

Comments of Consumer Reports on the Proposed Regulatory Framework to Reduce Salmonella Illnesses Attributable to Poultry Docket No. FSIS-2022-0029

December 16, 2022

Prepared by Brian Ronholm, Director of Food Policy Michael Hansen, Ph.D., Senior Scientist, and James E. Rogers, Ph.D., Director of Food Safety Research and Testing Submitted via Regulations.gov

The U.S. Department of Agriculture Food Safety and Inspection Service 1400 Independence Avenue, SW Washington, DC 20250-3700

Dear Sir or Madam,

Thank you for the opportunity to comment on the Food Safety and Inspection Service's (FSIS) Proposed Regulatory Framework to Reduce *Salmonella* Illnesses Attributed to Poultry.

Founded in 1936, Consumer Reports (CR) is an independent, nonprofit and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S.

We commend FSIS for putting forward this proposed regulatory framework since it has the potential for leading to meaningful poultry safety reform that results in less human *Salmonella* illnesses associated with poultry. We agree with the three major components of the Framework: requiring incoming flocks to be tested for *Salmonella* before entering an establishment, enhancing process control monitoring, and requiring enforceable final *Salmonella* product standards for raw poultry products.

For the *Salmonella* sampling of incoming flocks and the final *Salmonella* product standard, FSIS should be using measures that track human illnesses associated with the consumption of poultry products. We have conducted an analysis of FSIS' proposed Key Performance Indicator (KPI) for poultry which focuses on the relative abundance of the three serotypes of *Salmonella* most linked to human illnesses from consumption of poultry products–S. Infantis, S. Typhimurium and S. Enteritidis–compared to overall *Salmonella* levels. Our analysis shows that by using slightly different KPIs for chicken and turkey that the KPIs do track human *Salmonella* illnesses associated

with chicken or turkey, unlike overall *Salmonella* incidence levels, which do not track with human *Salmonella* illnesses associated with poultry. More detailed comments on the three components of the Proposed Regulatory Framework and our analysis of FSIS' proposed KPI for poultry are found below.

Component 1: Requiring incoming flocks be tested for Salmonella before entering an establishment

We strongly agree that FSIS should require that establishments i) characterize *Salmonella* as a "hazard reasonably likely to occur at receiving" and ii) require that incoming flocks be tested prior to entering the establishment as part of their HACCP program.

In terms of the predetermined target at receiving, we encourage FSIS to use a measure that tracks human *Salmonella* illnesses associated with consumption of poultry products. Thus, using the overall Salmonella levels (aka *Salmonella* performance standard) would not be a useful target since it doesn't track with human *Salmonella* illnesses associated with poultry. We also think that the predetermined target should be different for chicken and turkey.

For chicken, FSIS should initially focus on *Salmonella* serotypes Infantis, Typhimurium and Enteritidis–the three proposed serotypes for the new poultry KPI. For turkey, FSIS should initially focus on serotypes Infantis, Typhimurium and Reading.

We analyzed *Salmonella* data from 2016-2019, specifically reviewing FSIS quarterly sampling reports and IFSAC data for annual estimates of the percentage of human *Salmonella* illnesses attributed to chicken and turkey. We then calculated the KPI separately for chicken and turkey (and substituting S. Reading for S. Enteritidis in turkey, since Enteritidis doesn't appear in turkeys) (see Appendix A).

Our analysis showed that, from 2016-2019, the prevalence rate of *Salmonella* positives declined by over 13 percent in chicken (from 11.64 to 10.26 percent) and increased by over 55 percent in turkey (from 6.54 to 10.19 percent). The IFSAC data show that the percentage of human *Salmonella* illnesses attributed to chicken increased by 32 percent between 2016 - 2019 (from 12.7 to 16.8 percent), while illnesses attributed to turkey increased by 20 percent (from 5.5 to 6.6 percent).

Applying the proposed KPI just to chicken does link to human illness more effectively. The proposed KPI for chicken showed a 23 percent increase from 2016 – 2019 (from 40.8 to 50.3 percent), while the percentage of human *Salmonella* illnesses attributed to chicken showed an increase of 32 percent (from 12.7 to 16.8 percent).

Finally, we note that the focusing on the 3 serotypes for the KPI shows that they comprise 40%-50% of all *Salmonella* serotypes detected in chicken and 25% - 43% for turkey.

