Notices

Federal Register
Vol. 76, No. 134
Wednesday, July 13, 2011

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

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2008–0008]

Salmonella Verification Sampling Program: Response to Comments on New Agency Policies and Clarification of Timeline for the Salmonella Initiative Program (SIP)

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; response to comments; reopening of comment period.

SUMMARY: The Food Safety and Inspection Service (FSIS) is responding to comments on a January 28, 2008 **Federal Register** notice (73 FR 4767–4774), which described upcoming policy changes in the FSIS *Salmonella* Verification Program and outlined a new voluntary *Salmonella* Initiative Program (SIP) for meat and poultry slaughter establishments that agree to share internal food safety data with FSIS in order to receive waivers of regulatory requirements. SIP benefits public health in that it encourages slaughter establishments to test for microbial pathogens and to respond to the ongoing results by taking steps when necessary to regain process control and thus to minimize the presence of pathogens of public health concern. In addition, SIP enables FSIS to use establishment data to enhance public health protection. In this notice, the Agency is announcing several policy developments and changes regarding SIP. This notice also includes Agency responses to comments on SIP and on other issues discussed in the January 2008 **Federal Register** notice.

DATES: Comments are due by September 12, 2011. Policies regarding waivers for On-Line Reprocessing (OLR), the HAACP-based Inspection Models Project (HIMP), or any other slaughter process will be implemented by November 10, 2011.

ADDRESSES: FSIS invites interested persons to submit comments on the January 2008 notice referenced in this document with regard to SIP. Comments may be submitted by either of the following methods:

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

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

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2006–0034. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

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

SUPPLEMENTARY INFORMATION:

Background

Details of SIP 2011

SIP, as described in the January 2008 **Federal Register** notice, offers incentives to meat and poultry slaughter establishments to control *Salmonella* in their operations. SIP does this by granting waivers of regulatory requirements with the condition that establishments test for *Salmonella, Campylobacter* (if applicable), and generic *E. coli* or other indicator organisms and share all sample results with FSIS. SIP benefits public health because it encourages establishments to test for microbial pathogens, which is a key feature of effective process control. Also, under SIP establishments will share their data with FSIS to inform Agency policy on pathogens. Furthermore, if the establishment's results show it is not meeting the Agency's current performance standards for turkeys or young chickens, it is to increase testing, determine whether its waiver is affecting its public health protection performance, and take steps to regain process control in order to minimize the presence of pathogens of public health concern. Establishments currently operating under regulatory waivers will have to participate in SIP or drop their waivers. Establishments operating under waivers through HIMP will continue to operate as HIMP establishments but will have to conduct new testing under SIP. The primary policy decisions regarding SIP discussed in this notice, including recent developments and changes, include:

- The comment period for SIP issues has been extended to September 12, 2011.
- SIP is open to all establishments.
- Establishments that have received waivers under SIP terms and conditions are to begin submitting microbial testing data to FSIS within 60 days of publication of this notice.
- Establishments currently operating under waivers for OLR, HIMP, or any other slaughter process will have 120 days from publication of this notice to participate in SIP or else drop their waivers and return to conventional inspection.
- SIP establishments must agree to conditions prescribed in the January 2008 **Federal Register** notice, except that enumeration of weekly postchill samples will not be required.
- SIP establishments are not routinely required to provide FSIS with isolates, but, if requested, establishments must work with FSIS on a mutually agreeable means for doing so.
- The Agency is selecting no more than five establishments that applied in 2008 to receive waivers of regulations restricting line speeds. If necessary, FSIS will re-open the application

process until five establishments have been selected.

• A SIP establishment will not be suspended or lose its waiver solely because of its *Salmonella* testing results.

• FSIS is considering reducing the required frequency of testing for SIP establishments that meet the *Salmonella* performance standard for at least six months and can maintain that level of process control with reduced testing frequency.

• FSIS is also considering reducing the required frequency of testing for small and very small establishments that participate in SIP.

• The Agency intends to conduct its own unannounced, small-set sampling to verify the consistent performance of all establishments, including those participating in SIP.

• FSIS will begin evaluating whether establishments operating under SIP waivers are meeting the new *Salmonella* and *Campylobacter* performance standards with sample sets beginning in and after July 2011 as announced in a **Federal Register** notice of March 21, 2011 (76 FR 15282).

