared in any country. The danger lies in the processing, starting with the producers of poultry products and ending with the consumer. […] In the kitchen, infected poultry can lead to contamination of other food, especially if evisceration is done in the home."[89] The following year, in 1964, Woodburn concurred, "Since the meat is usually cooked to the well-done stage, the

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[85] Kosa, K. M., S. C. Cates, S. Bradley, E. Chambers IV, S. Godwin. (2015). Consumer-Reported Handling of Raw Poultry Products at Home: Results from a National Survey. *J Food Prot.* 78(1):180-186.

[86] Jarvis, N. A., *et al*. (2016). An overview of *Salmonella* thermal destruction during food processing and preparation. *Food Control*. 68:280-290.

[87] DeDonder., S., *et al*. (2009). Self-reported and observed behavior of primary meal preparers and adolescents during preparation of frozen, uncooked, breaded chicken products. *Brit Food J*. 111(9):915-929.

[88] Flippin, H. F., G. M. Eisenberg. (1960). The *Salmonella* Problem. *Trans Am Clin Climatol Assoc*. 71:95-106.

[89] Kampelmacher, E. H. (1963). Public Health and Poultry Products. *Brit Vet J*. 119(3):110-124.

consumption of poultry contaminated as the raw bird is less of a problem than the possible cross-contamination of the cooked product from the raw."[90] In a 2009 study, Luber concluded that cross-contamination in poultry products is of even greater importance than the risk associated with undercooking.[91]

Some *Salmonella* serovars also possess thermal resistant properties. Thermal resistance, and subsequent pathogenicity, is dependent on many factors including matrix, fat and protein content of the food, and *Salmonella* serotype. Therefore, recommended cooking temperatures may not always be successful in ridding a product of *Salmonella* and other harmful pathogens. Jarvis *et al*. showed that there can be "considerable differences in the time required for inactivation of *Salmonella*" depending on fat levels, even within the same bird species.[92] Dawoud *et al*. demonstrated that serotypes of the same species can respond differently to similar heat treatments and can survive over a wide range of temperatures. A particularly heat-resistant serotype of *Salmonella* Senftenberg (*S.* Senftenberg ATCC 43845) was found to survive at 80$_{o}$C for up to 24 hours.[93] Other conditions, such as fluctuating water activity levels and the addition of solutes (*e.g.*, sugar, salt), also affect thermal resistance levels. Preexposure to growth conditions and stress prior to thermal treatment can increase survival capability during processing. Heat-shocked cells, starved cells, desiccated cells, and those grown on carbon sources exhibit more thermal tolerance.

In summation, because the muscle tissue of healthy chickens and turkeys is sterile, *Salmonella* are not naturally occurring in or on poultry end products. Therefore, *Salmonella* is an

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[90] Woodburn, M. (1964). Incidence of Salmonellae in Dressed Broiler-Fryer Chickens. *Appl Microbiol*. 12(6):492-495.

[91] Luber, P. (2009). Cross-contamination versus undercooking of poultry meat or eggs – which risks need to be managed first? *Int J Food Microbiol*. 134:21-28.

[92] Jarvis, N. A., *et al*. (2016). An overview of *Salmonella* thermal destruction during food processing and preparation. *Food Control*. 68:280-290

[93] Chen, Z., *et al*. (2013). Thermal Inactivation of Desiccation-Adapted *Salmonella* spp. in Aged Chicken Litter. *Appl Environ Microbiol*. 79(22):7013-7020.

"added substance" in poultry end products within the meaning of 21 U.S.C. § 453(g)(1). Poultry cross-contamination commonly occurs during the slaughter and dressing of carcasses, specifically during defeathering and evisceration. In an effort to address this problem, FSIS implemented a strict no-VGC policy. Unfortunately, *Salmonella* contamination occurs at the microscopic level, and therefore, the visual carcass-by-carcass inspections mandated by the USDA since the mid-1950s are incapable of addressing current and developing food safety threats. Additionally, VGC-contaminated carcasses are often reprocessed using inefficacious washing methods.

Despite the countless outbreaks, massive recalls, and tragic consequences caused by the *Salmonella* Outbreak Serotypes, FSIS continues to treat *Salmonella* as an "indicator organism" and refuses to take the preventive approach necessary to mitigate outbreaks and deaths, instead opting to continue using ineffective reactionary methods.[94] *Salmonella*-tainted poultry products regularly end up in the hands of inexpert consumers. Research has shown that consumer mishandling spreads harmful pathogens in the home setting, which may lead to outbreaks.[95] Although cross-contamination is a more significant hazard than undercooking, studies also indicate that a vast majority of consumers do not know how to properly cook chicken. The mass

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[94] The USDA-FSIS's current performance standards, discussed in a study by the Meat and Poultry Dialogue Group, vividly demonstrate how inadequate the reactionary approach to recognizing *Salmonella* adulteration is in light of the regulatory body's duty to protect consumer health and welfare. The performance standard for *Salmonella* in ground chicken, for example, is 13 positives out of 52 samples, meaning that establishments with more than 13 positives in the 52 samples set are considered to have failed the performance standards. Thus, if a facility has 12 samples of ground chicken (or 23% of the samples) that test positive for *Salmonella*, the performance standard is passed. Further, even though establishments know that products contain the pathogen, "individual products in a sample set that test positive for *Salmonella* can still be sold to consumers without restrictions" because the products are only deemed unfit for sale *once a person become ill* after consuming the product.

[95] Notably, the FDA and CDC recently encountered the dangerous reality of *Salmonella* cross-contamination in the 2019 "pig ear dog treat" outbreak. By October 30, 2019, 154 people in 34 states were infected with multiple outbreak strains of *Salmonella* (including *Salmonella enterica* serotypes I 4,[5],12:i:-, Cerro, Derby, Infantis, London, Newport, and Rissen) which were traced back to "contact with pig ear dog treats." Advice provided on the CDC's website included washing any areas that held the implicated pig ears and washing hands after handling any such items in those areas. *See* "Outbreak of Multidrug-Resistant *Salmonella* Infections Linked to Contact with Pig Ear Dog Treats," CENTERS FOR DISEASE CONTROL AND PREVENTION (Oct. 30, 2019). *Available at* https://www.cdc.gov/salmonella/pet-treats-07-19/index.html.

education campaigns led by USDA-FSIS have failed and, overall, the current system is inadequate and flawed, representing an unmet threat to the public health.

D. Meat Products

i. Steven Romes, *Salmonella* Newport, 2018

In 2018, Steven Romes, of Gilbert, Arizona, was a healthy and athletic husband, father, and insurance underwriter. On September 3 of that year, he consumed medium-to-well done hamburgers as part of a Labor Day family cookout. Two days later, Steven fell violently ill with painful diarrhea, fever, and stomach cramps. Over the next few days, Steven's symptoms worsened. He was unable to consume any solids and was forced to lay on his bathroom floor because he did not have the strength to crawl back into bed after severe bouts of diarrhea and vomiting. On September 8, 2018, after his diarrhea progressed to bloody stools, Steven was rushed to the emergency room.

Urine tests in the emergency room revealed that Steven was suffering from acute kidney injury. He was admitted to the hospital and his illness was determined to be one of many illnesses in a nationwide outbreak of *Salmonella* Newport linked by public health officials to various ground and non-intact beef products manufactured by JBS USA, the world's largest meatpacker. The outbreak spurred one of the largest-ever recalls of ground beef—over 12 million pounds of ground beef, the meat of an estimated 13,000 animals, were recalled. The recall affected nearly 50 different JBS product lines, including its Grass Run Farms "100% Grass Fed Beef" line and its Cedar River Farms "Natural Beef" line. 255 cases[96] of *Salmonella* were identified across 32 states, 29% of

[96] A "case" was defined as "isolation of the outbreak strain [of *Salmonella*] from a patient during June 2018—March 2019," and an isolate was classified as an "outbreak strain" if it fell within the multidrug resistant clad (0-11 alleles by core genome multilocus sequencing type[cgMLST]). Plumb, I.D., *et al*. (2019). Outbreak of *Salmonella* Newport Infections with Decreased Susceptibility to Azithromycin Linked to Beef Obtained in the United States and Soft Cheese Obtained in Mexico — United States, 2018–2019. *MMWR Morb. Mortal Wkly Rep*. 68(33):713-717.

patients for whom information was available were hospitalized, 6% were admitted to an intensive care unit, and two died.[97]

Fourteen months before the recall, the decades old Tolleson, Arizona plant at the center of the outbreak had received numerous complaints of "egregious" livestock conditions. In July of 2017, FSIS issued a notice to Andre Noqueira, CEO and president of JBS Tolleson, Inc. accusing him of enabling "inhumane handling and slaughtering" practices at his facility.[98] The report states that, during a routine inspection, officials observed a number of "nonambulatory cows […] lying in distress." One cow was described as "mentally incoherent, having difficulty breathing, and repetitively making a kicking motion with its legs while moaning as if in pain." Despite these dreadful conditions, JBS was allowed to continue producing meat for human consumption.

