Notices

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

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

January 22, 2008.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Marketing Service

Title: Livestock & Meat Market News.

OMB Control Number: 0581–0154.

Summary of Collection: The Agricultural Marketing Act of 1946 (7 U.S.C. 1621), section 203(q), directs and authorizes the collection and dissemination of marketing information including adequate outlook information, on a market area basis, for the purpose of anticipating and meeting consumer requirements aiding in the maintenance of farm income and to bring about a balance between production and utilization. Livestock and Meat Market News provides a timely exchange of accurate and unbiased information on current marketing conditions affecting trade in livestock, meats, grain, and wool. Administered by the U.S. Department of Agriculture's Agricultural Marketing Service (AMS), this nationwide market news program is conducted in cooperation with approximately 30 States departments of agriculture. AMS will collect information using market reports.

Need and Use of the Information: The information provided by respondents initiates market news reporting, which must be timely accurate, unbiased, and continuous if it is to be meaningful to the industry. AMS will collect information on price, supply, demand, trends, movement, and other information of livestock, meat carcasses, meat and pork cuts, and meat byproducts. Several agencies, agricultural universities and colleges use the information collected to keep appraised of the current market conditions, movement of livestock and meat in the United States and to determine available supplies and current pricing.

Description of Respondents: Business or other for-profit; Individuals or households;

Number of Respondents: 1,109.

Frequency of Responses: Reporting: Weekly; Other (Daily).

Total Burden Hours: 11,640.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. E8–1380 Filed 1–25–08; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2006–0034]

Salmonella Verification Sampling Program: Response to Comments and New Agency Policies

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice, response to comments, and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing new policies for the Agency's *Salmonella* Verification Sampling Program and related activities conducted in meat and poultry establishments. These changes include publication of completed FSIS verification sample set results for establishments that show inconsistency in their ability to meet *Salmonella performance standards,* beginning with those from young chicken slaughter establishments; a voluntary incentive-based program for meat and poultry establishments that should yield significant data on attribution of human illness to FSIS-regulated products; and increasing the Agency's use of targeted sampling approaches and collaborative serotype and subtype data. FSIS is taking these actions to advance its efforts to achieve the Agency's public health goal of significantly reducing human cases of salmonellosis. This Notice explains the basis for these actions and responds to comments received by the Agency on its **Federal Register** Notice of February 27, 2006 (71 FR 9772–9777) on *Salmonella* policy.

DATES: Submit comments by February 27, 2008. The policies described in the Notice are planned to take effect March 28, 2008.

ADDRESSES: FSIS invites interested persons to submit comments on this Notice. Comments may be submitted by any 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. FSIS prefers to receive comments through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and, in the ''Search for Open Regulations'' box, select ''Food Safety and Inspection

Service'' and ''Notices'' from the agency drop-down menu and then click on ''Submit.'' In the Docket ID column, select the FDMS Docket Number to submit or view public comments and to view supporting and related materials available electronically. After the close of the comment period, the docket can be viewed using the ''Advanced Search'' function in Regulations.gov.

Mail, including floppy disks or CD–ROM's, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue, SW., Room 2534 South Building, Washington, DC 20250.

Electronic mail: fsis.regulationscomments@fsis.usda.gov.

All submissions received must include the Agency name and FDMS docket number FSIS–2006–0034.

All comments submitted in response to this Notice will be posted to the regulations.gov Web site. Comments will also be available for public inspection in 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: For further information contact Daniel Engeljohn, PhD, Deputy Assistant Administrator for Office of Policy, Program and Employee Development, FSIS, U.S. Department of Agriculture, Room 349–E, South Building, 14th and Independence SW., Washington, DC 20250–3700, (202) 205–0495, fax (202) 720–2025, e-mail: *daniel.engeljohn@fsis.usda.*

SUPPLEMENTARY INFORMATION:

Background

The actions announced in this Notice result from an Agency re-evaluation of its verification sampling program for *Salmonella* in meat and poultry establishments. Pertinent issues were raised in two previous FSIS **Federal Register** Notices published in April 2003 (68 FR 18593–18596) and February 2006 (71 FR 9772–9777). The Notice of April 2003 asked for public comment on FSIS practices and its then-current thinking about *Salmonella.* The February 2006 Notice responded to public comments on the 2003 Notice, announced changes in how the Agency schedules *Salmonella* verification sample sets and in how it reports sample results, and discussed outstanding concerns and possible new directions.

The *Salmonella* verification sampling program formally began with the Agency's Final Rule on Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems that issued on July 25, 1996 (61 FR 38805–38989; *http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93–016F.pdf*). Among other things, the PR/HACCP rule set *Salmonella* performance standards for establishments that slaughter selected classes of food animals or that produce selected classes of raw ground products. FSIS uses the *Salmonella* performance standards to ensure that each establishment is consistently achieving an acceptable level of performance with regard to controlling and reducing harmful bacteria on raw meat and poultry products. The microbiological performance standards for reduction of *Salmonella* in raw products, coupled with performance criteria for use with *E. coli* testing allow FSIS to verify the effectiveness of process controls in slaughter establishments.

