# Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

**[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

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is announcing and requesting comment on new pathogen reduction performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and not-ready-to-eat (NRTE) comminuted chicken and turkey products.

The Agency is also announcing its plans to begin sampling raw chicken parts to gain additional information on the prevalence and the microbiological characteristics of *Salmonella* and *Campylobacter* in those products. In addition, FSIS intends to begin an exploratory sampling of raw pork products for pathogens of public health concern, as well as for indicator organisms.

Finally, FSIS is announcing that it plans to use routine sampling throughout the year rather than infrequently sampling on consecutive days to assess whether establishments' processes are effectively addressing *Salmonella* and, where applicable, *Campylobacter* on poultry carcasses and other products derived from these carcasses, including chicken parts and comminuted chicken and turkey product. FSIS intends to perform this assessment using a moving window of sampling results.

FSIS will proceed with implementing the routine sampling of raw chicken parts and the changes to specified verification procedures on the dates announced in this notice. However, FSIS is seeking comments on its implementation strategy as part of its effort to continuously assess and improve the effectiveness of Agency policy.

**DATES:** Submit comments on or before March 27, 2015. In March 2015, the Agency plans to begin routine sampling of raw chicken parts as one of the several routine verification testing programs. Also, in March 2015, the Agency plans to begin using the moving window approach (explained below) rather than the consecutive day approach for assessing all verification testing.

In March 2015, FSIS intends to begin exploratory sampling of raw pork products. In March 2015, FSIS also intends to begin sampling imported poultry carcasses, imported raw chicken parts, and imported NRTE comminuted chicken and turkey for *Salmonella* and *Campylobacter.* Finally, in March 2015, FSIS will start posting aggregate reports showing the category distribution for comminuted chicken and turkey using historical data and new results based on the proposed standards for comminuted product. As data become available following the new testing that FSIS will begin in March, FSIS will also begin posting aggregate reports showing the category distribution for chicken parts, based on the proposed standards for parts.

After reviewing the comments received on this notice, beginning July 1, 2015, the Agency plans to begin posting individual establishment category information for poultry carcasses.

**ADDRESSES:** FSIS invites interested persons to submit comments on the new performance standards and other issues identified in the notice for comment. FSIS is not requesting comment on the new testing of imported product, chicken parts, or pork products because FSIS needs to begin this testing to gather additional information, and because FSIS is not assessing whether establishments producing these product meet performance standards at this time. Comments may be submitted by one of the following methods:

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

*Mail, CD–ROMs:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 355 E Street SW., Mailstop 3782, Room 8–163B, Washington, DC 20250–3700.

*Hand- or courier-delivered submittals:* Deliver to Patriots Plaza 3, 355 E Street SW., Room 8–163A, Washington, DC 20250–3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2014–0023. 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 to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 164–A, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Daniel L. Engeljohn, Ph.D., Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205–0495, or by Fax: (202) 720–2025.

## Background

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.

*Salmonella* and *Campylobacter* bacteria are among the most frequent causes of foodborne illness. These bacteria can reside in the intestinal tract of animals, including birds. *Salmonella* and *Campylobacter* contamination of raw poultry products occurs during slaughter operations, as well as during the live-animal rearing process (*e.g.,* on-farm contamination can coat the exterior of the bird and remain attached to the skin). Currently, events that cause contamination of raw carcasses cannot be eliminated through the commercial

production and slaughter practices employed in the United States. Contamination can be minimized, however, with the use of proper sanitary dressing procedures and by the application of antimicrobial interventions during slaughter and thereafter during fabrication of the carcasses into parts and comminuted product.

*Salmonella* and, to a lesser extent, *Campylobacter* may increase on raw poultry if the product is improperly stored at temperatures conducive to their growth. Moreover, if these pathogens are present on raw poultry, they will survive on the product if the product is not subjected to a full lethality treatment such as thorough cooking before being presented for human consumption. Also, if raw poultry is improperly handled during food preparation, *Salmonella* and *Campylobacter* can cross-contaminate other foods or food contact surfaces.

The *Salmonella* verification testing program began with the Agency's final rule ''Pathogen Reduction; Hazard Analysis and Critical Control Point'' (PR/HACCP Rule), which was issued on July 25, 1996 (61 FR 38805). Among other things, the PR/HACCP Rule set *Salmonella* pathogen reduction performance standards for establishments that slaughter selected classes of food animals or that produce selected classes of raw ground products. FSIS uses the pathogen reduction performance standards to ensure that eligible establishments are consistently controlling or reducing harmful bacteria on raw meat and poultry products.

The microbiological performance standards for the reduction of *Salmonella* in raw products allow FSIS to verify whether establishments have effective process controls to address *Salmonella.* The sample sets were designed to assess the presence of *Salmonella* in a specified number of samples collected daily for a sufficient number of days to discern an establishment's capability to sustain long term process control. For example, the 2011 broiler carcass pathogen reduction performance standard consisted of 51 samples with 5 positive samples being the acceptable limit in the set positive for *Salmonella.* Additionally, FSIS set criteria for which establishments were to be included in the verification testing program. Only broiler establishments that slaughter at least 20,000 birds annually are currently subject to FSIS *Salmonella* sampling and testing. A lower volume of birds would likely be slaughtered intermittently throughout the year rather than daily, and thus it would likely take a year or more to complete a set.

FSIS conducted the Nationwide Microbiological Baseline Data Collection Programs: Raw Chicken Parts Baseline Survey (RCPBS) from January 2012 to August 2012 to estimate the percent positive of various raw chicken parts sampled and the levels of *Salmonella, Campylobacter,* and indicator bacteria on these products. FSIS used this information to estimate national prevalence of the two pathogens on raw chicken parts. An overview of the RCPBS is available at *http://www.fsis.usda.gov/wps/wcm/connect/a9837fc8-0109-4041-bd0c-729924a79201/Baseline_Data_Raw_Chicken_Parts.pdf?MOD=AJPERES.*

Based on available data, about 85 percent of poultry products available to consumers are chicken,[1] and about 80 percent of the chicken product is in the form of raw chicken parts fabricated from broiler carcasses.[2] The amount of chicken parts available from fabricated broiler carcasses is larger than that of turkey carcasses that are fabricated into raw turkey parts and available to consumers. Also, there is more contamination of broiler carcasses with *Salmonella* and *Campylobacter* compared to turkey carcasses. For example, in 2008, FSIS found that broiler carcasses had a *Salmonella* prevalence of 7.5 percent,[3] while in 2009 turkey carcasses had *Salmonella* prevalence of 1.7 percent.[4] Given the higher percentages of these positives in broiler carcasses and higher volume of raw chicken parts produced, FSIS conducted its baseline on chicken parts only.