JBS USA's most recent public safety recall is, unfortunately, not their first. In February of the same year, Pilgrim's Pride Corporation, a Texas-based company operated by JBS USA, recalled more than 101,310 pounds of breaded chicken patties due to potential foreign-matter contamination.[99] In May of 2018, a JBS establishment in North Carolina recalled over 35,000 pounds of raw ground beef products due to plastic contamination.[100] However, unlike the February and May recalls, the October 2018 Tolleson ground beef recall is widely believed to be the consequence of a much more sinister side of the beef industry.

Although JBS and FSIS failed to provide detailed information regarding the original source of the *Salmonella* Newport outbreak, it is highly probable that the contamination was a result of blending tainted dairy cow meat with untainted meat.[101] Since the mid-1980s, dairy cows have

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[97] *Id.* at 1-2.

[98] "Notice of Intended Enforcement." *United States Department of Agriculture*, 2017.

[99] "News Release: Pilgrim's Pride Corporation Recalls Ready-to-Eat Chicken Products due to Possible Foreign Matter Contamination." *United States Department of Agriculture*, 2018.

[100] "News Release: JBS USA, Inc. Recalls Ground Beef Products Due to Possible Foreign Matter Contamination." *United States Department of Agriculture*, 2018.

[101] Plumb, I.D., *et al.*, at 3.

been identified as the primary reservoirs of *Salmonella enterica* serotype Newport. A paper published by the World Organization for Animal Health in 1997 referred to dairy cows as "the source of *Salmonella* Newport-contaminated hamburgers causing foodborne illness." Similarly, a CDC Morbidity and Mortality Weekly Report from April 2018 confirmed that dairy cows were the "ultimate outbreak source" of a multistate ground beef outbreak which lasted from October 2016 to July 2017 and claimed one life.[102]

Sick dairy cows are more likely than healthy ones to be "culled," or sold for meat. At large-scale, intensive dairy facilities, productivity is the name of the game. Dairy farmers must ensure that their cows are producing as much milk as possible. If their output drops for any reason, cows are sold to the meat industry and replaced. In the beef industry, dairy cow meat is commonly ground up and used as a padding ingredient in millions of patties; it is estimated to make up to 20 percent of the U.S. ground beef market.[103] A 2012 study revealed that "lean beef trimmings from cull cows are often blended with high-fat content beef trimmings […] to facilitate a consistent supply of ground beef that meets certain purchase specifications."[104] This process is normally of minimal concern but when the filler product—dairy cow meat—harbors *Salmonella*, the consequences can be disastrous.

Steven Romes was, and remains, a victim of those consequences. After a colonoscopy and three-day in-patient stay at the Dignity Health Mercy Gilbert Medical Center, Steven was finally discharged from the hospital. Unfortunately, his normal bowel habits and appetite never returned,

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[102] "Protracted Outbreak of *Salmonella* Newport Infections Linked to Ground Beef: Possible Role of Dairy Cows." *Centers for Disease Control and Prevention*, 2018.

[103] "Your Beef Checkoff Investment – Helping You Maximize Dairy Market Cow Value." *Cattlemen's Beef Board*.

[104] Loneragan, G. H., *et al*. (2012). *Salmonella* diversity and burden in cows on and culled from dairy farms in the Texas High Plains. *Foodborne Pathog Dis*. 9(6):549-555.

and he was diagnosed with Irritable Bowel Syndrome. Today, Steven can only tolerate bland foods and he still occasionally suffers from stomach cramps and diarrhea.

ii. The Porter Family, *Salmonella* I 4,[5],12:i-, 2015

On the afternoon of June 28, 2015, Rose and Roger Porter hosted a going away party at their home in Rainier, Washington. The Porters planned on moving to Costa Rica and wanted to celebrate with their family and friends one last time.

On June 27, Rose Porter picked up a whole hog from Stewart's Meats in McKenna, Washington. The next day, Rose cooked the pig just the way she was told to by Stewart's. Hours later, the Porters' home was filled with friends and family, many of whom were about to become seriously ill with *Salmonella* poisoning. It all seemed so easy and matter of fact in retrospect, as Rose recalls:

> When [the whole roasted hog] was done, I served it up. After everyone left, I cleaned everything up and threw out any food that was left over. We packed everything up and went to bed. The next day, I woke up with explosive diarrhea. I had a very busy day because we were packing up to move to Costa Rica. I had to get out of our house because we had renters coming in. I had to find us a hotel and I was dealing with my daughter not feeling well at all. She went with me for the day because she wanted to sleep in a bed at a hotel. I had to stop every half hour to use the bathroom. The diarrhea kept up.

Once Rose and Mikayla arrived at the hotel, all Mikayla could do was lie down and watch television. She fell asleep at 6 PM. By 2:30 AM, she was up and vomiting. Mikayla woke her mom up and, at 4:30 AM on June 30, they both headed to Providence St. Peter Hospital in Olympia, Washington. Joseph Pellicer, MD, was on duty in the emergency hospital and listed Mikayla's chief complaints as "abdominal pain, emesis, diarrhea, and fever." Rose explained that Mikayla had been sick since the morning before with severe diarrhea. By the evening, Rose stated that Mikayla "felt like she was on fire." Mikayla also described having shaking chills with fever and

Rose told Dr. Pellicer that she was having similar symptoms. Mikayla was miserable, wracked with body aches and pain that radiated up into both of her shoulders.

Dr. Pellicer did an exam and found Mikayla tachycardic with a heart rate of 125 and a diffusely tender abdomen. The doctor also observed that Mikayla was dehydrated with turbid urine, ketonuria, proteinuria, and dry mucus membranes. Despite these clinical symptoms, no cultures were sent to the lab and no stool sample was collected. Dr. Pellicer diagnosed Mikayla with "acute gastroenteritis." Just after 8 AM, he discharged Mikayla from the ER with a prescription for an antiemetic drug and clearance to travel to Costa Rica.

On July 2, 2015, the Porters landed in Costa Rica. Mikayla was still suffering from frequent bouts of diarrhea. Upon logging in to a social media website, Rose discovered that a party attendee's daughter was being hospitalized for *Salmonella* poisoning. Rose decided to take her daughter to the local ER—Beach Side Emergency Clinic in Santa Cruz Guancaste. Andrea Messeguer, MD, the medical director of the clinic, evaluated Mikayla and noted that she was lethargic with persistent abdominal pain in the periumbilical area. Because Mikayla was currently afebrile and able to orally hydrate, Dr. Messeguer told Rose she could watch her daughter at home.

Over the next day, Mikayla did little but drink ice water, sleep, and go to the bathroom. Unfortunately, things soon took a turn for the worse. Rose recalls:

> She started crying in the bathroom that she could not bear the stomach pains anymore and needed to go back to the doctor. She told me that she had blood coming out of her butt, that it had been that way for a while, and that she didn't know what to do. The amount of time between her going to the bathroom went from every 20 to 30 minutes to every five to 10 minutes. She was screaming in pain in the bathroom. She said that she felt like someone was stabbing her over and over again in the stomach.

