



# THE PROMISE AND PROBLEMS OF HACCP:

A REVIEW OF USDA'S APPROACH  
TO MEAT AND POULTRY SAFETY



Consumer Federation of America

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# INTRODUCTION

The Centers for Disease Control and Prevention (CDC) estimates that every year 48 million Americans are sickened, 128,000 are hospitalized, and 3,000 die from foodborne disease. An unknown number of Americans develop long-term health complications, such as arthritis and kidney failure, as a result of contracting a foodborne illness.<sup>i</sup>

While the CDC statistics represent illness and death from pathogens for all food sources, meat and poultry products are clearly associated with foodborne illnesses and outbreaks.<sup>ii</sup> The CDC found that twenty-two percent of outbreak-associated illnesses and twenty-nine percent of outbreak-associated deaths were attributable to meat and poultry products from 1998 to 2008.<sup>iii</sup><sup>1</sup>

Illnesses associated with meat and poultry products are estimated to cost U.S. society almost \$7 billion each year.<sup>iv</sup><sup>2</sup> An analysis of the pathogen/food pairs causing the greatest annual disease burden in the United States found that the top four were associated with meat and poultry products: *Campylobacter* in poultry, *Toxoplasma* in pork, *Listeria* in deli meats and *Salmonella* in poultry.<sup>v</sup>

Addressing the safety of meat and poultry products stretches back to the early 20th century when Upton Sinclair wrote his famous novel, *The Jungle*, which portrayed the harsh working conditions of the meatpacking industry and eventually spurred calls for stricter government oversight of the industry. When Congress passed the Federal Meat Inspection Act in 1906 and the Poultry Products Inspection Act in 1957 — the intent was clear: “It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.”<sup>vi</sup>

The U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) is tasked with the responsibility of carrying out that public health mission through its meat and poultry inspection program. The agency is

charged with protecting the public from the risks of contaminated meat and poultry products and the consequences of foodborne illness. Meat and poultry is sold to consumers with a seal of approval from the USDA which reads “Inspected and Passed,” communicating to the public that a government inspector has verified that the product they are about to purchase has met government standards for safety.

Yet government inspectors are not inspecting every single piece of meat that is sold to consumers. Rather, inspectors verify the effectiveness of company food safety systems which produce meat and poultry products. This work is done through FSIS’s primary food safety program, the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) regulation. FSIS also sets performance standards for reducing pathogens in meat and poultry products and implements sampling programs to identify whether a sample of products meet those standards.

This report examines the history of FSIS’s PR/HACCP rule, including its relationship to pathogen reduction performance standards, and the impact of the *Supreme Beef* court case in weakening FSIS’s authority to enforce its regulations. The report reviews independent critiques by government investigators of FSIS’s PR/HACCP program, how the program has evolved over the years, and some of FSIS’s most recent changes. Finally, the report makes recommendations to improve the HACCP program to reduce meat and poultry contamination and better protect consumers from foodborne illness.



1 Analyses based on outbreak data do not capture the extent of illnesses and deaths related to pathogens such as *Campylobacter*, which cause substantial illness but occur sporadically, and so are underrepresented in the CDC data.

2 Since information regarding the long-term health complications from foodborne illness is incomplete, societal costs are likely underestimated and could change with additional data.



# THE HACCP APPROACH TO FOOD SAFETY

In 1993, four children died and 623 people were sickened as a result of an outbreak of *E. coli* O157:H7 infections in the northwestern United States. The outbreak was eventually traced to undercooked hamburgers sold at Jack in the Box restaurants.<sup>vii</sup> The incident spurred Congressional inquiries and intense media scrutiny and was a wake-up call for the meat industry, federal and state governments, and the public. A number of changes occurred in the wake of the outbreak: upgrading of local health codes,<sup>viii</sup> revised cooking temperatures for ground beef in restaurants,<sup>ix</sup> a requirement that meat and poultry labels carry safe handling instructions,<sup>x</sup> and the establishment of active surveillance systems for foodborne illness.<sup>xi</sup>

As the federal agency charged with overseeing the safety of meat and poultry products, the Food Safety and Inspection Service (FSIS) at the U.S. Department of Agriculture (USDA) had the primary responsibility for responding to the outbreak. One of the agency's strongest responses occurred in 1994 when Michael Taylor, then the Administrator of FSIS, told a roomful of meat industry executives that "to clarify an important legal point, we consider raw ground beef that is contaminated with *E. coli* O157:H7 to be adulterated within the meaning of the Federal Meat Inspection Act."<sup>xii</sup><sup>3</sup> This meant that ground beef found to be contaminated with the deadly pathogen could not knowingly be sold to the public. Meat companies would have to take steps to ensure that the product they were shipping into commerce was free of *E. coli* O157:H7. FSIS substantially increased its testing for the pathogen and over the next decade the meat industry invested significant resources in efforts to reduce the prevalence of *E. coli* O157:H7 in ground beef.<sup>xiii</sup>

FSIS then proposed changes to its federal meat inspection program, based on a systematic, prevention-based process for identifying and controlling hazards in food production that had been pioneered by NASA scientists to ensure food safety for astronauts in space.<sup>xiv</sup> FSIS adopted the approach, known as the "Hazard Analysis and Critical Control Points (HACCP) System," which was in use by the food industry

since the early 1970s, but was not widely adopted until some years later. HACCP is a management system used by companies in which food safety is addressed through the identification and control of biological, chemical, and physical hazards all along the production process.<sup>xv</sup>

Previously, government meat and poultry inspectors took an organoleptic approach to overseeing meat and poultry production with inspectors relying primarily on sight, touch, and smell to determine whether meat was fit for human consumption. Inspectors focused on preventing diseased or filthy animals from entering the food supply and monitored the sanitation of facilities.<sup>xvi</sup> Under the new system, primary responsibility for producing safe food would be placed on the meat plants themselves with government inspectors providing oversight of the plant's food safety processes.

The National Academy of Sciences and the Government Accountability Office (GAO) had recommended adoption by USDA of a HACCP-like approach in numerous reports beginning in the early 1980s.<sup>xvii</sup> USDA's National Advisory Committee on Microbiological Criteria for Foods (NACMCF) endorsed HACCP in 1997 as an "effective and rational means of assuring food safety from harvest to consumption" and noted that "preventing problems is the paramount goal underlying any HACCP system."<sup>xviii</sup>

<sup>3</sup> A Texas meat processor unsuccessfully challenged this action in court: *Texas Food Industry Association, et al v Esty*, et al, United States District Court, W.D. Texas, Austin Division, December 13, 1994.

The control of food safety hazards in a HACCP system is based on seven principles that result in the prevention of food safety hazards throughout the production process. Serving as a foundation for the HACCP system are “prerequisite programs”<sup>24</sup> which ensure that the basic environmental and operating conditions necessary to produce safe food are in place.

Under HACCP, plants:<sup>xix</sup>

- Identify hazards that are likely to occur and likely to cause illness or injury;
- Determine critical control points (CCPs) at which control can be applied to prevent, eliminate or reduce a hazard;
- Establish critical limits at each CCP, which are the maximum or minimum values to which a parameter must be controlled to prevent, eliminate, or reduce the hazard;
- Establish monitoring procedures to determine whether a CCP is under control;
- Establish corrective actions whenever there is a deviation from established critical limits;
- Establish verification procedures to determine whether the HACCP system is functioning properly; and
- Establish and keep complete records of the HACCP system.

4 Prerequisite programs include activities such as sanitation procedures, maintenance, training, and environmental monitoring.

## THE IMPACT OF HACCP

### Public Health Impact

Identifying and fully quantifying the public health impact of the PR/HACCP rule is challenging because food contamination can occur at numerous points along the food supply chain and adequate assurance of food safety requires multiple steps and approaches that are often occurring simultaneously. Consequently, distinguishing the impact of any one program, such as HACCP, from all other activities that affect food safety is difficult. Still, most cost/benefit estimates on the PR/HACCP rule show that the benefits exceed the costs by wide margins.<sup>cxvii</sup>

The CDC, which tracks annually the incidence of foodborne illness in the United States, gives the PR/HACCP rule some credit for declines in the incidence of infections caused by *Yersinia*, *Listeria*, *Campylobacter*, and *Salmonella* from 1996 to 2001, which is the initial period of HACCP implementation.<sup>cxviii</sup> Other factors played a role as well: egg-quality assurance programs, improved agricultural practices, seafood and juice HACCP, new intervention technologies to reduce food contamination, food safety education programs, and increased attention to imported food.<sup>cxix</sup> In addition, concurrent changes in food distribution, retailing, and consumer behavior during that time period no doubt had an impact.<sup>cx</sup> As a National Research Council committee has cautioned, identifying a direct causation between the PR/HACCP rule and declines in foodborne illness is difficult.<sup>cxxi</sup>

So while it is likely that the PR/HACCP regulation played some role in the decline in foodborne illness from 1996 to 2001, there has been little progress in reducing foodborne illnesses since then. In reviewing CDC’s annual data on the incidence of foodborne illness (which refers to illnesses from all

food sources, not just meat and poultry products), the rate of illness for most of the major pathogens has either not changed or has increased since the early 2000s. Progress has been made in reducing illnesses from *E. coli* O157:H7, though in recent years that progress may be slipping. Also troubling is the fact that illnesses from non-O157:H7 STECs continue to trend upwards and the incidence of illnesses from non-O157 STECs is now higher than illnesses from *E. coli* O157:H7.