In the **Federal Register** notice of December 6, 2012, (77 FR 72686), FSIS informed establishments producing NRTE comminuted poultry products [5] that they were required to reassess their Hazard Analysis and Critical Control Point (HACCP) plans for these products. In that same notice, FSIS announced that it would expand its *Salmonella* sampling beyond ground chicken and turkey to include all forms of non-breaded, non-battered comminuted NRTE chicken or turkey products not destined for further processing into ready-to-eat (RTE) products. In addition, FSIS announced that it was moving its microbiological testing for *Salmonella* and *Campylobacter* for these products from a 25-gram test portion to 325 grams. Finally, FSIS explained that it would use the sampling results to determine the prevalence of *Salmonella* and *Campylobacter* in NRTE comminuted chicken and turkey and to develop pathogen reduction performance standards for these products.

FSIS began sampling and testing NRTE comminuted chicken and turkey products on June 1, 2013.[6] FSIS has posted the aggregate results of this testing for all finished products as part of its quarterly *Salmonella* report.[7]

On April 21, 2014, FSIS responded to all relevant comments received on the December 2012 notice. As the April 2014 notice explains, after carefully considering all of the comments, FSIS decided that it would proceed as announced with analyzing the comminuted product testing data to establish pathogen reduction performance standards for NRTE comminuted chicken and turkey as originally planned. FSIS also provided other updates, including the status of HACCP plan reassessments, information on Food Safety Assessments (FSAs) in establishments producing comminuted poultry product, and details on how FSIS intends to evaluate the exploratory testing data and information gathered from surveying its poultry inspection program personnel. A summary report of this survey, the FSIS Poultry Checklist, which also showed that the majority of establishments are not currently applying antimicrobials to raw poultry parts and NRTE comminuted poultry product components, is available on FSIS's Web site at *http://www.fsis.usda.gov/wps/wcm/connect/902e9de8-712c-4d74-a223-c9ef4b37464a/poultry-checklist.pdf?MOD=AJPERES.*

FSIS announced its *Salmonella* Action Plan (SAP) on December 4, 2013.[8] In the plan, FSIS announced that

[1] ERS, *http://www.ers.usda.gov/data-products/food-availability-(per-capita)-data-system.aspx.*

[2] NCC, 2011. Broiler Industry Marketing Survey Report, *http://members.www.nationalchickencouncil.org/wp-content/uploads/2013/02/2011-Broiler-Industry-Survey-Report.pdf.*

[3] FSIS, 2009. The nationwide microbiological baseline data collection program: Young chicken survey: July 2007– June 2008. U. S. Department of Agriculture, Washington D.C.

[4] FSIS, 2010. The nationwide microbiological baseline data collection program: Young turkey survey. August 2008—July 2009. U. S. Department of Agriculture, Washington D.C.

[5] FSIS considers ''NRTE comminuted poultry'' to be any NRTE chicken or turkey product that has been ground, mechanically separated, or hand- or mechanically deboned and further chopped, flaked, minced or otherwise processed to reduce particle size (77 FR 72687).

[6] This sampling and testing for *Salmonella* and *Campylobacter* did not include heat-treated NRTE comminuted chicken or turkey.

[7] *http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/quarterly-reports-salmonella.*

[8] *http://www.fsis.usda.gov/salmonella.*

it would complete a risk assessment and develop pathogen reduction performance standards for NRTE comminuted chicken and turkey and raw chicken parts. FSIS also announced in the SAP that it would explore developing a *Salmonella* sampling program for pork products. In March 2015, FSIS intends to begin an exploratory sampling of raw pork products for pathogens of public health concern, as well as for indicator organisms.

**Pathogen Reduction Performance Standards**

In general, illnesses should be reduced as establishments reduce the occurrence of pathogens on their products. Thus, consistent with the rationale discussed in the March 21, 2011 **Federal Register** notice,[9] reduced illnesses should result from the implementation of pathogen reduction performance standards to reduce the occurrence of pathogens on chickens and turkeys.

The Healthy People 2020 (HP2020) goal is to reduce human illness from *Salmonella* by about 25 percent by the year 2020.[10] In order to meet this objective for all poultry products, the Agency is proposing a pathogen reduction performance standard designed to achieve at least a 30 percent reduction in illnesses from *Salmonella* for chicken parts, comminuted chicken, and comminuted turkey.

The HP2020 goal for *Campylobacter* is to achieve a 33 percent reduction in human illnesses from this pathogen. For chicken parts and comminuted chicken, FSIS is proposing a pathogen reduction performance standard designed to reduce illness from *Campylobacter* by about 33 percent. However, because FSIS found the prevalence for *Campylobacter* in comminuted turkey to be especially low,[11] the highest practical reduction for this product was estimated to be 19 percent. Therefore, for this one product-pathogen pair, comminuted turkey and *Campylobacter,* FSIS is proposing a reduction less than its stated goal. The methods for developing the pathogen reduction performance standards and predictions for the public health effect of those standards are described in Public Health Effects of Raw Chicken Parts and Comminuted Chicken and Turkey Performance Standards (2015 Risk Assessment)(*http://www.fsis.usda.gov/wps/wcm/connect/afe9a946-03c6-4f0d-b024-12aba4c01aef/Effects-Performance-Standards-Chicken-Parts-Comminuted.pdf?MOD=AJPERES*). FSIS used the same methodology to estimate the public health effects for the young chicken and turkey performance standards in 2011.[12]

The 2015 Risk Assessment describes how *Salmonella*- and *Campylobacter*-positive samples will be used to categorize establishments as either meeting or not meeting the applicable performance standard for chicken parts or comminuted chicken or turkey. FSIS used a common analytical framework to estimate the improvements in public health (illnesses averted) associated with six separate pathogen reduction performance standards discussed as options considered in this notice. FSIS, based on the risk assessment predictions, estimated the reductions in salmonellosis and campylobacteriosis cases that would result if establishments made changes in their processes that would reduce the occurrence of these pathogenic bacteria in their products.

Should FSIS finalize these pathogen reduction performance standards, once the Agency begins testing to implement the standards, the risk assessment model presents different scenarios under which the desired percent reduction in salmonellosis cases could be achieved across both chicken parts and comminuted poultry products. The risk assessment model also describes different scenarios under which reductions in *Campylobacter* illnesses could occur.

Furthermore, despite a significant drop (a 9 percent decrease) in human illnesses from *Salmonella* in recent years, salmonellosis remains high in the U.S.[13] About 33 percent of all food related salmonellosis cases are associated with products regulated by FSIS. Of these FSIS-associated illnesses, poultry represents about 58 percent of the cases with 85 percent being associated with chicken and 15 percent being associated with turkey.[14] Of the illnesses from consuming chicken, FSIS estimates that 81 percent were associated with parts, 13 percent were associated with whole carcasses, and 6 percent were associated with comminuted product.[15]

FSIS considered the results of the 2015 Risk Assessment and selected performance standards for specified product-pathogen pairings based on the most likely within-establishment contamination distributions and a 50-percent compliance fraction for establishments not initially meeting the performance standard. Furthermore, FSIS chose, where feasible, performance standards expected to accomplish a reduction in *Salmonella* and *Campylobacter* illnesses on a product-pathogen pair basis of at least 30 percent and 33 percent, respectively.