On July 3, Rose brought Mikayla back to see Dr. Messeguer at the urgent clinic and told the doctor that there was now mucus and blood in her daughter's stools. Dr. Messeguer examined

Mikayla and performed a stool smear and culture. While at the clinic, Mikayla's diarrhea decreased in frequency and she was still holding down fluids, so the doctor diagnosed her with "bacterial gastroenteritis" until proven otherwise and sent her home.

It was not long before it was clear that Mikayla's condition was deteriorating. By the morning of July 4, her stools were entirely bloody. Rose, once again, rushed her back to the urgent care clinic. Upon their arrival, Dr. Messeguer asked to speak to Rose privately. She informed her that Mikayla was losing a lot of blood and may need a blood transfusion. However, the clinic did not have the equipment or resources necessary to perform the procedure. Dr. Messeguer told Rose that her daughter could die on the four to five-hour drive to Hospital CIMA San Jose, and therefore, Mikayla would need to be airlifted there.

Rose and Mikayla were both transported by helicopter to Hospital CIMA San Jose in Costa Rica. According to a memorandum written by Luis Picado, MD, Mikayla presented with a high-grade fever, bloody stools, general malaise, and moderate dehydration. He wrote, "On admission, she presented with clear signs of bacterial gastroenteritis and required intravenous rehydration and parenteral antibiotics to control the infection. Stool studies were positive for *Salmonella*."

Rose does not require a formal medical record to recall how things went for her daughter over the next several days. The memory is still fresh in her mind:

> For the next three days, I sat back and watched as my daughter cried in pain. I changed her bloody sheets when she couldn't make it to the bathroom. I didn't sleep for the first couple nights because I was so scared that she wouldn't wake up. [Mikayla] couldn't process food or water. The doctor told me that the bacteria had gotten into her system and shut it down completely. When she ate or drank, it would go straight through her. She wasn't getting any nutrition or hydration.
>
> The good news is that she is out of the hospital now. We have cut all pork out of our diets and are fearful of chicken and eggs. I have dealt with a husband over in Afghanistan and this was still the scariest thing I have ever been through. I can't say that I know what it is like to have a child die, but I do know what it is like to see a child on their deathbed.

> I have spent the last couple of months going over every detail that has happened over those two weeks. I felt totally responsible when this happened. I had to question all of my decisions as a mother. I felt like I poisoned my own child and everyone else that ate at my house. I lost friends from all of this. It was weeks later that I found out that, in the end, it wasn't my fault.

During the time of Mikayla's illness, Rose and Roger had their own *Salmonella* illnesses to contend with. On the helicopter ride to the hospital in San Jose, Rose's blood pressure plummeted, and she lost consciousness. Roger had gastroenteritis with uncontrollable diarrhea for several days. Rose and Roger still suffer from periodic bouts of diarrhea to this day.

The Porters were three of 152 diagnosed victims of a nationwide outbreak of multidrug resistant *Salmonella* I 4,[5],12:i:-. Stewart Meats' distributor of whole hogs was Kapowsin Meats. Laboratory testing of environmental samples at Kapowsin Meats by the Washington State Department of Health confirmed the presence of *Salmonella* I 4,[5],12:i:- in the facility. As a result of the investigation, Kapowsin Meats voluntarily recalled 523,380 pounds of pork products.

iii. ***Salmonella*** **in Beef and Pork – A Public Health Threat**

Salmonella illnesses and outbreaks are commonly attributed to raw meat and by-products of beef and pork. Between the years 1973 and 2011, one hundred of nearly 2,000 *Salmonella* outbreaks in the United States were traced back to beef, leading to 3,684 illnesses.[105] *Salmonella* is omnipresent on the hides and in the gut of feedlot cattle. A 2019 epidemiological study has revealed that 9.2% of cattle and 18.2% of beef contain the pathogen.[106] Another recent study has estimated that the gram-negative bacteria is present in up to 16% of North American cattle.[107] In a

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[105] Laufer, A. S., J. Grass, K. Holt, J. M. Whichard, P. M. Griffin, L. H. Gould. (2015). Outbreaks of *Salmonella* Infections Attributed to Beef – United States, 1973-2011. *Epidemiol Infect*. 143(9):2003-2013.

[106] Tegegne, F. M. (2019). Epidemiology of *Salmonella* and its serotypes in human, food animals, foods of animal origin, animal feed and environment. *J Food Nutr Health*. 2(1):7-14.

[107] Gutema, F. D., *et al*. (2019). Prevalence and Serotype Diversity of *Salmonella* in Apparently Healthy Cattle: Systematic Review and Meta-Analysis of Published Studies, 2000-2017. *Front Vet Sci*. 6:102.

2007 study by Stephens *et al*., *Salmonella* was isolated from all of the animals sampled, while *Escherichia coli* O157:H7 was only isolated from 42.5% of the animals.[108] Notably, 94% of oral cavity samples, 94% of hock samples, 88% of perineum samples, 86% of ventrum samples, 76% of back samples, and 74% of flank samples tested positive for *Salmonella*.

Contaminated pork also accounts for numerous foodborne *Salmonella* infections in the United States.[109] The 2015 annual report on foodborne illnesses in the U.S., published by CDC, revealed that pork meat was the second most important source of foodborne salmonellosis outbreaks.[110] In pork meat, pigs and swine, and the swine farm environment, the prevalence of *Salmonella* was 39.6%, 17.7%, and 7.9%, respectively.[111]

Cargill, Inc., the largest privately held corporation in the United States,[112] has been implicated in several *Salmonella* outbreaks, particularly in ground beef and turkey products. In 2012, *Salmonella* Enteritidis-tainted ground beef produced by Cargill sickened 40 people in eight states. In August of 2011, Cargill Meat Solutions recalled 36 million pounds of *Salmonella*-contaminated ground turkey after 136 persons from 34 states fell ill. In 2009, *Salmonella*-tainted ground beef produced at Beef Packers, a California-based plant owned by Cargill, sickened 68 people in 15 states.

The industry giant generates a large portion of its 115 billion-dollar yearly revenue from the manufacture and sale of USDA-regulated products including meat, poultry, and egg products. Cargill supplies nearly a quarter of the domestic meat market. All eggs used in U.S. McDonald's

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[108] Stephens, T. P., *et al*. (2007). Distribution of *Escherichia coli* O157 and *Salmonella* on Hide Surfaces, the Oral Cavity, and in Feces of Feedlot Cattle. *J Food Prot*. 70(6):1346-1349.

[109] Pires, S. M., A. R. Vieira, T. Hald, D. Cole. (2014). Source Attribution of Human Salmonellosis: An Overview of Methods and Estimates. *Foodborne Pathog Dis*. 11(9):667-676.

[110] Campos, J., J. Mourao, L. Peixe, P. Antunes. (2019). Non-typhoidal *Salmonella* in the Pig Production Chain: A Comprehensive Analysis of Its Impact on Human Health. *Pathogens*. 8(1):19.

[111] Tegegne, F. M. (2019). Epidemiology of *Salmonella* and its serotypes in human, food animals, foods of animal origin, animal feed and environment. *J Food Nutr Health*. 2(1):7-14.

[112] "America's Largest Private Companies." *Forbes*, 2018.

restaurants pass through their plants. It is safe to say that Cargill, Inc. has dealt with and felt the repercussions of foodborne illness. It is also safe to assume that Cargill has little financial incentive to advocate for more stringent food safety measures. However, Cargill has and continues to publicly promote the implementation of more modern, science-based measures.

