



**Consumer Federation of America**

# **Taking *Salmonella* Seriously**

**Policies to Protect Public Health under Current Law**

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## I. Introduction

No one knows exactly how *Salmonella* Heidelberg infected Noah Craten, but in September of 2013, at the age of 17-months, he was stricken with a persistent fever. His parents sought medical care early and often. Noah did not have the vomiting, bloody diarrhea, or other telltale signs of a *Salmonella* infection, so Noah's doctors treated him with antibiotics. They ordered test after test over the course of a month, but to no avail. Noah's condition deteriorated. Eventually, his doctors admitted him to the hospital, where they discovered a large abscess in his brain that required emergency surgery. It was not until two days after surgeons opened the toddler's skull that testing identified *Salmonella* as the culprit. To recover from his surgery, the doctors hooked up Noah to a ventilator and kept him in a medically-induced coma for days. Upon regaining consciousness, Noah began an arduous recovery process that included relearning how to speak.<sup>1</sup>

Noah was just one of 639 people in 29 states that were confirmed to have been sickened by an antibiotic resistant strain of *Salmonella* Heidelberg, linked to chicken produced by Foster Poultry Farms ("Foster Farms").<sup>2</sup> Overall, the outbreak likely affected thousands more. The Centers for Disease Control and Prevention (CDC) estimates that, for every one confirmed case of *Salmonella*, another 29 go unreported.<sup>3</sup> The Foster Farms outbreak drew attention to the danger posed by *Salmonella*<sup>4</sup> contamination in raw chicken,<sup>5</sup> and in its wake, USDA's Food Safety and Inspection Service (FSIS) issued new performance standards for *Salmonella* contamination in poultry parts and ground product, rather than on just whole turkey and chicken carcasses.<sup>6</sup> This was a sensible reform considering that most consumers do not buy whole chickens and turkeys.<sup>7</sup> Unfortunately, over four years since CDC declared the Foster Farms outbreak to be over, the problem of *Salmonella* in raw chicken, and in raw meat and poultry writ large, appears as bad as ever, with two large outbreaks—one linked to raw chicken and another to raw turkey—ongoing as of this writing.

Data posted by FSIS on November 23, 2018—the Friday after Thanksgiving—offer some insight into the lack of progress. The data shows for the first time which plants are meeting (category 1), nearly failing (category 2), and failing (category 3) the *Salmonella* performance standards for poultry parts and ground product, standards which have now been in effect for some two-and-a-half years. Most large poultry companies, including Koch Foods, Pilgrim's Pride, Perdue, and Sanderson Farms, have one or more chicken parts processing plants that are in "category 3," i.e. failing to prevent more than 15.4% of samples from testing positive for *Salmonella*. At some companies, such as Koch Foods, almost all of the plants are failing to meet the standard.<sup>8</sup>

The widespread incompliance attests to both the evolutionary fitness of the *Salmonella* organism, and the weak incentives under federal rules for poultry companies to attend to the bacteria. For nearly two decades, FSIS has responded to excessive *Salmonella* contamination at meat and poultry plants like those of Koch Foods by deploying additional inspectors and testing and conducting a "Food Safety Assessment," over and over again if necessary, all at taxpayer expense. Poor performing plants are not shut down if they fail to comply. Indeed, the agency has defended web-posting plants' compliance status

with the older, whole carcass based standards precisely because there were not “significant consequences to failing” to meet the standards otherwise.<sup>9</sup>

Publishing compliance data is helpful,<sup>10</sup> but it is not enough. *Salmonella* infection rates in the U.S. have remained stubbornly high, even as the disease burden of other foodborne pathogens has significantly declined.<sup>11</sup> In just the past few months, a rash of *Salmonella* outbreaks linked to meat and poultry have caused hundreds of confirmed illnesses, as the table below shows.<sup>12</sup>

**Salmonella Outbreaks Associated with Meat and Poultry in 2018 (so far)**

Date	Product	Salmonella Serotype	Confirmed Victims
Oct. 17, 2018	Raw chicken	<i>Salmonella</i> Infantis	92 victims, 21 hospitalizations
Nov. 15, 2018	Ground beef	<i>Salmonella</i> Newport	246 victims, 59 hospitalizations
Aug. 29, 2018	Raw chicken	<i>Salmonella</i>   4,[5],12:i:-	17 victims, 8 hospitalizations, 1 death
Nov. 16, 2018	Raw turkey	<i>Salmonella</i> Reading	164 victims, 63 hospitalizations, 1 death
April 6, 2018	Chicken salad	<i>Salmonella</i> Typhimurium	265 victims, 94 hospitalizations, 1 death

Again, for each of these illnesses, typically confirmed via stool sample, dozens more have likely gone unreported.

Government can, and should, do more to protect consumers from *Salmonella* poisoning, in particular through classifying *Salmonella* as an adulterant on meat and poultry. Such a classification is warranted for the same reasons that FSIS has treated *E. coli* O157:H7 as an adulterant in ground beef since 1994. Treating *Salmonella* as an adulterant could take at least five different forms. FSIS could consider meat and poultry “adulterated” if it is contaminated with: 1) any *Salmonella* at all (zero tolerance strategy); 2) particular *Salmonella* serotypes, such as those most associated with human illness (serotype strategy); 3) *Salmonella* that is a genetic match to a strain associated with an ongoing illness outbreak (outbreak strain strategy); *Salmonella* resistant to certain medically important antibiotics (antibiotic resistant strategy); or 4) high numbers of *Salmonella* bacteria (high pathogen load strategy).

This report explains why any of these strategies, or a combination of one or more of them, could protect consumers better than the status quo, and why the law and the latest scientific research support taking action now. Although the report’s primary recommendation—to treat *Salmonella* as an adulterant—is meant to apply to all raw meat and poultry, the report focuses on poultry, because it represents the most important source of *Salmonella* contamination among these products.<sup>13</sup>

**II. Protecting Consumers from *Salmonella*: What’s at Stake?**

Each year, *Salmonella* causes an estimated 1.2 million illnesses, 23,000 hospitalizations, and 450 deaths in the United States.<sup>14</sup> As the numbers suggest, most Salmonellosis cases pass without serious complications, but the bacteria nevertheless causes more hospitalizations and deaths than any other

microbiological pathogen in the U.S. food supply.<sup>15</sup> The associated medical bills alone are estimated to exceed \$3.7 billion each year.<sup>16</sup> Sometimes, an unlucky victim acquires the bacteria from a pet or another non-food source, but contaminated food causes the vast majority of salmonellosis cases.<sup>17</sup> And meat and poultry play an outsized role.<sup>18</sup>

The statistics underscore the need for more investment in preventing *Salmonella* contamination in raw meat and poultry.<sup>19</sup> Indeed, cost-benefit analyses have supported stronger consumer protections against *Salmonella* in other countries.<sup>20</sup> And while economic considerations should not obscure the human toll of continued inaction, they leave little doubt that the public health burden caused by *Salmonella* contaminated meat and poultry represents an enormous hidden subsidy to industry. To compensate Noah Craten's family for his injuries, an Arizona federal court jury returned a verdict against Foster Farms in the amount of \$6.5 million on March 1, 2018.<sup>21</sup> Yet most salmonellosis victims are never able to hold anyone accountable for making them sick.

Indeed, one reason that *Salmonella* takes such a toll on public health is that a correct diagnosis often eludes healthcare providers. The symptoms of *Salmonella* infection vary from one patient to the next. Fever, abdominal cramps, and diarrhea are among the most common signs, but as Noah Craten's story shows, not all infections manifest the most common symptoms. In the initial stages of infection, only a stool sample can confirm whether *Salmonella* is the cause.<sup>22</sup> An estimated 5% of patients suffer the misfortune of developing bacteremia, or bloodstream infection, from *Salmonella*, and in these patients, a blood or urine test may suffice to detect the bacteria.<sup>23</sup> But blood tests may turn up false negatives if a patient has taken antibiotics.<sup>24</sup> Recently, new testing has dramatically shortened the amount of time needed to confirm the presence of *Salmonella* in a clinical sample, increasing detection rates.<sup>25</sup> Yet because the new testing eliminates the need for growing an isolate of a living *Salmonella* specimen in culture, it does not give public health authorities the information they need to identify antibiotic resistant strains, or to make the links between disparate cases that signal an outbreak.<sup>26</sup>

Another factor that makes *Salmonella* deadly is antibiotic resistance.<sup>27</sup> The outbreak strains of *Salmonella* Heidelberg tied to Foster Farms, for example, were resistant to several commonly prescribed antibiotics. Antibiotic resistance in *Salmonella* is associated with a greater risk of hospitalization in infected individuals.<sup>28</sup> Livestock farming practices—particularly treating livestock with antibiotics—plays an important role in breeding antibiotic resistant *Salmonella* and other bacteria.<sup>29</sup> Overall, antibiotic-resistant infections kill an estimated 23,000 Americans each year.<sup>30</sup>

Fortunately, researchers have identified proven strategies to combat resistance, with some of the most dramatic success stories involving chicken.<sup>31</sup> Today, many of the largest poultry producers, including Perdue and Tyson, have largely phased out the use of antibiotics.<sup>32</sup> Other companies, however, have vehemently defended their continued reliance on the drugs. Most notoriously, the country's third-largest chicken producer, Mississippi-based Sanderson Farms, has gone so far as to air television commercials suggesting that competitors' "raised without antibiotics" labels are meaningless.<sup>33</sup> This aggressive posture raises broad concerns about the continued contribution of poultry to antibiotic resistance. It also raises more conventional food safety concerns, since the strategies for reducing antibiotics in raising poultry—better sanitation, biosecurity, vaccines, healthy feed additives—also tend to reduce the incidence of *Salmonella* in broiler flocks.

### III. The Status Quo: Failing to Protect Consumers from *Salmonella*

FSIS does not consider even the most virulent, antibiotic resistant strains of *Salmonella* to be *per se* adulterants. Nor does the agency consider meat and poultry adulterated when it is heavily contaminated with large numbers of *Salmonella* bacteria. Yet, the agency has recognized that *Salmonella* contaminated meat and poultry is “adulterated” after it is “associated with an illness outbreak.”<sup>34</sup> In other words, regulators are reacting to foodborne illness caused by *Salmonella* after people get sick, rather than preventing it from happening in the first place. This sort of reactive posture makes for weak consumer protections.

FSIS has not taken such a passive approach to regulating other pathogens in food. In 1994, the agency declared that it would treat *E. coli* O157:H7 in ground beef as an adulterant, after an outbreak associated with Jack in the Box restaurant hamburgers killed four children and sickened 623 others.<sup>35</sup>



A flyer created by food safety advocates in the wake of the *E. coli* O157:H7 outbreak associated with Jack in the Box Restaurants.

FSIS expanded its adulterant classification to a broader range of shiga-toxin producing *E. coli*, or STEC's, in 2011. At least with respect to *E. coli* O157:H7, the policy, and the industry response, has dramatically improved public health. Ground beef that tests positive for *E. coli* O157:H7 cannot be sold to the public, and so companies have found ways to prevent *E. coli* contamination from occurring. For *Salmonella*, however, the agency advises companies that chicken products can be sold if as much as 25% of them test positive.<sup>36</sup> Why? The answer is not that eliminating *Salmonella* is impossible. Countries like Sweden and Denmark have shown that this is not the case. And it is not because *Salmonella* is not a serious foodborne illness threat. The bacteria accounts for more deaths and hospitalizations each year

than any other foodborne pathogen. Rather, broad interpretation of two questionable and outdated legal precedents, intense industry pressure, and downright regulatory inertia, seem the most likely culprits.

It was not supposed to be this way. When FSIS declared *E. coli* O157:H7 an adulterant, it was the first time that the agency ever regulated raw products on the basis of microbiological contamination. In conjunction with this precedent, the agency overhauled its meat and poultry inspection program. Specifically, it adopted an approach based on the “Hazard Analysis and Critical Control Points” or “HACCP” (pronounced “has-sip”) system. In doing so, the agency moved away from “command and control” style regulations, towards a more performance-based approach.

