supplying similar information acceptable to RHS.

* * * * *

(d) When a dwelling requiring an environmental assessment is proposed for HPG assistance, the grantee will immediately contact the RHS office designated to service the HPG grant. Prior to approval of HPG assistance to the recipient by the grantee, RHS will prepare the environmental assessment in accordance with part 1940, subpart G, of this chapter with the assistance of the grantee, as necessary. Paragraph VIII of exhibit C of this subpart (available in any Rural Development State or District Office) provides further guidance in this area.

* * * * *

16. Section 1944.673 is amended by revising the section heading and paragraph (b) to read as follows:

§ 1944.673 Historic preservation and replacement housing requirements and procedures.

* * * * *

(b) Each applicant for an HPG grant will provide, as part of its preapplication documentation submitted to RHS, a description of its proposed process for assisting very low- and low-income persons owning historic properties needing rehabilitation, repair, or replacement. ''Historic properties'' are defined as properties that are listed or eligible for listing on the National Register of Historic Places. Each HPG proposal shall comply with the provisions of Stipulation I, A–G of the PMOA (RD Instruction 2000–FF), available in any Rural Development State or District Office. Should RHS be required to assume responsibility for compliance with 36 CFR part 800 in accordance with Stipulation III of the PMOA, the grantee will assist RHS in preparing an environmental assessment. RHS will work with the grantee to develop alternative actions or mitigation measures, as appropriate.

* * * * *

§ 1944.683 [Amended]

17. Section 1944.683 is amended by redesignating paragraphs (b)(3) through (b)(7) as paragraphs (b)(4) through (b)(8), respectively; by adding the words ''as well as for replacement housing'' after the word ''rehabilitation'' in newly redesignated paragraph (b)(4)(i) and after the word ''financed'' in newly redesignated paragraph (b)(8); and by adding a new paragraph (b)(3) to read as follows:

§ 1944.683 Reporting requirements.

* * * * *

(b) * * *

(3) The use of HPG and any other funds for replacement housing.

* * * * *

18. Section 1944.700 is revised to read as follows:

§ 1944.700 OMB control number.

According to the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for the information collection in this subpart is 0575–0115.

Dated: April 17, 1997.

Jill Long Thompson,

Under Secretary, Rural Development.

[FR Doc. 97–12315 Filed 5–12–97; 8:45 am]

BILLING CODE 3410–XV–U

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 308, 310, 381, and 416

[Docket No. 93–016T]

RIN 0583–AC28

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Technical Corrections and Amendments

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: FSIS is making technical corrections and amendments to the final rule, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,'' published on July 25, 1996. This document responds to technical and scientific questions raised in the final rule regarding *E. coli* testing and to issues discussed at the ''Technical Conference Regarding *E. coli* Verification Testing,'' the ''Pathogen Reduction/HACCP National Implementation Conference,'' and the ''Regional Implementation Conferences.'' Also, this document clarifies ambiguities brought to FSIS' attention and provides guidance on various technical issues. Additionally, this document corrects inadvertent omissions and addresses minor editorial oversights.

EFFECTIVE DATE: June 12, 1997.

ADDRESSES: Reference materials cited in this docket will be available for public inspection in the FSIS Docket Room, Room 3806, 1400 Independence Ave SW, Washington, DC 20250 from 8:30 a.m. to 1:00 p.m. and from 2:00 p.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Stolfa, Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation, (202) 205–0699.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 1996, FSIS published a final rule, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,'' (61 FR 38806). The new regulations (1) require that each establishment develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOP's); (2) require regular microbial testing for generic *E. coli* by slaughter establishments to verify the adequacy of the establishments' process controls for the prevention and removal of fecal contamination and associated bacteria; (3) establish pathogen reduction performance standards for *Salmonella* that slaughter establishments and establishments producing raw ground products must meet; and (4) require that all meat and poultry establishments develop and implement a system of preventive controls designed to improve the safety of their products, known as HACCP (Hazard Analysis and Critical Control Points).

With respect to the generic *E. coli* testing requirement, a number of questions were posed in the final rule, especially about how the requirement would be applied and what testing results might indicate in establishments that slaughter livestock.

Responses to those questions were received through written comments; through presentations and discussions at a public meeting convened by FSIS on September 12–13, 1996, specifically to discuss the generic *E. coli* testing requirement; at a national implementation conference in Washington, DC, September 30—October 3, 1996; and six subsequent regional implementation conferences occurring on October 15, 17, 22, 24, November 7 and 13, 1996, and at numerous briefings presented by FSIS representatives to a variety of audiences. Additionally, FSIS held the conference, ''Sanitation Standard Operating Procedures (Sanitation SOP's) and *E. coli* Testing Requirements,'' on January 23, 1997.

Through these comments and meetings, a number of technical questions have arisen which indicate the need for further clarification. Some of these have required a change in the

regulation; others simply require further technical guidance.

Technical Amendments

Sanitation Standard Operating Procedures

Questions were raised at the public meetings about the corrective actions an establishment might take in response to Sanitation SOP failures. Commenters suggested that the Agency make it clear that, in certain cases, improving the execution of the existing Sanitation SOP's, instead of revising the Sanitation SOP's, would be appropriate corrective action. In response to this concern, FSIS is amending section 416.15(b) to clarify that satisfactory corrective actions can include appropriate improvements in the execution of Sanitation SOP's.