Events Leading Up to SIP

FSIS is the public health regulatory agency in the U.S. Department of Agriculture (USDA) responsible for ensuring that the nation's commercial supply of meat, poultry, and processed egg products is safe, wholesome, and correctly labeled and packaged. FSIS establishes performance standards for *Salmonella* on carcasses and raw products that enter commerce and evaluates whether establishments are meeting the standards.

After an intensive review of the results of several years of this testing, FSIS published a **Federal Register** notice on February 27, 2006 (71 FR 9772–9777; Docket 04–026N) in which the Agency set forth three establishment performance categories for *Salmonella* based on current standards. The new performance Category 1 was set at an upper limit of no more than half the standard. Category 2 was set at more than half but not exceeding the standard. Category 3 included establishments exceeding the standard. In the 2006 **Federal Register** notice, FSIS stated that it intended to track the performance of the different product classes it samples for *Salmonella* over the next year and, after that time, publish the names of establishments in Categories 2 and 3 for any product class that did not have 90 percent of its establishments in Category 1.

On January 28, 2008, FSIS published a notice in the **Federal Register** (73 FR 4767–4774; Docket FSIS–2006–0034) in which it announced that the Agency would begin publishing monthly results of completed FSIS verification sets for establishments in Categories 2 and 3, beginning with young chicken slaughter establishments, which have been a primary concern for FSIS. Publication of Categories 2 and 3 young chicken slaughter establishments began on March 28, 2008. FSIS has continued to publish the names of these establishments on or about the 15th of each month since then. FSIS believes that doing so has provided a strong incentive for improved industry performance. After FSIS announced performance categories in 2006, 55–60 percent of non-compliant establishments moved to become compliant within two years (see 75 FR 27288–27294). FSIS is also considering publishing verification sampling results for other product classes.

In the 2006 **Federal Register** notice, the Agency stated that it intended to update the year long Nationwide Microbiological Baseline Data Collection Programs to better measure improvements in pathogen reduction in all classes of raw product. Both young chicken and young turkey microbiological baselines were completed in 2008 and 2009, respectively, and from them, FSIS developed updated performance standards for *Salmonella* and new performance standards for *Campylobacter.*

On May 14, 2010, FSIS published a **Federal Register** notice (75 FR 27288) in which it announced the forthcoming implementation of the 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, as stated above, the standards were based on recent FSIS Nationwide Microbiological Baseline Data Collection Programs. The standards are applied to sample sets collected and analyzed by the Agency to evaluate establishment performance with respect to requirements of the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) Final Rule. The Agency received detailed comments in response to the notice and published a follow-up notice on March 21, 2011 (76 FR 15282) responding to the comments. FSIS will begin evaluating whether establishments operating under SIP waivers are meeting the new *Salmonella* and *Campylobacter* performance standards with sample sets beginning in and after July 2011.

FSIS plans to begin focusing next on the *Salmonella* controls in market hog slaughter operations. In July 2011 the standards for *Salmonella* positives in young chicken and turkey will become 7.5 and 1.7 percent, respectively. Thus, as of July 2011 establishments slaughtering market hog carcasses will have the highest remaining permissible standard (8.7 percent) for *Salmonella* of all raw carcass product classes. Significantly, outbreaks resulting in human illness involving pork have been consistently identified on an annual basis, suggesting pork as a vehicle for salmonellosis. Between 2000 and 2007, about four outbreaks and 82 illnesses per year on average have been associated with pork. A simple yearly comparison suggests a decline from 2000 to 2002 (five, seven, and three outbreaks, respectively), followed by a period of stability from 2003–2006 (three, four, three, and three outbreaks, respectively) and an increase in 2007 (seven outbreaks and 236 illnesses). (Reference: *http://wwwn.cdc.gov/foodborneoutbreaks/.*)

The FSIS Nationwide Market Hog Microbiological Baseline Data Collection Program, which includes collecting carcass sponge samples at pre-evisceration and post-chill, is underway, and sample collection is expected to be completed in 2011. New performance standards for *Salmonella* will be developed based on the results from the year-long baseline survey.

FSIS has not provided any compliance guideline information for market hog slaughter operations. The Agency expects to remedy this situation by issuing guidelines within the next 120 days and to confer with the pork industry on *Salmonella* controls.