HACCP refers to a management system that private companies have long used to address biological, chemical, and physical food safety hazards. It was first developed by NASA scientists to prevent astronauts from suffering a foodborne illness in space.<sup>37</sup> Under its new HACCP rule, FSIS deemphasized the traditional organoleptic approach to meat and poultry inspection, derided by critics as “poke and sniff.” Compared to before, government inspectors spend less time conducting carcass-by-carcass inspection, and more time ensuring that plant employees are taking measures, including microbiological testing, at “critical control points” all along the production process where contamination can occur. Inspectors are also tasked with verifying that the measures are adequately designed and evaluated to prevent biological, chemical, and physical hazards. Because it shifts responsibility for food safety from government inspectors to the meat and poultry plants themselves, some skeptics have dismissed the HACCP rule as “Have a Cup of Coffee and Pray.”<sup>38</sup> However, advisory bodies including the National Academy of Sciences, the Government Accountability Office, and FSIS’s National Advisory Committee on Microbiological Criteria for Food, endorsed the reform.<sup>39</sup>

Unfortunately, an industry lawsuit significantly hampered the intended operation of these reforms shortly after FSIS adopted them. Under the HACCP regulation finalized in 1996, FSIS set pathogen reduction performance standards, i.e. limits on microbiological contamination, for *Salmonella* in seven raw meat and poultry products, including ground chicken and turkey, and whole chicken carcasses.<sup>40</sup> Based on surveys of contamination levels across the industry, these performance standards set a threshold for how often samples taken from a plant could test positive for *Salmonella*. For example, no more than 7.5% of ground beef samples were allowed to test positive for *Salmonella*, while nearly half—49.9%—of ground turkey samples could test positive.<sup>41</sup> The agency announced in its rulemaking that the *Salmonella* performance standards were “a first step in what FSIS expects to be a broader reliance in the future on pathogen-specific performance standards.”<sup>42</sup>

Broader reliance on microbiological performance standards, however, requires an effective enforcement mechanism. FSIS put that enforcement mechanism to the test in 1999 when it withdrew inspectors from a Texas meat processing and grinding facility, Supreme Beef Processors, effectively shutting down the plant. The agency had conducted three sets of *Salmonella* tests at Supreme Beef over the course of a year-and-a-half, and the company had failed all of them. When FSIS pulled its inspectors, however, Supreme Beef sued in federal court, arguing that the government did not have authority to withdraw inspection on the basis of microbiological testing alone. The United States District Court for the Northern District of Texas agreed, reasoning that *Salmonella* tests did not necessarily measure the actual conditions of the plant, and so FSIS could not find the conditions of the Supreme Beef plant “insanitary” under the Federal Meat Inspection Act.<sup>43</sup> On appeal, a three-judge panel of the Fifth Circuit Court of Appeals affirmed. The court did not vacate the *Salmonella* performance standard altogether, but

it prevented FSIS from taking enforcement action against a plant solely because it failed to meet microbiological standards.<sup>44</sup>

In reaching its conclusion, the *Supreme Beef* court reasoned that *Salmonella* “is not an adulterant per se . . . because normal cooking practices for meat and poultry destroy the *Salmonella* organism.”<sup>45</sup> In support of this proposition, the court cited the 1974 federal appeals court decision in *American Public Health Association v. Butz*, and specifically the *Butz* court’s declaration that “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.”<sup>46</sup> In fact, as discussed below, an abundance of evidence indicates that consumers need not be ignorant or stupid to fall victim to salmonellosis. Nevertheless, the *Supreme Beef* and *Butz* decisions have gone unchallenged, and FSIS has continued to rely on *Supreme Beef* in defense of its current policy, under which failure to meet *Salmonella* performance standards serves merely “as a basis to conduct an in-depth evaluation of the establishment’s HACCP systems.”<sup>47</sup> The industry’s widespread noncompliance with the *Salmonella* performance standards, and more importantly, the lack of progress in reducing *Salmonella* infections, attest to the inadequacy of this approach.

## IV. The Case for Treating *Salmonella* as an Adulterant in Raw Meat and Poultry

Foodborne illness statistics do not always give a clear indication of where efforts to protect consumers have succeeded. The numbers on *E. coli* O157:H7, however, are an exception. Following the 1994 decision to declare *E. coli* O157:H7 an adulterant in raw ground beef, illnesses associated with the pathogen plummeted from 2.6 cases per 100,000 population in 1996 to 1.1 cases per 100,000 in 2012.<sup>48</sup> Would a similar decision to declare *Salmonella* an adulterant in raw meat and poultry drive down *Salmonellosis* illnesses? Naysayers claim that *Salmonella* is far too ubiquitous in the food system for such a prohibition to prove feasible.<sup>49</sup> However, several important similarities between *Salmonella* and *E. coli* O157:H7 suggest that the discrepancy in their regulatory treatment is misguided. In particular, both organisms can cause serious illness and death, both organisms may cause illness even when they are present on food in relatively low numbers, and both cause illness as a result of common food handling and cooking practices.

### **Salmonella v. Shiga-Toxin Producing *E. coli* (STECs)**

	<i>Salmonella</i>	STECs (including <i>E. coli</i> O157:H7)
Severity	Victims usually recover without treatment in 4-7 days. Invasive infections occur in about 8% of lab confirmed cases, sometimes leading to severe illness or death, most commonly in people who are very young or old or have a weakened immune system.	Victims usually recover within 5–7 days. About 10% of infections, result in Hemolytic Uremic Syndrome, a severe, potentially life-threatening complication that particularly affects young children.
Infectious Dose	Contaminations levels < 100 CFU associated with some outbreaks. Risk increases with load.	Contamination levels less than < 10 CFU associated with some outbreaks. Risk increases with load.
Cooking Practices	Outbreaks have been linked to virtually all types of meat and poultry, including ground beef. Cross-contamination is a major risk factor.	Most contamination occurs in ground beef, with initial outbreaks linked to undercooked hamburger. Cross-contamination is a major risk factor.

Given these similarities, federal regulators should take a hard look at policies to regulate *Salmonella* as an adulterant. Fortunately, the law gives FSIS ample authority to act.

### IV.A. The Legal Case for Treating *Salmonella* as an Adulterant in Meat and Poultry

The FSIS position that *Salmonella* is not an adulterant “per se” dates back to 1971. That year, the American Public Health Association (APHA) filed a lawsuit demanding that USDA require a warning label and cooking instructions on raw meat and poultry. Otherwise, according to APHA’s suit, the USDA mark of inspection would mislead consumers and fail to “protect them against food poisoning caused by *Salmonella* and other bacteria.”<sup>50</sup> USDA responded that “the problem of controlling



salmonellosis in man is greatly complicated because of the widespread distribution of the organisms in the environment.” Moreover, “since there are numerous sources of contamination which might contribute to the overall problem it would be unjustified to single out the meat industry.”<sup>51</sup> An education campaign, rather than a label, would better address the problem, according to USDA.

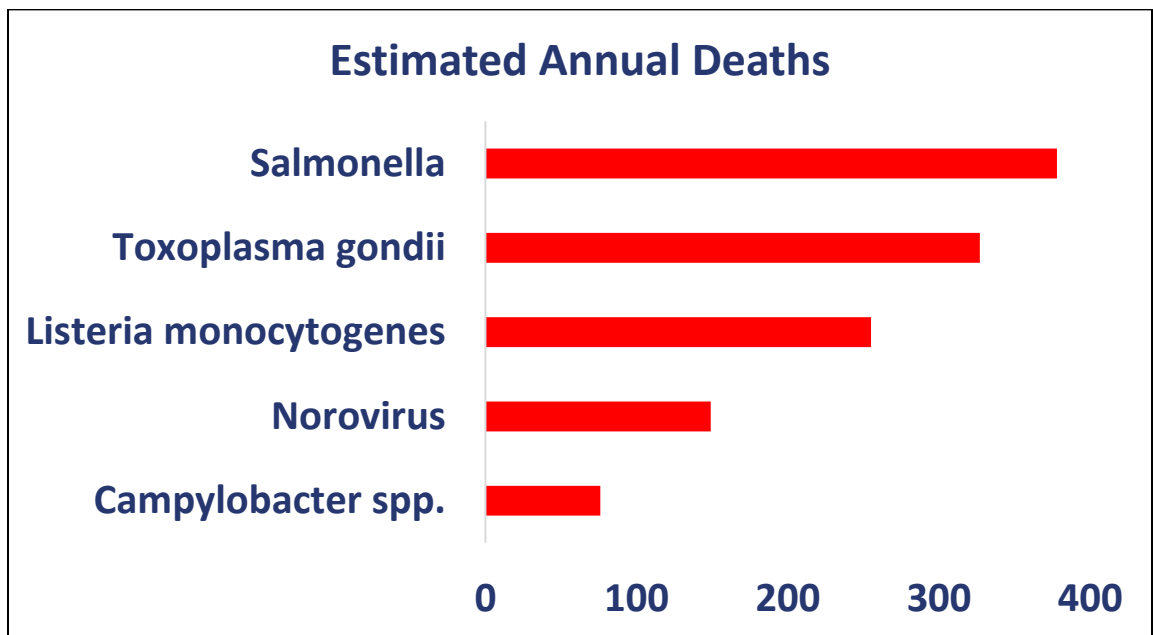
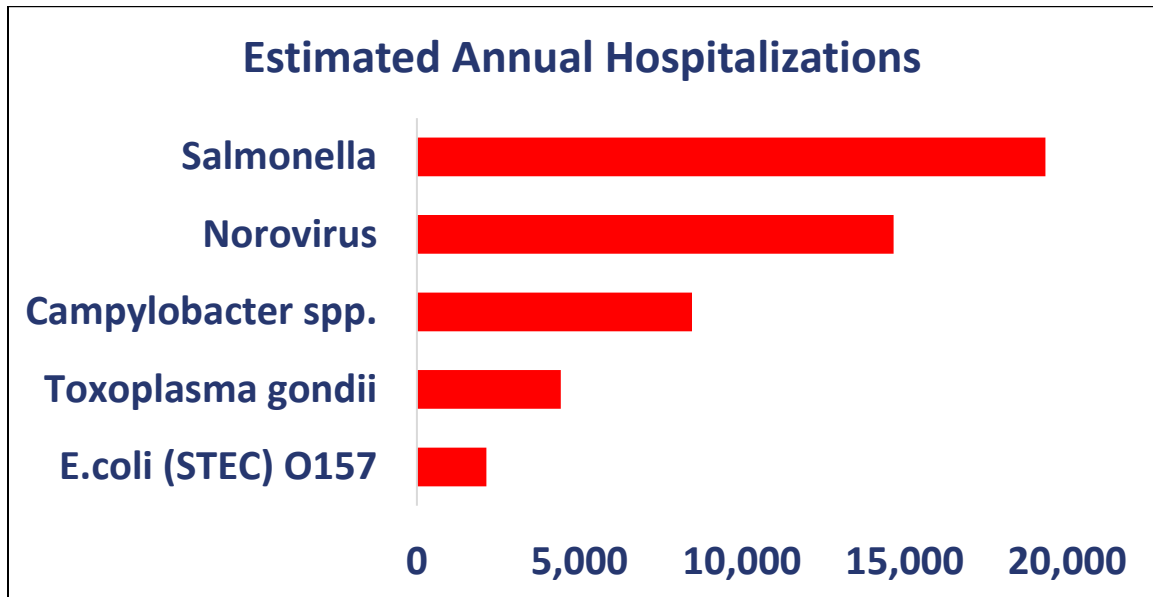
The federal courts agreed with USDA. In doing so, the D.C. Circuit Court of Appeals determined that raw meat contaminated with *Salmonella* is not adulterated for the purposes of the meat and poultry inspection laws. Forty years later, the appeals court’s opinion is striking not only for its chauvinism but also for its discordance with the scientific research on *Salmonella*. Today, that research reveals at least five ways in which the *Butz* decision is outdated, or simply wrong.



“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.”<sup>52</sup>

First, the *Butz* decision mischaracterizes the illness associated with *Salmonella* infections. According to the majority opinion, “Salmonellosis or ‘food poisoning’ caused by the ingestion of *Salmonellae* may produce nausea, abdominal cramps, vomiting, high fever, dizziness, headaches, dehydration and diarrhea.” As tragedies like the Noah Craten story make clear, however, the consequences of *Salmonella* infection can be much more serious. Indeed, in the past decade, epidemiologists estimate that *Salmonella* has caused several hundred deaths and tens of thousands of

hospitalizations each year in the U.S. As the graphs below indicate, the impacts exceed those of any other foodborne pathogen.



The most severe *Salmonella* infections tend to afflict the very old or very young, or members of vulnerable subpopulations, such as patients with HIV/AIDS, organ transplant recipients, and cancer patients.<sup>53</sup> Often, survivors have to battle with long-term health conditions such as reactive arthritis, ulcerative colitis, Crohn’s disease, and even eye problems.<sup>54</sup> In other words, Salmonellosis is much more serious than a day or two of “food poisoning.”