In 2014, the Pew Charitable Trusts, a non-profit, non-governmental organization, partnered with Cargill, Inc. to develop a set of recommendations to "improve the food-safety oversight system for meat and poultry" and to "transform the current system into one that is more science- and risk-based."[113] The two companies enlisted Meridian Institute to design and facilitate a multi-stakeholder dialogue process, in which twenty high-ranking persons from different industry sectors participated. Appendix A of Meridian Institute's final report, published in June of 2017, identifies these participants—among them: Todd Bacon, Senior Director of Quality Systems for McDonald's Corporation; Jon Hixson, Vice President of Corporate Affairs for Cargill; Mike Robach, Vice President of Corporate Food Safety for Cargill; and Rick Roop, Senior Vice President of Food Safety and Quality Assurance for Tyson Foods. [114]

The final report also disclosed the results of the dialogue; the executive summary states, "Cargill, Inc., and the Pew Charitable Trusts identified the following reasons for believing that the time was ripe for this initiative:

(1) Public-health-based: while there has been some progress, meat and poultry products remain **significant vehicles for foodborne illnesses** in the United States;

(2) Science-based: the inspection system developed more than 100 years ago **does not employ the most science-based means to protect consumers** from pathogenic contamination;

[113] "Recommendations to Modernize the Meat and Poultry Oversight System in the United States – Developed by the Meat and Poultry Dialogue Group." *Meridian Institute*, 2017.

[114] *Id.* at 38.

(3) Fiscal: taxpayers spend $1 billion each year on an inspection system that **cannot effectively assure the desirable level of safety**."[115]

The twenty participants (from Cargill, McDonald's, Tyson Foods, and The Kroger Company, among others) also discussed the state of the current regulatory system overseeing meat and poultry products in the United States. The report states 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." Indeed, the current inspection activities, which were implemented over a century ago, are outdated and vastly inadequate. At the beginning of the twentieth century, the largest food-safety risks—brucellosis, tuberculosis, and trichinellosis—could be detected and controlled using traditional organoleptic methods. However, as previously stated, *Salmonella* contamination cannot be detected organoleptically.

The muscle masses of healthy cattle and swine are sterile with the exception of small amounts of *Clostridia*.[116] Therefore, bacterial cross-contamination of intact muscle products must occur from extrinsic sources (*e.g.*, lymph nodes, gastrointestinal tract, and external carcass surfaces) during the slaughtering process. Because the presence of *Salmonella* in meat end products is a result of cross-contamination, *Salmonella* is an "added substance" in whole muscle beef and pork per 21 U.S.C. § 601(m)(1).

Two of the slaughtering steps of cattle and swine, dehiding and evisceration, are particularly likely to cause cross-contamination and introduce harmful pathogens to whole muscle end products. In a study by Fegan *et al.*, *Salmonella* was isolated from 68% of cattle hides in an

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[115] *Id.* at 2.
[116] Gill, C. O. (1979). A Review: Intrinsic Bacteria in Meat. *J Appl Bacteriol*. 47:367-378.

abattoir.[117] A larger study reported the results of numerous samplings; in nearly 100% of cases, cattle hides tested positive for the presence of *Salmonella*.[118] The study, conducted by Narvaez-Bravo *et al*., also determined that there was a positive correlation between the prevalence of *Salmonella* on the hides and the prevalence of the pathogen on the carcasses. The dehiding, or skinning, process is considered to be the primary contamination factor of cattle carcass surfaces. Similarly, hide removal is a significant source of contamination in the pork production chain. A 2013 report published by the National Pork Board states that "[the hide removal process] offers many opportunities to contaminate the carcass, in part because there is no prior treatment of the hide to remove contamination. As a result, the mechanical process of removing the hide may result in sporadic, random contamination of the edible tissue underneath."[119]

Evisceration takes place further down the slaughter line. As in poultry production, this step also carries a sizeable risk of contamination in cattle and pork. In cattle production, workers must take great care during evisceration to ensure that the intestinal tract and rumen of the animals are not punctured. Punctures often lead to the release of feces and/or ingesta, which may cause gastrointestinal cross-contamination of sterile muscle tissues. Narvaez-Bravo *et al*. indicated that nearly half of the intestinal feces collected from cattle contain *Salmonella*.[120]

During the slaughter of swine, the dehairing and polishing processes may also result in cross-contamination. Prior to being eviscerated, the animal carcasses undergo several sequential processing steps: scalding, dehairing, singeing, and polishing (in this order). Scalding loosens the

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[117] Stephens, T. P., G. H. Loneragan, T. W. Thompson, A. Sridhara, L. A. Branham, S. Pitchiah, M. M. Brashears. (2007). Distribution of *Escherichia coli* O157 and *Salmonella* on Hide Surfaces, the Oral Cavity, and in Feces of Feedlot Cattle. *J Food Prot*. 70(6):1346-1349.

[118] Narvaez-Bravo, C., *et al*. (2013). *Salmonella* and *Escherichia coli* O157:H7 Prevalence in Cattle and on Carcasses in a Vertically Integrated Feedlot and Harvest Plant in Mexico. *J Food Prot*. 76(5):786-795.

[119] "*Salmonella* in the Pork Production Chain." *National Pork Board*, 2013.

[120] Narvaez-Bravo, C., *et al*. (2013). *Salmonella* and *Escherichia coli* O157:H7 Prevalence in Cattle and on Carcasses in a Vertically Integrated Feedlot and Harvest Plant in Mexico. *J Food Prot*. 76(5):786-795.

hair in the follicle to allow for easy dehairing. While scalding reduces the microbial load, dehairing significantly increases it. The dehairing equipment is a known reservoir of bacterial contamination because its moving parts are notoriously difficult to clean. In 1993, Gill and Bryant reported that dehairing machines could contain populations of *Salmonella* as high as 100,000 per one gram of detritus material.[121] Bacteriological examinations revealed that 41% of cultures taken from a dehairing machine in a large abattoir tested positive for *Salmonella*.[122] In the same study, conducted in 1954, cultures taken from animals post-scalding (right before entering the dehairing machine) tested negative for *Salmonella*. Immediately after passing through the machine, a high percentage of the carcasses were positive for *Salmonella*. The researchers concluded that "it was apparent that the skins of many animals were inoculated with *Salmonella* as they passed through the dehairing machine." They also pointed out that "the meat processing industry clearly has sanitary problems difficult to control."[123]

The high levels of contamination are attributed to the mechanical action of the dehairing paddles, which introduces bacteria into the skin surface by scratching.[124] Furthermore, as each carcass passes through the machine, it is vigorously rotated with a tossing action. In the process, fecal material is "pressed out" of the relaxed anus, contaminating an otherwise uncontaminated carcass.

The subsequent step in the slaughtering process, known as singeing or flaming, somewhat reduces the microbial load. Unfortunately, the polishing process severely recontaminates the carcasses immediately after. Polishing removes any residual hair from previous operations. It also

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[121] Gill, C. O., J. Bryant. (1993). The contamination of pork with spoilage bacteria during commercial dressing, chilling and cutting of pig carcasses. *Int J Food Microbiol*. 16:51-62.

[122] Galton, M. M., W. V. Smith, H. B. McElrath, A. B. Hardy. (1954). *Salmonella* in Swine, Cattle and the Environment of Abattoirs. *J Infect Dis*. 95(3):236-245.

[123] Galton, M. M., W. V. Smith, H. B. McElrath, A. B. Hardy. (1954). *Salmonella* in Swine, Cattle and the Environment of Abattoirs. *J Infect Dis*. 95(3):236-245.

[124] "*Salmonella* in the Pork Production Chain." *National Pork Board*, 2013.

severely increases the risk of surface contamination. Polished carcasses are four times more likely to be contaminated with *Salmonella* than carcasses that do not undergo polishing.[125] The complex polishing machinery, composed of scrapers and other rubber elements, can accumulate large quantities of dirt (*e.g.*, hairs and parts of the epidermis) if it is not effectively cleaned and/or disinfected.[126] If the equipment is improperly sanitized, large numbers of bacteria can develop overnight, turning the scrapers into continuous sources of contamination.

Although the above information regarding cross-contamination in meat processing is alarming, research indicates that cross-contamination from gastrointestinal leakage, lymph nodes, or machinery may not be the most disconcerting cause of *Salmonella* contamination. Indeed, the fact that consumers, restaurant managers, and chefs do not know how to handle and cook meat adequately may be the most distressing of all potential contamination factors. The long-held speculation that mishandling is a prevalent cause of *Salmonella* contamination in home and restaurant-type settings has been extensively studied, especially in ground meat products.

