January 25, 2021

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

Re: Petition to Establish Enforceable Standards Targeting *Salmonella* Types of Greatest Public Health Concern while Reducing all *Salmonella* and *Campylobacter* in Poultry, and to Require Supply Chain Controls

To Whom It May Concern:

The petitioners Center for Science in the Public Interest, Consumer Federation of America, Consumer Reports, Stop Foodborne Illness, Mr. David Clubb, Ms. Amanda Craten, Ms. Diana Goodpasture, Ms. Mary Graba, and Ms. Melissa Lee respectfully submit the enclosed petition requesting that the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) establish enforceable standards targeting *Salmonella* types of greatest public health concern all *Campylobacter* in poultry, and to require supply chain controls.

Thank you for your consideration, replies and other communications related to this petition can be directed to me at ssorscher@cspinet.org, or 202-777-8397.

Sincerely,

Sarah Sorscher
Deputy Director of Regulatory Affairs
Center for Science in the Public Interest
Suite 300, 1220 L St. N.W.
Washington, D.C. 20005

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

Petition to Establish Enforceable Standards Targeting *Salmonella* Types of Greatest Public Health Concern while Reducing all *Salmonella* and *Campylobacter* in Poultry, and to Require Supply Chain Controls	))))))	Docket No._____

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CITIZEN PETITION

Submitted by:

Organizations
Center for Science in the Public Interest
STOP Foodborne Illness
Consumer Federation of America
Consumer Reports

and

Individuals
Mr. David Clubb
Ms. Amanda Craten
Ms. Diana Goodpasture
Ms. Mary Graba
Ms. Melissa Lee

January 25, 2021

Table of Contents

I. Introduction

A. Background

We have just seen the close of the year 2020, a year that will be remembered, among other things, for a global pandemic of COVID-19, a crisis that starkly illustrates the critically important role of public health in combatting infectious disease. At the beginning of the last decade, the U.S. Department of Health and Human Services established the Healthy People 2020 goals, a set of data-driven national objectives to improve the health and wellbeing of Americas over the course of the decade.[1] Among these goals were targets for reducing incidence of foodborne illnesses caused by *Campylobacter* and *Salmonella*, two of the foodborne bacteria associated with the highest burden of foodborne illness, from 12.7 and 15 cases of laboratory confirmed infections per 100,000 population per year to 8.5 and 11.4, respectively.[2] At the close of the decade, progress on both fronts was dismal: incidence of both *Campylobacter* and *Salmonella* remained as high, if not higher, than at the start of the decade, in spite of efforts by the U.S. Department of Agriculture FSIS and other public health stakeholders who have sought to drive those numbers down.[3]

Moving into the next decade, the Healthy People 2030 goals have established similar reduction targets of 10.6 and 11.1 cases of laboratory confirmed domestically acquired infections per 100,000 population per year for *Campylobacter* and *Salmonella*.[4,5] FSIS has expressed commitment to meeting the Healthy People 2030 targets, most recently with the release of the "Roadmap to Reducing *Salmonella*: Driving Change Through Science-Based Policy," in which the agency committed to moving forward existing *Salmonella* control initiatives and investing in further research.[6] While these programs represent progress – particularly developing new performance standards for beef and pork products – we are concerned that such modest steps to expand existing programs will not result in substantially better public health outcomes over the next ten years than the efforts over the past decade, especially considering the failures of prior efforts. To achieve greater progress, the agency must also be open to considering a new vision for *Campylobacter* and *Salmonella* control, one that more comprehensively addresses the risks that drive foodborne illness and provides standards and systems to specifically target these risks, ensuring effective change.

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[1] About Healthy People. Healthy People 2020 website. Updated October 8, 2020. Accessed January 5, 2021. https://www.healthypeople.gov/2020/About-Healthy-People

[2] Food Safety. Healthy People 2020 website. Updated October 8, 2020. Accessed January 6, 2021. https://www.healthypeople.gov/2020/topics-objectives/topic/food-safety/objectives

[3] Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019. *MMWR Morb Mortal Wkly Rep* 2020; 69: 509–514.

[4] Reduce infections caused by *Salmonella* — FS-04. Healthy People 2030 website. Accessed January 6, 2021. https://health.gov/healthypeople/objectives-and-data/browse-objectives/foodborne-illness/reduce-infections-caused-salmonella-fs-04

[5] Reduce infections caused by *Campylobacter* — FS-01. Healthy People 2030 website. Accessed January 6, 2021. https://health.gov/healthypeople/objectives-and-data/browse-objectives/foodborne-illness/reduce-infections-caused-campylobacter-fs-01

[6] Food Safety and Inspection Service. *Roadmap to Reducing Salmonella: Driving Change through Science-Based Policy*. Washington, D.C: U.S. Department of Agriculture, FSIS; 2020.

Accordingly, the undersigned groups submit this petition urging FSIS to modernize its food safety standards by establishing enforceable standards targeting *Salmonella* types of greatest public health concern while reducing all *Salmonella* and *Campylobacter* in poultry.[7] We also ask that FSIS ensure the safety of the food supply chain from farm to fork by requiring slaughter establishments to adopt and implement effective supply chain programs, and by publishing finalized versions of its "DRAFT FSIS Compliance Guidance for Controlling Salmonella and Campylobacter in Raw Poultry."[8]

Two of the undersigned groups, Consumer Federation of America and Consumer Reports, previously submitted a petition in January 2020 requesting that FSIS declare certain outbreak serovars to be *per se* adulterants in meat and poultry.[9] This petition does not modify that request, but instead lays out a regulatory framework and process for achieving the goals of that petition in poultry, while also addressing risks from *Campylobacter*.

B. About the Petitioners

Center for Science in the Public Interest is America's food and health watchdog. Since 1971, CSPI has worked to improve the public's health through better nutrition and food safety. The organization's work is supported primarily by subscribers to its Nutrition Action Healthletter, one of the nation's leading health newsletters. CSPI is an independent organization that does not accept government grants or corporate funding. CSPI has twice filed petitions to FSIS asking the agency to declare strains of antimicrobial resistant AMR *Salmonella* to be adulterants in meat and poultry, based on evidence of repeated multidrug-resistant *Salmonella* outbreaks tied to FSIS-regulated products, both of which were denied without prejudice.[10]

Consumer Federation of America (CFA) is an association of non-profit consumer organizations that was established in 1968 to advance the consumer interest through research,

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[7] We are not requesting specific prioritization of *Campylobacter* types because, although there are multiple serotypes within *C. jejuni*, they are not commonly differentiated from a risk assessment standpoint. However, antibiotic-resistant *Campylobacter* are considered a "serious" resistance threat by the CDC. (Centers for Disease Control and Prevention. *Antibiotic Resistance Threats in the United States, 2019*. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.) Therefore, to the extent that FSIS is able to target antimicrobial resistance genes in prioritizing *Salmonella* types, we encourage the agency to apply similar principles to targeting *Campylobacter*. Similarly, while the regulation of meat products under the Federal Meat Inspection Act (FMIA) falls beyond the scope of this petition, we encourage the agency to consider applying the principles described here to the control of *Salmonella*, *Camplylobacter*, and other pathogens in meat.

[8] Food Safety and Inspection Service. *Draft FSIS compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry*. Washington, D.C: U.S. Department of Agriculture, FSIS; 2015.

[9] Petition submitted by Marler Clark LLP to the U.S. Department of Agriculture Food Safety and Inspection Service 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). January 19, 2020. Accessed December 21, 2020. www.fsis.usda.gov/wps/wcm/connect/d2a7c76e-dda9-475d-bf35-4cb69f5fca24/20-01-marler-011920.pdf?MOD=AJPERES. Citizen Petition submitted by Marler Clark LLP to the U.S. Department of Agriculture Food Safety and Inspection Service 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), January 19, 2020.

[10] CSPI submitted petitions on *Samonella* on October 4, 2014 and May 25, 2011. Access petitions and FSIS final response at Food Safety and Inspection Service. Petitions. Last Updated December 17, 2020. https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/petitions

advocacy, and education. Today, more than 250 of these groups participate in the federation and govern it through their representatives on the organization's Board of Directors. CFA works to support food policies that promote transparency, empower consumers to make healthy choices, and ensure access to a safe and wholesome food supply.

Consumer Reports is a nonprofit organization that works for and with consumers for truth, transparency, and fairness in the marketplace. We use our independent and rigorous research, consumer insights, journalism, and policy expertise to inform people's purchase decisions, improve the products and services businesses deliver, and drive regulatory and fair competitive practices. Our work helps create a safer, fairer and more transparent marketplace.

Stop Foodborne Illness (STOP) is a non-profit organization that for over 25 years has worked with illness survivors and victims' families to advocate for and support best practices and continuous improvement in food safety. STOP called for reforms in the FSIS inspection program following the Jack in the Box outbreak in 1992-93 and was part of the consumer-industry coalition that supported and gained enactment of the Food Safety Modernization Act ("FSMA") in 2011. In addition to constituent support and policy advocacy, STOP collaborates with food companies to bring personal experiences with serious illness into company training and food safety culture programs.

Mr. David Clubb of Southlake, Texas. Mr. Clubb was hospitalized in 2009 with severe, continuous vomiting, diarrhea and cramping after he returned home from a job interview where he had been served a chicken salad that was contaminated with *Salmonella*. He ultimately spent 4 days in the hospital, losing 14 pounds as he drifted in and out of consciousness. During much of that time he was unable to see his wife and young children – one of whom had just returned home from an unrelated emergency surgery.

Ms. Amanda Craten of Gilbert, Arizona. Ms. Craten's son, Noah, was seriously injured at 18-months in an outbreak associated with *Salmonella* Heidelberg contaminated poultry in 2013. Noah has permanent health issues stemming from his illness. Ms. Craten is a member of the Board of Directors of STOP.

Ms. Diana Goodpasture of Barberton, Ohio. Ms. Goodpasture contracted *Salmonella* Heidelberg from a turkey burger in 2011 and developed potentially fatal heart failure due to her astonishingly low potassium levels, as well as dehydration due to diarrhea that nearly outran her IV fluids. She survived the ordeal, but continues to live with lasting consequences to her gastrointestinal and immune systems.

Ms. Mary Graba of Dayton, Minnesota. Ms. Graba contracted a *Campylobacter* infection from eating chicken. Over thirty years later, Mary's recovery is not complete, as she continues to experience long-term mobility issues, consequences she traces back to her bout with foodborne illness.

Ms. Melissa Lee of Sandy, Oregon. Ms. Lee's daughter, Ruby, was 10 months old when she suffered for several agonizing days in 2011 before being told she had antibiotic-resistant

Salmonella Heidelberg. Two months later it was determined that it came from ground turkey, which her family had used in meatballs with spaghetti.

C. Full Statement of the Action Requested

Pursuant to 9 C.F.R. § 392.5, the Petitioners request that the following actions be taken by FSIS:

1) Issue a regulation under 21 U.S.C. §§ 453(g), 458(a)(2) and U.S.C. § 463(b) to create modernized, enforceable, finished product standards for *Salmonella* types of greatest public health concern and *Campylobacter.* These standards should reduce, with an aim to ultimately eliminate, *Salmonella* types of public health concern from raw poultry, while continuing to target reductions in *Salmonella* and *Campylobacter* overall.
2) Require establishments to identify and control food safety risks within their supply chains, including risks from *Salmonella* and *Campylobacter*, by issuing a regulation under 21 U.S.C. §§ 453(g), 458(a)(2) and U.S.C. § 463(b).. Under this regulation, establishments would identify appropriate prerequisite programs and critical control points (CCP) and establish microbial testing programs to verify program effectiveness, including through testing of incoming raw materials.

II. Factual Basis for the Requested Actions

A. Background

1. *Salmonella* and *Campylobacter* in Poultry Pose Serious Health Risks

According to the U.S. Centers for Disease Control and Prevention (CDC), Americans experience approximately 1.35 million illnesses, 26,500 hospitalizations, and 420 deaths each year due to non-typhoidal (nt-) *Salmonella*, and nearly one in six of these infections (212,500 annually) exhibits antimicrobial resistance at some level.[11] Annual incidence of *Campylobacter* infections is even higher, at an estimated 1.5 million *Campylobacter* infections each year, nearly one-third of which show some antimicrobial resistance to antibiotics used to treat serious infections.[12] While *Campylobacter* less commonly leads to hospitalization and death than *Salmonella*, infected individuals are at risk for serious complications such as Guillain-Barre Syndrome and irritable

[11] Centers for Disease Control and Prevention. *Antibiotic Resistance Threats in the United States, 2019*. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.
[12] *Ibid*.

bowel syndrome.[13,14] In 2019, *Salmonella* and *Campylobacter* together accounted for over 71% of the confirmed bacterial and parasitic illnesses transmitted commonly by food and tracked by the CDC through its Foodborne Diseases Active Surveillance Network (FoodNet) surveillance system, as well as 72% of resulting hospitalizations and 59% of deaths.[15]

Analysis of outbreak data suggests that consumption of poultry meat represents the leading source of both *Salmonella* and *Campylobacter* illnesses among FSIS-regulated products, and a substantial proportion of such illnesses overall. The Interagency Food Safety Analytics Collaboration (IFSAC) attributes 20% of foodborne *Salmonella* and 66% of *Campylobacter* illnesses to either chicken or turkey.[16] From 2008 to 2018, 150 chicken-related salmonellosis outbreaks occurred in the U.S., resulting in 4,857 illnesses, 800 hospitalizations, and five deaths.[17] From 2008 to 2018, there were also 56 chicken-related *Campylobacter* outbreaks leading to 446 illnesses and 34 hospitalizations.[18] While proper poultry handling and cooking could help reduce illnesses due to contaminated poultry products, recent studies consistently show that typical consumer practices leave the population vulnerable to contaminated meat.[19,20,21]

The economic burden of illnesses due to *Salmonella* and *Campylobacter* in poultry are considerable, particularly when taking into account not just the direct medical costs, but also productivity losses, lost life expectancy, chronic illness, and other associated pain and suffering. According to a recent study that also considered all of these costs for 29 pathogen-food pairs in the United States, *Campylobacter* in poultry and nt-*Salmonella* in chicken represented the two costliest pairs studied ($6.9 billion and $2.8 billion annually, respectively).[22]

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[13] Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019. *MMWR Morb Mortal Wkly Rep* 2020; 69: 509–514.