In the January 2008 **Federal Register** notice, FSIS also announced that it would increase the Agency's use of targeted sampling and collaborative microbial serotype and subtype data. In addition, FSIS announced that it would exclude from the *Salmonella* verification testing program schedule any slaughter establishment that processes all carcasses slaughtered into ready-to-eat (RTE) product or that sends all of its raw products to another official federally inspected establishment for further processing into an RTE product. The notice also announced that establishments producing a low volume of raw ground beef would be removed from the scheduling frame for PR/HACCP verification sample sets. These establishments would be sampled for *Salmonella* at the same time they are sampled for *E. coli* O157:H7. FSIS is

now considering removing establishments slaughtering heifer and steers, regardless of size, from the scheduling frame for PR/HACCP verification sample sets and increasing sampling of raw ground beef and beef trim.

FSIS received no significant comments on these changes and therefore began implementing them immediately after the comment period ended. FSIS does not schedule an establishment for *Salmonella* verification testing if all product is processed for RTE. Such product is excluded from sampling regardless of whether it is processed as RTE in the slaughter establishment or diverted under establishment or FSIS control to another federally inspected establishment. A slaughter establishment producing RTE product subject to this exclusion and non-RTE carcasses is sampled for the non-RTE product classes only.

Similarly, FSIS removed establishments producing a low volume of raw ground beef (less than 1,000 pounds per day and fewer than 150 days per year) from the PR/HACCP verification sample set scheduling frame because these establishments will be sampled for *Salmonella* at the same time and manner in which they are sampled for *E. coli* O157:H7.

Response to Comments on SIP, SIP Policy Developments, and Comment Period Extension

In response to requests for additional time to comment on SIP, FSIS is re-opening the comment period for SIP issues for 60 days (see **DATES**) and setting a new timeline for establishments with existing OLR, HIMP, or any other slaughter process waivers to participate in SIP (see Implementation Timelines below). After the re-opened comment period ends, the Agency will evaluate all comments received on SIP and publish its response to those comments in a notice in the **Federal Register**.

Conditions for Participating in SIP

The Agency reconsidered the potential scope of SIP and decided not to limit the program to establishments that are meeting the current *Salmonella* standard for young chickens or turkeys as measured by FSIS. Additionally, establishments slaughtering classes of poultry other than young chickens and turkeys may participate in SIP. FSIS will allow those establishments to collect *Salmonella* data to determine an establishment-specific baseline of microbiological contamination that the establishment will use to demonstrate continuous process control in place of using the young chicken or turkey *Salmonella* performance standard.

FSIS decided not to suspend an establishment from the program or revoke its waiver solely because of its *Salmonella* testing results. The *Salmonella* status of an establishment is determined by FSIS sampling results. However, when applying for SIP an establishment agrees to take certain actions, which are described below, if its testing results show it is not meeting the current *Salmonella* standard for turkeys or for young chickens.

All establishments that apply to participate in the program must agree to certain conditions. An establishment selected for SIP is required to take samples for microbial analysis on each line every day and during each shift. The sample set of reference for *Salmonella* is 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 week, poultry slaughter establishments selected for SIP collect at least one sample at both rehang and postchill. Establishments collect the postchill sample at the approximate time the carcass sampled at rehang would move to postchill, so as to reflect the time it takes for a carcass to pass from rehang to postchill. Establishments are to analyze all samples for *Salmonella, Campylobacter* (if applicable), and generic *E. coli* or other indicator organisms but are not required to enumerate these samples.

In the event of an establishment exceeding the *Salmonella* standard in its own testing, the establishment must investigate whether the waiver conditions in the establishment's process contributed to, or caused, the lack of process control. The establishment must document its findings and the corrective and preventive actions taken to return to the current *Salmonella* standard of process control. The establishment must increase the frequency of its sampling for *Salmonella* until the current standard of process control is regained as shown by two consecutive sample sets with results meeting the current standard. FSIS inspection personnel will verify that a SIP establishment takes these actions when appropriate.

FSIS is considering the possibility of reducing the required frequency of testing of samples for SIP establishments that maintain the current standard for at least six months and can maintain that level of process control with reduced testing frequency. The Agency intends, however, to conduct its own unannounced, small-set sampling to verify the consistent performance of all establishments, including those participating in SIP. FSIS is also considering reducing the frequency with which small and very small establishments that participate in SIP will need to sample.

