

THE JOURNAL OF FEDERAL AGENCY ACTION

Editor's Note: A Lot Is Happening (Still)

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Department of Justice Launches Pilot Program to Reward Corporate Whistleblowers

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Department of Agriculture Food Safety and Inspection Service Announces Proposed Rule Under Salmonella Framework for Raw Poultry Products

Peter Tabor and Patrick G. Selwood

Treasury Department Issues Final Investment Advisers AML/CFT Program Rule

Darshak S. Dholakia, Thomas C. Bogle, Meagan Cox, and Emily Towill

Federal Trade Commission's Enforcement Action Against Avast Signals Increased Focus on Consumer Web Data

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Tribal General Welfare Exclusion Proposed Regulations Are an Overdue Win for Indian Country

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Federal Agencies Begin to Implement the Financial Data Transparency Act

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The End of Chevron Deference Could Spell Trouble for the Environmental Protection Agency PFAS "Hazardous Substance" Rule

Reza Zarghamee and Steve R. Brenner

What's Next After the Private Fund Adviser Rules?

Robin Bergen and Rachel Gerwin

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- 5 Editor’s Note: A Lot Is Happening (Still)**
Victoria Prussen Spears
- 9 Department of Justice Launches Pilot Program to Reward Corporate Whistleblowers**
Steven E. Fagell, Adam M. Studner, Addison B. Thompson, and
Brendan C. Woods
- 23 Department of Agriculture Food Safety and Inspection Service Announces Proposed Rule Under Salmonella Framework for Raw Poultry Products**
Peter Tabor and Patrick G. Selwood
- 31 Treasury Department Issues Final Investment Advisers AML/CFT Program Rule**
Darshak S. Dholakia, Thomas C. Bogle, Meagan Cox, and Emily Towill
- 37 Federal Trade Commission’s Enforcement Action Against Avast Signals Increased Focus on Consumer Web Data**
Kirk J. Nahra, Ali A. Jessani, and Amy Olivero
- 45 Securities and Exchange Commission Adopts New Regulation NMS Rules on Tick Sizes, Access Fees, and Market Data**
Andre E. Owens, Bruce H. Newman, Stephanie Nicolas, Tiffany J. Smith,
and Kyle P. Swan
- 51 Tribal General Welfare Exclusion Proposed Regulations Are an Overdue Win for Indian Country**
Kenneth W. Parsons and Rachel T. Provencher
- 61 Federal Agencies Begin to Implement the Financial Data Transparency Act**
Michael Nonaka, David H. Engvall, David Fredrickson, and
David B.H. Martin
- 65 The End of Chevron Deference Could Spell Trouble for the Environmental Protection Agency PFAS “Hazardous Substance” Rule**
Reza Zarghamee and Steve R. Brenner
- 69 What’s Next After the Private Fund Adviser Rules?**
Robin Bergen and Rachel Gerwin

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Department of Agriculture Food Safety and Inspection Service Announces Proposed Rule Under Salmonella Framework for Raw Poultry Products

Peter Tabor and Patrick G. Selwood*

In this article, the authors discuss the latest effort by the U.S. Department of Agriculture to reduce salmonella in poultry products, which effectively acknowledges that efforts to encourage consumers to eliminate salmonella through proper handling and cooking have not appreciably reduced salmonella-related illness associated with raw chicken and turkey products.

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) (collectively, the Agency)¹ recently issued a proposed rule² aimed at reducing salmonella contamination in raw poultry products destined for human consumption.³

The proposed rule comes on the heels of the Agency's final rule,⁴ published in May 2024, declaring salmonella an "adulterant" when present in certain quantities in breaded, stuffed, not-ready-to-eat (NRTE) chicken products.⁵ Under the proposed rule issued on July 29, 2024, raw chicken and turkey products containing certain salmonella serotypes and levels would be considered adulterated within the meaning of the Poultry Products Inspection Act.⁶ The Agency's proposal would also require poultry slaughter and processing establishments to implement internal procedures—including the use of monitoring and sampling programs—aimed at reducing these adulterants to prescribed regulatory limits and otherwise ensuring compliance with Agency standards. The Agency indicates it is taking these steps because, while current salmonella pathogen-reduction standards have yielded positive results in terms of reduced salmonella levels in raw poultry products, "these measures have yet to have an impact on human illness rates."