[14] Laughlin ME, Chatham-Stephens K, Geissler AL. Chapter 4: Travel-Related Infectious Disease: Campylobacteriosis. In: Centers for Disease Control and Prevention. CDC Yellow Book 2020: Health Information for International Travel. Oxford University Press; 2017: 180-181.

[15] Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019. *MMWR Morb Mortal Wkly Rep* 2020; 69: 509–514.

[16] Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2018 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States. GA and D.C.: U.S. Department of Health and Human Services, CDC, FDA, USDA-FSIS; 2020.

[17] National Outbreak Reporting System Dashboard (foodborne, 2008-2018, all outbreaks, *Salmonella*, chicken). Centers for Disease Control and Prevention website. Updated August 14, 2020. Accessed January 6, 2021. https://wwwn.cdc.gov/norsdashboard/

[18] National Outbreak Reporting System Dashboard (foodborne, 2008-2018, all outbreaks, *Campylobacter*, chicken). Centers for Disease Control and Prevention website. Updated August 14, 2020. Accessed January 6, 2021. https://wwwn.cdc.gov/norsdashboard/

[19] Langsrud S, Sørheim O, Skuland SE, et al. Cooking Chicken at Home: Common or Recommended Approaches to Judge Doneness May Not Assure Sufficient Inactivation of Pathogens. *PLoS One*. 2020; 15(4).

[20] Chen FC, Godwin S, Chambers D, et al. Contamination by Meat Juice When Shopping for Packages of Raw Poultry. *J Food Prot*. 2018; 81(5): 835-841.

[21] Evans EW, Redmond EC. Behavioral Observation and Microbiological Analysis of Older Adult Consumers' Cross-Contamination Practices in a Model Domestic Kitchen. *J Food Prot*. 2018; 81(4): 569-581.

[22] Scharff RL. Food Attribution and Economic Cost Estimates for Meat and Poultry-Related Illnesses. *Journal of Food Protection*. 2020; 83(6): 959-967.

2. FSIS's Current Regulatory Framework Fails to Adequately Control *Salmonella* and *Campylobacter* in Poultry

Ensuring the safety of animal source foods has long been a core focus for FSIS. The agency began its modern efforts to combat pathogens in raw meat and poultry with the creation of the Hazard Analysis and Critical Control Point (HACCP) regulation, issued in 1996.[23] The HACCP regulation requires establishments to identify food safety hazards that are "reasonably likely to occur," as well as identify "critical control points" (CCPs) or points in the process at which a control can be applied that will prevent the hazard.[24] For each CCP, the establishment must determine a "critical limit" and identify monitoring procedures and corrective actions to be taken in response to any deviation from the critical limit.[25] FSIS also required establishments to verify the adequacy of the establishments' process controls through microbial testing.[26] Finally, the agency instituted its own testing program and established enforceable performance standards for many meat and poultry products, which are based on the percentage of samples testing positive for *Salmonella* over a specified time period.[27] Under the 1996 rule, establishments that repeatedly tested above that threshold ran the risk of having inspections suspended, forcing them to cease operations. Notably, this regulatory *Salmonella* sampling is designed to verify process controls at plants, not to establish individual product safety, meaning *Salmonella*-positive products and lots can still be sold.[28]

The HACCP rule represented a fundamental change to FSIS's approach to food safety, broadening the agency's inspection approach beyond its more traditional focus on symptoms of animal disease and signs of visible contamination to more directly target invisible microbial contamination as the source of foodborne disease.

Pathogen-specific performance standards are at the heart of this approach. Each establishment's HACCP program is specifically calibrated to ensure the microbial performance standards are met, and the standards serve as the agency's key means of assessing effectiveness of an establishment's food safety controls. As the agency said in the final HACCP rule: "Pathogen-specific performance standards for raw products are an essential component of the FSIS food safety strategy because they provide a direct measure of progress in controlling and reducing the most significant hazards associated with raw meat and poultry products."[29]

In *Supreme Beef Processors, Inc. v. U.S Department of Agriculture* (2001), discussed further in Section III *infra*,, the U.S. Court of Appeals for the Fifth Circuit blocked FSIS from enforcing the performance standards directly, at least in relation to the ground beef processor involved in that case.[30] In response to that ruling, FSIS has drawn back from strict enforcement of

[23] Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems 61 Fed. Reg. 38806 (Jul. 25, 1996). ("Final HACCP Rule").
[24] 9 C.F.R. § 417.2(a)(1); 9 C.F.R. §417.2 (c)(2).
[25] 9 C.F.R. § 417.2(c)(3)
[26] Final HACCP Rule, at 38806.
[27] *Ibid.*
[28] Food Safety and Inspection Service. *Pathogen Reduction – Salmonella and Campylobacter Performance Standards Verification Testing.* Washington, D.C: U.S. Department of Agriculture, FSIS; 2019.
[29] Final HACCP Rule, at 38812.
[30] *Supreme Beef Processors, Inc. v. U.S. Dept., Agric,* 275 F.3d 432 (5th Cir. 2001).

its performance standards. Rather than withdraw inspection in an establishment that fails the applicable standard, an act that would force the establishment to stop operations, the agency considers an establishment's ability to meet the standards as a means to identify food safety issues and target regulatory resources towards correcting those problems.[31] In accordance with this approach, the agency removed its former poultry performance standards from its codified regulations and instead published updated standards for *Salmonella* and *Campylobacter* in poultry through notice in the Federal Register. The agency now also publicly posts the names of poultry slaughter establishments that have failed to meet those updated standards, generating market pressure for improved performance.[32,33]

In addition to posting the names of slaughter establishments that have failed to meet the performance standards, the agency may also request a product recall when specific products are linked to human illness. This policy was announced in 2012, following a high-profile outbreak of multidrug resistant *Salmonella* tied to Foster Farms. The agency indicated that it "likely will consider poultry product linked to illness outbreaks to be adulterated" and request that the establishment recall any product still in commerce.[34] While this action does not directly prevent outbreaks, the expense and negative publicity tied to such events provide some further incentive to control harmful *Salmonella*.

This regulatory structure has had some effect on industry behavior. Data presented by FSIS at its *Salmonella*: State of the Science meeting on September 22, 2020 show a clear downward trend in *Salmonella* contamination of FSIS-regulated products in concert with various modifications to the performance standard policy and sampling practices (Figure 1).[35]

[31] The agency will also consider ability to meet the performance standards as a criteria in considering waivers to operate at line speeds above the current regulatory limits. Food Safety and Inspection Service. *Constituent Update – February 23, 2018. FSIS's criteria for consideration of waiver requests from young chicken slaughter establishments to operate at line speeds up to 175 birds per minute.* Washington, D.C: U.S. Department of Agriculture, FSIS; 2018.

[32] Food Safety and Inspection Service. *Pathogen Reduction – Salmonella and Campylobacter Performance Standards Verification Testing.* Washington, D.C: U.S. Department of Agriculture, FSIS; July 31, 2019.

[33] *Salmonella* categorization of individual poultry establishments. Food Safety and Inspection Service website. Accessed January 6, 2021. https://www.fsis.usda.gov/wps/portal/fsis/home?1dmy&page=gov.usda.fsis.internet.newsroom&urile=wcm%3Apath%3A%2Ffsis-content%2Finternet%2Fmain%2Ftopics%2Fdata-collection-and-reports%2Fmicrobiology%2Fsalmonella-verification-testing-program%2Festablishment-categories

[34] HACCP Plan Reassessment for Not-Ready-to-Eat Comminuted Poultry Products and Related Agency Verification Procedures. 77 Fed. Reg. 72686, 72689 (Dec. 6, 2012).

[35] Hale KR. Salmonella Trends –What the Science Tells Us. Oral presentation at: USDA FSIS Virtual Public Meeting: Salmonella-State of the Science; September 2020.

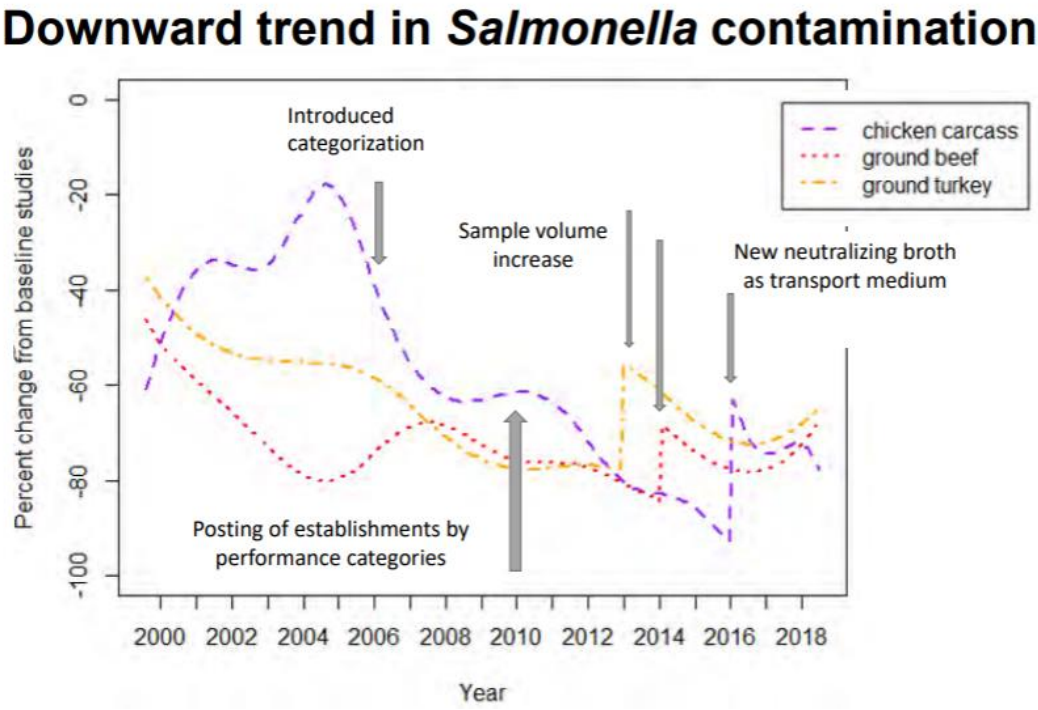

Figure 1: Downward Trend in Salmonella Contamination, 2000-2018.[36]

Nevertheless, contamination remains high in many products. In 2019, 31% of comminuted (ground) chicken and 8% of chicken parts sampled by FSIS contained *Salmonella*.[37] A 2014 to 2015 regional sampling of raw retail chicken cuts from a national supermarket chain showed *Salmonella* contamination prevalence ranging from 41% to 45% for skin and 12% to 23% for skinless meat.[38] High levels of contamination of chicken parts in particular raises concerns, as FSIS has estimated that parts account for 80% of all chicken products sold.[39] *Campylobacter* contamination is also widespread.[40] FSIS identified *Campylobacter* in 18% of chicken parts and

[36] Hale KR. Salmonella Trends –What the Science Tells Us. Oral presentation at: USDA FSIS Virtual Public Meeting: Salmonella-State of the Science; September 2020.
[37] Sampling Results for FSIS Regulated Products: Calculations. Food Safety and Inspection Service website. Updated November 6, 2020. Accessed January 6, 2021. https://www.fsis.usda.gov/wps/wcm/connect/68f5f6f2-9863-41a5-a5c4-25cc6470c09f/Sampling_Project_Results_Data.pdf?MOD=AJPERES
[38] Guran HS, Mann D, Alali WQ. Salmonella prevalence associated with chicken parts with and without skin from retail establishments in Atlanta metropolitan area, Georgia. *Food Control*. 2017; 73: 462–467.
[39] Changes to the Salmonella and Campylobacter Verification Testing Program: Proposed Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Related Agency Verification Procedures and Other Changes to Agency Sampling. 80 Fed. Reg. 3940, 3941 (Jan. 26, 2015) (Noting that chicken in turn constitutes 85% of all poultry products)..
[40] Unlike with *Salmonella*, which tends to be more prevalent on processed products (i.e. parts, comminuted) than whole carcasses, *Campylobacter* prevalence decreases with further processing. This prevalence pattern is likely due *Campylobacter*'s relative inability to multiply within food (unlike most other foodborne pathogens). It appears to be more sensitive to environmental stresses, such as exposure to oxygen, drying, acidity, heating, freezing, and prolonged storage.

21% of whole carcasses sampled in 2019.[41] In another large study, 50% of chicken breast samples (n=6138) collected from retail stores between 2002-2007 were found to be positive for the pathogen.[42]

Many of the strains of *Salmonella* and *Campylobacter* found on poultry products are resistant to antibiotics. Levels of *C. jejuni* resistance to some antibiotics have remained consistently high, with 40% of all chicken *C. jejuni* isolates resistant to tetracycline and 20% resistant to ciprofloxacin in 2018, according to data from the National Antimicrobial Resistance Monitoring System (NARMS).[43] Among the 2018 *Salmonella* isolates in NARMS from all chicken samples, 46% were resistant to tetracycline and 53% were resistant to streptomycin.[44] *Salmonella* resistance rates also may be increasing over time. From 2014 to 2018, multi-drug resistant (MDR) *Salmonella*, defined by NARMS in *Salmonella* as resistance to 3 or more antimicrobial classes, increased from 8.3% to 22% of total *Salmonella* isolates collected from regulatory plant HACCP sampling of chickens, mostly attributable to a rise in MDR *S.* Infantis isolates.[45,46]

Most importantly, measures taken to date to control contamination in poultry products have yet to have a significant impact on human illness rates. Data gathered on enteric infections from foodborne *Salmonella* and *Campylobacter* show that the rates are either unchanged or may actually be increasing over time. Whereas the Healthy People 2020 objectives had aimed to reduce the annual number of foodborne infections caused by *Salmonella* from 15.0 per 100,000 population in 2006-08 to 11.4 per 100,000 population by 2020, the CDC estimated that in 2019, Americans experienced 17.1 infections per 100,000, an *increase* of 14% from baseline (2006-08).[47,48] Likewise, the Healthy People 2020 objective was to reduce incidence of *Campylobacter* per 100,000 population from 12.7 in 2006-08 to 8.5 in 2020. Instead, the 2019 incidence was 19.5 per 100,000; representing a 53.5% increase from baseline.[49,50]

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[41] Sampling Results for FSIS Regulated Products: Calculations. Food Safety and Inspection Service website. Updated November 6, 2020. Accessed January 6, 2021. https://www.fsis.usda.gov/wps/wcm/connect/68f5f6f2-9863-41a5-a5c4-25cc6470c09f/Sampling_Project_Results_Data.pdf?MOD=AJPERES

[42] Zhao S, Young SR, Tong E. et al. Antimicrobial Resistance of *Campylobacter* Isolates from Retail Meat in the United States between 2002 and 2007. *Appl. Environ. Microbiol.* 2010; 76: 7949–7956.

