Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2018-0044]

Changes to the *Campylobacter* Verification Testing Program: Revised Performance Standards for *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey and Related Agency Procedures

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing and requesting comments on revised pathogen reduction performance standards for *Campylobacter* in not-ready-to-eat (NRTE) comminuted chicken and turkey products based on a microbiological method change from direct-plating to enrichment. The Agency is taking this step because the enrichment method more effectively recovers *Campylobacter* in contaminated poultry samples as compared to the direct-plating method.

FSIS will consider comments received on this notice before announcing the final standards in the **Federal Register** and assessing whether establishments are meeting the standards.

After collecting sufficient data, FSIS plans to propose and request comments on revised pathogen reduction performance standards for *Campylobacter* in young chicken and turkey carcasses and in raw chicken parts, also based on the enrichment method.

DATES: Submit comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

• *Federal eRulemaking Portal*: This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to http://www.regulations.gov. Follow the on-line instructions at that site for submitting comments.

• *Mail, including CD-ROMs, etc.*: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

• *Hand- or Courier-Delivered Submittals*: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2018-0044. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

Docket: For access to background documents or comments received, call (202)720-5627 to schedule a time to visit the

FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

FSIS is responsible for verifying that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled and packaged.

Campylobacter is the most common bacterial cause of foodborne illness in the United States. The Centers for Disease Control and Prevention (CDC) estimate *Campylobacter* infections affect 1.3 million people every year in the United States.[1] During 2018, CDC's Foodborne Diseases Active Surveillance Network, or FoodNet,[2] reported that the incidence of foodborne infection was highest for *Campylobacter* (19.5 per 100,000 population).[3] Most non-dairy, outbreak-associated *Campylobacter* illnesses are attributed to the consumption of poultry.[4] *Campylobacter* outbreaks are not commonly identified considering how often people get sick from this bacteria, but the frequency of outbreaks has been increasing.[5]

[1] https://www.cdc.gov/*Campylobacter*/faq.html
[2] https://www.cdc.gov/foodnet/index.html
[3] https://www.cdc.gov/mmwr/volumes/68/wr/mm6816a2.htm
[4] https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2016-report-TriAgency-508.pdf
[5] https://www.cdc.gov/*Campylobacter*/outbreaks/outbreaks.html

Poultry Carcasses and Raw Chicken Parts

FSIS finalized and announced *Campylobacter* performance standards for establishments that produce young chicken carcasses and turkey carcasses on May 14, 2010 (75 FR 27288). FSIS initially proposed to use the results from both the 1-mL direct-plating analytical method and the 30-mL enrichment analytical method to assess whether establishments were meeting the *Campylobacter* performance standards for young chicken and turkey carcasses.[6] However, on March 21, 2011, after further analysis and in response to public comments, FSIS announced that it would: only use the direct-plating method results to assess whether young chicken and turkey slaughter establishments were meeting the performance standards; also concurrently analyze young chicken and turkey carcass rinsates using the enrichment method; and conduct an internal analysis of all of these results – direct-plating and enrichment method generated results – to develop additional policy options (76 FR 15282). In July 2011, FSIS began compiling sample sets[7] to generate data to assess whether young chicken and turkey slaughter establishments were meeting the *Campylobacter* standards. Poultry slaughter establishments subject to the *Campylobacter* performance

[6] FSIS's direct-plating and enrichment analytical methods are described in the Microbiology Laboratory Guidebook, Chapter 41; at https://www.fsis.usda.gov/wps/wcm/connect/0273bc3d-2363-45b3-befb-1190c25f3c8b/MLG-41.pdf?MOD=AJPERES

[7] At the time, FSIS inspection program personnel were collecting poultry carcass samples over a defined number of sequential days of production to complete a sample set. In May 2015, FSIS began testing poultry carcasses using a continuous sampling program and discontinued the previous set-based verification projects.

standards were assessed against the standards based solely on the results generated using the direct-plating method. However, samples collected as part of these sample sets were analyzed concurrently using the enrichment method.