If finalized as proposed, the rule is likely to impose considerable financial and operational burdens on producers in America's

poultry industry, many of whom indicated their opposition to contemplated changes during the stakeholder engagement process prior to rulemaking and in response to this proposed rule when it was announced in late July 2024.

Background

Motivation

Salmonella is a significant contributor to food safety and human health concerns. According to the U.S. Centers for Disease Control and Prevention (CDC), food is the leading source of salmonella infections, and poultry is among the leading sources of foodborne salmonella illnesses. The CDC estimates that salmonella from all sources is responsible for 1.3 million illnesses, 26,500 hospitalizations, and 420 deaths each year. The Agency estimates that of the annual number of salmonella illnesses from poultry, 42,000 are associated with turkey, while 125,000 come from chicken products—the latter is estimated to cost the United States more than \$2.8 billion in economic losses annually.⁷

The Agency's efforts to curb rates of salmonella illness date back decades. With its "Pathogen Reduction; Hazard Analysis and Critical Control Point" (PR/HACCP) final rule, published in July 1996, the Agency began its salmonella-verification testing program.⁸ The PR/HACCP rule established salmonella pathogen reduction performance standards for establishments that slaughter or process certain classes of animals and raw ground meat products. Although these performance standards, which were regularly updated, achieved reductions in salmonella detections in poultry, there was no observable reduction in human illness.

Latest Development in Biden Administration's Trend of Increased Agency Regulation of the Poultry Industry

The USDA's approach⁹ under the Biden administration to addressing foodborne illness has been to place a greater onus on producers and processors to reduce the presence of the pathogen in food, including raw or NRTE poultry products. This is in part an acknowledgment that consumer behavior has not reduced incidents of foodborne illness associated with raw poultry products.

In early 2020, the Agency began receiving petitions from consumer advocacy organizations and other stakeholders, noting the failure of the Healthy People 2030 initiative¹⁰ to meet its salmonella reduction targets and requesting that USDA revise its approach to reducing salmonella illnesses associated with poultry products. Over the next three years, USDA continued to receive comments urging the department to take various steps to reduce the number of cases of salmonella illness in humans associated with poultry. In particular, a 2021 petition¹¹ submitted by the Center for Science in the Public Interest urged the Agency to take action against the salmonella strains that posed the greatest risks to human health risk by requiring that poultry establishments identify and control foodborne hazards within their supply chains.

In late 2021, the Agency announced it would begin gathering data in an effort to identify new steps to meet its goal of reducing salmonella human illness associated with poultry—a goal consistent with the Healthy People 2030 goal of a 25 percent reduction in salmonella illnesses. Through extensive stakeholder engagement, data gathering, and analysis, including industry pilot projects to evaluate different control strategies for salmonella in poultry products, the Agency took steps to identify the salmonella serotypes of greatest concern to human health and evaluated supply chain risks. In August 2022, in part based on its data collection, FSIS announced¹² that it would declare salmonella an adulterant in breaded and stuffed NRTE chicken products. The rule was finalized in May 2024.

The Proposed Rule

In announcing its proposed rule, the Agency noted that the “proposed framework is a systematic approach to addressing salmonella contamination at poultry slaughter and processing, which includes enforceable standards that will result in safer food for consumers and fewer illnesses.” The Agency assesses three main components of the framework in reverse order in the proposed rule, in terms of their effectiveness and the Agency’s intention to propose new requirements.