[43] NARMS Now. Food and Drug Administration website. Accessed January 6, 2021. https://www.fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/narms-now-integrated-data

[44] *Ibid.*

[45] *Ibid.*

[46] 2018 NARMS Update: Integrated Report Summary. Food and Drug Administration website. Updated December 20, 2020. Accessed January 6, 2021. https://www.fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/2018-narms-update-integrated-report-summary

[47] Food Safety. Healthy People 2020 website. Updated October 8, 2020. Accessed January 6, 2021. https://www.healthypeople.gov/2020/topics-objectives/topic/food-safety/objectives

[48] Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019. *MMWR Morb Mortal Wkly Rep* 2020; 69: 509–514

[49] Food Safety. Healthy People 2020 website. Updated October 8, 2020. Accessed January 6, 2021. https://www.healthypeople.gov/2020/topics-objectives/topic/food-safety/objectives

[50] Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019. *MMWR Morb Mortal Wkly Rep* 2020; 69: 509–514.

While some increase is probably attributable to an enhanced ability to identify infections thanks to the increasing clinical use of culture-independent diagnostic tests (CIDTs), authors of a 2019 FoodNet report indicated that "identification of infections that might not have been detected before adoption of CIDTs cannot explain the overall lack of progress."[51] Figures 2 and 3 support this conclusion, showing that in 2019, only 11% of *Salmonella* and 39% of *Campylobacter* infections were detected by CIDT only. The authors concluded that "[t]o better protect the public and achieve forthcoming Healthy People 2030 foodborne disease reduction goals, more widespread implementation of known prevention measures and new strategies that target particular pathogens and serotypes are needed."[52]

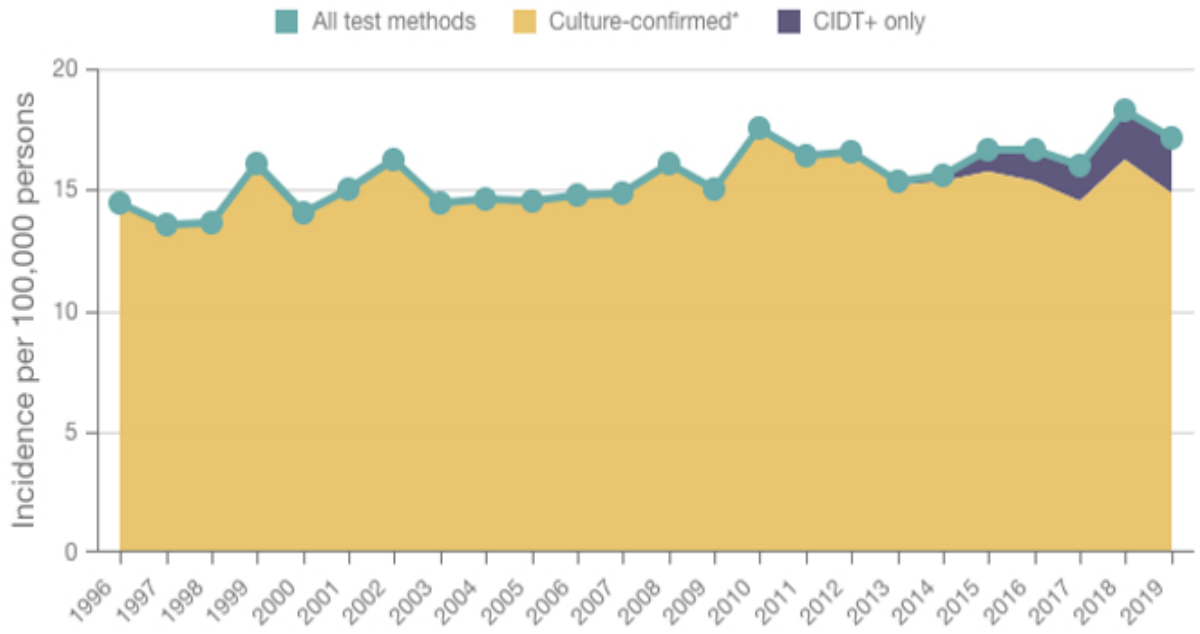

Figure 2: Incidence of *Salmonella* Infections by Year for FoodNet Sites 1996-2019[53]
*Culture confirmed includes those infections confirmed by culture only or by culture following a positive culture independent diagnostic test (CIDT).

[51] Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019. *MMWR Morb Mortal Wkly Rep* 2020; 69: 509–514.
[52] *Ibid*
[53] Pathogen Surveillance - *Salmonella*. Centers for Disease Control and Prevention website. Accessed January 6, 2021. https://wwwn.cdc.gov/foodnetfast

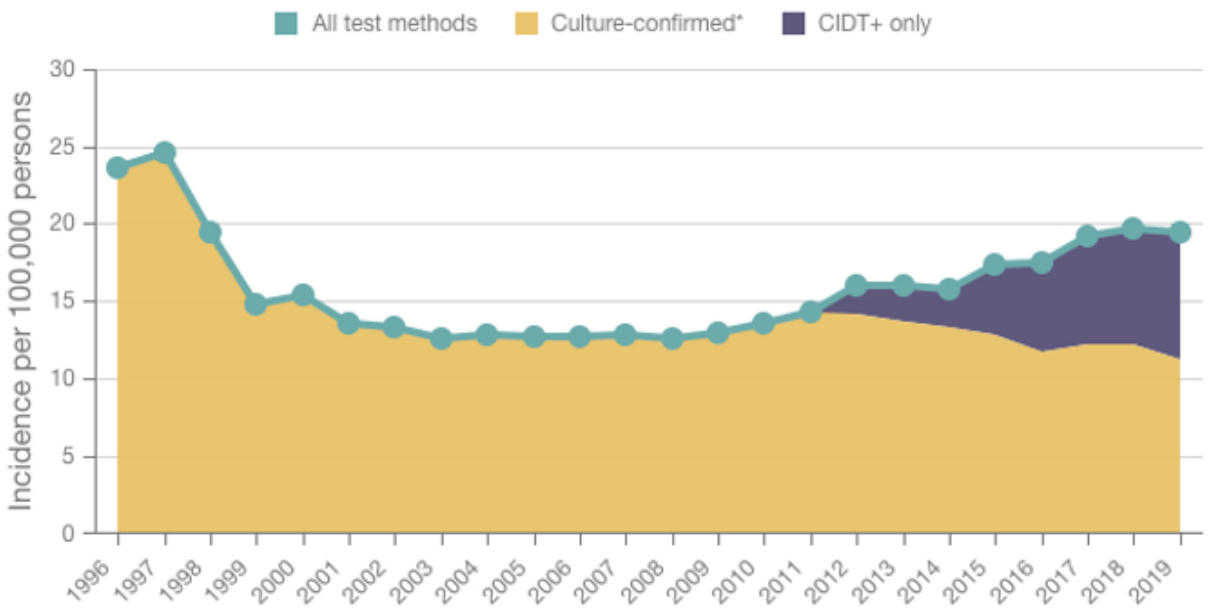

Figure 3: Incidence of Campylobacter Infections by Year for FoodNet Sites 1996-2019[54]
*Culture confirmed includes those infections confirmed by culture only or by culture following a positive culture independent diagnostic test (CIDT).

To achieve success in this decade, FSIS must consider new approaches to *Salmonella* and *Campylobacter* control. FSIS recently acknowledged the need for further efforts in its announcement of "Roadmap to Reducing *Salmonella*: Driving Change Through Science-Based Policy," stating that "[a]lthough … there has been an overall reduction in the occurrence of *Salmonella* on meat and poultry products over the past 20 years, there is still more work to be done. The food safety community did not meet the 2020 national public health goal for reduction of *Salmonella* illnesses, and FSIS remains committed to working toward achieving the Healthy People target set for 2030."[55]

The undersigned petitioners appreciate this latest effort to highlight the problem of *Salmonella*, and urge that the agency consider, along with latest food safety science, the need for modern regulatory standards that will ensure genuine oversight and accountability for prevention of the hazards that cause foodborne illness. It is time for FSIS to truly modernize its regulatory framework.

[54] Pathogen Surveillance - *Campylobacter*. Centers for Disease Control and Prevention website. Accessed January 6, 2021. https://wwwn.cdc.gov/foodnetfast
[55] Salmonella-State of the Science: Notification of public meeting. 85 Fed. Reg. 49619 (Aug. 14, 2020).

B. Requested Action 1: Enforceable Standards

1. The Agency's Current Performance Standards Are Inadequate

To bring U.S. public health goals for reducing *Salmonella* and *Campylobacter* illnesses into reach, FSIS must consider novel approaches. Chief among these should be re-examining the agency's standards for finished products. As noted above, the current performance standards used to assess *Salmonella* and *Campylobacter* in finished products have had only limited effectiveness in bringing down product contamination rates, while not impacting human illness numbers. In many cases the performance standards are met primarily through the application of extensive in-plant antimicrobial treatments, such as peracetic acid, chlorine, or cetylpyridinium chloride applied as sprays or "dips" during processing (after plucking and evisceration).[56]

One of the reasons these standards may have failed to achieve the desired public health outcome is that they aim to reduce the prevalence of all *Salmonella* equally despite well-documented variability in health risk among human *Salmonella* infections as a result of differences in virulence among individual *Salmonella* serotypes, strains, and genotypes, including presence of genes associated with antibiotic resistance.[57] Thus, the standards fail to effectively prioritize control efforts for the *Salmonella* most likely to make people sick, and treat a poultry product that is heavily contaminated with the most virulent strain of multidrug resistant *Salmonella* as equally wholesome and fit for human consumption as one bearing trace amounts of a much more innocuous strain.

This non-specific approach means that much of the effort invested into *Salmonella* control may have the effect of eliminating the most common *Salmonella* serotypes that are highly prevalent in poultry but not be sufficient for those commonly associated with human illness in the United States. Mismatches between the distributions of serotypes causing human illness and the serotypes on animal products have occurred since sufficient national data became available for analysis in the 1990s.[58] In poultry, the most prevalent serotype of *Salmonella* found in regulatory samples from 2004-2014 was *S.* Kentucky (Figure 4). But this serotype was not even within the top 7 serotypes implicated in human *Salmonella* infections during the same period (Figure 5). *S.* Kentucky accounted for only around 0.15% of culture-confirmed cases of human salmonellosis as tracked by the CDC from 1996 to 2019 (data not represented in figures).[59]

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[56] Thames HT, Sukumaran AT. A Review of *Salmonella* and *Campylobacter* in Broiler Meat: Emerging Challenges and Food Safety Measures. *Foods*; 2020; 9:776.

[57] Quantity of pathogen consumed, host susceptibility and the nature of the environment (food matrix) may also affect individual outcomes. See: Maurer JJ. Factors Affecting Variation in *Salmonella* Virulence. In: Gurtler J., Doyle M., Kornacki J. (eds) *Foodborne Pathogens. Food Microbiology and Food Safety.* New York, NY; Springer, Cham; 2017: 151-167.

[58] Sarwari AR, Magder LS, Levine P, et al. Serotype Distribution of Salmonella Isolates from Food Animals After Slaughter Differs from that of Isolates Found in Humans. *J Infect Dis*. 2001; 183(8): 1295-1299.