FSIS chose this objective for product-pathogen pairs for addressing *Salmonella* in FSIS-regulated products as it will help increase the likelihood that the HP2020 national goal of reducing human illness by 25 percent can be met across all poultry products. The proposed pathogen reduction performance standards for *Campylobacter* are also expected to achieve greater than a 30 percent reduction in campylobacteriosis from chicken parts and comminuted chicken, and a 19 percent reduction in illnesses from comminuted turkey.

In combination, FSIS estimates that the implementation of performance standards for chicken products (existing and those proposed in this notice) may result in about a 31 percent reduction in salmonellosis. The estimated combined impact of implementing performance standards for turkey products (existing and those proposed in this notice) is about a nine percent reduction in salmonellosis. The overall estimated impact on salmonellosis is about a 28 percent reduction for chicken and turkey products, thus satisfying the HP 2020 objective of 25 percent.

After it has considered comments received on this notice, FSIS will announce the final standards in the **Federal Register**.

*NRTE Comminuted Poultry—Salmonella*

For the purpose of developing a pathogen reduction performance standard for *Salmonella* in NRTE comminuted chicken and turkey products, FSIS evaluated the first eight months of data generated by the new sampling and testing program. FSIS chose to initiate development of a proposed standard now, using the first eight months of data, in order to expedite the process for proposing a new standard and for realizing the projected public health benefits from a final standard. FSIS does not expect there to be substantive differences in the first eight months of data compared to the overall outcome of a baseline testing

[9] 76 FR 15282.

[10] Available at *http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=14.*

[11] *Public Health Effects of Raw Chicken Parts and Turkey Performance Standards,* 2014. FSIS.

[12] 76 FR 15282; Mar. 14, 2011.

[13] *http://www.cdc.gov/mmwr/pdf/wk/mm6315.pdf.* These surveillance data are for all foods, not just FSIS-regulated foods.

[14] Painter, et al., 2013 available at *http://wwwnc.cdc.gov/eid/article/19/3/11–1866_article.*

[15] Available at *http://www.nationalchickencouncil.org/about-the-industry/statistics/how-broilers-are-marketed/.*

period lasting at least one full year to more fully assess seasonal variation. However, if substantial differences are seen, FSIS could determine the effects of those differences on the standard prior to implementation.

FSIS utilized its MLG 4.08 [16] method to analyze samples of NRTE comminuted chicken and turkey products and parts for *Salmonella.* FSIS also used the 2015 Risk Assessment, which took into account the establishment by establishment incidence of *Salmonella* in NRTE comminuted chicken and turkey products and the predicted illnesses averted as a consequence of reducing the percentage positive of these pathogens. Because it is using an on-going sampling approach, FSIS will be able to calculate national prevalence for *Salmonella* and *Campylobacter* at least on an annual basis.

To obtain a better estimate of the overall prevalence of *Salmonella* and *Campylobacter* than a simple percent positive estimate, FSIS weighted the *Salmonella* and *Campylobacter* percent positive estimates by the production volume of each establishment for which there were sampling results. Using the first eight months of data, the national prevalence for *Salmonella* in NRTE comminuted chicken is about 49 percent and in NRTE comminuted turkey is about 20 percent. The national prevalence for *Campylobacter* in NRTE comminuted chicken is about three percent, and in NRTE comminuted turkey is about one percent.

Given that mechanically separated chicken and turkey are typically not added to NRTE comminuted poultry products, results for these products were not used in developing the *Salmonella* contamination distribution used in the risk assessment or the volume-weighted percent positive prevalence (VWPP) estimates above. It is important to note that the prevalence estimates were determined using the larger 325-gram analytical portion—a 13-fold increase in size from the 25-gram portion used to make prior prevalence determinations.

FSIS is proposing pathogen reduction performance standards that would achieve at least a 30-percent reduction in salmonellosis on a product-pathogen basis as a result of a reduction in exposure of the public to this pathogen when handling and preparing the product for consumption. To achieve this result for NRTE comminuted chicken, FSIS is proposing a pathogen reduction performance standard for *Salmonella* of 13 positives out of 52 samples.

Under this standard, the expected number of illnesses avoided would be about 3,100 (uncertainty interval (UI): [17] 2,000–4,700). Based on the initial eight months of data collected, FSIS estimates that approximately 62 percent of establishments will initially fail the performance standard. As establishments make changes to meet the new performance standard, FSIS estimates that the VWPP of 49 percent from *Salmonella* in comminuted chicken would be reduced to 34 percent. Evidence regarding FSIS's testing to assess whether establishments met the chicken carcass *Salmonella* performance standard suggested an approximate 50-percent increase in the share of industry that met the performance standard after 24 months under the new performance standard.[18] Therefore, FSIS estimates that 50 percent of establishments that initially do not meet the new performance standard will meet it in about two years. FSIS expects the same for all products under the new standards announced in this notice, as further elaborated in the 2015 Risk Assessment.

For NRTE comminuted turkey, FSIS is proposing a performance standard that would achieve at least a 30- percent reduction in salmonellosis. FSIS is, therefore, proposing a pathogen reduction performance standard for *Salmonella* of seven positives out of 52 samples for NRTE comminuted turkey. With that standard, FSIS estimates that the expected number of illnesses avoided would be about 2,400 (UI: 1,500–3,600). Based on the initial eight months of data collected, approximately 58 percent of establishments are predicted to initially fail the performance standard. As establishments make changes to meet the new performance standard, FSIS estimates that the VWPP of 20 percent of *Salmonella* in NRTE comminuted turkey will be reduced to 14 percent.

*Raw Chicken Parts—Salmonella*

FSIS developed the *Salmonella* pathogen reduction performance standard for raw chicken parts using the RCPBS data. Based on the baseline results, FSIS estimates that the national prevalence of *Salmonella* in four pound portions of raw chicken parts is about 24 percent with a 95-percent confidence interval between 19 percent and 29 percent.

As stated above, FSIS is proposing at least a 30- percent reduction in salmonellosis from raw chicken parts. To achieve this reduction, FSIS is proposing a pathogen reduction performance standard for *Salmonella* of eight positives out of 52 samples for raw chicken parts. The expected number of illnesses avoided would be about 29,000 (UI: 18,900—45,400). Based on the 2012 chicken parts baseline data, approximately 63 percent of establishments are predicted to initially not meet the performance standard. As establishments make changes to meet the new performance standard, FSIS estimates that the VWPP of 28 percent of *Salmonella* in four pound portions of raw chicken parts (breasts, legs, and wings) will be reduced to 18 percent.

The RCPBS expressly excluded chicken parts that were marinated or injected. The sampling of such products was not originally planned for under the new performance standards. Although during the period of test sampling before the baseline survey began (the shakedown period), FSIS did respond to questions about injected product and identified that products should not be sampled as part of the RCPBS. However, during the baseline survey, inspectors at multiple establishments confirmed that they collected sample parts that had been injected. In addition, since the shakedown, FSIS has determined that the additional handling of injected products marinated in a clear solution likely could cause additional contamination, particularly of the exterior surface of the poultry 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) other than through the ingredient statement. FSIS will clarify that such products will be sampled as part of the exploratory chicken parts sampling that will start in March 2015 (detailed below). In addition, when the new performance standard for chicken parts is implemented, such products would be subject to sampling. FSIS invites comment on this issue.

