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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2009-0034]

New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments; New Compliance Guides

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing new performance standards for the pathogenic micro-organisms Salmonella and Campylobacter for use in young chicken and turkey slaughter establishments. The new performance standards were developed in response to a charge from the Food Safety Working Group. The Agency tentatively plans to implement these new performance standards for chilled carcasses in July 2010. The new standards are based on recent FSIS Nationwide Microbiological Baseline Data Collection Programs: the Young Chicken Survey and the Young Turkey Survey. The Agency invites comments on the new performance standards.

FSIS is also announcing that it has posted on its Web site the third edition of the compliance guide for controlling Salmonella and Campylobacter in poultry and a

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compliance guide on pre-harvest management to reduce E. coli O157:H7 contamination in cattle. FSIS issues guidance documents to present current Agency thinking on specific topics related to food safety. Though Agency guidance documents are recommendations rather than regulatory requirements and are revised as new information becomes available, FSIS encourages meat and poultry establishments to follow this guidance. FSIS requests comments on these guidance documents.

DATES: Comments are due by [INSERT DATE 60 DAYS AFTER PUBLICATION].

ADDRESSES: Comments may be submitted by either 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 online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Room 2-2127, George Washington Carver Center, 5601 Sunnyside Avenue, Mailstop 5474, Beltsville MD 20705-5474.

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Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2009-0034. 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 the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel Engeljohn, Ph.D., Deputy Assistant Administrator for Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, Room 349-E, Jamie Whitten Building, 14th and Independence, SW, Washington DC 20250-3700; telephone (202) 205-0495, fax (202) 720-2025; daniel.engeljohn@fsis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

FSIS is the public health regulatory agency in the U.S. Department of Agriculture (USDA) that is responsible for ensuring that the nation's commercial supply of meat, poultry, and processed egg products is safe, wholesome, and

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appropriately labeled and packaged. FSIS is a participant in the President's Food Safety Working Group (FSWG), which was created by President Obama in March 2009 to recommend improvements to the U.S. food safety system. The FSWG is chaired by Secretary of Agriculture Tom Vilsack and Health and Human Services Secretary Kathleen Sebelius. In July 2009, the FSWG published Key Findings (FSWG Key Findings) recommending a new, public health-focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

The FSWG charged FSIS with "cutting Salmonella risk in Poultry Products" by "develop[ing] new standards to reduce the prevalence of Salmonella in turkey and poultry" and by "establish[ing] a Salmonella verification program with the goal of having 90 percent of poultry establishments meeting the new standards by the end of 2010." These new Salmonella standards will be applied to sample sets from establishments included in the Agency's Salmonella Verification Program in the place of the performance standards for young chickens (as broilers) codified at 9 CFR 381.94 and the standards for turkeys announced in a Federal Register Notice of February 17, 2005. The FSWG further charged FSIS with "develop[ing] a new performance

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standard for Campylobacter for young chickens and turkeys.”

This notice announces that FSIS has developed such performance standards. The notice also describes the estimated public health impact that is likely to result if these standards are met.

The performance standards for young chickens and turkeys set out in this notice are based on the Agency’s recent Nationwide Microbiological Baseline Data Collection Programs: the Young Chicken Baseline Survey (YCBS), and the Young Turkey Baseline Survey (YTBS).

From July 2007 to June 2008, the YCBS collected and analyzed 6,550 samples at 182 establishments that slaughtered young chickens and produced whole carcasses under Federal inspection. Rinsate samples were taken both at rehang and postchill locations, from whole carcasses that were shaken in bags together with 400 mL of sample rinse solution. “Re-hang” refers to the location in the process after the picker and prior to evisceration of the bird. “Post-chill” refers to the point in the process where the carcasses exit the immersion chiller or other chill media (such as ice) after all slaughter interventions have taken place, but before entering coolers or proceeding to further processing.

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These samples were analyzed by different methods to estimate the prevalence or "qualitative" rate and the levels or "quantitative" measures (colony forming units per milliliter or cfu/mL) of two human pathogens, Salmonella and Campylobacter, and four non-pathogenic "indicator organisms" that track process control: generic Escherichia coli, Aerobic Plate Count (APC), Enterobacteriaceae, and total coliforms. Re-hang sample results were compared with post-chill sample results, and the comparison confirmed that microbial loads are significantly reduced by the time the carcasses reach post-chill.

