



Weaknesses in FSIS's Salmonella Regulation

How two recent outbreaks illustrate a failure to protect public health

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The safe food project seeks to reduce health risks from foodborne pathogens by strengthening federal government authority and the enforcement of food safety laws.

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Contents

- 1 Overview
- 3 Background
- 4 The FSIS approach to regulating salmonella
- 6 The FSIS response to the two recent outbreaks
- 9 A failure to protect public health
- 12 Key weaknesses in federal regulation and policies
- 13 Recommendations
- 13 Conclusion
- 14 Appendix: Summary findings from FSIS's notice of intended enforcement letters
- 15 Endnotes

Overview

According to the Centers for Disease Control and Prevention, two multistate outbreaks of salmonella infections—the first lasted from June 2012 to April 2013, and the second started on March 2013 and is ongoing—were linked to chicken produced by Foster Farms, the sixth-largest* chicken producer in the United States.¹ At least 523 people in 29 states and Puerto Rico were reported to public health authorities as having been sickened.²

Based on estimates by CDC, however, these outbreaks may have sickened as many as 15,000[†] people nationally due to the underdiagnosis of salmonella.³ The federal agency responsible for inspecting meat and poultry products, the U.S. Department of Agriculture's Food Safety and Inspection Service, or FSIS, issued a public health alert[‡] for the second outbreak⁴—but not the first. In neither instance did FSIS ask Foster Farms to institute a recall or stop shipping potentially contaminated chicken to market.⁵

The safe food project of The Pew Charitable Trusts analyzed the events surrounding these two outbreaks. It identified significant weaknesses in existing federal regulations and policies aimed at controlling salmonella contamination in poultry products.**

- Current limits on salmonella contamination for chicken, known as performance standards, and related policies do not adequately protect public health.
 - As opposed to other pathogens such as *Escherichia coli* O157:H7, the Food Safety and Inspection Service does not consider salmonella to be an adulterant in raw poultry, but treats it as an indicator organism used to determine whether a company is producing safe food based on the level of salmonella found.
 - Performance standards, which are not updated regularly, are based on the national prevalence of the pathogen in a specific product instead of public health impact.
 - There are no salmonella performance standards for chicken parts, which are purchased more widely than whole chickens.
 - FSIS tests products at chicken-slaughter plants once a year except for those considered “best performing,” which are tested every other year.[¶]

* Ranking determined by average weekly million-head slaughtered in continental U.S. plants for 2012. Foster Farms slaughtered a weekly average of 5.84 million heads in 2012. In the same year, Tyson Foods Inc., the largest U.S. chicken producer, slaughtered a weekly average of 35.4 million.

† According to CDC, for every case of salmonella reported to public health authorities, 29.3 others are underdiagnosed. The estimate in the text was obtained by multiplying the total number of cases reported in the two outbreaks (n=523) by 29.3.

‡ FSIS issues public health alerts about potential health risks for cases in which the agency cannot recommend a recall, such as when the source of the outbreak has not yet been identified. FSIS can also issue an alert to remind consumers of safe food-handling practices. (Source: <http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/current-recalls-and-alerts/recalls-and-public-health-alerts>.)

§ FSIS cautioned the company that it would close the plants after three days if corrective actions were not adequate. (Source: USDA Food Safety and Inspection Service, Notice of Intended Enforcement, accessed Nov. 7, 2013, <http://www.marlerblog.com/files/2013/10/Foster-Poultry-Farms-Est.-6137P.pdf>; <http://www.marlerblog.com/files/2013/10/Zorro-Leasing-10-07-13.pdf>; <http://www.marlerblog.com/files/2013/10/foster-farms-est-6137a-p1.pdf>.)

** This report focuses only on poultry; however, many of the recommendations are also relevant to meat products.

¶ “Best performing” establishments (or category 1) are those with lower numbers of salmonella-positive samples when they are tested. (Source: http://www.fsis.usda.gov/wps/portal/fsis/home!/ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbwsfDxdDDz9AtyMgnyMDf3dDPQLsh0VAcy6FX0!/?1dmy&page=gov.usda.fsis.internet.newsroom&urile=wcm%3Apath%3A/fsis-content/internet/main/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program/salmonella-verification-testing-program.)

- Companies receive advance notice from FSIS before samples from their facilities are tested for salmonella.
- FSIS cannot close a plant based only on results from its salmonella-verification testing.
- As part of prevention-based safety requirements, poultry plants are not required to treat the presence of salmonella as a “hazard likely to occur,” or a significant risk that needs to be controlled during processing and production.
- There are no requirements for farm-level control measures that would help reduce salmonella contamination in chickens before they arrive at slaughter facilities.