Raw products with established PR/HACCP performance standards include carcasses of cows/bulls, steers/heifers, market hogs, and young chickens (broilers). Processed products measured by performance standards include ground beef, ground chicken, and ground turkey. The performance standards for these product classes are based on the prevalence of *Salmonella* as determined from nationwide microbiological baseline studies that FSIS conducted before PR/HACCP was implemented. In addition, FSIS established a guideline level for young turkey carcasses, relying on a baseline study that the Agency published in 2005 (70 FR 8058–8060; *http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/02–046N.pdf*).

Under the *Salmonella* verification program as conducted from 1996 to 2006, the Agency verified that establishments are meeting a *Salmonella* standard or guideline by having FSIS inspection program personnel collect randomly-selected product samples from randomly-selected individual establishments over the course of a defined number of sequential days of production to complete a sample set. Generally, these tests were conducted once each year for each establishment. Procedures for doing this are described in Appendix E of the PR/HACCP Final Rule (61 FR 38917–38928). The product samples are sent to FSIS laboratories for analysis. The number of samples in a sample set varies by product class. The maximum number of positive samples allowed in a set is based on data from the nationwide baseline studies. The standards were defined on a product class basis so that an establishment operating at the baseline level would have an 80% chance of meeting the standard.

The Agency's February 2006 Notice announced specific actions that the Agency intended to take. FSIS has effected these actions over the last eighteen months. The following is a list of these actions and their current state of implementation:

1: Reporting results of each individual *Salmonella* test to establishments as they become available.

Implemented in July 2006.

2: Posting quarterly nationwide *Salmonella* data by product class.

Implemented in June 2006 beginning with the first quarter of 2006. See *http://www.fsis.usda.gov/Science/Quarterly_Salmonella_Results/index.asp.*

3: Collecting swab samples from turkey carcasses for *Salmonella* analysis.

Implemented in June 2006.

4: Classifying establishments in three process control categories according to their performance in completed sample sets relative to the regulatory performance standard or baseline guidance level for *Salmonella* percent positive in their product class, and scheduling sample collection according to these categories:

Category 1:—Establishments with percent positive *Salmonella* samples at 50% or less of the performance standard or guideline in the two most recent completed sample sets.

Category 2:—Establishments with percent positive *Salmonella* samples above 50% but not exceeding the standard/guideline in the most recent completed sample set.

Category 3:—Establishments with percent positive *Salmonella* samples exceeding the standard/guideline in the most recent completed sample set.

Implemented in July 2006 when a new scheduling algorithm, based on these process control categories, went into effect. The February 2006 Notice explained that a Category 1 ''establishment will [now] be tested no more than once a year, but at least once every two years, unless it gets a result that puts it in Category 2 or 3'' (71 FR at 9776). This algorithm has the effect of placing greater emphasis on scheduling young chicken establishments, which are currently the Agency's top priority.

5: Conducting Food Safety Assessments (FSAs) in establishments in Category 3 for *Salmonella* before sample set failure.

Implemented by FSIS Notice in August 2007.

6: Issuing a new compliance guideline on control of *Salmonella* for young chicken slaughter establishments.

Implemented in August 2006 with publication of ''Compliance Guideline

for Controlling *Salmonella* in Poultry, First Edition'' at *http://www.fsis.usda.gov/PDF/Compliance_Guideline_Controlling_Salmonella_Poultry.pdf*. A second edition, updated to include guidance for controlling *Campylobacter* as well, is in development.

7: Obtaining serotype (species) data from isolates and timely sharing of serotype data with establishments.

Implemented in May 2006. After one of the FSIS field service laboratories reports the analysis results, isolates of *Salmonella*-positive samples are serotyped to identify species at the USDA Animal and Plant Health Inspection Service's National Veterinary Services Laboratories in Ames, Iowa. In recent years virtually all samples positive for *Salmonella* have been serotyped. Identified serotypes are communicated to establishments as soon as they are reported by APHIS to FSIS, usually within two weeks after a sample has been reported as positive. A report listing aggregate identified serotypes by year was posted in August 2007 on the Agency Web site at *http://www.fsis.usda.gov/Science/Serotypes_Profile_Salmonella_Isolates/index.asp*.

8: Obtaining timely access to pulsed field gel electrophoresis (PFGE) subtype data identifying specific strains of *Salmonella* serotypes.

Implemented in August 2007 when FSIS and the Agricultural Research Service (ARS) signed a cooperative Memorandum of Agreement for subtype data sharing. Under this agreement, PFGE subtype information on *Salmonella* isolates collected by FSIS from meat and poultry products is matched with subtype information from isolates associated with human illness in PulseNet, a data base maintained by the Centers for Disease Control and Prevention (CDC). FSIS has routine access to data for all subtype isolates maintained by ARS, in a time frame short enough to be relevant to in-plant and public health investigations.

9: Updating baseline studies to better measure improvements in pathogen reduction in all classes of raw product.

Implemented; a new young chicken baseline began in June 2007, and a young turkey baseline is scheduled for 2008. Additional baselines are being planned for the future.

10: Monitoring process control changes and movement between Categories 1, 2, and 3 by tracking *Salmonella* percent positive in verification samples by product class over the course of a full year beginning in July 2006.