Applicability of E coli Testing Requirement

Species Required to be Sampled and Tested for E. coli

At the *E. coli* meeting, implementation conferences, and other briefings, numerous questions were raised about the applicability of the generic *E. coli* testing requirement. There were questions about whether generic *E. coli* testing was required for all types of livestock, i.e., cattle, sheep, swine, goats, horses, mules and other equines (9 CFR 301.2). There were questions about whether generic *E. coli* testing was required for all types of poultry, i.e., chickens, turkeys, ducks, geese and guineas. There were also questions about whether generic *E. coli* testing was required for all market classes of livestock and poultry.

Clarification is needed because of inconsistencies in terminology used in the preamble and the regulatory text. For example, the preamble states that ''establishments that slaughter livestock or poultry will be required to begin sampling and testing for *E. coli*''(61 FR 38844). This statement is inconsistent with section 310.25 of the regulations which refers only to ''cattle and/or hogs'' and subsequently ''swine'' and ''market hogs.'' This inconsistency also makes it necessary to amend the regulations to clarify that all market classes of cattle, swine, chickens, and turkeys must sample and test for generic *E. coli*.

FSIS intends that all establishments slaughtering livestock and poultry sample and test for generic *E. coli*. However, the regulatory requirement codified in section 310.25(a)(1) is limited to cattle and swine. FSIS will propose rules in the future to carry out its goal of applying the generic *E. coli* testing requirement to other types of livestock, such as sheep, goats, and equines. Until that rulemaking is completed, only cattle and swine are required to be sampled and tested for generic *E. coli* (9 CFR 310.25(a)(1)).

With regard to poultry, the preamble of the final rule states that minor species, such as ducks, geese, and guineas, would be addressed at a later date. The rulemaking proposal to extend the *E. coli* testing requirement to all types of livestock will also propose extending the requirement to all types of poultry. However, until that rulemaking is completed, only chickens and turkeys are required to be sampled and tested for generic *E. coli* (9 CFR 381.94(a)).

At this time, FSIS is making technical amendments to ensure that the terminology in sections 310.25 and 381.94 of the regulations applicable to generic *E. coli* testing is consistent with other FSIS regulations promulgated under the Federal Meat Inspection Act and the Poultry Products Inspection Act.

Therefore, in section 325.10(a)(1), the phrase ''cattle and/or hogs'' will be replaced with the phrase ''cattle and/or swine.'' In section 310.25(a)(2)(iii), ''Sampling frequency,'' the word ''Cattle'' will replace the word ''Bovines.'' In section 310.25(a)(2)(v)(A) the word ''cattle'' will replace the word ''bovines.'' In section 310.25(a)(5), Table 1, the phrase ''type of livestock'' will replace the phrase ''slaughter class;'' the ''Steers/heifers'' and ''Cows/bulls'' lines will become a single ''Cattle'' line having the lower limit, upper limit, number of samples and maximum number of marginal now permitted in both these slaughter classes; and ''Market hogs,'' will be redesignated as ''Swine.'' In section 381.94(a)(5), Table 1, the phrase ''slaughter class'' will be replaced with ''type of poultry,'' and the term ''broilers'' will be replaced by ''chickens.''

These terminology changes also will clarify that all market classes of cattle or swine are categorized as ''cattle'' or ''swine,'' and that all market classes of chickens and turkey are categorized as ''chickens'' or ''turkeys.''

Testing Requirements for Market Classes

Commenters and questioners also expressed confusion and sought clarification about the applicability of the generic *E. coli* testing requirement when no specific m/M criteria are available. They assumed that if FSIS has not performed baseline studies and established m/M criteria for evaluation of results, the requirement would not apply. Commenters and questioners expressed their expectations that FSIS would perform baseline studies for a large variety of market classes of livestock and poultry, such as spent hens, sows and boars, calves, as well as numerous types of livestock and poultry that are slaughtered, dressed or chilled by non-traditional methods. At virtually every public meeting where generic *E. coli* testing was discussed, participants identified new livestock or poultry categories for baseline data collection.

All market classes of cattle, swine, chickens and turkeys must be sampled and tested for generic *E. coli*. FSIS's initial baseline studies were conducted on separate market classes of cattle, swine, and chickens. In future baseline studies, the Agency will sample from all market classes of a type of livestock or poultry to develop m/M criteria representative of that type of livestock or poultry. The baseline study being developed for turkeys includes samples from all market classes.

FSIS considered whether the m/M criteria for broilers could be applied to all market classes of chickens, such as, fowl, heavy broilers, and rock Cornish hens. FSIS determined that this would be acceptable for three reasons:

1. The processing parameters likely to affect levels of generic *E. coli* on carcasses, such as the use of automatic eviscerating equipment and common bath chillers, the permitted levels of chlorine in poultry processing waters, and the likely handling during processing were essentially the same for all market classes of chickens.

2. The m/M levels of generic *E. coli* on chickens are expressed as CFUs/ml, rather than total CFUs per carcass, and the actual values at the 80th and 98th percentile have been rounded to the nearest whole $\log_{10}$; both of these practices have the effect of minimizing variability and normalizing values.

3. Broilers constitute the vast majority (94%) of chickens slaughtered in the United States. An alternative to using the broiler criteria for all chickens would be to conduct a baseline that includes all market classes. However, the preponderance of broiler results will mean that other market classes are highly unlikely to affect the criteria.