Recommendations

Based on its evaluation, Pew makes seven general recommendations for improving the control of salmonella in poultry and strengthening the agency’s response to outbreaks caused by these bacteria. FSIS should:

- Reconsider its approach to developing and implementing salmonella performance standards so they are:
 - Updated regularly to reflect changes in industry practices, such as the adoption of new technologies.
 - Directly linked to public health outcomes.
 - Useful in evaluating companies on a regular basis rather than one or two times over a two-year period as is currently the case.
 - Enforceable, which may require legislative action.
- Issue performance standards for chicken parts.*
- Conduct unannounced salmonella testing.
- Consider establishing limits on salmonella contamination for chickens when they enter into the slaughterhouse, which may require legislation.
- Communicate outbreaks to consumers via public health alerts as early as possible when there is sufficient epidemiological evidence linking illnesses to a company’s product, even if there is not a definitive link between specific products and patients.
- Close facilities under investigation for failing to produce safe food, and keep them closed until adequate control measures are in place.
- Be given mandatory recall authority.

The recent outbreaks of salmonella infections linked to Foster Farms⁵ have uncovered serious weaknesses in FSIS salmonella policies and regulations. The agency should make significant improvements in controlling salmonella contamination to reduce the number of preventable illnesses caused by contaminated poultry.[†]

* On Oct. 31, 2013, FSIS said it is going to issue performance standards for chicken parts in fiscal year 2014, but no specific date has been given. (Source: *Food Chemical News*, Nov. 1, 2013. Vol. 55, No. 32.)

† As this report was being finalized in December 2013, FSIS released a salmonella action plan highlighting the steps the agency is taking to better control the pathogen in meat and poultry. More can be found at <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/foodborne-illness-and-disease/salmonella/sap..>

Background

From early June 2012 to mid-April 2013, chicken contaminated with *Salmonella enterica* serotype Heidelberg caused a reported 134 sicknesses and 33 hospitalizations in 13 states. According to CDC, Foster Farms produced the tainted chicken.⁶

In March 2013, another outbreak linked to chicken produced at three other Foster Farms plants started.⁷ As of Dec. 6, 389 people were reported to be infected by seven strains of *S. Heidelberg*—one of which matched the strain of the first outbreak—in 23 states and Puerto Rico.⁸ A relatively high percentage of those infected, 40 percent, have been hospitalized and the strains are resistant to several commonly prescribed antibiotics. No deaths have been reported,⁹ but the number of infections is likely to increase because, as of Dec. 6, the outbreak was still ongoing.

About Our Report

The professional staff of the safe food project at The Pew Charitable Trusts, including Juliana Ruzante, D.V.M., M.P.V.M., Ph.D., and Sandra Eskin, JD, reviewed and analyzed public documents regarding the two most recent outbreaks of *Salmonella* Heidelberg infections, including reports and other documents produced by CDC* and FSIS.† Pew based the observations and conclusions in this report on its review of these documents, as well as correspondence and input from public health officials at the state and federal levels who were part of the outbreak investigation, and from FSIS. Foster Farms was given the opportunity to read this report prior to its publication.

Kirk Smith, D.V.M., M.S., Ph.D., supervisor of the Foodborne, Vectorborne, and Zoonotic Diseases Unit in the Acute Disease Investigation and Control Section of the Minnesota Department of Health, peer-reviewed the report. Other reviewers included staff with FSIS, CDC, and the Oregon Health Authority.

* “Multistate Outbreak of *Salmonella* Heidelberg Infections Linked to Chicken (Final Update),” Centers for Disease Control and Prevention, accessed Oct. 22, 2013, <http://www.cdc.gov/salmonella/heidelberg-02-13/index.html>; “Outbreak of *Salmonella* Heidelberg Infections Linked to a Single Poultry Producer—13 States, 2012–2013,” Centers for Disease Control and Prevention, accessed Nov. 7, 2013, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6227a3.htm>.

† “FSIS Issues Public Health Alert for Chicken Products Produced at Three Foster Farms Facilities,” USDA Food Safety and Inspection Service, accessed Oct. 22, 2013, <http://www.fsis.usda.gov/wps/portal/osis/newsroom/news-releases-statements-and-transcripts/news-release-archives-by-year/archive/2013/pha-100713>, and FSIS, Notice of Intended Enforcement, accessed Nov. 7, 2013, <http://www.marlerblog.com/files/2013/10/Foster-Poultry-Farms-Est.-6137P.pdf>; <http://www.marlerblog.com/files/2013/10/Zorro-Leasing-10-07-13.pdf>; <http://www.marlerblog.com/files/2013/10/foster-farms-est-6137a-p1.pdf>.

The FSIS approach to regulating salmonella

It is estimated that salmonella causes more than 1 million foodborne illnesses every year and is responsible for more hospitalizations and deaths than any other type of bacterium or virus found in food.¹⁰ A recent literature review has identified several long-term consequences of salmonella infections, ranging reactive arthritis to inflammatory bowel disease.¹¹ The health-related costs of salmonella to the nation run as high as \$11 billion a year.¹² Food is estimated to be the source of 90 percent of salmonella infections, with contaminated poultry believed to be a primary cause.¹³

Salmonella performance standards for raw poultry products

FSIS considers a number of disease-causing bacteria—including *Escherichia coli* O157:H7 and *Listeria monocytogenes*—to be “adulterants,” which give the agency the authority to prohibit any amount of these pathogens in specific food products. When an adulterant is found in food, FSIS can take advantage of its strongest enforcement tools, including withdrawing inspectors and thereby closing the plant.¹⁴

