



Consumer Federation of America

May 13, 2021

Sandra Eskin
Deputy Under Secretary for Food Safety
Food Safety and Inspection Service
U.S. Department of Agriculture

SUBMITTED VIA REGULATIONS.GOV

RE: Proposed rule to rescind regulations requiring condemnation of poultry affected with avian visceral leukosis complex (Docket No. FSIS-2021-0004)

Dear Deputy Under Secretary Eskin:

The Consumer Federation of America (CFA) writes to oppose the USDA Food Safety and Inspection Service's (FSIS) above-referenced proposed rule, which would grant the National Chicken Council's petition to allow slaughterhouses to sell meat from tens of thousands of cancer-ridden birds subject to condemnation under current rules. CFA is an association of over 250 non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy and education. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and food safety organizations.

Beyond establishing a disturbing precedent regarding when disease renders poultry "unsound or otherwise unfit for human food," the proposed rule raises food safety concerns. Even if cancerous chicken meat poses no direct danger to human health, chickens suffering from avian leukosis are more likely to carry high loads of foodborne pathogens like *Salmonella* and *Campylobacter*. FSIS has failed to consider how the proposed rule may lead poultry growers, and breeders, to reduce precautions against avian leukosis, and the extent to which increased consumer exposure to meat from chickens infected with avian leukosis would coincide with increased exposure to dangerous levels of foodborne pathogens of human health concern.

FSIS should not engage in piecemeal deregulatory efforts—particularly by removing longstanding protections for consumers from diseased animal meat—without ensuring that these efforts will not exacerbate the agency's decades long failure to reduce foodborne illness caused by contaminated chicken. To the extent that the agency acts on the Chicken Council's petition, it should do so in comprehensive reforms that also address CFA's and other consumer advocates' petitions for greater protections against foodborne pathogens in poultry, including enforceable, product-based

standards, and supplier verification requirements.¹ At the very least, FSIS should revise the proposed rule so that avian leukosis inspection requirements are waived only for those poultry processors that can provide supplier verification demonstrating that adequate precautions have been taken to mitigate vertical and horizontal avian leukosis transmission risks.

Chicken and Foodborne Illness

Chicken causes more foodborne illness than any other category of food. According to analysis of outbreak data, chicken is the leading cause of *Salmonella* illnesses (16.8%) and causes the overwhelming majority of *Campylobacter* infections (64.7%).² These two foodborne pathogens—*Campylobacter* and *Salmonella*—accounted for over 71% of the confirmed bacterial and parasitic illnesses transmitted commonly by food and tracked by the Centers for Disease Control and Prevention, according to the agency’s latest surveillance report.³ Pathogen contamination in chicken is ubiquitous. FDA retail sampling data indicates that 1 in every 25 packages of chicken at the grocery store is contaminated with *Salmonella*, and more than 1 in 10 are contaminated with *Campylobacter*.⁴ Pathogen contamination in chicken is also costly. One recent study of medical costs, productivity losses, lost life expectancy, chronic illness, and other pain and suffering associated with foodborne illness found that costs from *Campylobacter* in poultry and *Salmonella* in chicken (\$6.9 billion and \$2.9 billion, respectively) were the highest of 29 pathogen-food pairs studied.⁵

Chicken’s dismal food safety track record goes a long way towards explaining the last two decades’ stalled progress on reducing foodborne illness. The Healthy People 2020 goals set targets for reducing incidence of foodborne illnesses caused by *Campylobacter* and *Salmonella* from 12.7 and 15 cases of laboratory confirmed infections per 100,000 population per year to 8.5 and 11.4, respectively.⁶ But far from meeting those goals, the incidence of *Campylobacter* and *Salmonella* infections remains as high as ever.⁷ The Healthy People 2030 goals are actually higher now for *Campylobacter*, at 10.6 cases of laboratory confirmed domestically acquired infections per 100,000 population per year, and similar for *Salmonella* at 11.1 cases. For its part, FSIS has recognized that there is a problem, launching a new effort this past October to reduce *Salmonella* illnesses associated with poultry products. As detailed below, the proposed rule poses a serious risk of undermining that effort.