First and most significantly, the rule sets new limits for certain levels and serotypes of salmonella in raw chicken and ground turkey products.¹³ Violative products would be considered adulterated and

prevented from entering commerce. Specifically, the final framework states that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey are adulterated if they contain any type of salmonella at or above 10 colony forming units (CFU) per milliliter or gram in analytical portion (i.e., milliliter of rinsate or gram of product) and contain any detectable level of at least one of the salmonella serotypes of public health significance identified for that commodity. The proposed rule identifies the salmonella serotypes Enteritidis, Typhimurium, and I 4,[5],12:i:- for raw chicken carcasses, chicken parts, and comminuted chicken. The proposed rule identifies salmonella serotypes Hadar, Typhimurium, and Muenchen for raw comminuted turkey. These are the most highly virulent salmonella serotypes associated with these products identified in the FSIS chicken and turkey risk assessments. FSIS indicates the “salmonella serotypes of public health significance will likely change over time as the serotypes commonly associated with human illnesses change.” The Agency intends to reevaluate the salmonella serotypes of public health significance at least every three to five years and whenever new information becomes available.

Second, the proposed rule seeks to enhance industry control by updating the requirements in 9 C.F.R. 381.65(g) and (h) for poultry establishments to develop and implement a microbial monitoring program to prevent pathogen contamination throughout the slaughter system. Specifically, establishments would be required to “incorporate statistical process control (SPC) monitoring principles into their microbial monitoring programs (MMPs).” Notably, testing of product to ensure effectiveness of controls would require that sampled and tested product be held until test results were obtained and evaluated, with establishments required to have written plans for responding to circumstances where violations of the regulation are found. Notably, the Agency states it will make resources available to very small and very low-volume establishments to facilitate compliance with this requirement. Finally, FSIS proposes that establishments would be required to submit their microbial monitoring data to the Agency electronically.

Third, the Agency evaluated the need for more stringent pre-harvest measures for incoming chicken and turkey to reduce the pathogen load establishments would have to address in order to meet proposed limits for pathogen presence in products entering commerce.¹⁴ Notably, the draft framework under which this proposed rule was developed examined the role that preharvest

measures such as testing live birds for salmonella prior to receiving might have on reducing the incidence of salmonella in raw chicken and turkey. After evaluating both the cost and effectiveness of such measures, including the burden on small establishments, “FSIS has decided at this time not to establish a regulatory requirement that establishments characterize salmonella as a hazard reasonably likely to occur at receiving or that incoming flocks be tested for salmonella before entering an establishment.”

Agency’s Predicted Outcomes, Public Reception and Possible Implications

One of the main costs associated with the rule, if finalized as proposed, relates to holding product during testing. Specifically, the proposed rule would require that “establishments subject to FSIS verification sampling for adulterants maintain control of sampled product pending test results.” FSIS estimates the total costs to U.S. producers at between \$3.31 million and \$32.25 million.

According to the Agency, the proposed rule would save \$20.5 million annually—an estimate that includes benefits to consumers from lower illness rates and avoided costs from reducing the risk of outbreak-related recalls for poultry products.

In anticipation of legal challenges to this rule if finalized, the Agency indicates that, “if any of [its provisions] were to be set aside by a reviewing court, FSIS would intend for the remainder of this action to remain in effect.” In light of the U.S. Supreme Court’s decision in *Loper Bright Enterprises v. Raimondo*¹⁵ (effectively eliminating the deference courts must show to agency interpretations of vague statutory language), the Agency is preparing for this regulation to be challenged by stakeholders who disagree with its approach.

Conclusion

This FSIS proposed rule is a significant step by the Agency under the Biden administration to place more responsibility for product safety on establishments, effectively acknowledging that consumer behavior and practices are insufficient to reduce salmonella-related foodborne illnesses associated with raw chicken

and turkey products. This proposed rule's fate is uncertain with President-elect Trump set to move back into the White House in January. Both his views and those of his U.S. Department of Agriculture appointees (if/when confirmed), will impact the path forward, if any, for rulemaking.