Second, the *Butz* decision suggests that the only “preventive measures against *Salmonellae* are care in the cooking and storage of foods, and adequate refrigeration.” In fact, a wide range of interventions

(e.g., vaccination, pre- or probiotics, hot water or steam ultrasound carcass decontamination treatments, short-chain organic acid carcass washes, etc.) have been shown to reduce or eliminate *Salmonella* contamination at virtually every stage of production – before, during and after slaughter.<sup>55</sup> By employing these interventions, farmers and processors could greatly reduce the risks that consumers face in the kitchen from *Salmonella*.

The *Butz* court made a third mistake when it asserted that consumers can prevent illness with common handling and cooking practices. According to the court, “[t]o prevent cross-contamination from raw material to finished food, utensils, working surfaces and the hands of food preparers should be thoroughly washed.” Yet decades of research have shown that seemingly “thorough” cleaning—even running utensils through a commercial dishwasher—may not suffice to prevent the spread of *Salmonella*, which can adhere very tightly to commonly used food preparation surfaces such as stainless steel.<sup>56</sup>

In general, *Salmonella* cross-contamination is much more difficult to prevent than once thought. The World Health Organization has estimated that cross-contamination causes ten times as many *Salmonella* infections as eating undercooked poultry.<sup>57</sup> Research shows handwashing to be particularly fallible.<sup>58</sup> In a recent FSIS observational study, faulty handwashing after handling turkey burgers contributed to 6% of participants contaminating a salad that they prepared in a test kitchen.<sup>59</sup>

Avoiding undercooked poultry poses its own challenges. According to the *Butz* decision, “proper cooking destroys *Salmonellae*,” but research has shown that whether cooking is “proper,” or adequate to kill *Salmonella* depends in part on the quantity of the bacteria.<sup>60</sup> It also depends on the type of *Salmonella*: in one study, researchers found that killing a strain of *Salmonella enteritidis* in chicken broth required nearly twice as much cook time as other serovars.<sup>61</sup> *Salmonella* can even grow more heat resistant on food that is heated to “sublethal” temperatures, complicating the calculus behind slow-cooked roasts.<sup>62</sup>

Fourth, the *Butz* court maintained that “the inspection procedures now required by [law] do not include any investigation to detect the presence of *Salmonella* in meat or poultry, because no such microscopic examination is considered feasible as a routine matter.” Forty years later, this rationale is laughable. FSIS relies on modern analogues to “microscopic examination” to enforce its prohibition on *E.coli* O157:H7 and STECs in raw meat, and the agency regularly tests for *Salmonella*, and routinely compares the genomes of the *Salmonella* it finds in plants with those found in illness victims. Regulators, researchers, and companies themselves, use a variety of diagnostic methods to detect and characterize *Salmonella*, including culture-based, nucleic acids-based and immunology-based methods, as well as biosensors and biochemical assays.<sup>63</sup> Detecting *Salmonella* with these tests is clearly “feasible as a routine matter,” and it becomes more so every year as new technologies make testing faster, cheaper, more accurate, and more capable of distinguishing different types and levels of *Salmonella* bacteria.

Finally, the *Butz* court found that *Salmonella* “may be inherent in the meat” and therefore should not be considered an “added substance.” This is an important legal distinction because of how the meat and poultry inspection laws define an “adulterated” food.<sup>64</sup> Notably, however, just eight years after the *Butz* decision, the same federal appellate court decided in *Continental Seafood v. Schweickert*<sup>65</sup> that *Salmonella* is an “added substance” in shrimp, because “*Salmonella* in shrimp can result from human acts and can frequently be attributed to insanitary processing procedures.”<sup>66</sup> In support of that decision, the D.C. court cited the Fifth Circuit’s decision in *United States v. Anderson Seafoods*,<sup>67</sup> which held that if any part of

harmful food contamination is attributable to human acts, then all of the contamination is to be considered an added substance. As with shrimp, insanitary conditions cause *Salmonella* contamination in meat and poultry, whether on the farm or in the slaughterhouse.<sup>68</sup> Indeed, as early as the 1970s, epidemiologists have linked disparate Salmonellosis outbreaks in humans to contaminated animal feed shipped round the world.<sup>69</sup> So the law and the facts support viewing *Salmonella* as an “added substance,” and therefore treating *Salmonella* contaminated food as “adulterated.”

The Butz precedent is woefully outdated and scientifically wrong in 2018 and, therefore, should no longer be applied. Moreover, the government has all the authority it needs to treat *Salmonella* as an adulterant in raw meat and poultry. This could mean a “zero tolerance” approach to all *Salmonella*, or a more targeted strategy, focused on specific *Salmonella* serotypes, specific strains associated with outbreaks, antibiotic resistant *Salmonella* strains, or even excessive numbers of *Salmonella* cells on a product. Whatever the case, raw product deemed adulterated would have to be destroyed, diverted for cooking, or put through some other “kill step,” such as irradiation, just as with raw meat contaminated with *E.coli* O157:H7 or the six “STEC” strains. As mentioned above, the decision to classify *E.coli* O157:H7 as an adulterant has coincided with a sharp decline in infections from that bacteria. The evidence suggests that a policy to treat *Salmonella* as an adulterant could achieve similar success.

## **IV.B. The Policy Case for Treating *Salmonella* as an Adulterant in Meat and Poultry**

The industry and its allies maintain that the costs of eliminating *Salmonella* from meat and poultry would outweigh the benefits. This is a serious objection, but with little evidence to back it up. Undoubtedly, treating *Salmonella* as an adulterant would impose significant costs on industry, and might even require consumers to pay higher prices, at least initially. Yet costs have not stopped many other countries from adopting more stringent *Salmonella* control policies. As indicated, several policies could follow from a decision to treat *Salmonella* as an adulterant in raw meat and poultry. All of these approaches have associated costs and benefits, as discussed below.

### **IV.B.1. The Zero Tolerance Strategy: Lessons from Sweden**

The most straightforward, and potentially the most costly, way to treat *Salmonella* as an adulterant would simply parallel FSIS’ treatment of *E. coli* O157:H7. Any product with a detectable amount of *Salmonella* would be classified as adulterated, and prohibited from entering into commerce. Opponents of tighter regulation have tended to characterize *Salmonella* contamination as an unavoidable fact of nature.<sup>70</sup> Sweden and other Northern European countries, however, have shown that is not the case.

Sweden, in particular, has established a long track record of eradicating *Salmonella* from raw meat and poultry. Swedish public health authorities’ aggressive approach to *Salmonella* dates back to a 1953 outbreak of *Salmonella* Typhimurium associated with red meat, which killed more than 90 people and sickened more than 9,000.<sup>71</sup> In the years since, the country has developed a farm to fork control program that requires testing for *Salmonella* in animal feed, in animal housing and their surrounding environments, in the animals themselves, and in the end products that go to consumers.<sup>72</sup> Any positive finding triggers remedial measures to eliminate the *Salmonella*, including destroying infected flocks and discontinuing the use of infected holdings pending a demonstration that they no longer harbor the

bacteria.<sup>73</sup> The law designates food products contaminated with *Salmonella* as unfit for human consumption, and requires a recall if they have already gone to market.

As a result of these rules, *Salmonella* contamination in meat and poultry has been nearly eliminated in Sweden. According to the most recent surveillance data from 2017, over 10,000 samples taken from pig, cattle, and chicken carcasses in processing facilities failed to yield a single positive result.<sup>74</sup> Other countries that have taken the Swedish approach, or approximated it, have reported similarly dramatic reductions. In Norway, no positives were found among some 3,170 samples of “crushed meat” taken at retail in 2017.<sup>75</sup> The latest reporting from authorities in Finland, meanwhile, is that incidence of *Salmonella* among cattle, pigs, and poultry remains below 1% in samples taken on farms and in slaughterhouses.<sup>76</sup> Similarly, Denmark’s latest reporting shows prevalence levels below 1% in beef, pork and poultry samples taken at slaughter.<sup>77</sup>

The means to achieving these reductions are multi-faceted. They involve not just the slaughter and processing facilities but the farms where poultry are raised, the breeders that supply the chicks, and the feedmills that provide for the animals’ sustenance. Five principals guide the Swedish system:

1. Start with *Salmonella*-free day-old chicks.
2. Rear chicks in a *Salmonella*-free environment.
3. Provide feed and water free from *Salmonella*.
4. Regularly monitor and test for *Salmonella* in the whole production chain.
5. Take immediate action whenever *Salmonella* is detected.

Following these principles adds to production costs, but these days, not so much. While researchers estimated in 1994 that the marginal cost for Swedish growers to produce *Salmonella*-free broilers was 16 cents per bird, a more recent estimate pegs that number at just 2.6 cents, or less than 1 cent per pound of meat.<sup>78</sup> Moreover, recent cost-benefit analysis indicates that the public health consequences of even a moderate relaxation of the *Salmonella* control standards would outweigh the cost savings for Swedish growers.<sup>79</sup>

### **Comparing U.S. and Swedish *Salmonella* Regulation In Poultry**

Intervention	Sweden	United States
<i>Salmonella</i> Free Chicks	Yes	No
Growers Maintain <i>Salmonella</i> Free Growing Environment	Yes	No
Regular Testing Of Grow Houses And Feed Mills For <i>Salmonella</i>	Yes	No
Required Heat Treatment Of Feed	Yes	No
Contaminated Flocks Destroyed	Yes	No
Antimicrobial Sanitizers Used In Processing	No	Yes

How do the prevailing U.S. practices compare with those in Sweden? At every stage of the process, the U.S. industry tolerates *Salmonella* where their counterparts in Sweden do not.

The differences start at breeding. Just two poultry breeding companies—Aviagen and Cobb Vantress—dominate the industry worldwide and deliver the “grandparent” breeding stock to the large poultry “integrators”—companies like Pilgrim’s Pride, Perdue and Sanderson Farms that own hatcheries, farms, feedmills, slaughter and processing facilities. One of the two breeding companies, Cobb Vantress, is actually a wholly owned subsidiary of one of the largest “integrators,” Tyson Foods, Inc.<sup>80</sup> The two breeding companies can boast an impressive track record in supplying *Salmonella*-free chicks to Swedish producers.<sup>81</sup> In the U.S., however, the companies will sometimes deliver breeding stock infected with *Salmonella*. Although at least one of the breeding companies assures customers that flocks have not tested positive for a few *Salmonella* strains most associated with human illness—namely Enteritidis, Typhimurium, and Heidelberg—it offers no guarantee against infection generally.<sup>82</sup> This creates a risk of vertical transmission that may negate even the most careful controls adopted by a grower.

Given this lackluster start to the growing process, poultry companies’ failure to maintain a *Salmonella* free growing environment should come as no surprise. Prevailing U.S. practices on preventing *Salmonella* on the farm differ from those of Sweden in several respects. For example, while all Swedish broiler houses are enclosed with solid floors, walls and ceilings designed to be easily cleanable, many U.S. poultry houses, including those used for parent breeding flocks, have dirt floors and wood surfaces that complicate cleaning and disinfection. Moreover, Swedish growers remove used litter and let houses sit idle at least two weeks between broiler flocks. By contrast, U.S. growers may remove litter from houses for parent flocks, but usually reuse litter in broiler houses, managing *Salmonella* levels through a practice known as windrow composting.<sup>83</sup>

Swedish law requires testing of all feed ingredients prior to processing at the feed mill, with special steps taken for shipments that test positive. The law further requires that feed mills apply heat treatment to feeds to further guard against contamination.<sup>84</sup> In the U.S., the FDA regulates the safety of animal feed, and periodically tests feed for *Salmonella*. But the agency will only consider taking regulatory action upon discovery of a *Salmonella* serotype that is “pathogenic to the species of animals expected to get the feed.”<sup>85</sup> Some U.S. companies nevertheless heat treat feed, or rely on organic acids and other additives to lower the risks of feed transmitting *Salmonella* that causes human illness, but these actions are voluntary.<sup>86</sup>

Similarly, Swedish law requires periodic monitoring for *Salmonella* all along the supply chain, while in the U.S., federal inspectors test for *Salmonella* only at the slaughterhouse. Some companies do more, but on a voluntary basis. Foster Farms, for example, has implemented a heightened surveillance program that includes drag swab samples from grow houses to identify *Salmonella* contamination early in the growing process. Coupled with control strategies like more stringent biosecurity protocols and vaccinating parent flocks and broilers, the company has succeeded in significantly reducing *Salmonella* levels in its chicken.<sup>87</sup> Still, Foster Farms reports that contamination rates have persisted at around 5% in its California facilities, a far cry from Sweden’s virtual eradication of the bacteria.<sup>88</sup>

Most importantly, under the Swedish system, a confirmed *Salmonella* positive test triggers a series of costly and time consuming remedial steps and precautions against further contamination. These include a veterinary investigation to find the source of the *Salmonella*; thorough cleaning and disinfection of the grow house, feed mill, or other implicated facilities; destruction of contaminated flocks; composting manure from the flocks for at least six months to prevent environmental contamination;

and mandatory environmental testing before the closed facilities may reopen. In the U.S., *Salmonella* is tolerated as normal gut bacterial flora in poultry. At slaughter, FSIS sets purportedly mandatory *Salmonella* performance standards, but as discussed above, companies repeatedly violate those standards without significant consequences.