[59] Pathogen Surveillance – *Salmonella* Kentucky. Centers for Disease Control and Prevention website. Accessed January 6, 2021. https://wwwn.cdc.gov/foodnetfast

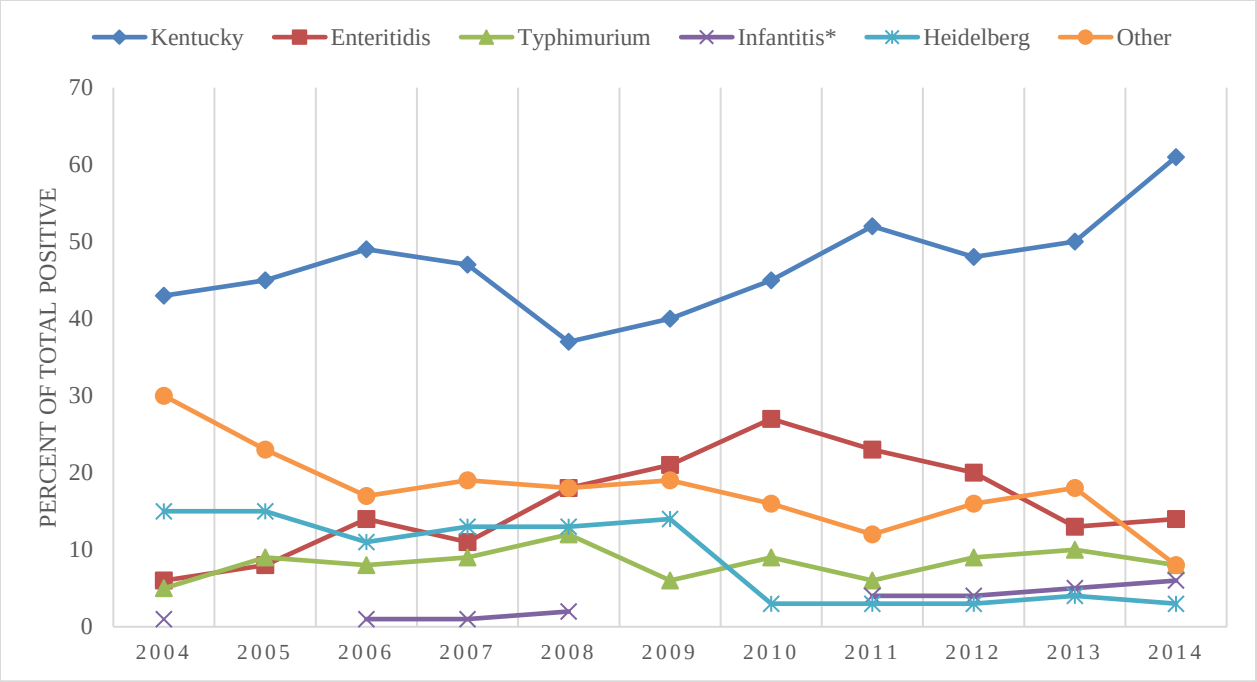

Figure 4: Profile of Serotypes from Analyzed PR/HACCP Verification Samples (top 5 individual serotypes in 2014 reported), Young Chicken (Broilers), by Year.[60]

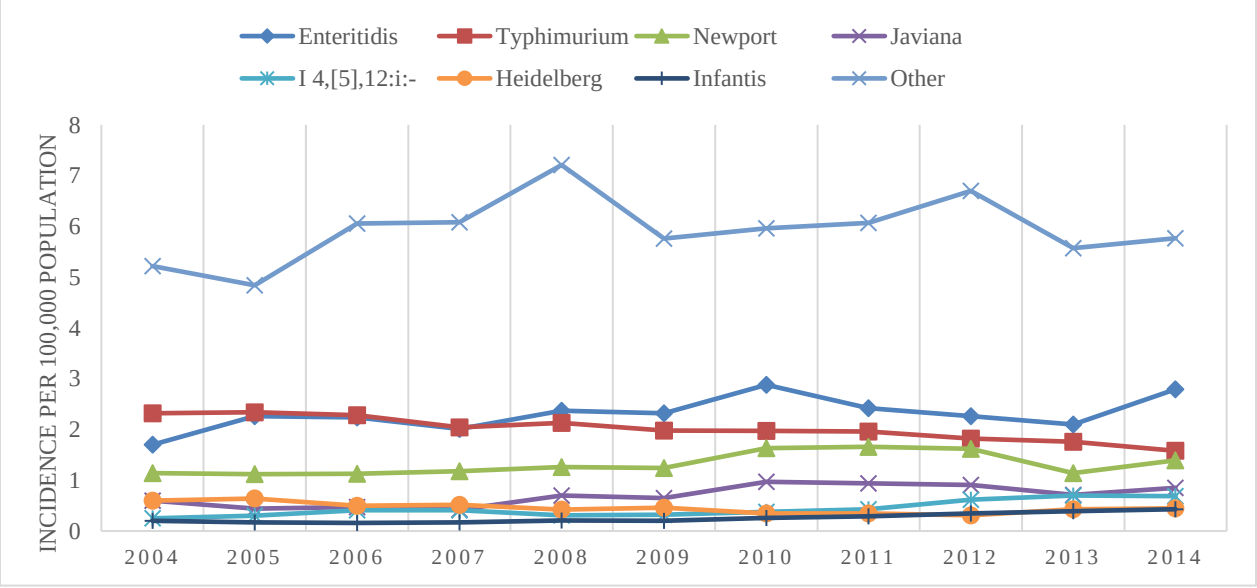

Figure 5: Incidence Rate of Culture-Confirmed Human Salmonella Infection Reported to Laboratory-based Enteric Disease Surveillance (LEDS) System (top individual serotypes in 2014 reported), by Year, United States.[61]

[60] Food Safety and Inspection Service. *Serotypes Profile of Salmonella Isolates from Meat and Poultry Products: January 1998 through December 2014*. Washington, D.C: U.S. Department of Agriculture, FSIS; 2017.
[61] Centers for Disease Control and Prevention. *National Enteric Disease Surveillance: Salmonella Annual Report, 2015*. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2017.

The high prevalence of relatively benign *Salmonella* isolates in product samples means efforts to control *Salmonella* risk that target prevalence alone fail to target the pathogens of greatest risk to consumers. One recent study modeled the effect of total *Salmonella* prevalence in individual lots of ground turkey on the risk of salmonellosis occurring from consumption of these lots and found that prevalence alone was not a good indicator of risk; other risk factors including number and virulence were too important to exclude.[62] Phrased differently, simply targeting modest reductions in *Salmonella* prevalence alone was not correlated with reduced salmonellosis. The author concluded that multiple indicators of risk should be incorporated in a holistic modeling approach to poultry food safety, rather than focusing on prevalence alone as the sole measure of risk.

Members of the meat industry, recognizing the opportunity for more targeted regulation, have encouraged FSIS to develop a better-calibrated, risk-based *Salmonella* standard that takes into account virulence by serotype. In October 2020 comments to the docket on FSIS's "Roadmap to Reducing Salmonella: Driving Change Through Science-Based Policy," the North American Meat Institute stated that "[n]ot all *Salmonella* are created equal and not all product positives will result in illness," arguing that "[a]ssessing only prevalence on all serovars will not target high-risk *Salmonella* serovars and, therefore, not likely reduce the number of possible illnesses."[63] The National Cattlemen's Beef Association submitted comments along similar lines, saying that "[c]onsumers are better protected from illness under a risk-based approach that focuses on the *Salmonella* serovars exhibiting the higher risk for pathogenicity that are found on products at higher levels."[64]

The current system also fails to ensure clear consequences for establishments that fail to meet the existing prevalence-based performance standards. As noted above, products contaminated with *Salmonella* are not treated as adulterated except on the rare occasion they are identified in an investigation of an outbreak that has already sickened consumers. This approach is inconsistent, reactive, and fails to adequately incentivize a modern preventive approach to food safety. As Robert O'Connor, Senior Vice President of Technical Services at a major poultry producer, Foster Farms, put it in a roundtable discussion in 2016:

> I think a performance standard for a known pathogen creates a conundrum. It sets a standard by which a processor is able to "leak" a pathogen into the marketplace. Subsequently, the processor only finds out that this [pathogen] leakage is a problem when illness becomes attributed to them. I view that as reacting to an 'open door, after the horse has left the barn.' It creates confusion. If a bacterium is a pathogen, how do you safely allow some of it into commerce?[65]

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[62] Oscar T. *Salmonella* Prevalence Alone Is Not a Good Indicator of Poultry Food Safety. *Risk Analysis*. 2020; [Online ahead of print] DOI: 10.1111/risa.13563. In addition, incidence and extent of undercooking, food consumption behavior, and host resistance all appeared to play a significant role in predicting disease risk.
[63] McCullough K. *Comment RE: Salmonella-State of the Science,Docket No. FSIS-2020-0025;* 85 Fed. Reg. 49619 (Aug. 14, 2020). Washington, DC: North American Meat Institute; 2020.
[64] Lane E. *Comment RE: Docket Number FSIS-2020-0025, Roadmap to Reducing Salmonella, Driving Change Through Science-Based Policy*. Washington, DC: National Cattlemen's Beef Association; 2020.
[65] O'Connor, R. Roundtable discussion at*: Lightening the Load: Teaming live production with processing to meet USDA's new limits for foodborne pathogens*. August, 2016; San Antonio, TX.

Food safety experts have long known that greater progress is achievable. In particular, the meat industry was able to achieve dramatic reductions in infection with *E. coli* O157:H7, which was declared an adulterant in ground beef by the agency in 1994.[66]

As stated in 2011 by the Federal Food Safety Working Group regarding *Salmonella*:

> We know that reducing contamination works. During the past 15 years, a dangerous type of *E. coli* infection, responsible for the recall of millions of pounds of ground beef, has been cut almost in half. Yet during that same time, *Salmonella* infection, which causes more hospitalizations and deaths than any other type of germ found in food and $365 million in direct medical costs annually, has not declined. Each year, 1 million people get sick from eating food contaminated with *Salmonella*. Applying lessons learned from reducing *E. coli* O157 infections could help reduce illness caused by Salmonella.[67]

Thus, greater gains are possible with *Salmonella* if the agency takes ambitious steps to target the most harmful *Salmonella* types, removing them from inspected products.

2. FSIS Should Establish a Framework to Target Salmonella Types of Greatest Public Health Concern

In 2018, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which is made up of government and nongovernment expert members and provides food safety advice to federal agencies, issued a report that provided a comprehensive framework for approaching *Salmonella* control strategies in poultry.[68] The report identified key opportunities to reduce *Salmonella* and prevent illness across the farm-to-table spectrum. Specific recommendations from the Committee included two priorities of particular relevance to this petition: (1) identification and development of "approaches that exclude serotypes of greatest public health concern from raw poultry products," and (2) identification of serotype-specific pre-harvest controls.[69] This petition urges the agency to develop a regulatory framework to support these two priorities by establishing new standards targeting *Salmonella* types of greatest public health concern.

One key lesson that can be gleaned from prior efforts by FSIS to tackle foodborne illness is that the agency is most successful when it sets clear, enforceable rules that target pathogens associated with the highest public health risk. The agency did just that when it set a zero-tolerance standard for *E. coli* O157:H7 in 1994, declaring that pathogen to be an adulterant in ground beef products. While the meat industry initially objected to this standard,[70] over time the

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[66] *Texas Food Industry Ass'n v. Espy,* 870 F. Supp. 143 (W.D. Tex. 1994) (concluding "the USDA's decision to consider *E. Coli* as an 'adulterant' is an interpretive rule").
[67] Federal Food Safety Working Group. *Federal Food Safety Working Group Progress Report*. Washington DC: The White House, The Federal Food Safety Working Group; 2011.
[68] National Advisory Committee on Microbiological Criteria for Food. Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *J Food Prot*. 2019; 82 (4): 645–668.
[69] *Ibid.*
[70] *E.g.*, *Texas Food Industry Ass'n v Espy,* 870 F.Supp. 143 (W.D. Tex. 1994).

industry was able to adapt its practices, bringing about dramatic reductions in both product contamination and human illness rates.

Controlling *Salmonella* in poultry necessarily presents a different set of challenges from controlling *E. coli* O157:H7 in ground beef. In particular, *E. coli* O157:H7 and the related six strains of Shiga-toxin producing *E. coli* (STEC) that have now been identified as adulterants represent a distinctly virulent pathogenic serogroup within *E. coli*.[71] By contrast, the *Salmonella enterica* species is composed of over 2600 serotypes, of which a fraction are responsible for most human *Salmonella* infections.[72,73] While some countries, most notably Sweden, have been able to effectively control all *Salmonella spp.* in poultry by using stringent national control and prevention programs, members of the U.S. poultry industry are quick to point out economic barriers to accomplishing this goal in the United States considering the high prevalence of *Salmonella* and the size and diversity of domestic poultry agriculture.[74,75,76,77] Given this backdrop, targeting the most harmful types of *Salmonella* for reduction, with an aim to eradicate, could serve as an effective intermediate approach to reducing human illness and achieving the Healthy People 2030 goals. These initial targets could be adjusted and expanded over time to build on successes and move towards more effective *Salmonella* control, taking advantage of new evidence, diagnostics, and interventions as they emerge.

Efforts targeting specific *Salmonella* serotypes can be highly effective if employed aggressively and consistently over a number of years. For example, a large outbreak of *S.* Heidelberg in 2013-14, linked to a major poultry producer on the West Coast, accelerated the adoption of multi-hurdle preharvest control efforts by that producer and similar-sized producers within the poultry industry.[78] The controls included amplifying programs to vaccinate broiler breeder flocks with a commercially available *S.* Typhimurium vaccine that was also effective against *S.* Heidelberg and potentially other antigenically related serotypes in the same "Group B" serogroup and requiring chicks from source flocks to be *S.* Heidelberg free.[79] These measures contributed to a 93% decline in the incidence of *S.* Heidelberg infections, from an incidence of 0.8 per 100,000 in 1996 down to 0.08 per 100,000 in 2019. Similar declines have occurred in *S.*

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[71] Shiga Toxin-Producing Escherichia coli. 76 Fed. Reg. 58157, 58158 (Sep. 20, 2011).
[72] Jajere SM. A review of *Salmonella enterica* with particular focus on the pathogenicity and virulence factors, host specificity and antimicrobial resistance including multidrug resistance. *Vet World*. 2019; 12(4):504-521.
[73] Centers for Disease Control and Prevention. *National Enteric Disease Surveillance: Salmonella Annual Report, 2016.* Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2018.
[74] Schwartz E. Can We Get to Zero Salmonella in Poultry? *Frontline*. May 12, 2015. Accessed January 11, 2021 https://www.pbs.org/wgbh/frontline/article/can-we-get-to-zero-salmonella-in-poultry/
[75] Lindblad J. *Lessons from Sweden's Control of Salmonella and Campylobacter in Broilers.* Paper and Presentation at: United States Department of Agriculture, Agricultural Outlook Forum; March 1-2, 2007; Washington, DC.
[76] Roberts T, Lindblad J. (2018) Sweden Led *Salmonella* Control in Broilers: Which Countries Are Following?. In: Roberts T, ed. *Food Safety Economics. Food Microbiology and Food Safety*. New York, NY: Springer, Cham; 2018: 231-250.
[77] Mead G, Lammerding AM, Cox N, et al. Scientific and technical factors affecting the setting of Salmonella criteria for raw poultry: a global perspective. *J Food Prot*. 2010; 73(8): 1566-1590.
[78] Tauxe R. Public Health Challenge of Salmonellosis in the 21st Century. Presentation at: *Salmonella: State of the Science*; September 22, 2020; virtual.
[79] *Ibid*.