Notes

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1. USDA is charged with implementing several acts of Congress, including the Poultry Products Inspection Act (PPIA), 21 U.S.C. § 451 et seq. Through the PPIA, Congress authorized the Secretary of Agriculture "to promulgate regulations 'to protect the health and welfare of consumers.'" *Dawkins ex rel. Est. of Dawkins v. United States*, 226 F. Supp. 2d 750, 752 (M.D.N.C. 2002) (21 U.S.C. § 451); see also 21 U.S.C. §§ 456, 463. The Secretary of Agriculture has delegated the task of administering the PPIA to FSIS, a sub-agency or branch of "[USDA] that focuses on ... food safety and inspection. *Dawkins*, 226 F. Supp. 2d at 751 (citing 9 C.F.R. § 300.2); *id.* ("Implementation of the PPIA is one of the 'primary regulatory responsibilities' of the FSIS.") (quoting 9 C.F.R. § 300.3(a)); see also 7 C.F.R. §§ 2.18(a)(1)(ii)(A), 2.53(a)(2)(i). This delegation includes, *inter alia*, implementing USDA's detailed regulations, many of which relate to poultry inspection and sanitation at processing plants. *Dawkins*, 226 F. Supp. at 752 (citing 9 C.F.R. § 381.1 et seq.). FSIS's principal means for carrying out these regulatory requirements is through conducting inspections of poultry-processing plants. *Dawkins*, 226 F. Supp. 2d at 752 ("The purpose of these inspections, consistent with the purpose of the PPIA, is to protect the 'health and welfare of consumers' 'by assuring that poultry products distributed to them are wholesome, not adulterated.'") (quoting 21 U.S.C. § 451).

2. https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-2023-0028.pdf.

3. See "USDA Proposes New Policy to Reduce Salmonella in Raw Poultry Products," USDA Press Release No. 0148.24, July 29, 2024; see also "Salmonella Framework for Raw Poultry Products," 89 FR 64678-01, 2024 WL 3673417(F.R.) (Aug. 7, 2024) (noting, *inter alia*, the Agency is proposing to revise the current regulations in 9 C.F.R. § 381.65 ("Poultry Products Inspection Regulations. Operating Procedures.") to include the requirements and policies set forth in the proposed rule).

4. https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-2022-0013F.pdf.

5. See “USDA Finalizes Policy to Protect Consumers from salmonella in Raw Breaded Stuffed Chicken Products,” USDA Press Release No. 0072.24, April 26, 2024.

6. <https://www.fsis.usda.gov/policy/food-safety-acts/poultry-products-inspection-act>. “The Poultry Products Inspection Act (PPIA), 21 U.S.C. §§ 451-472, was born out of a Congressional interest in protecting consumer health and welfare by enabling the Secretary of Agriculture to ensure that poultry products were ‘wholesome, not adulterated, and properly marked, labeled, and packaged.’” *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 909 (D.C. Cir. 2015) (quoting 21 U.S.C. § 451). The legislation achieves these goals in various ways, such as by requiring the Agency to ensure “that inspectors conduct a post-mortem inspection of all poultry processed for human consumption,” as well as by mandating Id. § 455(b). The PPIA also requires “condemnation and destruction for human food purposes of all poultry that is found to be adulterated, unless the poultry can be reprocessed under an inspector’s supervision so that it is found to be not adulterated.” *Food & Water Watch*, 808 F.3d at 909-10 (citing 21 U.S.C. § 455(b), (c)).

7. “Food Attribution and Economic Cost Estimates for Meat and Poultry-Related Illnesses,” Robert L. Scharff, *Journal of Food Protection*, 2020; 83(6): 959-967.

8. 61 FR 38806.

9. <https://www.usda.gov/media/press-releases/2021/10/19/usda-launches-new-effort-reduce-salmonella-illnesses-linked-poultry>.

10. A national program developed by the U.S. Department of Health and Human Services with the purpose of providing data-driven recommendations for achieving health-promotion and disease-prevention goals; <https://odphp.health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030>.

11. <https://www.fsis.usda.gov/policy/petitions/petition-submitted-center-science-public-interest>.

12. <https://www.usda.gov/media/press-releases/2022/08/01/usda-announces-action-declare-salmonella-adulterant-breaded-stuffed>.

13. The proposed salmonella serotypes of public health significance identified for raw chicken include Enteritidis, Typhimurium and I 4,[5],12:i:-; and for raw turkey include Hadar, Typhimurium, and Muenchen.

14. The proposed rule does not require poultry producers to test live chickens they receive.

15. *Loper Bright Enterprises v. Raimondo*, No. 22-451, 603 U.S. ____ (June 28, 2024).