

(c) An establishment did not have or maintain Sanitation Standard Operating Procedures in accordance with part 416 of this chapter;

(d) An establishment did not maintain sanitary conditions;

(e) An establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results as prescribed in §§ 310.25(a) or 381.94(a) of this chapter;

(f) An establishment did not comply with the Salmonella performance standard requirements as prescribed in §§ 310.25(b) and 381.94(b) of this chapter;

(g) An establishment did not slaughter or handle livestock humanely;

(h) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS program employee; or

(i) A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

#### **§ 500.7 Refusal to grant inspection.**

(a) The FSIS Administrator may refuse to grant Federal inspection because an applicant:

(1) Does not have a HACCP plan as required by part 417 of this chapter;

(2) Does not have Sanitation Standard Operating Procedures as required by part 416 of this chapter;

(3) Has not demonstrated that adequate sanitary conditions exist in the establishment as required by part 308 or part 381, subpart H, and part 416 of this chapter;

(4) Has not demonstrated that livestock will be handled and slaughtered humanely; or

(5) Is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

(b) If the Administrator refuses to grant inspection, the applicant will be provided the opportunity for a hearing in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

#### **§ 500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.**

(a) FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product under section 7 of the FMIA or under section 8 of the PPIA.

(b) FSIS will provide written notification that:

(1) Explains the reason for rescinding or refusing the approval;

(2) Provides an opportunity for the establishment to modify the marking, labeling, or container so that it will no longer be false or misleading; and

(3) Advises the establishment of its opportunity to submit a written statement to respond to the notification and to request a hearing.

(c) If FSIS rescinds or refuses approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product, an opportunity for a hearing will be provided in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

Done at Washington, DC on: November 17, 1999.

**Thomas J. Billy,**  
Administrator.

[FR Doc. 99-30603 Filed 11-26-99; 8:45 am]

**BILLING CODE 3410-DM-P**

## **DEPARTMENT OF AGRICULTURE**

### **Food Safety and Inspection Service**

#### **9 CFR Parts 310 and 381**

**[Docket No. 97-004F]**

**RIN 0583-AC32**

#### **Generic *E. coli* Testing for Sheep, Goats, Equines, Ducks, Geese, and Guineas**

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is requiring establishments that slaughter sheep, goats, horses, mules, and other equines, and establishments that slaughter ducks, geese, and guineas, to sample and test carcasses for generic *E. coli*. This final rule extends the sampling and testing requirements already applied to establishments that slaughter cattle, swine, chickens, and turkeys. Regular microbial testing by slaughter establishments is necessary to verify the adequacy of the establishment's process controls for the prevention and removal of fecal contamination and associated bacteria.

**EFFECTIVE DATE:** January 25, 2000.

**FOR FURTHER INFORMATION CONTACT:** Daniel L. Engeljohn, Ph.D., Director, Regulation Development and Analysis Division, Office of Policy, Program Development, and Evaluation, FSIS, Room 112 Annex Building, Washington, DC 20250-3700; telephone (202) 720-5627.

**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 establishments that slaughter cattle, swine, chicken, and turkey to verify the adequacy of each establishment's process control 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, a Hazard Analysis and Critical Control Point (HACCP) system.

At present, all inspected establishments that slaughter cattle, swine, chickens or turkeys must sample and test carcasses for generic *E. coli*. These establishments have developed sampling plans and sample at specified frequencies, locations, and sites. They maintain records of results and evaluate the results using either the m/M criteria developed in FSIS' baseline studies or, if m/M criteria are not available, statistical process control techniques. Establishments defined as "very low volume" may sample at an alternative frequency. Also, establishments operating under HACCP may develop alternative sampling frequencies if certain requirements are met. The Pathogen Reduction/HACCP final rule and the "Pathogen Reduction/HACCP; Technical Corrections and Amendment" final rule (62 FR 26211) provide detailed information about the need for these requirements.