After FSIS completed two sample sets for nearly 90 percent of the young chicken and turkey slaughter establishments, the results generated using both the 1-mL direct-plating and 30-mL enrichment methods were evaluated. FSIS announced in the *Constituent Update* on May 31, 2013 that it had evaluated the available *Campylobacter* sample set data[8] and the analysis at that time showed that the direct-plating method was sufficiently sensitive to identify poultry carcass establishments with substandard process control. Thus, on June 3, 2013, FSIS suspended the use of the 30-mL enrichment method for *Campylobacter* for young chicken and turkey carcasses.[9]

However, in July 2016, when FSIS modified its sampling procedure for young chicken and turkey carcasses and raw chicken parts by replacing buffered peptone water (BPW) with neutralizing BPW (nBPW), the Agency began to observe a marked and significant reduction in *Campylobacter* recovery from turkey carcasses and chicken parts using the 1-mL direct-plating method, suggesting nBPW affected *Campylobacter* recovery in these

[8] http://www.fsis.usda.gov/wps/wcm/connect/9a3a7078-0ff4-4ebc-8de6-ad889382fd7f/Const_Update_053113.pdf?MOD=AJPERES

[9] FSIS announced full discontinuation of this analysis for poultry carcasses on February 21, 2014 (79 FR 9875).

products. In May 2018, FSIS further investigated this effect by performing a side-by-side analysis of poultry carcasses and raw chicken parts samples with the direct-plating and enrichment methods and found significantly higher percentages of *Campylobacter* positive samples, indicating more effective recovery of *Campylobacter*, using the enrichment method as compared to the direct-plating method for young chicken carcasses (18 percent compared to 1 percent), turkey carcasses (1 percent compared to 0 percent) and chicken parts (16 percent compared to 2 percent). In the near future, FSIS also intends to propose and request comments on revised *Campylobacter* performance standards for these commodities based on the enrichment method.

Comminuted Poultry

On January 26, 2015, FSIS proposed new *Campylobacter* performance standards for NRTE comminuted chicken and turkey products and raw chicken parts, including a cost-benefit analysis (80 FR 3940), and released a risk assessment estimating the effect of these new performance standards on reducing *Campylobacter* illnesses attributed to these products (2015 Risk Assessment).[10] FSIS finalized the performance standards on February 11, 2016 (81 FR 7285).

[10] The 2015 Risk Assessment is available at https://www.fsis.usda.gov/wps/wcm/connect/afe9a946-03c6-4f0d-b024-12aba4c01aef/Effects-Performance-Standards-Chicken-Parts-Comminuted.pdf?MOD=AJPERES.

These *Campylobacter* performance standards were based on the 1-mL direct-plating method and, for both NRTE comminuted chicken and turkey products, specified one (1) allowable positive sample in 52 samples. In 2014, before these performance standards were announced, FSIS tested NRTE comminuted chicken, but not NRTE comminuted turkey products using the 30-mL enrichment method and found the enrichment method to have greater *Campylobacter* recovery and thus generate more positive results. In the February 2015 **Federal Register** notice, FSIS announced its intention to continue to perform the 30-mL enrichment method concurrently with the 1-mL direct-plating method for both NRTE comminuted chicken and turkey products, and to analyze data generated from both analytical approaches (81 FR at 7292). As part of this effort, all NRTE comminuted chicken and turkey product samples collected between June 2015 and May 2017 were analyzed for the presence of *Campylobacter* using both the 1-mL direct-plating method and the 30-mL enrichment method. In May 2017, FSIS suspended use of the enrichment method while it analyzed the data. The Agency resumed using the enrichment method concurrent with the direct-plating method on August 27, 2018.[11] These results were not affected by the July 2016 switch from BPW to nBPW because nBPW is not used to collect or test

[11] https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/archive/2018/ConstUpdate082718

NRTE comminuted poultry product samples.[12]