Component 2: Enhanced Establishment Process Control Monitoring and FSIS Verification

FSIS has proposed two changes as described in this Component linked to poultry slaughter and inspection. The first is to change the points at which samples are collected during their multipoint sampling efforts. The second would be to use a more statistics based approach to process control.

We agree that both changes would have the potential to provide FSIS and the industry additional and possibly better information as to what is happening during the slaughter process and to help the producer correct possible sanitary and processing problems. However, because of differences in equipment, plant layouts, etc., it is difficult to determine how the agency will implement such changes and that they be effective under all processing circumstances.

In fact, Consumer Reports would support not only moving the sampling points but would urge the agency to consider exploring additional sampling points based on its own sampling data or other research, in order to clearly determine at what point or points does the process deviate from acceptable standards or norms.

The second component of this proposed framework builds on HACCP, FSIS' prevention-based approach to food safety. To ensure pathogen control throughout slaughter and processing operations, FSIS may modify the existing requirements for indicator organism testing for process control and establish additional parameters to better define the required analysis of the data. As part of the proposal, establishments may be required to test for indicator organisms (e.g., aerobic plate count [APC], Enterobacteriaceae). FSIS would consider production volume when determining the frequency that establishments must collect samples.

The present guidance leaves the choice of the appropriate indicator to the plant/producer. Consumer Reports would prefer that the agency specify which indicators are required or preferred to accompany the new standard. Enterics are preferred since they have the best chance of representing fecal contamination and we feel that the new standard provides direction as to the number of samples taken. More would be better for confirmation of process control.

Also, it needs to be clearly understood that the changes proposed in this Component refer to improving process control using indicator bacteria, and the results are not directly related to the presence or amounts of *Salmonella* in poultry.

Component 3: Enforceable Final Product Standard

We strongly agree that FSIS should require enforceable final *Salmonella* product standards for raw poultry. We also believe that the standard used should be one that tracks human *Salmonella* illnesses associated with consumption of poultry products. As noted in our response to Component 1, perhaps FSIS could consider developing a standard primarily based on their proposed KPI, which we have shown does track human *Salmonella* illnesses associated with chicken and turkey.

Thus, we think that there should be separate standards for different poultry products. For chicken, the standards could be based on a KPI that is defined as the total number of serotypes of S. Enteritidis, S. Infantis and S. Typhimurium found in a year's *Salmonella* verification testing divided by the total of positive *Salmonella* detected in that same year. For turkey, the KPI should be like that for chicken except that the 3 serotypes should be S. Reading, S. Infantis and S. Typhimurium, since S. Enteritidis is not found in turkey (as least in FSIS *Salmonella* verification testing) and should be replaced by S. Reading. So, basically, the KPI is the percentage of all positive *Salmonella* samples that are made up of three specific *Salmonella* serotypes.

Our analysis of the FSIS *Salmonella* verification sampling program data from 2016 to 2019 shows that, for chicken, the KPI increases from 41% to 50%, clearly showing that the three serotypes are a significant fraction of all the *Salmonella* detected in chicken. For turkey, the KPI goes from 25% to

43%, showing that Reading, Infantis and Typhimurium are a good percentage of all the *Salmonella* detected in turkey.

Since we know that the proposed KPI, especially for chicken, does track human *Salmonella* illnesses associated with consumption of chicken products, perhaps FSIS could consider setting a standard for chicken that starts with setting a standard of, say, 50% of *Salmonella* samples coming from a plant, and then requiring that number to decrease by a certain percentage every year, since the KPI was 50% for 2019. FSIS has already proposed having the KPI decrease by 1% to 2% per year for the next five years. Perhaps they could consider having the KPI standard decrease by more than 2% per year.

Conclusion

Consumer Reports is very encouraged by this regulatory framework as *Salmonella* poses a potentially deadly risk to consumers. Because new measures to prevent *Salmonella* contamination are urgently needed to protect public health and prevent foodborne illness, we implore the agency to translate this framework into a proposed rule, and begin the formal regulatory process as quickly as possible.



Appendix A

CR Analysis: FSIS' Proposed Key Performance Indicator (KPI) For Salmonella in Poultry Will Be Effective

December 2022

As part of its new effort launched in October 2021 to reduce Salmonella illness linked to poultry, the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) proposed a new Key Performance Indicator (KPI) that aims to present a clearer assessment of progress toward the goal of reducing Salmonella illnesses by 25 percent. The new KPI would replace the current *Salmonella* performance standards, which have not been effective in tracking human illness rates.