Breasts, legs, and wings are the most frequently produced chicken parts in the U.S. (>90 percent).[19] During the

[16] MLG 4.08 is described at *http://www.fsis.usda.gov/wps/wcm/connect/700c05fe-06a2-492a-a6e1-3357f7701f52/MLG-4.pdf?MOD=AJPERES.*

[17] Uncertainty about total illnesses attributed to poultry is simulated to generate 5th and 95th quantile values. These values are multiplied by the predicted effects of the performance standards to generate 5th and 95th percentile values for the annual number of illnesses avoided by the performance standard.

[18] *http://www.sciencedirect.com/science/article/pii/S0956713512002393.*

[19] AMS, Northeast & Southern States Monthly Report Data CY2013.

RCPBS, FSIS sampled additional parts, including necks, giblets, quarter carcasses, and half carcasses. Because of their high production representation, only breasts, legs, and wings were included in the risk assessment, and the draft performance standard will only apply to these parts. However, because the other types of chicken parts are available to consumers and present an exposure potential for both *Salmonella* and *Campylobacter,* FSIS recommends that industry put process controls in place to reduce contamination on these products. In cases where FSIS is concerned about the sanitary conditions in establishments, such as when an establishment is implicated in a food-borne outbreak, FSIS may collect samples of these other chicken parts to ascertain the level of process control in the establishment. When FSIS determines that there is reason to believe that the establishment is failing to maintain sanitary conditions, FSIS will require the establishment to demonstrate improved process control as evidenced by lower contamination incidence in these other chicken parts.

In March 2015, the Agency plans to begin sampling raw chicken parts on an on-going basis. As with all of the pathogen reduction performance standards announced in this notice, FSIS will not begin applying the pathogen reduction performance standard for raw chicken parts until after it has considered comments received on this notice. Meanwhile, FSIS will gain experience in scheduling, collecting, and analyzing raw chicken parts for *Salmonella* and *Campylobacter.* In addition, FSIS will report back to establishments periodically information about the samples collected and found to be positive for *Salmonella* or *Campylobacter.*

FSIS does not expect that data will change substantially and, therefore, does not expect to re-propose the standards based on the new data. However, FSIS will analyze the data and will discuss it in the **Federal Register** notice announcing the final standards. If the data change substantially based on the new testing so that FSIS determines it should change the standards, FSIS would re-propose the standards.

As stated above, FSIS intends to establish its standards for parts based on its sampling of breasts, legs, and wings in the RCPBS and thus to focus its on-going sampling on those parts. However, because some other parts were sampled very infrequently during the 2012 RCPBS, FSIS has decided to also sample additional parts not only to ascertain the level of process control in individual establishments but to estimate that part's contribution to *Salmonella* and *Campylobacter* illnesses. FSIS may ultimately decide that it is necessary to propose additional pathogen reduction performance standards for these other chicken parts, particularly if there is evidence that establishments are not effectively controlling sanitary conditions associated with the production of these parts.

*NRTE Comminuted Poultry—Campylobacter*

FSIS developed the new standards using the 2015 Risk Assessment, which took into account the establishment by establishment prevalence of *Campylobacter* in NRTE comminuted chicken and turkey products and predicted illnesses averted as a consequence of reducing the prevalence of these pathogens. For the purpose of developing these pathogen reduction performance standards, as stated above, FSIS analyzed the first eight months of data generated from the new sampling program.

For NRTE comminuted chicken, a pathogen reduction performance standard for *Campylobacter* of one positive out of 52 samples should result in about a 37-percent reduction in *Campylobacter* illnesses from that product. The expected number of illnesses avoided would be about 1,300 (UI: 700–2,000). Approximately 24 percent of establishments are predicted to initially not meet the performance standard. As establishments make changes to meet the new performance standard, FSIS estimates that the VWPP of *Campylobacter* of 3.4 percent in NRTE comminuted chicken will be reduced to 2.1 percent.

For NRTE comminuted turkey, the current *Campylobacter* prevalence is so low that the Agency determined a 33-percent reduction could not be feasibly met. Thus, FSIS is proposing a pathogen reduction performance standard for *Campylobacter* for NRTE comminuted turkey of one positive out of 52 samples, which is estimated to result in about a 19-percent reduction in *Campylobacter* illnesses. The expected number of illnesses avoided as a result of such a reduction would be about 500 (UI: 300–700). The risk assessment estimates approximately nine percent of establishments will initially fail the performance standard. As establishments make changes to meet the new performance standard, FSIS estimates that the VWPP of *Campylobacter* of 1.2 in NRTE comminuted turkey will be reduced to about one percent.

FSIS developed the above pathogen reduction performance standards for *Campylobacter* using a direct plating laboratory method of analysis with a 1 ml test portion. FSIS plans to assess establishment performance relative to those standards based on the 1 ml portion size. However, given the lower sensitivity of this test, this fiscal year FSIS will begin concurrently analyzing a subset of NRTE comminuted poultry samples it collects for verification testing using an enrichment method of analysis with a larger test portion, a 30 ml test portion for chickens (MLG 41.03).[20] By increasing the potential for growth and recovery of injured cells, FSIS anticipates the enrichment method of analysis will detect more contamination. FSIS expects to analyze testing data generated from both analytical approaches. This analysis will allow FSIS to determine whether the pathogen reduction performance standards for *Campylobacter* in NRTE comminuted chicken and turkey should be revised from the above proposed standards to standards based on an enrichment method, such as with a 30 ml test portion.

*Raw Chicken Parts—Campylobacter*

The stated HP2020 national goal for percent reduction in campylobacteriosis cases is 33 percent. Based on the baseline results, FSIS estimates that the national prevalence of *Campylobacter* in four pound portions of raw chicken parts is about 22 percent with a 95-percent confidence interval between 19 percent and 25 percent. To meet a 32-percent reduction in campylobacteriosis, the 2015 Risk Assessment estimated that a pathogen reduction performance standard for *Campylobacter* in raw chicken parts of four positives out of 52 samples [21] would be sufficient. The expected number of illnesses avoided would be about 14,300 (UI: 8,400–23,100). Based on data generated from the 2012 RCPBS, approximately 46 percent of establishments are predicted to fail the performance standard. As establishments make changes to meet the new performance standard, FSIS estimates that the VWPP of 15.5 percent for *Campylobacter* in four pound

[20] More details about the analytical method are available at *http://www.fsis.usda.gov/wps/wcm/connect/0273bc3d-2363-45b3-befb-1190c25f3c8b/MLG-41.pdf?MOD=AJPERES.*

[21] FSIS chose not to reduce the standard to three positives out of 52 samples because it would exceed the HP2020 national goal in excess of 10 percent.

portions of raw chicken parts (breasts, legs, and wings) will be reduced to 10 percent.