On November 3, 1997, FSIS published a proposed rule in the **Federal Register** (62 FR 59305) proposing to extend the sampling and testing requirements for generic *E. coli* to meat establishments that slaughter sheep, goats, and equines and to poultry establishments that slaughter ducks, geese, and guineas. FSIS believes that regular microbial testing by all slaughter establishments is necessary to verify the adequacy of the establishment's process controls for the prevention and removal of fecal contamination and associated bacteria.

## Comments

FSIS received five comments during the public comment period that ended January 2, 1998. Two of the commenters are members of the meat industry, and two commenters represent industry trade associations. The fifth commenter is from the Ministry of Agriculture of a major U.S. trading partner. None of the commenters expressed any opposition to extending the generic *E. coli* sampling and testing requirements to minor species, and one commenter found both the costs and hours necessary for implementation to be reasonable.

The principal areas of disagreement with the proposed rule dealt with sampling/testing rates and sites. One of the commenters proposed that the sampling for sheep and goats be done less frequently than for cattle and swine. Another commenter disagreed with the application of the 1 per 300 sampling frequency and proposed an ovine sampling rate of 1 per 810 as being more appropriate for establishments that slaughter large numbers of sheep and lambs.

The sampling/testing site was another area about which there was disagreement with the proposal. One commenter expressed a preference for a single sampling site rather than the three sites proposed by FSIS. Another commenter disagreed with the proposed sampling sites and recommended that alternative sites be described in the final rule to accommodate different dressing systems.

The flank, brisket, and rump are the same sites that were used by FSIS when conducting the baseline studies for cattle and swine. FSIS' decision not to change sites is based on the fact that there are no available data to demonstrate that one-site sampling will provide results comparable to the baseline survey data.

Moreover, it is appropriate, under HACCP, that the same three sites be used for sampling all livestock carcasses. The Agency's understanding of the minor species' dressing practices is that these three sites are the most likely places where contamination would be found. Although species-specific data are not currently available, researchers at Colorado State University (CSU) are conducting sampling analysis at three locations on lamb carcasses: the leg (rump, for beef), flank, and breast (brisket, for beef). The Agency will consider amending the regulations if the CSU data indicate a persuasive need to considering other sampling sites. With regard to frequency of sampling/testing, FSIS proposed a maximum limit of 13

samples per day, as was done with poultry.

One commenter recommended a smaller template for lamb carcasses, such as an area between 3×3 inches and 5×5 inches. In response to this recommendation, FSIS agrees that a smaller template is reasonable for sheep and goats, smaller species than livestock species, and will specify a 5×10 cm template in its sampling procedures.

## The Final Rule

FSIS now is extending these sampling and testing requirements to sheep, goats, horses, mules, and other equines, defined as livestock in 9 CFR 301.2 (qq). All establishments slaughtering sheep, goats, horses, mules, or other equines now are required to meet the sampling and testing requirements in 9 CFR 310.25. Similarly, establishments that slaughter ducks, geese, and guineas now are required to meet the sampling and testing requirements in 9 CFR 381.94. These establishments will only be required to test sheep, goats, equines, ducks, geese, or guineas if they primarily slaughter these types of livestock or poultry. FSIS considers the livestock or poultry an establishment slaughters in the largest number to be that establishment's primary type of livestock or poultry slaughtered. Finally, this final rule also corrects an inadvertent inconsistency in the headings of §§ 310.25 and 381.94 that appeared in the proposed rule by including the phrase "process control verification criteria and testing" as well as removing the phrase "for *Salmonella*" in § 310.25.

## Sampling Frequencies and Definitions for Very Low Volume Establishments

For the Pathogen Reduction/HACCP final rule, FSIS used a methodology to select sampling frequencies so that, in the subgroup of establishments accounting for 99 percent of total production for each type of livestock or poultry, the 5 percent of establishments with the highest production volume would each conduct a minimum of 13 *E. coli* tests, or one complete test window each day. Under these frequencies, 90 percent of all cattle, 94 percent of all swine, 99 percent of all chickens, and 99 percent of all turkeys would be slaughtered in establishments conducting a minimum of one complete *E. coli* sampling window per day to provide a minimum, adequate basis for process control verification.