¹ See <https://consumerfed.org/testimonial/consumer-food-safety-groups-petition-usda-for-action-on-poultry-pathogens/>; <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/petitions>

² The Interagency Food Safety Analytics Collaboration (IFSAC), Foodborne illness source attribution estimates for 2019 for *Salmonella*, *Escherichia coli* 0157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States (2021), <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf>

³ Tack DM, Ray L, Griffin PM, 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>.

⁴ 2018 NARMS update: Integrated Report Summary Interactive Version, <https://www.fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/2018-narms-update-integrated-report-summary-interactive-version>

⁵ Scharff RL. Food Attribution and Economic Cost Estimates for Meat and Poultry-Related Illnesses. Journal of Food Protection. 2020; 83(6): 959-967.

⁶ Food Safety. Healthy People 2020 website. <https://www.healthypeople.gov/2020/topics-objectives/topic/food-safety/objectives>

⁷ Tack DM, Ray L, Griffin PM, 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.

Avian Leukosis

Avian leukosis complex is a mysterious disease, caused by infections from a group of avian retroviruses whose “pathogenic mechanisms are poorly understood.” All strains of avian leukosis viruses are “oncogenic,” i.e., they induce cancerous tumors. While chickens are the natural hosts for all avian leukosis viruses, they have also been isolated from pheasants, partridges, and quail. Infected chickens exhibit “few typical clinical signs,” which “may include inappetence, weakness, diarrhea, dehydration, and emaciation,” and becoming “depressed before death.”

In the proposed rule, FSIS also denominates Marek’s disease virus as a cause of avian leukosis. Like the avian leukosis retroviruses, Marek’s disease virus also causes cancerous tumors in chicken. However, a “highly protective” vaccine exists for Marek’s disease virus. In contrast, “[t]here is no treatment or vaccine available [for the avian leukosis retroviruses,] so eradication of avian leukosis viruses from breeding flocks is the most effective control method.”⁸

Eradicating the viruses in breeder flocks is critical because, like many foodborne pathogens such as *Salmonella*, avian leukosis viruses are vertically transmitted from hen to egg, in addition to horizontal transmission among birds. According to the Merck Veterinary Manual, which FSIS cites in the proposed rule:

Breeder flocks are evaluated for viral shedding by testing for viral antigens in the albumen of eggs with enzyme immunoassays or by biologic assays for infectious virus. Eggs from shedder hens are discarded, so that progeny flocks typically have reduced levels of infection. If raised in small groups, infection-free flocks can be derived with relative ease. These control measures are applied only to primary breeder flocks. Some breeders favor, and have virtually achieved, total eradication, **whereas others favor a reduced level of viral infection.**⁹

In other words, the chicken industry has the means to test for avian leukosis and keep it out of the food supply, although sometimes it chooses not to, presumably for economic reasons.

The Proposed Rule

FSIS has condemned chicken carcasses showing signs of avian leukosis since passage of the Poultry Products Inspection Act in 1957. The current regulations state plainly: “Carcasses of poultry affected with any one or more of the several forms of the avian leukosis complex shall be condemned.” 9 CFR 381.82.¹⁰ This means that under “traditional inspection,” FSIS inspectors evaluate each carcass and condemn those affected by avian leukosis. In plants operating under the New Poultry Inspection System, in which company “sorters” have taken over much of the “traditional” inspection duties, the rules requires processors to specially prepare the first 300 birds from each flock for an “offline” government inspector to look for signs of infection.

The proposed rule would grant the request made in the National Chicken Council’s March 1, 2019 petition “to treat lesions that could be suspected of being caused by avian leukosis as a trimmable

⁸ <https://www.merckvetmanual.com/poultry/neoplasms/lymphoid-leukosis-in-poultry?query=avian%20leukosis>

⁹ *Id.* (emphasis added)

¹⁰ §381.82 Diseases of the Leukosis Complex, <https://www.ecfr.gov/current/title-9/chapter-III/subchapter-A/part-381/subpart-K/section-381.82>

condition.”¹¹ The Chicken Council’s petition presents the rule change as an ideal manner of effectuating the previous administration’s Executive Order (EO) 13771 on Reducing Regulation and Controlling Regulatory Costs. Notably, this Executive Order has since been revoked.¹² In its petition, the Chicken Council argues that scientific understanding of avian leukosis has evolved such that we no longer need to worry about the dangers of eating cancer-ridden chicken, and in any event, “modern vaccination and breeding programs have all but eliminated avian leukosis.”¹³ Since “widespread industry efforts have effectively eradicated” avian leukosis, and the disease “does not pose a food safety risk to humans,” FSIS should stop condemning chickens that present with symptoms of the disease. In particular, the Chicken Council petition beseeches FSIS to stop requiring NPIS plants to go through the trouble associated with having an FSIS inspector check for signs of leukosis in the carcasses and viscera of the first 300 birds of each flock.¹⁴