These factors, taken together, mean that it would take very large differences among market classes to necessitate a change in the criteria found in the regulations. Accordingly, no amendment is being made and the criteria published in the July final rule will be applicable to all market classes of chickens.

FSIS expects that cattle and swine establishments will collect samples by sponging carcasses. If so, they will evaluate tests by the use of statistical process control, discussed below, and

the published m/M criteria in the regulations do not apply. FSIS will sample all market classes of either cattle or swine in its baseline studies to develop m/M criteria for samples collected by sponging carcasses.

Cattle and swine establishments collecting samples by excising tissue from carcasses will use the published m/M criteria. In the regulations the m/M criteria for the market classes cows/bulls and steers/heifers are the same. FSIS contends that these m/M criteria are applicable for other market classes of cattle because of the similarity in processing parameters and the methodology used to develop the m/M criteria. FSIS also believes that the m/M criteria for market hogs are applicable to other market classes of swine for the same general reasons. Therefore, the published m/M criteria apply to all market classes of cattle and swine.

While FSIS baseline surveys provide an appropriate national data base for establishment of m/M criteria, microbiological data bases with comparable accuracy and utility can be developed outside of FSIS. FSIS encourages industry members, academia, and other groups to work with the Agency to develop protocols for independent databases against which the 80th and 98th percentile definitions can be applied. In consultation with industry and consumer groups, FSIS may propose to publish these m/M values as criteria for evaluating results.

FSIS is still in the process of developing its long-term plan for baseline data collection studies. The plan will identify the types of livestock and poultry to be included in future baseline data collection efforts. Tentatively, the Agency has determined that types of livestock and poultry identified in the regulatory definitions are top priority candidates for FSIS baseline studies. For livestock, FSIS is considering developing baseline data collection studies for sheep, goats, and equines. For poultry, FSIS is conducting a baseline study for turkeys and is considering baseline data collection for ducks and geese. Representatives of State inspection programs and others have raised questions about FSIS intentions for baseline data collection on the voluntarily-inspected species, such as rabbits and ratites. FSIS will consider these requests for baseline data in developing its long-term plan.

Use of Statistical Process Control

The current m/M criteria apply to all classes of chickens, and to cattle and swine samples collected by excising tissue from carcasses. The m/M criteria for turkeys are still being developed. At this time, cattle and swine establishments collecting samples by sponging and turkey establishments will use statistical process control techniques to evaluate *E. coli* test results.

Statistical process control techniques are based on the principle that every product is produced by a process. All processes are subject to variation, which can be understood and controlled by statistical methods. A process that is in control is stable in terms of average level and degree of variation, i.e., it is predictable within limits and is ''doing its best.'' Control is attained, often by degrees, by detecting and eliminating special causes of variation, that is, causes not present at all times or not affecting all product output. Statistical process control initially involves evaluating data to determine process capability (the typical process performance level), then checking subsequent data to see whether they are consistent with this baseline level to ensure the process is in control and variations are within normal and acceptable limits. This is accomplished by checking for unreasonably high results, trends, etc., and looking for and correcting problems in the process when the signals occur.

Specific techniques of statistical process control include time plots, which chart measurements over time. This is the first technique to use with data collected over time and analyzed for patterns. Another technique is the control chart, which plots data over time but also displays an upper control limit for specific measurements, and a centerline, above and below which is an equal number of sample results. The centerline is in effect a median average. A sample result above the upper control limit would indicate the likely presence of a special cause of variation that needs to be addressed. Results within control limits indicate that the process is in control. Control charts are used for after-the-fact analysis of process performance and to assist in gaining and maintaining control of a process. In most situations more than one type of control chart is applicable. More detailed information on time charts and control charts can be found in texts on statistical process control, under the topic ''control charts.''

FSIS has concluded that statistical process control techniques will provide experience in ''process thinking'' (a central tenet of HACCP), develop an historical record of performance, and permit evaluation of the long-term stability of a process and determination of process capability (that is, how the process is actually working), and track the effectiveness of process improvement actions.

FSIS emphasizes that the value of microbiological testing is not negated by the lack of national m and M criteria against which to evaluate results. *E. coli* testing is intended to provide verification of process control for fecal contamination within individual establishments. While there is utility in being able to compare individual establishment data with national norms (i.e., national m and M criteria), the intent of the rule is to have microbial testing integrated into the overall process control procedure that establishments are implementing. In this context, establishment-specific databases, developed as establishments begin microbial testing, are also of value to individual establishments as a means of verifying their process control procedures.

FSIS is amending section 310.25 of the regulations to require establishments slaughtering cattle or swine to use either a three-site sponging or a three-site excision sample collection technique. This amendment to the meat regulations is necessary because of the inability to develop a conversion factor for results derived from two or three-site sample collection by sponging which correlates to the m/M criteria developed based on excision sampling methods used in conducting the baseline studies. If sponging is chosen, results must be evaluated using statistical process control techniques, because the m/M criteria derived from the baseline studies have not been validated for sample collection using sponging. If an establishment chooses to use the excision sample collection technique, results will be evaluated against national norms as expressed in the m/M criteria drawn from baseline studies. FSIS intends to give high priority in its baseline plan to collecting data that will support establishing m/M criteria using sponge sample collection techniques.