Typhimurium, which declined 72% between 1996 and 2019, from 4 per 100,000 to 1.3 per 100,000.[80]

These examples suggest that control efforts targeting specific serotypes can be effective at decreasing incidence of human illness from those serotypes. But efforts by industry to tackle specific serotypes have so far not led to overall reductions in incidence of salmonellosis. This lack of progress may be due at least in part to lack of a coordinated approach to prioritization, leading to an overly narrow focus on *S.* Typhimurium and *S.* Heidelberg, failing to target other virulent serotypes. For example, while *S.* Typhimurium (the current third leading serotype causing human illness) incidence decreased 13% in 2019 compared to 2016-2018 incidence, *S.* Infantis (the sixth leading serotype causing human illness) incidence increased 69% in the same time period. The fact that illness rates have increased in one serotype even as they decline in others may account at least in part for the lack of progress overall in incidence of salmonellosis in recent decades.[81]

As a first step to implementing a more systematic and coordinated approach, FSIS should work with stakeholders within industry, academia and the consumer and public health communities, as well as the Food and Drug Administration (FDA), CDC, and state and local public health and regulatory agencies to identify and prioritize *Salmonella* serotypes of greatest public health concern.

The European Union provides one potential model for such a process. In 2003, the European Union developed criteria defining a target list of serotypes according to: 1. the most frequent *Salmonella* serotypes in human salmonellosis on the basis of data collected through human health monitoring systems; 2. the route of infection (that is, the presence of the serotype in relevant animal populations and feed); 3. whether any serotype shows a rapid and recent ability to spread and to cause disease in humans and animals; and 4. whether any serotypes show increased virulence, for instance as regards to invasiveness, or resistance to relevant therapies for human infections.[82]

Considering how such criteria might be applied in the U.S. context, the 2016-2017 NACMCF Committee, while caveating that disease risk will necessarily vary by host, age, medical history, health status, and infectious dose, stated that "[a] few serovars are consistently associated with the greatest incidence of human disease," including *S.* Enteritidis, *S.* Newport, and *S.* Typhimurium.[83] These three remained the most common *Salmonella* serotypes reported in human infections in 2019, along with *S.* Javiana, *S.* I 4,[5],12:i:-, and *S.* Infantis.[84] *S.* Newport may or may

[80] Tauxe R. Public Health Challenge of Salmonellosis in the 21st Century. Presentation at: *Salmonella: State of the Science*; September 22, 2020; virtual.
[81] Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019. *MMWR Morb Mortal Wkly Rep* 2020; 69: 509–514.
[82] European Parliament and the Council of 17 November 2003 on the control of *Salmonella* and other specified food-borne zoonotic agents (2003). *Regulation (EC) No. 2160/2003.* Official Journal of the European Union L325/2.
[83] National Advisory Committee on Microbiological Criteria for Food. Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *J Food Prot*. 2019; 82 (4): 645–668.
[84] Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019. *MMWR Morb Mortal Wkly Rep* 2020; 69: 509–514.

not be as high a priority in poultry, as this serotype is uncommon on poultry products. By contrast, analysis of FSIS's poultry HACCP testing from 2014 identified a high prevalence of *S.* Typhimurium, *S.* Enteritidis, *S.* Infantis, and *S.* Heidelberg serotypes (along with the *S.* Kentucky serotype, which, as noted above, is not commonly associated with human illness) (Figures 4 and 5).

There has been an historical emergence of MDR in certain serotypes including *S.* Typhimurium and *S.* Newport.[85] More recent analysis of *Salmonella* in poultry suggest that *S.* Heidelberg, *S.* Typhimurium, *S.* Kentucky, and *S.* Senftenberg are more likely to be MDR.[86] The *S.* Typhimurium genomic element itself can characteristically carry resistance for up to five antimicrobials.[87] In the United States, multi-drug resistant *S.* Infantis is an increasing proportion of isolates causing human illnesses and those found in food animal cecal isolates from poultry.[88]

With regard to virulence, an analysis of 11 years of FoodNet data (1996-2006) differentiated *Salmonella* serotypes by clinical severity, finding that certain serotypes had significantly higher case fatality rates, hospitalization rates, and/or incidence of invasive disease.[89] Among the most common serotypes in the analysis, *S.* Enteritidis and *S.* Heidelberg had a significantly higher proportion of invasive disease than *S.* Typhimurium. *S.* Newport, by contrast, had a significantly lower proportion of invasive disease than *S.* Typhimurium, as well as a lower case fatality rate.

Based on these criteria, *S.* Typhimurium, *S.* Enteritidis, *S.* Infantis, and *S.* Heidelberg all stand out as high priorities based on their prevalence in both clinical and product isolates, virulence, and antibiotic resistance profiles. Other candidates for prioritization could include *S.* Newport and other *Salmonella* serotypes that can cause serious foodborne illness.[90]

Regardless of the initial list selected, FSIS should develop plans to update the priority list on a regular basis. The list of priority *Salmonella* types will likely evolve, as declines in the prevalence of one type could create ecological opportunities for another to expand. Serotypes once thought to be uncommon or relatively benign may be introduced or evolve to adopt new virulence factors or resistance genes, enhancing their risk. For example, researchers have found that

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[85] Hur, J, Jawale C, Lee JH. Antimicrobial Resistance of *Salmonella* Isolated from Food Animals: A Review. *Food Res. Int.* 2012; 45(2): 819-830.

[86] Shah DH, Paul NC, Sischo WC, et al. Population Dynamics and Antimicrobial Resistance of the Most Prevalent poultry-associated *Salmonella* serotypes. *Poult Sci*. 2017; *96*(3): 687-702.

[87] Niki M, Shakeel A, Zahid K, et al. Prevalence, Risks and Antibiotic Resistance of *Salmonella* in Poultry Production Chain. In*: Current Topics in Salmonella and Salmonellosis*. London, UK: InTechOpen; 2017: 216-234.

[88] 2018 NARMS Update: Integrated Report Summary. Food and Drug Administration website. Updated December 20, 2020. Accessed January 7, 2021. https://www.fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/2018-narms-update-integrated-report-summary

[89] Jones TF, Ingram LA, Cieslak, PR, *et al.* Salmonellosis outcomes differ substantially by serotype. *J Infect Dis*. 2008; 198(1): 109-114.

[90] As noted *supra*, some co-signatories to this petition previously co-signed a petition identifying 31 "outbreak serotypes" to be *per se* adulterants in meat and poultry products and continue to support that request that these be prioritized as adulterants. Petition submitted by Marler Clark LLP to the U.S. Department of Agriculture Food Safety and Inspection Service 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). January 19, 2020.

hospitalization and mortality rates for *S.* Dublin infection increased significantly in the United States between the 1996-2004 period (68% of cases hospitalized, 2.7% died) and the 2005-2013 period (78% of cases hospitalized, 4.2% died).[91] Similarly, a novel, highly virulent and antibiotic-resistant strain of *S.* Infantis also emerged as a growing threat in the United States in recent years, appearing first in human cases associated with travel to Peru and then spreading to chicken production in the United States, and caused a large outbreak attributed to chicken that involved 129 cases of infection, 25 hospitalizations, and 1 death across 32 states in 2018-19.[92,93] FSIS should plan to respond to and address emerging threats by revisiting and updating the priority list periodically and as-needed, ensuring that *Salmonella* control approaches keep pace with our emerging knowledge of the biology of the organism.

While the European Union process targeted serotypes of greatest public health concern, the introduction of new molecular methods may also now allow for even further specificity in targeting the *Salmonella* types of greatest public health concern in the United States. For example, researchers have already begun the process of identifying *Salmonella* pathogenicity islands (SPIs), or gene clusters located in certain areas of the chromosomes in the bacterial cells that are responsible for encoding the various virulence factors (adhesion, invasion, toxin genes, etc.).[94] The mobility of these genes opens the possibility for all serotypes to develop new and virulent subtypes over time. An FSIS prioritization framework that focuses initially on identifying priority serotypes can be adapted over time and may eventually be shifted to support more specific prioritization of interventions around genes, rather than serotypes.

Prioritizing specific genes would also open new avenues for combating antibiotic resistance. Resistance to fluoroquinolones, macrolides, and/or cephalosporins is considered especially dangerous for nt-*Salmonella* infections.[95,96] Compared with infections caused by susceptible strains, MDR strains of certain serotypes (e.g. MDR *S*. Typhimurium) have been associated with higher risk of invasive infection, more frequent hospitalization, and increased risk of death.[97] While the risk of resistance can be dealt with in part by prioritizing serotypes commonly associated with resistance genes, increasing adoption of whole genome sequencing technology and advances in understanding of the role of resistance genes may one day allow for policies and interventions that more specifically target the genes themselves, further enhancing efforts to control antibiotic resistance in the food system.

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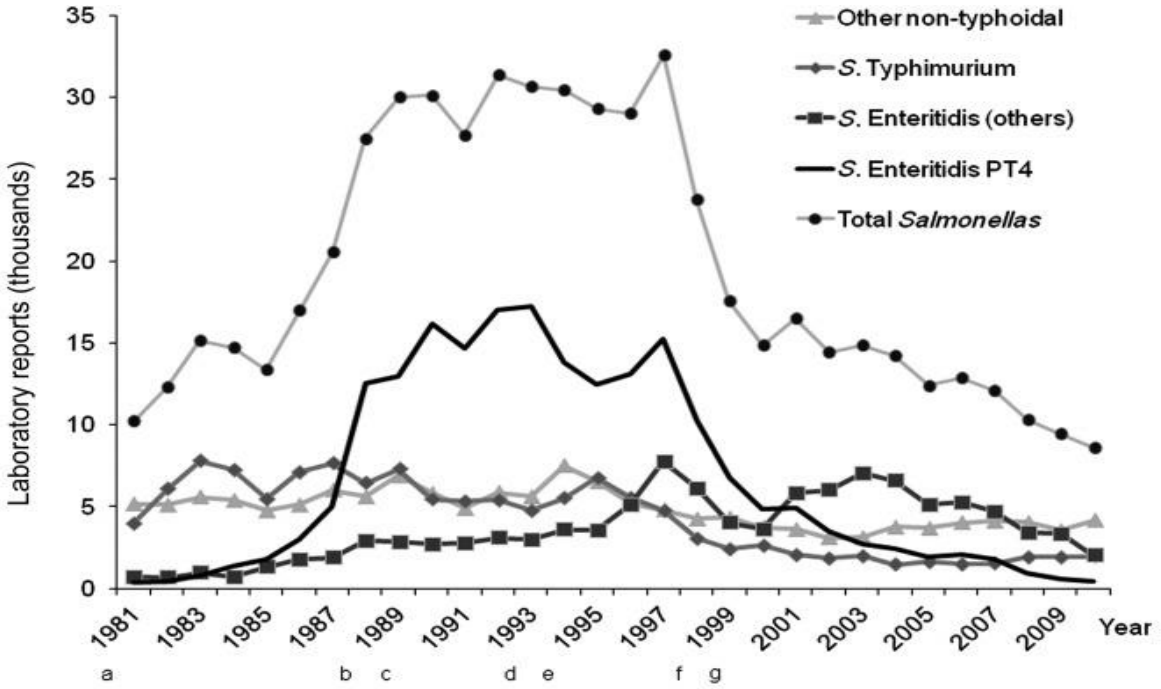
[91] Harvey RR, Friedman CR, Crim SM, et al. Epidemiology of *Salmonella* enterica serotype Dublin infections among humans, United States, 1968–2013. *Emerg Infect Dis.* 2017; 23(9): 1493-1501.
[92] Tauxe R. Public Health Challenge of Salmonellosis in the 21st Century. Presentation at: *Salmonella: State of the Science*; September 22, 2020; virtual.
[93] Outbreak of Multidrug-Resistant Salmonella Infections Linked to Raw Chicken Products: Final Update. Centers for Disease Control and Prevention website. Updated February 21, 2019. Accessed January 7, 2021. https://www.cdc.gov/salmonella/infantis-10-18/index.html
[94] Jajere SM. A review of *Salmonella enterica* with particular focus on the pathogenicity and virulence factors, host specificity and antimicrobial resistance including multidrug resistance. Vet World. 2019;12(4): 504-521. (pg 507)
[95] Angelo KM, Reynolds J, Karp BE, et al. Antimicrobial Resistance Among Nontyphoidal Salmonella Isolated from Blood in the United States, 2003-2013. *J Infect Dis*. 2016; 214(10): 1565-1570.
[96] Centers for Disease Control and Prevention. *Antibiotic Resistance Threats in the United States, 2019*. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.
[97] Parisi A, Crump JA, Glass K, et al. Health Outcomes from Multidrug-Resistant Salmonella Infections in High-Income Countries: A Systematic Review and Meta-Analysis. *Foodborne Pathog Dis*. 2018; 15(7): 428-436.

While these advances are highly promising, we urge FSIS not to treat the expanding scientific frontier as a barrier to regulatory action in the present. Commercial diagnostics and interventions targeting specific virulence or resistance genes, while not widely commercially available at present, may become increasingly common in the future. By contrast, there are today readily available commercial diagnostics and interventions to target poultry-associated *Salmonella* serotypes of greatest public health concern. Many leading producers already periodically test for the presence of certain highly virulent serotypes in poultry flocks and can tailor preharvest food safety programs based on the detection of those serotypes. As discussed in greater detail *infra*, such supply chain interventions may include targeted vaccines developed for specific serotypes and purchasing of chicks from suppliers certified to be free of priority serotypes. In addition, monitoring programs can be coupled with non-specific preharvest controls, such as biosecurity and sanitation, which can be enhanced for farms found to be affected by the priority serotype.

The widespread availability of these diagnostic technologies and effective interventions makes it possible to achieve meaningful public health progress in the near term by targeting the highest-risk *Salmonella* serotypes. For example, human salmonellosis infections in the United Kingdom declined substantially following an industry-led campaign to vaccinate both broiler-breeders and laying poultry flocks for *S.* Enteritidis (point e and f, Figure 6).



Key: (a) *S.* Enteritidis phage typing began; (b) CMO issued advice to vulnerable groups; (c) Compulsory slaughter began; (d) Compulsory slaughter revoked; (e) Vaccination of broiler-breeder flocks began; (f) Vaccination of laying flocks began; (g) "Lion Flock" fully vaccinated.