FSIS developed alternative sampling frequencies for establishments defined as "very low volume." If there are published m/M criteria for the type of livestock or poultry primarily

slaughtered, the establishment must sample that type of livestock or poultry at a minimum frequency of once per week, starting the first full week of operation after June 1 of each year 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 primarily slaughtered, a very low volume establishment must 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 that the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. This provision will be eliminated once m/M criteria are developed for the primary type of livestock or poultry slaughtered.

FSIS permits very low volume establishments to test at this frequency, in part, because of their relatively simple and stable production environments. Also, FSIS assumes that the total risk of exposure to enteric pathogens from products produced at such establishments would be small and roughly proportional to the amount of products produced. FSIS requires these establishments to begin testing in June because it is most important for these establishments to conduct testing during the summer months, when there is a seasonal peak in the occurrence of foodborne diseases attributable to the major bacterial pathogens.

The Pathogen Reduction/HACCP final rule (61 FR 38842) noted that very low volume cattle and swine establishments account for only 1.5 percent and 1.3 percent of overall production, respectively. Very low volume chicken and turkey establishments account for .05 percent and .01 percent of overall production, respectively.

FSIS is now requiring establishments that slaughter sheep, goats, and equines to sample at the same frequency now required for cattle, one test per 300 carcasses. Similarly, FSIS is requiring establishments that slaughter ducks, geese, and guineas to sample at the same frequency now required for turkeys, one test per 3,000 carcasses. FSIS also is requiring establishments that slaughter sheep, goats, equines, ducks, geese, and guineas, except those defined as very low volume establishments, to conduct sampling at a frequency of at least once per week to provide a minimum, adequate basis for process control verification.

FSIS is requiring "very low volume" establishments that slaughter sheep, goats, equines, ducks, geese, and guineas to 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 that the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. At this time, baseline studies have not been conducted to develop m/M criteria for sheep, goats, equines, ducks, geese, and guineas. When m/M criteria are developed for any of these types of livestock or poultry, FSIS intends to require sampling at a minimum frequency of once per week starting the first full week of operation after June 1 until a series of 13 tests has met those m/M criteria.

#### Sheep and Goats

In fiscal year 1993, 93 establishments slaughtered primarily sheep and goats. FSIS is requiring that these establishments sample at a frequency of one test per 300 carcasses or at least once a week, whichever is greater, unless they are very low volume establishments. At this sampling frequency, 85 percent of all sheep and goats will be slaughtered in establishments conducting a minimum of 13 samplings each day or one complete *E. coli* test window. A very low volume sheep or goat slaughter establishment is one that annually will slaughter no more than 6,000 head. Based on fiscal year 1993 data, 61 of the 93 establishments will be classified as very low volume and account for 1.9 percent of total sheep and goat production.

#### Equines

In fiscal year 1995, eight establishments slaughtered equines under Federal inspection for human food. These eight establishments slaughtered only equines. The Agency now is requiring that horse, mule, or other equine slaughter establishments sample at a rate of one per 300 carcasses or at least once a week, whichever is greater, unless they are very low volume establishments. Very low volume equine establishments are those that will annually slaughter no more than 6,000 equines. Two of the equine establishments, slaughtering 5.6 percent of overall production, will be classified as very low volume.

#### Ducks, Geese, and Guineas

In fiscal year 1995, there were 12 establishments that slaughtered primarily ducks and two establishments that slaughtered primarily geese. FSIS is not aware of any federally inspected establishment currently slaughtering guineas. FSIS now is requiring establishments that slaughter ducks,

geese, and guineas to sample at a frequency of one test per 3,000 carcasses or at least once a week, whichever is greater, unless they are very low volume establishments. At this frequency, 96 percent of all ducks will be slaughtered in establishments conducting a minimum of one *E. coli* test per day. Very low volume duck, geese, or guinea establishments are those that will slaughter no more than 60,000 ducks, geese, or guineas, respectively, a year.