Comparisons to more recent years have also shown little progress. Data from 2013 reveals statistically significant increases from 2006-2008 for illnesses from *Campylobacter*, and virtually no change for illnesses from *Listeria monocytogenes*, *Salmonella*, *E. coli* O157:H7 and non-O157 STECs.<sup>cxvii</sup> The current incidence of foodborne illness from the major pathogens remains far from U.S. government National Health Objective targets set for 2020.<sup>cxviii</sup>

### Economic Impact

Estimating the economic costs of HACCP is more straight-forward. A common concern of the meat and poultry industry during the debate on the PR/HACCP rule was the high cost of implementing the new requirements. An early analysis of the costs and benefits of the HACCP program by the GAO found that the estimated benefits to the public were far greater than the estimated costs of the program to the industry.<sup>cxvii</sup> GAO found that the cost of implementing the PR/HACCP rule varied by plant size and species slaughtered, but estimated that if the consumer bore the entire cost of plants’ HACCP implementation, the cost to consumers would be less than 50 cents per year. Another early report from USDA’s Economic Research Service (ERS) found

that the benefits of the PR/HACCP rule, in terms of lower medical costs of illness, lower productivity costs and fewer premature deaths, were far greater than the costs of HACCP implementation.<sup>cxv</sup>

Several years after implementation of the PR/HACCP rule, ERS reviewed the program and found that the costs of implementing the PR/HACCP regulation did not significantly increase the overall cost of production. ERS found that HACCP implementation raised a plant’s costs of production by about 1.1 percent — 0.4 cents per pound for poultry and 1.2 cents per pound for beef — and noted that the estimated costs to industry were less than one-half the decrease in health care costs associated with reductions in foodborne illnesses due to implementation of the PR/HACCP rule.<sup>cxvi</sup>

HACCP implementation had another important effect. A 2004 report by ERS found that implementation of HACCP spurred significant investments in food safety by the meat and poultry industry. From 1996 through 2000, meat and poultry plants as a whole spent about \$380 million annually and \$570 million in long-term investments to comply with the PR/HACCP regulation, and an additional \$360 million on long-term food safety investments that were not required by the PR/HACCP rule.<sup>cxvii</sup> Still, ERS noted that the annual cost of HACCP compliance amounted to “less than 1 percent of the cost of meat and poultry products.”<sup>cxviii</sup> ERS concluded that these investments in food safety would “undoubtedly have a beneficial effect for consumers in improving the safety of meat and poultry products and would benefit the industry in terms of reduced food safety risk and increased consumer confidence.”<sup>cxvix</sup>

# PR/HACCP PROPOSED RULE

In February 1995, FSIS issued proposed regulations that would apply HACCP across the meat and poultry industry, fundamentally shifting the paradigm regarding meat and poultry inspection. The agency acknowledged that its current inspection program, which was focused on sanitation requirements and inspecting for visible contamination of carcasses, did not directly target most of the pathogenic microorganisms of importance to human health. Moreover, FSIS did not hold meat and poultry establishments “legally responsible” for taking systematic, preventive measures to reduce or eliminate the presence of pathogens in meat and poultry products.<sup>xx</sup>

The key elements of FSIS’s proposed rule included:

1. All federally inspected establishments must develop and adhere to written standard operating procedures for sanitation;
2. All slaughter establishments must use an antimicrobial treatment on all carcasses;
3. All slaughter establishments must meet specific time requirements for chilling and cooling of finished carcasses and parts;
4. Raw product must be tested daily for *Salmonella* and establishments must achieve targeted reductions in the incidence of *Salmonella* compared to a national baseline; and

5. All establishments must adopt HACCP systems.<sup>xxi</sup>

In addition to requiring plants to test daily for *Salmonella*, a pathogen of “significant public health concern,”<sup>xxii</sup> FSIS also proposed to set a pathogen reduction performance standard for *Salmonella*, based on what was achievable in the industry under current science and technology. FSIS indicated in the proposed rule that the agency may adjust its standards downward in the future and that it may adopt similar targets for other pathogens at a later date.<sup>xxiii</sup>



## Consumer Group and Industry Perspectives on the Proposed Rule

While consumer groups and meat and poultry industry representatives generally supported FSIS's adoption of HACCP, the groups differed on many of the details in the proposed rule.

### The Meat and Poultry Industry

The meat and poultry industry, in general, had numerous incentives for adopting stronger food safety measures including customer demands, growing export opportunities, and consumer expectations. Though some industry members viewed FSIS's HACCP implementation as a way to reduce government inspection, even anticipating that adequate process control could serve as an incentive for less frequent agency oversight.<sup>xxxiv</sup>

Representatives from the meat industry opposed several elements of the rule, including proposals that all slaughter establishments use antimicrobial treatments and that establishments meet time and temperature requirements for chilling carcasses. The industry argued that these proposals continued FSIS's "command and control philosophy" and that plants should make those determinations rather than FSIS mandating them.<sup>xxxv</sup> Industry representatives argued that preapproval of HACCP plans by FSIS inspectors was unnecessary as companies would "assume the responsibility for an efficient and effective plan."<sup>xxxvi</sup> Representatives further opposed providing inspectors with the authority to suspend inspection at the plant on the basis of an invalid HACCP plan, because "it should be assumed that the HACCP plan is valid."<sup>xxxvii</sup>

Industry members viewed microbiological performance standards as contrary to HACCP's emphasis on prevention within the processing environment and suggested that performance criteria, such as measuring the actual validation of critical limits within each plan, was more appropriate.<sup>xxxviii</sup> Industry members also strongly opposed FSIS's proposal to require plants to test daily for *Salmonella*, questioning the agency's legal authority to require testing in the first place, raising concerns about the costs of pathogen testing, and arguing that the proposal was "inappropriate and serve[s] no useful purpose."<sup>xxxix</sup> Instead, industry members argued that generic *E. coli* was a more

appropriate organism for which to test as it serves as an indicator of fecal contamination and plants can use it to assess process control. In addition, industry members argued that testing for an indicator organism such as generic *E. coli* instead of a pathogen such as *Salmonella* was more accurate, more reliable, and less costly.<sup>xxx</sup>

### Consumer Groups

Consumer groups, on the other hand, raised concerns that FSIS's proposal was not sufficiently robust.<sup>xxxi</sup> Specifically, consumer groups supported FSIS's proposed interim steps — the use of antimicrobial treatments and time and temperature requirements for chilling carcasses — arguing that these activities were "essential to improving the safety of these products."<sup>xxxii</sup> Consumer groups opposed FSIS's decision not to require that HACCP plans be submitted to the agency and reviewed prior to implementation, noting that "systematic collection and review of HACCP plans...is the only way for USDA to ensure that industry has developed comprehensive and effective plans" and that all critical control points were identified, records properly designed and staff adequately trained.<sup>xxxiii</sup>

Consumer advocates strongly supported the use of performance standards to reduce pathogens in meat and poultry products;<sup>xxxiv</sup> in fact, many consumer groups based their tentative support of HACCP on FSIS's assurances that agency performance standards would be robust and regularly updated.<sup>xxxv</sup> Consumer groups further urged that FSIS move towards more public health-based standards rather than conduct costly and time-consuming national baseline studies or rely on "technology-based standards."<sup>xxxvi</sup> Finally, consumer groups stressed the importance of a rigorous program of microbial testing, including end-product testing, by establishments as well as government inspectors to verify that food was being produced safely.<sup>xxxvii</sup> Consumer groups supported a requirement that plants test for both generic *E. coli* and *Salmonella* as part of HACCP,<sup>xxxviii</sup> but also urged USDA to go further by identifying the pathogens that pose the greatest health risk and requiring companies to test their products for those pathogens.<sup>xxxix xl</sup>

# PR/HACCP FINAL RULE

The final rule maintained the requirement that all federally inspected establishments must implement HACCP systems to address hazards that are reasonably likely to occur in their operations. Establishments were also required to develop and implement written Sanitation Standard Operating Procedures (SSOPs)<sup>5</sup> to document plant cleaning schedules and track adverse sanitation conditions.<sup>xli</sup>

Eliminated, however, were other elements that FSIS had said could make a “significant contribution” to reducing pathogens, such as the proposed requirements that all slaughter establishments use an antimicrobial treatment on carcasses and that establishments meet specific

time/temperature requirements for cooling carcasses and parts. The industry had successfully argued that such requirements were “inconsistent with the HACCP philosophy,” insisting that each establishment have full control over its HACCP program with limited government interference.

PR/HACCP Proposed Rule	Industry comments	Consumer group comments	PR/HACCP Final Rule
All establishments must develop written SSOPs	Support	Support	All establishments must develop written SSOPs
Slaughter establishments must use antimicrobial treatment on carcasses	Oppose mandatory use of treatments	Support mandatory use of treatments	Dropped
Slaughter establishments must meet time requirements for chilling carcasses/parts	Oppose mandatory time/temperature requirements	Support mandatory time/temperature requirements	Dropped
Slaughter establishments must test daily for <i>Salmonella</i>	Oppose daily testing requirement; Oppose use of <i>Salmonella</i> as indicator of process control; Support use of generic <i>E. coli</i> as indicator organism	Support mandatory testing, but testing frequency should be greater than daily; Support use of <i>Salmonella</i> as indicator of process control; Support use of generic <i>E. coli</i> as indicator organism	Slaughter establishments must test for generic <i>E. coli</i> only (frequency based on volume); FSIS will set performance standards; FSIS will test for <i>Salmonella</i>
All establishments must implement HACCP systems	Support	Support	All establishments must implement HACCP systems

<sup>5</sup> Sanitation Standard Operating Procedures (Sanitation SOPs) are written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product.



FSIS declined to approve a plant's HACCP plan before it was implemented; again, the agency claimed that prior approval of HACCP plans would be contrary to "redefined roles and responsibilities inherent in the HACCP philosophy."<sup>xliii</sup> FSIS insisted that each establishment was responsible for developing its own HACCP plan and ensuring its adequacy. This decision would be challenged throughout implementation of HACCP, in particular by independent government investigators examining the effectiveness of the agency's program.

Most significant, however, was the change in testing requirements. FSIS dropped its requirement that plants test daily for *Salmonella* and did not require plants to conduct specific pathogen testing as advocated by consumer groups. Instead, FSIS opted to require slaughter plants to test for generic *E. coli*, which serves as an indicator of fecal contamination and insanitary conditions in the plant. FSIS maintained that testing for generic *E. coli* was more appropriate for verifying process control and that this testing would verify that the establishment had controlled its slaughter process and prevented the occurrence of fecal contamination.<sup>xliiii</sup>

FSIS had originally proposed daily testing for generic *E. coli*, but changed its requirement so that testing would be based on volume.<sup>xliv</sup> FSIS also did not establish a public health regulatory standard for generic *E. coli* testing; rather, FSIS set a non-enforceable benchmark, based on nationwide microbiological baseline surveys, for slaughter establishments to evaluate their generic *E. coli* test results. The agency indicated that it would not take action based on generic *E. coli* results alone, but would consider the results in conjunction with other information to determine whether regulatory action was warranted.

