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Administrator, Food and Nutrition Service.

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DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service
[Docket No. FSIS–2010–0029]

New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments: Response to Comments and Announcement of Implementation Schedule

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) published a Federal Register Notice on May 14, 2010 (75 FR 27288) in which it announced the forthcoming implementation of new performance standards for the pathogenic microorganisms Salmonella and Campylobacter for chilled carcasses in young chicken (broiler) and turkey slaughter establishments. The new performance standards were developed in response to a charge from the President’s Food Safety Working Group and based on recent FSIS Nationwide Microbiological Baseline Data Collection Programs. The standards will be applied to sample sets collected and analyzed by the Agency to evaluate establishment performance with respect to requirements of the Hazard Analysis and Critical Control Points (HACCP) Rule. The Agency received detailed comments submitted in response to the notice. This notice responds to those comments submitted and explains the changes adopted by the Agency after carefully evaluating comments. These changes include:

1. Updated Salmonella and new Campylobacter performance standards for young chickens and turkeys will take effect with Agency verification sample sets scheduled for July 2011.
2. All young chicken and turkey establishments will move to the highest scheduling priority due to the initiation of Campylobacter testing for these product classes.
3. All sample sets scheduled for young chicken and turkey establishments will be analyzed for both Campylobacter and Salmonella, and follow-up sample sets responding to sample set failure for either organism will be analyzed for both organisms.
4. Effective with sample sets begun in July 2011, the new Salmonella standards will accept five positive samples in a 51-sample set for young chickens and four positive samples in a 56-sample set for turkeys.
5. Effective July 2011 Salmonella performance Categories 1 and 2 for young chicken and turkey establishments, based on the new performance standards, will be applied exclusively for Agency internal analysis and quarterly aggregate reporting.
6. Web-posting of young chicken and turkey establishments that fail the new Salmonella standards ("Category 3") for their last set will begin as sample sets scheduled for July 2011 are completed.
7. Campylobacter performance standards and sample set criteria for tracking and reporting to establishments will be applied to results from the smaller of the two laboratory Campylobacter sample portions (1 mL), which detects higher levels of contamination, making the performance standards 10.4 percent for young chickens and 0.79 percent for turkeys.
8. Campylobacter sample set criteria for tracking and reporting 1 mL results are eight positive samples acceptable per 51-sample set for young chickens and three positive samples acceptable per 56-sample set for turkeys.
9. Campylobacter results from the larger of the two laboratory Campylobacter sample portions (30 mL for chickens, 24 mL for turkeys), which detects lower levels of contamination, will be used for Agency internal analysis.
10. Agency responses to Campylobacter sample set results will follow current Salmonella procedures for immediate follow-up testing for both organisms and for Food Safety Assessments when necessary.
11. Category 1/2/3 results will be posted in quarterly aggregate reports for all establishments producing raw products subject to FSIS Salmonella testing, including young chickens and turkeys under the new standards.

Docket: For access to background documents, go to the FSIS Docket Room at Room 2–127, George Washington Carver Center, 5601 Sunnywood Avenue, Mailstop 5474, Beltsville, MD 20705–5474 between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel Engeljohn, PhD, Assistant Administrator for Office of Policy and Program Development, FSIS, USDA, 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 USDA that is responsible for ensuring that the nation’s commercial supply of meat, poultry, and processed egg products is safe, wholesome, and 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 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 specifically 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 [calendar year] 2010.” (FSWG) These new Salmonella standards are to 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 Agency intends to issue a proposed rule that would formally rescind the codified standards that are no longer in effect. In consultations with the FSWG, the Agency committed to a number of other food safety initiatives to prevent illness, agreed to developing a new performance standard for Campylobacter for young chickens and turkeys.

The Agency accordingly published a Federal Register Notice on May 14, 2010 (75 FR 27288) in which it announced the July 2010 implementation of new performance standards for the pathogenic microorganisms Salmonella and Campylobacter for chilled carcasses in young chicken and turkey slaughter establishments. The May 14, 2010 notice announced that FSIS had developed such performance standards and predicted the public health impact that might result if, after two years of implementation, these standards are met by half of the establishments that would not meet them at first. The new performance standards for young chickens and turkeys were informed by, among other data sources, data collected during the Agency’s recent Nationwide Microbiological Baseline Data Collection Programs: The Young Chicken Baseline Survey (YCBS), and the Young Turkey Baseline Survey.
(YTBS) (Baselines). The May 14, 2010 notice detailed the baseline surveys and their use in developing the new performance standards.

Although FSIS had planned to implement the new standards in July 2010, the Agency decided to delay implementation until the many comments filed in response to the May 14, 2010 notice had been evaluated. This current notice responds to those comments and explains the policy changes made by the Agency based on its careful evaluation of the comments. These policy changes are listed in the notice Summary above and are further detailed in the responses to comments below.

The Agency cannot yet determine if it has met the FSWG goal of having 90 percent of poultry establishments meeting the new Salmonella standards by the end of Calendar Year (CY) 2010 as Salmonella verification set scheduling and sampling is an ongoing process and a number of establishments that started sets in CY 2010 were not completed by December 31, 2010. Partial sets are incommensurate, moreover, with the completed-set-based performance measures used by the Agency and the FSWG. Therefore, in preparing its CY 2010 accounting for this FSWG goal, FSIS plans to complete sample sets started in 2010 or earlier during the first quarter of 2011 and count those completed sets toward its final 2010 report. The Agency will cut off its 2010 sample set total on April 1, 2011 and issue its final 2010 accounting at that point. Any 2010-started sample sets not completed by April 1 will be applied toward CY 2011 totals once completed. The final CY total will thus comprise sets started no later than December 31, 2010 and completed no later than March 31, 2011. As of March 2011, 86.2 percent of young chicken slaughter establishments would have met the new standard for 2010. Also as of March 2011, 87.8 percent of young turkey slaughter establishments would have met the new standard for 2010.