Enrichment Method

As stated above, FSIS originally developed *Campylobacter* performance standards for NRTE comminuted chicken and turkey products using the 1-mL direct-plating method while simultaneously analyzing the same samples using the 30-mL enrichment method. The enrichment method enhances the probability of recovering *Campylobacter* from raw poultry samples. For both methods, the test portion consists of 325 grams of NRTE comminuted poultry suspended in 1625 mL of BPW. Because the direct-plating method requires at least 1,950 colony forming units (CFU) in the suspended mixture to be reasonably likely to detect a positive *Campylobacter* sample, its theoretical limit of detection (LOD) is 6 CFU/gram. The enrichment method requires at least 65 CFU in the suspended mixture for *Campylobacter* to be detected, giving it a theoretical LOD of 0.2 CFU/gram.

The enrichment method includes a two-day enrichment step, which may allow for the repair of bacteria injured by exposure to extremes of pH, temperature, pressure, antimicrobial compounds, or other injurious conditions and growth of any viable bacteria present. Therefore, the enrichment step

[12] The sampling procedures for NRTE comminuted chicken and turkey products can be seen at https://www.fsis.usda.gov/wps/wcm/connect/801ffca3-a226-45c4-ac68-10670e3ac32b/NRTE-Comminuted-Poultry-Sampling-Program.pdf?MOD=AJPERES.

increases the potential for the growth and recovery of *Campylobacter* cells injured during comminuted poultry processing steps as compared with the direct- plating method. The enrichment method for *Campylobacter* is comparable to the enrichment method currently used to assess the pathogen reduction performance standards for *Salmonella* in raw poultry.

The enhanced recovery of the enrichment method compared to the direct-plating method will improve FSIS's ability to distinguish establishments that are meeting or not meeting the *Campylobacter* performance standards. The *Campylobacter* performance standards proposed in this notice were revised to account for a microbiological method change and would retain the same potential benefits and costs as the original, 1-mL direct-plating-based performance standards. A peer-reviewed manuscript was published which explains the technical details used to determine the mathematical equivalence between the 1-ml direct-plating and 30-mL enrichment methods. The article uses the NRTE comminuted chicken performance standard as an example.[13] Brief explanations of FSIS's process for developing the current *Campylobacter* performance standards for NRTE comminuted chicken and turkey based on the 1-mL direct-plating method and the

[13] Williams, M.S., Ebel, E.D., Golden, N.J., 2018. Revising a Constrained 2-Class Attributes Sampling Plan When Laboratory Methods are Changed. Microbial Risk Analysis; https://doi.org/10.1016/j.mran.2018.12.002.

revised performance standards for NRTE comminuted chicken and turkey based on the 30-mL enrichment method are provided below.

How FSIS Develops *Campylobacter* Performance Standards

The current FSIS *Campylobacter* and *Salmonella* performance standards are based on a 2-class attributes sampling plan, which specifies a maximum number of positive samples out of a fixed number of total samples. This can also be expressed as a maximum allowable percent positive. Positive samples are those in which the pathogen is detectable using a microbiological assay. Since 2011, FSIS has taken a common approach to determine performance standards for each pathogen-product pair, and this approach is described most recently in the January 26, 2015 **Federal Register** (80 FR at 3942). Briefly, FSIS measures the public health effect of a performance standard as the number of illnesses avoided each year.[14] This effect is calculated from the volume-weighted prevalence of a contaminated poultry product before and after successfully implementing the performance standard. Volume-weighted prevalence means that establishments with higher production volumes have a greater influence on the overall prevalence estimates. Because the volume-weighted prevalence after implementing a performance standard cannot be known when the standard is proposed, FSIS models the impact of the

[14] Ebel, Williams et al. 2012. Simplified framework for predicting changes in public health from performance standards applied in slaughter establishments. Food Control 28:250-257.

performance standard by assuming that a certain percentage of establishments (and their production volume) would initially not meet the standard but eventually do meet it. This is referred to as the "compliance fraction."