FSIS substantially changed its approach regarding *Salmonella* testing from the proposed rule to the final rule. FSIS had originally proposed to require all slaughter establishments and establishments producing raw ground product to conduct daily microbial testing to determine compliance with targets for reducing *Salmonella*. Consumer groups supported the proposal,<sup>xlv</sup> but industry comments

to the agency raised concerns about using *Salmonella* as an indicator of process control, about the daily testing requirement, and about the cost burden to small establishments.<sup>xlvi</sup>

In the final rule, FSIS decided that the agency, not establishments, would conduct *Salmonella* testing as a measure of verifying compliance. Plants would not be required to test for *Salmonella* or any other microbial pathogen.<sup>xlvii</sup> The agency would use *Salmonella* as a target organism for pathogen reduction performance standards rather than its initial intention of relying on *Salmonella* testing as an indicator of process control. Establishments with a prevalence of *Salmonella* above the performance standard would be required to change their operation to meet the standard or face Agency sanctions.<sup>xlviii</sup>

Soon after the implementation of HACCP, FSIS issued several clarifications and modifications, including new requirements that all HACCP plans must contain at least one CCP per hazard and must be self-contained documents that do not refer to other practices, such as good manufacturing practices (GMPs), for controlling hazards.<sup>xlix</sup> This change came about because plants were purposefully limiting FSIS oversight by reducing the number of CCPs and hazards identified in their HACCP plans. Since FSIS inspectors were limited to reviewing a plant's HACCP plan, enforcement activities were focused around only what was in the plan and any activity that was outside that plan was off limits from a regulatory perspective. FSIS has since clarified its authority so that inspectors have access to all records that have a bearing on the safety of the product.

Over the years, FSIS has continued to revise HACCP to address gaps and problems as they arise. However, some problems have been identified repeatedly: failure of establishments to adequately identify microbial hazards that were likely to occur in their production process; inadequate justification of CCPs and critical limits; and failure of establishments to take effective corrective actions. In addition, FSIS would struggle with determining when to take enforcement action based on repetitive violations.

# PR/HACCP RULE and PERFORMANCE STANDARDS

In the proposed rule, FSIS emphasized the importance of establishing food safety standards, saying that “setting public health targets, guidelines, or standards is the most powerful and effective tool available for bringing about changes in FSIS-inspected establishments, especially slaughter establishments, that will reduce levels of pathogenic microorganisms and improve the safety of meat and poultry products.”<sup>1</sup>

Performance standards can help drive reductions in pathogen contamination as FSIS sets a standard to reduce contamination on particular products and then plants work to meet the standard. When the majority of plants are able to meet the standard, FSIS can revise the standard to incentivize further improvement.

Yet the promise of performance standards under HACCP has not been fully realized. Delays in developing new performance standards have resulted in numerous missed opportunities to reduce pathogen contamination in raw ground beef products and poultry products and drive continuous improvement across the industry.

For example, during implementation of HACCP, FSIS set a performance standard for *Salmonella* reduction in ground beef at 7.5 percent (i.e., no more than 5 samples testing positive for *Salmonella* out of 53 samples tested). This was based on the industry average estimated from baseline studies conducted before the PR/HACCP rule was implemented. At the time, FSIS claimed the system would spur continuous improvement because new baseline studies would be performed regularly and the standard would be raised to reflect the industry’s increasing capacity to control contamination and pathogens.

According to FSIS:

*The Salmonella standards being established are a first step in what FSIS expects to be a broader reliance in the future on pathogen-specific performance standards for raw products. FSIS plans to repeat its baseline surveys and collect substantial data through other means and, on that basis, adjust the Salmonella targets and possibly set targets for additional pathogens, as appropriate.*<sup>11</sup>

That statement was made eighteen years ago, and to date, no new performance standards for ground beef have been developed.<sup>6</sup>

Neither has FSIS regularly updated its standards for poultry. The poultry industry operated under the same *Salmonella* performance standard for young chickens for fifteen years before the agency revised the standard. A standard for *Campylobacter* was not developed until 2011; previously the poultry industry did not have to meet any standard for that pathogen.<sup>117</sup> Ground poultry producers operated under the original HACCP standard that permitted nearly half of the samples to test positive, until the agency finally proposed updating the standard in January 2015. No standards existed for poultry parts frequently purchased by consumers such as legs, wings and breasts, until the agency proposed new standards in early 2015.<sup>8</sup>

6 In September 2013, FSIS proposed a change to its sampling program for *Salmonella* in raw ground beef, beef manufacturing trimmings, bench trim, and other raw ground beef components. FSIS intends to use the results from its new sampling program to develop new *Salmonella* performance standards for ground beef; however those standards have not yet been developed.

7 In June 2011 FSIS revised the *Salmonella* performance standard for young chickens to be 7.5% percent (5 positive samples out of 51 sample set). At the same time the agency also began testing for *Campylobacter* and assessing industry performance based on a 10.4% standard (8 positive samples out of a 51 sample set).

8 When FSIS conducted baseline testing of poultry parts in 2012, the agency found high contamination rates – a 24% prevalence rate for *Salmonella* and a 21.7% prevalence rate for *Campylobacter*. The new standards for poultry parts are set at 15.4% for *Salmonella* and 7.7% for *Campylobacter*.

Product Type	Performance standard (percentage positive for <i>Salmonella</i> )*	Year standard was updated
Ground beef	7.5%	1996
Young chicken carcass	7.5%	2011
Young turkey carcass	1.7%	2011
Ground chicken (proposed)	25%	2015
Ground turkey (proposed)	13.5%	2015
Chicken parts (proposed)	15.4%	2015

\* 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, and Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule, 9 CFR Part 304, 1996.

However, it is clear that government performance standards can drive industry action. In a 2014 review of poultry slaughter and processing establishments, FSIS found that 73 percent of plants conducted testing for *Salmonella* on poultry carcasses and 68 percent conducted testing for *Campylobacter*, for which FSIS had established a standard. At the time of the review, FSIS had no standards for poultry parts, and the agency found that only four percent tested for *Salmonella* and one percent tested for *Campylobacter* on poultry parts.<sup>liii</sup>

Yet performance standards have not been specifically developed to meet public health objectives. Instead, FSIS performance standards have usually been designed around national industry baseline prevalence levels, many of which were conducted before the PR/HACCP rule was adopted.<sup>liv 9</sup> For example, until July 2011, the standard for *Salmonella* in young chicken carcasses was based on data from 1994-1995.<sup>lv</sup>

In developing more recent performance standards, the agency has been shifting to a more public health-oriented approach.<sup>hii</sup> Still, more work needs to be done to better link standards with public health outcomes and assess the effectiveness of the standards in meeting those objectives.

Finally, while FSIS sets performance standards for reducing *Salmonella* in meat and poultry products, these standards are limited by other regulatory determinations made by the agency. For example, since FSIS does not consider *Salmonella* to be an adulterant in raw product as it does *E. coli* O157:H7<sup>lvii</sup> and other Shiga toxin-producing *E. coli* strains,<sup>lviii</sup> there is no regulatory requirement that raw poultry or ground beef should be free from *Salmonella*.<sup>lix</sup> Instead, the agency performance standards serve as “acceptable levels” for *Salmonella* in products that are sold to the public. Yet *Salmonella* levels can increase on raw product if the product is improperly stored or handled, increasing the risk to consumers.

9 According to FSIS’ Progress Report on *Salmonella* and *Campylobacter* Testing of Raw Meat and Poultry Products, 1998-2012: “The performance standards are based on the prevalence of *Salmonella* as determined from the Agency’s nationwide microbiological baseline studies, which, except for the young chicken and turkey carcass product classes, were conducted prior to PR/HACCP implementation.” (emphasis added).



## SUPREME BEEF V. USDA

Soon after the PR/HACCP rule was implemented, FSIS's authority to enforce its performance standard for *Salmonella* was challenged by a beef processor. This resulted in a landmark court case that has hindered the agency's regulatory program ever since, limiting how the agency regulates meat and poultry products and its capacity to adequately protect consumers.

From June of 1998 to September of 1999, under the new PR/HACCP regulations, FSIS conducted three sets of *Salmonella* tests<sup>10</sup> at Supreme Beef Processors, a Texas-based meat processing and grinding facility. Each set failed to meet the standard; in one case, FSIS found 47 percent of the samples were positive for *Salmonella*. Under the PR/HACCP regulations, an establishment that failed to meet the *Salmonella* standard in three consecutive sample sets would be considered to have failed to maintain sanitary conditions and failed to maintain an adequate HACCP plan, resulting in FSIS suspending inspection at the establishment. Consequently, FSIS issued a Notice of Intended Enforcement Action, informing Supreme Beef that the agency intended to suspend inspection activities at the plant, which meant that the plant would be shut down.

Supreme Beef subsequently sued USDA in the North Federal District Court of Texas, alleging that in developing its approach to *Salmonella* testing, FSIS had overstepped its authority under the Federal Meat Inspection Act (FMIA). The judge in the case found that because FSIS's *Salmonella* tests did not necessarily measure the actual conditions of the plant, FSIS could not find the conditions of the Supreme Beef plant insanitary and therefore had no basis for finding the product adulterated and removing agency inspectors.<sup>1x</sup>

USDA appealed and in 2001, the Fifth Circuit Court of Appeals upheld the District Court's ruling

based on the agency's failure to prove that the presence of *Salmonella* in Supreme Beef's product was the result of insanitary conditions at that particular facility.<sup>11</sup> The Appeals Court affirmed the district court's decision that the FMIA did not give FSIS authority to shut down the plant in response to failed *Salmonella* tests when it was likely that the meat was contaminated with *Salmonella* before it reached the Supreme Beef facility.<sup>12</sup>

The Court disagreed with Supreme Beef's argument that "the USDA can *never* use testing of a final product for a non-adulterant, such as *Salmonella*, as a proxy for conditions within a plant." (emphasis added). However, in this case, failure to meet the *Salmonella* performance standard could not be grounds for closing the plant because the performance standard "regulates the procurement of raw materials" (in this case beef trimmings from a USDA-inspected slaughterhouse), rather than the conditions at the plant where USDA inspections were being withdrawn.<sup>13</sup>

It is important to note that the Court in *Supreme Beef* did not vacate the *Salmonella* performance standard altogether, and, although it is outdated, it still remains in effect.<sup>1xi</sup> However, in light of the Court's ruling, the agency cannot rely on the results of its testing to determine that a facility is necessarily unsanitary. Rather, it must have some additional basis for making this determination.