Phang and Bruhn reported that close to 90% of people are unaware of the FSIS-recommended internal temperature of 160^{o}F, or 71.1^{o}C, for ground beef.[127] In their study, participants were instructed to prepare burgers in the way that they normally would while knowingly being video recorded. The results were alarming: an average of 43 potential cross-contamination events were observed per household and consumers with and without food safety training exposed themselves to potential foodborne illness.

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[125] Sanchez-Rodriguez, J. A., *et al*. (2018). New insights on the risk factors associated with the presence of *Salmonella* on pig carcasses—Lessons from small slaughterhouses. *Food Control*. 87:46-52.

[126] Huis in't Veld, J. H. J., R. W. A. W. Mulder, J. M. A. Snijders. (1993). Impact of Animal Husbandry and Slaughter Technologies on Microbial Contamination of Meat: Monitoring and Control. *Meat Sci*. 36:123-154.

[127] Phang, H. S., C. M. Bruhn. (2011). Burger Preparation: What Consumers Say and Do in the Home. *J Food Prot*. 74(10):1708-1716.

Another study conducted by the Environmental Health Specialists Network (EHS-Net) uncovered staggering figures. The research study, conducted in restaurants from eight states (one restaurant per state), exposed the food handling practices of restaurant managers across the country. Many of the managers who were interviewed (65%) indicated that they had been working in the food service industry for over 15 years.[128] Despite their experience, the managers being interviewed also 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.[129]

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. Because these erroneous food handling practices carry high potential risks for *Salmonella* cross-contamination, these findings are particularly worrisome (especially since it is estimated that 80% of Americans

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[128] Bogard, A. K., C. C. Fuller, V. Radke, C. A. Selman, K. E. Smith. (2013). Ground Beef Handling and Cooking Practices in Restaurants in Eight States. *J Food Prot*. 76(12):2132-2140.

[129] "Color of Cooked Ground Beef as It Relates to Doneness." *United States Department of Agriculture*, 2013.

eat out at least once per week). The EHS-Net researchers responsible for conducting this study reported their results to CDC, FDA, USDA, and state and local health departments.

Cross-contamination is a significant source of *Salmonella* on ready-to-eat foods. In addition to studies showing consumer unawareness of food safety protocols, FSIS has also concluded that cross-contamination occurs in federally inspected establishments. Salmonellosis outbreaks in the mid-1970s prompted the USDA to promulgate a rule[130] requiring roast beef to be cooked. However, after the passage of the 1978 rule, additional outbreaks of salmonellosis from roast beef occurred, prompting the same agency to amend the cooking rule and publish an interim rule.[131] In the introduction to the 1982 Interim final rule for roast beef, FSIS wrote,

> Following the implementation of the cooking requirements, one outbreak of salmonellosis occurred in 1978 due to a deviation from the cooking requirements. No further outbreaks occurred until 1981**,** when a number of additional outbreaks occurred. In addition, recent surveys revealed the presence of salmonellae in cooked corned beef. Investigation has shown that the recent outbreaks of salmonellosis resulted because the processors did not use one of the prescribed cooking time and temperature combinations or failed to maintain good sanitary practices or failed to maintain adequate separation of raw and cooked product, thus permitting cooked product to become recontaminated and adulterated.

Note that this contamination occurred (and still occurs) in plants under federal inspection. 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 sophisticated consumers. Despite overwhelming evidence, FSIS deliberately chooses to continue placing the burden on consumers and remain idle regarding the risks of the *Salmonella* Outbreak Serotypes even in the face of severe illness and, in certain cases, impending death.

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[130] 9 CFR § 318.17 (1978).

[131] "Interim final rule – Production Requirements for Cooked Beef, Roast Beef, and Cooked Corned Beef." *Food Safety and Inspection Service, USDA*. FR 47142, pages 31854-31855 of the July 23, 1982, Federal Register. Docket No. 82-00411.

In the 1974 *American Public Health Association (APHA) v. Butz* case,[132] APHA, a key public health association in the U.S., accused the USDA of "misbranding" because the USDA was placing its mark of inspection on potentially compromised meat and poultry products. APHA argued that meat was commonly contaminated with *Salmonella*, yet it was being passed as "USDA inspected and passed" without the addition of a warning label or cooking instructions. USDA and the meat industry vehemently opposed the APHA. The USDA claimed that "it would be unjustified to single out the meat industry and ask that the [USDA] require it to identify its raw products as being hazardous to health."[133]

The D.C. Circuit Court of Appeals upheld the USDA's position, based on a factually unsupportable premise. The court ruled that the presence of *Salmonella* on meat does not constitute adulteration and stated, "As the Department said in its August 18, 1971 letter 'the American consumer knows that raw meat and poultry are not sterile and, if handled improperly, perhaps could cause illness.' In other words, 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."[134] As part of the court's opinion, Circuit Judge Robinson wisely dissented; he wrote:

> The court apparently takes the position that meat and poultry 'ordinarily' pose no threat of salmonellosis, because American consumers are aware of the problem and familiar with the precautions necessary to prevent its occurrence. That, however, is a debatable proposition, and appellants, with substantial backing, seriously dispute it. The record contains facts supporting appellants' assertion that people are not generally aware of the danger of salmonellae, much less of the safeguards required to avoid salmonellosis. Moreover, a study conducted for the Department of Agriculture and the Food and Drug Administration states that 'the vast majority of the public and personnel of various food-associated industries barely know that salmonellae exist. Many of them have suffered from

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[132] *American Public Health Ass'n. v. Butz,* 511 F.2d 331 (5th Cir. 1975).

[133] Nestle, M. (2003). *Safe Food: Bacteria, Biotechnology, and Bioterrorism*. California: University of California Press. 66.

[134] American Public Health Association *et al*. v. Earl Butz, 511 F.2d 331, 334 (D.C. Cir. 1975).

> salmonellosis, but they do not know why or how to avoid future incidents.' Nor is it any clearer that salmonellae in food do not ordinarily render it injurious to health. Meat, particularly pork, and poultry are likely to contain salmonellae when they reach the kitchens of our homes and restaurants, and each year more than two million people in this country contract salmonellosis.[135]

Despite years of studies and scientific advancement, the misguided rationale exposed by Judge Robinson survived into the new millennium and provided the basis for oft-cited dicta in the *Supreme Beef Processors, Inc. v. USDA* decision.[136] In that case, a Supreme Beef Processors plant failed three consecutive USDA *Salmonella* performance standards inspections in an eight-month span. In one test, nearly half of the ground beef samples from the plant tested positive for *Salmonella*. According to the USDA, the high levels of *Salmonella* indicated that the ground beef at the plants was produced under "insanitary conditions." When the USDA attempted to shut down Supreme Beef, however, the company immediately filed suit, claiming that it failed the performance standard not because of any condition in its facility, but because it purchased beef "trimmings" that had higher levels of *Salmonella* than other cuts of meat and, thus, the USDA was inappropriately regulating the procurement of raw materials.[137]

Notably, the court in *Supreme Beef* was not faced with the question of whether *Salmonella* was an adulterant because the USDA admitted that it did not recognize *Salmonella* as an adulterant *per se* under § 601(m)(1).[138] Rather the court clearly stated that it was faced with two issues to resolve "in order to determine whether the [USDA's] *Salmonella* performance standard is authorized under the FMIA." Those issues were:

> a) whether the statute allows the USDA to regulate characteristics of raw materials that are 'prepared packed or held' at the plant, such as *Salmonella* infection; and b) whether § 601(m)(4)'s 'insanitary conditions' such that product 'may have been rendered injurious to health' includes the presence of *Salmonella*-infected beef in a

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135 *Id.* 511 F.2d at 336.
136 275 F.3d 432 (5th Cir. 2001).
137 *Id.* at 441.
138 *Id.* at 442-43.