One other important difference that deserves mention relates to the use of antimicrobial processing aids or sanitizers. In the U.S., FSIS has encouraged poultry processors to apply these antimicrobials during equipment spraying, carcass washing, reprocessing, immersion chilling and post-chill treatment. In Sweden, and in the rest of Europe, poultry processors are not allowed to use sanitizers. Indeed, the EU has banned U.S. “chlorinated chicken” imports since 1997 because of sanitizer use.<sup>89</sup> Some recent studies have indicated that sanitizers skew microbiological testing results, making meat and poultry seem less contaminated than it is.<sup>90</sup> Indeed, FSIS recently reformulated its *Salmonella* testing aids to counter a documented “false negative” effect associated with several popular sanitizers.<sup>91</sup>

### Costs and Benefits

The Swedish approach is not new, but despite decades of experience, it has caught on only among a few immediate neighbors. Why? The main objection appears to be that eradicating *Salmonella* from larger poultry producing countries is too expensive. In 2010, scientists from 16 countries—including Sweden—collaborated in an effort to evaluate “zero-tolerance” policies toward *Salmonella* on chicken. The group recognized that “in Finland and Sweden, where effective control of *Salmonella* in the industry has been in place for a long time, there is a low prevalence of product contamination, which has considerably reduced consumer exposure to the pathogen in these countries.” Nevertheless, it concluded that “[c]omparable measures are not likely to be economically or technically feasible for direct application in all countries.”<sup>92</sup>

Notably, since that expert report published, Denmark has joined Sweden and Finland among the ranks of “*Salmonella* free” poultry producers formally recognized by EU authorities.<sup>93</sup> Like Sweden, Denmark embarked upon its campaign to eradicate *Salmonella* several years ago. In the U.S., where the most recent government survey data on retail ground turkey and raw chicken products shows *Salmonella* contamination in roughly 6% and 9% of those products, respectively,<sup>94</sup> making such a transition would likely require a significant investment of time and resources.

Were U.S. producers to incur marginal costs similar to those of their Swedish counterparts in eradicating *Salmonella*—i.e. \$0.026 per bird—the bill would come to around \$400 million per year. Large U.S. companies might, however, leverage economies of scale to drive down some of these costs. Sweden produces an estimated 80 million broilers per year,<sup>95</sup> as compared to 8.91 billion in the U.S.<sup>96,97</sup> On the other hand, reaching the Swedish level of protection would first require significant retrofits to many of the estimated 233,770 poultry farms in the U.S., along with substantial investments in the feed mills and other infrastructure that support those farms. How much U.S. producers would actually need to spend to eradicate *Salmonella* remains an open question that deserves serious consideration.



A Swedish broiler house.

In addition to the costs associated with treating *Salmonella* as an adulterant, some researchers have questioned the public health benefits associated with a policy to eradicate *Salmonella*. Most cases of foodborne illness are never traced back to a source, and differences among surveillance systems and reporting behavior complicate comparisons across countries. As a result, demonstrating the public health impact of policies to eliminate foodborne pathogens can pose significant challenges. While Sweden and other countries have made great progress in eliminating *Salmonella* in the food supply, they have not eliminated salmonellosis cases in humans. According to one recent analysis of data from European Union countries and the United States, “the correlation between *Salmonella* prevalence on raw chicken and salmonellosis in humans . . . is not significant.”<sup>98</sup>

On the other hand, proponents of the Swedish system point to higher rates of foreign travel, reporting, and detection, as factors that may obscure the public health benefits of the country’s more stringent control program.<sup>99</sup> A recent analysis of blood serum samples offers some support. Rather than rely on illness reporting, that study examined whether serum samples banked in different European countries contained antibodies indicative of a prior *Salmonella* infection. Evidence of infection was highly correlated with the reported levels of *Salmonella* prevalence among a country’s livestock, with researchers finding “a 10-fold difference” between the levels of “seroincidence” in Sweden, Finland, and Denmark, on the one hand, and countries with high reported *Salmonella* prevalence like Spain and Poland, on the other.<sup>100</sup>



The difficulty of coordinating a plan to eradicate *Salmonella* under current law poses an additional obstacle. FSIS only oversees the slaughterhouse. Without direct regulatory authority, FSIS cannot provide resources to growers like government subsidized insurance for lost flocks, an important component in the early days of the Swedish system’s development.<sup>101</sup> Of course, FSIS similarly lacks authority over cattle ranches and feedlots, and that has not prevented its policy on *E. coli* O157:H7 from stimulating widespread adoption of on-farm intervention strategies among ground beef processors.<sup>102</sup> For that matter, many ground beef processors have nearly eliminated *Salmonella* from their products to meet specifications for the National School Lunch Program, which refuses any shipment that tests positive for *Salmonella*, i.e. a “zero tolerance” approach.<sup>103</sup>

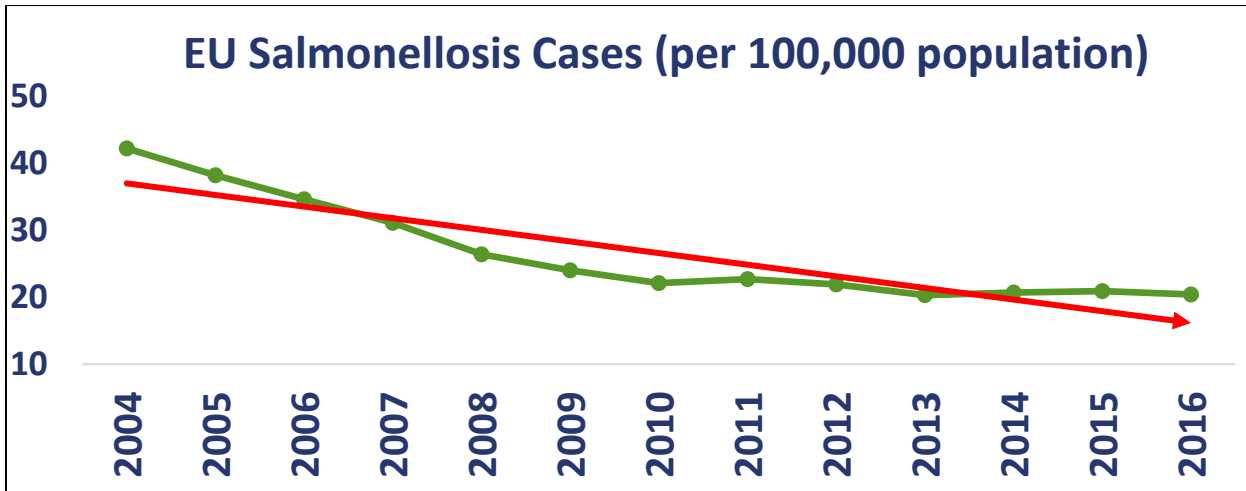
The structure of the poultry industry may also alleviate some coordination concerns. Vertically integrated operations produce the vast majority of poultry in the U.S.—90 percent of all chickens raised for human consumption, according to some estimates.<sup>104</sup> That means that, in most cases, the same companies that submit to FSIS testing in the slaughterhouse also exercise control over, for example, the extent to which feed mills control against *Salmonella* with heat treatments and heightened sanitation, or the extent to which growers implement biosecurity measures to protect against rodents—or even flies—transmitting *Salmonella* to flocks.

#### **IV.B.2. The Serotype Strategy**

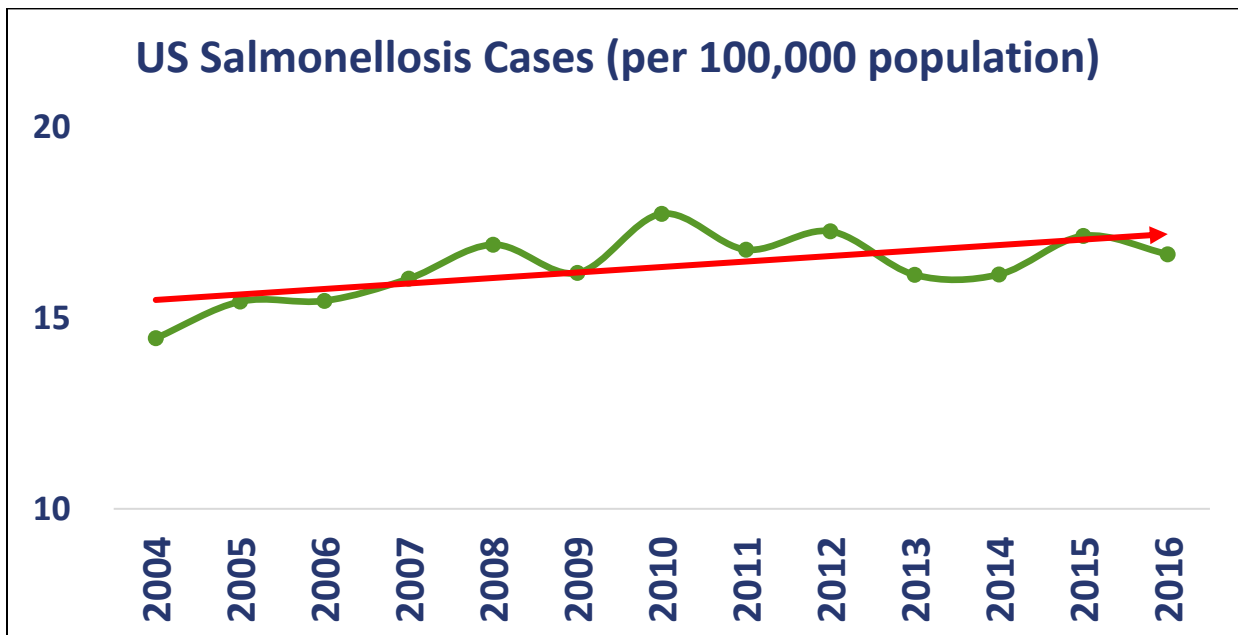
In 2003, the European Union pioneered a serotype-based approach to *Salmonella* control with European Commission Regulation No. 2160/2003. The rule directed the European Food Safety Authority (EFSA) to identify the *Salmonella* serotypes, or “serovars,” most detrimental to public health, and to define targets for each member state to achieve in reducing their prevalence.<sup>105</sup> Two years later, EFSA implemented common monitoring criteria and requirements for national control programs aimed at reducing the prevalence of *Salmonella Enteritidis*, *Hadar*, *Infantis*, *Typhimurium* and *Virchow* to less than 1% in breeding flocks. In the years to follow, EFSA rolled out similar protocols targeting *Salmonella Enteritidis* and *Typhimurium* in laying hens, broilers, and turkeys.<sup>106</sup>

These European Union wide initiatives to reduce *Salmonella* in poultry and egg production have been credited with a steep reduction in salmonellosis cases.<sup>107</sup> Indeed, the number of estimated salmonellosis cases in humans in the EU decreased from 200,000 cases in 2004, to less than 90,000 cases in 2014, albeit with further progress stalling in recent years.<sup>108</sup>

Reported Confirmed Human Cases of Non-Typhoidal Salmonellosis in the EU/EEA, by Month of Reporting, 2004–2016<sup>109</sup>



By contrast, salmonellosis cases in the U.S. have remained stubbornly high, as data from CDC, depicted in the graph below, make clear.<sup>110</sup>



Proponents of targeting specific serotypes point out that not all *Salmonella* bacteria contribute a similar burden to public health. While *Salmonella* Enteritidis bears a strong association with foodborne illness the world over, *Salmonella* Kentucky commonly shows up in sampling at U.S. chicken processors, but rarely in the clinical samples taken from foodborne illness victims in the U.S. The table below presents the serotype frequency for *Salmonella* isolates found in clinical samples, which are taken from victims of foodborne illness, samples taken from meat and poultry products at retail, and samples taken

at the slaughterhouse during routine HACCP inspections. Notably, just five *Salmonella* serotypes account for over half of the reported clinical cases. Two of these serotypes—S. Enteritidis and S. Typhimurium—also make up a bulk of the *Salmonella* contamination found on the samples taken in retail and slaughter establishments. Yet the one that turns up most frequently in those sample--S. Kentucky—does not even make the list of the twenty most common serotypes found among patients.<sup>111</sup>

If some strains of *Salmonella* rarely make people sick, then efforts to reduce their prevalence might not be the best investments in public health, or so the argument goes. Conversely, a better public policy might encourage companies to channel food safety resources into preventing contamination by the *Salmonella* serotypes most associated with foodborne illness, such as S. Enteritidis, S. Typhimurium, and S. Newport.