10 A set consists of samples from a plant's finished product for 53 consecutive days; more than 5 positive samples results in a plant failing that set.

11 In fact, the agency inspector involved in the case had told the trial court that *Salmonella* had most likely come into the facility "through *Salmonella* contaminated carcasses" that Supreme Beef had purchased from a slaughterhouse for further processing, and the USDA had also conceded that meat grinding operations, such as Supreme Beef, have no means of removing *Salmonella* from meat.

12 The Court concluded that the plain meaning of the words "whereby rendered" in this definition of adulteration indicated that "a deleterious change in the product must occur while it is being 'prepared, packed, or held' owing to insanitary conditions." Accordingly, the Court held, "a characteristic of the raw materials that exists before the product its 'prepared, packed, or held' . . . cannot be regulated by the USDA under § 601(m)(4)." *Id.* (emphasis added).

## FSIS Response to *Supreme Beef*

In the wake of the *Supreme Beef* decision, FSIS began using its *Salmonella* testing to highlight facilities that deserved more scrutiny, in order to generate the additional evidence of insanitary conditions that would be required to take action. This has led to complicated workarounds in which FSIS sends in teams of inspectors to scour an establishment's HACCP system and records for extended periods of time in order to identify problems and insist on corrective actions.<sup>lxii</sup>

For example, in August 2002, FSIS developed new procedures for plants that fail *Salmonella* tests.<sup>lxiii</sup> While FSIS declared that the new procedures “constitute a more scientific and systematic approach to food safety and to the enforcement of current regulations,” the approach only highlighted the deficiencies in FSIS's authority raised by the *Supreme Beef* case. If a plant failed the agency's *Salmonella* testing set, FSIS would initiate a review of the plant's food safety system and allow the plant to reassess its HACCP plan and take corrective actions. Then the agency would schedule another set of *Salmonella* tests. If the plant failed again, the agency would conduct a more extensive review of the plant's food safety system, provide an opportunity for corrective action, and schedule another sampling set. And so on. Ultimately, the new procedures allowed a plant to continue operating despite continually failing agency testing for *Salmonella*.

Since the *Supreme Beef* case gutted the agency's ability to shut down a plant for failing to meet the *Salmonella* standard, FSIS instead focused its *Salmonella* strategy on developing incentives for plants to reduce their *Salmonella* rates. In

2006, the agency developed new performance categories for *Salmonella* (still based on the original HACCP standards) and began publishing monthly results of completed FSIS *Salmonella* verification sets for establishments in Categories 2 and 3, plants that were at half of the standard or exceeded the standard, respectively.<sup>lxiv lxxv</sup> Another effort, the voluntary *Salmonella* Initiative Program, provides waivers of certain provisions of federal regulations such as limits on chilling time and temperature, reprocessing of contaminated poultry carcasses, and line speeds. In return, plants are required to test daily for *Salmonella*, *Campylobacter*, and generic *E. coli* and share all sample results with FSIS.<sup>lxvi lxxvii 14</sup>

Consumer advocates and members of Congress<sup>lxviii</sup> have called for legislation to provide FSIS with explicit authority to enforce its performance standards.<sup>15</sup> A 2003 Institute of Medicine panel also called on Congress to “grant the regulatory agencies clear authority to establish, implement, and enforce food safety criteria, including performance standards, and the flexibility needed within the administrative process to update these criteria.”<sup>lxix</sup> Such authority would allow FSIS to hold meat and poultry producers accountable for meeting standards for safety.

Express authority would also change the way FSIS deals with poor performing plants. Rather than spend time and resources working to bring a plant back into compliance, FSIS could suspend inspection at the plant. Authority to shut down a plan would provide a powerful incentive to companies to remain in compliance, as plant shutdowns disrupt a plant's business and cost the company money.

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13 The Court also rejected the argument that the *Salmonella* performance standard was a valid exercise of regulatory authority because *Salmonella* can be transferred from infected meat purchased from a slaughterhouse to non-infected meat through the grinding process, on the grounds that the standard at issue did “not purport to measure the differential between incoming and outgoing meat products in terms of the *Salmonella* infection rate.” Thus, the Court held, “the performance standard... cannot serve as a proxy for cross-contamination because there is no determination of the incoming *Salmonella* baseline.”

14 Incentives to participate included a directive to inspectors not to cite a plant for noncompliance if it exceeded the number of acceptable positives of the current *Salmonella* standard during FSIS testing, but complied with all the other requirements of the SIP protocol.

15 Immediately following the *Supreme Beef* decision, Senator Tom Harkin introduced the Pathogen Reduction and Enforcement Act to give FSIS the authority to enforce its performance standards. Senator Kirsten Gillibrand's Safe Meat and Poultry Act contains enforceable performance standards as a central provision in the legislation. Most recently, Senator Dick Durbin and Congresswoman Rosa DeLauro introduced the Safe Food Act, establishing a single food safety agency, which included enforceable performance standards. So far none of these bills have been voted on by Congress.

## PATHOGENS AS ADULTERANTS

In the wake of the *E. coli* O157:H7 outbreak linked to Jack in the Box hamburgers, FSIS made the ground-breaking determination that raw ground beef contaminated with *E. coli* O157:H7 would be considered adulterated within the meaning of the Federal Meat Inspection Act (FMIA).<sup>cxv</sup> This was a critical step in addressing a deadly pathogen that had made hundreds of consumers sick and killed four children. The meat industry sued USDA over this action but a court upheld FSIS's interpretation of the FMIA. FSIS later expanded the types of products covered under the adulteration determination to include raw ground beef components such as beef trim and intact beef cuts intended for further processing. In 2011, FSIS expanded its list of pathogens considered to be adulterants to include six additional strains of Shiga toxin producing *E. coli* — O26, O45, O103, O111, O121, and O145.<sup>cxvi</sup> FSIS reasoned that the six strains were similarly virulent, had a low infectious dose, and had been linked to food-borne illness outbreaks that had sickened consumers.<sup>cxvii</sup>

FSIS also considers ready-to-eat products adulterated if they are contaminated with *Listeria monocytogenes*, *Salmonella*, or *E. coli* O157:H7. Designating these pathogens as adulterants is especially important for ready-to-eat products such as deli meats and hot dogs, which many consumers assume are safe to eat without further cooking or reheating.

FSIS maintains a “zero tolerance” policy for pathogens the agency considers adulterants, which means that a product containing any amount of that pathogen cannot be sold to the public. FSIS tests for the pathogens in the relevant products to enforce the “zero tolerance” standard, which spurs industry testing as well. The combination of a zero tolerance standard and testing has likely been a contributing factor in driving down rates of *E. coli* contamination in meat products. Since the consequence of finding *E. coli* O157:H7 in ground beef is so severe, the meat industry has expended substantial resources and effort to ensure that their products are not contaminated with the pathogen.

When it comes to *Salmonella* in raw products, however, the approach is very different: FSIS does not consider *Salmonella* to be an adulterant. As a result, it is perfectly legal for companies to sell to consumers raw ground beef or poultry products that are contaminated with *Salmonella*.

In justifying the different approach, the agency relies on a forty-year-old court case which claimed that ordinary cooking practices will generally destroy the pathogen and that proper handling is likely sufficient to prevent cross-contamination. In that case, *APHA v Butz*, which dealt with labeling of meat and poultry products, USDA argued that many foods are contaminated with *Salmonella* and “it would be unjustified to single out the meat industry and ask that the [USDA] require it to identify its raw products as being hazardous to health.”<sup>cxviii</sup> A DC Circuit Court of Appeals upheld the position of the USDA, stating that “the presence of salmonellae on meat does not constitute adulteration” under the definition in the Federal Meat Inspection Act (21 U.S.C. § 601 (m)).<sup>cxix</sup>

The *Supreme Beef* case reiterated this position, citing *APHA v Butz*, and stating “*Salmonella*, present in a substantial proportion of meat and poultry products, is not an adulterant, per se... This is because normal cooking practices for meat and poultry destroy the *Salmonella* organism.” As a

result raw beef and poultry contaminated with *Salmonella* can be labeled “inspected and passed” by USDA inspectors and legally sold to consumers.<sup>cxv</sup> This legal interpretation largely ignores the risk of cross-contamination from contaminated products, particularly in food preparation.

Not all the judges in *APHA v Butz* agreed with the final decision. Judge Spottswood W. Robinson III, in his dissenting opinion, questioned whether consumers were really aware of the dangers of *Salmonella* and familiar with the necessary precautions to prevent its occurrence. The judge stated: “Nor is it any clearer that salmonellae in food do not ordinarily render it injurious to health. Meat, particularly pork, and poultry are likely to contain salmonellae when they reach the kitchens of our homes and restaurants, and each year more than two million people in this country contract salmonellosis.”<sup>cxvii</sup>

For years consumer groups have urged FSIS to declare *Salmonella* an adulterant. A 2011 petition by the Center for Science in the Public Interest and supported by consumer advocacy groups requested that FSIS use its interpretive rulemaking authority to declare four separate strains of antibiotic-resistant *Salmonella* — Hadar, Heidelberg, Newport, and Typhimurium— as adulterants under both the Federal Meat Inspection Act and the Poultry Products Inspection Act.<sup>cxviii</sup> Antibiotic resistant strains of *Salmonella* are a particular threat to human health because they are resistant to many of the drugs normally used to fight infection, reducing the medical treatment options available. In addition, these strains are often among the most frequent serotypes identified in retail meat products, and outbreaks of antibiotic-resistant pathogens are becoming more common. FSIS denied the consumer group's petition after a three year review, stating that additional data on the characteristics of antibiotic resistant *Salmonella* were needed to determine whether certain strains could be considered adulterants.<sup>cxviii</sup> In October 2014, CSPI resubmitted its petition with additional data, though the agency has not yet responded.<sup>cxix</sup>

In the absence of a formal declaration of adulteration, the agency has begun to take small steps to address the problem of product contaminated with *Salmonella*. In 2007, FSIS urged a recall of ConAgra frozen pot pies contaminated with *Salmonella* that had sickened consumers.<sup>cx</sup> In 2011, FSIS requested Cargill Meat Solutions conduct a recall for 36 million pounds of ground turkey products contaminated with antibiotic-resistant *Salmonella* Heidelberg, after 79 people were sickened in 26 states.<sup>cxii</sup> These actions were unusual since FSIS typically does not request that a company recall a product contaminated with a pathogen that is not an adulterant, like *Salmonella*.