But salmonella in raw poultry products is not treated as an adulterant. FSIS does use the bacteria as an “indicator organism”—when present in products above a certain level, it indicates that the slaughter plant is not effectively controlling microbial contamination.¹⁵

To evaluate whether a facility is adequately controlling bacterial contamination, FSIS sets product-specific performance standards, or percentages of samples that test positive for salmonella. These standards are based on the national prevalence in a specific product.¹⁶

The national prevalence of salmonella is determined by baseline studies. Neither these nor performance standards, however, are updated regularly to reflect changes in industry practices, such as the adoption of new technology. For instance, until July 2011 the standard for salmonella in young chicken carcasses was based on data from 1994-95.¹⁷ FSIS conducted a new baseline study in 2007-2008 to update the data,¹⁸ but the agency took another three years to revise and finalize the performance standard for young chicken.¹⁹ (See Table 1.) The new standard set a percentage for the presence of salmonella contamination in young chickens that is lower than its predecessor.

Even though chicken parts are more frequently consumed than whole chickens,²⁰ there are no salmonella performance standards for them. In 2012, FSIS concluded its first baseline study for chicken parts, which estimated that the prevalence nationally of salmonella in these products is 24 percent.²¹ It is not clear why the prevalence of salmonella in chicken parts is so much higher than that in whole birds (7.5 percent).²² FSIS plans to propose a performance standard for chicken parts, but the agency has not indicated when that will be put in place.

Performance standards in practice

FSIS has interpreted a 2001 appellate court decision as prohibiting it from closing a plant or using any of its other enforcement tools when a company fails to meet a salmonella performance standard. In *Supreme Beef Processors Inc. v. USDA*, the Court of Appeals for the Fifth Circuit upheld a lower-court ruling that the USDA does not have the authority to shut down a meat-processing plant based only on the fact that it repeatedly failed tests for salmonella contamination.²³ Some critics of FSIS believe its application of this decision is too broad.²⁴

Because of its interpretation of the *Supreme Beef* case, the agency has developed “workarounds”—a series of increasingly resource- and time-intensive inspections and investigations—to deploy when a company repeatedly

Table 1

FSIS's Performance Standards for Meat and Poultry Products

Product Type	Performance standard (percentage positive for salmonella)*	Year standard was updated*	Year baseline study was conducted†
Young chicken carcass	7.5%	2011	2007/2008
Young turkey carcass	1.7%	2011	2008/2009
Ground chicken	44.6%	1996	1995‡
Ground turkey	49.9%	1996	1995‡
Ground beef	7.5%	1996	1993/1994
Chicken parts	There are no standards at this time.	—	2012

* New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments: Response to Comments and Announcement of Implementation Schedule, Food Safety and Inspection Service, 76 FR 15282, accessed Nov. 11, 2013, <https://www.federalregister.gov/articles/2011/03/21/2011-6585/new-performance-standards-for-salmonella-and-campylobacter-in-young-chicken-and-turkey-slaughter>. And "Pathogen-Reduction; Hazard Analysis, and Critical Control Point (HACCP) Systems Final Rule," 9 CFR Part 304, 1996.

† Food Safety and Inspection Service, Baseline Data, accessed Nov. 18, 2013, <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/baseline/baseline>.

‡ FSIS announced on Dec. 6, 2012, that it would begin sampling to determine the prevalence of salmonella in "comminuted" (raw ground and similar non-intact product) poultry and would use the data to develop new performance standards. (Source: www.fsis.usda.gov/OPPDE/rdad/FRPubs/2012-0007.pdf.)

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fails to meet salmonella performance standards. During these additional inspections and investigations, however, a company is still allowed to produce and ship food. Moreover, FSIS tests the best-performing establishments only every other year, and all companies are notified when they will be tested. Prior notice of testing would allow a company to alter its processes temporarily to ensure adequate results. To counteract such responses, FSIS issued a directive to its in-plant inspectors advising them to "request expedited scheduling of FSIS salmonella verification sampling when an establishment has substantially altered its food safety system or temporarily changed its process."²⁵

Hazard analysis and critical control points

Since 2000, U.S. meat and poultry plants have followed an approach to food safety known as "hazard analysis and critical control points." This preventive program requires facilities to systematically evaluate and address food safety problems through a written plan. FSIS reviews the plans every year, and in-plant inspectors are responsible for evaluating them and making sure companies follow them day to day.²⁶ Although the agency does not mandate which hazards a company needs to address, it "strongly" recommends that salmonella be included.²⁷

The FSIS response to the two recent outbreaks

The first outbreak: June 2012 to mid-April 2013

FSIS has never issued any statements to consumers about this outbreak. The only information available to the public was a report posted on CDC's website and an article published in *Morbidity and Mortality Weekly Report*.²⁸ (See Table 2.) FSIS previously issued public health alerts for potential risks when a recall cannot be recommended.²⁹ Its failure to do so during the 2012-13 outbreak is notable because of the strong epidemiological and microbiological evidence and other information available to the agency linking Foster Farms chicken to the illnesses. (See Table 2.) In particular, 79 percent of patients affected by this outbreak reported consuming chicken in the week before they became sick.³⁰ This percentage was significantly higher than could be expected, based on a CDC survey.³¹ Public health officials in Oregon³² and Washington State,³³ where the outbreak was first detected, issued news releases on Feb. 14, 2013, notifying the public about the rise in cases of salmonella illnesses linked to chicken.

