

SAFE FOOD COALITION

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January 27, 2019

Dr. Mindy M. Brashears
Deputy Under Secretary for Food Safety
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue SW
Mailstop 3758, Room 6065
Washington, DC 20250-3700

RE: Docket No. FSIS-2018-0045: Changes to the Salmonella Verification Testing Program: Proposed Performance Standards for Salmonella in Raw Ground Beef and Beef Manufacturing Trimmings and Related Agency Verification Procedures

Dear Deputy Under Secretary Brashears:

The undersigned members of the Safe Food Coalition appreciate the opportunity to submit comments on the Food Safety and Inspection Service's (FSIS's) proposed performance standards for *Salmonella* in ground beef and beef trim. An update to the rules protecting consumers from *Salmonella* in these products is long overdue, and we commend FSIS for taking action.

The proposed standards will undoubtedly improve food safety by exposing poor performing companies and creating new incentives for investment in reducing pathogen contamination. However, FSIS should go further. Specifically, the agency should treat raw ground beef contaminated with *Salmonella* to be adulterated, and withhold the USDA mark of inspection until an establishment can show that it has remediated the problem, much the same way that FSIS currently treats raw ground beef contaminated with *E. coli* O157:H7 and certain other Shiga toxin-producing *E. coli* (STECs). Such a policy is justified given the increasing virulence and frequency of antibiotic resistance in *Salmonella*,¹ the risks posed by popular ground beef cooking and handling practices; the feasibility of a zero tolerance policy for *Salmonella* in ground beef, as demonstrated by the National School Lunch program; and the limitations that industry lawsuits have imposed on USDA's capacity to enforce the proposed performance standards.

¹ See, e.g., Mukherjee et al. "Increasing Frequencies of Antibiotic Resistant Non-typhoidal Salmonella Infections in Michigan and Risk Factors for Disease" Front. Med., 08 November 2019, <https://doi.org/10.3389/fmed.2019.00250>.

The Public Health Burden of *Salmonella* Tainted Beef

Foodborne illness caused by *Salmonella* in beef is a serious problem. Overall, *Salmonella* causes an estimated 1.35 million illnesses, 26,500 hospitalizations, and 420 deaths each year in the United States.² The associated medical bills alone are estimated to exceed \$3.7 billion each year.³ Based on the latest data, the Interagency Food Safety Analytics Collaboration attributes 6.4% of these foodborne *Salmonella* illnesses to beef.⁴ For its part, FSIS estimates in the proposed standards that some 80,000 annual cases of salmonellosis are associated with consumption of cuts of intact beef and ground beef contaminated with *Salmonella*.⁵

Outbreaks of salmonellosis linked to ground beef show no signs of abating. As noted in the proposed standards, just in the last year, two large outbreaks of *Salmonella* infections linked to ground beef caused over 400 reported cases, over 120 hospitalizations, and at least one death. The establishments implicated in those outbreaks issued recalls of over 10 million pounds of ground beef, much of which had already made its way to consumers.⁶

The Reality of Ordinary Ground Beef Cooking and Handling Practices

Although *Salmonella* contamination occurs less frequently in raw beef than in poultry, it appears to sicken a disproportionate number of consumers, in part because of ordinary cooking and handling practices used by a significant proportion of consumers. When FSIS announced that it would consider ground beef contaminated with *E. coli* O157:H7 to be adulterated in 1994, the agency justified its interpretation in part by noting that “ground beef... has traditionally been cooked by many people in a manner that does not destroy the organism.”⁷ In the years since, these traditional consumer preferences have proven stubbornly persistent. Indeed, recent survey data indicates that more than one in four adults do not adequately cook ground beef, serving hamburgers “rare,” “medium rare,” or “medium.”⁸ Many of these consumers are following popular recipes, which fail to inform consumers of the risks associated with eating undercooked beef, or USDA’s instruction to cook beef to an internal temperature of 160 degrees Fahrenheit to avoid foodborne illness.⁹

Undercooking is not the only way that ground beef makes people sick. Even the consumer that cooks ground beef to a safe temperature may neglect safe handling practices that result in cross-contamination. In a 2018 observational study commissioned by FSIS, researchers found that “48

² See Centers for Disease Control and Prevention. “Salmonella,” <https://www.cdc.gov/salmonella/index.html>

³ USDA Economic Research Service. Cost Estimates of Foodborne Illnesses, Cost of foodborne illness estimates for Salmonella (non-typhoidal) (10/7/2014), <https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx#48498>

⁴ <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2017-report-TriAgency-508.pdf>

⁵ Notice at 57688.