The Agency believes that the policy changes made in this notice, which will be implemented in July 2011, will encourage the poultry industry to reduce Salmonella in poultry and thereby further reduce the risk of human illnesses.

Foreign Government Programs

Foreign countries that are eligible to export poultry products to the United States must apply inspection, sanitary, and other standards that are equivalent to the United States. Thus, FSIS applies to poultry products. Thus, in evaluating a foreign country’s poultry inspection system to determine the country’s eligibility to export products to the United States, FSIS will consider whether Salmonella or Campylobacter methods and procedures that the country applies are equivalent to those that FSIS uses.

Response to Comments on the Federal Register Notice of May 14, 2010

Administrative Procedure Questions

Some comments claimed that the Agency is violating the Administrative Procedure Act (APA) by effectively promulgating a “regulation” without following due notice-and-comment procedure.

FSIS Response: The Agency does not agree that FSIS policies explained herein are regulations subject to notice-and-comment requirements under the APA or are otherwise in violation of the APA. The policies and performance standards, including the testing process the Agency will undertake, do not impose requirements on establishments. We would note, however, that the Agency has sought to engage industry and all interested parties in the subject matter of this notice, has provided extensive opportunity for public comment, delayed implementation to carefully consider issues that were raised in comments, and made various substantive changes to policies based on those comments. We would also note that this is not a novel approach and that notice establishing standards against which to measure establishment performance has been accomplished before through Federal Register notices in 2005 (70 FR 8058) and 2006 (71 FR 9772) (referenced in the May 14, 2010 notice). In 2008, FSIS further articulated how the Agency intended to evaluate whether industry was adequately controlling for Salmonella in carcasses (73 FR 4767).

Salmonella Posting Rationale

Several comments expressed opposition to the Agency’s decision to apply the new standards requiring fewer positives for Category 1 status than has been the case and that posting Category 2 establishments unrealistically differentiates such establishments from those in Category 1.

FSIS Response: The Agency believes that its policy of posting establishments that are not in the highest performance rank has stimulated improvement in industry performance, as was shown in the Agency’s experience after announcing performance categories in 2006 when 55–60 percent of non-compliant establishments moved to become compliant within two years. FSIS, however, recognizes that some establishments that have been excluded from posting may now be included based on the same level of performance. While the Agency will implement updated Salmonella and new Campylobacter performance standards for young chickens and turkeys with Agency verification sample sets scheduled for July 2011, establishments that complete sample sets begun in or after July 2011 will be Web-posted only if they have failed the new standards. Web-posting of Category 2 and 3 establishments that began sets under current standards will continue until these establishments have completed sets under the new standards.

Effective with samples sets starting in or after July 2011, Salmonella performance Categories 1 and 2, based on the new performance standards, will be applied exclusively for Agency internal analysis and not for posting purposes. The Agency will post quarterly aggregate reports showing the Category 1/2/3 distribution for each relevant product class subject to FSIS Salmonella testing but will not identify individual establishments. In order to accomplish this, the Agency will determine Category 1 and 2 performance criteria for young turkey establishments.

The Agency believes that this policy change is reasonable given the general progress of the poultry industry in reducing positive rates from the 1996 HACCP baselines to current rates.

Though the “pass-fail” approach is to be taken with young chickens now as well as turkeys, as stated in the May 14, 2010 notice, the smaller prevalence on young turkey carcasses permits a less stringent compliance criterion that is consistent with the Agency’s stated objectives of substantially reducing pathogen presence. Thus, the young chicken standard allows an establishment operating at the baseline prevalence approximately an 80 percent chance of passing. The turkey standard, however, is based on a much lower prevalence and so the turkey standard’s higher chance of passing of 99+ percent is appropriate.

Connection Between Salmonella Contamination of Chicken Carcasses and Human Illness

Several comments doubted that there is a connection between Salmonella contamination of chicken carcasses and the occurrence of cases of human salmonellosis.

FSIS Response: The Agency believes that there is a connection between Salmonella contamination and human illness and that poultry contamination continues to contribute significantly to salmonellosis. Evidence of the
connection of salmonellosis and contaminated chicken products can be found in the outbreaks that have been associated with chicken (CDC food borne outbreaks) and a 2004 case control study conducted by the Centers for Disease Control and Prevention (CDC) that has linked salmonellosis with chicken products (A.C. Kimura et al.; Kimura et al. study). Furthermore, in a Memorandum to the Record dated January 18, 2011, CDC re-affirmed that “Poultry products are an important vehicle for human Salmonella and Campylobacter infections in the United States” (posted with this notice at http://www.fsis.usda.gov/Regulations_&_Policies/2011_Notices_Index/index.asp). Since raw chicken products (ground and carcasses) continue to show greater Salmonella prevalence than is found with other food classes (Salmonella Testing Tables), it is likely that the source of the contamination was chicken carcasses rather than other non-chicken ingredients such as spices that may be used with such products. The Agency has concluded, using the available data and the best science available, that reducing Salmonella on chicken carcasses would reduce risk of illness and thus potentially reduce the occurrence of illnesses.

The Agency further notes, however, that the commenter’s evidence to support the assertion of no connection was based on the human illness FoodNet database (see discussion below). Salmonellosis cases due to poultry are only a subset of all salmonellosis cases reported through the CDC FoodNet program. The total number of salmonellosis cases stem from all sources including cattle, swine, eggs, fish, fruits and vegetables. Thus an observed correlation (negative or positive) between Salmonella occurrence in poultry carcasses at post chill and salmonellosis from FoodNet data cannot be used to assert a causal relationship between poultry contamination and salmonellosis. Further, the available salmonellosis data cannot be stratified by food vehicle (e.g., poultry), given the lack of food attribution data within the FoodNet database. Given this data gap, it is entirely conceivable that a reduction of salmonellosis due to one food product such as poultry could be negated by an increase in salmonellosis due to another product or unrelated vehicle. In any case, the Agency believes that the available evidence leads to the conclusion that Salmonella occurrence in poultry has the potential to cause salmonellosis in humans.