In FY 1995, 25 establishments slaughtered 19.2 million ducks. Only 12 establishments slaughtered primarily ducks. These establishments produced 98.7 percent of all ducks slaughtered under Federal inspection. One of the 12 establishments produces less than 0.2 percent of ducks slaughtered and will be defined as a very low volume duck establishment.

Eight establishments under Federal inspection slaughtered 159,000 geese in FY 1995. Only two establishments slaughtered primarily geese and only one of these establishments slaughters more than 60,000 geese.

#### Alternative Sampling Frequencies

Establishments operating under a validated HACCP plan in accordance with 9 CFR 417.2(b) will be permitted to substitute an alternative frequency if the alternative is an integral part of the establishment's verification procedures for its HACCP plan. Establishments will not be allowed to use an alternative frequency if FSIS determines, and notifies the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's process controls.

#### Sampling Plans

Establishments that slaughter sheep, goats, equines, ducks, geese, and guineas will prepare written specimen collection procedures. The procedures will include the identification of employees designated to collect samples, the location(s) of sampling, how sampling randomness is achieved, and how samples are handled to ensure sample integrity. The written procedures will be made available to FSIS upon request.

#### Sampling Locations

Establishments that slaughter sheep, goats, and equines will collect samples from chilled carcasses. Carcasses boned before chilling (hot boned) will be sampled after the final wash. For ducks, geese, and guineas, samples will be taken from the end of the chilling process, after the drip line. If the bird is boned before chilling, the sample will

be taken from the end of the slaughter line instead of the end of the drip line.

#### Sampling Sites

Samples from sheep, goat, and equine carcasses will be taken by sponging tissue from three sites: the flank, brisket, and rump. The sponge is to be placed afterward in an amount of buffer to transfer any *E. coli* to a solution, which then is analyzed for *E. coli*. Hide-on carcasses will be sampled by sponging from inside the flank, inside the brisket, and inside the rump. Samples from ducks, geese, and guineas will be collected by taking whole birds from the end of the chilling process after the drip line and rinsing them in an amount of buffer appropriate to the type of bird being tested.

#### Recordkeeping

Establishments will enter test results onto a process control chart or table and record the results in terms of colony forming units per milliliter (cfu/ml) for poultry carcasses or per square centimeter (cfu/cm<sup>2</sup>) for livestock carcasses. Establishments will use the records to evaluate test results. These records will be maintained at the establishment for 12 months and must be made available to inspection program personnel upon request. Inspection program personnel will review results over time to verify effective and consistent process control.

#### Evaluation Criteria

Establishments will evaluate results using statistical process control techniques until such time as m/M criteria are established for these types of livestock and poultry. FSIS intends to give high priority in its baseline plan to collect data that will support establishing m/M criteria for ducks and geese, and sheep.

#### International Implementation

The Federal Meat Inspection Act and the Poultry Products Inspection Act require that meat and poultry products imported into the United States be produced under an inspection system that is equivalent to the U.S. inspection system. In determining the equivalency of a foreign country's eligibility to import meat or poultry products into the United States, FSIS evaluates the laws, policies, and administration of that country's inspection system. This assessment includes on-site reviews of individual establishments, laboratories, and other facilities within the foreign system. With this final rule, countries that export products of sheep, goats, equines, ducks, geese, and guineas to the United States must implement

equivalent generic *E. coli* sampling and testing programs as a condition of maintaining eligibility for access to the U.S. market.

The burden for demonstrating equivalence rests with the exporting country, and the United States is free to set any level of protection it considers appropriate to control or eliminate a foodborne hazard. Equivalent regulatory systems need not be identical. FSIS has established a level of protection that domestic establishments must achieve. Exporting countries may propose alternative methods of achieving equivalent levels of protection and are advised to consult with FSIS on any proposed alternatives that they believe will meet U.S. requirements.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This final rule has been determined to be not significant, and therefore, has not been reviewed by the Office of Management and Budget.

