ConsumersUnion
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Comments of Consumers Union on
United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS)
Changes to the *Salmonella* and *Campylobacter* Verification Testing Program:
Proposed Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Related Agency Verification Procedures and Other Changes to Agency Sampling
Docket No. FSIS-2014-0023

Consumers Union[1] (CU) welcomes the opportunity to comment on the United States Department of Agriculture (USDA) Food Safety Inspection Service's (FSIS') proposed pathogen reduction performance standards for *Salmonella* and *Campylobacter* in some raw chicken parts (e.g. breasts, legs and wings) and not-ready-to-eat (NRTE) comminuted chicken and turkey, their decision to begin sampling of other raw chicken products for *Salmonella* and *Campylobacter*, to sample raw pork products for pathogens of public health concern, and to make changes to the sampling procedures used for bacterial assessments and verification .

Reasons for Concern

We share FSIS' concern about *Salmonella* in poultry products. In 2011, there were two outbreaks involving ground/comminuted turkey product. The 2011 multi-drug-resistant *Salmonella* Hadar outbreak associated with turkey burgers sickened 12 people in 10 states and led to a recall of 54,960 pounds of turkey burger.[2] The 2011 multiple-drug-resistant *Salmonella* Heidelberg outbreak associated with ground turkey product sickened 136 people in 24 states and led to 1 death; more than 36 million pounds of ground turkey were ultimately recalled.[3] A 2011 report by the University of Florida's Emerging Pathogens Institute on pathogen food combinations with the greatest impact on public health ranked *Salmonella* in poultry as fourth in

[1] Consumers Union is the public policy and advocacy arm of *Consumer Reports*. Consumers Union is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. It conducts this work in the areas of telecommunications reform, health reform, financial reform, and other areas. *Consumer Reports* is the world's largest independent product-testing organization. Using more than 50 labs, auto test center, and survey research center, the nonprofit organization rates thousands of products and services annually. Founded in 1936, *Consumer Reports* has over 8 million subscribers to its magazine, website, and other publications.

[2] Centers for Disease Control and Prevention (CDC). 2011a. Investigation Announcement: Multistate Outbreak of *Salmonella* Hadar Infections Associated with Turkey Burgers.
At: http://www.cdc.gov/salmonella/hadar0411/040411/index.html

[3] CDC. 2011b. Investigation Update: Multistate Outbreak of Human *Salmonella* Heidelberg Infections Linked to Ground Turkey. At: http://www.cdc.gov/salmonella/heidelberg/111011/index.html

terms of contaminated foods causing the greatest decline in Quality Adjusted Life Years, and third in terms of hospitalizations and death.[4] Overall, the report found that contaminated poultry ranked as the number one food category with the greatest public health impact. In addition, according to Centers for Disease Control and Prevention (CDC) estimates, based on FoodNet Surveillance data, *Salmonella* is one of the few foodborne pathogens that have not declined in the past fifteen years. In 2012, the incidence of salmonellosis was 16.42 cases per 100,000, well above the 2020 National Health Objective of 11.4 cases per 100,000.[5] Further, data from the National Antimicrobial Resistance Monitoring System (NARMS) show that *Salmonella* levels in poultry products are five to ten times higher than levels in ground beef or pork chops.[6] Clearly, FSIS needs to take action on *Salmonella* in poultry products.

Detailed comments
Performance standards

We commend FSIS for developing performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and NRTE comminuted chicken and turkey, and for designing those performance standards to achieve at least a 30 percent reduction in salmonellosis on a product-pathogen basis. In general, we believe the proposed performance standards are appropriate. Given the low prevalence of *Campylobacter* in comminuted turkey, 1.2%, we think having a performance standard of 1.9%, or one positive out of 52 samples, is acceptable. However, we believe that the performance standard for *Salmonella* in comminuted chicken, which is to be set at 25%, could be set at an even stricter margin, to encourage more rapid change in the market.