Efficacy of Performance Standards
Several comments from industry argued that tightening Salmonella performance standards since 2006 has not resulted in fewer cases of human salmonellosis and thus particular further tightening the standards would be pointless and punitive. They argue that available evidence (from CDC FoodNet data sets) did not support the Agency’s predictions that there would be benefits derived from decreases in Salmonella found on carcasses at post chill.

FSIS Response: There are important reasons why it is not appropriate to examine CDC salmonellosis rates and compare these data directly to trends of Salmonella incidence for inferring the impact of reduction of Salmonella contamination for any particular commodity and salmonellosis rates. Specifically, it is important to distinguish the two surveillance datasets available from the CDC used to analyze outbreak trends and foodborne illness. First, the CDC National Outbreak Reporting System (NORS) (http://www.cdc.gov/foodborneoutbreaks/), referred here as outbreak data, provides information on reported outbreaks (defined as two or more illnesses associated with a single vehicle (product) that caused the illness). The source of the contamination is investigated (the pathogen and food product responsible for the outbreak); however, about 50 percent of confirmed Salmonella outbreaks do not have a known food vehicle. Second, the Foodborne Diseases Active Surveillance Network (FoodNet) (http://www.cdc.gov/foodnet/) produces annual case rates for several major foodborne pathogens, including Salmonella. FoodNet data tracks salmonellosis cases presently in 10 states, presently covering about 1/7 of the U.S. population (46 million). The majority of reported FoodNet cases reflect sporadic cases of Salmonella (for example, only six percent of 2007 reported FoodNet cases were outbreak-related 2007 annual report). There is no information regarding the food product that was (or might have been) associated with the illness. Therefore, FoodNet data are only available as aggregated information from cases due to all sources thought to be foodborne, including all food products such as those categories of foods defined by the CDC—including fish, crustaceans, mollusks, dairy, eggs, beef, game, pork, poultry, grains-beans, oils-sugars, fruits-nuts, fungi, leafy vegetables, root vegetables, sprout, vine-stalk vegetables (Painter et al., et al.). Thus an observed correlation (negative or positive) between Salmonella occurrence in chicken carcasses at post chill and FoodNet salmonellosis cannot be used, by itself, to assert a causal relationship between chicken contamination and salmonellosis. Unfortunately, as mentioned above, the FoodNet database reflecting trends of salmonellosis rates cannot be stratified by food vehicle (e.g., chicken), given the lack of food attribution data. However, for all food sources, the incidence of Salmonella-caused human illness declined approximately eight percent from the beginning of surveillance in 1996 to the most recently released annual report case rate in 2007 (as opposed to the most recently released preliminary report in 2009), with most of the reductions in the earlier years. This trend (or lack of trend) though cannot be assumed true for product-specific trends: It is possible that reduction of salmonellosis due to one food product such as chicken could be negated by the increase in salmonellosis due to another product or unrelated vehicle, such as produce, thus causing the stable case rate in recent years. Consequently, even if there is not a positive correlation of salmonellosis rates and the incidence of contamination rates on young chicken carcasses over time, it would not be possible to dismiss the likelihood that Salmonella occurrence in chicken and salmonellosis are causally connected.

The data presented above are part of a weight of evidence approach to refute the assertion that there is no connection between the presence of Salmonella on broilers and human illnesses. Additional evidence can be gleaned by performing trend analyses comparing either CDC outbreak data or the serotype data contained within FoodNet to FSIS verification results (FSIS Serotype Data).

Campylobacter Performance Standards
Some comments questioned the validity of applying Campylobacter performance standards, given the fragility of the organism and the relatively low risk associated with all but highly-contaminated servings or samples.

FSIS Response: After evaluating comments pointing out the complexities of Campylobacter and considering the Agency’s lack of experience with verification sampling for this organism, FSIS has decided that it will track and report Campylobacter results to establishments and will not post the names of establishments that fail to meet the new Campylobacter standards. The Campylobacter standards and sample set criteria for tracking and reporting to establishments.
will be applied to results from the smaller of the two laboratory
Campylobacter sample portions (1 mL) described in the May 14, 2010 Notice, which detects higher levels of contamination. The Campylobacter sample set criteria for tracking and reporting 1 mL results are eight positive samples acceptable per 51-sample set for young chickens and three positive samples acceptable per 56-sample set for turkeys. Campylobacter results from the larger of the two laboratory Campylobacter sample portions (30 mL for chickens, sponge plus 24 mL sponge diluent for turkeys), which detects lower levels of contamination, will be used for Agency internal analysis.

Agency responses to Campylobacter sample set results will follow current Salmonella procedures for immediate follow-up testing for both organisms and for Food Safety Assessments (FSAs) when deemed necessary.

The Agency notes that the implementation of Campylobacter standards and sampling in July 2011 will mean that all poultry establishments will move to the highest priority in the Agency scheduling algorithm as “new” establishments. Each set scheduled under the new standards will be tested for both Campylobacter and Salmonella. Furthermore, any establishment that fails a set for either organism will be moved to the second-highest priority for scheduling to conduct an immediate follow-up set, and the samples taken in the follow-up set will be analyzed for both organisms. FSIS believes that this more intensive sampling approach will provide a significant incentive for establishments to increase process control for both pathogens.

Category 1/2/3 results will be posted in quarterly aggregate reports for all establishments producing raw products subject to FSIS Salmonella testing, including young chickens and turkeys under the new standards including Campylobacter. FSIS will evaluate industry performance trends with regard to both Salmonella and Campylobacter. In response to adverse trends, the Agency may consider actions that could include, among other things, posting young chicken and turkey Category 2 establishments, posting all establishments that fail any applicable performance standards, or posting non-categorized individual sample set results from all establishments producing raw products subject to such testing. Any such actions would be announced in a Federal Register notice.