Using the sampling and production volume data collected from each eligible establishment, FSIS can estimate the impact of all possible performance standards. Establishments are classified as meeting or not meeting each possible performance standard. The compliance fraction is then used to estimate the number of avoided or reduced illnesses. FSIS's current performance standards for *Campylobacter* in poultry were intended to achieve at least a 33-percent reduction in illnesses, a target based on Healthy People 2020 goals.[15,16] The proportion of establishments and their production volume initially not meeting the performance standard also allows FSIS to estimate the costs associated with implementing the performance standard (i.e., the costs to industry).

How FSIS Developed the Current *Campylobacter* Performance Standards for NRTE Comminuted Chicken and Turkey using the 1-mL Direct-Plating Method

To estimate the illnesses reduced by the current NRTE

[15] HHS. (2010). "Healthy People Topics & Objectives: Food Safety." Reduce infections caused by *Campylobacter* species transmitted commonly through food http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=14. Once the Healthy People 2030 objectives have been finalized, FSIS intends to assess whether changes to its performance standards are warranted.

[16] Although the Healthy People 2020 goal of 33-percent reduction in *Campylobacter* illnesses was achieved with other poultry products, the most restrictive and achievable performance standard for NRTE comminuted turkey is 1 positive in 52 samples, which would achieve a 19-percent reduction in *Campylobacter* illnesses.

comminuted chicken and turkey *Campylobacter* performance standards, FSIS sampled establishments producing NRTE comminuted chicken and/or turkey products between June 2013 and May 2014. Each sample was tested for *Campylobacter* using the 1-mL direct-plating method. Three important factors varied across the establishments: production volume, prevalence of contaminated samples, and the number of samples collected. Underlying all of the results is a statistical distribution of volume-weighted establishment prevalence accounting for these factors.[17] This distribution is demonstrated as the smooth line in Figure 1 (a).

The risk assessment model uses estimates from the statistical distribution of volume-weighted prevalence and assumes a 50-percent compliance fraction to predict the illness reduction. Figure 1 (b) shows the predicted illnesses reduced by *Campylobacter* performance standards based on 1-mL direct-plating data collected between 2013 and 2014. Using this curve, and FSIS's stated intent of at least a 33-percent illness reduction for *Campylobacter* from NRTE comminuted chicken, FSIS selected a performance standard of one (1) allowable positive out of 52 samples, or a maximum allowable percent positive of 1.9. FSIS actually predicted a 37-percent reduction in the illness rate for *Campylobacter* after implementing the NRTE comminuted chicken

[17] Williams, M.S., Ebel, E.D., Cao, Y., 2013. Fitting distributions to microbial contamination data collected with an unequal probability sampling design. Journal of Applied Microbiology 114, 152-160.

performance standard, corresponding to an annual reduction of approximately 1,300 illnesses.