FSIS sent an investigation team to plants linked to this outbreak in December 2012.³⁴ Results from these assessments have not been released.³⁵

The second outbreak: March 2013–ongoing

FSIS contacted Foster Farms on July 25, 2013, notifying it of the ongoing outbreak associated with some of its poultry products and production facilities.³⁶ But not until Sept. 9 did FSIS send investigation teams to four Foster Farm plants to conduct in-depth inspections and intensive salmonella testing.³⁷ On Oct. 7, FSIS sent three of those plants a Notice of Intended Enforcement informing the company that the agency was considering closing them. In the notices,³⁸ the agency listed a series of violations and revealed the results of the intensive investigation done in September. The agency concluded that “although the presence of the outbreak strain alone is not evidence that product is adulterated, presence on product coupled with illnesses suggest that the sanitary conditions in the establishment could pose a serious ongoing threat to public health.”³⁹ (See Appendix.)

The issuance of the three notices was supported by the results of intensified salmonella-verification tests conducted a month earlier during FSIS's inspections,⁴⁰ as well as the findings related to this outbreak described in Table 2. FSIS gave Foster Farms three days to implement corrective measures, and during this period the three facilities implicated continued to produce and ship products that might have been contaminated.* After the three-day period and upon evaluation, the agency determined that it would not close the plants because Foster Farms had submitted and implemented immediate substantive changes to slaughter and processing that allowed it to keep operating. At the same time, FSIS indicated that, going forward, its inspectors would verify that the control measures put in place by the company would be implemented on an ongoing basis and would continue intensified sampling for at least the next 90 days.⁴¹

On the day FSIS issued the enforcement notices to Foster Farms, it also issued a public health alert.⁴² The alert did not include information on product types and production lots. By contrast, the agency had cited the absence of this information as its reason for not issuing an alert in the 2012-13 outbreak.⁴³

* In the notices of intended enforcement, FSIS said it would close the plants after three days if the company's corrective actions were not adequate.

Table 2

Evidence That Linked the Two Outbreaks to Chicken Products From Foster Farms

Epidemiological, microbiological, and traceback evidence

Type of Evidence	2012-2013 Outbreak	2013 Outbreak (ongoing)
Epidemiological	Initial state-based interviews found that chicken had been commonly consumed by those with <i>S. Heidelberg</i> infections.	
	Multistate questionnaire showed that 79 percent of patients reported consuming chicken in the week before they became sick. This percentage was significantly higher than what would be expected when compared with the Foodborne Diseases Active Surveillance Network Population Survey of Healthy Persons (2006-2007), which summarizes demographic characteristics, food consumption, and animal-exposure information from about 15 percent of the population in the United States.	Multistate questionnaire showed that 80 percent of patients reported consuming chicken in the week before they became sick.
	Seventy-one percent of patients (36 out of 51) with brand information reported exposure to Foster Farms chicken or to a brand likely produced by Foster Farms.	Seventy-nine percent of patients (48 out of 61) with brand information reported exposure to Foster Farms chicken or to a brand likely produced by Foster Farms.
Microbiological	Four unopened chicken samples from three Washington patients' homes were tested for salmonella; all yielded the outbreak strain.	One unopened chicken sample from a Washington patient's home tested for one of the salmonella outbreak strains. The chicken was produced by Foster Farms.
		Two samples of leftover rotisserie chicken from the home of patients in California tested positive for one of the outbreak strains. The chicken was produced by Foster Farms.
Traceback	Shopper card records from nine patients indicated they had bought Foster Farms chicken before they became sick.	FSIS results identified four of the seven outbreak strains from multiple chicken product samples at the Foster Farms facilities implicated in this outbreak.
	The four unopened packages of chicken that tested positive for the outbreak strain were traced back to two Foster Farms slaughter plants.	

Epidemiological evidence: Based upon statistical tests that determine the strength of the association between a food and those who are sick (i.e., how likely it is to have occurred by chance alone) and whether more than one food might be involved.

Microbiological evidence: Bacteria with the same DNA fingerprint as that collected from patients in the outbreak are obtained from the suspected food.

Traceback evidence: Other information from patients, such as shopper cards or credit card receipts, provides a link to the suspected food.

Source: "Outbreak of *Salmonella Heidelberg* Infections Linked to a Single Poultry Producer—13 States, 2012-2013," Centers for Disease Control and Prevention, accessed Nov. 7, 2013, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6227a3.htm> and "Multistate Outbreak of Multidrug-resistant *Salmonella Heidelberg* Infections Linked to Foster Farms Brand Chicken," Centers for Disease Control and Prevention, accessed Oct. 22, 2013, <http://www.cdc.gov/salmonella/heidelberg-10-13/index.html>.