SIP establishments are not routinely required to provide FSIS with isolates, but, if requested, establishments must work with FSIS on a mutually agreeable means for doing so.

Every establishment that wishes to participate in the SIP must agree to share its food safety data with FSIS and make the data available for copying or electronic transfer to the Agency. Establishments may obtain instructions on how to share microbial data results with FSIS via an electronic data sharing template by e-mailing the SIP Mailbox at *SIP.Mailbox@fsis.usda.gov.* FSIS understands that many meat and poultry establishments have viewed such data as confidential commercial information. Pursuant to USDA's Freedom of Information Act (FOIA) regulations (7 CFR 1.1 *et seq.*), FSIS is responsible for making the determination with regard to the disclosure or nondisclosure of information in agency records that has been submitted by a business. When, in the course of responding to an FOIA request, an agency cannot readily determine whether the information obtained from a person is confidential business information, the Agency will seek to obtain and carefully consider the views of the submitter of the information and provide the submitter an opportunity to object to any decision to disclose the information. FSIS will protect establishments' confidential business information from public disclosure to the extent authorized under FOIA and in conformity with USDA's FOIA regulations.

FSIS will, however, combine data submitted by individual establishments in SIP and publish the aggregated results on a quarterly basis. The data from establishments participating in SIP will play an important role in improving public health protection by providing many additional sample results for Agency evaluation in developing public health policies related to decreasing foodborne illness. On a quarterly basis, FSIS will analyze the aggregated microbial data from SIP establishments to evaluate the overall effects of the waivers. In developing these quarterly evaluations, the data analysts may consider observed patterns of the aggregated SIP establishment microbial data, together with an assessment of potential associations between the

microbial testing results and various SIP establishment factors (*e.g.,* location and type of antimicrobial interventions and selected information related to processing procedures, etc.) recorded on the electronic data sharing template.

Waivers of Regulatory Requirements Under SIP

In return for meeting the conditions of SIP, the Agency grants establishments appropriate waivers of certain regulatory requirements, based upon establishment proposals and documentation, under FSIS regulations at 9 CFR 303.1(h) and 381.3(b). These regulations specifically provide for the Administrator to waive for limited periods any provisions of the regulations to permit experimentation so that new procedures, equipment, or processing techniques may be tested to facilitate definite improvements.

SIP establishments do not need to repeat in-plant protocols or submit microbial monitoring test results to FSIS. Establishments requesting participation in SIP need simply to agree to the conditions of SIP regarding pathogen testing and sharing of test result data with FSIS as described above.

SIP applications and requests for waivers should be sent to *isabel.arrington@fsis.usda.gov* and should follow the guidance procedures for waivers and notifications and protocols posted on the FSIS Web site at *http://www.fsis.usda.gov/OPPDE/op/technology/New_Technology_Waiver.pdf* and *http://www.fsis.usda.gov/OPPDE/op/technology/guidance.pdf.*

Waivers of Line Speed Restrictions Under SIP

The January 2008 **Federal Register** notice also stated that FSIS would select ''no more than five establishments in which any waiver of regulatory requirements may affect inspection whereby additional inspectors are needed.'' Additional inspectors would be necessary for establishments that receive waivers of regulatory restrictions on line speed, which has been a subject of interest for industry. Establishments desiring additional FSIS inspection personnel under SIP were asked to show that they had (1) For all *Salmonella* sample sets collected by FSIS since February 2006, a positive rate of half the rate required to be in Category 1 (*e.g.,* 5 percent for young chickens), as well as for establishment-collected sample sets completed within the past quarter, and that they had (2) identified *Salmonella* as a hazard reasonably likely to occur in their HACCP plans or had written controls in place to address *Salmonella* within the Sanitation Standard Operating Procedures or other HACCP prerequisite programs. Qualifying establishments were asked to request these waivers within 15 days of publication of the January 2008 **Federal Register** notice. The Agency is selecting no more than five establishments from the requests it received after the 2008 notice. Due to the time that has elapsed, FSIS is evaluating the requests of establishments that had previously volunteered under the prior criteria on completeness of application, as well as on other considerations such as geographic location, number of FSIS inspectors needed, prior participation in SIP for other regulatory waivers, and FSIS data needs for ongoing policy development. If additional plants are needed to fill the five slots, FSIS will ask for additional volunteers.