In addition, the performance standards for *Salmonella* and *Campylobacter* in raw chicken parts are flawed because they do not include all chicken parts, excluding necks, giblet, quarter carcasses and half carcasses. Thus, there is a category of raw chicken parts which still have no performance standard for *Salmonella* and *Campylobacter*, which we believe is unacceptable. The whole point of developing performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and NRTE comminuted chicken was to ensure that all raw/NRTE chicken products had such performance standards. FSIS should develop *Salmonella* and *Campylobacter* standards for the other raw chicken products not covered (e.g., necks, giblet, quarter carcasses and half carcasses)—we commend FSIS for deciding to sample these other chicken parts for *Salmonella* and *Campylobacter*—but, in the meantime, FSIS should apply the same performance standard (e.g., 15.4% for *Salmonella* and 7.7% for *Campylobacter*) to these excluded parts as to the covered parts (e.g., breasts, legs, and wings).

FSIS also noted that in developing the performance standards for *Salmonella* and *Campylobacter* in raw chicken parts, they used data from the Nationwide Microbiological Baseline Data

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[4] Batz MB, Hoffman S, and JG Morris. 2011. *Ranking the Risks: The 10 Pathogen Food Combinations with the Greatest Burden on Public Health*. At: http://www.epi.ufl.edu/sites/www.epi.ufl.edu/files/RankingTheRisksREPORT.pdf

[5] Table 1 in CDC. Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 1996–2012. *MMWR*, 62(15): 283-287. At: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6215a2.htm?s_cid=mm6215a2_e

[6] Table 6 in NARMS. 2013. *Retail Meat Report 2011*. At: http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM334834.pdf

Collection Programs: Raw Chicken Parts Baseline Survey (RCPBS), conducted from January 2012 to August 2012. FSIS pointed out that the RCPBS expressly excluded raw chicken parts that were marinated or injected. We agree with FSIS that they should include raw chicken parts that have been injected or marinated with a clear solution, along with the other chicken parts (e.g., necks, giblets, quarter carcasses and half carcasses) that FSIS will sample for *Salmonella* and *Campylobacter* and indicator organisms. We also agree with FSIS' rationale for why raw chicken parts injected or marinated with clear solutions should be included, because "the additional handling of injected products marinated in a clear solution could cause additional contamination … and that these products look no different to the consumer than products not injected or marinated (when done with a clear solution that may not be evident to the individual preparing the product)."[7] In the meantime, FSIS should apply the same performance standard (e.g., 15.4% for *Salmonella* and 7.7% for *Campylobacter*) to these excluded parts as to the covered parts (e.g., breasts, legs, and wings).

In developing the performance standard for *Campylobacter* in poultry, FSIS used a direct plating laboratory method of analysis with a 1 ml test portion, rather than using an enrichment method of analysis which uses a larger test portion, 30 ml, for chicken (MLG 41.03). Previously, we drew attention to this switch in methodology as the FSIS noted that the 1 ml test portion was less sensitive, and we thought it could underestimate prevalence of *Campylobacter* and argued that the qualitative enrichment test (e.g., 30 ml) should be used to evaluate establishment compliance.[8] Since FSIS again points out in the current notice that the direct plating method is likely less sensitive than the enrichment method in detecting *Campylobacter*, we agree with, and commend, FSIS for deciding to use both sampling methods on NRTE comminuted poultry samples as part of the verification testing for *Campylobacter* and then to compare those data. We believe that the performance standard for *Campylobacter* in NRTE comminuted chicken and turkey should be based on the most sensitive test. If the qualitative enrichment test is more sensitive, we do not think the proposed performance standards for *Campylobacter* should be raised to accommodate that test. Rather, establishments should redouble their efforts to reduce *Campylobacter* contamination in their facilities.

Changes to sampling procedures

FSIS has proposed a number of changes to sampling procedures used in verification sampling. We commend FSIS for recognizing that Verification Sampling cannot accurately determine the prevalence of *Salmonella* in comminuted poultry products, as we have previously noted.[9]

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[7] Pg. 3943 in FSIS. 2015. [Docket No. FSIS-2014-0023] Changes to the *Salmonella* and *Campylobacter* Verification Testing Program: Proposed Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Related Agency Verification Procedures and Other Changes to Agency Sampling. 80 *Federal Register*, No. 16, Monday, January 26, 2015.