The Agency has used the postchill sample results from the YCBS, weighted by volume, to estimate the prevalence of Salmonella and Campylobacter on inspected and passed young chicken carcasses. These prevalence estimates constitute the new performance standards announced in this notice. These performance standards will apply to all young chickens, including roasters and Cornish game hens. The Agency intends to use the same sample collection and analysis procedures that it used in the baseline.

The YTBS report is being prepared for publication. In the YTBS, FSIS collected and analyzed 1,442 carcass sponge samples at the re-hang and post-chill locations from young turkeys (including young breeder turkeys) slaughtered in 58

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Federal establishments from August 2008 to July 2009.

Inspection program personnel used two sponges, each moistened with 25 mL of solution, for each carcass sampled at the two locations. They swiped each sponge over 100 cm² of the thigh and back of one half of the carcass (50 cm² on each part). One of the two sponges used at each location was used to analyze for Salmonella and the other for Campylobacter. For Salmonella samples, each sponge plus the 25 mL of solution was enriched to determine the presence or absence of Salmonella. For Campylobacter samples, from each 25 mL sponge sample portion, 1-1.3 mL was extracted for the direct plating test, which is referred to as the "1 mL" procedure.

The 1 mL procedure provides data on levels of organisms present but is relatively insensitive because of the small size of the sample portion analyzed and thus detects positive samples with higher levels of organisms. The remaining 24 mL of solution, which contains the sample sponge, was enriched so as to detect positive samples with low levels of organisms and thus to help estimate prevalence. Thus, the sample results were used to estimate the prevalence or "qualitative" rate and the levels or "quantitative" measures of the same organisms as for the YCBS. The Agency used the postchill sample results from

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the YTBS, weighted by volume, to estimate the prevalence of Salmonella and Campylobacter at postchill. The Agency then used those estimates of prevalence to develop the new performance standards announced in this notice. The sample collection and analysis procedures used in assessing compliance with the performance standard will be the same as used in the baseline. A technical paper on the method used to develop the performance standards is posted at the FSIS Web site with this notice at http://www.fsis.usda.gov/regulations_&_policies/2010_Notices_Index/index.asp.

These performance standards are derived from the poultry baseline surveys and from 2008-2009 Salmonella Verification Program data. FSIS estimated the potential public health impacts of the proposed performance standards¹. For estimating potential public health impacts regarding the Salmonella standards, the Agency used both the baseline data and the more current verification data because of changes observed in the industry since the collection of the baseline data, which may lead to slight under-estimates of prevalence relative to other approaches.

¹ These estimates include a variety of assumptions. An area of considerable uncertainty is the determination of the number of attributed illness because the existence of Salmonella or Campylobacter itself does not mean that there is a human health impact because the true FSIS share of Salmonella and Campylobacter illnesses caused from consumption of poultry is unknown.

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For estimating the potential impact of the Campylobacter standards, only baseline data were available. Note that FSIS's estimates of the potential reductions in human illnesses from Salmonella and Campylobacter should be considered separately; it is not appropriate from a scientific standpoint to add them together. A technical paper on the method used to develop the potential public health impacts is posted at the FSIS Web site with this notice at http://www.fsis.usda.gov/regulations_&_policies/2010_Notices_Index/index.asp.

FSIS intends to conduct more frequent baseline studies, at intervals not greater than every four years, and to make appropriate adjustments to these performance standards based on the results of the studies. Given the performance standards discussed in this notice, the Agency requests comments on practical and realistic goals for reducing the prevalence of microbial pathogens.

Salmonella Performance Standards

Salmonella bacteria are among the most frequently-reported causes of foodborne illness. The bacteria live in the intestinal track of humans and other animals, including birds. Salmonella contamination of raw meat and poultry products occurs during slaughter operations, as well as

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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, such events cannot be eliminated, and contamination of raw carcasses will result unless a lethality antimicrobial treatment is applied (e.g., irradiation). These events, however, can be minimized. Salmonella and, to a lesser extent, Campylobacter may increase on pre-cooked poultry if subjected to temperature abuse. However, levels present on and in raw poultry product would only survive on the product presented for human consumption if it is not cooked thoroughly. Also, if poultry is improperly handled, Salmonella and Campylobacter can cross-contaminate other foods or food contact surfaces.