FSIS also is amending section 381.94 of the regulations to require turkey establishments to evaluate results using statistical process control techniques. This amendment is necessary because FSIS has not completed the development of m/M criteria for turkeys.

Establishments evaluating test results using statistical process control techniques will be subject to the regulatory provisions for failure to test and record (9 CFR 310.25(a)(7) and 381.94(a)(7)). Such establishments will not be subject to the regulatory provisions for the failure to meet criteria (9 CFR 310.25(a)(6) and 381.94(a)(6))

until such time as m/M criteria are developed and added to the regulations. The Agency intends to establish m/M criteria for each type of livestock and poultry based on national norms. Therefore, the requirements to utilize statistical process control techniques is temporary.

Sampling Frequencies

There are three amendments related to the following topics: (1) The requirement that establishments sample at the greater of one sample per week or the published frequency for each type of livestock or bird; (2) the requirement that all establishments are required to sample only the type of livestock or poultry which they slaughter in the largest number; (3) adjustments to sampling directions for very low volume establishments that do not operate each week or operate on a seasonal basis. Each of these three amendments is discussed below.

Sampling Frequencies For Very Low Volume Establishments

The final rule states that very low volume establishments ''shall collect one sample per week starting the first full week of June and continuing through August of each year.'' FSIS is aware that some very low volume establishments do not operate every week or operate only seasonally. Therefore, this requirement is amended to provide flexibility and accommodate all very low volume establishments. The revised regulations require that very low volume establishments begin sampling the first full week they operate after June 1 and continue collecting one sample per week in each week they operate until they have met their sampling requirement.

As discussed in the final rule, FSIS requires slaughter establishments to record and evaluate *E. coli* results in a ''moving window'' of 13 consecutive results, and the Agency is permitting very low volume establishments to conduct as few as 13 tests per year, in part because of their relatively simple and stable production environments.

If there are published m/M criteria for the type of livestock or poultry a very low volume establishment slaughters in the largest number, the establishment must sample that type of livestock or poultry at a minimum frequency of once per week until a series of 13 tests has met those m/M criteria.

If there are no m/M criteria for the type of livestock or poultry slaughtered in the largest number, a very low volume establishment must sample a minimum of once per week until 13 samples are collected. If the establishment does not slaughter their primary type of livestock or poultry for 13 weeks per year, the establishment must still collect one sample each week in which they conduct those slaughter operations. This provision will be eliminated once m/M criteria are developed for the type of livestock or poultry that is slaughtered in the greatest number.

One Type per Establishment

The final rule states that if a very low volume establishment slaughters multiple types of livestock or poultry, the establishment shall collect samples from the type it slaughters in the largest number. FSIS intended that this provision apply to all establishments. However, because of an inadvertent omission, this language was not incorporated into the regulatory text for all establishments. Therefore, FSIS is amending the regulations so that each slaughter establishment, regardless of size, conducts generic *E. coli* testing on the type of livestock or poultry that it slaughters in the largest number.

The purpose of the testing is not lot acceptance, but rather to provide each establishment with a microbial indication of how effective its sanitary dressing procedures are in preventing contamination of carcasses by fecal material, ingesta, and associated bacteria. The preamble stated that the required testing and criteria are intended to provide an initial basis for slaughter establishments and FSIS to begin using microbial testing to evaluate the adequacy of process control. To meet this regulatory objective, it is not necessary that all slaughter types be sampled. Whether the establishment slaughters one type or multiple types, *E. coli* test results provide information that establishments can use to verify their process controls over sanitary dressing.

Minimum Sampling Frequencies

The preamble to the final rule stated that establishments, except for very low volume establishments, must test at the frequencies established in the regulations or at a minimum of at least once per week. This weekly minimum requirement was inadvertently not incorporated into the regulatory language for other than very low volume establishments. These technical amendments add the once per week minimum to the regulatory language. Under this amendment, an establishment slaughtering 9,000 cattle and sampling at the once per week minimum shall collect 52 samples, rather than 30, as required by 1 test per 300. Obviously, the minimum of 52 assumes the establishment slaughters cattle each week during the year.

Sampling Sites

Two specific questions raised in the final rule with respect to the technical specifications of the generic *E. coli* testing requirement for cattle and swine carcasses addressed the issue of sample sites on carcasses. The questions were: ''[a]re there more appropriate anatomical sites for microbial testing than those adopted?'' and ''[a]re there worker safety concerns regarding sampling from difficult to reach carcass sites, and how can they be mitigated?''

The final reports, ''Analysis of ARS Baseline and Sponge Data'' and ''FSIS Comparison of Baseline Excision and Two-Site Sponge Method,'' describe results of data collection efforts by ARS and FSIS in cattle and swine establishments to compare sponge and baseline excision sampling methods and to seek conversion factors that would make sponge results comparable to baseline results. The baseline excision method for each slaughter class was defined in the protocol for the baseline study and specified the sites to sample, the area of tissue to analyze, and the amount of buffer to add to the tissue.

The final rule specified sampling cattle and swine with a sponge from the same three sites from which FSIS collected excision samples in baseline studies. During the comment period, industry representatives expressed concerns over inefficiencies and safety hazards associated with sampling the rump of cattle and the ham of swine. During preparation of the final rule, FSIS initiated a data collection effort by ARS to evaluate sponge methods with one or three sites, and to seek conversion factors that would make sponge results comparable to baseline results and to the m/M values derived therefrom. In response to the comments on the 3-site sponge method, the Agency conducted further data collection to compare a 2-site sponge method with the baseline method.