Clinical <i>Salmonella</i> Samples, 2015			Retail <i>Salmonella</i> Samples, 2015			HAACP <i>Salmonella</i> Samples, 2015		
Serotype	Isolates		Serotype	Isolates		Serotype	Isolates	
	N	(%)		N	(%)		N	(%)
Enteritidis	471	19.9%	Kentucky	70	17.2%	Kentucky	535	27.2%
Typhimurium	251	10.6%	Typhimurium	64	15.7%	Enteritidis	308	15.7%
Newport	232	9.8%	Enteritidis	47	11.5%	Typhimurium	215	10.9%
I 4,[5],12:i:-	149	6.3%	Reading	43	10.6%	Schwarzengrund	124	6.3%
Javiana	147	6.2%	Heidelberg	39	9.6%	Heidelberg	122	6.2%
Muenchen	73	3.1%	Muenchen	25	6.1%	Montevideo	83	4.2%
Infantis	72	3.0%	Saintpaul	18	4.4%	Infantis	74	3.8%
Heidelberg	68	2.9%	Schwarzengrund	10	2.5%	I 4,[5],12:i:-	53	2.7%
Poona	61	2.6%	I 4,[5],12:i:-	10	2.5%	Reading	43	2.2%
Saintpaul	60	2.5%	Hadar	9	2.2%	Thompson	40	2.0%
Montevideo	53	2.2%	Derby	8	2.0%	Muenchen	35	1.8%
Oranienburg	53	2.2%	Infantis	8	2.0%	Dublin	31	1.6%
Braenderup	52	2.2%	Johannesburg	7	1.7%	Anatum	23	1.2%
Mississippi	47	2.0%	Senftenberg	7	1.7%	Braenderup	21	1.1%
Thompson	43	1.8%	Albany	6	1.5%	Hadar	19	1.0%
Norwich	28	1.2%	Agona	5	1.2%	Agona	19	1.0%
Paratyphi B var. L(+ tartrate+	28	1.2%	Braenderup	4	1.0%	Johannesburg	16	0.8%
I 4,[5],12:b:-	21	0.9%	Newport	3	0.7%	Mbandaka	15	0.8%
Bareilly	19	0.8%	Rissen	3	0.7%	Cerro	14	0.7%
Rubislaw	17	0.7%	Livingstone	3	0.7%	Senftenberg	14	0.7%

Serotype does not always serve as the best predictor, however, of whether a given strain of *Salmonella* will cause more illness than another. The Enteritidis serotype is “somewhat unusual” for its relatively low genetic variability, which renders it a fairly constant risk. By contrast, strains of other serotypes, such as *Salmonella* Heidelberg, may not become public health menaces until after acquiring genetic traits for virulence and antibiotic resistance.<sup>112</sup> Focusing on serotypes therefore might conceivably lead to policies to overinvest in vaccinations and other strategies to eliminate the “adulterant” serotypes, and underinvestment in more generally applicable strategies like better sanitation.

Treating certain *Salmonella* serotypes as adulterants raises other practical concerns. The EU first implemented its rules to stamp out targeted serotypes in breeding flocks, before moving on to the broilers and laying hens themselves. The approach underscores the need for comprehensive food safety controls that go back not only to the farm but to the sources of the inputs going to the farm. As already discussed, FSIS can only indirectly force processors to adopt controls outside of the slaughterhouse.

Finally, the prevailing testing methodologies for determining whether a food contains a particular *Salmonella* serotype take at least 24 hours, although new techniques offer the promise of faster results.<sup>113</sup> By contrast, popularly available tests for *E. coli* O157:H7 take a third of that time.<sup>114</sup> This allows companies to hold product pending testing results, so-called “test-and-hold.” The longer wait time for serotype testing would complicate the prospect of a similar “test-and-hold” regime to divert *Salmonella* contaminated product before it goes to market, or more specifically, product contaminated with the “adulterant” *Salmonella* serotypes.

#### IV.B.3. The Outbreak Strain Strategy

In a policy finalized in 2014, FSIS declared that “when [raw] poultry or meat products are associated with an illness outbreak and contain pathogens that are not considered adulterants [such as *Salmonella*], FSIS likely will consider the product linked to the illness outbreak to be adulterated.”<sup>115</sup> Consistent with that policy, FSIS could treat as an adulterant any *Salmonella* strain that bears the same genetic fingerprint as one that has caused an ongoing illness outbreak. This would mean, for example, that if public health authorities detected a genetically identical strain of say, *Salmonella* Reading, in a hundred case patients, and subsequently FSIS found that same strain of *Salmonella* Reading in a sample taken from a turkey processing plant, FSIS would declare the product from which the sample was taken to be adulterated.

In comments made during the rulemaking process in 2013, Consumer Reports urged the agency to adopt a policy similar to the one described above. Specifically, the organization asked FSIS to consider adulterated any raw meat or poultry bearing any *Salmonella* strain with the same Pulsed-Field Gel Electrophoresis (PFGE) pattern as the *Salmonella* strain involved in an illness outbreak, regardless of where the food was produced.<sup>116</sup> FSIS rejected that request, citing comments from industry “that deeming certain strains of *Salmonella* adulterated when linked to an illness would penalize establishments for events beyond their control.”<sup>117</sup> Instead, FSIS has required epidemiological, microbiological, and trace back evidence to determine that a product is “associated with” or “linked to” an illness outbreak. The standard has led to prolonged periods of inaction during outbreaks such as the one associated with Foster Farms chicken, even when the evidence seemed to leave little doubt as to the source of the illnesses.<sup>118</sup>

Since FSIS finalized its policy on products “associated with illness outbreaks” in 2014, widespread adoption of whole genome sequencing (WGS) technology has provided a new impetus for rethinking the agency’s approach. Experts describe the difference between PFGE and WGS technology as “comparing all of the words in a book (WGS), instead of just the number of chapters (PFGE), to see if the books are the same or different.”<sup>119</sup> In other words, WGS poses little risk of mistaken identity. Currently, FSIS performs WGS on all *Salmonella* isolates that it collects from its regulatory testing program. For every sample taken by FSIS in a slaughter or processing facility that tests positive for *Salmonella*, the agency grows an isolate of the *Salmonella* bacteria from the sample, and uploads the

genetic profile of that bacteria to a database that includes the genetic profiles of bacteria found in patients with confirmed cases of salmonellosis.<sup>120</sup> In this way, federal regulators can, and do, routinely match the genetic “fingerprint” of *Salmonella* bacteria taken from plants, with that of *Salmonella* bacteria that have caused illness outbreaks.

Notably, finding a particular strain of *Salmonella* in a plant may not signify that the products from that plant caused an outbreak. A common supplier of chicks or feed, for example, could result in a common strain of bacteria spreading far and wide, and so before that strain has reached “Plant A,” it may have already contaminated Plant B’s products and caused an outbreak. Under the “outbreak strain” strategy, Plant A’s and Plant B’s contaminated products would receive similar treatment, even though Plant A’s products may not have caused any illness, yet.

The *Salmonella* Reading outbreak linked to raw turkey products, first reported by CDC in July of 2018, illustrates how the outbreak strain strategy would differ from the status quo. As of November 8, 2018, FSIS had identified the outbreak strain in raw turkey product samples from 22 slaughter and 7 processing establishments.<sup>121</sup> As of this writing, however, FSIS had only announced one product recall related to the outbreak—91,388 pounds of raw ground Jennie-O brand turkey products. The Jennie-O product was apparently singled out because investigators found “an intact, unopened package” of the product, which harbored the outbreak strain, in a case-patient’s home.<sup>122</sup> Under the proposed strategy, not just Jennie-O products but those from all of the 22 slaughter and 7 processing establishments that tested positive for the outbreak strain would be considered “adulterated.” Similarly, raw chicken from the 58 slaughter and processing plants where FSIS testing identified a multi-drug resistant strain of *Salmonella* Infantis, linked to 92 confirmed illnesses as of this writing, would not be allowed to enter into commerce.<sup>123</sup>

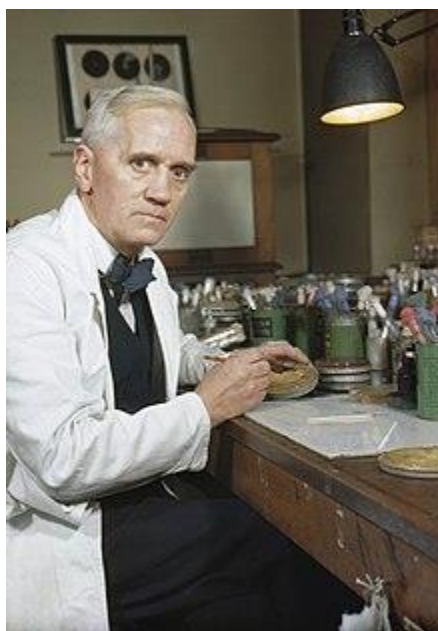
Employing the outbreak strain strategy would likely improve public health, since it would prevent product with demonstrably dangerous *Salmonella* bacteria from going on the shelves. The strategy has its drawbacks, however. During FSIS’s earlier rulemaking, one company argued that the presence of an outbreak strain on a product serves as a poor predictor of risk, because pathogen load plays such an important role. Consider the scenario in which FSIS finds the outbreak strain in two plants, but the number of *Salmonella* bacteria in Plant A’s products never exceed more than a handful, while Plant B’s products are teeming with tens or hundreds of thousands of cells. As discussed below, some research indicates that, under such a scenario, Plant B is likely responsible for causing many more illnesses than Plant A. Accordingly, FSIS might be justified in differentiating between Plant A’s and Plant B’s product. Another drawback relates to testing. Testing for a particular genetic profile requires even more time than testing for serotypes, and of course, identifying a problematic strain is impossible before an outbreak actually strikes. In this sense, treating outbreak strains of *Salmonella* as adulterants is an inherently reactive strategy. It can also be a fairly narrowly targeted strategy, however, and it is less reactive than the current FSIS policy on foods “associated with an illness outbreak.”

#### **IV.B.4. The Antibiotic Resistance Strategy**

Antibiotic resistance has played an important role in many *Salmonella* outbreaks, including the Foster Farms outbreak in 2013-2014. Because the strain of *Salmonella* Heidelberg that caused that outbreak was resistant to several commonly prescribed antibiotics, victims like Noah Craten were at greater risk of more severe infection and hospitalization. The association between antibiotic resistance

and severe foodborne illness has led members of Congress to propose legislation that would force FSIS to treat antibiotic resistant *Salmonella* as an adulterant.<sup>124</sup> The Center for Science in the Public Interest (CSPI) has also petitioned FSIS, twice, to declare four antibiotic resistant (“ABR”) serotypes of *Salmonella* to be adulterants in meat and poultry.<sup>125</sup>

FSIS has denied CSPI’s petition, twice, and its reason for doing so are instructive.<sup>126</sup> First, the agency rejected the notion that ABR *Salmonella* is an “added substance” because “ABR microorganisms may be present in food animals regardless of whether the animals have had exposures to antibiotics.” The agency also differentiated ABR *Salmonella* from STECs—the only microorganisms classified as adulterants on raw or “not-ready-to-eat” products—on the basis of STECs’ “relatively low infectious dose,”<sup>127</sup> and their virulence. In its response to CSPI, FSIS emphasized that antibiotic resistance does not always correlate with increased foodborne illness risk, and sought to distinguish the virulence factors that supported classifying STECs as adulterants, versus the “more varied and less identifiable” virulence factors that make certain *Salmonella* bacteria so dangerous. Underlying all of FSIS’ analysis is the presumption that *Salmonella* is neither an added substance, nor an adulterant—a presumption that is unsupported for the reasons discussed above.