⁶ <https://www.cdc.gov/salmonella/newport-10-18/index.html>; <https://www.cdc.gov/salmonella/dublin-11-19/index.html>

⁷ Michael R. Taylor, Change and Opportunity: Harnessing Innovation to Improve the Safety of the Food Supply, Address at the 1994 American Meat Institute Annual Convention (Sept. 29, 1994).

⁸ <https://www.fda.gov/media/101375/download>

⁹ See, e.g. Sam Sifton, “Hamburgers, Tavern Style,” *N.Y. Times*, <https://cooking.nytimes.com/recipes/1016596-hamburgers-tavern-style>; Bobby Flay “Perfect Burger” recipe, <https://www.foodnetwork.com/recipes/bobby-flay/perfect-burger-recipe-1957542>.

percent of participants cross-contaminated spice containers due to lack of handwashing” after preparing burgers, and “5 percent of participants transferred bacteria to salads they prepared and would have immediately served if cooking at home.”¹⁰

Salmonella is Becoming More Dangerous

These exposure risks from *Salmonella* in ground beef are particularly concerning given the spread of antibiotic resistant *Salmonella*. *Salmonella* isolates from cattle tend to harbor fewer antibiotic resistant strains of *Salmonella* than those from other species like turkey.¹¹ However, antibiotic resistance in *Salmonella* Dublin, a serotype commonly present in cattle, has been increasing in recent years.¹² Although *Salmonella* Dublin does not often cause human disease, when it does, “it tends to be more invasive and require antibiotic treatment, making it a rare but concerning serotype.”¹³ Human patients infected with this strain experience a 67 percent hospitalization rate, with three percent of cases resulting in death. These hospitalization and mortality rates are significantly higher than for patients infected with S Typhimurium (24.2 percent hospitalized, 0.6 percent mortality), the serotype responsible for the most human infections.¹⁴

A 2019 outbreak of *Salmonella* Dublin infections linked to ground beef resulted in 13 cases, of which 9 were hospitalized and 1 died.¹⁵ Fortunately, this outbreak appears to have been small in scale and duration, but if this same virulent strain were to contaminate a larger quantity of ground beef, the consequences for consumers would be devastating. Moreover, while none of the isolates taken from case patients in the most recent outbreak were antibiotic resistant, the increasing frequency of resistance in *Salmonella* Dublin isolates found in government sampling suggests that may change in future outbreaks.

Incentives for Compliance with the Proposed Standards are Inadequate

The proposed performance standards, while a step forward from the existing requirements, are not adequate to ensure meaningful reductions in *Salmonella* contamination in ground beef. The first

¹⁰ <https://www.usda.gov/media/blog/2018/06/28/millions-americans-dirty-hands-are-spreading-dangerous-bacteria>.

The study involved “turkey burgers” but the available evidence indicates that consumers handle ground turkey and ground beef in similar fashion.

¹¹ The National Antimicrobial Resistance Monitoring System: NARMS Integrated Report, 2015. Laurel, MD: U.S. Department of Health and Human Services, FDA, 2017, p. 5, *available at*:

<https://www.fda.gov/media/108304/download>. J.K. Varma, et al., Hospitalization and Antimicrobial Resistance in *Salmonella* Outbreaks, 1984-2002, 11 *Emerging Infect. Diseases* 943 (2005); F.J. Angulo, et al., Evidence of an Association Between Use of Anti-microbial Agents in Food Animals and Anti-microbial Resistance Among Bacteria Isolated from Humans and the Human Health Consequences of Such Resistance, 51 *J. Veterinary Med., Series B*, 374 (2004). <https://www.fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/2015-narms-integrated-report>

¹² *Id.* (“In 2015, MDR [multi-drug resistance] in *Salmonella* serotype Dublin continued to increase, accounting for 11 out of 12 human isolates and 28 out of 31 cattle PR/HACCP isolates.”).

¹³ *Id.* at 6.

¹⁴ Jones TF, Ingram LA, Cieslak PR, et al. Salmonellosis outcomes differ substantially by serotype. *J Infect Dis.* 2008;198:109-114.