Implemented. In the February 2006 Notice, the Agency established its goal of having 90% of all meat and poultry establishments manufacturing raw classes of product subject to *Salmonella* testing in Category 1 by October 1, 2010. In addition, FSIS explained that it would consider taking action to provide incentives for enhanced public health protection if that benchmark had not been met by July 2007. As of the benchmark date of June 30, 2007, Category 1 included 73% of turkey establishments, 72% of young chicken establishments, 60% of market hog establishments, 59% of cow/bull establishments, and 45% of steer/heifer establishments. As of September 30, 2007, Category 1 included 84% of turkey establishments, 73.5% of young chicken establishments, 63% of market hog establishments, 61% of cow/bull establishments, and 45% of steer/heifer establishments. While these results did not reach the July 2007 benchmark, they are encouraging signs of progress. Though the Agency is encouraged by this progress, it has continuing concerns about the adverse effects of *Salmonella* on public health. FSIS has determined, therefore, that more robust incentives, including publication of establishment verification sampling results, are necessary to encourage the industry to improve its performance in controlling *Salmonella*.

Public Health Concerns

To put the 2006–2007 results of the *Salmonella* verification program cited above in perspective, CDC has reported that in 2006 *Salmonella* serotypes accounted for 38.6% of all human foodborne infections, making it the most common human foodborne pathogen (*http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5614a4.htm?s_cid=mm5614a4_e*). Moreover, the U.S. Department of Health and Human Services National Food Safety Objectives ''Healthy People 2010''—which USDA and FSIS use to guide strategic planning for public health—set a goal of 6.8 cases of salmonellosis per 100,000 persons by 2010 (*http://www.healthypeople.gov/document/tableofcontents.htm*). The 2006 rate for human *Salmonella* infections reported by CDC is 14.81 cases per 100,000 persons, more than double the target rate for Healthy People 2010. This represents only a slight decrease in overall human infections from *Salmonella* serotypes from an incidence of approximately 16.8 cases per 100,000 persons in the CDC reference period of 1996–98.

Meat and poultry products contain some serotypes of *Salmonella* that are rarely found in human patients suffering from salmonellosis, but other serotypes found in various meat and poultry products are among those often identified in human cases. The seven most commonly identified *Salmonella* serotypes causing human infection in the United States according to the CDC are *Typhimurium*, *Enteriditis*, *Newport, Javiana, Montevideo, Heidelberg*, and I 4, [5], 12:i:–. Combined, these serotypes accounted for 64% of human cases of salmonellosis. The CDC notes that of these seven most common *Salmonella* serotypes found in human infections in 2006, only *Typhimurium* has declined since the 1996–98 baseline study, and its incidence since 2003 has been stable. *S. Enteriditis*, however, has increased by 28% since 1996–98. *S. Newport*, which has shown signs of mutation toward multi-drug resistance, has increased by 42% since 1996–98.

Most importantly, the CDC has determined that poultry is an effective vector for *S. Enteriditis*, a cause of human infections. A FoodNet case-control study found that human infections that were associated with eating chicken displayed *Enteriditis* bacteriophage type (PT) strains that matched the predominant strains that are isolated from chickens. This match in PT strains indicates that the association in the cases between eating chicken and human illness was causal.

FSIS has reported its own data showing an increase during calendar years 2000–2005 in the frequency of isolation in young chickens of *Salmonella*, particularly *S. Enteriditis* (*http://www.fsis.usda.gov/Science/Progress_Report_Salmonella_Testing/index.asp*). The percent positive of *Salmonella* samples in young chicken establishments tested by the Agency's PR/HACCP verification program increased from 11.5% in 2002 to 12.8% in 2003, 13.5% in 2004, and 16.3% in 2005. In 2006, however, the Agency's testing program showed the lowest percentage of young chickens that had tested positive for *Salmonella* in several years—11.4%. This 30% decrease in percent positive samples from 2005 is noteworthy, particularly given that beginning with 2006 FSIS has directed its resources toward testing young chicken establishments with variable or highly variable process control in order to reverse the upward trend in percent positives seen in such establishments. This one-year reversal is promising, though the change in FSIS sampling direction in 2006 makes comparisons of percent positive samples with previous years uncertain. The trend will need to be confirmed and of course sustained.

During the 2000–2005 period, the annual number of *S. Enteriditis* isolates found by FSIS increased more than four-fold, and the percentage of establishments with sample isolates positive for *Enteriditis* increased by nearly three-fold (*http://www.cdc.gov/ncidod/EID/vol12no12/06–0653.htm*). During 2000–2005, the number of states with *Enteriditis* isolates found in young chickens sampled by FSIS increased by 71%. Moreover, the predominant *Enteriditis* bacteriophage types found were PT 13 and PT 8, strains isolated from human infections associated with eating chicken as described in the CDC report cited above. FSIS data from 2006 show that the proportion of *Enteriditis* found among all poultry isolates of *Salmonella* jumped from 7.71% in 2005 to 13.66%, a 77.2% increase (*http://www.fsis.usda.gov/PDF/Serotypes_Profile_Salmonella_Tables_&_Figures.pdf#page=61*).