FSIS also recognizes that evaluation of the effects of line speed on food safety should include the effects of line speed on establishment employee safety. To obtain preliminary data on this matter, FSIS has asked the National Institute for Occupational Safety and Health (NIOSH) to evaluate the effects of increased line speed as part of the SIP waiver program. NIOSH has stated its willingness to evaluate the effects of increased production volume on employee health, with a focus on musculoskeletal disorders and acute traumatic injuries. NIOSH's activities may ultimately include observation of work processes and practices; collection of company payroll, personnel, and injury and illness records; interviews with plant managers, supervisors, and employees; health surveys of employees; and videotaping and measurement of specific aspects of job tasks. NIOSH will prepare a report based on its findings of short-, intermediate-, and long-term effects from the process modifications. NIOSH will make recommendations as needed. FSIS will use any available data from NIOSH activities to inform its decisions as it moves forward with planned regulatory reform. FSIS will require that establishments granted waivers for regulatory line speeds under SIP cooperate with NIOSH.

Implementation Timelines

The Agency stated in its May 16, 2008 Constituent Update that it would implement SIP as soon as possible for establishments that do not have an existing waiver. As stated in the January 2008 **Federal Register** notice, FSIS strives to respond to requests for waivers within 60 days. The Agency gives priority to those establishments that are already meeting the most recent young chicken or turkey standard. FSIS will contact establishments that have already submitted requests to participate in SIP but have not met the conditions for a waiver.

Because FSIS is re-opening the comment period for SIP, FSIS is updating the timeline announced in the January 2008 **Federal Register** notice for establishments that are operating under waived regulations for HIMP, OLR, or any other slaughter process.

Under the previous timeline, FSIS stated that an establishment that chooses to terminate its HIMP waiver or has an HIMP waiver terminated at six months after publication of the January 2008 **Federal Register** notice could apply for a waiver under SIP after a waiting period of nine months after termination of the old waiver (73 FR 4772). This new timeline will also apply to establishments operating under waivers that affect the slaughter process. Under this new timeline, all of these establishments will have 120 days from publication of this notice to decide whether they will continue to operate under the waiver by complying with the provisions of SIP or else operate without a waiver. Any establishment that chooses not to participate in SIP and thereby drop its waiver should give FSIS written notice of when and how it will return to operating without a waiver in order for the Agency to plan to restructure inspection responsibilities at that establishment. If the establishment does not provide such written notice, FSIS will notify the establishment of the steps necessary to return the establishment to operating without a waiver.

During that 120-day period, establishments desiring to continue these waivers under SIP will need to apply for SIP and agree to comply with its provisions. FSIS encourages these establishments to begin submitting applications to participate in SIP as soon as possible. After the 120-day period following this **Federal Register** notice, HIMP, OLR, or any other slaughter process waivers will only be continued if the establishment has agreed to participate in SIP.

Establishments that have applied for and received other waivers under SIP terms and conditions and have been operating with SIP procedures are to begin formally submitting their microbial testing data to FSIS within 60 days of this notice.

Response to Comments on Publication of Salmonella Sample Set Results as Described in the Federal Register Notice of January 28, 2008

Time for Comments

Several comments stated that the comment period of 30 days provided in the notice was too brief to allow for proper consideration of the issues described there.

Response: As stated above, the Agency is re-opening the comment period for certain issues involved with SIP that have not yet been resolved.

FSIS notes, however, that publication of *Salmonella* verification sample set results by establishment was first presented publicly in the **Federal Register** notice of February 27, 2006, and was extensively discussed in the notice of January 28, 2008. The Agency also discussed publication of establishment *Salmonella* results at a public meeting on August 7, 2007 (*http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2007–0026.htm*), and presented detailed plans for publication in its Constituent Update of August 31, 2007 (*http://www.fsis.usda.gov/News_&_Events/Const_Update_083107/index.asp*). Given this history, FSIS believes that the notice's 30-day period for comments on publication of establishment *Salmonella* results was appropriate.

Categories

Some comments asserted that the performance Categories 1, 2, and 3 used to determine posting are arbitrary and not founded in public health science.