Among Salmonella-contaminated poultry carcasses, the number of Salmonella organisms is generally low. It is thought that human cases of salmonellosis likely result when those small numbers of Salmonella bacteria are subject to conditions that allow them to grow to sizeable doses between production and consumption. Because the occurrence of any Salmonella on a carcass poses a potential hazard for consumers, measuring contamination, and thus setting standards, refers to estimated prevalence of Salmonella among samples collected from facilities and not to the

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quantitative level of individual samples. A different approach is needed for Campylobacter, as explained below. The Appendix to this notice provides a detailed history of Agency actions regarding Salmonella.

New Salmonella Standard for Young Chickens

The estimated prevalence of Salmonella in young chicken carcasses at post-chill based on volume-weighted YCBS baseline data collected from July 2007 through June 2008 is 7.5%. Based upon its evaluation of this new baseline data, the Agency has concluded that it should revise its performance standard to further improve establishment control of Salmonella in young chickens in order to reduce illnesses attributed to this product. The Agency will lower the performance standard to the current level indicated by the new baseline data accordingly, revise establishment categories, and continue to publish the names of establishments that do not meet the new Category 1 criteria. The Agency will continue its qualitative approach to analyzing Salmonella samples for presence/absence under the new performance standard, leaving unchanged the current sample procedures for Salmonella requiring 51 samples per set. Inspection program personnel will continue to collect 400 mL of

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rinsate for each sample, from which a 30 mL portion is analyzed.

Under the new performance standard, the Agency will:

- Establish a new performance standard of **7.5 percent** based on the estimated prevalence of Salmonella-positive results from the 2007-8 YCBS data.
- Continue collecting and analyzing a 51-sample set.
- Set 5 out of 51 positive samples as the maximum number of positives allowed to achieve the new performance standard, which will provide an 80 percent probability of an establishment meeting the standard when operating at the 7.5% performance standard.
- Continue the Category 1/2/3 approach as determined by an establishment's most recent sets:
 - Category 1 = **two consecutive sets with no more than two positives**
 - Category 2T = **two positives or fewer in last set, 3 or more positives in prior set**
 - Category 2 = **last set with 3-5 positives, any result in prior set**
 - Category 3 = **last set with six or more positives, any result in prior set**
- Continue publishing Category 2 and 3 establishments based on the performance standard in effect when the last sample set was begun. FSIS will continue to follow the criteria it uses to select establishments for posting - Category 2 and 3 establishments are posted, Category 1 and 2T establishments are not posted, and establishments in a product class will not be published if 90 percent of its eligible establishments are in Category 1 and no establishment is in Category 3.
- Prioritize the scheduling of testing of young chicken establishments that are not meeting the new standard.

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Under the current performance standard, approximately 82 percent of young chicken establishments eligible for the Salmonella Verification Program are in Category 1. Under the new performance standard, approximately 57 percent of eligible establishments would be in the new Category 1, representing a significant tightening beyond the current Category 1. Another 28 percent is in new Category 2, and 15 percent is in new Category 3.

The Agency's experience after 2006 with the industry response to Salmonella policies implemented that year leads the Agency to estimate that approximately half of the 15 percent of establishments that would not meet the new standard will improve their food safety systems to do so during the first two years of implementation. Much of that improvement, we believe, would likely occur in the first year. This would result in a shift of 7-8 percent of establishments meeting the new standard. This improved performance, when added to the 85 percent of establishments that already meet the new standard, would result in more than 90 percent of establishments meeting the new standard and thus, meeting the FSWG goal to be accomplished by the end of 2010.

The Agency has applied a model to estimate the potential public health impact of the proposed performance

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standards. The model contains considerable uncertainty about the relationship between the rate of contamination on raw carcasses and human illness as well as assumptions about how establishments will change their behavior as a result of the new guidance. Under the assumption that the 7-8 percent of establishments improving performance to meet the new standard would improve to the average of those establishments that already meet the new standard, the Agency estimates that after the first two years of implementation, it is possible that approximately 26,000 human illnesses would be averted annually when compared to the period prior to implementation of the standard. This would be a reduction of approximately 12 percent of human illnesses from the current 220,000 attributed to this cause, as discussed in the public health impacts paper referenced above. This would be a permanent structural reduction of 26,000 illnesses averted for each future year as compared to before implementation.