In the proposed rule, FSIS largely repeats the Chicken Council’s argument, maintaining that “Avian Leukosis is now rare and, if present, is usually restricted to a few localized lesions such as enlarged feather follicles, possibly a few lymphoid tumors on an organ, or an enlarged spleen, which do not render other parts of the carcass unwholesome or unfit for human food.” Meat from such diseased chicken is “wholesome,” according to FSIS, because “while several studies confirmed the presence of antibodies to [avian leukosis] viruses in people working in poultry slaughter and processing establishments, there have been no indications that these poultry diseases are involved in human disease, including cancer or Multiple Sclerosis.” The proposed rule does not provide estimates on the extent to which biosecurity lapses, resulting in avian leukosis caused by retroviruses, account for the estimated 62,445 chickens condemned for leukosis. It does, however, acknowledge that vaccines against Marek’s disease sometimes fail to take effect, in which case “visceral leukosis will be present on a flock basis.” When this happens, under the current rule, “FSIS will adjust the NPIS inspection procedures and slow the line to inspect each carcass with its corresponding viscera,” condemning birds that show signs of disease. Under the proposed rule, however, this inspection “would no longer be necessary because the carcasses of birds with leukosis lesions on their viscera would not be considered adulterated and any tumors present on the carcass, regardless of the cause, would be trimmed and removed by establishment employees before the carcass is presented to the FSIS online inspector.”

As a result of these rule changes, FSIS estimates that industry would be able to sell some 62,445 birds that would otherwise be condemned for leukosis, resulting “in industry cost savings of approximately \$352,883 per year.” The proposed rule does not predict that industry may save on costs associated with reduced vaccinations against Marek’s disease, or reduced efforts to control the spread of the avian leukosis retroviruses, although presumably the return on these investments would decline with the proposed rule change. Neither the Chicken Council nor FSIS considers the possibility that ignoring a category of disease that previously served as the basis for condemnation might lead to greater incidence of that disease.

¹¹ National Chicken Council (NCC), Petition to Treat Avian Leukosis as Trimmable Condition, <https://www.fsis.usda.gov/federal-register/petitions/petition-treat-avian-leukosis-trimmable-condition>

¹² <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-revocation-of-certain-executive-orders-concerning-federal-regulation/>

¹³ National Chicken Council petition *supra* note 11.

¹⁴ *Id.*

Avian leukosis and food safety

Assuming *arguendo* that avian leukosis does not pose a direct risk to human health, the proposed rule nonetheless raises food safety concerns insofar as it may result in higher incidence of the foodborne pathogens *Campylobacter* and *Salmonella*, which cause an estimated 1.9 million foodborne illnesses in the United States each year.¹⁵ Studies show that chickens with avian leukosis are more susceptible to both of these foodborne pathogens. For example, USDA researchers found that roosters infected with avian leukosis-J strain virus were more likely to test positive for *Campylobacter* than non-infected birds, and the infected roosters had an average 3.5 times higher level of *Campylobacter* cells per sample unit taken.¹⁶ A study of avian leukosis and *Salmonella* tells a similar story, with avian leukosis infected chickens testing positive for *Salmonella* at a rate (17.8%) nearly three times higher than non-infected birds (6.1%).¹⁷

The coincidence of leukosis and foodborne pathogens raises food safety concerns related to the proposed rule in two ways. First, under the proposed rule, as FSIS indicates, consumers would eat meat from an estimated 62,445 chickens that would have otherwise been condemned for leukosis. Because this meat is more likely to be contaminated with *Campylobacter* and *Salmonella*, in higher levels, it may increase the foodborne illness burden.¹⁸ Second, the proposed rule may lead poultry breeders and growers to invest less than otherwise in precautions against avian leukosis, resulting in more flocks that succumb to the disease, and an accompanying increase in foodborne pathogen prevalence and loads.¹⁹