ARS compared the baseline method with the final rule's three-site sponge method and with a one-site sponge method, the one site being flank for cattle and belly for swine. They collected data on a total of 280 carcasses in one cattle establishment and one swine establishment and presented summaries of their results at the September 12–13, 1996, FSIS *E. coli* conference. FSIS later performed further statistical analyses on the results in response to comments at the conference. The results of these analyses are described in detail in the reports, and summarized here.

Because the lowest detectable levels (LDLs) of the sponge methods were well below the LDL of the baseline method, the sponge methods were expected to find more *E. coli* positives than the baseline method. The three-site sponge resulted in more *E. coli* positives than the baseline method for both cattle and swine. However, whereas the one-site sponge method found more *E. coli* positives for cattle, it gave less for swine (i.e., the difference in sites appeared to affect the prevalences found by the two sponge methods).

Since the two-site sponge method had not been included in the ARS study, FSIS undertook comparison of this sampling method with the baseline method. The Agency collected data on a total of 825 carcasses in three cattle establishments and four swine establishments. Results of this effort are presented in detail in the reports and are summarized here.

Once again, the sponge method was expected to result in more *E. coli* positives than the baseline method because of its lower LDL, and it did for all three cattle establishments sampled. However, sponging resulted in considerably fewer *E. coli* positives than the baseline method in three of the four swine establishments. One establishment, however, had 100 percent *E. coli* prevalence by both the two-site sponge and the baseline methods. That establishment also had higher levels of *E. coli* than the other swine establishments.

In addition to the qualitative comparison of sponge and baseline methods in terms of prevalence, FSIS also evaluated sponge results quantitatively in terms of recovery of bacteria relative to the baseline method. It was evident from the results that the sponge methods generally gave lower average microbial counts than the baseline method.

Where possible given the available data, FSIS evaluated recovery by two alternate methods suggested at the *E. coli* conference. However, there were several difficulties with getting reasonable estimates of recovery. First, numerous negative baseline results left recovery undefined for many carcasses. Second, the two recommended methods of defining recovery gave seriously different recovery values. Third, the sponge method gave appreciably more negative results for swine than the baseline method. All of these difficulties caused FSIS to abandon the effort to find a conversion factor.

In view of these findings, FSIS has determined that, at the present time, the third sampling site is necessary. If data can be developed that support a change to fewer, more accessible sampling sites, the Agency is very willing to consider them. In addition, as described above, livestock slaughtering establishments that want to relate their results to national norms may use the excision technique and the m/M criteria associated with the baseline studies.

Sampling Locations

Sampling location in the process is a factor for comparability of an establishment's results with the criteria derived from baseline studies. Establishments that slaughter, dress or chill types of livestock or poultry by using non-traditional methods, such as hot boning of swine and poultry and chilling of split turkey carcasses, may not be able to collect samples at the exact location in the slaughter process as was used in the baseline studies. FSIS is amending section 310.25(a)(2)(ii) to provide for sample collection after final wash, if sampling chilled carcasses is not possible. Similarly, FSIS is amending section 381.194(a)(2)(ii) to provide for sample collection after the final wash, if sampling at the end of the drip line is not possible.

Additionally, questions have arisen about whether random carcass sampling can only occur when carcasses are in the cooler. It is not FSIS's intention to limit random carcass sample selection in the cooler. The random sampling can be carried out before carcasses enter the cooler so that carcasses selected for sampling can be placed in a separate and convenient location in the cooler. The regulations require establishments to include in their written procedures how sampling randomness will be achieved (section 310.25(a)(2)(i)).

Technical Guidance

This section provides technical guidance for the following areas: (1) definition of very low volume slaughter establishment; (2) counting employees to determine establishment size for HACCP implementation; (3) FSIS intentions on rules of practice.

Very Low Volume Slaughter Establishments

The regulations define very low volume establishments for cattle, swine, chickens, and turkeys. These definitions are expressed in terms of the number of animals or birds slaughtered annually. Establishments should use 1996 slaughter data to determine whether they meet the definition. Livestock and poultry slaughtered under the custom exemption need not be counted.

Size Categories For HACCP Implementation

For purposes of determining whether an establishment is large, small, or very small, FSIS has established the following guidelines for counting employees. These guidelines combine the Small Business Administration procedures for counting employees to determine establishment size and the FSIS definition of ''official establishment.'' All paid employees who work within the official establishment are to be counted, whether full time, part time, or temporary. Employees should be counted whether or not they perform duties related to inspected products. Employee numbers should be averaged over a year.

One exception to the above guidance covers situations where headquarter's employees for firms with multiple establishments are located at one official establishment and their assigned duties are related to the company and not specifically to the official establishment where they are located. Such employees need not be counted. In addition, administrative staff, for example, billing and bookkeeping staff, working outside the official premises need not be counted. Unpaid family members of the owner or operator also need not be counted. Large firms that have employees engaged full-time in buying or selling products should count such staff even though they usually work outside the establishment.