Additional public health benefits could potentially be realized as more establishments move into the new Category 1 status. The Agency will carefully analyze data on individual establishments to see if further public health benefits can be projected if establishments increasingly move into the new Category 1 status.

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Campylobacter Performance Standard for Young Chickens

Campylobacter species, including C. jejuni, C. coli, and C. lari, can be isolated from the intestinal tract of poultry and poultry products. The two most frequently occurring Campylobacter species of clinical significance for human consumption of food are C. jejuni and C. coli. These species are the ones most often isolated in poultry products.

Until the recent baselines, the Agency had limited data on Campylobacter, in part because of difficulties with available methodology to account for presence and numbers of this pathogen. In 2005, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) was asked to address Campylobacter, particularly with regard to the analytical utility of methodologies for the upcoming YCBS. In its final report (NACMCF on Campylobacter methodology), the NACMCF recommended that FSIS adapt the direct plating enumeration methodology to detect and enumerate Campylobacter that had been developed by USDA's Agricultural Research Service (ARS).

In the YCBS, accordingly, rinsate samples were analyzed using two distinct procedures adapted from the ARS methodology. A quantitative detection and enumeration procedure was used to analyze both re-hang and post-chill

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rinsate samples, and a qualitative detection method, which included an enrichment step, was used only with the rinsates obtained from post-chill samples. FSIS is revising its Microbiology Laboratory Guidebook, Section 41.00, to include these qualitative and direct plating quantitative procedures for the isolation, identification, and enumeration of C. jejuni/coli/lari present in poultry rinses and sponges. FSIS will use these procedures in the verification testing for Campylobacter that it intends to conduct, as discussed in this notice.

With the methodology employed in the baseline and in the verification testing described in this notice, all 51 samples taken for a set are to be analyzed both for Salmonella, using the standard Agency method, and Campylobacter. Each portion of sample rinsate used for Campylobacter analysis will be subdivided into two portions, one of 1 mL and one of 30 mL. The 1 mL and the 30 mL portions of this test are begun in the laboratory at the same time. The result for the 1 mL portion is available before the result for the 30 mL portion. The 1 mL portion is plated for both qualitative (presence/absence) and quantitative (enumeration) results. The 30 mL portion is first enriched and then plated for qualitative (presence/absence) results only. The 30 mL

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enrichment-based test laboratory procedure increases the practical sensitivity of testing primarily by accommodating significantly larger test portions. Thus it can detect as few as 1 bacterial cell (referred to as Colony Forming Unit or CFU) per 30 mL portion. Therefore the theoretical Limit of Detection (LOD) per portion is calculated as 0.03 CFU per mL.

The 1 mL direct plating test procedure, on the other hand, is relatively less sensitive in practice because of its much smaller size and has a LOD of 1 CFU per mL rather than 0.03 CFU per mL, which means that direct plating with the 1 mL portion will tend to detect samples with higher contamination. Detecting samples with higher contamination is crucial to addressing the public health concerns with regard to Campylobacter contamination. If the 1 mL portion is qualitatively negative, then the 30 mL portion will be used to determine whether the sample is positive or negative for Campylobacter. As the 1 mL procedure is relatively less sensitive and detects samples with higher contamination, positive 1 mL results are considered positive for the 30 mL procedure as well. This approach, which was used in the YCBS, will conserve limited laboratory resources without having a negative impact on the verification program.

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The 1 mL procedure offers the benefit of providing quantitative data by enumerating the organisms present in these higher-load samples, thus informing the Agency about the prevalence of high-load samples. The 30 mL procedure can detect lower-load samples when necessary but, because of the enrichment step required, cannot provide meaningful quantitative data on initial contamination levels.

New Performance Standard for Campylobacter in Young Chicken Carcasses

In light of the FSWG recommendations discussed above, FSIS has concluded that it should foster and encourage improved establishment control of Campylobacter in young chickens by setting a performance standard based upon the YCBS prevalence. The performance standard for Campylobacter comprises two factors based on YCBS prevalence: one specifying the percentage of 1 mL portions that are positive, and the other specifying the percentage of total sample-specific positive results counting either the 1 mL or the 30 mL rinsate portions as positive. Accordingly, the Agency will:

- Test each of the 51 samples in a Salmonella verification set for Campylobacter using the initial 1 mL quantitative portion. If the 1 mL procedure is negative, the 30 mL procedure will be performed.
- Establish a performance standard for the 1 mL portion at 10.4 percent, which is the YCBS estimated

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prevalence for 1 mL portions, with no more than 8 positive samples from the 1 mL results.