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Where Does Salmonella Contamination Come From?

Food safety starts at the farm

The salmonella family of bacteria includes over 2,300 variations, or serotypes. The bacteria live in the intestinal tracts of infected animals and humans. Strains that cause no symptoms in animals can make people sick, and vice versa.*

Only a thorough investigation can identify the source of contamination. But there are a number of possibilities to consider, including that the bacteria were passed down to the “broiler” birds (chickens sold to grocery stores and restaurants) from the breeder flock (the birds used to lay the eggs that will become broilers), or that contamination came from the feed.

Infected birds carry the bacteria in their guts into slaughterhouses and processing plants, and their feces can contaminate their carcasses and those of other birds.

In the United States, efforts to reduce salmonella in meat and poultry start at slaughter. However, countries such as Denmark[†] and Sweden[‡] have made remarkable progress in controlling salmonella with a combination of approaches at the farm level—enhanced hygiene, control of feed, and regular testing of flocks, for example—while keeping their poultry industries profitable and internationally competitive. Experience in those countries and research elsewhere,[§] have shown that safety control measures starting at the farm level are essential to achieving significant and long-lasting reductions in salmonella contamination.

*“Salmonella Questions and Answers,” FSIS, accessed Nov. 14, 2013, <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/foodborne-illness-and-disease/salmonella-questions-and-answers/>.

† Henrik C. Wegener, “Danish initiatives to improve safety of meat products,” *Meat Science* 84(2010): 276-283.

‡ Ministry of Agriculture, Food and Fisheries (Sweden), *Country report on the Swedish experience relating to the control of salmonella in the national herd, with specific focus on the salmonella policy related to poultry production, and the results regarding salmonella prevalence and human salmonellosis incidence*, accessed Nov. 14, 2013, <http://www.fao.org/docrep/meeting/004/ab456e.htm>.

§ Oliver Bucher, et al., “Evaluating interventions against Salmonella in broiler chickens: applying synthesis research in support of quantitative exposure assessment,” *Epidemiology and Infection* 140 (2012): 925-945.

A failure to protect public health

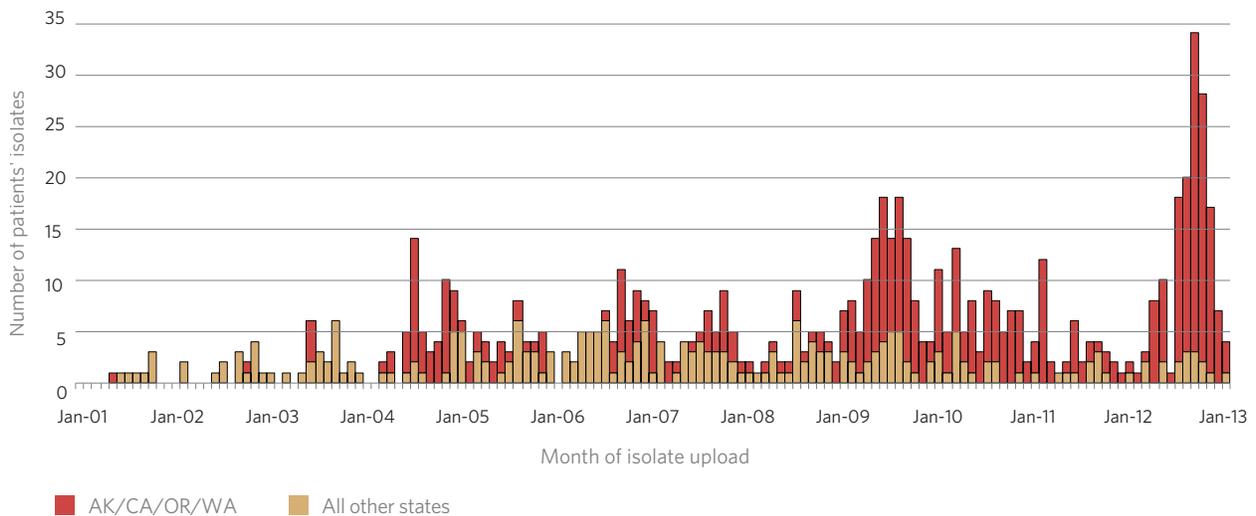
Based on the available evidence and circumstances, FSIS's response to both outbreaks was insufficient to protect public health. In the first outbreak, the agency did not issue a public health alert although it had previously done so based on comparable evidence.⁴⁴ In the second, FSIS did not immediately suspend production in the three Foster Farms plants while the company worked to implement changes in its slaughter and production process. In neither case did the agency request a recall. FSIS's failure to suspend production in the three plants during its investigation or to ask Foster Farms to recall its product is particularly striking because of the strong evidence gathered during investigations of the two outbreaks⁴⁵ (see Table 2) and the findings from the agency's inspections of the three plants.⁴⁶ (See Appendix.)