The Administrator made an initial determination that this 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).

This final rule is an extension of the Pathogen Reduction/HACCP rule, which is economically significant. Many aspects of that economically significant rule, such as the public health risks associated with pathogens present in fecal contamination and the potential health benefits of pathogen reduction, are applicable to this rule. In the Final Regulatory Impact Assessment (FRIA)(61 FR 38945, July 25, 1996) for the Pathogen Reduction/HACCP rule, FSIS addressed these areas in detail.

By extending the requirement for generic *E. coli* testing to additional types of livestock and poultry, this final rule will increase the effectiveness of pathogen reduction efforts and generate proportional increases in predicted public health benefits. The benefits assessment in the FRIA was based on a proportional reduction assumption: that is, an assumption was made that a reduction in pathogens at the manufacturing level leads to a proportional reduction in foodborne illness. Public health benefits are quantified in terms of reduced cost of foodborne illness.

This final rule will affect an estimated 101 federally inspected livestock slaughter establishments and a smaller number of State inspected livestock slaughter establishments. The total of 101 federally inspected establishments includes 11 establishments that slaughter only sheep and goats, 82

establishments that slaughter cattle and/or swine but slaughter sheep or goats as their primary type of livestock, and eight establishments that slaughter equines. In addition, there are 574 establishments that slaughter sheep or goats but are not affected because they primarily slaughter cattle or swine.

This final rule also will affect an estimated 14 federally inspected poultry slaughter establishments and possibly a few State inspected poultry slaughter establishments. These include 12 federally inspected establishments that slaughter primarily ducks and two establishments that slaughter primarily geese. There are 14 establishments that also slaughter ducks and/or geese, but are not affected because they slaughter primarily chickens or turkeys. There are currently no establishments that slaughter guineas under Federal inspection.

#### **Executive Order 12898**

Pursuant to Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," FSIS has considered potential impacts of this final rule on environmental and health conditions in low-income and minority communities.

This final rule extends the sampling and testing requirements already applied to establishments that slaughter cattle, swine, chickens, and turkeys. As explained in the economic impact analysis above, the Final Regulatory Impact Assessment (FRIA) for the Pathogen Reduction/HACCP final rule addressed in detail the fact that this rule will generally benefit FSIS, the regulated industries, and consumers. The final rule will not require or compel meat or poultry establishments to relocate or alter their operations in ways that could adversely affect the public health or environment in low income and minority communities. Further, this final rule will not exclude any persons or populations from participation in FSIS programs, deny any persons or populations the benefits of FSIS programs, or subject any persons or populations to discrimination because of their race, color, or national origin.

#### **Cost Analysis**

This analysis is based on the same estimates and assumptions that were used to develop the FRIA for the Pathogen Reduction/HACCP rule and include:

(1) An average cost of \$24 for collecting and analyzing a sample for generic *E. coli*.

(2) A cost of \$640 for the preparation of a sampling plan. This estimate is

based on 25 hours at \$25.60 per hour, the average wage of a quality control manager.

(3) A cost of \$403 per establishment for an estimated three out of four establishments that would require extra training for aseptic sampling.

(4) An estimate of 26 sample collections annually by very low volume slaughter establishments. (The proposed requirement is a minimum of 13.)

(5) An estimate of five minutes to record and review laboratory results for each sample by an employee earning \$13.42 per hour.

#### **Sheep, Goats, and Equines**

Unless otherwise specified, this cost analysis is based on data from the Agency's Enhanced Economic Database. This database includes Animal Disposition Retrieval System (ADRS) data from FY 1993. Sheep and goat production were combined in the Enhanced Economic Database. Although the proposed rule treats sheep and goats as two separate types of livestock, the cost analysis is based on combined sheep and goat production. This has a minimal impact on the accuracy of the cost estimates.