| Product | *Salmonella* prevalence (percent) | *Campylobacter* prevalence (percent) | Maximum acceptable percent positive | | Performance standard | |
|---|---|---|---|---|---|---|
| | | | Salmonella | Campylobacter | Salmonella | Campylobacter |
| Broiler Carcasses ..... | 7.5 | 10.4 | 9.8 | 15.7 | 5 of 51 ..... | 8 of 51. |
| Turkey Carcasses ..... | 1.7 | 0.79 | 7.1 | 5.4 | 4 of 56 ..... | 3 of 56. |
| Comminuted Chicken ..... | ∧*49 | ∧*3.4 | 25.0 | 1.9 | 13 of 52 ..... | 1 of 52. |
| Comminuted Turkey ..... | ∧*19.9 | ∧*1.2 | 13.5 | 1.9 | 7 of 52 ..... | 1 of 52. |
| Chicken Parts ..... | ∧*28 | ∧*15.5 | 15.4 | 7.7 | 8 of 52 ..... | 4 of 52. |

∧ volume-weighted percent positive
* based on eight months of data

**Changes to Related Verification Sampling Procedures**

On August 28, 2013, FSIS published in the **Federal Register** a notice announcing changes to its *Salmonella* sampling program for raw beef products (78 FR 53017). In the August 2013 notice, FSIS also announced that it was considering alternatives to set-based sampling for *Salmonella,* including routine sampling (similar to what FSIS uses for Shiga toxin-producing *Escherichia coli* (STEC) sampling) with a moving window approach to assess process control.

On June 5, 2014, in the **Federal Register** notice responding to comments received on the August 2013 **Federal Register** notice, FSIS reiterated that it was considering using on-going scheduled sampling with a moving window approach to assess process control for all *Salmonella* performance standards (79 FR 32436). FSIS is affirming those plans for addressing *Salmonella* and will proceed with implementing those plans. Below, FSIS is providing more explanation of how the change will work when scheduling samples and assessing process control in establishments.

FSIS does not collect imported raw poultry products for *Salmonella* and *Campylobacter* analysis. However, on June 29, 2014, FSIS began analyzing for *Salmonella* all imported raw beef samples it collects for STEC analysis (79 FR 32436; Jun 5, 2014).

Thus, in March 2015, FSIS will begin analyzing for *Salmonella* (and *Campylobacter*) imported raw broiler and turkey carcasses, NRTE comminuted chicken and turkey products, and raw chicken parts. FSIS will use enumeration and serotype data of this testing to identify trends within the sampling data, to determine whether an isolate has a historical association with human illness, and to identify clusters of patterns. In addition, FSIS will post aggregate results of this testing on the FSIS Web site as part of its quarterly report on *Salmonella.*

*Salmonella* is not an adulterant in raw poultry products. Therefore, a positive test result for *Salmonella* in imported raw poultry product sampled by FSIS import inspection personnel would not result in regulatory control actions at port-of-entry. However, consistent findings of *Salmonella* would raise concern about the effectiveness of the country's food safety system, which could influence the focus and timing of the next audit of the country or result in other appropriate action.

*Routine Sampling*

Consistent with what it announced in its August 2013 **Federal Register** notice, FSIS will replace its existing *Salmonella* sampling set-approach with a routine sampling approach for all FSIS-regulated products subject to *Salmonella* and *Campylobacter* verification testing. This includes for broiler and turkey carcasses and chicken parts. FSIS has already moved to routine sampling for comminuted poultry, ground beef, and beef manufacturing trimmings.

FSIS has determined that its current set-based *Salmonella* sampling program cannot be used to estimate prevalence for several reasons.[22] First, FSIS's scheduling algorithm disproportionately focuses sample collection based on past performance under the *Salmonella* performance standards. As a result, FSIS may not sample from establishments maintaining consistent process control (Category 1—establishments continuously achieving 50 percent or less of the pathogen reduction performance standard, *i.e.,* meeting or surpassing the standard) for a year or more, while those with highly variable process control (Category 3—establishments that have exceeded the pathogen reduction performance standard, *i.e.,* not meeting the standard) could be scheduled quite often. An establishment with variable process control (Category 2—establishments that have not continuously achieved 50 percent or less of the pathogen reduction performance standard, nor have they exceeded the standard) could be sampled at least annually. Such disproportionate sample collection results in not all establishments having a known probability of being selected for sampling.

Second, once a sample set begins, an establishment is aware that it will be sampled every day the product is produced over the next few months (or longer for smaller plants that produce less frequently) until the set is complete. This knowledge might create a bias because establishments may, intentionally or not, adhere more conscientiously to proper sanitary procedures during this time. This adherence could result in lower numbers of positive *Salmonella* results than would occur otherwise, and any prevalence calculation would be underestimated.

By sampling establishments with a proper frequency and continuously throughout the year, FSIS would be able to calculate the national prevalence of *Salmonella* and *Campylobacter.* FSIS intends to use the ongoing estimation to monitor changes in prevalence over time and to correlate those changes with the effectiveness of Agency policies and procedures.

FSIS will begin using, in lieu of set-based sampling, routine sampling for all products that it samples as part of its *Salmonella* verification sampling program, such as broiler and turkey carcasses, as well as those products for which new standards are contemplated, such as ground beef at the 325-gram sample size and beef manufacturing trimmings. Taking into account risk factors including production volume and past establishment testing

[22] *http://www.fsis.usda.gov/wps/wcm/connect/56b2ccbd-ad57-4311-b6df-289822d28115/Prevalence_Estimates_Report.pdf?MOD=AJPERES.*

performance (*i.e.,* positive *Salmonella* and *Campylobacter* test results), FSIS will sample eligible product from the largest-volume establishments four or five times per month (once per week), on average, and will decrease incrementally the number of samples it collects from establishments producing less volume. FSIS may sample a small number of establishments up to six times per month because the risk factor for that particular volume category/product combination is much higher than that for other combinations. FSIS has described its overall strategy for directing its *Salmonella* and *Campylobacter* sampling resources in its *FY 2015 Annual Sampling Program Plan.*[23]

Some large volume establishments, in particular young turkey slaughter establishments, may produce eligible product for only a few months of the year. Under the existing set-based *Salmonella* sampling program, these establishments rarely complete a sampling set within the year. To assess process control in establishments with concentrated seasonal production, FSIS will intensify sampling at these establishments when in production to obtain the samples needed to assess process control using the moving window. FSIS will use historical sampling data collected from the particular establishment to determine the frequency of sampling.

FSIS does not currently sample eligible product for *Salmonella* from poultry establishments that produce less than 1,000 pounds per day (*i.e.,* very small establishments) or from poultry slaughter establishments that operate under a religious exemption. Therefore, FSIS does not have *Salmonella* or *Campylobacter* data from these establishments for young chickens, turkeys, NRTE comminuted chicken or turkey, and raw chicken parts. At the time that the new pathogen reduction performance standards are implemented, FSIS intends to begin sampling eligible product 3–4 times per year from these establishments. FSIS anticipates that it will begin sampling eligible product that had been exempted from *Salmonella* verification testing in approximately 95 poultry slaughter establishments operating under a religious exemption, and approximately 580 poultry establishments that produce less than 1,000 pounds per day. FSIS expects to eventually implement pathogen reduction performance standards to assess process control at these poultry establishments.