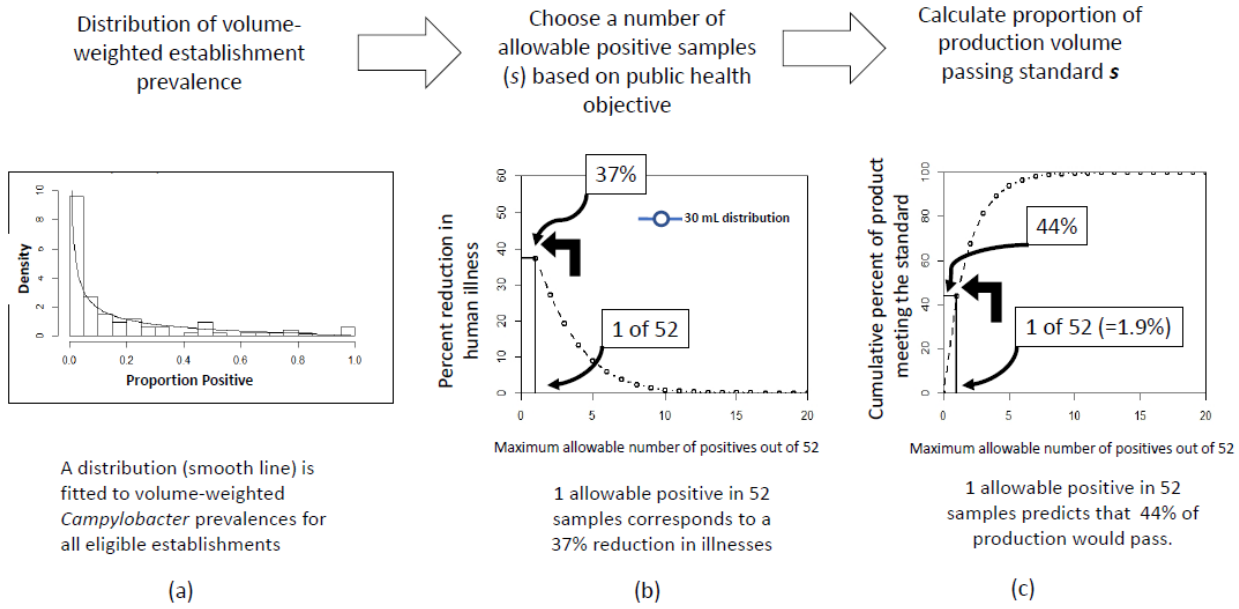
The statistical distribution is also used to determine the proportion of NRTE comminuted chicken product that would meet a *Campylobacter* performance standard of one (1) positive out of 52 samples. Figure 1 (c) shows the proportion of product that would meet the performance standard based on the 1-mL direct-plating data collected from 2013 – 2014. With a performance standard of one (1) positive out of 52 samples, 56 percent of all NRTE comminuted chicken product (corresponding to 24 percent of eligible establishments) would initially not meet the standard. FSIS used this information to estimate the associated costs.

The same procedures were used to determine the *Campylobacter* performance standard for NRTE comminuted turkey product. FSIS determined that the direct-plating method-based performance standard of one (1) allowable positive in 52 samples in NRTE comminuted turkey product would provide a 19-percent illness reduction, and 20 percent of production volume (which accounts for 9 percent of eligible establishments) would initially not meet the standard.[18]

Figure 1. Example demonstrating how FSIS calculated the illness reduction and costs associated with the current NRTE comminuted chicken *Campylobacter* performance standard. Panel (a)

[18] FSIS initially intended for *Campylobacter* performance standards to reduce illness by approximately 33 percent. However, because FSIS found the prevalence for *Campylobacter* in comminuted turkey to be especially low, the highest practical illness reduction for this product was estimated to be 19 percent. The revised standard based on the 30-mL enrichment method was therefore designed to achieve the same predicted illness reduction of 19 percent.

demonstrates the statistical distribution of volume-weighted sampling results. Panel (b) demonstrates how illness reduction estimates were used to choose a performance standard. A 37-percent illness reduction would be achieved by a performance standard of one (1) positive in 52 samples. Panel (c) demonstrates how different performance standards would affect the proportion of product that would initially meet each potential standard, which FSIS used to calculate the associated costs to industry. A performance standard of one (1) positive in 52 samples would predict that 44 percent of production volume would initially meet the standard. This corresponds to 56 percent of production volume (24 percent of establishments) that would initially not meet the standard. The "direction" of the arrows reflects the process FSIS used to determine the performance standard, illness reduction, and industry costs. FSIS uses the performance standard to predict illness reduction in panel (b) and industry costs in panel (c).



How FSIS Revised the *Campylobacter* Performance Standards for NRTE Comminuted Chicken and Turkey Using Data Generated using the 30-mL Enrichment Method

As is discussed above, from June 2015 through May 2017, FSIS tested all NRTE comminuted chicken samples using both the

1-mL direct-plating and 30-mL enrichment methods. There were approximately five times as many samples that tested positive for *Campylobacter* using the 30-mL enrichment method as compared to the 1-mL direct-plating method (i.e., 267 versus 53). FSIS believes this increase was facilitated by a larger test portion size (30-mL compared to 1-mL) and the potential for growth and recovery of injured *Campylobacter* cells allowed by the enrichment process.