[8] Rangan UR, Clock S and K Newsom-Stewart. 2014. Comments of Consumers Union on U.S. Department of Agriculture Food Safety Inspection Service's Proposed Rule: Discontinuation of the Qualitative (30 mL) Campylobacter Analysis for Young Chickens. Docket No. FSIS-2013-0037. At: http://www.regulations.gov/#!documentDetail;D=FSIS-2013-0037-0002

[9] Hansen, M. 2013. Comments of Consumers Union on United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) HACCP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and Related Agency Verification Procedures Docket No. FSIS-2012-0007. At: http://consumersunion.org/wp-content/uploads/2013/04/USDA_comm_poultry_0413.pdf

Consequently, we agree with FSIS about the proposed move to a routine sampling approach for all FSIS-regulated products subject to *Salmonella* and *Campylobacter* verification testing. Rather than set-based sampling, FSIS will now do routine sampling of all products that it samples as part of its *Salmonella* verification sampling program. Thus, FSIS will now sample establishments with a proper frequency and continuously throughout the year. We agree with FSIS that it should take into account risk factors such as production volume and past establishment testing performance when determining the sampling frequency. Consequently, we also agree with FSIS' proposal to sample the largest-volume establishments four or five times per month, or up to 6 times per month, and to decrease the number of samples it collects from establishments producing less volume.

We also agree with FSIS' decision to start sampling imported raw poultry products (e.g., raw broiler and turkey carcasses, NRTE comminuted chicken and turkey products, and raw chicken parts) for *Salmonella* and *Campylobacter* and will use enumeration and serotype data in such testing. We also agree with FSIS' decision to post the aggregate results of testing of such imported products on the FSIS web site as part of its quarterly report on *Salmonella*. In addition, FSIS should post such information on *Campylobacter* as well.

We also agree with FSIS that it should start sampling eligible product for *Salmonella* that comes from poultry slaughter establishments that produce less than 1,000 pounds per day (580 establishments) or that are operated under a religious exemption (95 establishments); previously such establishments were exempt from sampling. We agree with the FSIS proposal to begin sampling eligible product from these establishments 3 to 4 times per year and to treat these low volume establishments as separate populations and to report how well those establishments are performing, including such information as percentage positive, 25^{th}, 50^{th}, and 75^{th} percentiles.

We also agree with FSIS on their use of a moving window approach, whereby is will evaluate the number of positive samples out of the number of samples taken in a given time period. FSIS has proposed using a 52-week window. If samples are taken weekly, then when the establishment is sampled for the 53^{rd} time, the data from week one is dropped, while the data from week 53 is added. This shifting is repeated with each new week. We think the use of a 52 week window might not be as health protective as possible, since there could be seasonal fluctuation in pathogen prevalence. We urge FSIS to carefully look at the prevalence data they collect to see if there are strong seasonal fluctuations in pathogen prevalence. If so, we urge FSIS to use a smaller moving window that is less than 52 weeks, so as to maximize the health protective effect.

Performance categories for establishments

In 2006, FSIS published a **Federal Register** notice (71 FR 9772-9777; Docket 04-026N) that announced a new agency policy for reporting the results of FSIS' *Salmonella* testing program. That notice established three performance categories for establishments. Category 1 was set at an upper limit of no more than half the performance standard. Category 2 was set at more than half but not exceeding the standard, while Category 3 was for establishments exceeding the performance standard. The 2006 FR notice also pointed out that FSIS planned to test all the establishments over the following year for *Salmonella,* and to publish the names of

establishments in Categories 2 and 3 for any product class that did not have 90 percent of its establishments in Category 1.

Given that FSIS is moving from a set-based *Salmonella* verification sampling program to a routine sampling system using a moving window approach, FSIS has decided to include a time component in their performance categories for establishments. Thus, Category 1 would refer to establishments that achieved 50% or less of the performance standard during any completed 52-week moving window over the last six months. Category 2 would refer to an establishment that met the performance standard for all completed 52-week moving windows but has results greater than 50% of the standard during any completed 52-week moving window over the last six months. Category 3 would refer to establishments that have exceeded the performance standard during any completed 52-week moving window over the last six months. Take the performance standard for *Salmonella* in raw chicken parts (e.g., breasts, wings, and legs) of 15.4%, which translates into 8 positive samples out of 52. A Category 1 establishment for *Salmonella* in raw chicken parts would have to have no more than 4 positive samples out of 52 (e.g., 7.7% or less); a Category 2 establishment would have between 5 and 8 positive samples out of 52; and a Category 3 establishment would have more than 8 positive samples out of 52—all based on a 52-week moving window over the last six months.