In addition, an emerging concern for the Agency is the *Salmonella* serotype having the antigenic formula I 4,[5],12:i:–, which has been increasingly recognized by CDC since the mid-1990's in human illness cases. In 2006 the serotype was the 7th most commonly identified serotype in U.S. human surveillance data. FSIS began reporting antigenic formulas in 2004. In 2004 and 2005, I 4,[5],12:i:– was the sixth most commonly identified serotype in young chicken isolates, and in 2006 it was the fifth most commonly identified serotype in young chicken isolates.

FSIS notes that product classes other than young chickens have not shown such persistent upward trends, and the percentage of positive verification samples has declined for all three beef product classes. The Agency has become concerned, however, about the rise in human illnesses attributable to *S. Newport* beginning in the late 1990's. *S. Newport*, which has shown signs of developing resistance to antibiotics, is found most notably in the cattle classes and especially ground beef but has been detected in all FSIS-regulated commodities.

Posting of Completed Verification Sample Set Results

Given the concerns described above with serotypes of human health significance and the fact that the goal of having 90% of establishments in Category 1 was not reached by July 1, 2007, FSIS will begin publishing completed *Salmonella* sample set results from young chicken slaughter establishments with variable (Category 2) and highly variable (Category 3) process control. This decision was foreshadowed in the February 2006 Notice when the Agency stated that by providing information on *Salmonella* performance:

> FSIS believes it would be providing the appropriate incentive for the meat and poultry slaughter industry to attain consistent, good control for *Salmonella*. (71 FR at 9776)

The Agency believes that it is appropriate to begin by publishing the results from young chicken slaughter establishments because the Agency's consistent priority has been to address the adverse trends in *Salmonella* percent positive samples seen in young chickens during 2000–2005 and the serotypes of human health significance found in them. A prototype table for Web posting of these results has been published on the Agency Web site (*http://www.fsis.usda.gov/PDF/Salmonella_Initiative_Prototype.pdf*). Posting of these results will begin 60 days after the publication of this Notice. Posting of results from Category 2 and 3 establishments slaughtering other product classes will begin 120 days after the publication of this Notice.

FSIS believes it important to publish results from establishments in these categories of greater concern because targets set by the agency have not been met, despite the Agency's allocation of a greater amount of its verification sampling program resources to establishments in Categories 2 and 3 since 2006. FSIS is still considering, however, whether publishing completed verification sample set results from young chicken slaughter establishments showing consistent (Category 1) process control, as well as from other meat and poultry product classes, would be useful in terms of creating incentives for greater process control. FSIS will closely monitor Freedom of Information Act (FOIA) requests related to this issue, as well as comments received, and expand or modify the publication process as necessary. As with the individual sample results that have been reported to establishments since 2006, all unpublished completed sample set results are available upon request under FOIA.

***Salmonella* Initiative Program (SIP)**

FSIS stated in the February 2006 **Federal Register** Notice (71 FR at 9776):

> [T]he Agency is aware that limits on linespeeds are a concern to both the young poultry slaughter and the hog slaughter industries. If widespread action within these industries controlled *Salmonella* contamination such that the Agency, in its testing of carcasses, consistently found industry-wide results at half or below half the current standard/baseline guidance, FSIS would be prepared to consider allowing the industries to study whether linespeeds could be increased above the current regulatory limits. * * * Such studies could be conducted through existing regulatory provisions for a waiver of the meat and poultry regulations (9 CFR 303.2 and 381.3).

Since the February 2006 Notice, poultry establishments have expressed interest in specific waivers that would either permit an increase in the volume of birds slaughtered or allow the chilling of eviscerated carcasses in a different manner than is allowed by existing time/temperature requirements.

The Agency has developed the *Salmonella* Initiative Program (SIP) to offer such waivers to Category 1 establishments, which have already met the current FSIS goals, as an incentive for volunteer meat and poultry slaughter and processing establishments to increase process control efforts for *Salmonella* and *Campylobacter*. Although the February 2006 **Federal Register** notice discussed specifically allowing young poultry and hog slaughter industries to study whether linespeeds could be increased above the current regulatory limits, all slaughter or processing establishments that produce product subject to *Salmonella* standards or guidelines would be eligible to apply for the SIP. The SIP was published as a prototype on August 31, 2007 (*http://www.fsis.usda.gov/PDF/Salmonella_Initiative_Program_Criteria.pdf*). The SIP is designed to facilitate definite improvements in ongoing control for *Salmonella* in all classes of raw product subject to *Salmonella* standards or guidelines, as stated in 9 CFR 303.1(h) and 381.3(b). The SIP will have the further benefit of providing key microbial data to the Agency from sampling and analysis conducted by establishments that would volunteer for the SIP. For SIP, the Agency will waive provisions of the meat and poultry regulations so that new procedures, equipment, or processing techniques can be tested. To participate in the SIP, establishments must submit a request in accordance with specific criteria.

Program Criteria

To be eligible, an establishment must be in Category 1 as a result of FSIS *Salmonella* verification sample testing, with at least one of the sample sets being completed since February 2006. An establishment selected for the Program must provide FSIS with copies of relevant information about its food safety system (e.g., interventions in use, volume of production, evisceration equipment type, line speeds, laboratory analytic procedures, and establishment sample set percent positive rate).