- Establish the performance standard for the sample-specific positive results, which is the YCBS estimated sample-specific prevalence for 1 mL and 30 mL results combined, at 46.7 percent with no more than 27 of 51 samples positive in any combination of 30 mL and 1 mL results. As the 1 mL procedure is relatively less sensitive and detects samples with higher contamination, positive 1 mL results will be considered positive for the 30 mL procedure as well.

This standard will allow the Agency to gauge both overall frequency of contamination and the frequency of greater than expected carcass contamination levels. The 1 mL component of the standard was added based on the Agency's understanding that higher than expected numbers of Campylobacter on chicken carcasses present a different challenge to public health than with Salmonella. Campylobacter is found more frequently, but it is not able to grow at temperatures below approximately 86 degrees Fahrenheit. Thus, high levels of this pathogen are unlikely at the point of consumption, unless they were present at high levels before the product left the establishment. Conversely, Salmonella can grow at colder temperatures, but positive carcasses tend to have low initial levels of contamination. This Campylobacter performance standard therefore addresses the need to

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minimize the frequency of greater than expected levels of Campylobacter contamination on carcasses.

After 90 percent of eligible establishments have been sampled for two full sets, which the Agency estimates will be accomplished by 2012, the Agency will consider setting establishment categories 1/2/3 for Campylobacter under the new performance standard (separate from Salmonella) and publishing Campylobacter Category 2/3 establishments.

Based on the Agency's experience with the industry response to Salmonella policies implemented in 2006 (discussed above), the Agency estimates that 50 percent of establishments that at present would not meet the new Campylobacter standard would likely improve their food safety systems to meet the standard during the first two years of implementation. Assuming 75 percent of establishments meeting the new standard, the public health impact model for Campylobacter estimates that after the first two years of implementation, it is possible, not withstanding considerable uncertainty, that approximately 39,000 human illnesses would be averted annually as compared to the period before implementation, a reduction of approximately 10 percent from the current 400,000 attributed to this cause, as discussed in the potential public health impacts paper referenced above. This result

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could yield a permanent structural reduction of 39,000 illnesses averted for each future year as compared to before implementation. Note however that past reductions in Salmonella prevalence do not necessarily imply that industry has the resources and the technical ability to further reduce pathogen levels. There is likely a lower limit to pathogen levels that can be achieved with current technologies.

Additional public health benefits could potentially be realized if the Agency decides to implement a Category 1/2/3 approach, and establishments move into the new Category 1 status. As with the Salmonella verification program, the Agency will analyze data on individual establishments sampled in the YCBS to evaluate whether further benefits could be predicted if establishments increasingly move into a hypothetical Campylobacter Category 1 status.

This Campylobacter testing program would require additional funding in fiscal year 2011 to implement because of its associated demand on laboratory resources. New employees will need to be hired and trained, and laboratory supplies purchased, to run the tests. The President's budget request for fiscal year 2011 includes a funding request for this testing.

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Salmonella Performance Standard for Young Turkey Carcasses

The Agency has decided to take a different approach to Salmonella in turkeys. Past FSIS sampling data suggest that the prevalence of Salmonella-positive broiler and turkey carcasses was similar (FSIS 1995 Broiler chicken baseline study; FSIS 1998 Young turkey baseline study; Baseline Data). FSIS sampling data from the YTBS suggest that the prevalence of Salmonella-positive whole young turkey carcasses is now substantially less than the prevalence of Salmonella-positive young chicken carcasses. The prevalence estimate at post-chill for whole young turkey carcasses was about 1.7 percent, more than a 10-fold decrease from the prevalence estimated from the previous turkey baseline. The Agency notes, furthermore, that under the Category 1/2/3 approach used since 2006, more than 90 percent of young turkey slaughter establishments have been in Category 1 and none in Category 3. Thus, the Category 2 establishments from this class have not been published.