To further clarify its new approach, FSIS explained in a 2013 notice that it would consider as adulterated product contaminated with *Salmonella* that is linked to an outbreak because it is “unsound, unhealthful, unwholesome or otherwise unfit for human food.”<sup>cxliii</sup> While consumer groups applauded this step, they pointed out that this was a reactive approach, in that consumers have to become sick before the agency will take action. The groups urged FSIS to ultimately declare *Salmonella* an adulterant in raw product, so the agency can take more effective action to address *Salmonella* contamination.<sup>cxliii</sup>

# CRITIQUES OF HACCP

FSIS has made numerous efforts over the years to adapt or adjust its HACCP program based on new data and information or changing conditions in the meat and poultry industry. Frequently, changes have been made in response to foodborne illness outbreaks or in-depth examinations that identified gaps in the system. FSIS has often developed creative ways to address concerns raised by independent investigators and stakeholder groups. However, fundamental problems continue.

In the years since the PR/HACCP regulations went into effect, the USDA's Office of Inspector General (OIG) and the U.S. Government Accountability Office (GAO) have issued multiple reports evaluating FSIS's implementation of the program and providing recommendations for improvement. Some of these reports examined specific aspects of HACCP at the request of members of Congress while other reports were conducted in response to large nationwide outbreaks, which highlighted gaps in the food safety system.

Taken as a whole, the reports identify long-term problems with the implementation of HACCP by both the industry and the agency. Often, subsequent reports demonstrate that actions FSIS previously committed to take were either not implemented or did not fully address concerns raised by the investigators. Further, the agency has often been slow to follow up on OIG and GAO recommendations. In 2004, OIG issued a

report evaluating FSIS's response to 80 corrective actions identified in a 2000 report and found that only 58 of the recommendations had been successfully implemented.<sup>lxx</sup>

The first major independent analysis of HACCP was a report in 2000 in which the OIG found that while FSIS and the industry were making good progress in moving to the HACCP approach, several areas required greater attention.<sup>lxxi</sup> These areas — HACCP plan development, microbial testing, and repetitive deficiencies — remain problematic, as evidenced by the fact that OIG and GAO have continued to raise them in subsequent reports. Two of these issues — the failure of establishments to adequately develop their HACCP plans and the problem of multiple reoccurring violations — provide good examples of the ongoing challenges of HACCP implementation and the consequences of failing to fully address these problems.

## OIG AND GAO CRITIQUES OF FSIS IMPLEMENTATION OF HACCP

### 1. Failure to adequately develop a HACCP plan

- Plants fail to identify hazards, justify actions and take effective corrective actions
- FSIS fails to identify problems with plants' HACCP plans and enforce regulations
- FSIS fails to require plants to identify pathogens as hazards likely to occur
- FSIS does not approve plant HACCP plans

### 2. Multiple reoccurring violations

- Plants cited for multiple reoccurring violations with little consequence
- Plants' corrective actions do not address problems
- FSIS fails to identify criteria for determining repetitive violations and taking appropriate enforcement action

## 1. FAILURE TO ADEQUATELY DEVELOP A HACCP PLAN

As noted repeatedly by OIG and GAO, a key problem with FSIS's implementation of its PR/HACCP rule is that too often plants fail to adequately design their HACCP plans. At the same time, FSIS fails to identify problems with plants' plans and enforce agency regulations.

Specifically, plants repeatedly fail to identify hazards likely to occur, do not adequately justify their selection of CCPs and critical limits, and fail to take effective corrective actions. If hazard analyses are not done correctly, then HACCP plans will be ineffective. In addition, accurate identification of CCPs is fundamental to controlling food safety hazards.<sup>lxxii</sup>

Further, FSIS does not require plants to treat the presence of specific pathogens like *E. coli* O157:H7 or *Salmonella* as a "hazard likely to occur."<sup>16</sup> An early review of HACCP implementation by the GAO found that nearly half of the plants the agency studied (13/28) contained statements that a particular food safety hazard was not reasonably likely to occur because it was controlled through Good Manufacturing Practices (GMPs),<sup>17</sup> regulations that are separate from the PR/HACCP rule. Under HACCP, if plants do not identify particular hazards, they are not obligated to address those hazards.<sup>lxxiii</sup> On occasion, FSIS has required plants to reassess their HACCP plans to determine whether they are adequately addressing specific hazards;<sup>lxxiv</sup> however, FSIS has left the final determination in most cases up to each plant.

The OIG has repeatedly noted that there are no procedures for FSIS to approve a plant's HACCP plan, something that consumer advocates had argued for prior to HACCP implementation. The agency has repeatedly refused to consider the recommendation, saying that approval of HACCP plans goes against the "philosophy of HACCP."

Numerous OIG and GAO reports showed that the lack of adequate HACCP plans has been a recurring problem, implicated in several serious foodborne illness outbreaks:

- A 2002 GAO report found that a majority of plants identified by FSIS as having potentially serious food safety risks did not include a complete hazard analysis nor did those plants

adequately identify critical control points in their processes. GAO also found that inspectors were not consistently identifying and documenting failures of plants' HACCP plans.<sup>lxxv</sup>

- A 2003 OIG audit of FSIS's oversight of the ConAgra Beef Company in Greeley, Colorado which was implicated in a nationwide outbreak of *E. coli* O157:H7 found that ConAgra had assumed that *E. coli* O157:H7 was a hazard not likely to occur in its ground beef production.<sup>lxxvi</sup>
- A 2004 OIG report following a *Listeria* outbreak in the northeastern U.S. linked to turkey deli meat produced by Pilgrim's Pride Foods found that the plant had reassessed its HACCP plan in 1999 but incorrectly concluded that *Listeria monocytogenes* was a hazard not likely to occur and consequently had no testing program or preventive controls for the pathogen.<sup>lxxvii</sup>
- A 2005 OIG report looking at HACCP implementation at very small plants found that all food safety hazards were not being identified and addressed in plants' hazard analyses and changes in production processes were not being updated in plant HACCP plans.<sup>lxxviii</sup>
- A 2014 OIG report on FSIS efforts to address pathogens in poultry highlighted several outbreaks of *Salmonella* and *Campylobacter* infections in which the implicated plants had inadequate HACCP plans that did not identify *Salmonella* or *Campylobacter* as a hazard likely to occur.<sup>lxxix</sup>

Additionally, in FSIS's own investigation of a nationwide outbreak of antibiotic resistant *Salmonella* infections in 2014, linked to poultry produced by Foster Farms, the agency found that the implicated Foster Farms facilities had identified *Salmonella* as a hazard not reasonably likely to occur, and questioned whether Foster Farms could support that decision considering the high percentage rates for *Salmonella* found at the plants.<sup>lxxx</sup>

16 This may be changing. In the agency's final rule on the modernization of poultry slaughter inspection, FSIS required all poultry slaughter establishments to "develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by **enteric pathogens** and fecal material throughout the entire slaughter and dressing operation" and to incorporate those procedures into the establishment HACCP plan, sanitation SOPs, or other prerequisite programs. (emphasis added).

17 Good Manufacturing Practices serve as the minimum sanitary and processing requirements for producing safe food. They typically address equipment, facilities, sanitation, pest control, training, and plant design.



## a. FSIS Response - EIAOs, Food Safety Assessments, and HAVs

FSIS has, over the course of a number of years, instituted a series of actions to evaluate a plant's HACCP plan in greater depth in certain situations. The agency frequently deploys additional inspection resources at poor-performing plants after a problem has been discovered. Even with this extensive investment of resources, FSIS has continued to find that plants' HACCP plans are inadequate and the agency has had to develop new and additional procedures to more fully evaluate plant HACCP plans.

In 2001, the agency designated Consumer Safety Officers, who have the technical expertise to review the scientific soundness of HACCP plans, to conduct in-depth verification reviews of HACCP plans in plants with serious safety problems. These consumer safety officers would eventually morph into the current cadre of Enforcement Investigations and Analysis Officers (EIAOs), which FSIS routinely deploys to review plants' food safety systems after serious negative inspection findings.

The agency also developed Food Safety Assessments (FSAs) to more closely evaluate HACCP plans.<sup>lxxxvi</sup> FSAs are scheduled within six months after FSIS begins inspecting a new plant, and every four years thereafter. FSAs can also be scheduled "for cause" if the agency determines that a further analysis of an establishment's HACCP plan is necessary.<sup>lxxxvii</sup> FSAs require extensive inspection resources, typically taking about two to four weeks to complete. In an FSA, EIAOs consider the totality of food safety aspects of a facility and its products with a focus on the plant's hazard analysis, HACCP plan, Sanitation SOPs, testing, and other relevant programs. Following

completion of the FSA, EIAOs recommend whether any enforcement actions are warranted.

Despite these procedures, FSAs conducted by the agency through 2006 found that plants were still not identifying hazards likely to occur, could not support decisions on selection of CCPs and critical limits, and their corrective actions were ineffective resulting in the continued occurrence of safety problems.<sup>lxxxviii</sup> 18 Since FSIS has refused to approve plants' HACCP plans, the agency has had to invest resources in additional procedures to identify deficiencies that plants should have addressed at the outset.