FSIS developed a revised *Campylobacter* performance standard by fitting a statistical distribution of the volume-weighted prevalence and then finding the point that reaches the same illness reduction goal determined for the current, 1-mL direct-plating-based performance standard, which was a 37-percent reduction in illnesses. Figure 2 (a) shows the predicted illnesses reduced by potential *Campylobacter* performance standards based on the 30-mL enrichment data collected between 2015 and 2017. A 37-percent reduction in illnesses could be achieved with a 30-mL enrichment method-based standard of five (5) positives in 52 samples. That is, the point on the 30-mL curve that reaches a 37-percent reduction in illnesses corresponds to a performance standard of five (5) positives in 52 samples.

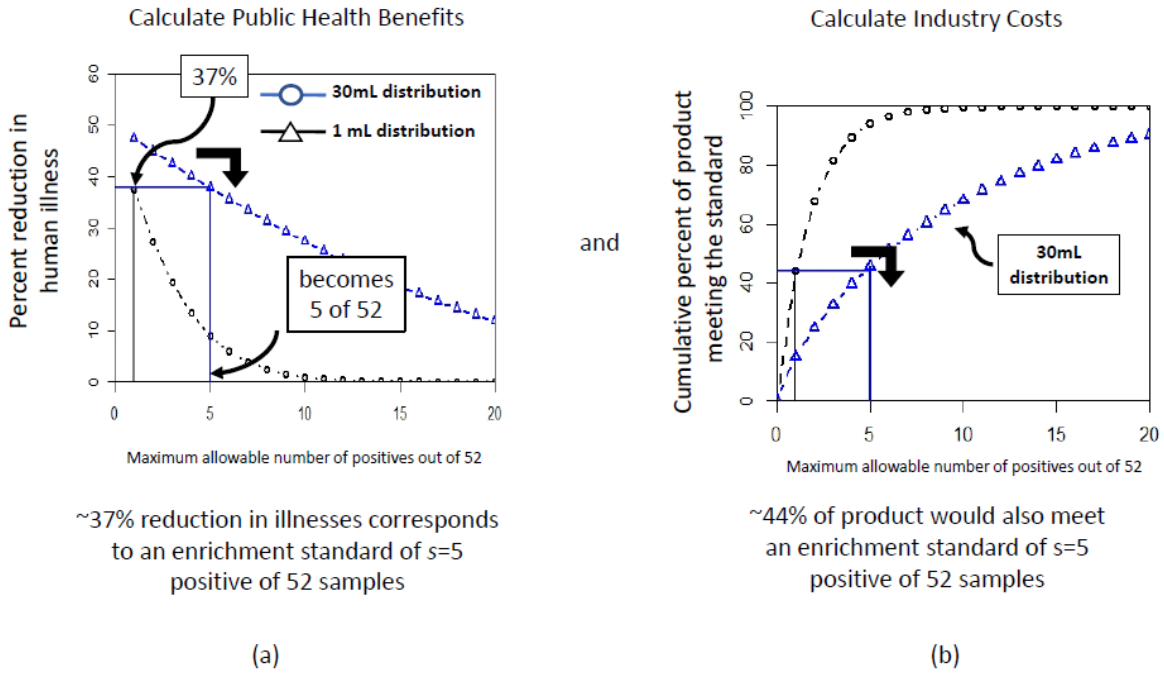
Similarly, the 1-mL direct-plating and 30-mL enrichment-based curves were used to determine the proportion of NRTE

comminuted chicken product that would initially be classified as meeting/not meeting the standard. Figure 2 (c) shows that a performance standard of five (5) allowable positives in 52 samples would result in 44 percent of production volume meeting the standard. That is, the point on the 30-mL curve corresponding to five (5) positives in 52 samples results in 44 percent of the production volume meeting the performance standard, and 56 percent not meeting it. A more detailed description of the methodology, and the treatment of statistical uncertainty is presented in the peer-reviewed technical manuscript (Williams et al, 2018; citation 12).