Salmonella data sources: Health Protection Agency; Health Protection Scotland; Public Health Agency of Northern Ireland

Figure 6: Laboratory reports of human salmonellosis cases in the United Kingdom, 1981-2010.[98]

S. Enteritidis and *S.* Typhimurium have also been specifically targeted by the European Food Safety Authority (EFSA), with current annual prevalence goals set at 1% of broiler flocks or less.[99] In 2016, the EU broiler flock prevalence of these two target *Salmonella* serovars was only 0.21%.[100] Nine Member States reported in 2016 that 0% of their broiler flocks had tested positive.[101]

These targets were achieved in large part through even stricter testing, and removal, of positive breeding flocks from the production chain. Current target serotypes for breeding flocks are *S.* Enteritidis, *S.* Typhimurium, *S.* Hadar, *S.* Virchow, and *S.* Infantis, with a goal set at 1% or

[98] O'Brien SJ. The "decline and fall" of nontyphoidal *Salmonella* in the United Kingdom. *Clin Infect Dis.* 2013; *56*(5): 705-710

[99] Commission Regulation (EU) 200/2012 of 8 March 2012, Concerning a Union Target for the Reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in Flocks of Broilers, as Provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council Text with EEA relevance (p. 1 ¶5).)

[100] European Food Safety Authority, European Centre for Disease Prevention and Control. The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2016. *EFSA J.* 2017; 15(12): 5077.

[101] *Ibid.*

less of flocks.[102] The breeding flock prevalence of these five target serovars was 0.54% in 2016, while the overall *Salmonella* prevalence in breeding flocks was just 1.47%.[103]

In addition to monitoring programs, vaccines provide another effective means for targeting serotypes of greatest public health concern, by reducing both horizontal and vertical transmission. Many studies have demonstrated that vaccinating breeders for *Salmonella* can significantly impact the prevalence of bacteria in broilers at processing. For example, Dorea et al. (2010) found a *Salmonella* prevalence of 23% in broilers coming from a vaccinated hen program, versus 34% prevalence among birds from a comparable unvaccinated program.[104] Recent studies by Zoetis support the company's claims that broiler vaccination with a live vaccine could also help reduce the incoming load of various serotypes of *Salmonella* at processing.[105]

Because its multiple serotypes and serogroups display different surface antigens, vaccines for *Salmonella* must be formulated to be serotype specific and often have limited efficacy for heterologous serotypes (across serogroups).[106] As a result, while serotype specific vaccines are available, poultry producers can also vaccinate breeder flocks with a custom "autogenous" vaccine composed of *Salmonella* serotypes currently circulating in their flocks.[107,108]

FSIS could support and accelerate these programs by developing a regulatory framework to target *Salmonella* serotypes of greatest public health concern in raw poultry products and eventually achieve reductions in human illness similar to what has already been accomplished in other countries

3. FSIS Should Create Modernized, Enforceable Standards

We urge FSIS to initiate a rulemaking process create modernized, enforceable, finished product standards. In so doing, the agency should target *Salmonella* types of greatest public health concern and seek to reduce, with an aim to eliminate, these strains from products over time, while maintaining measures to control *Campylobacter* and *Salmonella* overall on raw poultry.

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[102] Commission Regulation (EU) 200/2012 of 8 March 2012, Concerning a Union Target for the Reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in Flocks of Broilers, as Provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council Text with EEA relevance (p. 1 ¶5).)

[103] European Food Safety Authority, European Centre for Disease Prevention and Control. The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2016. *EFSA J.* 2017; 15(12): 5077.

[104] Dórea FC, Cole DJ, Hofacre C, et al. Effect of Salmonella vaccination of breeder chickens on contamination of broiler chicken carcasses in integrated poultry operations. *Appl Environ Microbiol*. 2010;76(23): 7820-7825.

[105] Da Costa M, Cookson K, Schaeffer J. Live *Salmonella* Typhimurium Vaccination: Reducing *Salmonella spp*. Loads from the Field to the Processing Plant. Zoetis US website. Accessed January 7, 2021. https://www2.zoetisus.com/content/_assets/docs/Poultry/Live-Salmonella-Typhimurium-vaccination-reducing-Salmonella-spp.-loads-from-the-field-to-the-processing-plant.pdf

[106] Barrow PA. *Salmonella* infections: immune and non-immune protection with vaccines. *Avian Pathol.* 2007; 36: 1–13 (pg 4)

[107] Schaffer E. A Salmonella Solution? *Meat and Poultry*. July 24, 2020. Accessed January 12, 2020. https://www.meatpoultry.com/articles/23452-a-salmonella-solution

[108] Roundtable Discussion at: *Lightening the Load: Teaming live production with processing to meet USDA's new limits for foodborne pathogens*. August, 2016; San Antonio, TX

A non-detect, or zero-tolerance standard, while challenging for *Salmonella* overall given the current high levels of prevalence, may be more readily achievable for specific priority serotypes, some of which have an extremely low prevalence. Overall average annual percentages from an aggregate dataset of HACCP and NARMS isolates (2002-2012) revealed a relatively low prevalence for some of the most harmful serotypes: *S.* Enteritidis (2%) *S.* Heidelberg (2%), *S.* Typhimurium (2%), *S.*I 4,[5],12:i:- (0.31%), *S.* Infantis (0.16%).[109] FSIS may also opt to phase in a zero tolerance standard over time, providing short-term targets for reductions while setting a timeline to apply a zero-tolerance standard after industry has implemented additional controls to effectively eliminate the targeted serotypes from poultry production. This would include, for example, implementing preharvest programs to exclude the targeted serotypes from live birds, as well as developing processes to detect the targeted strains prior to slaughter and ensure products from contaminated flocks are segregated and diverted for further cooking. The relatively low prevalence quoted above suggests that diversion of contaminated product for further cooking would have only a limited impact upon the overall supply of cooked and uncooked products.

FSIS should also maintain its current measures to control *Campylobacter* and *Salmonella spp*. overall on raw poultry. Such a standard incentivizes establishments to maintain controls to reduce contamination overall, including the serotypes that are not identified as being of greatest public health concern, such as *S.* Kentucky. All *Salmonella* serotypes have the potential to cause human illness, with risk varying depending on the patient's age, medical history, health status, and infectious dose. To address this risk, FSIS should set more ambitious reduction targets, as well as re-codify the standards to make them legally enforceable (the legal basis for this action is discussed *infra*).[110]

FSIS should also consider adapting its current prevalence-based performance standard to include quantitative testing, which could ensure that when *Campylobacter* and *Salmonella* are present on a product, they are present at low levels less likely to cause human illness. Such testing is not used in the current sampling for performance standards, which look at whether a sample is positive or negative without attempting to quantify the level of bacteria present on the product.[111] Commercial diagnostic tests are now available that allow for rapid quantification of the amount of bacterial contamination on the product, and this technology could be applied to performance standards to ensure better assessment of the risks associated with products entering commerce. As the NACMCF committee noted, "[t]here is a growing body of data that indicates testing for *Salmonella* on the final product should be quantitative rather than presence or absence in order to better understand what is happening to levels of *Salmonella*."[112]

Quantitative thresholds provide a potential means of addressing risks by ensuring that any contamination remains below the potential infectious dose (i.e. the minimum number of live bacteria that it will take to cause illness) or below levels which may become harmful after typical

[109] Shah DH, Paul NC, Sischo WC, Crespo R, & Guard J. Population dynamics and antimicrobial resistance of the most prevalent poultry-associated *Salmonella* serotypes. *Poult Sci*. 2017; 96(3): 687-702.
[110] The legal basis for this is discussed *infra*.
[111] Food Safety and Inspection Service. *Pathogen Reduction – Salmonella and Campylobacter Performance Standards Verification Testing.* Washington, D.C: U.S. Department of Agriculture, FSIS; 2019.
[112] National Advisory Committee on Microbiological Criteria for Food. Response to Questions Posed by the Food Safety and Inspection Service Regarding Salmonella Control Strategies in Poultry. *J Food Prot*. 2019; 82 (4): 645–668.

consumer at-home temperature mismanagement.[113] While the infectious dose can be dependent on a range of pathogen, host, and environmental factors, as the dose increases, the probability of illness will likely also increase for *Salmonella* and *Campylobacter.*[114,115,116] The NACMCF committee suggested that specific thresholds could also be set for individual serotypes of public health importance.[117]

As with *Salmonella*, FSIS should establish an enforceable standard for *Campylobacter* that provides meaningful incentives for processors to implement a holistic program of pre-harvest and processing controls. Unlike *Salmonella*, *Campylobacter* is rarely classified by serotype for public health purposes, and therefore we are not requesting that the agency prioritize *Campylobacter* of greatest public health concern.[118] The agency may nevertheless set enforceable standards based on prevalence and may consider applying quantitative standards to reduce *Campylobacter* contamination over time.

As with *Salmonella*, approaches to *Campylobacter* may proceed incrementally. In the European Union, a stepwise approach to control of *Campylobacter spp.* was initially recommended by authorities, whereby process hygiene criteria would get stricter over time.[119] This stemmed from the recognition that "control of *Campylobacter* continues to prove challenging, as vertical transmission does not appear to be an important risk factor and all depends on how effective the biosecurity measures are at excluding *Campylobacter* from the broilers."[120] The commission's 2017 *Campylobacter* regulation mandates improvements in slaughter hygiene, a review of process controls, and improvement in biosecurity measures if sufficient samples of carcasses after chilling have >1,000 cfu/g.[121] As described in further detail *infra*, the available evidence also suggests that *Campylobacter* may require a different set of interventions than *Salmonella*, particularly when it comes to pre-harvest controls.

[113] McEntire J, Acheson D, Siemens A, et al. The Public Health Value of Reducing *Salmonella* Levels in Raw Meat and Poultry. *Food Production Trends*. 2014; 34(6): 386-392.
[114] Akil L, Ahmad HA. Quantitative Risk Assessment Model of Human Salmonellosis Resulting from Consumption of Broiler Chicken. *Diseases*. 2019; 7(1): 19.
[115] Teunis PFM, Bonačić Marinović A, Tribble DR, Porter CK, Swart A. Acute Illness from Campylobacter jejuni May Require High Doses While Infection Occurs at Low Doses. *Epidemics*. 2018; 24: 1-20.
[116] McEntire J, Acheson D, Siemens A, et al. The Public Health Value of Reducing *Salmonella* Levels in Raw Meat and Poultry. *Food Production Trends*. 2014; 34(6): 386-392.
[117] Such thresholds could be important, for example, in establishing regulatory limits if a zero-tolerance standard were not adopted immediately for some common serotypes of public health concern.
National Advisory Committee on Microbiological Criteria for Food. Response to Questions Posed by the Food Safety and Inspection Service Regarding Salmonella Control Strategies in Poultry. *J Food Prot*. 2019; 82 (4): 645–668.
[118] Nevertheless, the agency may consider prioritization strategies, and should research identify specific virulence traits within the broader category of *Campylobacter.*
[119]Commission Regulation (EU) 2017/1495 of 23 August 2017, Amending Regulation (EC) No 2073/2005 as Regards *Campylobacter* in broiler carcasses (Text with EEA relevance), ¶ 10.
[120] *Ibid.*
[121] *Ibid.*

C. Requested Action 2: Supply Chain Controls

FSIS officials, as well as other United States food safety experts both within and outside of government, have repeatedly recognized the need for "comprehensive farm-to-table" risk management and the potential for pre-harvest interventions to enhance public health.[122] As former FSIS Administrator Dr. Barbara Masters stated at a 2005 United States Department of Agriculture (USDA) conference, Advances in Pre-Harvest Reduction of *Salmonella* in Poultry,

> What happens before the animal gets to the establishment certainly has a great impact on the establishment's ability to address hazards at the processing establishment. And it certainly has an impact on our agency's ability to verify what the establishment is doing to address those hazards. While we recognize our regulatory authority is at the regulated establishment, we realize it's critical and what critical impact we can have by looking at the pre-harvest level.[123]

Such an approach also recognizes that pathogens are not limited to a single production environment and can move from livestock and poultry to produce and other commodities without regard to regulatory oversight. In 2011, Federal Food Safety Working Group (FSWG) members emphasized the need for federal food safety agencies (FSIS, FDA, and CDC) to work together, given there is "a common interest in working with the scientific, agricultural and public health communities to solve the problem of infection and transmission of foodborne disease organisms at the point of livestock and fresh produce production." [124] FSIS and its partner agencies at USDA were instructed to identify effective and innovative pre-harvest tools and lead dissemination of best practices among industry stakeholders.

FSIS's alignment with a comprehensive, farm-to-table approach to minimizing poultry hazards is further reflected in work under the agency's 2013 *Salmonella* Action Plan. The "DRAFT FSIS Compliance Guidance For Controlling Salmonella and Campylobacter in Raw Poultry," issued under that plan in 2015, states that pre-harvest interventions are a "part of an integrated approach to reduce the public health impact of *Salmonella* and *Campylobacter*."[125] Within this document, FSIS recommends "best practice" interventions for 1) Breeder Flock & Hatchery, 2) Growout House, 3) Bedding, 4) Feed, 5) Water, and 6) Transportation, and included estimates for the efficacy of pre-harvest control products such as vaccines, direct-fed microbials, prebiotics, and organic acids.

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[122] *Salmonella* Questions and Answers. Food Safety and Inspection Service website. Updated August 7, 2013. Accessed January 7, 2021. https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/foodborne-illness-and-disease/salmonella-questions-and-answers/

[123] Masters B. Opening Remarks. *Advances in Pre-Harvest Reduction of Salmonella in Poultry*; August 25, 2005; Athens, GA.

[124] Federal Food Safety Working Group. *Federal Food Safety Working Group Progress Report*. Washington DC: The White House, The Federal Food Safety Working Group; 2011

[125] Food Safety and Inspection Service. *Draft FSIS compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry*. Washington, D.C: U.S. Department of Agriculture, FSIS; 2015.

FSIS encourages establishments to require suppliers to adopt preharvest "best practices" and to incorporate them into their overall HACCP system.[126] In its final *Salmonella* Action Plan Update, the agency pledged to "continue to analyze the data that becomes available in the literature on pre-harvest activities, and that it will evaluate whether to recommend further changes to pre-harvest practices to reduce *Salmonella* contamination."[127] FSIS also re-affirmed its commitment to updating this guidance in the agency's recently-released *Salmonella* Roadmap.[128]

As noted above, adopting new standards to target *Salmonella* serotypes of greatest public health concern will accelerate and create strong incentives for adoption of pre-harvest interventions because many of the options available for targeting specific *Salmonella* serotypes (e.g., vaccination, flock monitoring programs) must be implemented preharvest. Yet adoption of such standards alone will be insufficient to ensure the necessary changes to reduce illnesses due to *Salmonella* infection without further effort by slaughter and processing establishments to ensure appropriate controls are being implemented within their supply chains prior to receiving birds.