Several comments stressed that an establishment with only one current completed sample set that is at or below half of the performance standard should not be in Category 2 simply because it lacks two completed sample sets at the level required for Category 1. Several comments argued that requiring two successive sets at or below half the performance standard for Category 1 is inconsistent with determining Category 2 or 3 status by a single set, the most recent one.

One comment from a public interest group saw no need to publish results from Category 1 establishments, although a comment from another public interest group stated that results from Category 1 establishments should be published as well as results from establishments in Categories 2 and 3. A similar point was made in another comment arguing that if establishment data are to be published at all, results should be reported for all categories. Two other comments stated that only Category 3 results should be published. One comment asserted that no results should be published.

Response: The Agency stated in its February 2006 **Federal Register** notice that, as would be expected, establishments performing very well overall do so consistently and predictably. Establishments that perform less well overall are much less consistent and thus pose a greater concern for public health protection. Given these observed tendencies, the Agency believes that encouraging establishments to perform consistently at or below half the standard is a meaningful and practical approach to improving public health protection. Such encouragement is especially pertinent when a product class has shown a relatively high prevalence of *Salmonella.* In such a case, establishments aiming at a prevalence rate lower than the standard will tend to improve the performance of the overall product class. As stated above, this 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 presented information in the February 2006 notice indicating that the selection of the Category 1 and Category 2 criteria was based, in part, on long-term Agency experience showing a statistically significant difference in the likelihood that serotypes of *Salmonella* that are common causes of human illness are present in sample sets from Category 2 establishments versus those in Category 1. At that time, these differences were particularly evident for the young chicken class.

For any classes of raw products, a reduction of *Salmonella* by half or more based on the current performance standard would have practical implications for continuous improvement in the control of this enteric pathogen. When a new standard is established through a new baseline study and is published, FSIS expects to re-set the Category designations, again differentiating Category 1 from Category 2 by using the practical application of the ''at or below half the standard'' criterion.

The Agency agrees with the comment that an establishment with its last verification sample set at or below half the standard, but with the prior set above half but not exceeding the standard, should not simply be posted as a Category 2. The Agency has been categorizing these cases as ''2T'' with ''T'' standing for Transitional to Category 1. Similarly, an establishment with its last verification sample set at or below half the standard, but with the prior set exceeding the standard, is also categorized as ''2T.'' This approach recognized that two sets needed to be at or below half the standard for Category 1, while still recognizing progress by transitional establishments. Beginning with the Quarterly Progress Report for April–June 2008, the aggregate Quarterly Progress Reports have presented such ''2T'' establishments separately from Category 2 establishments.

Also beginning with the second quarter 2008 Progress Report, FSIS ceased counting in aggregate totals any establishment with only one completed set. Since 2006 the aggregate Quarterly Progress Reports had reflected all results and included in either Category 2 or Category 3 any establishment that had not attained a Category 1 classification by having its two most recent FSIS sets at or under half the standard. Thus, the quarterly aggregate reports included establishments that had completed only one set and had not exceeded the standard in that set in Category 2, and included establishments that had completed only one set but did exceed the standard in that set in Category 3. To clarify these matters, the Agency determined that it would neither post an establishment with only one completed FSIS sample set (*e.g.,* new establishments) nor count that establishment in the aggregate Category 2 or 3 totals. With the new *Salmonella* and *Campylobacter* performance standards going into effect in July 2011 (76 FR 15282), FSIS will transfer existing data for establishments with two sample sets completed for calculation of categories.

Statistical Standards

Some comments asserted that the number of positive samples acceptable per *Salmonella* sample set is too stringent in that an establishment operating either at the standard, or for Category 1 at or below half the standard, has an approximately 25 percent chance of exceeding the target level with any given sample set. These comments urged that the number of samples acceptable be increased to provide a lower chance of exceeding the target level when an establishment is operating over some period at the target level. Another comment conversely asserted that with product classes that have standards with odd numbers of acceptable positives, the Agency should round down to determine the ''at or below half'' criterion for inclusion in Category 1. For instance, the maximum number of positives acceptable out of 56 samples for the turkey carcass class has

been 13, and the Category 1 criterion was rounded up by the Agency to accept seven or fewer positive results rather than six or fewer positives.