In addition, FSIS proposes to update the category status of each eligible establishment on a monthly basis, based on their performance after the last six months. FSIS also plans to categorize such establishments for *Campylobacter* as well as *Salmonella*. We agree with FSIS on all these points. We think it does make sense to modify the definition of category status of an establishment, based on a time component. We also agree with FSIS that once the establishments have been categorized using the new system, such categorization should be updated monthly based on their performance over the last six months.

In addition, we strongly agree with FSIS' decision to web-post the Category status for *all* eligible establishments for just the reason that FSIS cites, which is that web-posting provides greater transparency and gives the public information to make informed food safety decisions. Previously, FSIS had only posted establishments in Category 2 or 3, so consumers didn't know if an establishment that was not posted was in Category 1 or had not yet been categorized. Posting of category status for all eligible establishments for each product type is a step forward for consumers. We agree with FSIS on how it will incorporate data from the set-based sampling with the new sampling that uses the moving window approach. For maximum transparency, since FSIS will be recategorizing establishments on a monthly basis, we recommend that FSIS post aggregate reports on a monthly basis showing the Category 1/2/3 distribution for each relevant product class subject to FSIS *Salmonella* and *Campylobacter* testing. At minimum, FSIS should post such aggregate reports on a quarterly basis.

Agency actions

When an establishment, utilizing the new moving windows approach to sampling, does not meet a performance standard, FSIS simply immediately conducts a follow-up sampling. If such sampling shows a high number of positives or serotypes of human health significance, FSIS may perform Incident Investigation Team testing. We think FSIS can and should take stronger action.

First, we **believe that any *Salmonella* strain/serotype with the same PFGE pattern as the *Salmonella* strain/serotype involved in an illness outbreak will likely pose a similar public health risk and therefore should be declared an adulterant, regardless of where it was produced and FSIS should request that the establishment recall the product.**

Second, we believe that just as FSIS determined that certain serogroups of *E. coli* (e.g., O157:H7, O26, O45, O103, O111, O121, and O145) are adulterants,[10] certain serotypes of *Salmonella* should be considered adulterants. As an initial step toward this goal, **we believe that FSIS should decide that any *Salmonella* serotype that appears on CDC's top 20 list of *Salmonella* serotypes of human health concern,[11] and that is also antibiotic resistant should be considered an adulterant.** The serogroups of *Salmonella* on CDC's top 20 list are the ones causing the most human illness. Thus, any finding of such *Salmonella* serotypes should cause FSIS to request that the establishment recall the product.

Finally, we urge FSIS to update its guidance[12] on how establishments can address *Salmonella* and *Campylobacter* in poultry to include additional suggested pre-harvest and post-harvest controls and to put this new updated guidance out as soon as possible, including information on the effectiveness of pre-harvest controls to reduce pathogens in live poultry, as suggested by the Government Accountability Office.[13]

Respectfully submitted,

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[10] FSIS. 2011. 9 CFR Parts 416, 417, and 430 [Docket No. FSIS–2010–0023] Shiga Toxin-Producing Escherichia coli in Certain Raw Beef Products. 76 *Federal Register*, No. 182, Tuesday, September 20, 2011. At: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2010-0023.pdf

[11] At: http://www.cdc.gov/ncezid/dfwed/PDFs/SalmonellaAnnualSummaryTables2009.pdf

[12] FSIS. 2010. The Compliance Guideline for Controlling *Salmonella* and *Campylobacter* in Poultry, Third Edition, May 2010. At: http://www.fsis.usda.gov/wps/wcm/connect/6732c082-af40-415e-9b57-90533ea4c252/Compliance_Guide_Controling_Salmonella_Campylobacter_Poultry_0510.pdf?MOD=AJPERES

[13] GAO. 2014. USDA Needs to Strengthen it Approach to Protecting Human Health from Pathogens in Poultry Products. GAO-14-744. At: http://www.gao.gov/assets/670/666231.pdf