Establishments are very small if they have fewer than 10 employees or annual sales of less than $2.5 million. In calculating annual sales, establishments should count all sales of inspected meat and poultry products produced at the establishment. Inspected product excludes product produced under a retail or custom exemption provision. Furthermore, ''Pass Through'' product that is produced in another establishment and resold without any further processing need not be counted. ''Pass Through'' includes the operation referred to as ''breaking bulk,'' if this operation involves only separating and resorting ''intact'' packages prepared at another establishment.

FSIS Intention Regarding Rules of Practice

The final rule stated that, upon an establishment's failure to test and record, inspection would be suspended in accordance with rules of practice that ''will be adopted for such proceedings upon a finding by FSIS that one or more provisions of subparagraphs (a) (1)–(4) of this section have not been complied

with and written notice has been provided to the establishment.'' FSIS has determined that a separate set of rules of practice for generic *E. coli* testing is not necessary. The Agency does, however, intend to review and propose revisions to its rules of practice (9 CFR 335.1 and 381.230). It plans to complete this process before the first HACCP implementation date, January 26, 1998. In the meantime, the Agency will use existing rules of practice for enforcement of Sanitation SOP's requirements and for enforcement actions when establishments fail to test and record results of generic *E. coli* analysis.

Technical Corrections

FSIS is making three technical corrections to the final rule. The first corrects the inadvertent requirement that custom and retail exempt establishments, as defined in section 303.1 of the Federal meat inspection regulations, comply with the requirements for Sanitation SOP's. These establishments are required to meet general sanitation requirements, including those in section 308.3. When FSIS drafted the final rule, it amended section 308.3 to ensure that meat and poultry establishments not only meet the general sanitation requirements but also comply with the regulations in Part 416, which require Sanitation SOP's. However, FSIS never intended to require custom and retail exempt establishments to comply with Sanitation SOP's. To clarify that point, FSIS is amending section 308.3 to include language that explicitly exempts these establishments from the part 416 requirements.

Secondly, FSIS is updating the footnotes in the ''*Salmonella* Performance Standards'' table (Table 2) in section 381.94(b)(1) of the poultry products inspection regulations. Footnote ''b'' states that the ''Broiler'' data was based on partial analysis and was subject to confirmation upon publication of the baseline survey. The baseline survey is complete and published. There are no changes to the numbers related to broilers. FSIS is, therefore, removing footnote ''b.'' Also, with the deletion of footnote ''b,'' the footnote designated as ''d'' (an editorial oversight omitted a footnote ''c'') will be redesignated as footnote ''b.''

Finally, FSIS is correcting the references in sections 325.10(a)(3) and 381.94(a)(3) to the AOAC International by updating the regulatory text and a footnote in the regulatory text to reflect the organization's new name and the current edition of its publication. Also, FSIS is clarifying what establishments must do if they intend to have samples analyzed by a method approved by a scientific body other than the AOAC International.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be significant and, therefore, has been reviewed by the Office of Management and Budget.

The Administrator has determined that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601).

The Pathogen Reduction/HACCP final rule included a Final Regulatory Impact Assessment (FRIA) (61 FR 38945). The technical corrections and amendments do not change the cost and benefit estimates and impact assessments presented in the FRIA.

The technical amendments regarding Sanitation SOP's clarify the regulatory language to more accurately explain what FSIS intended corrective actions to encompass. There is no change in regulatory impact or cost of Sanitation SOP's. Similarly, the regulatory amendments that change terminology in sections 310.25(a) and 381.94(a) do not affect any regulatory requirements.

The technical amendments regarding statistical process control clarify how turkey establishments and livestock establishments collecting samples by sponging will analyze test results until m/M criteria are developed. This change will not affect the cost estimates.

In the Preliminary Regulatory Impact Analysis (PRIA) for the Pathogen Reduction/HACCP proposed rule, FSIS concluded that for each microbiological sample it would take 5 minutes ''* * * to prepare the paperwork and review the results of the sample analysis and plot the results on a statistical process control chart.'' In the FRIA, the Agency used this 5 minute estimate as the time it takes to record a window of *E. coli* test results and compare such results with m/M criteria. The Agency still believes that it takes approximately the same amount of time to conduct either of these processes.

FSIS has amended the regulations to clarify how sampling and testing must be conducted on hot-boned or hide-on product. These are not new requirements.

The FRIA estimated generic *E. coli* testing costs using an upper bound estimate of 24 dollars per sample. To develop this upper bound estimate for *E. coli* sampling, FSIS examined cost estimates reported in the PRIA and current cost estimates for FSIS testing programs. The proposed rule required establishments to collect *Salmonella* samples by excising tissue from carcasses, and therefore, the cost estimate factored in the time it takes to sample in such a manner. Similarly, FSIS samples are collected by excising tissue, and FSIS cost analyses of its testing program reflect this fact. Because sponging carcasses presumably takes less time to perform than excising tissue from carcasses, FSIS is confident that the cost estimates reported in the FRIA are upper bound estimates. FSIS expects all establishments to use the sponging method because excising tissue takes more time and devalues the carcasses. However, because the cost estimates were based on excision, establishments choosing to excise tissue should not incur costs greater than 24 dollars a sample.