In 2011, FSIS announced yet another approach, the Hazard Analysis Verification (HAV) procedure, a new quarterly procedure intended to focus on the "foundational elements of an establishment's HACCP plan;"<sup>lxxxix</sup> however, the agency has yet to fully implement the procedure in all plants.<sup>lxxxix</sup> 19 In its description of the new HAV procedure the agency telegraphed the problems that it expected to find, stating that the procedure would be used to verify that the plant was addressing the applicable food safety hazards, check that there is at least one CCP per hazard, and that the plant can justify any decision that applicable hazards are not likely to occur.<sup>lxxxv</sup> Both HAVs and FSAs are clear attempts to address failures of establishments to adequately implement some of the foundational elements of HACCP, such as hazard analyses and establishment of CCPs. Yet the OIG noted that HAV procedures still failed to address a second, long-standing criticism that FSIS still did not specify what corrective or enforcement measures should be taken when deficiencies are found.

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18 From FSIS'S Compliance Guideline for Controlling *Salmonella* and *Campylobacter* in Poultry (May 2010): "The Food Safety Assessments conducted through 2006 indicated that some plants struggle to put in place an effective food safety system. General findings included inconsistencies between the hazard analysis and the selection of the CCP and critical limits. Hazards were identified in the hazard analysis, but there was no indication why they were not reasonably likely to occur. Supporting documentation was lacking for decisions that a hazard was not reasonably likely to occur. Prerequisite programs lacked records showing how the prerequisite program was effective in preventing certain potential hazards from being reasonably likely to occur in the process...When corrective actions were taken, they were often ineffective. Deviations would occur and reoccur. Documentation would reflect the deviation, but the same corrective actions were carried out repeatedly without any regard to whether or not they were successful. Many plants did not address *Salmonella* specifically as a pathogen likely to be present."

19 FSIS differentiated the new HAV procedure (carried out by inspection personnel) as a focus on the basis of a plant's HACCP program while FSAs (conducted by EIAOs) were a more comprehensive assessment of a plant's food safety system.

## 2. MULTIPLE REOCCURRING VIOLATIONS

Another major problem with FSIS's implementation of HACCP is that establishments are repeatedly cited for reoccurring violations related to a plant's HACCP plan but with little consequence. As documented by the OIG and GAO, this is because FSIS has failed to identify specific criteria for determining when a violation is repetitive and needs stricter enforcement action.

The GAO first raised this concern in 1999 noting that FSIS regulations “do not explicitly state the number or types of noncompliance notices”<sup>20</sup> that can result in a determination that a plant's HACCP system has failed.<sup>lxxxvi</sup> A 2000 OIG report found “numerous repetitive critical deficiencies with the same cause where permanent corrective action had not been taken or enforcement actions initiated” because FSIS had not issued instructions on addressing repetitive violations.<sup>lxxxvii</sup> A 2002 GAO report repeated the charge, finding that FSIS was not consistently identifying repetitive violations because the agency had not established “specific, uniform, and clearly defined criteria to its inspectors to use in determining when a violation is repetitive.”<sup>lxxxviii</sup> GAO noted that identifying and accurately documenting repetitive violations was “critical” in deciding whether a HACCP plan is flawed and whether the agency should take appropriate enforcement action.<sup>lxxxix</sup>

GAO further found that FSIS was not consistently ensuring that actions plants took were effective in eliminating repetitive violations, particularly those relating to the agency's “zero tolerance” standard for visible fecal contamination. GAO noted that although plants are required to take corrective action each time a violation is cited, the number of repetitive violations in various plants — 109 in one plant alone — showed that FSIS had not ensured that recurring violations were eliminated.<sup>xc</sup>

A 2003 *New York Times* investigation showed that despite a history of reoccurring violations at meat plants, FSIS delayed enforcement activity or more forceful action, threatening to shut down a plant but never following through.<sup>xc</sup> As noted in the article, the government has “too often waited until meat

became contaminated — and people have become sick — before forcing plants to make safety changes.”

Subsequent reports reiterated this problem, with investigations into several serious foodborne illness outbreaks revealing that plants had histories of repeat violations:

- A 2003 OIG report on the ConAgra recall found that FSIS issued multiple noncompliance records (NRs) to ConAgra for fecal contamination but the agency took no decisive enforcement action; instead allowing the company to implement stopgap measures such as increased supervision or employee training.<sup>xcii</sup>
- A 2004 OIG report on *Listeria* also found that FSIS did not adequately enforce its regulations at the plant and issued relatively few NRs during the time recalled product was produced. OIG noted that deficiencies were “corrected” multiple times in a single day, meaning that the problem was not adequately addressed.<sup>xciii</sup>
- A 2005 OIG report on very small plants found that repetitive noncompliances were not adequately corrected at half of the plants audited.<sup>xciv</sup>
- A 2007 OIG report on FSIS's efforts to develop a risk-based inspection model, found that FSIS had still not issued sufficient guidance on how to evaluate repetitive noncompliance violations for when further enforcement action must be taken.<sup>xcv</sup> OIG pointed to two large recalls by establishments (United Food Group LLC and Topps Meat Company LLC<sup>xcvi</sup>) in which inspectors issued multiple NRs for sanitary deficiencies but did not adequately link deficiencies which could have demon-

20 A noncompliance record, or NR, is a written record that documents noncompliance with FSIS regulations. An NR notifies the establishment of the noncompliance and that it should take action to remedy the situation and prevent its recurrence. While some NRs may be written for violations not related to food safety, the OIG and GAO analysis of FSIS' NR policy predominantly focuses on NRs related to food safety programs such as HACCP or sanitation procedures. However, information on NRs for individual plants is not readily accessible; typically such information must be requested through a Freedom of Information Act (FOIA) request, a timely process.

strated a pattern of problems. Both companies were linked to foodborne illnesses and ultimately recalled millions of pounds of ground beef.

- A 2013 OIG report on FSIS’s swine inspection pilot program<sup>xcvii</sup> found that FSIS allowed plants to repeatedly violate food safety regulations without repercussion. According to the report, FSIS issued 44,128 noncompliance records to 616 plants during FY 2008-2011. Only 28 plants were suspended, even though “some plants repeated violations as egregious as fecal matter on previously cleaned carcasses.” OIG found that 21 percent of noncompliance reports at the 20 most-cited swine plants were for repeat violations.

In FSIS’s own investigation of the 2014 nationwide outbreak of antibiotic resistant *Salmonella* infections linked to poultry produced by Foster Farms, FSIS found the implicated Foster Farms plants had “multiple and reoccurring” noncompliances for insanitary conditions, including fecal material on carcasses, insanitary food contact surfaces, and direct product contamination.<sup>xcviii</sup>



### a. FSIS Response — Linking Noncompliance Records

FSIS has made frequent revisions to agency notices and directives to its inspection force about how to handle enforcement actions. However, the agency’s changes have yet to fully address the problem.

In responses to the OIG and GAO criticism, FSIS cited its Directive 5000.1,<sup>xcix</sup> noting that the standard for determining further enforcement action is “proof that product has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.” The OIG has disagreed with this assessment, pointing out that Directive 5000.1 was in effect during their audit reviews, yet did not suffice to resolve the deficiencies that were found.<sup>c</sup> Instead, OIG has encouraged FSIS to link related NRs and develop evaluation criteria that would provide a basis for determining when an establishment’s corrective actions were inadequate and when additional enforcement actions should be initiated.<sup>ci</sup>

The most recent version of Directive 5000.1, updated in 2011, does instruct inspectors to link related noncompliances, review possible trends with plant management, and consider whether a Food Safety Assessment should be conducted. However, the agency still has not provided adequate guidance to its inspectors on how to assess repetitive violations, the number of associated noncompliances that would demonstrate a trend, and when inspectors should escalate enforcement actions.

As late as 2013, the OIG raised concerns that FSIS enforcement policies do not deter repeat violators: “There are no quantifiable criteria explaining when actions such as suspensions or Notices of Intended Enforcement should be issued.” The OIG further noted that FSIS directives do not quantify the number of violations which would constitute “multiple or recurring noncompliance,” or mandate when to suspend a plant.<sup>cii</sup> As a result, OIG found that plants repeatedly violated the same regulations with little or no consequences.

## HACCP-BASED INSPECTION MODELS PROJECT (HIMP)

Even as it was finalizing its PR/HACCP rule, FSIS was testing new inspection methods that would provide the industry with more control over its HACCP systems. In 1997, FSIS proposed the HACCP-Based-Inspection Models Project (HIMP), designed “to produce a flexible, more efficient, fully integrated meat and poultry inspection system.”<sup>cxiv</sup> Slaughter plant employees would conduct tasks, such as inspecting each carcass and identifying other problems such as bruises or ingesta on the carcasses. FSIS inspectors would oversee these activities, rather than conduct them as was the existing approach. Inspectors would also conduct offline food safety activities such as verifying compliance with Sanitation SOPs and other HACCP regulatory requirements.<sup>cxiv</sup>

The HIMP model has been controversial from the beginning. The American Federation of Government Employees, which represents federal inspectors, initially sued the USDA, arguing that under the law federal inspectors were required to conduct carcass-by-carcass inspection.<sup>cxvi</sup> A U.S. appeals court agreed, though after further court action, USDA was permitted to pilot a revised version of HIMP, in which 20 broiler plants, five young turkey plants, and five market hog plants participated.

In a 2001 report, GAO was strongly critical of the HIMP pilot program.<sup>cxvii</sup> GAO found the data from the pilot plants to be inconclusive in demonstrating improved food safety performance and raised concerns that FSIS did not require plant employees to be trained in tasks previously performed by federal inspectors. GAO further noted that HIMP plants had volunteered to participate in the pilots and were not randomly selected, so the results from the HIMP pilots could not be generalized to all chicken slaughterhouses.

FSIS maintained the pilot program, but did not seek to expand it until January 2012, when the agency proposed substantial changes to its inspection system for all young chicken and turkey slaughter establishments. Under the proposal, FSIS turned over to company employees some activities previously conducted by federal inspectors and reduced the number of inspectors to one per slaughter line.<sup>cxviii</sup> FSIS maintained that its rule would provide the establishment with greater control over their lines and greater flexibility over their production process, a key goal of industry.<sup>cxix</sup> As part of the proposal, FSIS required all poultry plants to develop procedures to prevent contamination of carcasses and parts by pathogens and fecal material; develop written procedures to ensure that carcasses contaminated with visible fecal material do not enter the chiller; and conduct microbial sampling at the pre-chill and post-chill points in their systems.