The same procedures were used to revise the *Campylobacter* performance standard for NRTE comminuted turkey product. FSIS determined that an enrichment method-based performance standard of five (5) allowable positives in 52 samples would provide a 19-percent illness reduction, and 20 percent of production volume (which accounts for 9 percent of eligible establishments) would initially not meet the revised performance standard.

Figure 2. Example of how the predicted illness reduction based on 1-mL direct-plating method generated data was used to revise the *Campylobacter* performance standard established using 30-mL enrichment method generated data. Panel (a) demonstrates how illness reduction estimates were used to choose a performance standard. A 37-percent reduction in illnesses is predicted by a performance standard of one (1) positive in 52 samples for the 1-mL direct-plating data from 2013-2014, or five (5) positives in 52 samples for the 30-mL enrichment data from 2015-2017.

Panel (c) demonstrates how different performance standards would affect the proportion of NRTE comminuted chicken product that would initially meet each potential standard, which FSIS used to calculate the associated costs to industry. A *Campylobacter* performance standard of either one (1) positive in 52 samples (1-mL direct-plating) or five (5) positives in 52 samples (30-mL enrichment) would predict that 44 percent of production volume would meet the standard, and 56 percent would not meet it. These data are used to determine the associated costs. Note the "direction" of the arrows is reversed from Figures 2 (a) and 2 (b). FSIS first determines the predicted illness reduction and then uses the corresponding performance standard to determine the associated costs.



Revised Pathogen Reduction Performance Standards

FSIS is proposing revised performance standards to improve the Agency's ability to identify *Campylobacter* contamination in NRTE comminuted chicken and turkey products using the enrichment method. A summary of the revised *Campylobacter* performance standards for NRTE comminuted poultry products is provided in Table 1. Should FSIS finalize these proposed performance

standards, FSIS will announce the final standards in the **Federal Register** before assessing whether establishments meet the standards. Any changes to the performance standards for *Campylobacter* in young chicken and turkey carcasses, and in raw chicken parts, will be proposed in a separate **Federal Register** notice.

As described above, FSIS has revised the pathogen reduction performance standards for *Campylobacter* in NRTE comminuted chicken and turkey products based on the 30-mL enrichment method, such that the same public health objectives announced in 2015 for the 1-mL direct-plating method-based standards are achieved.

Minimum Number of Samples to Assess Performance

FSIS uses the following formula to estimate the minimum number of samples (n) needed to assess establishment performance: n = (1/percent positive allowed) x 100 (80 FR at 3947). Revising the *Campylobacter* performance standard from one allowable positive per 52 samples (1.9 percent) to five allowable positive samples per 52 samples (9.6 percent) changes the minimum number of samples needed to assess establishments from (1/1.9%) x 100), or 52 samples, to (1/9.6%) x 100, or 10.4 samples. Because samples are necessarily whole numbers, a fractional number is rounded up to the next highest whole number. Therefore, 11 samples would be the minimum number of

samples needed to assess performance for *Campylobacter* in both NRTE comminuted chicken and comminuted turkey producing establishments under the revised standards. Significantly, since the proposed revised performance standards reduce the minimum number of samples needed to assess establishment performance, FSIS would be able to assess performance for a greater number of otherwise eligible establishments.

Table 1. Revised performance standards for *Campylobacter* in NRTE comminuted chicken and turkey products

Product	Revised performance standard for *Campylobacter*	Revised maximum allowable percent positive*	Revised minimum number of samples to assess
NRTE Comminuted Chicken (325 g sample)	5 of 52	9.6	11
NRTE Comminuted Turkey (325 g sample)	5 of 52	9.6	11

*Consistent with existing FSIS procedures, if the total number of samples in a 52-week moving window ranges from 11 to 51, FSIS will subtract 1 from the number of positive samples to calculate the percent positive, which is compared to the revised maximum acceptable percent positive determined by dividing 5 by 52 to determine the Category. If the total number of samples in a moving window exceeds 51, FSIS will calculate a percent positive without subtracting 1 from the number of positives.