> plant or the increased likelihood of cross-contamination with *Salmonella* that results from grinding such infected beef.[139]

Because the USDA never disputed Supreme Beef's contention that the "trimmings" were the cause of the performance standard failures, the court accordingly concluded that § 601(m)(4) could not be used to regulate "characteristics of raw materials that exist before the meat product is 'prepared, packed or held' and thus, the USDA's regulation failed.[140] Put simply, the court held that the USDA could not declare a product was adulterated due to insanitary conditions based only on the plant's end product because only examining the end product did not rule out the possibility that the *Salmonella* may have come in with the raw material.[141]

Contrary to *Butz* and those of its outdated assertions to which *Supreme Beef* refers, if thorough cooking was effective, poultry and pork, ordinarily well-cooked, would not be at the top of the CDC's salmonellosis attribution list. Research has further reinforced the supposition that cross-contamination, and not simply proper cooking, must be a priority. A review paper, published in 2009, concluded that cross-contamination seems to be "of greater importance than the risk associated with undercooking of poultry, meat, or eggs."[142]

This danger is by no means a recent development. The August 18, 1971 letter referenced by the D.C. Circuit Court of Appeals in *Butz* was the first of its kind. However, prior to this letter, USDA had acknowledged the need for training of food service workers and consumers. In 1969,

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139 *Id.* at 439 [emphasis added].

140 The court even explicitly stated that "the regulation fails, but **not** because it measures *Salmonella* levels and *Salmonella* is a non-adulterant. The performance standard is invalid because it regulates the procurement of raw materials." *Id.* at 441 [emphasis added].

141 The *Supreme Beef* court's reference to the flawed conclusions of *Butz* received heavy criticism. For instance, the Consumer Federation of America discussed *Supreme Beef v. USDA* in April 2015, writing that "[t]his legal interpretation relies on outdated precedent—particularly the D.C. Circuit Court's 1974 decision in *American Public Health Association v. Butz*—that is unsupported by science." *See* "Taking *Salmonella* Seriously: Policies to Protect Public Health under Current Law." *Consumer Federation of America*, 2018.

142 Luber, P. (2009). Cross-contamination versus undercooking of poultry meat or eggs – which risks need to be managed first? *Int J Food Microbiol*. 134:21-28.

the National Academy of Sciences (NAS), at the request of FDA and USDA, released a comprehensive report titled "An Evaluation of the *Salmonella* Problem." In the 200-page document, NAS investigated the nature of the U.S. *Salmonella* problem and made recommendations to USDA to mitigate the contributing factors. The half-a-century-old report addresses many of the concerns discussed in this petition including cross-contamination,[143] hazardous slaughtering practices,[144] consumer mishandling and miseducation,[145] and genetic plasticity,[146] among others.

The report states that the *Salmonella* problem is "exacerbated by traditional slaughtering and handling practices that help to spread the contaminants from one carcass to another."[147] In order to solve this issue, one of the recommendations made by NAS was to implement a "massive educational program." A 1970 letter written by USDA in response to the NAS report shows that the agency "[concurred] in this recommendation" and agreed that it "should continue and intensify educational programs" and "expand educational efforts."[148] The NAS report also confirms that USDA is well aware that consumers have very little knowledge of foodborne illnesses and food safety handling practices. The report states that "the vast majority of the public and personnel of the various food-associated industries barely knows that salmonellae exist" and that "they do not know why or how to avoid future incidents." USDA is aware of consumer incapacity and has previously agreed that additional education is required, yet a year after concurring with nearly all of the NAS report's recommendations, the agency changed its stance, stating that "the American

[143] *Id.* at 2, 121, 122.
[144] *Id.* at 2, 118, 121, 122.
[145] *Id.* at 13, 16.
[146] *Id.* at 4, 7, 60, 61.
[147] Foster, E. M., *et al*. *An Evaluation of the Salmonella Problem*. Washington D.C.: National Academy of Sciences, 1969. Web (Google eBook).
[148] "A Review of the NAS-NRC Report." *Microbiological Subgroup of the USDA Food Safety Committee*, 1970.

consumer knows that raw meat and poultry are not sterile and, if handled improperly, perhaps could cause illness." Results of the 1974 GAO Report to Congress showed that 74% of household cooks did not know that *Salmonella* was a bacterium that could cause food poisoning. Sixty-six percent of women indicated that they did not know how to minimize the spread of *Salmonella* within their homes.[149]

Following the tragic 1993 Jack in the Box *E. coli* O157:H7 outbreak that killed four children, Michael Taylor, then-current FSIS Administrator, made a brave step in the right direction; he announced that *E. coli* O157:H7 would be deemed an adulterant in raw ground beef. In *Texas Food Industry Association, et al., v. Mike 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.[150] The dangers of *Salmonella*, still, were ignored even though the cited reasons clearly apply to the *Salmonella* Outbreak Serotypes as well.

While most *Salmonella* outbreaks occur from infectious doses over 100 CFU, low level exposure has been proven to result in sporadic disease.[151] Additionally, the prevalence of *Salmonella* in North America is speculated to be greater than that of any Shiga toxin-producing *E. coli* (STEC).[152] Salmonellosis has been associated with long-term sequelae including reactive arthritis, IBS, and life-threatening bacteremia. Finally, research on the ten most predominant

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[149] 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).

[150] *Texas Food Industry Association, et al., v. Mike Espy*, 870 F. Supp. 143. United States District Court, W.D. Texas, Austin Division. (1994).

[151] Teunis, P. F. M., F. Kasuga, A. Fazil, I. D. Ogden, O. Rotariu, N. J. C. Strachan. (2010). Dose-response modeling of *Salmonella* using outbreak data. *Int J Food Microbiol*. 144:243-249.

[152] Brashears, M. M., B. D. Chaves. (2017). The diversity of beef safety: A global reason to strengthen our current systems. *Meat Sci*. 132:59-71.

Salmonella serotypes from ground beef has revealed that each individual serotype can survive internal temperatures below, and sometimes at, the FSIS-recommended "doneness" temperature of 71.1oC.[153] In the study, each serotype survived rare, medium rare, medium, and medium well levels of cooking.[154] *Salmonella* Agona, a particularly heat-resistant serovar, survived in ground beef cooked to an internal temperature of 71.1oC (equivalent to a "well done" degree of doneness). In a second study, pork loin chops were cooked to various levels of doneness (rare, medium, and well-done) in either a gas hob or a traditional static oven—two of the most common cooking methods for pork meat. The results indicated that well-done cooking in a static oven was the only treatment that could completely inactivate *Salmonella*.[155] Pork loin chops cooked "well done" in a gas hob still tested positive for the pathogen.

In summary, those who have studied these issues most carefully (including corporations such as Cargill, with a clear vested interest in the industry's success) continue to advocate for a more modern and science-based regulatory system for meat, poultry, and egg products—and for good reason: salmonellae in raw ground beef and pork products are "ordinarily injurious."[156] Because deep tissue lymph nodes often cannot be removed and are protected from antimicrobial surface interventions, the pathogen, in many cases, cannot be avoided. Bacterial contamination of intact meat end products originates from extrinsic sources (*e.g.*, lymph nodes, gastrointestinal tract, external carcass surfaces) and occurs during the slaughter and dressing of carcasses via cross-contamination. In whole muscle beef and pork products, salmonellae are "added substances."[157]

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[153] Stopforth, J. D., R. Suhalim, B. Kottapalli, W. E. Hill, M. Samadpour. (2008). Thermal Inactivation D- and z-Values of Multidrug-Resistant and Non-Multidrug-Resistant *Salmonella* Serotypes and Survival in Ground Beef Exposed to Consumer-Style Cooking. *J Food Prot*. 71(3):509-515.

[154] "Degree of Doneness." *Certified Angus Beef*.

[155] De Cesare, A., E. Domenech, D. Comin, A. Meluzzi, G. Manfreda. (2018). Impact of Cooking Procedures and Storage Practices at Home on Consumer Exposure to *Listeria Monocytogenes* and *Salmonella* Due to the Consumption of Pork Meat. *Risk Anal*. 38(4).

[156] Per 21 U.S.C. § 601(m)(1).

[157] Per 21 U.S.C. § 601(m)(1).