¹⁵ <https://www.cdc.gov/salmonella/dublin-11-19/index.html>

standards for *Salmonella* in ground beef were developed by rulemaking in 1996.¹⁶ Under that initial rule, FSIS could detect *Salmonella* in up to 7.5% of samples (5 of 53) collected from an establishment, without any enforcement consequences. If an establishment exceeded this rate, however, FSIS would eventually withdraw its inspectors, effectively shutting down production. According to FSIS, the introduction of “microbiological performance standards” were “part of a fundamental shift in FSIS regulatory philosophy and strategy,” away from “intensive ‘command-and-control’ prescription” towards a system that sets objective targets while “provid[ing] industry with the flexibility to devise the optimal means of achieving food safety objectives.”¹⁷

Microbial performance standards sit at the heart of this approach because of their direct connection to human illness, as stated in the 1996 Final HACCP Rule:

Pathogen-specific performance standards for raw products are an essential component of the FSIS food safety strategy because they provide a direct measure of progress in controlling and reducing the most significant hazards associated with raw meat and poultry products.¹⁸

Not long after the rule went into effect, however, industry successfully challenged FSIS’s authority to enforce microbial performance standards, seriously undermining the effectiveness of the new regulatory system.

According to the Fifth Circuit Court of Appeal’s decision in *Supreme Beef v. USDA*, FSIS cannot withdraw inspectors from a ground beef processor solely because it fails to meet performance standards for a pathogen, so long as FSIS does not consider that pathogen to be an adulterant.¹⁹ Rather, FSIS must additionally show that the conditions in the establishment are “insanitary” for the purposes of the Federal Meat Inspection Act. This has led the agency to use performance standards as a trigger for more rigorous inspection. According to the proposed performance standards, “FSIS has used *Salmonella* failures as a basis to conduct an in-depth evaluation of the establishment’s Hazard Analysis and Critical Control Point systems, including its HACCP plan and Sanitation Standard Operating Procedures.” As described further below, FSIS also regularly posts the results of performance standard testing online, a process that further motivates compliance with the standards by allowing major customers (including retail and foodservice chains) to select producers that comply with the standards.

Over the years, this system has resulted in modest reductions in *Salmonella* prevalence. While the performance standard set in 1996 requires fewer than 7.5 percent of samples to test positive for *Salmonella*, only 3.89 percent of ground beef sampled by FSIS in 2018 tested positive for *Salmonella*.²⁰ These numbers likely reflect an improvement, yet a system that allows approximately 4 percent of ground beef to carry *Salmonella* still places consumers at unacceptable risk. The proposed performance standard does not go far enough to reduce these rates, setting the standard at 2 of every 48 samples

¹⁶ FSIS. “Pathogen Reduction; Hazard Analysis and Critical Control Point Systems” [“PR/HACCP Rule”], 61 *Fed. Reg.* 38805 (July 25, 1996), available at: <https://www.fsis.usda.gov/wps/wcm/connect/e113b15a-837c-46af-8303-73f7c11fb666/93-016F.pdf?MOD=AJPERES>

¹⁷ *Id.* at 38836.

¹⁸ *Id.* at 38812.

¹⁹ *Supreme Beef Processors, Inc. v. U.S. Dept. of Agriculture*, 275 F.3d 432, 440 (5th Cir. 2001).

²⁰ <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/sampling-project-results>

(4.2 percent), slightly above the current average detected by FSIS. This level still permits substantial contamination and would allow establishments to continue to knowingly sell product that is known to be contaminated with *Salmonella*.

FSIS's own risk assessment also indicates that the proposed approach would not be fully successful even at ensuring a contamination rate of 2 of every 48 samples. The risk assessment assumes that just "50% of establishments not meeting the standard initially will eventually meet it."²¹ The other 50% will continue to put out product with higher levels of contamination, while draining public resources devoted to an increased inspection presence.

There is no need to settle for such half measures. The presence of *Salmonella* in ground beef "ordinarily render(s) it injurious to health," and so FSIS is well within its authority to interpret *Salmonella* as an adulterant in ground beef.²² Doing so will create much stronger incentives to drive down contamination, because establishments that do not meet the standards will not be allowed to sell their product.