Such establishments would be expected to operate under a waiver to 9

CFR 310.25 or 381.94 (Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards). An establishment selected for the SIP will be required to take samples for microbial analysis on each line every day and during each shift. The sample set is to be the same size as that used by FSIS for verification testing of the specific product class, but, unlike current FSIS practice, the establishment may take multiple samples on one day. Each month establishments selected for the Program and maintaining a Category 1 level of performance must, upon FSIS request, provide the Agency with the *Salmonella* isolates from a randomly selected establishment-collected set.

Each week poultry slaughter establishments selected for the SIP will collect at least one sample at both rehang and post chill. Establishments will collect the postchill sample at the approximate time the carcass sampled at re-hang would move to postchill, so as to reflect the time it takes for a carcass to pass from rehang to post chill. The establishment is to analyze the samples for *Campylobacter*, generic *Escherichia coli*, and *Salmonella*. At least monthly, at least one rehang sample and one matched post-chill sample positive for any of these microorganisms must be enumerated. The results must be provided to FSIS at least quarterly.

The *Salmonella* percent positive rate for all sample sets collected by either FSIS or the establishment will need to be maintained at or below half the acceptable number of positive samples in the current standard/guideline—e.g., 6 or fewer positive results from a randomly selected set of 51 young chickens. If at any time the percent positive rate, with either FSIS or establishment testing, exceeds half the acceptable number of positive samples in the current standard/guideline, the establishment must immediately suspend operating under any waiver of the regulations, as well as intensify the frequency of daily testing. A Category 1 level must be re-established within one quarter for the establishment to remain in the SIP.

A selected establishment that at any time falls to a Category 2 or 3 level will have to provide FSIS with all *Salmonella* and *Campylobacter* isolates from all establishment-collected sets for each week until it meets the requirements for a Category 1 establishment, which must be accomplished within one quarter. FSIS will conduct serotyping and PFGE subtype pattern identification for the isolates and then, in collaboration with CDC, assess the patterns against clinical isolate patterns in PulseNet. FSIS will provide information to the establishment about its samples monthly.

The Agency will check on establishment process control under SIP by evaluating the laboratory performing microbial testing for an establishment to ensure that the laboratory is following appropriate procedures, reviewing establishment data to ensure that the establishment is operating at a Category 1 level, and conducting unannounced sampling. For such unannounced sampling, FSIS would obtain a portion of the establishment's samples collected that day. For samples resulting in the collection of rinsate, FSIS would gather 200 milliliters of the 400 milliliters of the rinse liquid used in establishment sampling per the PR/HACCP final rule. For ground product samples, FSIS would take one-half of the establishment collected sample, of a weight sufficient for testing. These ''split samples'' would be analyzed by FSIS for *Salmonella* and used to determine whether the establishment is maintaining effective and consistent process control and whether its testing procedures are valid. Internal Agency statistical analysis suggests that use of 12 samples per quarter would not provide definite verification that the establishment is in fact operating at a Category 1 level, but that given a certain number of positive samples (e.g., 3 out of 12 for young chickens), it would be sufficient to indicate that FSIS can no longer be confident that the establishment is operating at a Category 1 level. Such results would indicate that the processes to control *Salmonella* may be out of control and therefore warrant further investigation and action by FSIS. As with the individual sample results that have been reported to establishments since 2006 and any unpublished completed sample set results, the results from unannounced sampling are available upon request under FOIA.

FSIS will terminate the Program in establishments that cannot regain a Category 1 status within one quarter—i.e., an establishment must have percent positive *Salmonella* samples at 50% or less of the performance standard or baseline guideline.

Establishments must agree that they will provide FSIS with at least 30 days notice if they decide to terminate their participation in the program.

Application Process

All SIP applications and requests for waivers should follow the guidelines for submitting notifications and protocols for new technologies posted on the FSIS Web site at *http://www.fsis.usda.gov/regulations/New_Technology_Notification_&_Protocol_Submission/index.asp*. Applications should be addressed to Dr. Isabel Arrington at: *Isabel.Arrington@fsis.usda.gov.*

FSIS foresees no limit on the number of slaughter or processing establishments selected for the Program provided that no changes in inspection would be required. The Agency, however, will select no more than five establishments in which any waiver of regulatory requirements may affect inspection whereby additional inspectors are needed. Preference for selection of establishments where FSIS inspection personnel would be increased will be given to those establishments 1) with a positive rate for all sample sets collected by FSIS since February 2006 of half the rate required to be in Category 1 (e.g., 5% for young chickens), as well as for establishment-collected sample sets completed within the past quarter, and 2) that in their HACCP plans identify *Salmonella* as a hazard reasonably likely to occur or have written controls in place to address *Salmonella* within the Sanitation Standard Operating Procedures or other HACCP prerequisite programs. Establishments requesting waivers that would require additional inspectors will have 15 days after the publication of this Notice to submit their requests. Establishments that have already submitted applications before the publication of this Notice do not need to re-submit their applications.