Response: A prudent establishment should strive to operate with more effective process control over time at a relatively lower level of positive samples if it is to preclude exceeding its target level. This is the case because FSIS standards have been traditionally set with a certain probability of failure for an establishment operating in fact precisely at the standard. For this reason, an establishment wishing to avoid any failures should aim its process control efforts at achieving a performance below the standard. The Agency views this relative stringency as a necessary and important incentive to improving performance in controlling *Salmonella.*

In addition, FSIS is clarifying that its intent was not to round up the number of acceptable positives. When this practice of rounding up was called to its attention, FSIS changed its practice to rounding down. Thus, FSIS now rounds down for standards with an odd number of acceptable positives. For example, the acceptable number of *Salmonella* positives for turkey carcasses had been set at six rather than seven positives out of 56 samples. The Agency rounds down in determining the standard for any product class with a standard that accepts an odd number of positive samples.

Time Lag for Establishment Category Change

Several comments argued that publishing the names of establishments in Categories 2 and 3 each month is unfair and unrepresentative, in that FSIS sample set results may be months old before they are superseded by another set, and that the establishment has no way to demonstrate significant improvement in the meantime. Some comments stated that the Agency should use establishment data to evaluate an establishment's significant improvement and thus recognize movement to a higher degree of control sooner than would be possible with use of FSIS data alone for this determination. These comments noted that something like this approach is envisioned with SIP. One comment stated that an establishment's published category standing should be updated immediately upon movement between categories rather than monthly.

Response: Monthly updates are sufficiently frequent to provide current information concerning the *Salmonella* category status of establishments. The Agency schedules verification sample sets for Category 3 establishments first, followed by Category 2, and then Category 1. Furthermore, the Agency intends to use unannounced, small-set sampling to verify the consistent performance of all Category 1 establishments. In this way, improvement in performance that would lead to movement from Category 3 to 2 or from Category 2 to 1 is registered as soon as possible. FSIS notes that an establishment's consistent performance at half the standard or lower would preclude any concern on this score.

Any movement of an establishment from Category 2 or 3 into Category 1 must be based upon FSIS testing. The verification program is based on Agency *Salmonella* testing, and at this time, FSIS can see no reason to modify that design. Moreover, as stated above, FSIS tests frequently enough, particularly for Category 3 establishments, that there is no need for FSIS to rely on the establishment's testing. Under the *Salmonella* and *Campylobacter* standards (76 FR 15282) to be implemented in July 2011, FSIS will not publish names of Category 2 poultry establishments. To date, poultry establishments are the only classes of raw product that have been published.

Qualitative vs. Quantitative Data

Several comments noted that FSIS *Salmonella* verification sampling data are qualitative (presence/absence) rather than quantitative (number of microorganisms present), thus giving no indication of actual concentration or dose level.

Response: The Agency's baseline studies have included enumeration of microbial populations of positive *Salmonella* samples. After analyzing the two most recent year long poultry microbiological baselines (2008 and 2009), the Agency has noted that the number of microorganisms present in positive samples did not vary to any significant degree from the positive samples analyzed in the older surveys, despite a significant decline in prevalence from the older surveys. Therefore, FSIS does not believe that there is a compelling need to enumerate positive *Salmonella* samples.

Salmonella Serotypes of Human Health Significance

Some comments stated that simply publishing the number of positive samples does not convey the true potential threat to public health because an establishment may have multiple samples that are positive for *Salmonella* serotypes that are rarely associated with human illness.

Response: The Agency agrees that identifying *Salmonella* serotypes of human health significance is an important factor in public health protection. Consequently, FSIS includes serotype information when notifying establishments of sample results and in the End-of-Set Letter detailing the overall results of a completed FSIS set. FSIS also publishes aggregate serotype data in an annual report (*http://www.fsis.usda.gov/Science/Q1–4_2008_Salmonella_Serotype_Results/index.asp*).