Consumer groups strongly opposed the proposal, citing significant food safety concerns with the proposed rule.<sup>cl</sup> Groups representing poultry plant workers<sup>cli</sup> government inspectors,<sup>clii</sup> groups supporting humane handling of livestock<sup>cliii</sup> and members of Congress<sup>cliv</sup> all raised concerns as well.

Consumer groups urged FSIS to require plants to test for *Salmonella* and *Campylobacter*, the two pathogens most commonly associated with raw poultry; argued that FSIS should require establishment employees to be trained to carry out their new duties; and opposed the proposal to allow each plant to decide the appropriate level of “defects” on carcasses, which can include bruises, scabs, feathers, ingesta, and a variety of poultry-specific diseases.<sup>clv</sup> The groups specifically called into question the data on which FSIS relied to develop its proposal, noting that the agency’s own risk assessment showed a limited impact on reducing *Salmonella* contamination and an “ambiguous” impact on reducing *Campylobacter* contamination.<sup>clvi</sup> The groups pointed out that data from the HIMP pilot project did not demonstrate substantially stronger public health protections for consumers.<sup>clvii</sup>

A 2013 GAO report questioned the data on which the agency had relied to develop its proposal.<sup>clviii</sup> GAO said that data, such as *Salmonella* verification data, which FSIS used to compare pilot plants with plants under traditional inspection, was not designed for such a comparison and that FSIS selectively used data from the pilot program, relying on data from two 2-year periods instead of using data from the entirety of the pilot project’s ten years. The GAO further noted that biases in the sample of young chicken plants participating in the pilot program continue to prevent generalizations from the pilot program to all poultry plants in the U.S. As a result, the GAO stated, “FSIS may not have assurance that its evaluation of the pilot project at young chicken plants provides the information necessary to support the proposed rule for poultry—both chickens and turkeys.”<sup>clix</sup>

FSIS finalized the poultry rule in August 2014. Consumer group Food & Water Watch and the American Federation of Government Employees, in separate lawsuits, sued the agency to stop the rule, arguing that the new system violates the law requiring inspectors to condemn adulterated carcasses and to oversee online reprocessing of birds.<sup>clx</sup> In February 2015, a judge dismissed the Food & Water Watch lawsuit, though the consumer group immediately appealed the decision.<sup>clxi</sup>

Despite concerns raised by government investigators and consumers groups, and problems identified in other countries, FSIS continues to push this controversial model as the next evolution of HACCP. In its FY 2014 annual performance plan, FSIS states it will develop economic analyses for a beef slaughter proposed rule “consistent with the poultry slaughter modernization regulations.”<sup>clxii</sup> At the same time, FSIS has already declared that HIMP-style beef slaughter approaches in Canada, Australia, and New Zealand are equivalent to the U.S. meat and poultry inspection system and has allowed meat produced under those systems to be imported from those countries. This was done despite the agency having no data on how HIMP would work for beef inspection because the agency has never conducted a pilot program on beef in the U.S. Instead, despite the differences in the species and without providing adequate justification for doing so, the agency used its HIMP pilot project in pork to determine that beef slaughter systems in those countries were equivalent.<sup>clxiii clxiv</sup>

Some plants conducting beef slaughter under those foreign systems have had significant problems. The most notable was a recall in September 2012 — the largest in Canadian history — of millions of pounds of Canadian beef contaminated with *E. coli* O157:H7, of which 2.5 million pounds entered the U.S.<sup>clxv</sup> In addition, multiple shipments of beef, mutton and goat meat produced by Australian plants under the Australian version of HIMP have been stopped at the U.S. border due to fecal contamination.<sup>clxvi clxvii</sup>

While FSIS’ own assessment of the pork pilot program found HIMP plants to be performing as well as non-HIMP plants,<sup>clxviii</sup> independent assessments have raised concerns. The GAO identified deficiencies with FSIS’s hog pilot program similar to the problems raised by the agency’s poultry pilot project, including a lack of comparable data, an inability to generalize from the pilot program to hog plants nationwide, and a lack of information to determine whether the pilot program was meeting its identified purposes.<sup>clxix</sup>

These criticisms echoed comments from the OIG in a recent report, which found that FSIS could not determine whether the goals of the hog pilot were met because FSIS did not adequately oversee the pilot program. OIG noted that “since FSIS did not provide adequate oversight, HIMP plants may have a higher potential for food safety risks.”<sup>clxx</sup> The OIG found that three of the ten plants cited with the most non-compliance records continued to participate in the program because FSIS’s enforcement policies did not deter swine slaughter plants from repeatedly violating the Federal Meat Inspection Act.

# FSIS SAMPLING PROGRAMS

Testing is an essential component of any HACCP program to verify that an establishment is maintaining control of its production processes. FSIS developed its own sampling programs to assess the effectiveness of plant HACCP systems, determine compliance with agency performance standards and monitor the proportion of finished product that may potentially be contaminated.<sup>ciii</sup> FSIS also uses its sampling programs to incentivize the meat and poultry industry to reduce the presence of pathogens on products they produce.<sup>civ</sup>

FSIS conducts microbiological sampling for four major sets of pathogens: *E. coli* O157:H7 and other Shiga toxin-producing strains of *E. coli*, *Salmonella*, *Campylobacter*, and *Listeria monocytogenes*. Positive test results in these programs can trigger additional, intensified verification sampling or other agency actions to verify that the establishment's corrective actions are adequate to ensure its process is back in control.

FSIS revised its sampling programs over the years, targeting sampling at establishments that may present a greater risk based on specific factors such as production volume and history of poor sample results. The agency is also seeking ways to conduct more regular testing in order to better capture ongoing verification of establishments. As efforts to reduce pathogen contamination continue, one future challenge for the agency is how to design a sampling program to measure plant performance when pathogen levels are very low.

Revisions to agency sampling programs have occurred over time. For *E. coli* O157:H7 sampling, FSIS has expanded the types of products it samples several times in order to capture all the components of ground beef.<sup>cv</sup> Currently the agency only conducts sampling for the six additional strains of Shiga toxin-producing *E. coli* in beef trim, but may expand its testing to other ground beef components in the future.

For *Salmonella* and *Campylobacter*, FSIS focuses its sampling on establishments with a higher rate for



those pathogens and categorizes the establishments based on their sampling results. Establishments which fail FSIS's *Salmonella* testing are identified on the agency's website monthly; the agency will do the same for *Campylobacter* results once it has accumulated sufficient data.<sup>cvi</sup>

FSIS testing of ready-to-eat meat and poultry products for *Listeria monocytogenes* and *Salmonella* is both random and risk-based.<sup>cvi</sup> When product, food contact surfaces, and environmental surfaces are found positive for either *Salmonella* or *Listeria monocytogenes*, FSIS conducts targeted, follow-up sampling after the establishment has taken corrective actions.

## Limitations to FSIS Testing Programs

### a. Lack of pathogen testing requirement

One problem with FSIS's approach to testing is that the agency does not require meat and poultry plants to test for specific pathogens. The only testing requirement for meat and poultry plants in FSIS regulations is for plants to test for generic *E. coli* as originally established in the PR/HACCP rule. During debate on the rule, consumer groups stressed that testing for generic *E. coli* only (and not pathogens) makes it impossible to monitor whether products have a lower incidence of the specific pathogens that make consumers sick.<sup>cxiii</sup>

In addition, by not requiring plants to test for specific pathogens, the agency has lost the opportunity to analyze substantial amounts of potential data to ensure that plants are producing a safe product. The agency also missed an opportunity to put pressure on plants, particularly in the poultry industry, to reduce *Salmonella* contamination.<sup>cxix</sup> Even in the agency's poultry slaughter final rule, FSIS did not require plants to test for *Salmonella* or *Campylobacter*, the two pathogens most commonly associated with raw poultry. While the agency did require plants to test at two points along the slaughter line, it was left up to the plant to decide which organism to test.<sup>21</sup>

Many meat and poultry plants do conduct extensive testing for specific pathogens, an indication of the value of pathogen testing as a verification activity in their facilities. However, testing by plants is not as universal as would be expected. According to an August 2008 *E. coli* checklist conducted by the agency, "testing is more frequently em-

ployed by processing establishments than interventions, but is still a minority practice."<sup>cx</sup> The highest rate of *E. coli* O157:H7 testing (40%) was in Beef Trim Fabrication operations. Grinding establishments tended to have higher testing rates with about 50 percent of beef grinding establishments testing finished product.<sup>cxii</sup>

### b. Prior notification of testing

Currently, FSIS provides establishments with notification before the agency is going to take a sample. While in some cases this is necessary so the plant can hold the product pending test results, the approach can also affect the representativeness of the sample. FSIS procedure for sampling is to ship the sample collection kit to the plant several days in advance of when a scheduled sample collection will begin.<sup>cxiii</sup> This gives the plant a warning that the agency will soon conduct sampling, which could prompt the plant to make changes in advance of the testing.

Evidence that plants might take steps to bias government sampling results surfaced in 2012 when FSIS issued Notice 66-12 to its inspection personnel, warning them that plants could be altering the outcome of FSIS sampling sets.<sup>cxiiii</sup> The notice warned that plants may be temporarily changing or increasing the levels of antimicrobials used in their food safety processes during *Salmonella* verification sampling, then returning to pre-sampling conditions once FSIS sampling was complete. It is unclear how widespread this practice is, but such activities would reduce the accuracy

of FSIS testing results and limit the confidence that the results represent typical operating conditions in the plant.

### c. Frequent and regular sampling

FSIS sampling for *Salmonella* has typically consisted of a set of 52 consecutive daily samples. This approach means that establishments are sampled intensively for a short period of time and then not sampled over a much longer period. This has made it impossible to determine whether establishments are consistently maintaining adequate levels of process control over time.