Currently, the lack of regulatory attention to on-farm or “pre-harvest” interventions to control foodborne pathogens, particularly *Salmonella*, has seriously undermined public health in the United States. While major trading partners in the European Union have enjoyed significant reductions in salmonellosis, progress has stagnated for the past two decades in the United States.²⁰ Recent genetic research attributes the rapid spread of virulent *Salmonella* to “centralized origins at the pinnacle of poultry production.”²¹ Just two companies, Aviagen and Cobb-Vantress, a wholly owned subsidiary of Tyson Foods, now dominate the poultry breeding industry. Because foodborne pathogens, and avian leukosis complex viruses, are vertically transmitted, and because over 3 million broiler chickens may be derived from a single pedigree hen, decisions made by the poultry breeding industry have enormous food safety implications. The proposed rule appears to assume that the industry’s efforts

¹⁵ Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, Griffin PM. 2011. Foodborne illness acquired in the United States—major pathogens. *Emerg. Infect. Dis.* 17:7–15.

¹⁶ N.A. Cox, J.L. Wilson, M.T. Musgrove, R.J. Buhr, J.E. Sandler, B.P. Hudson, “Positive Relationship of the Avian Leukosis-J Strain Virus to the Detection of *Campylobacter* in the Digestive Tract and Semen of Broiler Breeder Roosters,” *Journal of Applied Poultry Research*, Vol. 13, Issue 1, 2004, Pages 44-47, ISSN 1056-6171, <https://doi.org/10.1093/japr/13.1.44>. (<https://www.sciencedirect.com/science/article/pii/S1056617119314096>)

¹⁷ Huang JQ, JK Xin, C Mao, F Zhong and JQ Chai, 2013. “Co-infection of avian leukosis virus and *Salmonella* pullorum with the preliminary eradication in breeders of Chinese local ‘Shouguang’ chickens.” *Pak Vet J*, 33(4): 428-432.

¹⁸ ¹⁹ See, e.g. Jennifer McEntire et al. The Public Health Value of Reducing *Salmonella* Levels in Raw Meat and Poultry, *Food Protection Trends*, Vol 34, No. 6, p.386-392, available at: <http://www.foodprotection.org/files/food-protection-trends/NovDec-14-McEntire.pdf> (noting that “data suggest that the probability of illness is increased as exposure to greater numbers of *Salmonella* increases.”).

²⁰ See Petition *supra* note 1.

²¹ Li, S., He, Y., Mann, D.A. et al. Global spread of *Salmonella* Enteritidis via centralized sourcing and international trade of poultry breeding stocks. *Nat Commun* 12, 5109 (2021). <https://doi.org/10.1038/s41467-021-25319-7>

to control avian leukosis are entirely independent of how FSIS handles leukosis infected birds. That assumption lacks support and should be subject to further consideration by the agency.

Supplier verification

As noted above, the proposed rule raises food safety concerns to the extent that it would increase the consumption of meat from chicken presenting with avian leukosis, and possibly increase the incidence of avian leukosis in the U.S. broiler chicken population, because a chicken with avian leukosis is more likely to be contaminated with high levels of *Salmonella* and *Campylobacter*. For this reason, FSIS should not finalize the proposed rule.

Should the agency nevertheless determine that it must offer relief to chicken processors, it should offer waivers on a case-by-case basis, rather than eliminating avian leukosis inspection writ large. Under such a waiver process, the agency should require supplier verification from processors to support the assertion that avian leukosis has indeed been “effectively eradicated” from their supply chains. This verification could include vaccination records for Marek’s disease virus, and documentation of the biosecurity measures taken to control the spread of the avian leukosis retroviruses, including test results from each flock.

Conclusion

In light of the lack of progress in reducing foodborne illnesses caused by chicken, FSIS should take special care to ensure that any reforms to chicken inspection do not make matters worse. The proposed rule raises serious concerns that a newly tolerant approach to cancerous chicken meat would result in significant increases in *Salmonella* and *Campylobacter* infections. Accordingly, FSIS should not finalize the proposed rule.

Thank you for your consideration of these comments.

Sincerely,

Thomas Gremillion
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