We therefore urge FSIS to require establishments to adopt supply chain programs, following similar steps already undertaken by the FDA in its regulations establishing preventive controls for processed food. Specifically, these FDA regulations include a requirement that a "supply-chain program" be established for raw materials and other ingredients that a receiving facility identifies as "containing a hazard(s) reasonably likely to occur and in need of control."[129] Under these FDA regulations, facilities must require supply chain controls to mitigate hazards and verify that those controls have been appropriately applied to raw materials and other ingredients to address those hazards. Likewise, the European Union also has similar standards, and the USDA has already established the Quality System Assessment (QSA) Program specifically to assist the U.S. Poultry Industry in meeting their requirements.[130]

Applying supply-chain principles for live food animals is consistent with USDA's existing HACCP framework, which generally does not prescribe controls or mandate that specific measures be used to control hazards. Instead, such a program would require that establishments adopt individualized plans that ensure they are purchasing raw materials (i.e., live birds) that are safe and that adequate steps have been taken to identify and reduce hazards within the supply chain. Establishments would carry out validation, verification, and re-assessment activities to ensure the effectiveness of preharvest controls by their suppliers. This could include carrying out microbial testing of incoming birds, either prior to transport, at entry to the slaughterhouse,[131] or immediately

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[126] Food Safety and Inspection Service. *Draft FSIS compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry*. Washington, D.C: U.S. Department of Agriculture, FSIS; 2015.
[127] Food Safety and Inspection Service. *The FSIS Salmonella Action Plan: A Two Year Update*. Washington, DC: U.S. Department of Agriculture, FSIS; 2016.
[128] Food Safety and Inspection Service. *Roadmap to Reducing Salmonella: Driving Change through Science-Based Policy*. Washington, D.C: U.S. Department of Agriculture, FSIS; 2020.
[129] Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. 80 Fed. Reg. 55908, 56098 (Sep. 17, 2015), *codified as* 21 C.F.R. §117.405 *et seq*.
[130] Poultry Export Verification Program. United States Department of Agriculture, Agriculture Marketing Services website. Accessed December 3, 2020. https://www.ams.usda.gov/services/imports-exports/poultry-exports
[131] In some other countries, for example, this occurs through boot swab testing of flock houses 10-14 days prior to scheduled transport for slaughter. *See for example*: Lindblad, J. (2007). Lessons from Sweden's Control of *Salmonella* and *Campylobacter* in Broilers (Paper and PowerPoint). Retrieved from https://EconPapers.repec.org/RePEc:ags:usaose:8109

post-mortem, prior to evisceration. We envision that FSIS would verify the effectiveness of such programs through inspection of the establishments' plan and testing records. As discussed *infra*, the agency also has authority to conduct its own testing to verify the effectiveness of pre-harvest controls, under the agency's antemortem inspection authority.

A supply chain program would help FSIS expand past its current narrow regulatory focus on slaughter and processing, which misses a critical upstream opportunity to minimize bacterial contamination of live birds prior to receipt at slaughter establishments. In particular, FSIS's current approach emphasizes testing of products post-slaughter and processing, an emphasis that promotes heavy reliance on post-slaughter controls, such as anti-microbial sprays or dips, to achieve compliance.

Evidence from other countries has established the effectiveness a more holistic, multi-hurdle approach that sets targets for reducing *Salmonella* contamination at every step in the supply chain, including live production. Beginning in the 1970s, Sweden implemented programs that required strict on-farm biosecurity, sanitation, and monitoring.[132] From 1995 to 2005, only 13 pooled slaughterhouse samples were found to be positive for *Salmonella* out of over 42,000.[133]

Emphasis on preharvest preventive policies can also be highly effective at reducing human illnesses. Cases of salmonellosis plummeted in Denmark after the implementation of that country's control program, with the number of reported human *Salmonella* infections falling from 4,276 cases in 1994 to 1,775 in 2005. [134,135] In 2019, only 0.2% of human salmonellosis cases in Denmark were directly attributed to domestic chicken.[136]

These successful programs all incorporated pre-harvest interventions to control *Salmonella* in primary production, reducing *Salmonella* prevalence starting at the farm. In 2005-2006, an EU study found that 23% of broiler flocks with at least 5,000 birds were *Salmonella* positive.[137] All Member States have now been required to adopt national control programs in order to accomplish common EU goals regarding the prevalence of *Salmonella* in primary production.[138] The programs have been highly effective: by 2016 the EU-level prevalence of *Salmonella* in broiler flocks was

[132] Lindblad J. *Lessons from Sweden's Control of Salmonella and Campylobacter in Broilers.* Paper and Presentation at: United States Department of Agriculture, Agricultural Outlook Forum; March 1-2, 2007; Washington, DC.
[133] Lindblad J. *Lessons from Sweden's Control of Salmonella and Campylobacter in Broilers.* Paper and Presentation at: United States Department of Agriculture, Agricultural Outlook Forum; March 1-2, 2007; Washington, DC.
[134] Wegener HC, Hald T, Lo Fo Wong D, et al. *Salmonella* Control Programs in Denmark. *Emerg Infect Dis*. 2003; 9(7): 774-780.
[135] Christensen T, Andersen L (2007). Case Study #3-12: Salmonella Control in Denmark and the EU. In: Per Pinstrup-Andersen and Fuzhi Cheng, eds. *Food Policy for Developing Countries: Case Studies*. Ithaca, NY: Cornell University; 2007.
[136] National Food Institute. *Annual Report on Zoonoses in Denmark 2019*. Kemitorvet: Technical University of Denmark; 2020.
[137] European Food Safety Authority. Report of the Task Force on Zoonoses Data Collection on the Analysis of the Baseline Survey on the Prevalence of Salmonella in Broiler Flocks of Gallus gallus, Part A. *EFSA J*. 2007; 98: 1-85.
[138] European Food Safety Authority Panel on Biological Hazards. Scientific Opinion on the *Salmonella* control in poultry flocks and its public health impact. *EFSA J*. 2019; 17(2): 5596.

reported at just 2.6%, nearly nine times lower than it had been a decade earlier.[139] Supply chain programs are a critical step towards achieving similar successes in the United States.

Control of *Campylobacter* will likely require specific supply chain controls that differ from those needed to address *Salmonella*, as there are major differences in the organisms' biology, epidemiology, and immunology.[140] For example, while vertical transmission of *Salmonella* is likely, evidence does not point to vertical transmission as a source of *Campylobacter*.[141,142] Conversely, lapses in farm biosecurity appear to be more consequential for *Campylobacter* than *Salmonella*.[143] Sweden has found success by enhancing farm-level hygiene (rodent and bird barriers, employee protocols), bringing their percentage of *Campylobacter*-positive flocks down from 20% in 1991 to 10% in 2006.[144] In comparison, a 2013 study of 55 flocks from a large U.S. commercial broiler production company detected Campylobacter in on-farm samples from 64% of flocks and in processing samples from 87% of flocks.[145] At the present time, there is no commercially available vaccine for *Campylobacter,* however work is ongoing on a vaccine and shows promise.[146]

As with *Salmonella,* multiple control activities are expected to prevent *Campylobacter* from entering the broiler house and infecting the birds.[147] In the EU, EFSA performed a *Campylobacter*-specific analysis and in 2020 released eight recommendations for *Campylobacter* control measures: vaccination, feed and water additives, discontinued thinning, employing few and well-trained staff, avoiding drinkers that allow standing water, addition of disinfectants to drinking water, hygienic anterooms at broiler house entrances, and designated tools per broiler house.[148]

III. Legal Basis for the Requested Actions

FSIS's legal authority to grant the requested actions is derived from the Poultry Products Inspection Act (PPIA), which charges the agency with verifying, through the continuous

[139] European Food Safety Authority, European Centre for Disease Prevention and Control. The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2016. *EFSA J*. 2017; 15(12): 5077.
[140] European Food Safety Authority Panel on Biological Hazards. Scientific Opinion on the *Salmonella* control in poultry flocks and its public health impact. *EFSA J*. 2019; 17(2): 5596.
[141] *Ibid.*
[142] European Food Safety Authority Panel on Biological Hazards. Update and review of control options for *Campylobacter* in broilers at primary production. *EFSA J*. 2020; 18(4): 6090.
[143] European Food Safety Authority Panel on Biological Hazards. Scientific Opinion on the *Salmonella* control in poultry flocks and its public health impact. *EFSA J*. 2019; 17(2): 5596.
[144] Lindblad J. *Lessons from Sweden's Control of Salmonella and Campylobacter in Broilers.* Paper and Presentation at: United States Department of Agriculture, Agricultural Outlook Forum; March 1-2, 2007; Washington, DC.
[145] Berghaus RD, Thayer SG, Law BF, et al. Enumeration of Salmonella and Campylobacter spp. in Environmental Farm Samples and Processing Plant Carcass Rinses from Commercial Broiler Chicken Flocks. *Appl Environ Microbiol*. 2013; 79(13): 4106-4114.
[146] Meunier M, Guyard-Nicodème M, Vigouroux E, et al. Promising new vaccine candidates against Campylobacter in broilers. *PLoS One*. 2017; 12(11).
[147] Newell, D.G.; Fearnley, C. Sources of *Campylobacter* Colonization in Broiler Chickens. *Appl. Environ. Microbiol*. 2003; 69: 4343–4351.
[148] European Food Safety Authority Panel on Biological Hazards. Update and review of control options for *Campylobacter* in broilers at primary production. *EFSA J*. 2020; 18(4): 6090.

inspection of slaughter and processing establishments, that poultry products produced in the United States are not adulterated.[149] The mark of inspection can be applied only after the product is inspected and "found to be not adulterated," placing the burden of proof on the regulated establishment to show that the product is in compliance with the law.[150] Poultry may not be slaughtered or processed for human food except in compliance with these requirements.[151]

In passing the PPIA, Congress declared that its intent was to ensure that decisions to condemn poultry products "shall be supported by scientific fact, information, or criteria."[152] The statute empowers FSIS to promulgate "such rules and regulations needed to carry out" the provisions of the PPIA,[153] and the agency requires that inspection be "rendered pursuant to the regulations and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator."[154]

The term "adulterated" is defined under 21 U.S.C. § 453(g), which states, in relevant part, that a poultry product may be adulterated:

> (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. [or]
> …
> (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

To prevent adulterated poultry products from entering commerce, the PPIA directs FSIS to conduct an ante-mortem inspection of every live animal prior to slaughter. Specifically, 21 U.S.C. § 455(a) provides:

> For the purpose of preventing the entry into or flow or movement in commerce of, or the burdening of commerce by, any poultry product which is capable of use as human food and is adulterated, the Secretary shall, where and to the extent considered by him necessary, cause to be made by inspectors ante mortem inspection of poultry in each official establishment processing poultry or poultry products for commerce or otherwise subject to inspection under this chapter.

[149] Poultry Products Inspection Act. 21 U.S.C. § 451 *et seq*.
[150] 21 U.S.C. 457(a) (requiring that poultry products bear the mark of inspection only after they are "found to be not adulterated"); *See also* FSIS Statutes and Your Role, Training for FSIS Public Health Veterinarians. November 6, 2013. ("Remember that product cannot move out of the establishment into commerce until it has been inspected and marked as passed. This means that you must be able to find that product is NOT adulterated. The burden of proof is on the establishment.")
[151] 21 U.S.C. § 458.
[152] 21 U.S.C. § 452.
[153] 21 U.S.C. § 463(b).
[154] 9 CFR § 381.4.

The adulteration definition under 21 U.S.C. § 453(g)(1) empowers FSIS to define specific pathogens as adulterants, and FSIS successfully relied on parallel language in the Federal Meat Inspection Act (FMIA) in 1994 in determining that *E. coli* O157:H7 is an adulterant in ground beef,"[155] and again in 2011 in declaring six additional non-O157 strains of Shiga-toxin producing *E. coli* (STEC) to be adulterants under the statute.[156]

As the agency stated in its 1999 policy statement explaining the basis for its determination that *E. coli* O157:H7 is an adulterant in ground beef, "[g]iven the low infectious dose of [*E. coli* O157:H7] associated with foodborne disease outbreaks and the very severe consequences of an [*E. coli* O157:H7] infection, the Agency believes that the status under the FMIA of beef products contaminated with [*E. coli* O157:H7] must depend on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed."[157] Thus, when a highly virulent pathogen is present on raw product, the product is considered adulterated, unless there is adequate assurance that subsequent handling will render the pathogen harmless.