Public Health Predictions

Some comments criticized the Agency’s predictions of illness reduction, including (1) the assumptions used, and (2) that such reductions were not possible because the standard would primarily affect small volume establishments (Potential Public Health Impact). The Agency notes that the public health predictions made in the May 14, 2010 Federal Register notice were derived from the latest available illness-attrition data published by the CDC in 1999. Updated data have been published recently by the CDC (CDC updated data). The Agency has adjusted its public health predictions accordingly. These public health predictions depend on establishments that currently do not pass the new performance standards changing their processes to pass. Although FSIS has some historic evidence regarding industry behavior in response to previous measures (i.e., Salmonella HACCP verification program data and categorization of establishments in that program [FSIS 2006]), the true behavior of the industry in response to the new performance standards is unknowable in advance. If the status quo remains and no establishments change their processes to meet the new performance standards, zero illnesses will be avoided. If all initially noncompliant establishments were to become compliant, approximately 11,000 illnesses due to Campylobacter could be avoided. Based on the past response of the industry to the previous guidance where approximately 50 percent of noncompliant establishments became compliant (FSIS, 2006), the Agency predicts that, two years after implementation, as many as 5,000 fewer cases of human illness due to Campylobacter might occur each year. The Agency’s detailed response to comments on its approach to making public health predictions is contained in Appendix I.

Turkey Salmonella Issues

Comments noted that the Agency’s Young Turkey Baseline Survey (YTBS) found 0.35 percent of post-chill samples positive for Salmonella and asked the Agency to explain the discrepancy between the YTBS and FSIS HACCP verification sampling results. In light of the lowered performance standards and these other concerns, comments requested a “grace period” for turkey establishments failing under the new standards, using an average over two sets before posting establishments.

FSIS Response: As an initial matter, FSIS notes and regrets the error in the report “The Nationwide Microbiological Baseline Data Collection Program: Young Turkey Survey August 2008—July 2009” where the report erroneously stated that 0.35 percent of the analyzed post chill samples were found with Salmonella; in the report FSIS also correctly stated that “The estimated prevalence for Salmonella was 1.73 percent * * *” (pages 9 and 11). Reference was made to a technical report: “Technical Paper for Performance Guidance for Broilers and Young Turkey at Post-chill,” that explains the estimation procedure used (Technical Paper). In that technical report, FSIS addressed this issue of the difference of percentages of positive results between the two sampling programs. The comparison between the percentages of positive Salmonella results showed a higher percentage with the HACCP verification sampling, though the difference was not statistically significant. A more detailed response to these comments is attached in Appendix II.
Campylobacter Methodology

Questions

Use of Large-Portion Campylobacter Procedure for Performance Standards

Comments on the proposed Campylobacter performance standards for chickens and turkeys suggest removing the larger sample test portion of the compliance criteria (30 mL for chickens and sponge plus 24 mL sponge diluent for turkeys). Remaining would be the test to detect relatively high levels based on analyses of 1 mL portions for chickens and turkeys.

FSIS response: The Agency believes that a performance standard based on the 1 mL is most efficient in that it targets samples with higher levels of Campylobacter, which have a greater probability of inducing human illness by cross-contamination and surviving cooking compared to lower levels. The performance criteria (number of positive samples acceptable per sample set) for tracking and reporting to establishments will be eight positive samples acceptable per 51-sample set for young chickens and three positive samples acceptable per 56-sample set for turkeys.

Data collected for the 30 and sponge plus 24 mL sponge diluent enrichment will be used primarily for Agency internal analysis but will also be aggregated and posted quarterly by performance category to show the progress of the chicken and turkey industries. If there is no improvement in these data over time, FSIS may consider implementing the performance standard using the larger-portion sample results as well.

Dose-Response Level for Campylobacter

Comments cited studies claiming that the threshold of concern for Campylobacter in broilers is much higher than the new Campylobacter performance standard and questioned the standard’s relevance to public health.

FSIS Response: The threshold dose-response concept implies that there is a very low probability of illness below a certain dose. The 500 Colony Forming Units/gram (CFU/g) threshold suggested would translate into roughly 50,000 CFU as a minimum dose to cause illness assuming a serving of about 100 grams. This assertion is in contrast to the available data. Campylobacter human feeding trials show human illness can result in healthy adult males fed 500 CFU and 800 CFU (Robinson, 1985; Black et al., 1988). If such low levels can result in human illness among healthy adult males, it is reasonable to assume that lower doses might result in human illness in traditionally sensitive populations, such as the young, the old, and the immuno-compromised. Given these concerns, the Agency believes that establishing a performance standard from baseline data is warranted.

Campylobacter Fragility

A comment stated that the Campylobacter organism is very fragile and is unlikely to survive regular processing and handling and thus questioned the need or usefulness of creating a performance standard for it.

FSIS Response: The FSIS Young Chicken Baseline Survey, 2007–2008, found about 46 percent of sampled chicken carcasses at post-chill had Campylobacter. FSIS does not have data to confirm or deny the presence of Campylobacter on finished product or at retail. However, two Consumer Reports of retail sampling programs for leading national brands of young chickens, published in January of 2007 and 2010 respectively, found about 81 and 62 percent of retail young chickens contaminated with Campylobacter (Consumer Reports). Given the limited sampling, these results cannot be generalized to the retail market as a whole. In addition, however, the National Antibiotic Resistance Monitoring System (NARMS) annual retail meat survey reported that between 2002 and 2008 the incidence of Campylobacter on chicken breasts was between approximately 40 and 60 percent (NARMS).

As Campylobacter does not grow at normal distribution temperatures, it is likely that Campylobacter organisms are able to survive the commercial processes and current interventions employed by the industry. In view of these facts, the Agency believes that it is appropriate to apply Campylobacter standards for tracking and reporting to establishments and for Agency internal analysis, follow-up testing, and Food Safety Assessments when deemed necessary.