Moreover, this large producer had been linked to other salmonella illnesses—specifically, a 2004 outbreak of *S. Heidelberg* infections in Oregon and Washington, which also matched the DNA fingerprint of the 2012-13 outbreak strain.⁴⁷ The number of patients sickened by the outbreak strain decreased in 2004 after the Food Safety and Inspection Service conducted more intensive inspections and testing.⁴⁸ (See Figure 1.)*

Figure 1

Number of DNA Fingerprints from Patients Matching the Outbreak Strain.

Comparison of the number of patients' isolates matching the *S. Heidelberg* outbreak strain from Alaska, California, Oregon, and Washington state with the number from all other states, by month of uploads to PulseNet from 2001 to 2012.



Source: *Outbreak of Salmonella Heidelberg Infections Linked to a Single Poultry Producer—13 States, 2012–2013*, Centers for Disease Control and Prevention, accessed Nov. 7, 2013, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6227a3.htm>.

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* In 2009, there was again an increase in cases with the same DNA fingerprint of the 2012-13 outbreak. Although not linked to an outbreak or to Foster Farms products, this event triggered action by FSIS. As in 2004, the number of patients with the outbreak strain decreased after that. (See Figure 1.)

Although the Food Safety and Inspection Service does not have the authority to issue a recall, it can ask a company to do so. Companies also can independently recall their products. Neither occurred in the two most recent outbreaks.* The agency's failure to take action appears to contradict its own policy. In December 2012, FSIS reiterated its policy, which states that when not-ready-to-eat poultry or meat products are "associated with an illness outbreak and contain pathogens that are not considered adulterants, FSIS likely will consider the product linked to the illness outbreak to be adulterated. In such cases, the agency would request that the establishment recall the product if it is still in commerce."⁴⁹ Moreover, FSIS included related language in the three notices of intended enforcement.⁵⁰ The agency indicated it did not request a recall because, despite its efforts to identify the products causing the illnesses, no data were available that enabled investigators to pinpoint the types of contaminated chicken products—for example, chicken breasts, whole chickens, or ground chicken—or production dates or lots.⁵¹

Both outbreaks raise the question of whether FSIS should have mandatory recall authority, which existing law does not provide. In the case of the Food and Drug Administration, Congress amended the food safety law in 2011 to grant the agency authority to issue a mandatory recall⁵² for the approximately 80 percent of the food supply it regulates—everything except meat, poultry, and processed egg products.⁵³ Many legislative proposals introduced over the past decade to modernize meat and poultry safety laws have included provisions giving USDA mandatory recall authority.⁵⁴

Recalls can protect consumers after contaminated products have been sold, but the more important question is whether FSIS has effective policies to prevent contamination in the first place. These two outbreaks challenge the inspection service's approach to salmonella contamination. According to public statements by Foster Farms⁵⁵ and information provided by FSIS,⁵⁶ the company's facilities were considered among the best-performing plants, with little or no salmonella positive results on chicken carcasses. However, microbiological tests done by FSIS in early September 2013 detected levels of contamination much higher than the current salmonella performance standard for whole chickens in a variety of products, including poultry parts and whole chickens, from the three plants implicated in the outbreak. (See Appendix.)

The current approach for setting performance standards, based on the industry's national average prevalence of salmonella, does not drive significant reductions in contamination[†] because it does not factor in public health outcomes, such as a reduction in the incidence of foodborne illnesses over time.[‡]

In addition, as noted above, the agency does not mandate which hazards a company needs to address, but only "strongly" recommends that salmonella be included. According to the FSIS's Notices of Intended Enforcement, the Foster Farms plants implicated in the second outbreak had identified salmonella as a "hazard not reasonably

* Two retail companies voluntarily recalled Foster Farms chicken they had sold out of safety concerns after learning about the most recent 2013 outbreak. Source: "Recall alerts," Kroger, accessed Oct. 24, 2013 http://www.kroger.com/help/Pages/recall_alerts.aspx and <http://www.cdc.gov/salmonella/heidelberg-10-13/advice-consumers.html>

† According to Phil Derfler, FSIS's deputy administrator, the agency is pursuing new ways to set performance standards that would achieve a particular public health protection level, such as a 25 percent reduction in the estimated number of illnesses associated with a product. (SOURCE: Phil Derfler, personal correspondence, Nov. 13, 2013.)

‡ In FSIS's strategic plan for FY2011-16, the agency states its goals in terms of reduction of salmonella illnesses. However these have not translated into the development and implementation of new and improved performance standards. Source: http://www.fsis.usda.gov/wps/wcm/connect/65602d92-d017-4edc-8536-5ed6aaa6b52a/Strategic_Plan_2011-2016.pdf?MOD=AJPERES.

A Fix to Enhance Surveillance of Foodborne Pathogens and Help Monitor Plant Performance

The National Antimicrobial Resistance Monitoring System, or NARMS*—a collaboration among state and local public health departments, CDC, the U.S. Food and Drug Administration, and USDA—regularly collects meat and poultry samples at retail outlets and tests them for bacteria to monitor trends in antimicrobial resistance. The DNA fingerprints of the bacteria cultured from the meat samples are uploaded to a national database† that CDC can access during an investigation of a foodborne-illness outbreak. However, as Pew pointed out in a previous report,‡ the samples are not identified with the names of the brand and processing plants that produced them, or by their purchase dates.

