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Docket Clerk, U.S. Department of Agriculture,
Food Safety and Inspection
Service, 1400 Independence Avenue
SW, Mailstop 3758, Room 6065,
Washington, DC 20250–3700

Re: Salmonella -- State of the Science [Docket No. FSIS–2020–0025]

The Pew Charitable Trusts appreciates this opportunity to comment on the Roadmap to Reducing *Salmonella*, recently released by the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS). Pew’s Safe Food Project, created in 2009, advocates for policies and practices that reduce foodborne illness. Much of its current work focuses on bringing down the number of *Salmonella* infections linked to poultry.

Twenty-five years after FSIS finalized its landmark Pathogen Reduction (PR)/HAACP rule, the fundamental question related to *Salmonella* is: has the number of *Salmonella* infections linked to meat and poultry decreased? The answer is no:

- After some initial reductions, the incidence of *Salmonella* infections has not significantly decreased since 2000.¹
- The U.S. did not meet the Healthy People 2020 goals for *Salmonella* reduction, which was set at 11.4 cases per 100,000. In fact, not only did the nation not meet this goal, those infections increased in 2019 to 17.1 cases per 100,000.²
- While the incidence of human infections caused by certain *Salmonella* serotypes has declined, others have increased.²
- Multi-year outbreak data from the Interagency Food Safety Analytics Collaboration (IFSAC) shows that the estimated percentage of foodborne *Salmonella* illnesses attributed to meat and poultry has not gone down. Those attributed to chicken have, in fact, gone up, and the proportion of illnesses attributed to turkey remained relatively steady over the five-year reporting period.³

¹ Centers for Disease Control and Prevention (CDC). FoodNet Fast. <https://wwwn.cdc.gov/foodnetfast/>.

² D. Tack et al, “Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019,” *MMWR Morb Mortal Wkly Rep* 2020;69:509–514. https://www.cdc.gov/mmwr/volumes/69/wr/mm6917a1.htm?s_cid=mm6917a1_w.

³ Interagency Food Safety Analytics Collaboration (IFSAC). Foodborne illness source attribution estimates for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak

IFSAC estimates of percentages of foodborne *Salmonella* illnesses attributed to meat and poultry

	2013	2014	2015	2016	2017
Chicken	10.4	11.6	11.8	12.7	14.0
Turkey	6.9	6.4	6.4	5.5	6.2
Pork	9.3	9.7	10.5	10.8	10.3
Beef	9.1	8.3	7.3	6.9	6.4
Other meat and poultry	0.9	0.9	0.9	1.1	1.1
Total	36.6	36.9	36.9	37	38

Given the lack of progress in reducing *Salmonella* infections over more than two decades, FSIS is long overdue in reconsidering its approach to this particular pathogen. The regulations and policies currently in place are clearly not working to bring down human illnesses associated with the products the agency regulates. As the chart above illustrates, with nearly 40% of foodborne salmonellosis cases currently attributed to meat and poultry, there is no question that effective efforts by FSIS to reduce the number of *Salmonella* infections would have a significant impact on the burden of foodborne illness.

FSIS’s *Salmonella* Roadmap is missing an important opportunity to articulate a bold, visionary approach to achieve more effective *Salmonella* control in U.S. food animal production. Most of its content uncritically assesses the comparatively ineffective approaches undertaken to date by the agency. Its few, suggested new paths may prove fruitful but lack concrete milestones and timelines for accomplishing them. The Roadmap focuses on agency policies that the agency has followed for many years and have led to unsatisfactory outcomes. It appears that most of the agency’s interest is focused on the already documented reductions in the rates of *Salmonella* contamination in meat and poultry products,⁴ while little discussion addresses how to rectify the sharp disconnect between decreases in contamination of meat and poultry products and the desired reduction in human illnesses.

FSIS must be genuinely bold if it is to succeed in tackling this persistent public health challenge. Discussed below are important changes to FSIS’s central tools – performance standards and data collection– that Pew strongly recommends must happen in order for the agency to succeed in improving food safety and reducing the burden of human salmonellosis. Pew welcomes the

surveillance data, United States. Atlanta, Georgia and Washington, District of Columbia: U.S. Department of Health and Human Services, CDC, FDA, USDA/FSIS. 2013 – 2017. <https://www.cdc.gov/foodsafety/ifsac/annual-reports.html>.

⁴ While *Salmonella* contamination in meat and poultry products has decreased, the direction and magnitude of reduction is not consistent over time or across commodities, as demonstrated by a recent paper by FSIS researchers, published in *the Journal of Food Protection*. The paper also underscores how slow the progress towards reducing *Salmonella* has been. Further, the authors note that “there may have been little to no actual reduction in *Salmonella* contamination of chicken carcasses between roughly 2011 and 2017.” M. Williams et al, “Changes in *Salmonella* Contamination in Meat and Poultry Since the Introduction of the Pathogen Reduction and Hazard Analysis and Critical Control Point Rule,” *J Food Prot* (2020) 83 (10): 1707–1717. <https://doi.org/10.4315/JFP-20-126>.

opportunity to work with FSIS and other stakeholders to develop effective policies to reduce *Salmonella* infections linked to meat and poultry products.