At the very low positive rates seen in whole young turkey carcasses, sample sets much larger than those currently collected (i.e., many more than 56 samples per set) would be necessary to detect real differences in establishment performance. The Agency believes that

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resources that have been used in tracking category status for this product can be better utilized to address more pressing public health concerns, including pathogens found in ground turkey and turkey parts that have an increasing market share for the young turkey product class.

For these reasons, the Agency has decided to establish an acceptable positive rate for whole young turkey carcasses that is lower than the current acceptable positive rate, but high enough that an establishment actually operating at the YTBS prevalence will have at least a 99 percent probability of meeting the new standard. The 99 percent probability chosen for the new acceptable positive rate would allow fewer positive results in a set of 56 samples than under the current turkey carcass performance standard. This approach will permit the Agency to better utilize its resources, to focus its activities on public health issues, and, at the same time, to continue to monitor or evaluate industry performance. Specifically, the Agency will:

- Establish a new performance standard of 1.7 percent for postchill with no more than 4 positive samples in a 56-sample set, providing an approximate 99.7 percent probability of an establishment meeting the standard when actually operating at the performance standard.
- Continue the 56-sample set under the new standard.

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- Publish the names of establishments that do not meet the performance standard in their last set based on that set having begun after implementation of this new standard.
- Exclude young turkey slaughter establishments from posting if 90 percent of establishments meet the new performance standard.
- Prioritize scheduling of testing at turkey establishments not meeting the new standard.

Based on current FSIS Salmonella Verification Program data on establishment performance levels, 82 percent of eligible establishments would initially meet the new performance standard for turkeys with no more than 4 positive samples out of 56 in the last set. This level of performance would come close to meeting the FSWG goal of 90 percent of establishments meeting the new standard by the end of 2010. Using our public health impact model, the Agency estimates approximately 100 human illnesses averted annually after the first two years of implementation as compared to the period before implementation, a reduction of approximately 1.5 percent from the current 9,000 attributed to this cause, as discussed in the public health impacts paper referenced above. This public health impact could yield a permanent structural reduction in illnesses.

The Agency believes that this performance standard, setting a level below the current standard for Category 1,

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will provide an incentive for the turkey industry to continue to improve its process control. As noted above, FSIS estimates that only 82 percent of turkey establishments will meet the new standard under their current performance levels. Since the Agency plans to begin publishing the names of establishments that do not meet the new standard, the Agency has concluded that a significant incentive will be established for immediate improvement in the turkey industry and for consistent maintenance of good performance. This new approach can be accomplished under the current sampling and testing infrastructure and current funding levels. The agency plans to commence publishing the names of establishments that do not meet the standard in sets begun after implementation of the new standard.

Campylobacter Performance Standard for Young Turkey Carcasses

The estimated prevalence of Campylobacter at post-chill derived from the YTBS is about 1.1 percent. As it did with its approach to Salmonella in young turkeys discussed above, the Agency is setting a low performance standard for Campylobacter with an acceptable positive rate that provides a higher probability of meeting the standard when an establishment is actually operating at the

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standard. Unlike with Campylobacter in young chickens, however, the percent positive in young turkeys is so low, especially with the 24 mL results (as described above), that a single performance standard is indicated for any combination of 1 mL or 24 mL results. FSIS intends to:

- Establish a new performance standard at the YTBS prevalence of 1.1 percent with no more than 3 positive samples in a 56-sample set from any combination of 1 mL or 24 mL results, providing an approximate 99.7 percent probability of an establishment meeting the standard when actually operating at the performance standard.
- Continue the 56-sample set under the new standard.
- Prioritize scheduling of testing at young turkey establishments not meeting the new standard.
- After 90 percent of establishments have been sampled for two full sets (estimated by 2012), post names of establishments that do not meet the standard in the last set on the Agency Web site.
- Exclude young turkey slaughter establishments from posting if 90 percent of establishments meet the new standard.

Based on our estimates, 81 percent of eligible establishments would initially meet the new performance standard. Using our public health impact model, the Agency estimates that approximately half of the establishments that would not now meet the new standard will improve their performance to do so. This assumption provides an estimate of approximately 100 human illnesses averted after the first two years of implementation as a permanent structural

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reduction as compared to before implementation. This result would be a reduction of approximately five percent from the current 1,700 illnesses attributed to this cause, as discussed in the potential public health impacts paper referenced above.