The three technical amendments relating to sampling frequencies do not change the regulatory impact and cost to establishments. In the FRIA the Agency based its cost estimates on the assumption that establishments would sample at a minimum of 52 times a year. Also, the cost estimates assumed that establishments would only sample and test the type of livestock or poultry slaughtered in the largest number. Lastly, FSIS's analysis assumed that very low volume establishments sample and test once per week until the results show that they meet the published criteria.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. In this final rule: (1) all state and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Requirements

The Pathogen Reduction/HACCP final rule included a paperwork analysis (61 FR 38862) prepared in accordance with the Paperwork Reduction Act. FSIS has determined that the technical corrections and amendments in this rule do not change any information collection burden hours. The paperwork and recordkeeping burden hours were developed using the assumptions in the FRIA, discussed above.

Final Rules

List of Subjects

9 CFR Part 308

Meat inspection.

9 CFR Part 310

Meat inspection, Microbial testing.

9 CFR Part 381

Poultry and poultry products, Microbial testing.

9 CFR Part 416

Meat inspection, Poultry and poultry products.

For reasons set forth in this preamble, 9 CFR chapter III is amended as follows:

PART 308—SANITATION

1. The authority citation for part 308 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53

2. Section 308.3 is amended by revising the last sentence of paragraph (a) to read as follows:

§ 308.3 Establishments; sanitary conditions; requirements.

(a) * * * The provisions of part 416 of this chapter apply to all establishments, *except* establishments that are exempt in accordance with § 303.1 of this chapter.

PART 310—POST MORTEM INSPECTION

3. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

4. Section 310.25 is amended by revising paragraphs (a)(1), introductory test (a)(2)(ii),(a)(2)(iii), (a)(2)(v)(A), (a)(3), (a)(4), and (a)(5) to read as follows:

§ 310.25 Contamination with microorganisms; pathogen reduction performance standards for Salmonella.

(a) * * *

(1) Each official establishment that slaughters cattle and/or swine shall test for *Escherichia coli* Biotype 1 (*E. coli*). Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number. The establishment shall:

* * * * *

(2) Sampling requirements.

(i) * * *

(ii) *Sample collection.* The establishment shall collect samples from all chilled swine or cattle carcasses, *except* those boned before chilling (hot-boned), which must be sampled after the final wash. Samples shall be collected by either sponging or excising tissue from three sites on the selected carcass. On cattle carcasses, establishments shall sponge or excise tissue from the flank, brisket and rump, *except* for hide-on calves, in which case establishments shall take samples by sponging from inside the flank, inside the brisket, and inside the rump; on swine carcasses, establishments shall sponge or excise tissue from the ham, belly and jowl areas. [1]

(iii) *Sampling frequency.* Slaughter establishments, *except* very low volume establishments as defined in paragraph (a)(2)(v) of this section, shall take samples at a frequency proportional to the volume of production at the following rates:

Cattle: 1 test per 300 carcasses, but at a minimum one sample each week of operation.

Swine: 1 test per 1000 carcasses, but at a minimum one sample each week of operation.

* * * * *

(v) *Sampling in very low volume establishments.*

(A) Very low volume establishments annually slaughter no more than 6,000 cattle, 20,000 swine, or a combination of cattle and swine not exceeding 6,000 cattle and 20,000 total of both types. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

* * * * *

(3) *Analysis of samples.* Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists) [2] or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of CFU/cm^2 of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) *Criteria for evaluation of test results.*

(i) An establishment excising samples from carcasses is operating within the criteria when the most recent *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1.—EVALUATION OF E. COLI TEST RESULTS

Type of livestock	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Cattle	Negative [a]	100 CFU/cm^2	13	3

[1] A copy of FSIS's ''Guidelines for *E. coli* Testing for Process Control verification in Cattle and Swine Slaughter Establishments'' is available for inspection in the FSIS Docket Room.

[2] A copy of the current edition/revision of the ''Official Methods of AOAC International,'' 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877–2417.

TABLE 1.—EVALUATION OF E. COLI TEST RESULTS—Continued

Type of livestock	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Swine	10 CFU/cm[2]	10,000 CFU/cm[2]	13	3

[a] Negative is defined by the sensitivity of the method used in the baseline study with a limit of sensitivity of at least 5 cfu/cm[2] carcass surface area.

(ii) Establishments sponging carcasses shall evaluate *E. coli* test results using statistical process control techniques.

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

5. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470, 7 CFR 2.18, 2.53

Subpart K—Post Mortem Inspection; Disposition of Carcasses and Parts

6. Section 381.94 is amended by revising paragraphs (a)(1) introductory text, (a)(2)(ii), (a)(2)(iii), (a)(2)(v)(A), (a)(3), (a)(4); and (a)(5) Table 1; by redesignating paragraph (a)(5) as (a)(5)(i); by adding a new paragraph (a)(5)(ii); and by removing the footnote b in Table 2 of paragraph (b)(1) and removing the symbol ''b'' as it appears after the term ''Broiler'' and redesignating footnote d as footnote b to read as follows:

§ 381.94 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) * * *

(1) Each official establishment that slaughters poultry shall test for *Escherichia coli* Biotype I (*E. coli*). Establishments that slaughter more than one type of poultry and/or poultry and livestock, shall test the type of poultry or livestock slaughtered in the greatest number. The establishment shall:

* * * * *

(2) Sampling requirements.