In cattle processing, dehiding and evisceration increase the risk for cross-contamination. In swine production, scalding and singeing reduce the microbial load, while dehairing, polishing, and evisceration recontaminate the carcasses. Cross-contamination within homes and restaurants is equally important, frequently underestimated, and, according to qualified researchers, impossible to control.[158] Poor hygiene and unsafe food handling practices are rampant. Consumers are unaware of the risks of foodborne illness and use unreliable subjective measures to determine doneness. Furthermore, certain *Salmonella* serotypes can survive the FSIS-recommended internal temperatures.

VI. ORDINARILY INJURIOUS 'OUTBREAK' SEROTYPES

In 2013, the CDC released an online "Atlas of *Salmonella* in the United States"; the Atlas contains 42 years of laboratory-confirmed research on thirty *Salmonella* serovars including Agona, Anatum, Berta, Blockely, Braenderup, Derby, 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. The truth of the matter is that *Salmonella* Outbreak Serotypes have been identified, extensively studied, and individually involved in deadly foodborne illness outbreaks time and time again. Pathogenic serotypes have demonstrated their ability to cause disease; they have proven to be "ordinarily injurious" and, therefore, they are adulterants by definition.[159] Even if FSIS refuses to categorize Outbreak Serotypes as adulterants on the basis

[158] Carrasco, E., A. Morales-Rueda, R. M. García-Gimeno. (2012). Cross-contamination and recontamination by *Salmonella* in foods: A review. *Food Res Int*. 45:545-556.

[159] Per 21 U.S.C. § 601(m)(1) and 21 U.S.C. § 453(g)(1): "if it 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."

that they are "added substances," the agency should deem pathogenic strains adulterants in meat and poultry products on the basis that they are ordinarily injurious to the health of consumers.

Modern methods of serotyping have revolutionized the way scientists go about tracking and identifying strains of bacteria. 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. WGS, a highly-suitable technology for *Salmonella* detection, is far more specific than the previous gold standards, namely Pulsed-field Gel Electrophoresis (PFGE) and Multiple-locus Variable-number Tandem Repeat Analysis (MLVA).[160] While MLVA often demonstrates a higher discriminatory power than PFGE, neither of the two methods comes close to WGS. 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. In a 2019 paper published by the American Society for Microbiology, Kovac effectively summarizes one such instance: "One of many positive outcomes [of using WGS] is a successful investigation of a *Salmonella* Bareilly outbreak where comparative genomics led to the identification of an international source of contaminated tuna that would have otherwise remained under the radar."[161] Another equally positive outcome occurred during a recent egg outbreak in the UK: WGS analysis established a clear link between eggs, humans, and environmental *S.* Enteritidis isolates.[162]

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[160] Rantsiou, K., *et al*. (2018). Next generation microbiological risk assessment: opportunities of whole genome sequencing (WGS) for foodborne pathogen surveillance, source tracking and risk assessment. *Int J Food Microbiol*. 287:3-9.

[161] Kovac, J. (2019). Precision Food Safety: A Paradigm Shift in Detection and Control of Foodborne Pathogens. *mSystems*. 4(3).

[162] Inns, T., *et al*. (2015). A multi-country *Salmonella* Enteritidis phage type 14b outbreak associated with eggs from a German producer: 'near real-time' applications of whole genome sequencing and food chain investigations, United Kingdom, May to September 2014. *Euro Surveill*. 20(16):21098.

Consequently, public health agencies now routinely employ WGS in outbreak investigations and compare isolates from victims of foodborne illness to those from food and food production environments.[163] Whole genome sequences and surveillance data are uploaded to an open-access database commonly known as GenomeTrakr. As of early 2019, the GenomeTrakr network had sequenced over 317,000 isolates.[164]

Although all *Salmonella* serotypes are potentially pathogenic to humans, the ten most prevalent *Salmonella* serotypes—Enteritidis, Newport, Typhimurium, Javiana, Monophasic Typhimurium (I 4,[5],12:i:-), Infantis, Muenchen, Montevideo, Braenderup, and Thompson—are responsible for nearly 60% of all NTS-associated human illnesses.[165] Forty-one percent of *Salmonella*-related human disease is caused by the top three serovars—Enteritidis (16.8%), Newport (10.1%), and Typhimurium (14.5%, including Monophasic strains). Several fewer common serotypes are known for their ability to escape the GI tract and cause dangerous systemic diseases. These particularly hazardous serotypes include *S.* Heidelberg, *S.* Oranienburg, *S.* Panama, *S.* Poona, *S.* Sandiego, and *S.* Schwarzengrund.[166]

Some hosts are carriers; they are not affected by serotypes that may be pathogenic to others. Poultry, swine, and cattle are carriers of *Salmonella* serotypes that are pathogenic to humans. Each

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[163] In the past decade there has been an additional revolution in the identification of these outbreak strains by the development of Whole Genome Sequencing (WGS). The specificity of WGS in linking foods to human cases is far greater than earlier identification methods such as Kaufman White serotyping, Pulsed Field Electrophoresis (PFGE), or Multi-Virulence-Locus Sequence Typing (MVLST). In 2014, FSIS implemented WGS in its laboratories for *Salmonella* and *Listeria monocytogenes*. https://www.fsis.usda.gov/wps/wcm/connect/6e1e899a-45c7-40db-80fd-b43ab22cae56/Dessai-Food-Safety-053018.pdf?MOD=AJPERES. In the past year, numerous papers on the use of WGS for public health and regulatory purposes have been published in several scientific journals. The papers have included authors from CDC, FDA, and FSIS. Foodborne Pathogens and Disease published a special issue in July of this year: https://www.liebertpub.com/doi/10.1089/fpd.2019.2662.

[164] "GenomeTrakr Fast Facts." *U.S. Food & Drug Administration*, 2019.

[165] "National Enteric Disease Surveillance: *Salmonella* Annual Report, 2016." *Centers for Disease Control and Prevention*, 2016.

[166] National Advisory Committee on Microbiological Criteria for Foods. (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *J Food Prot*. 82(4):645-668.

of the thirty serotypes on CDC's "Atlas of *Salmonella*" has been involved in an outbreak and/or isolated from ill humans.[167] Some serovars have a narrow host range, known as "host-restricted," whereas others have a broad host spectrum, known as "host-adapted" or "generalist" serotypes.[168]

While swine continues to play a central role in the dissemination of Typhimurium serotypes to humans, *S.* Typhimurium can infect a broad range of warm-blooded animals.[169] Similarly, while *S.* Enteritidis is typically associated with poultry and products thereof, it is a generalist serotype. Despite the implementation of regulatory programs intended to reduce the prevalence of Enteritidis in chicken, infections have not declined in over 10 years.[170]

Most *Salmonella* serovars, including *S.* Heidelberg, Derby, Montevideo, Anatum, and Infantis, are host-adapted. Anatum, one of the most frequently isolated serovars in beef, is also prevalent in swine. In a 2019 systematic review paper, researchers identified Montevideo as the most dominant and frequent *Salmonella* serotype in healthy cattle.[171] The same study concluded that five of the ten most frequently reported cattle-associated serotypes— Montevideo, Newport, Typhimurium, Anatum, and Mbandaka—are frequently traced back to human illness.

Certain serotypes are host restricted. For example, *Salmonella* Dublin usually exclusively infects cattle, while *S.* Choleraesuis and *S.* Derby typically infect pigs.[172] Derby is one of the most

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[167] Some of the serovars listed on CDC's "Atlas of *Salmonella*" have never been involved in meat or poultry outbreaks. Nevertheless, Outbreak Serotypes were all, without exception, associated with human illnesses. There is no doubt that Outbreak Serotypes not commonly found in meat or poultry today could eventually show up in these products.

[168] Jajere, S. M. (2019). A review of *Salmonella enterica* with particular focus on the pathogenicity and virulence factors, host specificity and antimicrobial resistance including multidrug resistance. *Vet World*. 12(4):504-521.

[169] Ferrari, R. G., *et al*. (2019). Worldwide Epidemiology of *Salmonella* Serovars in Animal-Based Foods: A Meta-analysis. *Appl Environ Microbiol*. 85(14):1-56.