The Agency plans to begin posting the names establishments that do not meet the new standard in 2012. The Agency believes this plan provides an incentive for further improvements in process control in the turkey industry and for consistent maintenance of good performance.

Compliance Guides

The agency has posted on its Significant Guidance Documents Web page ([Significant Guidance](#)) the third edition of a compliance guide for poultry slaughter. The guide includes new pre-harvest recommendations for controlling Salmonella and recommendations for controlling Campylobacter in poultry. FSIS has also posted on its Significant Guidance Documents Web page a compliance guide on known practices for pre-harvest management to reduce E. coli O157:H7 contamination in cattle. This guide focuses on the prevention of E. coli O157:H7 through reduced fecal shedding and during live animal holding before slaughter.

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These two compliance guides represent current FSIS thinking, and FSIS encourages establishments to begin using them. The guides present recommendations and not regulatory requirements.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this document, FSIS will announce it online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_&_policies/2010_Notices_Index/index.asp. 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, recalls, 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 and farm groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is available on the FSIS Web page. Through the Listserv and the Web page, FSIS is able to provide information to a much

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broader and more diverse audience. In addition, FSIS offers an e-mail subscription service that provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/news_and_events/email_subscription/. 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

Alfred V. Almanza,
Administrator.

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APPENDIX

Salmonella has been a major concern for the Agency for many years. In 1996 FSIS published the final rule "Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems" (61 FR 38806; Jul. 25, 1996), which established, among other measures, pathogen reduction performance standards for Salmonella bacteria for certain slaughter establishments and for establishments producing certain raw ground products (9 CFR 310.25(b)(1) and 381.94(b)(1)). Salmonella was selected as the target organism because it was at that time the most common cause of foodborne illness known to be associated with meat and poultry products. It is present to varying degrees in all major species, and interventions targeted at reducing it may be beneficial in reducing contamination by other enteric pathogens.

The pathogen reduction performance standards established for Salmonella in the PR/HACCP Final Rule covered raw product classes including carcasses of cows/bulls, steers/heifers, market hogs, broilers (young chickens), and ground beef, ground chicken, and ground turkey. The Agency later developed a performance standard for turkeys based on a 1997 baseline survey (2005 Turkey Performance Standard). In the PR/HACCP final rule, FSIS

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required that the prevalence of Salmonella contamination in each of the major species and in raw ground products be reduced by each establishment to a level below the current national baseline prevalence.

These Salmonella performance standards reflected the estimated prevalence found by the Agency's nationwide microbiological baseline surveys, which were conducted before the PR/HACCP rule was adopted (Baseline Data). Each performance standard was a target prevalence for a given product class using the same sample portion and collection and analytical procedures that were used in the baseline, for example, 20 percent positive for whole young chicken carcasses from 400-mL rinse samples collected at post-chill.

The PR/HACCP rule also established a Salmonella Verification Program, in which FSIS inspection personnel assess industry performance by collecting product samples from individual establishments over the course of a defined number of sequential days of production to complete a sample set, with product samples being sent to FSIS laboratories for analysis. Establishments were made subject to sampling if they produced sufficient product annually to complete a sample set, which for young chicken slaughter establishments means approximately 20,000 birds

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slaughtered per year. The PR/HACCP rule further specified the maximum number of Salmonella-positive samples acceptable per sample set consisting of a specified number of samples.

The Agency selected the maximum number of positive samples acceptable per set so as to meet two objectives. The Agency determined a number that would provide a reasonable probability of passing the set for an establishment that in actuality is operating precisely at the performance standard. The Agency also wanted the number chosen to provide a relatively high probability of failing the set for an establishment that in actuality is operating precisely at the performance standard. This relatively high probability of failing the set was intended to encourage establishments to minimize the chance of failure by aiming at tighter process control and lower numbers of positives.

The Agency chose an "80 percent rule" - i.e., an establishment actually operating at the performance standard has an approximately 80 percent chance of passing the set and therefore an approximately 20 percent chance of failing. For young chickens, the baseline prevalence was estimated to be 20.0 percent of carcasses positive for Salmonella, and using the "80 percent rule" resulted in a

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requirement that there be no more than 12 positive samples out of a 51-sample set. For turkeys, the baseline prevalence was estimated to be about 19.6 percent of carcasses positive for Salmonella, and using the "80 percent rule" resulted in a requirement that there be no more than 13 positive samples out of a 56-sample set. This same approach is used for the new performance standards announced in this notice.