Campylobacter Methodology

Several comments asked for clarification on appropriate methods for use by establishments to verify compliance with the new Campylobacter standards.

FSIS Response: The Agency testing program to verify establishment performance against the new standards will collect young chicken rinsates and turkey carcass sponges to be tested for Campylobacter using a method described in the Microbiology Laboratory Guidebook (MLG), which is available on the FSIS Web site at http://www.fsis.usda.gov/PDF/MLG_41_00.pdf. Contrary to a misleading note in the May 14, 2010 notice implying that the method was being significantly revised, no substantive changes to this method are anticipated at this time.

The MLG 41 method for poultry rinsates and carcass sponges is designed to be selective for the Campylobacter species of interest. FSIS will perform testing for detection and enumeration of Campylobacter jejuni, C. coli, and C. lari. According to CDC data, C. jejuni and C. coli cause the majority of Campylobacter illnesses in the U.S. The National Advisory Committee for Microbiological Criteria of Foods (NACMCF) recommended the use of methodology to specifically target these Campylobacter species so FSIS encourages industry testing to include these species.

The MLG method includes two procedures. In the first procedure (MLG 41 Section 41.5), an aliquot of the rinsate or sponge/buffered peptone water (BPW) combination is plated directly to the Campy-Cefex plating medium and then incubated under microaerophilic conditions for 48 hours at 42 °C.

In the second procedure (MLG 41 Section 41.6.1 or 41.6.2), an aliquot of rinsate or sponge/BPW combination is cultured in blood free Bolton enrichment broth plus Bolton broth selective supplements under microaerophilic conditions for 48 hours at 42 °C and then a small amount of enriched culture is streaked to Campy-Cefex plating medium and incubated under microaerophilic conditions for 48 hours at 42 °C.

The theoretical limit of detection is considerably higher for the direct plating sample compared with the enriched sample. For both procedures, multiple colonies that are typical of the appearance of Campylobacter are picked from the Campy-Cefex plating medium and confirmed as Campylobacter jejuni, coli, or lari (Campylobacter j/c/l) using microscopy to assess cell morphology and motility, and a latex agglutination serological testing procedure that identifies Campylobacter specifically belonging to these three species. To determine establishment performance relative to the performance standards, samples by the direct plating procedure with one or more colonies confirmed as Campylobacter j/c/l would be considered positive. Samples positive by either or both procedures will be recorded by FSIS and used for internal Agency analysis and quarterly aggregate reports.

Establishments that wish to perform Campylobacter testing to verify their process control procedures can use the FSIS MLG method. Alternatively,
establishments may rely on methods that have been validated to provide equivalent or superior sensitivity. For example, verification testing programs based solely on enriching samples could provide equivalent sensitivity compared with the FSIS method. To be comparable with the FSIS method, confirmatory methods should be demonstrated to be capable of detecting C. coli, C. jejuni, and C. lari. However, FSIS realizes that C. lari is rarely encountered in poultry samples. The culture and identification procedures in MLG 41 are not optimized for detection of non-Campylobacter j/c/l species.

Questions related to specific Campylobacter methods used by establishments should be directed to the AskFSIS sampling queue at http://www.fsis.usda.gov/Businesses/index.asp.

One comment queried why available Polymerase Chain Reaction (PCR) methodology is not used by the Agency. FSIS Response: For its baseline testing, FSIS applied standard culture methodology recommended by the NACMCF for detecting and quantifying levels of Campylobacter on poultry samples. Non-proprietary traditional culture methodology offers advantages for reliability of results, the potential for confirming and subtyping isolates, and implementation of testing in a broad range of laboratories that may not have access to equipment for PCR or similar testing technologies. FSIS plans to apply the same NACMCF-recommended methodology used in the baseline study for future verification testing. However, FSIS is encouraging development and validation of alternative testing methodologies for detecting and quantifying Campylobacter.

Sample Collection Methods—Turkey Sponge vs. Chicken Rinse

One comment questioned the Agency use of different sampling methodologies for young chickens and turkeys, asserting that the turkey methodology is biased against finding Salmonella and Campylobacter.

FSIS Response: FSIS agrees that sampling methodology has an impact on pathogen detection and enumeration. Because different sampling methodologies are used for chicken and turkey carcasses, FSIS has not proposed to compare data for these commodities. FSIS agrees that rinsate sampling, even without complete recovery of attached pathogens, provides a representative sample for internal and external carcass surfaces. Because the turkey baseline sample was taken in the mid-1990s, FSIS had attempted to use 600 mL rinsate sampling for turkey carcasses. However, because the typical turkey carcass was quite large and heavy, the manual rinse procedure posed problems for effective sampling and workplace safety. Following that initial study, FSIS adopted an industry recommendation to use a sponge to sample a 100 cm² area of the turkey carcass. To compare the effectiveness of rinse vs. sponge sampling, FSIS conducted two baseline studies, Young Turkey Rinse Baseline (1996–1997) and the Young Turkey Sponge Baseline (1997–1998). The two baseline studies demonstrated a comparable Salmonella prevalence of 18.6 percent and 19.6 percent, respectively. For the most recent turkey carcass baseline study in 2009, FSIS considered sampling skin from the neck flap or other areas of the carcass, but these sampling procedures also present technical and logistical challenges. FSIS agrees that sponge sampling likely under-represents the prevalence of Campylobacter on turkey carcasses, but this approach, applied consistently over time to sampling continues to provide an effective means to identify establishments where process control may be less robust.

General questions were raised about Agency policies regarding Campylobacter following implementation of the new performance standards.