This new KPI also will inform the process related to the "Proposed Regulatory Framework to Reduce Salmonella Illnesses Attributable to Poultry," a document released by FSIS in October 2022 that outlines a new strategy to control *Salmonella* in poultry products and more effectively reduce illness rates.

This updated proposed regulatory framework replaces previous Salmonella reduction efforts announced by the agency that includes pathogen reduction performance standards for *Salmonella* in poultry that FSIS uses to assess the food safety performance of establishments that slaughter and process poultry. The performance standards are designed to meet public health goals such that if most establishments meet pathogen reduction performance standards, a reduction in *Salmonella* illness due to FSIS-regulated products should follow. The present *Salmonella* performance standard for poultry is the overall presence of *Salmonella* in the sampled poultry type (e.g., whole chicken, chicken halves and quarters, chicken parts, comminuted chicken, turkeys, etc.), regardless of their link to human illness.

However, the present *Salmonella* performance standard for chicken linked to verification testing does not do an adequate job of tracking human illness rates because although overall *Salmonella* rates have declined, human illness rates have increased. This clearly points to a disconnect in the data and also demonstrates that not all *Salmonella* strains should be considered equal as the current system does.

The *Salmonella* Performance Standards linked to the verification testing program began in 2016. Between 2015 - 2020, the level of *Salmonella* on chicken has decreased by approximately 70 percent, as noted in an FSIS presentation to the consumer stakeholder meeting in August 2021. During that same time period, the occurrence of consumer illnesses attributed to *Salmonella* in chicken, has increased by approximately 30 percent. Thus, the use of *Salmonella* Performance Standards in poultry has not resulted in a decrease in consumer illnesses attributed to *Salmonella* in chicken. Given this, FSIS developed a new KPI for *Salmonella* in poultry that more clearly focuses on the *Salmonella* serotypes that are most linked to human illness – Enteritidis, Infantis, and Typhimurium. The KPI would be defined as the total number of these three serotypes linked to human illness found in a year's *Salmonella* verification testing divided by the total of positive *Salmonella* detected in that same year. FSIS is proposing that for the next 5 years, this KPI will be calculated, with the goal of having the KPI decrease by a total of 10 percent over those 5 years. FSIS also plans to have a single KPI for poultry and plans to combine *Salmonella* data from chicken and turkey.

Calculating the New KPI

To determine the potential effectiveness of FSIS' proposed KPI on effectively tracking *Salmonella* illnesses, *Consumer Reports* analyzed *Salmonella* data from 2015 – 2019, specifically reviewing quarterly sampling reports found on the <u>FSIS website</u>.

For each year, we determined the total number of samples taken; total number of *Salmonella* positive samples; total number of positive samples for *Salmonella* Enteritidis, *Salmonella* Infantis, and *Salmonella* Typhimurium; and calculated the KPI value. We also used the reports of the Interagency Food Safety Analytics Collaboration (IFSAC)—jointly run by HHS, CDC, FDA and USDA/FSIS—from 2016 to 2019 for the annual estimates for percentages of human illnesses from *Salmonella* that are attributed to chicken and turkey. (The summary data from these two sources can be found in Tables 2 and 3.)

In addition to calculating the KPI for poultry as a whole we also developed a *Consumer Reports* KPI, which simply calculates separate KPIs for chicken and turkey. This was done for two reasons. First, there are far more chicken samples than turkey samples taken each year, with the number of chicken samples being roughly six times higher than the number for turkey ones. The number of *Salmonella* positive samples in chicken was almost 12.5 times the number in turkey in 2017 (2,305 vs 185), and just over 6 times the number for 2019 (2,345 vs 380). Second, the FSIS' proposed KPI involves looking at the total number of positive chicken or turkey samples for the Enteritidis, Infantis, and Typhimurium serotypes, compared to the total number of all *Salmonella* positive samples from chicken and turkey, yet *Salmonella* Enteritidis was not even found in any turkey sample between 2016 and 2019. In addition, the FSIS KPI for poultry does not even include *Salmonella* Reading, even though there was an outbreak of human illness linked to this serotype in turkey from 2017 to 2019.