Establishments participating in the SIP can request waivers to FSIS regulations if they can demonstrate that operating under such waivers would facilitate definite improvements, as provided for in 9 CFR 303.1(h) or 381.3(b), whereby half the Category 1 criterion for *Salmonella* is maintained. An establishment may further request a waiver to any other regulatory requirement that it can demonstrate can be appropriately waived under 9 CFR 303.1(h) or 381.3(b). The Agency will respond to requests for waivers within 60 days.

Establishments that are currently operating under waived regulations for On-Line Reprocessing (OLR) will have six months from the date of publication of this Notice to decide if they wish to continue under a waiver by applying for the SIP or otherwise revert to operating without a waiver. After that six-month period, all OLR waivers will be terminated. An establishment that chooses to terminate its OLR waiver or has an OLR waiver terminated at six months after publication of this Notice can apply for a waiver under SIP after

a waiting period of nine months after termination of the old waiver.

Establishments that are currently operating under waived regulations for the HACCP-based Inspection Models Project (HIMP) will also have six months from the date of publication of this Notice to decide if they wish to continue receiving waivers by applying for the SIP or otherwise revert to operating without a waiver. After that six-month period, all HIMP waivers will be terminated. An establishment that chooses to terminate its HIMP waiver or has an HIMP waiver terminated at six months after publication of this Notice can apply for a waiver under SIP after a waiting period of nine months after termination of the old waiver.

FSIS plans to continue developing the SIP to collect data that would allow the Agency to determine the appropriateness of a regulation incorporating elements of the SIP into a public health based poultry slaughter inspection system.

Restructuring the *Salmonella* Verification Program

Sampling and Testing Initiatives

To meet the complex challenge for public health protection presented by *Salmonella,* FSIS has decided that it will need to sample meat and poultry products targeted through the use of available data. This type of targeted approach represents a shift from randomly based sampling of all meat and poultry establishments, regardless of the relative risk posed, that the Agency conducted before July 2006 when it defined the three process control categories for meat and poultry establishments according to their performance relative to a performance standard or guideline.

Using the new sample scheduling algorithm adopted in 2006, each month FSIS now schedules approximately 75 new verification sample sets for *Salmonella* in raw classes of product. FSIS allocates its sampling resources within classes of raw product based on consideration of specified criteria. If criterion 1 (All new plants regardless of product class) does not obligate all 75 available sample sets, then criterion 2 (All Category 3 plants regardless of product class) is fulfilled; when criterion 2 does not obligate all available sample sets, then criterion 3 (All Category 2 plants, depending upon product class) would be fulfilled, etc. (For a full discussion of the sample scheduling algorithm, see *http://www.fsis.usda.gov/Science/Scheduling_Criteria_Salmonella_Sets/index.asp.*) As a result of allocating resources in this way, rather than sampling randomly, FSIS is now able to fulfill many of the higher priority criteria, *i.e.* the Agency is able to complete current sampling of establishments of greater concern.

Because Category 1 establishments are normally not scheduled for verification sampling until at least a year after their last set, the Agency is developing an algorithm for random unannounced sampling to be conducted at all Category 1 establishments during the period that may extend up to two years between full *Salmonella* verification sets. The purpose of this unannounced sampling algorithm is to ensure that establishments currently in Category 1 maintain their performance. The Agency's current thinking is that it will conduct quarterly, random sampling at Category 1 establishments. As with the individual sample results that have been reported to establishments since 2006 and any unpublished completed sample set results, the results from unannounced sampling are available upon request under FOIA.

The Agency has recognized that low-volume raw ground beef producers, producing less than 1000 pounds of product per day, constitute a large part of the sampling frame for establishments eligible for verification sample set scheduling though they account for a very small proportion of the raw ground beef supply. Since production of ground beef at these establishments may not occur throughout a week or month, sampling them for *Salmonella* may be extended for a year or more before a set is completed, as opposed to no more than a couple of months of sampling for higher volume establishments.

Consequently, FSIS is developing plans for modifying its sampling procedures at very low-volume establishments. The Agency has determined that a more practical approach for low volume establishments would be to test the samples that are already being collected at these establishments for *E. coli* O157:H7 for *Salmonella* as well. As a result, these establishments will be removed from the PR/HACCP verification sample set scheduling frame. The FSIS field service laboratories will perform qualitative testing for the presence or absence of *Salmonella* using the same methodology, discard criteria, and reporting as those in place for *Salmonella* ground beef HACCP samples. Samples that screen positive will be quantitatively analyzed, i.e. the *Salmonella* organisms present will be enumerated, using the MPN (Most Probable Number) procedure.

Import samples from ground beef or trim may also be tested for *Salmonella* as well as other pathogens of public health concern, with the PFGE patterns being entered into PulseNet for attribution purposes.

FSIS will exclude from the *Salmonella* verification testing program schedule any slaughter establishment that processes all carcasses slaughtered into ready-to-eat (RTE) product or diverts all of its raw products to another official federally-inspected establishment for further processing into a RTE product. If the establishment is undergoing sampling for *Salmonella*, but then elects to send all affected product to RTE, FSIS will continue to sample until the set is completed. At the end of the set, FSIS will verify that all product will be designated for further processing into RTE product within the establishment or in another Federal establishment. If and when such establishments again produce raw product for sale, they will be re-scheduled for *Salmonella* verification sets.