In the 1996 PR/HACCP rule, FSIS indicated that the pathogen reduction performance standards would be changed as new data became available, and that the Agency would periodically repeat its baseline surveys to obtain updated data. FSIS intends to use the new Salmonella performance standard for young chickens that it is announcing in this Notice in the place of the performance standard codified at 9 CFR 381.94.

In that regulation, FSIS stated that an establishment that failed to meet the standard in three consecutive sample sets would be considered to have failed to maintain sanitary conditions and to maintain an adequate HACCP plan. The Agency said the failure would cause it to suspend inspection at the establishment. In December 2001, the U.S. Court of Appeals for the Fifth Circuit (Supreme Beef Processors, Inc. v. USDA, 275 F.3d 432) affirmed a ruling

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by the U.S. District Court for the Northern District of Texas (Supreme Beef Processors, Inc. v. USDA, 113 F. Supp. 2d 1048) that USDA did not have the authority to suspend inspection at an establishment solely on the basis of Salmonella test results for the raw meat product produced at the establishment. FSIS had suspended inspection at Supreme Beef Processors, Inc., for failing the standard in three consecutive Agency sample sets. The District Court held that 21 U.S.C. 604(m)(4) focused on a processor's plant and not on the condition of its meat. The Court further held that the presence of Salmonella in the finished product did not render the product "injurious to health" within the meaning of §601(m)(4). The Appellate Court agreed, and further held that 21 U.S.C. 601(m)(4), and hence the Salmonella performance standards, cannot be used to regulate the characteristics of incoming raw materials used in the raw ground beef.

Since the Supreme Beef case, FSIS has used results from its verification testing program as a measure of establishment process control for reducing exposure of the public to pathogens. FSIS expects establishments 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

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effective in encouraging improved establishment control of pathogens.

After our review and evaluation of the testing results for several years, in which the frequency with which Salmonella was found in testing at young chicken establishments rose, FSIS published a Federal Register Notice on February 27, 2006 (71 FR 9772-9777; Docket 04-026N). This notice, among other things, announced a new Agency policy for reporting the results from the Agency's Salmonella testing program and established three performance categories for establishments. Performance Category 1 was set at an upper limit of no more than half the standard. Category 2 was set at more than half but not exceeding the standard. Category 3 was for establishments exceeding the standard. Thus, for young chickens, Category 1 performance for a set was defined as no more than six positive samples out of a 51-sample set, Category 2 as more than six but no more than 12 positives, and Category 3 as more than 12 positives in a set. For turkeys, Category 1 was defined as no more than six positive samples out of a 56-sample set, Category 2 as more than six but no more than 13 positives, and Category 3 as more than 13 positives in a set.

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In the 2006 Federal Register Notice, FSIS stated that it intended to track establishment performance with respect to the different product classes sampled for Salmonella over the next year and, after that time, publish the names of establishments in Categories 2 and 3 for any product class that did not have 90 percent of its establishments in Category 1. After the 2006 Federal Register notice, the Agency added a second feature to its Salmonella testing and reporting program. In addition to having 90 percent of eligible establishments in Category 1, in order to be exempt from having any of its establishments published, a product class must not have any establishment in Category 3.

In 2008, FSIS published a notice in the Federal Register (73 FR 4767-4774; Jan. 28, 2008) explaining certain policy decisions relating to the Salmonella program and announcing that the Agency would begin publishing monthly results of completed FSIS verification sets for establishments in Categories 2 and 3, beginning with young chicken slaughter establishments. In that notice, the Agency clarified that Category 1 status requires two successive sets at no more than half the standard, but that Categories 2 and 3 are determined by the most recent set. Since publishing that notice, the Agency has created a

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Category 2T for establishments whose most recent set was at Category 1 level but whose prior set was above half the standard. Such establishments are counted in aggregate statistics but are not published individually. Publication of Category 2 and 3 young chicken establishments began in March 2008, and FSIS continues to publish the names of these establishments on or about the 15th of each month. The production class of whole young turkey carcasses has had more than 90 percent of establishments in Category 1 and no establishments in Category 3 and thus has not had Category 2 establishments published. The Agency believes that publishing Category 2 and 3 establishments has provided an effective incentive for improving performance.