FSIS Response: The Agency will respond to a sample set failure for either organism by immediately scheduling a follow-up set, the samples of which will be analyzed for both organisms. An FSA will automatically be triggered under the current criteria for failing the Salmonella and Campylobacter methodology for Campylobacter until FSIS develops specific methodology for a Campylobacter FSA. The Agency will not set an automatic Campylobacter FSA trigger until two full sample sets have been completed under the new standard for 90 percent of the eligible establishments in the product class, at which time the Agency will evaluate the results to determine the best food safety and public health policy. The Agency may, however, conduct an FSA for any establishment failing the Campylobacter performance standard for two sets straight or in the case of egregious failure of a single set. The concept for an egregious failure is based on a comparison of the establishment’s performance for the set versus establishments’ performances on other sets during some specific period of time. Thus, the actual criterion for determining an egregious failure could, and is expected to, change over time. The criterion is based on first determining an 80th percentile of the distribution of establishment-specific prevalences of positive results over some specified period, and then determining a cutoff threshold for the number of positive results in a set such that if exceeded for a set would be considered an egregious occurrence. Using the Young Turkey Baseline Survey and a statistical model using empirical Bayes estimation procedures for developing a tentative criterion, the Agency estimated the 80th percentile of the establishments’ specific estimated prevalence to be 18 percent. The compliance criterion would therefore be 14 positive samples out of a 51 sample set. Fifteen or more positive results would be considered egregious given there would be more than 95 percent confidence that the true underlying establishment-specific prevalence during the period of sampling exceeded 18 percent, based on an assumption that positive results are distributed randomly following the binomial distribution. However, as mentioned above, FSIS expects this threshold value to change over time as data from the HACCP verification samples are analyzed.

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 notice, FSIS will announce it online through the FSIS Web page located at http://www.fsis.usda.gov/regulations/policies/Federal_Register_Notices/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, 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. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food
Appendix I

Comments questioned the design and development of the Agency’s public health predictions. In developing its public health predictions, FSIS used a “prevalence-based” approach to estimate the impact of the proposed performance standards. The approach used in this model assumes that contamination levels on broiler carcasses are independent of the frequency of contaminated carcasses. If the prevalence of Salmonella-contaminated carcasses and the levels of Salmonella on contaminated carcasses are positively correlated, then this assumption would likely be conservative in models that estimate the reduction in illnesses associated with a reduction in prevalence. Nevertheless, the available evidence does not reject this assumption. For samples that were test-positive, the average concentration of Salmonella per mL at sample rinsate was 0.16 and 0.14 CFU in the 1995 and 2008 baseline surveys, respectively (FSIS 1996, FSIS 2009). Yet, the prevalence of positive carcasses was demonstrably different in those surveys, 20 percent and 7.5 percent, respectively.

Estimates of the reduction of Salmonella incidence (presence/absence) as a result of compliance with the proposed performance standards were used for estimating the averaged number of illnesses as a consequence of implementing these performance standards. A detailed description of the underlying model follows.

The true annual number of poultry-related illnesses is determined by only three components. The first is the number of servings, denoted as N_{avg}, consumed in the U.S. It is reasonable to assume that this number does not fluctuate wildly from year to year. The second component describes the frequency of exposure to contaminated servings, denoted by P(exp). It is reasonable to assume that P(exp) is proportional to the percent of positive carcasses (i.e., it only differs by a simple scaling factor). The final component is the probability that an individual serving derived from a contaminated carcass causes illness. Let this be denoted by P(ill/exp). This component contains all the factors that FSIS does not control, such as storage, handling, cooking practices, and pathogenicity of different strains that are circulating in any given year. Taking all three factors into account, the number of illnesses is

\[ N_\text{ill} = N_{\text{avg}} P(\text{ill}/\text{exp}) P(\text{exp}). \]

This formula summarizes all the components that go into any food-safety risk assessment. Thus, there are actually very few assumptions involved with the estimation. The source of uncertainty that was evaluated in the document was the uncertainty about the proportion of non-compliant establishments that would modify their production practices in order to meet the new standard. The analysis of this parameter does indeed demonstrate that the true effect of the performance standard varies directly with this parameter. Nevertheless, FSIS has provided historic evidence that suggests that this parameter will not be zero and may approach 50 percent or more.

The comment implied that FSIS estimates are not correct because only small establishments would be affected and it would not be possible that such impact could lead to FSIS’ estimates of averted illnesses. FSIS disagrees with this assertion and believes that some larger volume establishments would be affected and thus the estimates of averted illnesses reflect this belief. The technical paper attached to the May 14, 2010 Federal Register Notice (Technical Paper) that explained in detail the derivation of the performance standard, explains also how the proposed standards would affect the prevalence. In that document, Equation 3 provides the formula that was used to compute the expected prevalence, which as described above FSIS assumed is proportional to P(exp), for product that would be associated with passing the compliance rule. Similarly, a formula was computed for the expected prevalence for product that would be associated with establishments that fail the compliance criterion. These formulas explicitly treat establishments as “different” depending upon their results from the baseline.

Because the formula of Equation 3 explicitly treats establishments as “different” depending upon their results from the baseline, it was not assumed that all large or medium volume establishments would pass the compliance criterion. The compliance criterion is designed such that if an establishment were meeting the standard exactly—that is, the establishment’s prevalence was in fact the standard of 7.5 percent—then the establishment would fail the compliance criterion 20 percent of the time. Thus, in modeling the impact, such an establishment would contribute to the estimate of the expected number of illnesses prevented because it would be expected that 20 percent of such establishments would make improvement.

Though FSIS believes these assumptions are reasonable, only time can validate their appropriateness. Though it is possible that establishments, even if they fail, might not make any changes, such a possibility would not invalidate the model. In sum, FSIS believes that the model reflects a reasonable expectation.