New KPI Tracks Illness Rates More Effectively

The *Salmonella* verification sampling program showed a marked increase in sampling of both chicken and turkey. Between 2016 – 2019, the number of annual *Salmonella* samples increased by 40 percent in chicken (from 16,333 to 22,859) and 35 percent in turkey (from 2,768 to 3,728). At the same time, the prevalence rate of *Salmonella* positives declined by over 13 percent in chicken (from 11.64 to 10.26 percent) and increased by over 55 percent in turkey (from 6.54 to 10.19 percent).

The IFSAC data show that the percentage of human *Salmonella* illnesses attributed to chicken increased by 32 percent between 2016 - 2019 (from 12.7 to 16.8 percent), while illnesses attributed to turkey increased by 20 percent (from 5.5 to 6.6 percent).

So, while the *Salmonella* prevalence rate in chicken declined by 13 percent, the percentage of human *Salmonella* illnesses attributed to chicken increased by 32 percent, clearly demonstrating

that prevalence rate of *Salmonella* is not linked to human illness. For turkey, the prevalence rate of *Salmonella* increased by over 55 percent while the percentage of human *Salmonella* illnesses attributed to turkey increased by 20 percent.

If you combined chicken and turkey data, the prevalence rate of *Salmonella* positives declined by 6 percent (from 10.91 to 10.26 percent), while the percentage of human *Salmonella* illnesses attributed to poultry increased by 28.6 percent between 2016 – 2019 (from 18.2 to 23.4 percent), also suggesting that prevalence rate of *Salmonella* in poultry is not linked to human illness attributed to these sources.

Conversely, applying the proposed KPI just to chicken does link to human illness more effectively. The proposed KPI for chicken showed a 23 percent increase from 2016 - 2019 (from 40.8 to 50.3 percent), while the percentage of human *Salmonella* illnesses attributed to chicken showed an increase of 32 percent (from 12.7 to 16.8 percent) (see Table 2).

Applying the proposed FSIS KPI just to turkey shows an increase of over 167% from 2016 - 2019 (from 4.4% to 11.8%), while the percentage of human *Salmonella* illnesses attributed to turkey only increases by 20% (from 5.5% to 6.6%), suggesting that the KPI for turkey is only weakly linked to human illness (see Table 3). This could be due to the fact that the proposed KPI for turkey includes *Salmonella* Enteritidis—which was not found in turkey between 2016 and 2019. It also doesn't include *Salmonella* Reading, which has been linked to outbreaks of human *Salmonella* illnesses attributed to turkey in 2017 - 2019 and is far more prevalent than either *Salmonella* Infantis or *Salmonella* Typhimurium.

If an alternate KPI is calculated (aka KPI/Reading) for turkey – substituting *Salmonella* Reading in place of *Salmonella* Enteritidis – the KPI/Reading more closely tracks human *Salmonella* illnesses attributed to turkey than the KPI which doesn't include *Salmonella* Reading. KPI/Reading increased by 72.5% from 2016 – 2019 (from 24.9% to 42.9%), compared to a 20% increase in human *Salmonella* illnesses attributed to turkey (see Table 3).

If we group together the chicken and turkey data, as proposed by FSIS, then the FSIS poultry KPI increases by 19.5% (from 37.7% to 45%), while the percentage of human *Salmonella* illnesses attributed to poultry increased by 28.6% (from 18.2% to 23.4%), which suggests that the KPI for poultry is linked to human illness.

The linkage to human illness appears even more enhanced if a modified KPI is applied – showing a 25% increase (from 39.5% to 49.4%), while the percentage of human *Salmonella* illnesses attributed to poultry increases by 28.6%.

Conclusion

The proposed KPI by FSIS will be a more accurate and effective indicator for tracking human *Salmonella* illnesses compared to current *Salmonella* performance standards. To further improve the KPI's accuracy, and enhance its scientific plausibility, *Consumer Reports* recommends that it be modified by calculating separate KPIs for chicken and turkey. As analyzed above, for chicken, this would involve counting *Salmonella* Enteritidis, *Salmonella* Infantis, and *Salmonella* Typhimurium; and for turkey, *Salmonella* Infantis, and *Salmonella* Typhimurium and *Salmonella* Reading.