Sir Alexander Fleming is credited with the discovery of the world’s first antibiotic (Penicillin G)

Tellingly, although FSIS did not go so far as to consider what sort of sampling or testing regimes might be needed to effectuate a ban on ABR *Salmonella*, the agency made a point of noting the “relatively easy” testing available for STECs. By contrast, phenotypic testing of *Salmonella* for antibiotic-resistance characteristic requires more time and resources, in large part because the *Salmonella* cells in samples must be isolated and grown on an enrichment medium.<sup>128</sup> The upshot is that a strategy targeting ABR *Salmonella*, like one targeting *Salmonella* serotypes, cannot easily employ a “test-and-hold” regime, meaning greater reliance on recalls and a higher cost to industry and consumers.

Treating ABR *Salmonella* as an adulterant would, however, deliver significant public health benefits. It would directly help to prevent many serious outbreaks caused by ABR *Salmonella*, and it

would also indirectly help to address outbreaks associated with *Salmonella* strains susceptible to antibiotics because practices to eliminate ABR *Salmonella* tend to cause *Salmonella* levels overall to decline. And although animals that never take antibiotics may still acquire antibiotic resistant bacteria, researchers have documented a clear correlation between antibiotic use among animals and antibiotic resistant bacteria in a given geographic area.<sup>129</sup> A policy focused on ABR *Salmonella* would therefore create a strong incentive to better control the use of antibiotics in meat and poultry production, with ancillary benefits for modern medicine and public health generally.

#### **IV.B.5. The High Pathogen Load Strategy**

Theoretically, just one viable *Salmonella* bacterium may cause illness, and some studies of outbreaks have found that less than a hundred *Salmonella* “colony forming units,” or CFU, have sometimes sufficed for an “infective dose.”<sup>130</sup> Particularly with respect to raw meat and poultry, however, higher loads create a much higher risk of infection, in part because of cross-contamination.<sup>131</sup> This relationship raises the question of whether industry and regulators should go beyond testing whether a raw meat or poultry product harbors *Salmonella*, and attempt to characterize how much of the bacteria is present. If the bacterial load exceeds some threshold of concern, the sampled product might be considered adulterated, and the “hot lot” from which it was taken cannot go to market.

This type of enumeration-based strategy has several advantages. As with the serotype and antibiotic resistance strategies described, it could target more problematic *Salmonella* contamination to better align regulatory compliance efforts with public health goals. An enumeration-based approach also lends itself to scaling. Depending on where regulators set the contamination level threshold, it could scarcely disrupt business as usual, or approximate a Swedish-style blanket ban on *Salmonella* contaminated foods. Finally, this strategy avoids some of the testing lags associated with screening *Salmonella* for particular serotypes, outbreak strains, or antibiotic resistance.

Scientific research has gone a long way towards characterizing a dose-response relationship in *Salmonella*. The data for this research has come from studies of (mostly adult male) human volunteers, studies of animals, and epidemiological investigations following outbreaks, all of which have important limitations.<sup>132</sup> Nevertheless, they support the need to treat foods with high levels of *Salmonella* as adulterated.<sup>133</sup> Contamination levels of meat and poultry products vary considerably. In 2007-2008, FSIS estimated the microbial counts on 1500 chicken carcass samples that tested positive for *Salmonella*. While 11% of the samples fell below the limit of detection for the test, some 34% exceeded that limit by 2-3 orders of magnitude, and a small subset of less than one percent exceeded it by 4 orders of magnitude or more.<sup>134</sup> These heavily contaminated specimens pose a high risk of infection.

Of course, highly contaminated samples may occur very infrequently, requiring a high number of tests and samples to provide some assurance that companies have actually taken adequate controls. The current FSIS *Salmonella* testing regime of one sample per week clearly does not fit the bill. On the other hand, to verify the effectiveness of controls against *E.coli* O157:H7 in beef, FSIS directs companies to test a combined slurry of 60 samples per 10,000 pound “lot” of beef trim.<sup>135</sup> A similar program could test for “hot lots” with excessively high *Salmonella* counts.

Testing methodologies for *Salmonella* at a given level have evolved rapidly in recent years. Estimating the number of *Salmonella* cells in a sample has traditionally been so expensive and time-consuming that it has hindered USDA’s ability to replicate baseline surveys like the one cited above.

Determining whether a sample exceeds a given threshold is simpler, however, and the testing technology has evolved rapidly in recent years. One new testing platform evaluates the levels of ribosomal RNA to determine whether a sample meets a given quantitative threshold in just 4-5 hours.<sup>136</sup> Such a rapid turnover time would mean that meat and poultry processors could “test-and-hold” product without having to reengineer their entire production process.

Determining the appropriate threshold for an enumeration based approach poses a significant challenge. The likelihood that a food contaminated with *Salmonella* will make someone sick depends on many factors other than the number of *Salmonella* cells that the person ingests, including the person’s general health, whether she is eating on a full or empty stomach, and characteristics of the contaminated food, such as whether it is in solid or liquid form.<sup>137</sup> The contribution of these factors complicates attempts to pin down a definitive “minimum infective dose,” not to mention calculate back from it. Ideally, FSIS would start with a health-based enumeration-based standard that demonstrably helps to avoid some illness, and then ratchet it down. An enumeration standard could be unhelpful, however, insofar as it fails to impose a meaningful control on *Salmonella* contamination and displaces the existing prevalence-based standards, which, however imperfect, help to discriminate between the best and worst food safety performers.

## V. Conclusion

Treating *Salmonella* as an adulterant may seem like a bold stroke, but similar policies have succeeded in other countries and, indeed, in the U.S. Since 2003, the National School Lunch Program has implemented a “zero tolerance” policy towards *Salmonella* in ground beef. The program tests every 10,000 pound lot that it receives and rejects any shipment that tests positive. Beef companies supplying the program have responded by dramatically reducing contamination levels to less than 1%. Whether a similar approach could work for ground beef more broadly, or for all of meat and poultry, deserves consideration, as do the strategies discussed herein, namely, focusing on particular *Salmonella* serotypes, outbreak-related strains, antibiotic-resistant strains, or high pathogen loads.



## Policy Comparison Matrix

Policy	Scope	Pros	Cons	Jurisdictions Applying
“Zero Tolerance” strategy	Any product with detectable level of <i>Salmonella</i> deemed adulterated	-Most protective of public health -Does not require sophisticated or time consuming testing	-Most costly to implement	Sweden, Finland, Denmark
Serotype strategy	Any product with detectable level of designated <i>Salmonella</i> serotypes deemed adulterated	-Protects against serotypes most associated with human illness	-Serotype not always a good indicator of illness risk -Test time to identify serotype	European Union
Targeting <i>Salmonella</i> strains linked to an ongoing outbreak	Any product with detectable level of <i>Salmonella</i> that is a genetic match to strains associated with a cluster of human illness deemed adulterated	- Protects against bacteria directly associated with human illness.	-Reactive in nature; -Test time to identify matching genomes exceeds 24 hours	Unknown
Targeting Antibiotic Resistance	Any product with detectable level of <i>Salmonella</i> resistant to designated antibiotics deemed adulterated	-Protects against resistant bacteria, which is associated with more frequent and severe illness. -Provides incentive for decreasing use of antibiotics in livestock agriculture	-Would not cover some ‘antibiotic susceptible’ strains that cause significant illness -Test time to identify antibiotic	Unknown
Targeting High Pathogen Load	Any product with <i>Salmonella</i> load that exceeds designated threshold (e.g. 100 CFU/g) deemed adulterated	-Protects against foods or “hot lots” with large numbers of <i>Salmonella</i> bacteria, which are associated with more frequent and severe illness. -Rapid (4-5 hour) testing available	-May not result in public health gains depending on designated threshold, testing protocol -Moving target given ongoing bacterial growth	Unknown. New Zealand has implemented standard for <i>Campylobacter</i> , in conjunction with prevalence testing

## Appendix

# A Brief History of SALMONELLA

**~1885**

USDA pathologist **Dr. Theobald Smith successfully isolates *Salmonella* bacteria** from hog cholera specimen. The bacteria is named after his boss, Daniel Salmon.

**1905**

Upton Sinclair **publishes *The Jungle***. Six months later, Congress passes the **Federal Meat Inspection Act (FMIA)**.

**1953**

*Salmonella Typhimurium* outbreak associated with red meat **kills more than 90 people and sickens more than 9,000** in Sweden.

**1957**

Congress passes the **Poultry Products Inspection Act (PPIA)**.

**1974**

The D.C. Circuit rules in *American Public Health Association v. Butz* that ***Salmonella* is not an adulterant under the FMIA or PPIA** 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.”

**1981**

USDA’s Food Safety and Quality Service is reorganized and the **Food Safety and Inspection Service (FSIS) is created**.

**1993**

*E. coli* O157:H7 outbreak in the Pacific Northwest linked to Jack-in-the-Box **causes 400 illnesses and four deaths**.

**September 29, 1994**

Administrator Michael Taylor announces that FSIS considers “**raw ground beef that is contaminated with *E. coli* O157:H7 to be adulterated**” under the FMIA.

**July 25, 1996**

FSIS issues landmark **Pathogen Reduction/HACCP Systems rule**.

**1997**

**EU bans imports from the US** and other countries of poultry treated with antimicrobial processing aids.

**December 6, 2001**

Fifth Circuit Court of Appeals rules in *Supreme Beef Processors, Inc. v. USDA* that **FSIS cannot take enforcement action against meat processors** on the basis of *Salmonella* testing results alone.

**November 17, 2003**

**European Commission issues *Salmonella* control rule** that targets certain serotypes in livestock.

**August 3, 2011**

Cargill Meat Solutions, Inc. **recalls 36 million pounds of turkey** for suspected contamination with *Salmonella* Heidelberg **implicated in 136 illnesses and one death**.

**July 12, 2014**

Foster Farms **recalls an “undetermined amount” of chicken products** for suspected contamination with *Salmonella* Heidelberg **implicated in 634 illnesses**.

**February 11, 2016**

**FSIS finalizes updated standards** for *Salmonella* and *Campylobacter* in ground poultry and poultry parts.

**November 23, 2018**

FSIS publishes data indicating nearly all major poultry companies are operating plants that **fail to comply with the new rules**.

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<sup>1</sup> Stanley Rutledge, Stop Foodborne Illness “Spend a Moment With Amanda Craten,” June 5, 2018), [http://www.stopfoodborneillness.org/spend-a-moment-with-amanda\\_craten/](http://www.stopfoodborneillness.org/spend-a-moment-with-amanda_craten/)

<sup>2</sup> Centers for Disease Control and Prevention. “Multistate Outbreak of Multidrug-Resistant Salmonella Heidelberg Infections Linked to Foster Farms Brand Chicken (Final Update),” (July 31, 2014) [“Foster Farms Report”] <https://www.cdc.gov/salmonella/heidelberg-10-13/>.

<sup>3</sup> See, e.g. James Andrews. “Outbreak Case Counts: Why Official Numbers Fall Far Below Estimates.” *Food Safety News*, (Apr. 3, 2014), <https://www.foodsafetynews.com/2014/04/outbreak-case-counts-why-official-numbers-fall-far-below-estimates/>

<sup>4</sup> Throughout this report, the term *Salmonella* refers to non-typhoidal strains of the bacteria.

<sup>5</sup> See, e.g., PBS Frontline. “The Trouble with Chicken,” (May 11, 2015), <https://www.pbs.org/video/frontline-trouble-chicken/>

<sup>6</sup> See USDA Food Safety and Inspection Service. “New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures,” (Feb 11, 2016), <https://www.regulations.gov/document?D=FSIS-2014-0023-0020> (“Parts Rule”).

<sup>7</sup> See Alejandra Ramirez-Hernandez, Mindy M. Brashears, and Marcos X. Sanchez-Plata (2018) Efficacy of Lactic Acid, Lactic Acid-Acetic Acid Blends, and Peracetic Acid To Reduce Salmonella on Chicken Parts under Simulated Commercial Processing Conditions. *Journal of Food Protection*: January 2018, Vol. 81, No. 1, pp. 17-24. <https://doi.org/10.4315/0362-028X.JFP-17-087> (“more than 85% of poultry meat in the United States is consumed as parts instead of whole Carcasses”).