Appendix II

Comments noted differences in FSIS baseline and PR/HACCP verification data. To explore the question in more depth, FSIS examined its HACCP verification and Baseline data since the baseline survey (August 2008–July 2010) for comparison purposes. As the Agency has discussed in other communications, percentages of positive results from HACCP verification data should not be interpreted as an estimate of prevalence because the sample and establishment selections are not designed for statistical purposes but rather for verification activities. Thus, the HACCP verification sampling program takes disproportional numbers of samples in some establishments over time. In the period being discussed, 2362 samples were taken from 35 establishments—82 were positive, for a percent positive rate of 3.47. Five establishments, with 8–12 positive results, accounted for 49 positive results. No other establishments had more than five positive results. Thus there appears a distinction between the performances of these five establishments and all other establishments. If results from these five establishments were deleted, the percentage of positive results from the remainder (1872 samples) is 1.76. This percentage is congruent with the Baseline estimate of prevalence. However, the establishment-effect was not seen in the Baseline in part because the numbers of samples per establishment were not large, particularly during the period from April to July when most of the HACCP samples were analyzed. The following table classifies data by sampling program, period of time, and whether or not the sample was taken from one of the 5 establishments referred to above. The column heading “Estab Relative Positive Rates” distinguishes the results from the 5 establishments (High) from the others (Low).

<table>
<thead>
<tr>
<th>April percent to July</th>
<th>Estab relative positive rates</th>
<th>Samples HACCP (#)</th>
<th>Positive HACCP (#)</th>
<th>Positive HACCP (percent)</th>
<th>Samples base (#)</th>
<th>Positive base (#)</th>
<th>Positive base (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No ....................</td>
<td>Low .........................</td>
<td>387</td>
<td>2</td>
<td>0.52</td>
<td>842</td>
<td>7</td>
<td>0.83</td>
</tr>
<tr>
<td>Yes ....................</td>
<td>Low .........................</td>
<td>1485</td>
<td>31</td>
<td>2.09</td>
<td>416</td>
<td>11</td>
<td>2.64</td>
</tr>
<tr>
<td>No ....................</td>
<td>High ........................</td>
<td>70</td>
<td>6</td>
<td>8.57</td>
<td>118</td>
<td>3</td>
<td>2.54</td>
</tr>
<tr>
<td>Yes ....................</td>
<td>High ........................</td>
<td>420</td>
<td>43</td>
<td>10.24</td>
<td>66</td>
<td>3</td>
<td>4.55</td>
</tr>
</tbody>
</table>
From this table an explanation of why the percentage of positive samples for the HACCP verification sample program is greater than the estimated prevalence derived from the Baseline survey data. On a relative scale, by examining the table one can see where the larger "true" differences between cell-specific percentages occur and where small differences occur and identify the factors and their values that are associated with large differences. For example, consider the cells with data from establishments that are classified as having "low" relative positive rates (second column of table) thus excluding data from the 5 establishment identified above with exceptionally high percentages of positive results. And within those cells, consider the differences of the two percentages within each of the periods identified in the April–July column (no, yes). These cells are in bold in the above table. Differences of percentages can be computed in two directions: (1) Differences of the percentages in the same rows, and (2) differences in the same columns. The first direction (in the same rows): For the first row, data not collected between April to July, the difference is computed as: 0.83 percent (for the Baseline) minus 0.52 percent (for the HACCP data), which is equal to 0.31 percent; for the second row, data collected between April–July, the difference is computed as: 2.64 percent – 2.09 percent = 0.55 percent. So the two row-specific differences are 0.31 percent and 0.55 percent. Now compute the differences for results in the same columns: For the baseline cells, the difference computed as: 2.64 percent (for data collected between April–July) minus 0.83 percent (for data collected not between April–July) which is equal to 1.81 percent; for the HACCP cells, the corresponding difference is computed as: 2.09 percent – 0.52 percent = 1.57 percent. So the two column-specific differences are 1.81 percent and 1.57 percent. These two percentages average to 1.69 percent. These two column-specific differences are quite a bit larger than the two row-specific differences. This period and 0.55 percent, which average to 0.43 percent. In other words, the average of the differences of percentage when comparing the percentages in different periods is about 4 times the average of the differences of percentages when comparing the percentages in different sampling programs. Thus on a relative scale, this relationship suggests that an important variable or factor that "explains" the variation of percentages is the period in which the data were collected.

The third and fourth rows of the table contain percentages of positive results for the 5 establishments that performed poorly on the HACCP samples. It can be seen that for the Baseline samples, for these establishments, the percentages of them that were positive were larger than the corresponding percentages for the other establishments (in the first two rows). For example, for the samples not collected during April–July, the percentage of positive samples for these 5 establishments was 2.54 percent versus 0.83 percent for the samples collected from the other establishments, and for the samples collected during April–July the two percentages are 4.55 percent and 2.64 percent, respectively. The relationship of the percentages for the different periods of sampling is also in the same direction as seen for the percentages given in the first two rows of the table; that is, the percentages of positive results for the samples from the HACCP verification sample program were higher than during April–July: larger than the corresponding percentages for the samples not taken during April–July. Thus these results, associated with the 3rd and 4th rows of the above table, support the assessment that "period of sampling" is an important explanatory variable, as well as supporting that the "group of establishments" is an important explanatory variable.

The difference of percentage positive results between the HACCP verification and Baseline sampling programs is, it appears, a result of the differences of proportions of samples between the two programs, associated with the above two explanatory variables. Specifically, there are large differences of the proportions of samples for the two different years in the same establishments and from the two designated periods: (1) Close to 21 percent of the HACCP samples were from the 5 poorer performing establishments, whereas about 13 percent of the Baseline samples were from these establishments; and (2) about 80 percent of the HACCP samples were from the period April–July, whereas about 33 percent of the Baseline samples were from the same period.