FSIS’s current approach of basing performance standards on prevalence is not working to improve public health, so the agency should consider revising the standards to include quantification and other factors that are relevant to human health risk

Pew shares FSIS’s goal to ground its regulations and policies on science and data; however, the agency’s continued reliance on a prevalence-based performance standard (i.e. where only presence/absence of the pathogen is taken into consideration to measure an establishment’s performance) does not represent the *best* science. It might have represented the best science in 1995, but it clearly does not in 2020.

For many years, experts have questioned the effectiveness of standards based on prevalence alone. A decade ago, a team of top *Salmonella* and food experts noted:

Salmonella contamination is usually expressed in terms of prevalence, but evidence from microbiological risk assessment indicates that levels of contamination can be even more important to public health, and efforts at any stage of production or processing that reduce the level of *Salmonella* on the end product will reduce risk. With the development of better means of enumerating *Salmonella* and methods that are internationally acceptable, this aspect should receive greater attention in the future, enabling more heavily contaminated items to be identified and suitable interventions developed.⁵

Other publications and risk assessments^{6,7,8} over nearly two decades have reinforced the view that concentration of pathogens in foods is important when trying to reduce microbial risk. For example, a quantitative risk assessment (QMRA) conducted in Canada was able to reduce the predicted probability of illness by 40% when the concentration level of *Salmonella* in chicken breast at retail was reduced by 50%.⁹ In addition, a study in Belgium also found that chicken

⁵ G. Mead, et al., “Scientific and technical factors affecting the setting of *Salmonella* criteria for raw poultry: a global perspective.” *Journal of Food Protection* vol. 73,8 (2010): 1566-90. doi:10.4315/0362-028x-73.8.1566.

⁶ A Havelaar et al., “Fine-tuning Food Safety Objectives and risk assessment,” *Int J Food Microbiol.* 2004 May 15;93(1):11-29. doi: 10.1016/j.ijfoodmicro.2003.09.012. PMID: 15135579.

⁷ E Lambertini et al., “The public health impact of different microbiological criteria approaches for *Salmonella* in chicken parts,” *Microbial Risk Analysis.* 2019. 12: 44-59. <https://doi.org/10.1016/j.mran.2019.06.002>.

⁸ T Oscar, “*Salmonella* Prevalence Alone Is Not a Good Indicator of Poultry Food Safety,” *Risk Analysis* 2020. <https://doi.org/10.1111/risa.13563> (2020).

⁹ H. Smadi and J Sargeant, “Quantitative risk assessment of human salmonellosis in Canadian broiler chicken breast from retail to consumption,” *Risk Anal.* 2013 Feb;33(2):232-48. doi: 10.1111/j.1539-6924.2012.01841.x. Epub 2012 May 22. PMID: 22616714. This was the most significant decrease, followed by reducing the reuse of contaminated cutting boards (29%), improving hand washing practices (15%), and finally improving cooking practices (5%).

meat above 1 CFU/g was most likely to be associated with human salmonellosis.¹⁰

Pew urges the agency to use the best science, its team of risk assessors, and available, modern analytical methods to develop aggressive performance standards that are more likely to result in significant reduction in *Salmonella* infections. The Roadmap states in its “Looking Forward” section that future agency activities *might* include, “examining and considering semi-quantitative methods for *Salmonella* enumeration to inform future risk assessments.” We strongly support this action and encourage FSIS to immediately begin conducting risk assessments to explore the public health impact of semi-quantitative and quantitative performance standards (i.e. those based on concentration of pathogens or bacterial load).

Today, there is technology that enables rapid enumeration of *Salmonella* in meat and poultry. Modern PCR tests are able to process samples in a matter of hours and have been used regularly by at least one large turkey processor (i.e. Cargill) to prevent highly contaminated products from reaching consumers.

In addition to considering quantification, FSIS should examine other innovative approaches to setting performance standards by targeting specific serotypes of public health importance and by focusing on virulence. In a recent paper, a researcher with USDA’s Agricultural Research Service demonstrated, using a QMRA, the importance of evaluating multiple risk factors when developing standards, such as concentration, virulence, and data from post-processing risk factors (e.g., temperature abuse, cross contamination).⁶ The author noted that *Salmonella* prevalence alone was not a good indicator of poultry food safety because there were other risk factors that need to be considered. He demonstrated that even though ground chicken had a lower *Salmonella* prevalence than ground turkey at meal preparation, it posed a higher risk of salmonellosis because it was contaminated with higher numbers of more virulent serotypes of *Salmonella* than ground turkey.⁶

Researchers at Cornell University are currently conducting research, partially funded by Pew, that examines how FSIS could incorporate into its strategies information about the virulence and public health relevance of different *Salmonella* serotypes and subtypes to reduce the public health impact of human salmonellosis attributed to meat and poultry. The results of this research could generate a framework for identifying emerging virulence genes and propose a way to integrate it into a modernized approach to setting performance standards.