A Zero Tolerance for *Salmonella* in Ground Beef is Feasible and More Protective of Consumers

Fortunately, the experience of the National School Lunch Program (NSLP) shows that getting *Salmonella* out of ground beef is not only possible, but cost-effective. USDA's Agricultural Marketing Service (AMS) has succeeded in eliminating *Salmonella* contamination from over \$150 million worth of ground beef purchased each year for school meals, with just 0.7% of samples taken from active suppliers of the program testing positive for the pathogen.²³

The AMS zero tolerance policy is long-standing, dating back to 2001.²⁴ AMS further strengthened its standards in 2009, following revelations that a company issued a recall for ground beef with suspected multi-drug resistant *Salmonella* contamination from several retailers, but not from schools.²⁵ Since 2009, AMS has performed more frequent and rigorous testing for *Salmonella*, and required additional slaughter procedures to control pathogens, such as removal of major lymph glands and application of at least two processing interventions.²⁶ AMS requires establishments to demonstrate that they meet these standards before contracting with them. If a shipment of ground beef tests positive for *Salmonella*, AMS sends it back, and the supplier may not sell it to another USDA program.²⁷ AMS will ban suppliers whose products repeatedly fail tests. Recent analysis of the NSLP by

²¹ Risk assessment at ____.

²² See 21 U.S.C. 601(m).

²³ Michael Ollinger and John Bovay. "Strict Standards Nearly Eliminate Salmonella From Ground Beef Supplied to Schools." *Amber Waves*, (Feb. 02, 2015), available at: <https://www.ers.usda.gov/amber-waves/2015/januaryfebruary/strict-standards-nearly-eliminate-salmonella-from-ground-beef-supplied-to-schools/>

²⁴ <https://www.webmd.com/food-recipes/food-poisoning/news/20010405/bush-reverses-plan-to-end-salmonella-tests-on-school-lunch-meat#1>

²⁵ <https://abcnews.go.com/Health/recall-tainted-beef-include-school-lunches/story?id=9226381>

²⁶ Michael Ollinger, Joanne Guthrie, and John Bovay, *The Food Safety Performance of Ground Beef Suppliers to the National School Lunch Program*, USDA, Economic Research Service, (Dec. 2014) available at: <https://www.ers.usda.gov/publications/pub-details/?pubid=45329>

²⁷ *Id.* at 7.

government researchers indicates that zero tolerance for *Salmonella* is cost-effective, and the NSLP policy has driven down pathogen contamination dramatically.²⁸

The proposed performance standards suggest it would not be feasible to eliminate *Salmonella* from the food supply more broadly, saying that “[c]urrently, events that cause contamination of beef carcasses cannot be completely eliminated from commercial slaughter, fabrication, or further processing operations.” Yet similar claims could also have been made against eliminating O157:H7 and other STECs from ground beef. While it is true that some contamination may occur during slaughter, declaring these strains to be adulterants has driven the development of effective control measures, which have dramatically reduced contamination rates, and in turn, human illness.²⁹ In addition, USDA has required establishments to institute a “test and hold” program, whereby ground beef is not distributed until it has been sampled and tested negative for O157:H7.³⁰ Positive samples can then be diverted for cooking, avoiding food waste while ensuring that harmful pathogens are rendered harmless before the meat is offered to the consumer.

In the Absence of an Adulterant Determination, FSIS Should Use All of the Tools at its Disposal to Ensure Compliance

Barring the adoption of a zero-tolerance strategy for *Salmonella* in ground beef, FSIS should ensure that establishments have strong incentives to comply with performance standards. We therefore support several actions the agency has proposed to encourage compliance with the standards. Specifically, we support the proposal to take additional verification actions for establishments that do not meet performance standards.³¹

We also support the proposal to post the category of individual establishments monthly on the FSIS website. We strongly agree with FSIS that “web posting delivers greater transparency, thereby providing the public with the tools and information it needs to make informed food safety decisions.”³² Indeed, USDA’s Economic Research Service (ERS) has found a “strong correlation” between the availability of this information, and poultry processors’ success in meeting food safety goals.³³ According to ERS, web-posting data provides a “tool for encouraging compliance with food

²⁸ *Id.*

²⁹ Following the 1994 decision to declare *E. coli* O157:H7 an adulterant in raw ground beef, illnesses associated with the pathogen plummeted from 2.6 cases per 100,000 population in 1996 to 1.1 cases per 100,000 in 2012. See Craig W. Hedberg, Jeff B. Bender, Fernando Sampedro, Scott J. Wells. “Potential Impacts of Classifying Specific Strains of *Salmonella* with Multi-Drug Resistance as Adulterants in Ground Beef and Poultry Products,” (Jan. 2015), <https://www.foodpolicy.umn.edu/policy-summaries-and-analyses/potential-impacts-classifying-specific-strains-salmonella-multi-drug> citing Center for Disease Control and Prevention. Incidence and trends of infection with pathogens transmitted commonly through food — Foodborne diseases active surveillance network, 10 U.S. Sites, 1996–2012. *MMWR* 2013 62(15); 283-287.