The above is an explanation of the differences between the two sampling programs’ percentages of positive results. FSIS had been considering the possibility of both temporal and establishment effects in developing its performance standard approach. FSIS addressed this issue by relaxing the criterion for failing a set of the at least 99 percent criterion, would mean that in 112 samples there should be no more than six positive results. Using an average could place an establishment in a more difficult situation. For example, if there were five or six positive results, the establishment would then only at most one or no positive results would be permitted for the second set in order to pass. An establishment in such a situation would fail if there were more than one or zero positive results—a difficult standard even if the establishment had the best processes. On a failure (e.g., two or three positive results within the set), a third set would be needed, in the meantime, the establishment would have failed to meet the standard, when in fact the establishment’s process might actually be in control. Thus, following the comment’s suggestion actually would be increasing the type 1 error rate by resulting in listing of establishments at a time in which their process is most likely to be in control, and increasing the so-called type 2 errors of not posting an establishment when its process was not performing well. Rather the FSIS approach is timelier: When sufficient evidence exists (in this case, with 99.7 percent confidence, or a type 1 error rate of 0.3 percent) that the standard is not being met, then the establishment would be listed, and if on a second set, the establishment passes with no more than four positive results, the establishment’s name would be removed.

FSIS believes that HACCP verification data examined above support the Agency’s
position. For the two-year period for which data were analyzed, five establishments had seven, seven, nine, nine, and 10 positive results (the same five establishments with the largest number of positive results identified above). Of these, three establishments had a second full set of 56 samples, with a total number of six positive results (one, two, and three), for a rate of 3.6 percent, still above average. These three establishments though would have met the standard and thus would have been taken off the list. If the proposed grace period option were operating, then it would have been established if there had been six positive results instead of seven for one of the sets; in such a case, any of results from the second sets given above would have resulted in the establishment not meeting the standard, and the establishment’s name would have been listed. Under FSIS’ system, in this case the establishments would have been listed after the first set when there was sufficient evidence for adding that the establishments’ processes were not as good as could be relative to the rest of the industry, and then removed after the second set, success, when the latest evidence would not be sufficient for such an adduction.

In conclusion, FSIS believes that its system prevents type 1 errors from occurring often and is timelier regarding when poor performing establishments would be listed. FSIS believes that its policy is appropriate for maintaining the status quo, and inducing poorer performing establishments to improve their processes to a level consistent with the industry’s overall performance. By relaxing the required degree of confidence to 99 percent from 80 percent confidence, FSIS believes that it has provided a reasonable policy with regard to small deviations from the standard for which the establishment could and should address without being listed. For the compliance guideline for the turkey performance standard, the actual degree of confidence is 99.7 percent. As a consequence, FSIS does not believe a “grace period” is necessary; that if an establishment fails to meet the standard compliance criterion it would indicate that the establishment’s process can be improved. In addition, (1) The discrepancy between the baseline and HACCP percentages of positive results can be “explained” for the most part by the disproportional distribution of samples over time and over establishments; (2) HACCP verification data show that over 90 percent of the sets in the time period analyzed had no more than three positive results, and thus for the most part it seems that establishments have been performing recently at or better than the specified performance standard.

[FR Doc. 2011-6585 Filed 3–18–11; 8:45 am]
BILLING CODE 4703–10–P

DEPARTMENT OF AGRICULTURE

Forest Service

Sanders County Resource Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of Sanders County Resource Advisory Committee Meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Pub. L. 92–463) and under the Secure Rural Schools and Community Self-Determination Act of 2000 (Pub. L. 106–393) the Lolo and Kootenai National Forests’ Sanders County Resource Advisory Committee will meet on April 21, 2011 at 7 p.m. in Thompson Falls, Montana for a business meeting. The meeting is open to the public.

DATES: April 21, 2011.

ADDRESSES: The meeting will be held at the Thompson Falls Courthouse, 1111 Main Street, Thompson Falls, MT 59873.

FOR FURTHER INFORMATION CONTACT: Randy Hojem, Designated Federal Official (DFO), District Ranger, Plains Ranger District, Lolo National Forest at (406) 826–3821.

SUPPLEMENTARY INFORMATION: Agenda topics include solicitation for new RAC project proposals, reviewing progress on current projects, and receiving public comment. If the meeting location is changed, notice will be posted in local newspapers, including the Clark Fork Valley Press, and Sanders County Ledger.

Dated: March 14, 2011.

Randy R. Hojem,
District Ranger.

[FR Doc. 2011–6503 Filed 3–18–11; 8:45 am]
BILLING CODE 4310–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

[02090DP30910]

Upper Rio Grande Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Upper Rio Grande Resource Advisory Committee will meet in Monte Vista, Colorado. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) and in compliance with the Federal Advisory Committee Act. The purpose is to review and recommend project proposals to be funded with Title II money.

DATES: The meeting will be held on April 11, 2011 and will begin at 10 a.m.

ADDRESSES: The meeting will be held at the South Fork Community Building, 0254 Highway 149, South Fork, Colorado. Written comments should be sent to Mike Blakeman, San Luis Valley Public Lands Center, 1803 West U.S. Highway 160, Monte Vista, CO 81144. Comments may also be sent via e-mail to mblakeman@fs.fed.us, or via facsimile to 719–852–6250.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the San Luis Valley Public Lands Center, 1803 West U.S. Highway 160, Monte Vista, CO 81144.

FOR FURTHER INFORMATION CONTACT: Mike Blakeman, RAC coordinator, USDA, San Luis Valley Public Lands Center, 1803 West U.S. Highway 160, Monte Vista, CO 81144; 719–852–6212; E-mail mblakeman@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) Introductions of all committee members, replacement members and Forest Service personnel; (2) Review status of approved projects; (3) Review, evaluate and recommend project proposals to be funded with Title II money; (4) Create a timeline to receive and review new project proposals and schedule the next meeting; and (5) Public Comment. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting.

Dated: March 15, 2011.

Dan S. Dallas,
Forest Supervisor.

[FR Doc. 2011–6531 Filed 3–18–11; 8:45 am]
BILLING CODE 4310–11–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 20–2011]

Foreign-Trade Zone 106—Oklahoma City, OK Application for Reorganization/Expansion Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Port Authority of Greater Oklahoma City, grantee of FTZ 106, requesting authority to reorganize and expand the zone under the alternative site framework (ASF)