FSIS should revise its performance standards so that they better incentivize the use of effective, on-farm, pre-harvest interventions that could reduce contamination

There is a clear consensus that to effectively control *Salmonella* contamination, the pathogen load on livestock and poultry entering the slaughterhouse must be reduced as much as possible, so that post-harvest measures can reduce the remaining contamination. Many on-farm interventions – including vaccines, probiotics, and biosecurity – have been developed since the

¹⁰ M Uyttendaele et al., “Comparing the effect of various contamination levels for *Salmonella* in chicken meat preparations on the probability of illness in Belgium,” *J. Food Prot.* 2009 Oct;72(10):2093-105. doi: 10.4315/0362-028x-72.10.2093.

Pathogen Reduction/HACCP rule was finalized. However, there are currently few -- if any -- meaningful regulatory and financial incentives for companies to use these interventions more broadly.

Recent decreases in human illnesses caused by *S. Typhimurium* and *S. Heidelberg* have been attributed, among other measures, to on-farm interventions adopted by the poultry industry¹¹ in response to high-profile multi-state outbreaks. This experience demonstrates the efficacy of those interventions and the ability of industry to adopt them on a large scale.

The fact that FSIS does not have direct authority to regulate on the farm does not preclude it from incentivizing the use of pre-harvest interventions. There are a number of actions it could take. First, FSIS should update and finalize its *2015 Draft Compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry*, which includes helpful guidance on effective pre-harvest interventions.

Second, the agency should go beyond this step and explore amending its HACCP regulations to add a program that was included by the Food and Drug Administration in its regulations establishing preventive controls for processed food. The FDA regulations include a requirement that a “supply-chain program” be established for raw materials and other ingredients that a receiving facility identifies as hazardous. Suppliers of those ingredients must provide a receiving facility with documentation verifying that the ingredients being supplied are safe.

Such a “supply-chain program” for live food animals is consistent with a HACCP system; it would not prescribe what pre-harvest measures must be used but, rather, it would require that the suppliers of livestock and poultry verify that animals and birds being supplied are safe. This proposal is not the first time that FSIS has discussed the pre-market stage of animal agriculture in the context of HACCP. For example, section 417.2 of the PR/HACCP final rule requires every establishment to conduct a hazard analysis and to develop a prevention-based HACCP plan to address those hazards. It directs establishments to include in that plan food safety hazards that occur “before, during, and after entry into the establishment.”¹² This language clearly suggests some measure of agency oversight to mitigate food safety hazards that occur on the farm, prior to arrival of livestock and poultry at a slaughtering establishment.

Moreover, FSIS has taken regulatory actions that indirectly affect on-farm practices that could reduce the level of pathogens on livestock and poultry arriving for slaughter. For example, the agency issued a notice in 2012 requiring poultry establishments producing “Not Ready to Eat” (NRTE) comminuted (ground) poultry products to reassess their HACCP plans to take into account several *Salmonella* outbreaks linked to their products. In that notice, FSIS directed that establishments producing comminuted product should evaluate the adequacy of *Salmonella* interventions applied to source materials and the effectiveness of these interventions in reducing *Salmonella*. Moreover, they should also consider “incoming variability of *Salmonella* levels” in live birds and on parts. The agency went further and recommended that establishments producing NRTE comminuted poultry implement purchase specifications that require raw materials to have

¹¹ The 2019 FoodNet report speculates this is due to the widespread practice of vaccinating chickens against *S. Typhimurium*, which shares antigens with *S. Heidelberg*.

¹² 61 Fed. Reg. 38806,38869 (1996), (emphasis added).

been treated with an intervention shown to reduce *Salmonella*.¹³

Expanded surveillance efforts are needed to obtain a more complete picture of *Salmonella* contamination in meat and poultry

Pew encourages FSIS to explore new strategies to maximize existing data collection through FoodNet, NARMS, isolates associated with inspection activities, and proprietary and private laboratory data. Through these strategies, it will obtain a more complete picture of *Salmonella* contamination in livestock and poultry operations from farm to fork and develop more effective control strategies. On-going information on pathogen prevalence and load throughout the food-production continuum will enable establishments to continuously calibrate pre-harvest and in-plant interventions. The agency should also focus on improving the availability of meta-data while at the same time addressing the broader question of whether new or complementary data collection tools may be needed.

Conclusion

Pew appreciates this opportunity to comment on the FSIS Roadmap to Reducing *Salmonella* and urges the agency to take more aggressive, effective action that will reduce *Salmonella* infections linked to meat and poultry products.



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¹³ 77 Fed. Reg. 72686, 72688 (2012).