Table 1

Comparison of Proposed FSIS KPI, CR Modified KPI and IFSAC Attribution Figures

(percentage of human Salmonella illnesses)

	FY 2016	FY 2017	FY 2018	FY 2019
CHICKEN				
<i>Salmonella</i> IFSAC* FSIS KPI**	12.7% 40.9%	14.0% 44.0%	14.3% 49.2%	16.8% 50.4%
CR KPI**	40.9%	44.0%	49.2%	50.4%
TURKEY				
<i>Salmonella</i> IFSAC* FSIS KPI** CR KPI ^{***}	5.5% 4.4% 24.9%	6.2% 4.9% 17.9%	6.7% 9.5% 43.3%	6.6% 11.8% 42.9%
ALL POULTRY (Chicken and Turkey)				
<i>Salmonella</i> IFSAC* FSIS KPI CR KPI	18.2% 37.7% 39.5%	20.2% 41.2% 42.1%	21.0% 45.0% 48.5%	23.4% 45.0% 49.4%

* all Salmonella serotypes, including ones not linked to human illness.

** percentage of total *Salmonella* detected in that year that are from the following *Salmonella* serotypes: Infantis, Typhimurium or Enteritidis.

*** percentage of total *Salmonella* detected in that year that are from the following *Salmonella* serotypes: Infantis, Typhimurium or Reading

Chicken

year	S. Enteriditis sero	S. Infantis sero	<u>S. Typhimurium</u>	Total # serotypes	Salm KPI
5	(Q1, Q2, Q3, Q4)	(Q1, Q2, Q3, Q4)	(Q1, Q2, Q3, Q4)		
FY 2016	120, 114, 102, 103	22, 17, 16, 41	63, 65, 54, 60	478, 468, 419, 537	777/1902 =
	[439]	[96]	[242]	[1,902]	.4085
FY 2017	125, 145, 134, 121	53, 58, 74, 112	51, 50, 53, 40	538, 525, 592, 652	1016/2307 =
	[525]	[297]	[194]	[2,307]	.4404
FY 2018	125, 215, 180, 92	118, 138, 133, 126	33, 69, 48, 27	617, 782, 683, 571	1304/2653 =
	[612]	[515]	[177]	[2,653]	.4915
FY 2019	79, 130, 122, 111	129, 146, 155, 162	39, 40, 33, 33	551, 653, 556, 579	1179/2339 =
	[442]	[592]	[145]	[2,339]	.5041
	IFSAC % Salm illness	Salm CR KPI	IFSAC % Salm	Salm chicken +	FSIS Salm
	chicken related		illnesses chicken	turkey FSIS KPI	chicken %+
			+ turkey related		
FY 2016	<u>12.7</u>	.4085	18.2	785/2083 = .3768	1901/16333
					= .1164
FY 2017	<u>14.0</u>	.4404	20.2	1025/2491 = .4115	2305/18772
					= .1228
FY 2018	<u>14.3</u>	.4915	21.0	1333/2960 = .4503	2651/21239
					= .1248
FY 2019	<u>16.8</u>	.5041	23.4	1224/2719 = .4502	2345/22859
					= .1026

Table 3

Turkey

year	<u>S. Enteriditis sero</u>	<u>S. Infantis sero</u> (Q1, Q2, Q3, Q4)	<u>S. Typhimurium</u> (Q1, Q2, Q3, Q4)	Total # serotypes	Salm KPI
	<i>Reading</i> (Q1, Q2, Q3, Q4)				
FY 2016	0, 0, 0, 0 [0]	0, 0, 0, 0 [0]	2, 4, 2, 0 [8]	42, 61, 34, 44	8/181 =
	9, 10, 8, 10 [37]			[181]	.0442
FY 2017	0, 0, 0, 0 [0]	0, 0, 6, 3 [9]	0, 0, 0, 0 [0]	38, 40, 50, 56	9/184 =
	3, 3, 8, 10 [24]			[184]	.0489
FY 2018	0, 0, 0, 0 [0]	2, 5, 8, 7 [22]	2, 0, 0, 5 [7]	53, 77, 90, 87	29/307 =
	14, 19, 39, 32 [104]			[307]	.0945
FY 2019	0, 0, 0, 0 [0]	4, 8, 10, 5 [27]	3, 5, 6, 4 [18]	76, 127, 103, 74	45/380 =
	31, 36, 26, 25 [118]			[380]	.1184
	IFSAC % Salm illnesses	Salm KPI	Salm Reading		
	turkey related		KPI		
FY 2016	5.5	.0442	45/181 = .2486		
FY 2017	<u>6.2</u>	.0489	33/184 = .1793		
FY 2018	<u>6.7</u>	.0945	133/307 = .4332		
FY 2019	<u>6.6</u>	.1181	163/380 = .4289		