In addition, FSIS will identify and sample all sub-groups of raw classes of product that are not currently tested in full verification sets. For example, FSIS intends to identify and sample all ratite or religious-exempt operations, at least quarterly. FSIS will report individual results back to establishments, determine the aggregate percent positive rate for each sub-group of product classes, and post the aggregate percent positive rate for the subgroup at the Agency Web site. FSIS will also identify and implement a data analysis plan to ensure that the Agency is aware of adverse trends in percent positive samples. As with all pathogen-positive samples, isolates will be further assessed for their PFGE patterns and the patterns will be included in PulseNet for attribution purposes.

Data Usage

As noted above, the Agency committed in the last several years to serotyping all isolates of *Salmonella* that it finds in sampling meat and poultry products. In the past, sampling for *Salmonella* showed only positive or negative results, indicating the presence or absence of detectable *Salmonella* but not the specific dominant serotype present in a positive sample. *Salmonella* includes at least 2500 serotypes, or subspecies, and many of them are rarely associated with human illness.

As discussed above, isolates from *Salmonella*-positive samples are sent from the FSIS Field Service laboratories to the USDA–APHIS National Veterinary Services Laboratories (NVSL)

for bacteriophage serotyping. FSIS reports the identified serotypes that NVSL finds in the product to the originating establishment after it receives the results from APHIS. Obtaining and sharing serotype information in this way enables both FSIS and meat and poultry establishments to determine and monitor the serotypes of human health significance that are appearing in Agency sampling. All identified serotypes are now aggregated by year and reported on the Agency Web site at *http://www.fsis.usda.gov/Science/Serotypes_Profile_Salmonella_Isolates/index.asp*.

The Agency is beginning to use the level of common serotypes of human health significance, based on percentile distributions of available serotype data, in evaluating establishment performance. For young chickens, for example, 0–1 such serotypes of human health significance in a verification set of 51 samples would be considered a low level, 2–4 would be a medium level, and 5 or more would be a high level. FSIS is now including the level of serotypes of human health significance in the End of Set letter it sends to each establishment upon completion of a verification sample set for *Salmonella*. This serotype information will help an establishment in evaluating and improving its process control performance.

The Agency schedules a Food Safety Assessment (FSA) at any establishment with either a medium or high level of serotypes of human health significance found in the most recent *Salmonella* verification sample set. An FSA is scheduled as soon as possible for any establishment that has failed a *Salmonella* verification set before the full set has been completed, as was announced in the February 2006 **Federal Register** Notice on Salmonella policy.

Because the Agency is now able to complete sampling for many high priority establishments, it is beginning to advance sample set scheduling of Category 1 establishments based on the presence of serotypes of human health significance in the product. In some cases, this factor may mean that, even though an establishment is in Category 1, it will be tested within one year of the completion of its last sample set.

Identifying the specific serotypes found in FSIS sampling was an important advance in estimating the impact of meat and poultry products on public health. A fundamental issue for the Agency has been what the public health community calls ''the attribution gap''—the question of the relationship between findings of Salmonella in meat and poultry products and human cases of salmonellosis. In serotyping all samples that are positive for Salmonella, FSIS has taken a key initial step toward answering this question and intends to take further steps in the near future.

An even more targeted approach that is now being used extensively is subtyping, which identifies the specific genetic strains found in positive samples. All FSIS sample isolates are PFGE-subtyped by the Agricultural Research Service (ARS), which also tests isolates for Anti-Microbial Resistance (AMR) as mentioned above in reference to *S. Newport.*

As of August 2007, FSIS has continuous direct access to the ARS VetNet database for PFGE subtypes. FSIS is now able to compare the PFGE patterns from its positive samples to those available in the CDC PulseNet database of cases of human illness. As a result, FSIS should be able to get a clearer picture of whether, and the extent to which, the products that it regulates are contributing to human illness.

The Agency is also exploring the possibilities for sharing and use of industry data as a supplement to data gathered by FSIS and other public organizations. On August 8–9, 2007, FSIS hosted a public meeting of the National Advisory Committee on Meat and Poultry Inspection (NACMPI) to review and discuss, among other things, mechanisms for sharing industry data with FSIS (see *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2007–0027.htm).* The SIP described above is designed in part to obtain data from the industry beyond what FSIS is able to gather itself. The serotyping and enumeration data obtained from the SIP may be particularly useful in answering the question of to what degree human illnesses result from FSIS-regulated products.

Response to Comments on the Federal Register Notice of February 27, 2006

In deciding how to proceed, the Agency considered the nine comments it received during the comment period on the Notice it published in February 2006 (one comment was sent twice in different formats and registered twice). One additional comment that was received well after the comment period closed involved an industry proposal for a specific incentive program.

Categories

One comment stated that the performance categories should be expanded to capture more nuances in plant performance over time. This point was echoed by other commenters, who expressed concern that the 3-category scheme is too broad.

FSIS Response: The Agency continues to believe that the 3-category scheme is appropriate. It is easy to administer, and it captures the most important information regarding *Salmonella* control in establishments.