FSIS recently changed its sampling set approach for raw ground beef and poultry products. In June 2014, the agency began analyzing for *Salmonella* contamination in all samples of raw ground beef, beef manufacturing trimmings, bench trim, and other raw ground beef components that the agency collects for Shiga toxin-producing *E. coli* analysis.<sup>cxiv</sup> This is a positive step that should result in more frequent and regular sampling of ground beef for *Salmonella* and provide a better indication of plant's ongoing process control. The agency has also shifted to a routine sampling approach for all products subject to testing for *Salmonella* and *Campylobacter*, including poultry carcasses, poultry parts and ground poultry, which should provide a better basis for agency verification.<sup>cxv</sup> However, the agency will not routinely conduct follow-up sampling or take enforcement action in response to a single *Salmonella* positive since *Salmonella* is not considered an adulterant.

21 The agency admitted in the poultry slaughter final rule that testing for generic *E. coli* "may not be the most effective way for [poultry] establishments to monitor the effectiveness of their process control procedures." This was a point consumer groups had raised with FSIS in the mid-90s during deliberations on the PR/HACCP rule.

## CASE STUDY: FOSTER FARMS

A recent illustrative example of the failings of FSIS's HACCP program and lack of sufficient authorities occurred when poultry company Foster Farms was linked to a nationwide outbreak of antibiotic-resistant *Salmonella* infections, sickening 634 people in 29 states.<sup>clxxi</sup> Thirty-eight percent of ill persons were hospitalized; a particularly high rate likely caused by the antibiotic-resistant characteristics of the pathogen.

FSIS's investigation at the multiple Foster Farms establishments implicated in the outbreak identified poultry products that contained the same PFGE patterns as the outbreak strains of *Salmonella*. Intensified testing by the agency found nearly 25% of the samples were positive for *Salmonella*.

Following its investigation, FSIS issued a Notice of Intended Enforcement Action (NOIE) to the three Foster Farms slaughter establishments involved in the outbreak,<sup>clxxii</sup> stating that the establishments had identified *Salmonella* as a food safety hazard not reasonably likely to occur, and questioning whether Foster Farms could support that decision considering the high percent positive rates for *Salmonella* found at the plants. The establishments also failed to reassess their HACCP plans and had "multiple and reoccurring" noncompliances for insanitary conditions, including fecal material on carcasses, insanitary food contact surfaces, and direct product contamination.

Consumer advocates insisted that Foster Farms recall their product in light of the ongoing illnesses, the high hospitalization rate, the antibiotic resistant nature of the *Salmonella* strains, and the results of FSIS's intensified verification sampling.<sup>clxxiii</sup> The plants were allowed to remain open, however, and despite the mounting *Salmonella* illnesses and the findings in the establishments, FSIS did not request that Foster Farms conduct a recall of its products. Instead, in October 2013, FSIS released a public health alert, notifying the public of the ongoing outbreak. FSIS said that it could not urge Foster Farms to recall the product because the agency was unable to link the illnesses to a specific product and a specific production period. And, since *Salmonella* is not considered an adulterant, contaminated product could legally be sold to consumers.

In an interview with industry publication *Meatingplace* at the time the agency issued its public health alert, an FSIS official referenced the *Supreme Beef* case as a barrier to FSIS's efforts to address *Salmonella*. He said that FSIS "wouldn't just take the *Salmonella* performance as the sole determinant of removing inspection; we would take into account a broader range of inspection

findings... We would not shut a plant down just because they didn't meet (the standard), but if there was other evidence of insanitary conditions similar to what is happening now at Foster Farms."<sup>clxxiv</sup>

Without a recall, contaminated product remained on store shelves and in consumers' homes as the outbreak continued. At the time the public health alert was issued, the CDC had identified 278 illnesses in 18 states associated with the outbreak. Eight months later, on March 1, 2013, the CDC reported that the outbreak was still ongoing and the case count had more than doubled to 621 persons in 29 states sickened with seven strains of antibiotic resistant *Salmonella* Heidelberg. (Ultimately the case count would rise to 634 before the outbreak was declared over).

In July 2014, FSIS finally announced that Foster Farms was conducting a limited recall of approximately one million pounds of product produced on several dates in March.<sup>clxxv</sup> The recall occurred because FSIS was finally able to link Foster Farms product from a specific production lot with a specific illness in California.<sup>clxxvi</sup> Yet, many consumer advocates said that the recall was too little, too late.<sup>clxxvii</sup>

The Foster Farms case is a prime example of multiple gaps in FSIS's food safety program colliding, resulting in contaminated product that sickened hundreds of consumers. Those gaps include:

- Foster Farms plants had not identified *Salmonella* as a hazard likely to occur in their HACCP plans, prompting FSIS to question whether the company could justify that decision. And, FSIS did not require plants to treat the presence of *Salmonella* as a hazard likely to occur.
- The plants had multiple, reoccurring noncompliances that had not been adequately addressed by the plant or FSIS inspectors.
- Despite remarkably high levels of *Salmonella* contamination on product produced by Foster Farms, the product could be legally sold in commerce because FSIS does not consider *Salmonella* an adulterant.
- At the time of the outbreak, FSIS had not developed performance standards for *Salmonella* for products consumers typically purchase such as poultry parts or ground poultry.
- Even with standards for poultry parts, FSIS is hampered from taking effective action to enforce those standards by the *Supreme Beef* decision. The agency cannot close a plant solely for failing *Salmonella* performance standards.

# CONCLUSION AND RECOMMENDATIONS

The adoption of HACCP by FSIS and the meat industry has resulted in benefits to food safety and public health. Yet additional improvements have been hindered by gaps in the implementation of HACCP, which have left consumers vulnerable. Two major gaps include the failure of plants to develop adequate HACCP plans and the failure of FSIS to establish a clear policy for when multiple, reoccurring non-compliances should be elevated to more stringent enforcement action.

Further, more effective FSIS actions may be constrained by the court decision in the *Supreme Beef* case and a lack of explicit authority to enforce performance standards. Not wanting to test the scope of the case, the agency has instead engineered roundabout procedures to address problems that could be resolved more quickly using a more straightforward approach. The agency's failure to regularly update performance standards to reduce pathogen contamination in meat and poultry products is also a major deficiency. And while the agency has been updating its sampling program to better target risky plants and products, additional improvements are needed.

Gaps in the oversight system can put consumers at unnecessary risk from foodborne illness from meat and poultry products. FSIS can make many changes to improve its program under current law. However, to truly modernize the meat and poultry inspection program, Congress must modernize the laws and provide the agency with updated, explicit enforcement authorities focused on improving public health.<sup>22</sup> Until then, the following steps are critical to making the HACCP system more effective in protecting consumers from foodborne illness.

## 1. Develop a better mechanism to ensure the adequacy of HACCP plans

FSIS has consistently refused to review and approve HACCP plans, claiming that to do so would go against the "philosophy of HACCP." Yet, plants are regularly identified by the OIG, GAO and even

FSIS as not having HACCP plans that adequately control the relevant hazards. As a result, the agency has had to expend additional resources to review HACCP plans at problematic plants, often only after a problem has been identified and consumers have been exposed to contaminated food. At the very least, FSIS should develop a better mechanism to ensure that new HACCP plans are adequate before an establishment begins producing product. When plans are found to be seriously deficient, FSIS should take more stringent enforcement action against the establishments that created them.

## 2. Require plants to identify pathogens most commonly associated with particular products as hazards likely to occur and address them in their HACCP plans.

A common finding by the OIG, GAO, and even the agency itself is that plants fail to identify in their HACCP plans a particular microbial hazard that is common to the product being produced. This problem is often identified in the wake of a large outbreak of foodborne illness. It occurs despite the fact that FSIS provided the industry with a Hazards and Controls Guide for meat and poultry products.<sup>cxvi</sup> FSIS should require plants producing certain products with known hazards to identify and address those specific hazards in their HACCP plans. This requirement should not preclude plants from identifying other hazards, but would provide greater assurances that plants are at least addressing hazards that are generally known to occur in particular products.

<sup>22</sup> Fully modernizing meat and poultry inspection laws requires more than what is listed here; the recommendations listed only reflect authorities related to HACCP and performance standards.



### 3. Establish clear procedures for reoccurring violations

As the OIG and GAO have repeatedly documented, FSIS has not established a clear procedure for addressing multiple, reoccurring violations in plants. As a result, plants are allowed to continue to violate food safety requirements with little or no repercussions. FSIS should establish clear procedures for inspectors to follow in identifying repeat violations, in determining which violations are considered most problematic, and in deciding when to initiate increased enforcement action.

### 4. Regularly update performance standards and develop public health-based standards

FSIS has not routinely updated its performance standards as promised under the PR/HACCP regulation. This failure has resulted in FSIS using outdated safety standards that have not kept up with industry advances or new data. FSIS should update its performance standards on a frequent and regular basis to drive continuous improvement across the industry. Moreover, performance standards have historically been based on current industry performance baselines or technological capacity. Instead, the agency should continue to develop more public health-based standards to ensure a focus on improving public health outcomes, and regularly assess the effectiveness of the standards.

### 5. Seek explicit authority from Congress to enforce performance standards

The fallout from the *Supreme Beef* court decision means that the agency is precluded from taking aggressive action if a plant fails to meet pathogen reduction performance standards. FSIS has developed sophisticated workarounds to meet the challenges posed by *Supreme Beef*, but a more straightforward approach would better protect public health. Congress should provide the agency with explicit authority to set and enforce performance standards for pathogen reduction, including the authority to close down a plant if a plant is failing to meet those standards.

### 6. Improve agency sampling programs

FSIS has revised its sampling programs to better target risky plants and products and provide greater assurance of plants' performance. However the agency's sampling programs could be improved by requiring plants to test for specific pathogens, reducing sampling biases that arise from prior notification, and further developing approaches to ensure ongoing verification. One solution to reduce sampling bias is for FSIS to ensure that sample collection kits are always available onsite at the plant. This would alleviate the bias of plant managers making changes to their food safety program in anticipation of the sample collection.

## RECOMMENDATIONS

1. Develop a better mechanism to ensure the adequacy of HACCP plans.
2. Require plants to identify specific pathogens as hazards in their HACCP plans.
3. Establish clear procedures for reoccurring violations.
4. Regularly update performance standards and develop public health-based standards.
5. Seek authority from Congress to enforce performance standards.
6. Improve FSIS sampling programs.

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