³⁰ See FSIS. “Not Applying the Mark of Inspection Pending Certain Test Results,” 77 *Federal Register* 73401-73411, (Dec. 10, 2012), <https://www.fsis.usda.gov/wps/portal/frame-redirect?url=https://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0044FN.htm>.

³¹ Notice at 57692.

³² Notice at 57691.

³³ Michael Ollinger, James Wilkus, Megan Hrdlicka, and John Bovay. “Public Disclosure of Tests for *Salmonella*: The Effects on Food Safety Performance in Chicken Slaughter Establishments.” Economic Research Report No. (ERR-231), (May 2017), <https://www.ers.usda.gov/publications/pub-details/?pubid=83660>

safety” that does not “require costly regulatory oversight and labor devoted to compliance,” but rather creates a market where “buyers determine the appropriate level of food safety and costs.”³⁴

FSIS also should share additional data on *Salmonella* isolates detected in ground beef and other FSIS-regulated products, including unique whole-genome sequencing (WGS) identifiers. As noted in the proposed performance standards, “FSIS monitors relevant databases (e.g., those maintained by the CDC and the National Institutes of Health) for clinical isolates that match (via WGS) food isolates obtained by FSIS in its sampling of products produced by official establishments. This monitoring gives FSIS early warning that an outbreak involving an establishment’s product could be developing.” The same identifiers that FSIS uses to monitor outbreaks should help inform ground beef and trim purchasers of an establishment’s food safety risk. Using publicly available databases of clinical isolates, purchasers could easily determine whether a *Salmonella* strain found in a particular establishment matches one found in a case patient. Currently, however, FSIS does not share the WGS data it holds with the public—or even with establishments themselves, unless the establishment or a trade group specifically requests this information, or the establishment is implicated by traceback or epidemiological data in an outbreak investigation. As Senator Gillibrand and Representative DeLauro pointed out in a recent letter to Secretary Perdue, “by disclosing [WGS] data, USDA will foster market-based incentives for safer meat and poultry.”³⁵ FSIS should not delay further in adopting this market-friendly reform.

Standards for Beef Trim are Necessary and Appropriate

The 1996 *Salmonella* performance standards apply only to ground beef, and not to beef trim. The proposed performance standards seek to extend standards to beef trim. As the proposed performance standards explain, beef trim refers to the “primary component of raw ground beef” and includes “trim of any size and primal or subprimal cuts, such as chucks, rounds, or shanks, or boneless beef of any size used at the slaughter establishment for non-intact use, or that is intended for raw non-intact use by other establishments.” We agree that “a performance standard is needed for beef manufacturing trimmings to assist grinding establishments that purchase this product for further processing in managing *Salmonella* contamination in their ground beef.” We further agree with FSIS that microbiological performance standards for beef trim would help to “address the market failure from information asymmetry between producers and buyers.” Notably, AMS requires that its ground beef suppliers only use trim and other “inputs” from AMS-approved slaughter establishments, which are subject to additional controls, such as removal of lymph nodes.³⁶

Conclusion

Our understanding of foodborne illness has progressed significantly since 1996, when the current microbiological performance standards for ground beef were finalized. Thanks in part to the

³⁴ *Id.* at 25.

³⁵ <https://delauero.house.gov/media-center/press-releases/amid-multistate-ground-beef-salmonella-outbreak-delauero-and-gillibrand>

³⁶ See ERS, *supra* note 15.

leadership of USDA's AMS, we now know that consumers need not sacrifice food safety for the sake of affordability, nor tolerate any *Salmonella* contamination at all in ground beef. We commend FSIS for taking this step to reduce *Salmonella* contamination in ground beef, and encourage the agency to go further, following the lead of AMS, and take bold action to protect consumers by declaring raw ground beef contaminated with *Salmonella* to be adulterated.

Thank you for your consideration of these comments.

Sincerely,

Consumer Federation of America

Food & Water Watch

Government Accountability Project

National Consumers League