Quarterly Summary of Salmonella Positives

Several comments asserted that data presented as a quarterly aggregate could be misleading since testing is ''biased'' toward plants with marginal or substandard performance and because of seasonal variation in *Salmonella* positives. On the other hand, another comment stated that, since establishments will now receive individual sample results as soon as they are available, they can adjust their processes so as to avoid ''failing'' sets and thus may make performance appear to be better than it is.

FSIS Response: The Agency's decision to sample a higher percentage of establishments, as described above, and to present establishments in performance categories relative to a standard or guideline removes inherent ''bias'' that could have been introduced by simply presenting gross percentages of positive samples. Sampling a higher percentage of establishments captures better the relative performance of different product classes, and categorizing establishments according to a performance standard or guideline better defines the differences between establishments.

Posting of Completed Sets by Establishment

One comment stated that posting such results will be confusing to the public.

FSIS Response: The Agency believes that the 3-category system is easily understandable, that it appropriately and effectively describes significant differences between categories of establishments, and that posting results will provide a valuable incentive to improve process control. Should we find that the public is confused by the information, we will revise our approach to ensure that the information is meaningful and easily understood.

Testing Frequency

One comment stated that the current annual frequency of testing will not provide adequate evidence of sustained process control, particularly for Category 1 establishments, which may only be tested once every two years. The

same comment raised questions as to how the Agency adjusts sampling for establishment size and volume. Two other comments urged the Agency not to reduce testing frequency for Category 1 establishments.

FSIS Response: The Agency has carefully considered all pertinent factors to maximize testing and data productivity. FSIS intends to stagger testing of Category 1 establishments so that a full 24 months will not pass before an establishment is tested again. Further, the Agency intends to conduct random, unannounced sampling of Category 1 establishments during the period between full verification sample sets. For these reasons, FSIS believes that its frequency of testing will ensure that the status of a Category 1 establishment is appropriately tracked. It is also important to note that FSIS does not regard the Salmonella results alone as an indication of ''adequate evidence of sustained process control''. Verification of process control will rely on an establishment's ability to meet Salmonella performance standards, the establishment's own generic *E. coli* test results, FSIS inspectional observations, reports of illness associated with product produced at an establishment, and other factors.

Performance Standards

One comment noted that the performance standards should be reevaluated through regularly updated baseline studies. Another comment stressed that continual improvement sought by statistical process control approaches requires the tightening of standards. On the other hand, one comment argued that the Agency's focus on reducing performance to a fraction of the standard or guideline ignores the validity of the baseline-derived standard/guideline as an index of realistic process capability.

FSIS Response: The Agency is committed to updating baseline studies when needed. The Agency does not agree that establishing performance objectives at one-half of the performance standard/guideline ignores a baseline standard and that the Agency's objectives for process control are realistic and necessary. FSIS believes that further knowledge of attribution factors will show that continual improvement in reducing occurrence of human pathogens in meat and poultry will reduce the incidence of human salmonellosis.

Salmonella Subtyping Methodology

One commenter recommended phage-typing over pulsed field gel electrophoresis (PFGE) for subtyping, and another commenter said more discussion was needed before the Agency should choose to use PFGE data. Another comment, on the other hand, recommended PFGE for subtyping.

FSIS Response: Phage-typing is primarily used in reference laboratories and is impractical for regulatory purposes. The Agency believes that PFGE has proven to be a valid and appropriate methodology for obtaining subtype information from verification sampling and baseline studies.

Enumeration of Salmonella and Attribution Questions

One comment urged the Agency to conduct enumeration analysis of its verification samples in order to investigate the causal factors in human salmonellosis related to dose level.

FSIS Response: Enumeration is very expensive and of doubtful value for practical regulatory purposes that are qualitative in nature. FSIS, however, is committed to exploring questions of attribution for human disease and recognizes that enumeration of *Salmonella* would have a positive role to play in such an investigation. For this reason, the Agency is requiring participants in the *Salmonella* Initiative Program to enumerate a portion of their *Salmonella* and *Campylobacter* isolates.

Incentives and Further Actions

One comment stated that the Agency should begin posting all completed sample sets immediately rather than first allowing a one-year period for collecting data to determine whether publication of establishment results was necessary. Two comments urged the Agency not to consider any modifications in inspection practices without strong evidence of superior establishment performance.

FSIS Response: The Agency believes that the lead-time announced in the February 2006 Notice of one year (from July 2006 to July 2007) for tracking results was appropriate. The key point is that the Notice informed the industry that process control improvements were crucial and needed to be accomplished in a timely manner. The Agency agrees that modifications in inspection should only occur if there is strong evidence of superior establishment performance, and it is exploring such possibilities in the *Salmonella* Initiative Program for Category 1 establishments described above.

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/2007_Notices_Index/*. 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 e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/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 they have the option to password protect their accounts.

Done in Washington, DC on: January 22, 2008.

Alfred V. Almanza,

Administrator.

[FR Doc. E8–1432 Filed 1–25–08; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Resurrection Creek Restoration Phase II Project Environmental Impact Statement

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: The Chugach National Forest, Seward Ranger District will prepare an environmental impact statement for the implementation of a stream and riparian restoration project along a two-mile segment of Resurrection Creek within active mining claims. The environmental impact statement will evaluate the environmental consequences of the proposed restoration project and will also address a supplemental mining plan of