NARMS provided extremely relevant data for the two outbreaks discussed in this report. The DNA fingerprint of the *S. Heidelberg* cultured from patients during the first 2012-13 outbreak, for example, has been found since 2002 in samples of Foster Farms chicken.[§] In addition, 98 percent of the *S. Heidelberg* isolated from chicken retail samples from 2002 to 2011 that matched the DNA fingerprint of the first outbreak strain were from Foster Farms chicken.** Moreover, in the most recent outbreak, NARMS laboratories isolated four of the seven outbreak strains from five retail samples of Foster Farms chicken breasts and wings collected in California. ††

Outbreak investigations would be resolved more quickly if the names of the brand and processing plants were uploaded onto the national database,‡‡ together with the DNA fingerprint of the bacteria cultured from the meat sample. FSIS could also routinely monitor the database to identify plants that repeatedly produce contaminated products, and take steps to prevent problems.

* National Antimicrobial Resistance Monitoring System, accessed Nov. 7, 2013, <http://www.fda.gov/animalveterinary/safetyhealth/antimicrobialresistance/nationalantimicrobialresistancemonitoringsystem/default.htm>.

† Centers for Disease Control and Prevention, PulseNet, accessed Nov. 7, 2013, <http://www.cdc.gov/pulsenet/>.

‡ The Pew Charitable Trusts, “Too Slow: An Analysis of the 2011 Salmonella Ground Turkey Outbreak and Recommendations for Improving Detection and Response,” accessed Nov. 11, 2013, http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/13003_GroundTurkey_P15a-web.pdf 2013.

§ “Outbreak of *Salmonella* Heidelberg Infections Linked to a Single Poultry Producer—13 States, 2012-2013.”

**Ibid.

†† “Multistate Outbreak of Multidrug-resistant *Salmonella* Heidelberg Infections Linked to Foster Farms Brand Chicken.”

‡‡ Centers for Disease Control and Prevention, PulseNet, accessed Nov. 7, 2013.

likely to occur,” a determination that the agency said the company was “unable to support.” This deficiency was not identified until FSIS inspectors came into the plants in September 2013.⁶

Furthermore, the fact that some strains of salmonella from the 2013 outbreak have proven to be resistant to commonly prescribed antibiotics creates a new urgency to curb contamination. A petition was filed with FSIS by the Center for Science in the Public Interest in 2011 requesting that antibiotic-resistant strains of salmonella be declared adulterants, which would require the agency to ensure adequate sampling and testing to detect the pathogen and remove contaminated products from the food supply.⁵⁷ The agency has not responded to the petition.

* In the beginning of January 2012, FSIS issued a proposed rule--Modernization of Poultry Slaughter Inspection--in which the agency would declare that enteric pathogens such as salmonella in food would be considered “hazards reasonably likely to occur.” Therefore, if finalized, this regulation would require poultry plants to address these pathogens in their food safety plans. (Source: Modernization of Poultry Slaughter; 9 CFR Parts 381 and 500. Federal register vol. 77, N.18, Jan. 27, 2012.)

Key weaknesses in federal regulation and policy

The analysis of the events surrounding these two outbreaks identified the following weaknesses in existing federal regulations and policies pertaining to salmonella contamination in poultry products:

- Current limits on salmonella contamination for chicken, known as performance standards, and related policies do not adequately protect public health.
 - As opposed to other pathogens such as *Escherichia coli* O157:H7, the Food Safety and Inspection Service does not consider salmonella to be an adulterant in raw poultry, but treats it as an indicator organism used to determine whether a company is producing safe food based on the level of salmonella found.
 - Performance standards, which are not updated regularly, are based on the national prevalence of the pathogen in specific products instead of public health impact.
 - There are no salmonella performance standards for chicken parts, which are purchased more widely than whole chickens.
 - FSIS tests products at chicken slaughter plants once a year except for those considered “best performing,” which are tested every other year.
 - Companies receive advance notice from FSIS before samples from their facilities are tested for salmonella.
 - FSIS cannot close a plant based only on results of its salmonella-verification testing.
- As part of prevention-based safety requirements, poultry plants are not required to treat the presence of salmonella as a “hazard likely to occur,” or a significant risk that needs to be controlled during processing and production
- There are no requirements for farm-level control measures that would help reduce salmonella contamination in chickens before they arrive at slaughter facilities.

Recommendations

Based on its evaluation, Pew makes seven general recommendations for improving the control of salmonella in poultry and strengthening the Food Safety and Inspection Service's response to outbreaks caused by these bacteria.