(i) * * *

(ii) *Sample collection*. Samples shall be collected by taking a whole bird from the end of the chilling process, after the drip line, and rinsing it in an amount of buffer appropriate to the type of bird being tested. If the bird is boned before chilling (hot boned poultry), the sample shall be taken from the end of the slaughter line instead of the end of the drip line.[1]

(iii) *Sampling frequency*. Slaughter establishments, *except* very low volume establishments as defined in paragraph (a)(2)(v) of this section, shall take samples at a frequency proportional to the establishment's volume of production at the following rates:

Chickens: 1 sample per 22,000 carcasses, but at a minimum one sample per each week of operation.

Turkeys: 1 sample per 3,000 carcasses, but at a minimum one sample each week of operation.

* * * * *

(v) *Sampling in very low volume establishments*

(A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys or a combination of chickens and turkeys not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments slaughtering turkeys in the largest number shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments slaughtering chickens in the largest number shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

* * * * *

(3) *Analysis of samples*. Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)[2] or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of CFU/ml of rinse fluid. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of poultry slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) *Criteria for evaluation of test results.*

(i) * * *

[1] A copy of FSIS's ''Sampling Technique for *E. coli* in Raw Meat and Poultry for Process Control Verification'' is available for inspection in the FSIS Docket Room.

[2] A copy of the current edition/revision of the ''Official Methods of AOAC International,'' 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877–2417.

TABLE 1.—EVALUATION OF E. COLI TEST RESULTS

Types of poultry	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Chickens	100 CFU/ml	1,000 CFU/ml	13	3
Turkeys	N.A.[a]	N.A	N.A	N.A.

[a] Not available; values for turkeys will be added upon completion of data collection program for turkeys.

(ii) For types of poultry appearing in paragraph (a)(5)(i) Table 1 of this section that do not have m/M criteria, establishments shall evaluate *E. coli* test results using statistical process control techniques.

* * * * *

PART 416—SANITATION

7. The authority citation for part 416 continues to reads as follows:

Authority: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

8. Section 416.15 is amended by revising paragraph (b) to read as follows:

§ 416.15 Corrective Actions.

* * * * *

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

Done at Washington, DC, on May 7, 1997.

Thomas J. Billy,

Administrator.

[FR Doc. 97–12397 Filed 5–7–97; 3:21 pm]

BILLING CODE 3410–DM–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

RIN 3150–AF68

Informal Small Entity Guidance

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to add a provision that provides a method for small entities to contact the NRC for assistance in interpreting or complying with regulatory requirements. The final rule is necessary to comply with the Small Business Regulatory Enforcement Fairness Act. The final rule describes how the NRC will assist small entities that are licensed by the NRC.

EFFECTIVE DATE: May 13, 1997.

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Chief, Rules Review and Directives Branch, Office of Administration, Washington, DC 20555–0001; telephone 301–415–7162; Web address http://www.dlm1@nrc.gov, or Michael T. Lesar, Chief, Rules Review Section, Rules Review and Directives Branch, Office of Administration, Washington, DC 20555–0001; telephone 301–415–7163; Web address http://www.mtl@nrc.gov. Small businesses can obtain information from the Commission's hotline telephone system by calling 1–800–368–5642.

SUPPLEMENTARY INFORMATION:

Background

In March 1996, Congress enacted the Small Business Regulatory Enforcement Fairness Act (SBREFA), Public Law 104–121. Congress found this legislation necessary because ''small businesses bear a disproportionate share of regulatory costs and burden'' and ''fundamental changes * * * are needed in the regulatory and enforcement culture of Federal agencies' to make them more responsive to small businesses (Sections 202 (2) and (3) of the Act).

Simplifying Compliance

Subtitle A of SBREFA provides a number of initiatives that are intended to make it easier for small entities to understand and comply with agency regulations. In particular, the subtitle provides that, ''Whenever appropriate in the interest of administering statutes and regulations within the jurisdiction of an agency, it shall be the practice of the agency to answer inquiries from small entities concerning information on and advice about compliance with such statutes and regulations.'' Agencies are expected to interpret and apply the law, or regulations implementing the law, to specific sets of facts that are supplied by the small entity. Furthermore, agencies are required to establish a program to receive and respond to these types of inquiries.

The NRC and Small Entities

Since the Regulatory Flexibility Act was enacted in 1980, the NRC has considered the special needs of small businesses and has worked to address them. In 1983, the NRC surveyed its materials licensees to create an economic profile sufficient to consider regulatory alternatives tailored to the size of the licensee. After analyzing the data and consulting with the Small Business Administration (SBA), the NRC developed size standards to determine which of its licensees would qualify as small entities for the purposes of compliance with the Regulatory Flexibility Act (50 FR 50241; December 9, 1985).

In 1993, the NRC completed a second survey to update the economic profile of its materials licensees. Subsequently, the NRC revised its size standards on April 11, 1995 (60 FR 18344). The revised size standards included separate standards for business concerns that are manufacturing entities, adjusted its receipts-based size standard to accommodate inflation, eliminated the separate $1 million size standard for private-practice physicians and applied the revised receipts-based size standard of $5 million to this class of licensees, and codified the size standards in § 2.810 of 10 CFR. The NRC has considered the economic impact of its regulatory actions on small entities. In particular, the NRC used its size standards to tier the annual license fee imposed by the NRC's final rules implementing the Omnibus Budget Reconciliation Act of 1990 (56 FR 31472; July 10, 1991 and subsequent years), thereby reducing the impact of the fee rules on small entities.

In this and other areas, the NRC has responded to the comments and suggestions it has received from small entities. The NRC intends to continue