The serotypes most commonly found in FSIS-regulated products have all been associated with human illness. For example, *S.* Kentucky is the most commonly reported serotype in FSIS-regulated young chicken products, and the CDC reported that in 2006 this serotype was associated with 123 illnesses, ranking it at 33 in the top 50 serotypes associated with illnesses that year. Research has shown that when *Salmonella* contamination is present in a product sample, multiple serotypes are not uncommon. Our current methodology used for sample analysis allows FSIS to determine the presence of any *Salmonella,* regardless of serotype. One bacterial colony is tested to determine serotype and is reported to establishments. This single colony is not necessarily the only serotype present, nor is it necessarily the most common serotype in the product. The Agency uses the *Salmonella* verification program as a measure of process control, not an indicator of the prevalence or diversity of different *Salmonella* serotypes on FSIS-regulated products. This measure of process control is appropriate because current interventions and technologies for the reduction of *Salmonella* target all serotypes; so the presence of any one serotype indicates a possible lapse in process control, which could allow the outgrowth of any serotype that might be present in the product.

Domestic and International Trade Effects

Two comments urged the Agency to consider the possible negative effects posting results that would have on the international competitiveness of the U.S. meat and poultry industry. Commenters worried that publication could lead to unwarranted trade barriers on the grounds of food safety.

Response: Industry performance has shown that meat and poultry establishments have adequate means to attain Category 1 status. Improved international trade competitiveness is likely to result from a lower incidence of Salmonella and the production of

fewer products positive with serotypes of human health concern. FSIS notes that completed sample set results have always been available through FOIA, but the Agency has not seen any marked increases in foreign FOIA requests for such data. Given these facts, FSIS does not believe that establishments have significant grounds for concern because of Web publication of completed sample set results.

Paperwork Reduction Act

FSIS has reviewed the paperwork and recordkeeping requirements in this notice in accordance with the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*) and has determined that the paperwork requirements constitute a new information collection.

Title: Salmonella Initiative Program (SIP).

Type of Collection: New.

Abstract: Currently, nine establishments are operating under SIP. The information collection burden incurred by these nine establishments is covered under the Procedures for the Notification of New Technology information collection currently approved by OMB (0583–0127).

The Agency is selecting no more than five establishments that applied in 2008 to receive waivers of regulations restricting line speeds. If necessary, FSIS will re-open the application process until five establishments have been selected. The information collection burdens incurred by these establishments will also be included under 0583–0127.

This notice opens SIP to all slaughter establishments, and all establishments receiving a waiver must participate in SIP. Data collected by the additional number of establishments coming under the expanded SIP program will constitute a new information collection.

SIP offers incentives to meat and poultry slaughter establishments to control *Salmonella* in their operations. SIP does this by granting waivers of regulatory requirements with the condition that establishments test for *Salmonella, Campylobacter* (if applicable), and generic *E. coli* or other indicator organisms and share all sample results with FSIS. If the establishment's results show it is not meeting the Agency's current performance standards for turkeys or young chickens, it is to increase testing, determine whether its waiver is affecting its public health protection performance, and take steps to regain process control to minimize the presence of pathogens of public health concern. Establishments currently operating under regulatory waivers will have to participate in SIP or drop their waivers. Establishments operating under waivers through the HACCP-based Inspection Models Project (HIMP) will continue to operate as HIMP establishments but will have to conduct new testing under SIP.

SIP is now open to all slaughter establishments. Establishments that have received waivers under SIP terms and conditions are to begin submitting microbial testing data to FSIS within 60 days of this notice. Establishments currently operating under waivers for on-line reprocessing or HIMP or any other slaughter process will have 120 days from publication of this notice to participate in SIP or else drop their waivers and return to conventional inspection.

FSIS will begin evaluating young chicken and turkey slaughter establishments operating with SIP waivers under new performance standards with sample sets beginning in or after July 2011.

Estimate of Burden: FSIS estimates that annually it will take approximately 686.6 hours per respondent.

Respondents: Official slaughter establishments that are under a waiver.

Estimated number of Respondents: 300

Estimated number of Responses per Respondent: 2,081

Estimated Total Annual Burden on Respondents: 206,000 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue, SW., Room 6065, South Building, Washington, DC 20250, (202) 720–0345.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this document, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/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, recalls, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade and farm groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is available on the FSIS Web page. Through the Listserv and the Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-mail subscription service that provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/.* Options range from recalls to export information, regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password-protect their accounts.

Done at Washington, DC, on July 8, 2011.

Alfred V. Almanza,

Administrator.

[FR Doc. 2011–17625 Filed 7–12–11; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Mines Management Inc. Montanore Project, Kootenai National Forest, Lincoln County, MT

AGENCY: Forest Service, USDA.