<sup>8</sup> USDA FSIS. “Salmonella Categorization of Individual Establishments for Poultry Products,” Reporting period for this data: October 29, 2017–October 27, 2018, *available at*: [https://www.fsis.usda.gov/wps/portal/fsis/home/!ut/p/a0/04\\_Sj9CPykssy0xPLMnMz0vMAFGjzOINAg3MDC2dDbwsfDxdDDz9AtyMgnYMDf3dDPQLsh0VAcy6FX0!/?1dmy&page=gov.usda.fsis.internet.newsroom&uril=wcm%3Apath%3A%2Ffsis-content%2Finternet%2Fmain%2Ftopics%2Fdata-collection-and-reports%2Fmicrobiology%2Fsalmonella-verification-testing-program%2Festablishment-categories](https://www.fsis.usda.gov/wps/portal/fsis/home/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAFGjzOINAg3MDC2dDbwsfDxdDDz9AtyMgnYMDf3dDPQLsh0VAcy6FX0!/?1dmy&page=gov.usda.fsis.internet.newsroom&uril=wcm%3Apath%3A%2Ffsis-content%2Finternet%2Fmain%2Ftopics%2Fdata-collection-and-reports%2Fmicrobiology%2Fsalmonella-verification-testing-program%2Festablishment-categories) (last visited Nov. 26, 2018).

<sup>9</sup> USDA FSIS Parts Rule, *supra* note 6, (“FSIS speculates that this rise [in the proportion of positive *Salmonella* carcasses during the mid-2000s] was because there were rarely significant consequences to failing a *Salmonella* set.”).

<sup>10</sup> See Michael Ollinger, James Wilkus, Megan Hrdlicka, and John Bovay. “Public Disclosure of Tests for Salmonella: The Effects on Food Safety Performance in Chicken Slaughter Establishments.” *Economic Research Report No. (ERR-231)*, (May 2017), <https://www.ers.usda.gov/publications/pub-details/?pubid=83660> [“ERS Report”]

<sup>11</sup> Batz, M. B., S. Hoffmann, and J. G. Morris, Jr. 2011. Ranking the risk: the 10 pathogen-food combinations with greatest burden on public health. *Emerging Pathogens Institute*, University of Florida, Gainesville.

<sup>12</sup> CDC. Reports of Active *Salmonella* Outbreak Investigations, <https://www.cdc.gov/salmonella/outbreaks-active.html> (last visited Nov. 25, 2018).

<sup>13</sup> See FSIS. “Parts Rule,” *supra* note 6 noting that “data from the National Antimicrobial Resistance Monitoring System (NARMS) show that the incidence of *Salmonella* in poultry products is five to ten times higher than that in ground beef or pork chops.”).

<sup>14</sup> See Centers for Disease Control and Prevention. “Salmonella,” <https://www.cdc.gov/salmonella/index.html> [“CDC information on Salmonella”] (last visited Nov. 26, 2018).

<sup>15</sup> *Id.*

<sup>16</sup> USDA Economic Research Service. Cost Estimates of Foodborne Illnesses, Cost of foodborne illness estimates for *Salmonella* (non-typhoidal) (10/7/2014), <https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx#48498> (last visited Nov. 26, 2018).

<sup>17</sup> CDC Information on *Salmonella supra* note 14.

<sup>18</sup> See Dewey-Mattia D, Manikonda K, Hall AJ, Wise ME, Crowe SJ. Surveillance for Foodborne Disease Outbreaks — United States, 2009–2015. *MMWR Surveill Summ* (2018)67(No. SS-10):1–11. DOI: <http://dx.doi.org/10.15585/mmwr.ss6710a1> (noting that, for the period 2009–2015, *Salmonella* in chicken was the third largest pathogen-food category pair responsible for illnesses associated with an outbreak, and chicken and pork were the top two food categories responsible for the most outbreak-associated illnesses caused by all pathogens.).

<sup>19</sup> Raw meat and poultry represent a significant, albeit not exclusive, source of salmonellosis. In recent years, the U.S. Food and Drug Administration has pursued several major policy reforms, including the so-called “Egg Safety Rule” and various regulations implemented pursuant to the Food Safety Modernization Act, to attempt to reduce the incidence of *Salmonella* infections associated with the food products that it regulates. This report does not attempt to evaluate those efforts. See U.S. FDA. “Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation,” 74 *Fed. Reg.* 33029 (July 9, 2009) *available at*: <https://www.federalregister.gov/documents/2009/07/09/E9-16119/prevention-of-salmonella-enteritidis-in-shell-eggs-during-production-storage-and-transportation>; see also FDA, FDA Food Safety Modernization Act, <https://www.fda.gov/food/guidanceregulation/fsma/> (last visited Nov. 26, 2018).

<sup>20</sup> See, e.g. Martin Wierup & Stig Widell (2014) Estimation of costs for control of *Salmonella* in high-risk feed materials and compound feed, *Infection Ecology & Epidemiology*, 4:1, DOI: 10.3402/iee.v4.23496;

<sup>21</sup> Business Wire, “Pritzker Hageman Wins \$6.5 Million Verdict in Landmark *Salmonella* Case” (March 12, 2018), <https://www.businesswire.com/news/home/20180312005082/en/Pritzker-Hageman-Wins-6.5-Million-Verdict-Landmark>

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- <sup>22</sup> Molly Freeman, “Fecal Matters: It All Starts with a Stool Sample,” (Feb. 19, 2013), <https://www.foodsafety.gov/blog/stoolsample.html>
- <sup>23</sup> David Acheson, Elizabeth L. Hohmann; Nontyphoidal Salmonellosis, *Clinical Infectious Diseases*, Volume 32, Issue 2, 15 January 2001, Pages 263–269, <https://doi.org/10.1086/318457>.
- <sup>24</sup> Drew Falkenstein, “All You Need To Know About Salmonella,” (Apr. 11, 2015), <https://www.foodpoisonjournal.com/food-poisoning-information/what-you-need-to-know-about-salmonella-2/>
- <sup>25</sup> Huang JY, Henao OL, Griffin PM, et al. Infection with Pathogens Transmitted Commonly Through Food and the Effect of Increasing Use of Culture-Independent Diagnostic Tests on Surveillance — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2012–2015. *MMWR Morb Mortal Wkly Rep* 2016;65:368–371. DOI: <http://dx.doi.org/10.15585/mmwr.mm6514a2>
- <sup>26</sup> *Id.*
- <sup>27</sup> See, e.g. Douglas E. Cosby, Nelson A. Cox, Mark A. Harrison, Jeanna L. Wilson, R. Jeff Buhr, Paula J. Fedorka-Cray; Salmonella and antimicrobial resistance in broilers: A review, *The Journal of Applied Poultry Research*, Volume 24, Issue 3, 1 September 2015, Pages 408–426, <https://doi.org/10.3382/japr/pfv038> (“With the emergence of antimicrobial resistance, the pathogenicity and virulence of certain Salmonella serotypes have increased and treatment options are decreasing and becoming more expensive.”).
- <sup>28</sup> Centers for Disease Control and Prevention, NARMS – Combating Antibiotic Resistance with Surveillance, <https://www.cdc.gov/narms/faq.html> (last visited Nov. \_\_, 2018)
- <sup>29</sup> See Brad Spellberg, Gail R. Hansen, Avinash Kar, Carmen D. Cordova, Lance B. Price, and James R. Johnson, “Antibiotic Resistance in Humans and Animals,” Discussion Paper (June 22, 2016), <https://nam.edu/wp-content/uploads/2016/07/Antibiotic-Resistance-in-Humans-and-Animals.pdf>
- “For example, in Quebec, eliminating cephalosporin use in broiler chicken eggs led to precipitous declines in cephalosporin-resistant Enterobacteriaceae in both retail chicken meat and humans, even though human use of antibiotics held constant. When the chicken industry partially resumed injecting cephalosporin in broiler chicken eggs in 2006–2007, cephalosporin resistance began to increase again in both animals and humans. Similarly, for use in poultry the United States instituted a complete ban on fluoroquinolones in 2005 and a partial ban on cephalosporins in 2012. Subsequently, FDA testing in 2014 found no fluoroquinolone resistance in retail poultry samples and declining rates of ceftriaxone resistance in Salmonella.” *Id.* (internal citations omitted).
- <sup>30</sup> Centers for Disease Control and Prevention, Antibiotic Resistance Threats in the United States (2013), available at: <https://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf>. More recently, in 2016, one leading researcher called the CDC’s 2013 estimate, which in turn was based on 2011 data, “a gross underestimate” with the actual toll “probably twice that number.” Madlen Davies. “Superbugs killing twice as many people as government says,” *The Bureau of Investigative Journalism*, (Dec. 11, 2016) <https://www.thebureauinvestigates.com/stories/2016-12-11/superbugs-killing-twice-as-many-people-as-government-says> (quoting Ramanan Laxminarayan, director of the Center for Disease Dynamics, Economics & Policy).
- <sup>31</sup> See Spellberg, *supra* note 29.
- <sup>32</sup> See Dan Charles. “Perdue Goes (Almost) Antibiotic-Free,” *NPR: The Salt*, (Oct. 7, 2016), <https://www.npr.org/sections/thesalt/2016/10/07/497033243/perdue-goes-almost-antibiotic-free>; Tom Polansek, “Tyson Foods accelerates shift away from antibiotics in chicken,” (Feb. 21, 2017), *Reuters*, <https://www.reuters.com/article/us-tyson-foods-livestock-antibiotics-idUSKBN16026O>.
- <sup>33</sup> See Sanderson Farms. “The Truth About Antibiotics and Chicken,” <https://sandersonfarms.com/blog/truth-antibiotics-chicken/> (last visited Nov. 26, 2018).
- <sup>34</sup> FSIS. HACCP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and Related Agency Verification Procedures Notice, 77 Fed. Reg. 72686-01 (Dec. 6, 2012), <https://www.federalregister.gov/documents/2012/12/06/2012-29510/haccp-plan-reassessment-for-not-ready-to-eat-comminuted-poultry-products-and-related-agency>; see also Alice Green, Stephanie Defibaugh-Chavez, Aphrodite Douris, Danah Vetter, Richard Atkinson, Bonnie Kissler, Allison Khroustalev, Kis Robertson, Yudhbir Sharma, Karen Becker, Uday Dessai, Nisha Antoine, Latasha Allen, Kristin Holt, Laura Gieraltowski, Matthew Wise, Colin Schwensohn, and the Food Safety and Inspection Service (FSIS) Salmonella Heidelberg Investigation Team, “Intensified Sampling in Response to a Salmonella Heidelberg Outbreak Associated with Multiple Establishments Within a Single Poultry Corporation,” *Foodborne Pathogens and Disease* 2018 15:3, 153-160 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5865244/> (explaining that “[d]uring this [the Foster Farms] outbreak, a recall was initiated when leftover product with identifying package information was tested and found to contain an outbreak strain indistinguishable from that of the case-patient who consumed it in the week before illness onset.”).
- <sup>35</sup> Jeff Benedict, “Food Safety Since Jack in the Box: Progress Made and Progress Still Needed.” *Food Safety News*, (Jan. 30, 2013), <https://www.foodsafetynews.com/2013/01/food-safety-since-jack-in-the-box-progress-made-and-progress-still-needed/>
- <sup>36</sup> FSIS. Parts Rule, *supra* note 6.
- <sup>37</sup> See generally Chris Waldrop. “The Promise and Problems of HACCP: A Review of USDA’s Approach to Meat and Poultry Safety,” (Aug. 2015), <https://consumerfed.org/reports/the-promise-and-problems-of-haccp-a-review-of-usdas-approach-to-meat-and-poultry-safety/>
- <sup>38</sup> See, e.g. Ellen Silberger. *Chickenizing Farms and Food: How Industrial Meat Production Endangers Workers, Animals, and Consumers* (2016), at 169.

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<sup>39</sup> See Waldrop, *supra* note 37.

<sup>40</sup> Food Safety and Inspection Service, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems," Final Rule, 61 Federal Register at 38847 (July 25, 1996), <https://www.fsis.usda.gov/wps/wcm/connect/e113b15a-837c-46af-8303-73f7c11fb666/93-016F.pdf?MOD=AJPERES>

<sup>41</sup> *Id.* at 38865-67.

<sup>42</sup> *Id.* at 38812.

<sup>43</sup> *Supreme Beef Processors, Inc. v. U.S. Dept. of Agriculture*, 113 F.Supp.2d 1048 (N.D.Tex.,2000).