[170] "Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food – Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2015-2018." *Centers for Disease Control and Prevention*, 2019.

[171] Gutema, F. D., *et al*. (2019). Prevalence and Serotype Diversity of *Salmonella* in Apparently Healthy Cattle: Systematic Review and Meta-Analysis of Published Studies, 2000-2017. *Front Vet Sci*. 6:102.

[172] "Salmonellosis: Paratyphoid, Nontyphoidal Salmonellosis." *The Center for Food Security & Public Health*, 2013.

frequently reported *Salmonella* serotypes in swine, yet it is not among the main causes of outbreaks in humans. Nevertheless, *S.* Derby has been implicated in several foodborne illness outbreaks.

Several serotypes of medical importance (*e.g.*, Dublin, Newport, Enteritidis, Choleraesuis, Typhimurium) harbor virulence plasmids containing genes that code for serum resistance, fimbriae, and other factors.[173] Innocuous strains of *Salmonella* can evolve over time and develop comparable virulence and antimicrobial mechanisms.[174] *S.* Heidelberg, a primarily poultry-adapted serotype, has acquired *saf* fimbrial genes, antibiotic resistance factors, cell adhesion virulence functions, and "evolved as a bovine-adapted lineage with increased colonization and virulence," according to Antony *et al*.[175] The *saf* operon, while generally absent in *S.* Heidelberg, is present in serotypes Typhi and Typhimurium, and is widely believed to contribute to human pathogenesis. Today, experts believe that the "markedly increased death losses [due to *S.* Heidelberg are] clinically comparable to those seen in herds infected with *S.* Dublin, a known serious pathogen of

[173] Foley, S. L., A. M. Lynne. (2008). Food animal-associated *Salmonella* challenges: Pathogenicity and antimicrobial resistance. *J Anim Sci*. 86(14):173-187.

[174] Another serotype of concern is *S.* Kentucky. *See* Ferrari, R. G., *et al*. (2019). Worldwide Epidemiology of *Salmonella* Serovars in Animal-Based Foods: A Meta-analysis. *Appl Environ Microbiol*. 85(14):1-56. *Salmonella* Kentucky, a major serotype isolated from poultry and one of the top ten isolated from beef, has been increasingly reported in the U.S. *See* Arya, G., *et al*. (2017). Epidemiology, Pathogenesis, Genoserotyping, Antimicrobial Resistance, and Prevention and Control of Non-Typhoidal *Salmonella* Serovars. *Curr Clin Micro Rpt*. 4:43-53. Although Kentucky is only implicated in about 100 cases of human salmonellosis each year, its prevalence in domestic food animals may pose a public health risk in the future. In a 2019 paper, Ferrari *et al.* recommended "careful monitoring" of Kentucky. *See Appl Environ Microbiol*. 85(14):1-56. A recent Pennsylvania study found that 29% of animal-derived *S.* Kentucky isolates matched "the sequence type found in human clinical isolates collected over the same time period." *See* Rauch, H. E., D. Vosik, S. Kariyawasam, N. M'ikanatha, N. W. Shariat. (2018). Prevalence of Group I *Salmonella* Kentucky in domestic food animals from Pennsylvania and overlap with human clinical CRISPR sequence types. *Zoonoses and Public Health*. 65(7):831-837. The authors concluded that "the overlap between specific subtypes in human salmonellosis patients and domestic food animals over the same period warrants continued monitoring of our food chain." Between 2002 and 2008, Denmark, England and Wales, France, and the United States reported 489 cases of human *S.* Kentucky cases, all of which were attributed to a single clone displaying high-level resistance to ciprofloxacin. *See* Le Hello, S., *et al.* (2011). International Spread of an Epidemic Population of *Salmonella enterica* Serotype Kentucky ST198 Resistant to Ciprofloxacin. *J Infect Dis*. 204(5):675-684. In response to these observations, Le Hello *et al.* stated, "[h]eightened awareness by national and international health, food, and agricultural authorities is necessary to implement measures to monitor and limit the spread of this strain."

[175] Antony, L., *et al*. (2018). Genome divergence and increased virulence of outbreak associated *Salmonella enterica* subspecies *enterica* serovar Heidelberg. *Gut Pathog*. 10:53.

cattle." A recent multistate outbreak of multidrug resistant *S.* Heidelberg was traced back to calves.

Although *Salmonella* Dublin is not listed in the CDC's *Salmonella* Atlas, it is listed as one of Petitioners' Outbreak Serotypes for various reasons. As stated above, *S.* Dublin is a bovine-adapted pathogen. Exposure to products contaminated with *S.* Dublin can cause human infections and invasive bacteremia.[176] Although *S.* Dublin is a rather uncommon cause of human salmonellosis, a relatively high proportion of cases involving the serotype are associated with systemic infections.[177] In a recent research paper, Holschbach stated that "no current discussion of bovine salmonellosis could be complete without acknowledging the increasing public health concern regarding [*S.* Dublin's] relevance as an important zoonosis [and] the risk that contaminated dairy and dairy beef products can pose to human health…."[178] Indeed, Dublin is increasingly being identified among bovine *Salmonella* isolates and has become one of the most multidrug-resistant serotypes.[179] USDA-FSIS is currently investigating a multistate outbreak of *Salmonella* Dublin infections linked to ground beef.[180] As of December 2019, the outbreak has caused nine hospitalizations and one death. On November 18, 2019, Central Valley Meat Co. recalled 34,222 pounds of ground beef products that may have been contaminated with *Salmonella* Dublin.

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[176] Mangat, C. S., S. Bekal, R. J. Irwin, M. R. Mulvey. (2017). A Novel Hybrid Plasmid Carrying Multiple Antimicrobial Resistance and Virulence Genes in *Salmonella enterica* Serovar Dublin. *Antimicrobial Agents and Chemotherapy*. 61(6).

[177] Costa, R. A., *et al*. (2018). Urocystitis and Ureteritis in Holstein Calves with Septicaemia Caused by *Salmonella enterica* Serotype Dublin. *Journal of Comparative Pathology*. 164:32-36.

[178] Holschbach, C. L., S. F. Peek. (2018). *Salmonella* in Dairy Cattle. *Veterinary Clinics of North America: Food Animal Practice*. 34(1):133-154.

[179] Hsu, C. H., *et al.* (2019). Comparative Genomic Analysis of Virulence, Antimicrobial Resistance, and Plasmid Profiles of *Salmonella* Dublin Isolated from Sick Cattle, Retail Beef, and Humans in the United States. *Microb Drug Resist*. 25(8):1238-1249.

[180] "Outbreak of *Salmonella* Infections Linked to Ground Beef." *Available at* https://www.cdc.gov/salmonella/dublin-11-19/index.html.

VII. CONCLUSION

In light of current scientific and medical research, the health hazards posed by Outbreak Serotypes of *Salmonella enterica* subsp. *enterica* are undeniable. It has become evident that a limited number of serovars are responsible for the vast majority of outbreaks and cases of human foodborne illness. Each year, *Salmonella* causes 1.35 million illnesses, 26,500 hospitalizations, and 420 deaths in the United States.[181] The ten most prevalent *Salmonella* serotypes are responsible for 59% of all NTS-associated human illnesses.[182] Forty-one percent of *Salmonella*-related human disease is caused by the top three serovars.

Accordingly, the Petitioners urge the administration of FSIS to issue an interpretive rule declaring Outbreak Serotypes of *Salmonella* adulterants within the meanings of the FMIA and PPIA. By banning recurring serotypes in meat and poultry products, FSIS will take a significant leap forward in ensuring the safety of American consumers.

As the burden of *Salmonella* infection within the U.S. steadily increases, immediate action on this issue is critical.

Very truly yours,

Marler Clark LLP, PS, on behalf of:
Rick Schiller
Steven Romes
The Porter Family
Food & Water Watch
Consumer Federation of America
Consumer Reports

[181] "*Salmonella* Homepage." *Centers for Disease Control and Prevention*, 2019.
[182] "National Enteric Disease Surveillance: *Salmonella* Annual Report, 2016." *Centers for Disease Control and Prevention*, 2016.