FSIS should:

- Reconsider its approach to developing and implementing salmonella performance standards so they are:
 - Updated regularly to reflect changes in industry practices, such as the adoption of new technologies.
 - Directly linked to public health outcomes.
 - Useful in evaluating companies on a regular basis rather than one or two times over a two-year period as is currently the case.
 - Enforceable, which may require legislative action.
- Issue performance standards for chicken parts.
- Conduct unannounced salmonella testing.
- Consider establishing limits on salmonella contamination for chickens when they enter into the slaughterhouse, which may require legislation.
- Communicate outbreaks to consumers via public health alerts as early as possible when there is sufficient epidemiological evidence linking illnesses to a company's product, even if there is not a definitive link between specific products and patients.
- Close facilities under investigation for failing to produce safe food, and keep them closed until adequate control measures are in place.
- Be given mandatory recall authority.

Conclusion

The two recent outbreaks of *S. Heidelberg* linked to chicken bring into sharp focus the ineffectiveness of FSIS's approach to minimizing salmonella contamination in poultry products. The agency's response to the evidence collected by the states, CDC, and its own investigation efforts was inadequate to protect public health. Despite its efforts to work around the limitations of existing statutes and case law, significant salmonella contamination persists and thousands of people are getting sick with preventable foodborne illnesses.

Appendix: Summary findings from FSIS's notice of intended enforcement letters

From letters sent to three Foster Farms plants implicated in the 2013 outbreak.

FSIS Findings	Foster Farm Establishment*		
	#6137A in Fresno, CA	# 6137 in Livingston, CA	# 7632 in Fresno, CA
Percentage of tested samples that were positive for salmonella (n=150)	25.3% (n=38)	26.7% (n=40)	24.7% (n=37)
Number of isolates of <i>S. Heidelberg</i>	38	30	33
Number of noncompliance records for findings of fecal material on carcasses from Jan. 1, 2013, to Sept. 27, 2013	12	34	10

Excerpts from the notices of intended enforcement:

- "Although presence of the outbreak strain alone is not evidence that product is adulterated, presence on product coupled with illnesses suggests that the sanitary conditions in the establishment under which the product is produced could pose a serious ongoing threat to public health."
- "The frequency of microbiologically-relevant positive findings suggests that the slaughter, dressing, and further processing of raw poultry product, including the prevention of contamination and the pathogen reduction interventions, are inconsistent and unreliable to control the pathogen of concern."
- "Your establishment has failed to demonstrate that it has adequate controls in place to address *Salmonella* in your poultry products as evidenced by the continuing illness outbreak."
- "Your establishment's control measures and antimicrobial interventions in your Slaughter, Raw Intact and Raw Non Intact operations are not sufficient to control *Salmonella*, specifically, *Salmonella Heidelberg*."
- "Your establishment identifies *Salmonella* as a food safety hazard not reasonably likely to occur in your Raw Intact and Raw Non Intact processes."
- "As evidenced by the multiple *Salmonella* positive test results (. . .) your establishment is unable to support that *Salmonella* is a biological food safety hazard not reasonably likely to occur in your Raw Intact and Raw Non Intact processes."
- "Your establishment has failed to implement adequate control measures to address the prevalence of *Salmonella* in your poultry products."
- "Your establishment is unable to support the decisions in your Raw Intact and Raw Non Intact hazard analyses."
- "Your establishment failed to adequately reassess the HACCP plan and modify the plan to control food safety hazards that could be introduced inside or outside the establishment."
- "FSIS has identified multiple noncompliances including but not limited to findings of poor sanitary dressing practices, insanitary food contact surfaces, insanitary non food contact surfaces and direct product contamination as evidenced by the documentation of a considerable number of recurring noncompliance records issued to your establishment for preoperational, operational, and SPS noncompliances."
- "FSIS has determined your HACCP system is inadequate."
- "Your establishment has failed to operate and produce poultry products in a manner that complies with Title 9 CFR 416.1."
- "You are unable to effectively implement and maintain your HACCP system or demonstrate that your establishment's process controls are functioning as intended to prevent or control *Salmonella* in your process."
- "The prevalence of *Salmonella* in finished poultry products poses a risk to public health. As demonstrated by the FSIS *Salmonella* verification testing, your establishment has failed to prevent the production of products contaminated with *Salmonella* and of a serotype known to cause human illness."

* In addition to the three plants in California, FSIS tested a Foster Farms plant in Kelso, OR. Out of the 150 samples taken, 1.3 percent (n=2) were positive for salmonella and all were *S. Heidelberg*, but only one matched one of the DNA fingerprints of the last outbreak.

Source: USDA Food Safety and Inspection Service, Notice of Intended Enforcement, accessed Nov. 7, 2013, <http://www.marlerblog.com/files/2013/10/Foster-Poultry-Farms-Est.-6137P.pdf>. And <http://www.marlerblog.com/files/2013/10/Zorro-Leasing-10-07-13.pdf> <http://www.marlerblog.com/files/2013/10/foster-farms-est-6137a-p1.pdf>.

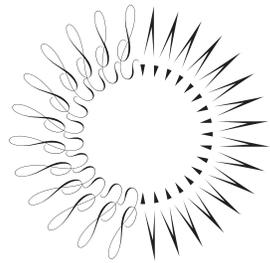
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