<sup>44</sup> *Supreme Beef Processors, Inc. v. U.S. Dept. of Agriculture*, 275 F.3d 432, 440 (5th Cir. 2001).

<sup>45</sup> *Id.*

<sup>46</sup> *Id.* citing *American Pub. Health Ass'n v. Butz*, 511 F.2d 331, 334 (D.C.Cir.1974)

<sup>47</sup> FSIS. "Modernization of Swine Slaughter Inspection" 83 *Fed. Reg.* 4780, 4786 (Feb. 1, 2018)

<https://www.federalregister.gov/d/2018-01256/p-113>

<sup>48</sup> Craig W. Hedberg, Jeff B. Bender, Fernando Sampedro, Scott J. Wells. "Potential Impacts of Classifying Specific Strains of Salmonella with Multi-Drug Resistance as Adulterants in Ground Beef and Poultry Products," (Jan. 2015), <https://www.foodpolicy.umn.edu/policy-summaries-and-analyses/potential-impacts-classifying-specific-strains-salmonella-multi-drug> citing Center for Disease Control and Prevention. Incidence and trends of infection with pathogens transmitted commonly through food — Foodborne diseases active surveillance network, 10 U.S. Sites, 1996–2012. *MMWR* 2013 62(15); 283-287.

<sup>49</sup> See, e.g. Emma Schwartz. "Can We Get to Zero Salmonella in Poultry?" *PBS Frontline* (May 12, 2015),

<https://www.pbs.org/wgbh/frontline/article/can-we-get-to-zero-salmonella-in-poultry/>

<sup>50</sup> *APHA v. Butz*, 511 F.2d 331, 334 (D.C. Cir. 1974).

<sup>51</sup> *Id.* citing USDA Letter of July 21, 1971 (internal quotations omitted).

<sup>52</sup> *Id.* Photo courtesy of the Historical Society of the District of Columbia Circuit,

[http://dcchs.org/USCA/DavidBazelon\\_1940\\_6.jpg](http://dcchs.org/USCA/DavidBazelon_1940_6.jpg)

<sup>53</sup> See Patricia L. Cummings, Frank Sorvillo, and Tony Kuo. Salmonellosis-Related Mortality in the United States, 1990–2006, *Foodborne Pathogens and Disease* 2010 7:11, 1393-1399, <https://www.liebertpub.com/doi/10.1089/fpd.2010.0588> (reviewing U.S. death records for the period 1990-2006 and finding "Salmonellosis was reported as an underlying or associated cause of death among 1316 persons.); see also Sperber, Steven J., and Charles J. Schlepner. 1987. "Salmonellosis During Infection with Human Immunodeficiency Virus." *Review of Infectious Diseases* no. 9 (5):925-934. doi: 10.1093/clinids/9.5.925; Acheson, David, and Elizabeth L. Hohmann. 2001. "Nontyphoidal Salmonellosis." *Clinical Infectious Diseases* no. 32 (2):263-269. doi: 10.1086/318457; Holmberg, Scott D., et al. 1987. "Health and Economic Impacts of Antimicrobial Resistance." *Review of Infectious Diseases* no. 9 (6):1065-1078. doi: 10.1093/clinids/9.6.1065.

<sup>54</sup> Maryn McKenna. "Food Poisoning's Hidden Legacy," *Scientific American*, (Apr. 1, 2012),

<https://www.scientificamerican.com/article/food-poisonings-hidden-legacy/>; Center for Foodborne Illness Research and Prevention, *The Long-Term Health Outcomes of Selected Foodborne Pathogens* (Nov. 12, 2009), [http://www.foodborneillness.org/cfi-library/CFI\\_LTHO\\_PSP\\_report\\_Nov2009\\_050812.pdf](http://www.foodborneillness.org/cfi-library/CFI_LTHO_PSP_report_Nov2009_050812.pdf)

<sup>55</sup> See, e.g. EFSA. 2004. "Opinion of the Scientific Panel on biological hazards (BIOHAZ) related to the use of vaccines for the control of Salmonella in poultry " *EFSA Journal*, no. doi:10.2903/j.efsa.2004.114.; EFSA 2010. "Scientific Opinion on a Quantitative Microbiological Risk Assessment of Salmonella in slaughter and breeder pigs " *EFSA Journal*, no. 8 (4):1547.

<sup>56</sup> Cliver, D. O. 2006. "Cutting boards in Salmonella cross-contamination." *J AOAC Int* no. 89 (2):538-42. Carrasco, Elena, et al. 2012. "Cross-contamination and recontamination by Salmonella in foods: A review." *Food Research International* no. 45 (2):545-556. doi: <http://dx.doi.org/10.1016/j.foodres.2011.11.004>.

<sup>57</sup> WHO, FAO. 2002. "Risk assessments of Salmonella in eggs and broiler chickens." *Microbiological Risk Assessment Series* 2 ["WHO Risk Assessment"]

<sup>58</sup> Montville, R., et al. 2002. "Risk assessment of hand washing efficacy using literature and experimental data." *Int J Food Microbiol* no. 73 (2-3):305-13.

<sup>59</sup> Cates et al. "Food Safety Consumer Research Project: Meal Preparation Experiment Related to Thermometer Use." (May 18, 2018), available at: <https://www.fsis.usda.gov/wps/wcm/connect/cb222383-1e02-471a-8657-c205eda92acf/Observational-Study.pdf?MOD=AJPERES>

<sup>60</sup> WHO Risk Assessment, *supra* note 57.

<sup>61</sup> Juneja, V. K., et al. 2001. "Thermal Inactivation of Salmonella spp. in Chicken Broth, Beef, Pork, Turkey, and Chicken: Determination of D- and Z-values." *Journal of Food Science* no. 66 (1):146-152. doi: 10.1111/j.1365-2621.2001.tb15597.x.

<sup>62</sup> Breslin, T. J., et al. 2014. "Evaluation of Salmonella thermal inactivation model validity for slow cooking of whole-muscle meat roasts in a pilot-scale oven." *J Food Prot* no. 77 (11):1897-903. doi: 10.4315/0362-028X.JFP-14-035.

<sup>63</sup> Lee, Kyung-Min, et al. 2015. "Review of Salmonella detection and identification methods: Aspects of rapid emergency response and food safety." *Food Control* no. 47 (0):264-276. doi: <http://dx.doi.org/10.1016/j.foodcont.2014.07.011>.

<sup>64</sup> 21 U.S.C. § 601(m)(1)

<sup>65</sup> 674 F.2d 38 (D.C. Cir. 1982).

<sup>66</sup> *Id.* at 40.

<sup>67</sup> 622 F.2d 157 (1980).

- <sup>68</sup> Heyndrickx, M., Vandekerchove, D., Herman, L., Rollier, I., Grijspeerdt, K., and De Zutter, L. (2002). Routes for Salmonella contamination of poultry meat: epidemiological study from hatchery to slaughterhouse. *Epidemiol. Infect.* 129, 253–265. doi: 10.1017/S0950268802007380.
- <sup>69</sup> See, e.g., Martin Wierup. “Production of Soybean-Derived Feed Material Free from Salmonella Contamination: An Essential Food Safety Challenge.” (May 3, 2017), available at: <https://www.intechopen.com/books/soybean-the-basis-of-yield-biomass-and-productivity/production-of-soybean-derived-feed-material-free-from-salmonella-contamination-an-essential-food-saf> (“A striking example emphasizing the potential of contaminated animal feed to act as a source of Salmonella infections in humans occurred when Salmonella agona emerged as a public health problem in several countries due to the widespread use of contaminated fish meal that was imported as feed material” in the period 1968-1972.).
- <sup>70</sup> See, e.g. National Chicken Council, “Statement on CDC Investigation of Salmonella Infantis,” (Oct. 17, 2018) (“the fact is raw chicken is not sterile, and any raw agricultural product, whether its fresh fruit, vegetables, fish, meat or poultry, is susceptible to naturally occurring bacteria that could make someone sick if improperly handled or cooked.”), <https://www.nationalchickencouncil.org/ncc-statement-on-cdc-investigation-of-salmonella-infantis/>.
- <sup>71</sup> Wahlström H, Sternberg Lewerin S, Sundström K, Ivarsson S (2014) Estimation of the Expected Change in Domestic Human Salmonella Cases in Sweden in 2010, Given a Hypothetical Relaxation of the Current Salmonella Control Programme. *PLoS ONE* 9(3): e89833. <https://doi.org/10.1371/journal.pone.0089833>.
- <sup>72</sup> Tanya Roberts and Johan Lindblad. “Sweden Led Salmonella Control in Broilers: Which Countries Are Following?” in *Food Safety Economics*, ed. Tanya Roberts (forthcoming 2019).
- <sup>73</sup> *Id.*
- <sup>74</sup> Surveillance of infectious diseases in animals and humans in Sweden 2017. National Veterinary Institute (SVA), Uppsala, Sweden, available at: [http://www.sva.se/globalassets/redesign2011/pdf/om\\_sva/publikationer/surveillance-2017-w.pdf](http://www.sva.se/globalassets/redesign2011/pdf/om_sva/publikationer/surveillance-2017-w.pdf)
- <sup>75</sup> “The surveillance programmes for Salmonella in live animals, eggs and meat in Norway 2017,” Norwegian Veterinary Institute, available at: [https://www.vetinst.no/overvaking/salmonella/\\_/attachment/download/2968a2fa-43ff-4ec9-aa8f-0d19199e3a83:286e8e9825dccb56ae9b9a8ca160166f7cb8c605/2018\\_OK\\_Salmonella\\_Report%202017.pdf](https://www.vetinst.no/overvaking/salmonella/_/attachment/download/2968a2fa-43ff-4ec9-aa8f-0d19199e3a83:286e8e9825dccb56ae9b9a8ca160166f7cb8c605/2018_OK_Salmonella_Report%202017.pdf)
- <sup>76</sup> “Animal diseases in Finland 2016,” Finnish Food Safety Authority Evira, available at: [https://www.evira.fi/globalassets/tietoa-evilasta/julkaisut/julkaisusarjat/elaimet/evira\\_publications\\_4\\_2017.pdf](https://www.evira.fi/globalassets/tietoa-evilasta/julkaisut/julkaisusarjat/elaimet/evira_publications_4_2017.pdf)
- <sup>77</sup> Anonymous, 2016. Annual Report on Zoonoses in Denmark 2017, National Food Institute, Technical University of Denmark, available at: <https://www.food.dtu.dk/english/-/media/Institutter/Foedevareinstituttet/Publikationer/Pub-2018/Rapport-Annual-Report-on-Zoonoses-2017.ashx?la=da&hash=4D9E579C2B146B6DDA569A12912652518AA0590F>
- <sup>78</sup> Roberts, *supra* note 72.
- <sup>79</sup> Sundström K, Wahlström H, Ivarsson S, Sternberg Lewerin S (2014) Economic Effects of Introducing Alternative Salmonella Control Strategies in Sweden. *PLoS ONE* 9(5): e96446. <https://doi.org/10.1371/journal.pone.0096446>
- <sup>80</sup> See, e.g. Tyson Foods, Inc. Press Release: “Tyson Foods and Cobb Vantress Partner with OneEgg to Launch Sustainable Egg Farm in Haiti.” (May 3, 2017).
- <sup>81</sup> Roberts *supra* note 72 (“In 2016, the Swedes detected Salmonella in just one grandparent flock following importation and a quarantine period. That flock was destroyed, as are all flocks that test positive for Salmonella in Sweden.”).
- <sup>82</sup> According to an emailed response from a representative of Aviagen, the company will regularly destroy flocks infected by certain *Salmonella* strains “most associated with human illness,” but the company relies on other means, such as vaccines and probiotics, to address the risk of vertical transmission of other *Salmonella* strains. [on file with author].
- <sup>83</sup> Compare Roberts *supra* note 72 with Terrence O’Keefe, “How Tyson Foods and Cargill control Salmonella in poultry live production,” *WATTAgNet.com*, (Aug. 11, 2013), <https://www.wattagnet.com/articles/21902-how-tyson-foods-and-cargill-control-salmonella-in-poultry-live-production>
- <sup>84</sup> Roberts *supra* note 72.
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42% ranged from 0.0301 to 0.3 Most-Probable-Number (MPN)/mL, 34% ranged from 0.301 to 3.0 MPN/mL, and only 11 (0.007%) samples were above 30 MPN/mL.”)

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