Before FSIS begins using these samples to assess process control at establishments previously excluded from verification sampling, it will provide notice in the **Federal Register**. Meanwhile, FSIS expects to treat the low volume establishments as separate populations and to report how well the population of establishments is performing, including such information as percentage positive, 25th, 50th, and 75th percentile.

*Moving Window Approach*

Without discrete sampling sets, a different approach is needed to assess process control in establishments within a routine sampling program. When assessing process control under a moving window approach, FSIS intends to evaluate, over a certain period of time, a number of sequential results from a single establishment. Thus, given the fixed timeframe of one year (52 weeks) for which an establishment has been sampled, FSIS would assess the first moving window by evaluating the number of positive samples out of the number of samples taken within the 52-week period. As an example, if an establishment has five *Salmonella* positives within 52 samples (one sample per week for a year), then the establishment passed the performance standard if the performance standard allows five positive samples among 52 samples. When the next sample is taken (week 53, in this example), the moving window would shift forward the fixed timeframe of one year (52 weeks); that is, the original week 1 (and the original first sample) is excluded, while the most recent week is included in the new 52-week moving window. This shifting is repeated with each new week and allows FSIS to continuously assess the process control of an establishment.

FSIS chose a 52-week moving window because it will appropriately average expected fluctuations, for example, those that result from seasonal variation. Nevertheless, FSIS intends to periodically assess its results to determine if adjustments to the 52-week moving window are appropriate.

For highest-volume establishments, FSIS expects to collect 52 samples within the 52-week moving window. In this case, to assess process control (at establishments producing products with performance standards measured in 52 samples), one need only to count the number of positives test results within the 52-week moving window. So, as an example, the proposed performance standard for *Salmonella* in raw chicken parts is eight positives out of 52 samples. Assuming 52 samples were collected from the establishment within a 52-week moving window, if the establishment has eight or fewer *Salmonella* positives within that 52-week timeframe, then it would pass the performance standard. If, on the other hand, the establishment has nine or more *Salmonella* positives within that same 52-week timeframe, then it would fail the performance standard.

The following table demonstrates what FSIS has determined to be the minimum number of samples for each product class by pathogen.

| Product | Max Acceptable percent positive | | Minimum number of samples | |
|---|---|---|---|---|
| | Salmonella | Campylobacter | Salmonella | Campylobacter |
| Broiler Carcass | 9.8 | 15.7 | 10 | 10 |
| Turkey Carcass | 7.1 | 5.4 | 14 | 19 |
| Comminuted Chicken | 25.0 | 1.9 | 10 | 52 |
| Comminuted Turkey | 13.5 | 1.9 | 10 | 52 |
| Chicken Parts | 15.4 | 7.7 | 10 | 13 |

Previously, FSIS held the same standard to all eligible establishments within a product class. However, FSIS found that some lower volume establishments would take over a year and sometimes two years to complete a set. Thus, to assess process control in establishments that FSIS samples less often than weekly (*i.e.,* lower volume establishments), FSIS will assess establishment performance (as percent positive) based on the (likely variable) number of samples collected and positive results within the 52-week moving window.

[23] Available at *http://www.fsis.usda.gov/wps/wcm/connect/cb091bde-4900-45ec-8bf5-980dc9496bd1/Sampling-Program-Plan-FY2015.pdf?MOD=AJPERES.*

To illustrate this point, if a small establishment producing raw chicken parts is sampled fewer than 52 times in the 52-week moving window, only 26 times, for example, with three of those samples testing positive for *Salmonella,* 26 will be the denominator while three would be the numerator. This gives the establishment a percent positive of 11.5 percent ((3⁄26) × 100 = 11.5%). In this example, the resulting percent positive is less than 15.4 percent, the acceptable percent positive for the proposed performance standard for *Salmonella* in raw chicken parts ((8⁄52) × 100 = 15.4%). As such, the establishment would pass the performance standard.

Given that *Salmonella* is not an adulterant in raw product, FSIS determined that any performance standard for *Salmonella* or *Campylobacter* should use one or greater as the acceptable number of positives results. A performance standard of zero maximum acceptable positives is actually a zero-tolerance standard. With one acceptable positive as the numerator, FSIS used the following formula to estimate the minimum number of samples (n) needed to assess process control at an establishment:

n = (1/percent positive allowed) − 100.

So, for example, if the performance standard is 5 percent (the percent positive allowed), then (1⁄5.0) − 100 = 20 samples is the minimum number of samples required to assess process control. Although, as another example, if the performance standard is 20 percent then (1/20.0) − 100 = 5 samples is the minimum number of samples required to assess process control. However, to decrease the margin of error, FSIS has deemed 10 as the minimum number of samples required to assess process control in an establishment.

FSIS acknowledges that less-than-weekly sampling plans may result in a higher probability of mis-categorizations. However, FSIS chose the above method for assessing process control in lower volume establishments to limit the duration these establishments would remain in Category 2 or 3, if effective corrective actions are taken by the establishment. FSIS requests comment on how it plans to assess process control in lower volume establishments.

A 52-week moving window does not necessarily mean that FSIS must wait one year before it can determine whether an establishment has met a performance standard. Using the broiler carcass performance standard as an example (5 acceptable positives or fewer constitute passing while 6 or more is failing), if a high volume chicken slaughter establishment that is sampled weekly gets six positives in less than 52 weeks, FSIS can deem that establishment to have failed the performance standard no matter how many uncollected samples remain in the establishment's 52-week moving window.

*Defining Categories*

Under the existing set-based *Salmonella* verification sampling program, FSIS classifies establishment performance relative to the pathogen reduction performance standard (by product class) using the 3-category establishment classification system announced on February 27, 2006 (71 FR 9772). FSIS will continue using this classification system under routine sampling. However, for all products sampled under routine *Salmonella* verification sampling, FSIS plans to modify the time component of those definitions as follows:

I. Category 1. Consistent Process Control: Establishments that have achieved 50 percent or less of the performance standard during all completed 52-week moving windows over the last six months.

II. Category 2. Variable Process Control: Establishments that meet the standard for all completed 52-week moving windows but have results greater than 50 percent of the standard during any completed 52-week moving window over the last six months.

III. Category 3. Highly Variable Process Control: Establishments that have exceeded the performance standard during any completed 52-week moving window over the last six months.

Because of the potential for frequent changes in category status once the first moving window is complete, FSIS felt a time component was needed to provide stability. Upon completion of their first 52-week moving window, FSIS intends to update the category status for each eligible establishment, after the pathogen reduction performance standards are finalized and implemented for that product category. Thereafter, FSIS expects to re-categorize establishments monthly based on their performance over the last six months. Finally, FSIS expects to categorize establishments for *Campylobacter* process control similarly as for *Salmonella.*

With the addition of the 6-month time period, establishments can expect to remain in Category 2 or 3 no shorter than 26 weeks. This lower bound is based on a scenario where an establishment's positive results are clustered at the beginning of the 52-week moving window. Alternatively, if an establishment's positive results are clustered at the end of the 52-week moving window, it would take a minimum of 69 weeks to move out of that category. However, based on analysis of its current set-based verification sampling results, FSIS does not believe these extreme scenarios are likely. FSIS data suggests that positive results would be more evenly distributed throughout the moving window and not clustered.