Changes to Related Agency Procedures

Once FSIS begins assessing whether establishments meet the revised *Campylobacter* performance standards, FSIS would use the categorization methodology, as well as the web posting procedures announced in the **Federal Register** on November 9, 2018

(83 FR 56046; Nov. 9, 2018). As explained in the November 2018 **Federal Register** notice, the Category status reported on the public website would be based on FSIS sample results during the 52-week window ending the last Saturday of the previous month, and would not include follow-up sampling results, if any were collected and analyzed, as part of the window.

In addition, establishments would not be categorized as *meeting* or *not meeting* as previously announced in the February 2016 **Federal Register** notice. Instead, FSIS would categorize eligible establishments using the same 3-category system it uses for poultry establishments currently subject to a *Salmonella* pathogen reduction performance standard. The criteria for each category are as follows:

- **Category 1:** Establishments that have achieved 50 percent or less of the maximum allowable percent positive during the most recently completed 52-week moving window.

- **Category 2:** Establishments that meet the maximum allowable percent positive but have results greater than 50 percent of the maximum allowable percent positive during the most recently completed 52-week moving window.

- **Category 3:** Establishments that have exceeded the maximum allowable percent positive during the most recently completed 52-week moving window.

All other FSIS verification procedures outlined in the February 2016 **Federal Register** notice are unchanged.

Additional Information

Should these *Campylobacter* standards for comminuted poultry products be finalized, FSIS will post aggregate *Campylobacter* sampling results relative to categories and prevalence estimates for NRTE comminuted chicken and turkey products, consistent with how FSIS handles *Salmonella* postings.[19] FSIS would also announce when it expects to begin posting individual establishment category information in the **Federal Register** notice that announces final *Campylobacter* standards for comminuted poultry products.

Cost-Benefit Analysis

The February 2016 **Federal Register** notice announcing pathogen reduction performance standards for *Salmonella* and *Campylobacter* in NRTE comminuted chicken and turkey products and raw chicken parts included a supplementary cost-benefit analysis (2016 CBA).[20] The 2016 CBA estimated the economic effects of the

[19] The information is posted at https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program/aggregate-data.

[20] U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS). (2016). Final Cost-Benefit Analysis Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards; available at:

new pathogen reduction performance standards for *Salmonella* and *Campylobacter* in both NRTE comminuted poultry and raw chicken parts. The 2016 CBA used estimates on whether establishments would meet the standards and illness reduction estimates from the 2015 Risk Assessment, which relied on results obtained using the direct-plating method.

As explained above, FSIS is proposing to revise the pathogen reduction performance standards for *Campylobacter* in NRTE comminuted chicken and turkey products based on an enrichment method. To ensure the revised performance standards would be statistically equivalent to the previously announced *Campylobacter* standards for these products, FSIS analyzed 2015 - 2017 sample results generated using both the enrichment and direct-plating methods. Based on this analysis, FSIS concluded the revised pathogen reduction performance standards are consistent with the previously announced standards in terms of the estimated reduction in illnesses and the percent of the industry expected to initially not meet the performance standards (Williams et al, 2018; citation 12). Therefore, the associated costs and public health benefits of the revised performance standards remain unchanged from those estimated in the 2016 CBA.

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https://www.fsis.usda.gov/wps/wcm/connect/2f98f0a2-6a89-4316-aa95-86e5b103610f/CBA-Salmonella-Campy-2014-0023F-022016.pdf?MOD=AJPERES

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: http://www.fsis.usda.gov/federal-register.

FSIS also will announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250-9410.

Fax: (202)690-7442.

E-mail: *program.intake@usda.gov.*

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202)720-2600 (voice and TDD).

Done at Washington, DC:

Carmen M. Rottenberg,

Administrator.

[FR Doc. 2019-16765 Filed: 8/5/2019 8:45 am; Publication Date: 8/6/2019]