Based on what we now know about *Salmonella*, such assurance can no longer be provided for the most virulent strains of this pathogen. Decades of behavioral and epidemiological research have amply demonstrated that ordinary consumer cooking practices will not adequately prevent outbreaks of salmonellosis. Studies continue to show that a minority of home cooks adhere the USDA-recommended food safety practices for raw poultry, suggesting these products are harmful as ordinarily consumed by Americans.[158]

Moreover, it is now well recognized that *Salmonella* is difficult to eliminate, in part because it can adhere very tightly to commonly used food preparation surfaces such as stainless steel.[159,160] A risk assessment conducted by the World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO) in 2002 concluded that "washing reduces the incidence of cross-contamination, but not completely."[161] Decades of research have provided ample evidence that washing surfaces and hands -- even cleaning utensils in commercial dishwashers -- may not be sufficient to prevent the spread of *Salmonella.*

In addition, our petition requests that FSIS focus specifically on the types of *Salmonella* of greatest public health concern, meaning the agency would be declaring only the most virulent strains of *Salmonella* to be adulterants under 21 U.S.C. § 453(g)(1), a finding that would support creating a zero-tolerance standard for such strains. As two of the petitioners have argued

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[155] *Texas Food Industry Ass'n v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994).
[156] Shiga Toxin-Producing E coli. 76 Fed. Reg. 58157 (Sep. 20, 2011).
[157] Beef Products Contaminated with Escherichia Coli O157:H7. 64 Fed. Reg. 2803. (Jan. 19, 1999)
[158] Kosa KM, Cates SC, Brophy J, et al. Older Adults and Parents of Young Children Have Different Handling Practices for Raw Poultry. *J Food Prot*. 2019; 82(2) :200-206. *See also*: Nikos-Rose, K. Risky Food Safety Practices in Home Kitchens. UC Davis College of Agricultural and Environmental Sciences. July 9, 2014.
[159] Cliver DO. Cutting boards in Salmonella cross-contamination. *J AOAC Int.* 2006 ;89(2): 538-42.
[160] Carrasco E, Morales-Ruenda A, Garcia-Gimeno RN. Cross-Contamination and Recontamination by Salmonella in Foods: A Review. *Food Res Int.* 2012; 45(2): 545-556.
[161] World Health Organization, Food and Agriculture Organization of the United Nations. *Microbiological Risk Assessment Series - 2: Risk Assessments of Salmonella in Eggs and Broiler Chickens – 2*. Geneva, Switzerland, 2002.

previously,[162] *Salmonella* is present in the gastrointestinal tract of live birds but is not normally found in the muscle tissue of healthy animals, making its way onto the flesh of the poultry product only through contamination during slaughter and dressing.[163] This means all *Salmonella* may be considered an "added substance," and as such would be an adulterant to the extent that it "may render [the product] injurious to health" under (g)(1). Certainly, the types of *Salmonella* of greatest public health concern would meet such a standard.

Even if the USDA considered *Salmonella* not to be an "added substance," serotypes of greatest public health concern could meet the legal standard as an adulterant on the ground that such strains "ordinarily render [the product] injurious to health." We expect that the agency will consider the pathogenicity and virulence of specific strains of *Salmonella* in determining whether to declare such strains to be adulterants, and that the incidence and severity of human illnesses caused by these types will be sufficient to meet the "ordinarily … injurious to health" standard.

Applying these factors to designate certain *Salmonella* strains as adulterants would be consistent with the agency's past analysis. For example, in February 2018 the agency rejected a petition by CSPI, one of the undersigned petitioners, to declare certain multidrug resistant strains of *Salmonella* to be adulterants, in part based on the fact that "antibiotic resistance alone is not an appropriate basis for determining whether a strain is considered an adulterant" and that "numerous factors, including genetic, environmental, and host-specific factors, interact to make a particular strain pathogenic and virulent." Accordingly, the agency should apply those factors in prioritizing *Salmonella* types of greatest public health concern and making an adulteration finding regarding these strains.[164] The designation would also be consistent with past agency decisions to determine that pathogens that are not typically considered adulterants, like *Salmonella* and *Campylobacter*, can be considered adulterants in specific instances when a contaminated product is tied to cases of human illness through an outbreak investigation.[165] Similar logic can be applied to highly virulent strains of *Salmonella*, which will likely be commonly associated with human illnesses.

Judicial precedent does not prevent FSIS from adopting the requested actions. In a 1974 appeals court ruling, *Am. Pub. Health Asso. v. Butz*, the D.C. Circuit took the position that meat

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[162] Citizen Petition submitted by Marler Clark LLP to the U.S. Department of Agriculture Food Safety and Inspection Service 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), January 19, 2020. See note 59. Accessible at https://www.marlerblog.com/case-news/petition-for-an-interpretive-rule-declaring-outbreak-serotypes-of-salmonella-enterica-subspecies-enterica-to-be-adulterants-within-the-meanings-of-21-u-s-c-%C2%A7-601m1-and-21-u/

[163] Gill, CO. A Review: Intrinsic Bacteria in Meat. *J Appl Bacteriol*. 1979; 47: 367-378.

[164] Rottenberg CM. Letter to Laura MacCleery, Director Regulatory Affairs, Center for Science in the Public Interest. February 7, 2018. Accessed December 22, 2020. https://www.fsis.usda.gov/wps/wcm/connect/b3f61f6e-47e5-4164-ac60-913c1ff66b26/FSIS-response-CSPI-020718.pdf?MOD=AJPERES FSIS rejected the Center for Science in the Public interest argument that multidrug resistant ("ABR") *Salmonella* was an "added substance" on the ground the prevalence of resistance was increased by human actions: *i.e.* the use of antibiotics in agriculture. However, that decision was similarly based the agency's finding that ABR *Salmonella* was not a "unique 'substance'" distinct from other *Salmonella* and did not address whether all *Salmonella* could be considered an "added substance."

[165] HACCP Plan Reassessment for Not-Ready-to-Eat Comminuted Poultry Products and Related Agency Verification Procedures. 11 Fed. Reg. 72686, 72689 (Dec. 6, 2012).

contaminated with *Salmonella* need not be labeled with safe handling instructions because "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."[166] That case involved *Salmonella* overall and did not specifically address the question of whether FSIS had the authority to declare certain highly virulent strains of *Salmonella* to be adulterants based on evidence of human illness outbreaks. Regardless, subsequent decades of food safety research have now amply disproven the court's assumptions in that case: ordinary cooking practices are not, in fact, sufficient to protect consumers against outbreaks, particularly from the highly virulent strains of *Salmonella* that are responsible for the bulk of human illnesses.

In addition to supporting a zero-tolerance standard for serotypes of greatest public health concern, 21 U.S.C. § 453(g)(1), would also authorize the agency to employ enforceable quantitative thresholds to ensure that any *Salmonella* or *Campylobacter* that is permitted on poultry products is maintained at low enough levels less likely to cause human illness. Such a determination could be supported by dose-response studies demonstrating that the risk of infection is elevated above the quantitative threshold designated by the agency for each pathogen or subtype. Such a standard would be authorized regardless of whether the agency considers *Salmonella* or *Campylobacter* to be an "added substance," because the standard would be based on dose-response studies demonstrating that "quantity of such substance" is sufficient to ordinarily result in human illness.[167]

FSIS also has the authority to create enforceable standards for *Salmonella* and *Campylobacter* under 21 U.S.C. § 453(g)(4), which allows the agency to find a poultry product to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. It was paragraph (g)(4), along with parallel authority from the FMIA, that formed part of the regulatory basis for the agency's modern HACCP requirements in 1996, which are now codified in 9 CFR Part 417.[168]

Paragraph (g)(4) also serves as the authority for the agency to establish supply chain programs tailored to the risks inherent in their operations and the manner in which those risks are controlled. The current HACCP rule promulgated under that authority already specifically directs establishments to address, as appropriate, hazards both "introduced in the establishment" and "introduced outside the establishment, including food safety hazards that occur before… entry into the establishment."[169] The supply chain program envisioned under this petition would expand upon the same principles to ensure that establishments are appropriately considering hazards that can be controlled by suppliers.

In addition, the agency has authority to verify the effectiveness of supply chain controls through its antemortem inspection authority under 21 U.S.C. § 455(a). This section empowers the agency to conduct an antemortem inspection "where and to the extent considered by him necessary," "[f]or the purpose of preventing the entry into or flow or movement in commerce

[166] *Am. Pub. Health Asso. v. Butz*, 167 U.S. App. D.C. 93, 511 F.2d 331,334 (1974).
[167] 21 U.S.C. § 453(g)(1).
[168] Final HACCP Rule at 38837.
[169] 9 C.F.R. § 417.2.

of… any poultry product which is capable of use as human food and is adulterated." As the agency recently noted in its proposed rule on the regulation of genetically engineered animals, which would authorize FSIS to conduct a food safety review for genetically engineered food animals, "[n]either [the PPIA or the FMIA] specifies how far in advance examinations or reviews relative to this inspection can occur."[170] The agency could therefore rely on the antemortem inspection provisions to verify supply chain programs and review testing records for incoming flocks prior to slaughter. The agency would also be authorized to conduct its own antemortem verification testing "where and to the extent considered by him necessary" to prevent adulteration, which could include sampling of live birds at the slaughter facility or on farms to verify that *Salmonella* and *Campylobacter* are being adequately controlled.

The agency is not precluded from adopting this approach by *Supreme Beef*, a 2001 decision by the Fifth Circuit invalidating a portion of the original 1996 HACCP rule. The court in that case held that the original performance standard for *Salmonella* in ground beef was invalid because it rendered establishments accountable for product contamination that occurred prior to entry into the regulated establishment.[171] In *Supreme Beef*, a beef grinding operation had repeatedly purchased ground beef "trimmings" carrying high levels of *Salmonella* contamination, resulting in a ground beef end product which frequently tested positive for *Salmonella* in violation of the performance standard then in effect for ground beef. Taking note of the agency's agreement that *"Salmonella*, present in a substantial proportion of meat and poultry products, is not an adulterant *per se*," the court held that FSIS could not apply a standard that effectively regulated the *Salmonella* levels of incoming raw materials, and must limit its enforcement against a particular establishment to address only the contamination that occurs within that regulated establishment itself.[172]

In so doing, the Fifth Circuit read the "whereby it may have been rendered injurious" language in the statute to require that "a deleterious change in the product must occur while it is being 'prepared, packed or held' owing to insanitary conditions" that could be identified within the establishment itself.[173] On that basis, the court held that "a characteristic of the raw materials that exists before the product is 'prepared, packed or held' in the grinder's establishment cannot be regulated by the USDA."[174]

The Fifth Circuit also separately considered whether FSIS had the power to regulate incoming raw materials, just as it regulates other contamination sources, because *Salmonella* can be spread to non-infected meat during processing. But the court rejected this approach on the ground that the performance standard in that case failed to identify a "deleterious change" in the product because it failed to show a "differential between incoming and outgoing meat products in terms of the Salmonella infection rate."[175] In essence, while FSIS is generally permitted to define sanitary conditions to minimize bacterial contamination, it may direct that effort only at preventing

[170] Animal and Plant Health Inspection Service and Food Safety and Inspection Service. Regulation of the Movement of Animals Modified or Developed by Genetic Engineering. Proposed Rule. 85 Fed. Reg. 84269, 84273-4 (Dec. 28, 2020).
[171] *Supreme Beef v. U.S. Dep't of Agric*, 275 F.3d 432 (5th Cir. 2001).
[172] *Supreme Beef* at 440
[173] *Ibid.*
[174] *Ibid.*
[175] *Supreme Beef* at 442.

contamination that occurs within the establishment itself, not towards contaminated that takes place prior to entry into the establishment.

The court never fully explained why the "insanitary conditions" rendering a deleterious change to the product could not have occurred at previous suppliers. The 5th Circuit's reading of this provision also diverges from an earlier decision *United States v. Nova Scotia Food Products Corp*., in which the Second Circuit interpreted identical language in the Food, Drug, and Cosmetic Act (FFDCA) to allow regulations to address micro-organisms already present in fish prior to arriving at a regulated facility.[176] The court in that case emphasized that "when we are dealing with the public health, the language of the Food, Drug and Cosmetic Act should not be read too restrictively, but rather as 'consistent with the Act's overriding purpose to protect the public health.'"[177] Given the lack of alignment between the ruling in *Supreme Beef* and modern sanitation best practices, it is possible that a court considering the issue today would arrive at an interpretation supporting these rules.

Regardless, this petition presents no conflict with *Supreme Beef* because the actions requested herein are aimed specifically at addressing contamination that occurs within the slaughter establishment itself. The rules governing the beef grinder in *Supreme Beef* addressed a standard that regulated raw meat "trimmings" that were already contaminated with pathogens prior to entry into the grinding establishment. By contrast, poultry flesh is sterile prior to slaughter, and it is only during slaughter and subsequent processing that *Salmonella*, *Campylobacter*, and other pathogens are transferred from the gastrointestinal tract of the bird to the end product. Moreover, because *Supreme Beef* addressed the processing of one meat product into another, it did not consider FSIS's antemortem inspection authority under 21 U.S.C. § 455(a), which authorizes the agency to ensure the effectiveness of food safety controls prior to slaughter.

In addition, whereas the *Salmonella* under consideration in *Supreme Beef* was not an adulterant, we have urged the agency to adopt an approach that allows for the ultimate elimination of *Salmonella* types of greatest public health concern, meaning such strains could be considered adulterants. In addition, any quantitative thresholds employed by the agency would also ensure that products with contaminated above the standard would be considered adulterated. Finally, any *Salmonella* or *Campylobacter* may be considered an adulterant to the extent it is associated with an outbreak of human illness.

Just as FSIS is permitted to require establishments to develop a sanitation plan excluding rodents, insects, and other pests that are a source of pathogens entering a slaughter establishment, it may require establishments to develop a supply chain program to verify that reasonable controls have been used to exclude the pathogens that arrive on live birds. If anything, the ability to control pathogen loads in live birds is even more critical to modern sanitation practices, because of the extremely high risk that pathogens will be transferred from the live animals to the poultry products. Such control can only be assured through science-based preventive management of hazards that arise throughout the supply chain, an approach already expressly contemplated by the FSIS in its HACCP rules, which are now a well-recognized element of modern preventive controls.

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[176] *United States v. Nova Scotia Food Products Corp*., 568 F.2d 240 (2d Cir.1977).
[177] *Ibid.* at 246 (quoting *United States v. Bacto-Unidisk*, 394 U.S. 784, 798, 22 L. Ed. 2d 726, 89 S. Ct. 1410 (1969)).

IV. Conclusion

The petitioners thank FSIS for considering the requested actions presented in this petition. As outlined above, we urge FSIS to identify *Salmonella* types of greatest public health concern and replace current poultry performance standards with enforceable standards for both *Salmonella* and *Campylobacter*. We also request that FSIS promulgate a rule requiring supply chain controls for slaughter establishments. Given the continuing public health burden of *Salmonella* and *Campylobacter*, individuals and families in the United States deserve food safety standards that protect them from the risks posed by the foods inspected by this agency. In the interest of protecting public health and meeting the reasonable expectations of America's consumers, the time has come to set enforceable finished product standards and extend necessary reforms to the U.S. poultry industry based on a risk-based approach. We look forward to working with FSIS and other stakeholders in achieving these goals.

Respectfully submitted,

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