FSIS has analyzed the 6-month time period and determined it to have minimal impact on the categorization of establishments that are most likely to meet the standard. Our analysis suggests that, depending on the underlying pathogen prevalence at an establishment, the impact could range from no increase in probability to about a 7-fold increase. However, the higher-end increase is predominantly for those establishments already with a low probability of not meeting the standard, so the absolute probability of not meeting the standard remains low. For example, if an establishment had a 0.1 percent chance of not meeting a standard during a 52-week moving window, its probability of not meeting the standard during the 6 months after completion of that moving window would be about 0.7 percent. FSIS requests comment on its planned modifications and the impact of the 6-month time period on the categorization of establishments.

*Web-Posting*

The Agency's policy of web-posting establishments' process control performance has stimulated improvement in industry performance, as was shown in the Agency's experience after announcing in 2006 that it was considering posting the names of broiler and turkey slaughter establishments in Category 2 and 3. Within two years after the announcement, but before names were actually posted, the number of broiler slaughter establishments that had been in Category 3 decreased by approximately 55 percent. Furthermore, the percentage of broiler slaughter establishments in Category 1 increased by nearly 40 percent. Once FSIS began posting establishment names and their process control performance, the turkey slaughter establishments responded particularly to the challenge that FSIS identified for the industry. The Agency said that if 90 percent of the broiler or turkey industry attained Category 1 status with no establishments in Category 3, FSIS would no longer publish the names or process control performance of the establishments. The

turkey slaughter establishments met the challenge proffered by FSIS, and FSIS stopped publishing the names of the turkey slaughter establishments.

Another example of how the categorization of establishments was used by the industry involved those establishments that produced a product referred to as NRTE stuffed chicken breast that appeared as RTE, such as Chicken Kiev. Multiple illnesses were traced to this product containing raw chicken. As a mitigation strategy for reducing the likelihood of the product being contaminated with *Salmonella,* establishments that produced the product cited a purchase specification requirement for using only chicken breast meat supplied by Category 1 establishments. Because FSIS was not posting the Category 1 status of establishments, industry internally worked out how to address this issue, but there was no verification of this specification provision by FSIS. FSIS noted at the time that without posting Category 1 status, there was confusion by consumers and industry as to whether establishments not listed as Category 2 or Category 3 establishments were actually Category 1 or had not yet been categorized.

Consequently, FSIS intends to post the category status for all eligible establishments because web-posting provides greater transparency, thereby providing the public with the tools and information that it needs to make informed food safety decisions. After reviewing the comments received on this notice, beginning July 1, 2015, the Agency plans to begin web-posting individual establishment category information for chicken and turkey carcasses. FSIS will finish sample sets begun before February 2015 and will not begin any new sampling until March, at which time FSIS will begin sampling chicken and turkey carcasses using the moving window approach, rather than the set approach. FSIS will assess what category establishments are in as of July 1, using combined historical set data and sample results beginning March 2015. In July, FSIS will then post the category establishments are in. For example, once FSIS begins the new sampling approach in March, FSIS may collect 24 samples from March 1 through June 30, 2015, at some establishments. In July, FSIS will assess those 24 results and the previous 28 results assessed under the set approach. Based on those most recent 52 samples, FSIS will assess which category the establishment is in and post that category. FSIS will then monthly re-categorize establishments, based on the last 52 samples, until sufficient data is available to look at the previous six months of windows as described above.

Until July, FSIS will continue to web-post existing Category 3 poultry carcass establishments. In addition, the Agency will post aggregate reports quarterly showing the Category 1/2/3 distribution for each relevant product class subject to FSIS *Salmonella* and *Campylobacter* testing, as applicable. Therefore, FSIS will continue to post aggregate reports for chicken and turkey slaughter establishments showing category distribution for current performance standards for carcasses. In addition, starting in March, FSIS will begin posting aggregate reports showing the category 1/2/3 distribution for chicken parts as data become available, and comminuted chicken and turkey using historical data and new results beginning in March based on the proposed standards. FSIS invites comments on how it plans to web-post establishments.

*Agency Actions*

FSIS has used the results from its verification testing program as a measure of establishment process control for reducing exposure of the public to pathogens. Under the HACCP regulations, establishments need to control their processes to ensure that public exposure to pathogens is minimized. The Agency has found that using pathogen reduction performance standards in this way is effective in encouraging improved establishment control of pathogens, and that it has resulted in reduced human illnesses.[24]

Under the new standards and under the new moving window approach, when an establishment does not meet a performance standard (*i.e.,* the number of positive samples within a specified timeframe exceeds the maximum acceptable for that product class), FSIS will immediately conduct follow-up sampling. Follow-up samples will be analyzed for both *Salmonella* and *Campylobacter,* where applicable. Because FSIS has experience with follow-up samples associated with the *Escherichia coli* O157 testing program, FSIS will assess whether this approach will work for *Salmonella* and *Campylobacter* testing. In essence, either 16 or eight follow-up samples are collected depending upon the size and production volume of the establishment. FSIS will analyze follow-up sampling data independent of the moving window approach to assess whether the establishment is making or has made changes to its food safety system to improve its process control.

As FSIS does now when establishments do not meet performance standards, FSIS will conduct a for-cause FSA at the establishment that produced the product. In addition, even when establishments meet the performance standards, if FSIS *Salmonella* or *Campylobacter* verification testing data from an establishment show a high number of positives or serotypes of human health significance, FSIS may perform Incident Investigation Team testing or conduct a for-cause FSA that includes collection of samples or take other appropriate actions, such as additional sanitary dressing verification procedures, at the establishment that produced the product.

In May 2010, FSIS issued guidance on how establishments can address Salmonella and Campylobacter in poultry.[25] FSIS is updating this guidance to include additional suggested pre-harvest and post-harvest controls. The Agency intends to make the updated guidance available to the establishments soon. In response to a Government Accountability Office recommendation, FSIS will include information in the guidance on the effectiveness of pre-harvest controls to reduce pathogens in live poultry (USDA Needs to Strengthen its Approach to Protecting Human Health from Pathogens in Poultry Products, September 2014 at *http://www.gao.gov/assets/670/666231.pdf*).

**Cost-Benefit Analysis**

FSIS has considered the economic effects of new pathogen reduction performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and NRTE comminuted poultry. The full analysis is published on the FSIS Web site as supporting documentation to this notice. FSIS is seeking comment on the accuracy of the information and assumptions used in the cost-benefit analysis. A summary of the analysis is below.

*Industry Costs*

Establishments will incur costs as they make changes to their processes in order to meet the new standards. FSIS estimates that approximately 63 percent of raw chicken parts producing establishments, 62 percent of NRTE

[24] *http://www.sciencedirect.com/science/article/pii/S0956713512002393; http://online.liebertpub.com/doi/abs/10.1089/fpd.2011.0951.*

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

comminuted chicken producing establishments, and 58 percent of NRTE comminuted turkey producing establishments will not meet the new *Salmonella* standards. FSIS estimates that approximately 46 percent of raw chicken parts producing establishments, 24 percent of NRTE comminuted chicken producing establishments, and 9 percent of NRTE comminuted turkey producing establishments will not meet the new *Campylobacter* standards.

Establishments that initially do not meet the standard but aspire to do so will need to make changes to their production processes to lower the prevalence of *Salmonella* and *Campylobacter* in their products. Changes could include pre-harvest interventions, such as vaccination programs, well-timed feed withdrawal, clean and dry litter and transportation, and supplier contract guarantees of pathogen-free flocks. During processing, establishments could add additional cleaning procedures, apply chemical antimicrobials to parts and source materials for comminuted poultry product and provide additional sanitation training to employees. For the purposes of the cost-benefit analysis, FSIS used the cost of adding antimicrobial solutions to poultry parts as a proxy for the costs of interventions and changes that could be implemented. FSIS used this approach based on information from FSAs in response to broiler *Salmonella* sets not meeting the standards and information from the FSIS Poultry Checklist explained above. Through FSAs, FSIS found that the majority of establishments added antimicrobials to the production process as a corrective action, suggesting that an antimicrobial intervention would be the most likely response should an establishment not meet the proposed performance standards. Also, information from the FSIS Poultry Checklist showed that the majority of establishments are not applying antimicrobials to raw poultry parts and source materials for comminuted poultry product.

To account for uncertainty in the proportion of establishments making changes to their production processes in order to meet the new standards, FSIS provided cost estimates for a range (30, 40, and 50 percent) of establishments initially falling short of but eventually meeting the standards in two years. These costs are summarized and annualized over 10 years at a discount rate of 7 percent in Table 1.

TABLE 1—TOTAL INDUSTRY COSTS ANNUALIZED [1]

| Compliance level of establishments not meeting standard | Cost component | Primary estimate ($mil) | Low estimate ($mil) | High estimate ($mil) |
|---|---|---|---|---|
| 30% | Capital Equipment | 2.15 | | |
| | Antimicrobial Solution | 6.54 | 4.61 | 8.46 |
| | Microbiological Sampling | 9.27 | 6.18 | 12.36 |
| | HACCP Validation & Training | (*) | | |
| Total Costs | 17.96 | 12.94 | 22.97 | |
| 40% | Capital Equipment | 2.86 | | |
| | Antimicrobial Solution | 8.72 | 6.14 | 11.28 |
| | Microbiological Sampling | 9.82 | 6.52 | 13.05 |
| | HACCP Validation & Training | (*) | | (*) |
| Total Costs | 21.40 | 15.52 | 27.19 | |
| 50% | Capital Equipment | 3.58 | | |
| | Antimicrobial Solution | 10.89 | 7.68 | 14.12 |
| | Microbiological Sampling | 10.40 | 6.91 | 13.81 |
| | HACCP Validation & Training | (*) | | |
| Total Costs | | 24.87 | 18.17 | 31.51 |

[1] Costs annualized at a discount rate of 7 percent over 10 years.
* Approximately $3,800 at 30% compliance, $5,100 at 40% compliance, and $6,400 at 50% compliance—values too small to display in table.

*Agency Costs*

FSIS does not expect to incur any additional costs as a result of introducing new performance standards. FSIS allocates a fixed number of samples by product class, sampling project, and pathogen each year. FSIS does not anticipate the need to exclude any of the other testing programs allocated to other product classes. FSIS intends to test carcasses at the level that is needed. In order to accommodate the proposed sampling programs, FSIS will adjust the currently allotted young chicken (''Broiler'') and young turkey sampling programs for *Salmonella* and *Campylobacter* to include testing of raw chicken parts and not-ready-to-eat comminuted chicken and turkey. In this case, samples that could be allocated to test carcasses will be moved closer to the consumer and be used on parts and NRTE comminuted poultry products. Therefore, FSIS will not expend additional resources to implement the proposed performance standards.

*Public Health Benefits*

As establishments make changes to their production processes and reduce the prevalence of *Salmonella* and *Campylobacter* in chicken parts and NRTE comminuted poultry, public health benefits will be realized in the form of averted illnesses. For each assumed compliance level FSIS estimated the cost savings associated with the percentage reduction in human illnesses as calculated in the 2015 Risk Assessment. The results of this calculation were annualized over 10 years at a discount rate of 7 percent, and are displayed in Table 2.

TABLE 2—PUBLIC HEALTH BENEFITS ANNUALIZED [1]

| Compliance level of establishments not meeting the standard (%) | Primary estimate ($mil) | Low estimate ($mil) | High estimate ($mil) |
|---|---|---|---|
| 30 | 50.87 | 31.84 | 79.89 |
| 40 | 79.66 | 50.43 | 125.89 |
| 50 | 109.10 | 68.80 | 171.24 |

[1] Benefits annualized over 10 years at a discount rate of 7 percent.

*Summary of Net Benefits*

Table 3 displays the total costs and benefits expected from the implementation of performance standards for chicken parts and comminuted poultry. All values have been annualized over 10 years at a 7 percent discount rate. For all compliance levels considered, the performance standards result in net benefits.

TABLE 3—SUMMARY OF NET BENEFITS [1]

| Compliance level of establishments not meeting the standard (%) | Cost/benefit component | Primary estimate ($mil) | Low estimate ($mil) | High estimate ($mil) |
|---|---|---|---|---|
| 30 | Industry Costs | (18.0) | (12.9) | (23.0) |
| | FSIS Costs | ..... | ..... | ..... |
| | Public Health Benefits | 50.9 | 31.8 | 79.9 |
| Net Benefits | ..... | 32.9 | 18.9 | 56.9 |
| 40 | Industry Costs | (21.4) | (15.5) | (27.2) |
| | FSIS Costs | ..... | ..... | ..... |
| | Public Health Benefits | 79.7 | 50.4 | 125.9 |
| Net Benefits | ..... | 58.3 | 34.9 | 98.7 |
| 50 | Industry Costs | (24.9) | (18.2) | (31.5) |
| | FSIS Costs | ..... | ..... | ..... |
| | Public Health Benefits | 109.1 | 68.8 | 171.2 |
| Net Benefits | ..... | 84.2 | 50.6 | 139.7 |

[1] All costs and benefits annualized over 10 years at a 7 percent discount rate.

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*Additional Public Notification*

FSIS will announce this notice online through the FSIS Web page located at *http://www.fsis.usda.gov/federal-register.*

FSIS will also make copies of this **Federal Register** publication available 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 constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic 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 to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC on: January 21, 2015.

**Alfred V. Almanza,**

*Acting Administrator.*

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