There are 11 establishments that slaughter only sheep and goats. This final rule will extend mandatory generic *E. coli* testing to these establishments. Each of these 11 establishments will be required to develop a sampling plan at a cost of \$640 per establishment or \$7,040 in total. This cost would include items such as preparing a written plan, establishing sampling procedures, locating a laboratory and arranging for necessary supplies, and developing the statistical process control techniques to be used for analyzing results.

This analysis assumes that eight establishments (75 percent) would require training in aseptic sampling at a cost of \$3,224 (8 times \$403). Three of the eleven establishments will be very low volume establishments and will analyze 26 samples per year for a recurring cost of \$1,872. Based on production data and a sampling rate of one in 300, the other eight establishments will analyze a total of 8,015 samples annually at a cost of \$192,360. Recording and reviewing costs for 8,015 samples will require 668 hours annually and cost \$8,970. The annual recording and reviewing costs for the three very low volume establishments will be \$87 (6.5 hours at \$13.43 per hour).

As discussed above, there are 82 establishments that slaughter cattle and/or swine but slaughter sheep or goats as their primary type of livestock. There

will be no additional cost for 58 of these establishments because these 58 are now required to conduct sampling as very low volume cattle or swine slaughter establishments and will be very low volume sheep or goat establishments under this rule. The impact on these 58 establishments will be a shift in the type of livestock sampled. The Agency is not aware of any basis to conclude that establishments could not make this shift without additional costs for sampling plan development.

The other 24 establishments within the 82 that slaughter cattle and/or swine and sheep or goats are now required to test cattle or swine. However, under this final rule, they will have to conduct additional analyses based on their sheep or goat production. Their sheep/goat

production is greater than the larger of their cattle or swine production. As they shift from cattle or swine to sheep or goats, annual sampling will increase by 2,928 samples or \$70,272 per year. Annual recording and reviewing costs will be \$3,277 (244 hours at \$13.43 per hour).

This final rule will also extend mandatory generic *E. coli* testing to 8 establishments that slaughter equines for human food. Based on FY 1995 ADRS data, these eight establishments will be required to conduct 469 analyses per year. It is assumed they will all have to develop sampling plans (\$640 each) and that six will have to obtain training in aseptic sampling (\$403 per establishment). Two of the eight establishments that slaughter equines will meet the definition for a very low

volume establishment. The total recurring cost for 469 analyses will be \$11,256. Recording and reviewing costs will be \$525 per year (39 hours at \$13.43 per hour).

In conclusion, there are 43 federally inspected livestock slaughter establishments that will experience increased costs under this final rule. The one time up-front costs will total \$17,802, \$5,642 for training in aseptic sampling and \$12,160 for sampling plan development. The total recurring cost for the 43 establishments will be \$288,619, \$275,760 for sample collection and analysis and \$12,859 for recording and reviewing test results.

All the costs discussed above for establishments that slaughter sheep, goats, and equines are summarized in Table 1.

TABLE 1.—COSTS FOR IMPLEMENTING GENERIC E. COLI SAMPLING PROGRAMS IN SHEEP, GOAT, AND EQUINE ESTABLISHMENTS

Production category	Number of establishments	Training for aseptic sampling	Sampling plan development	Sample collection and analysis (recurring)	Recording and review (recurring)
Exclusively Sheep or Goats with Annual Production over 6,000 ..	8	\$2,418	\$5,120	\$192,360	\$8,970
Exclusively sheep or Goats with Annual Production under 6,000	3	806	1,920	1,872	87
Primarily Sheep or Goats with Annual Production over 6,000 .....	24	.....	.....	70,272	3,277
Equine .....	8	2,418	5,120	11,256	525
Total .....	43	5,642	12,160	275,760	12,859

**Ducks, Geese, and Guineas**

The ADRS data show that 28 federally inspected establishments slaughtered ducks and/or geese in FY 1995. FSIS is not aware of any establishment slaughtering guineas. Six establishments slaughtered only the types of poultry covered by this final rule. This final rule extends mandatory generic *E. coli* testing to six federally inspected poultry establishments that are not currently required to test. There are eight poultry slaughter establishments that currently test chickens or turkeys, but slaughter more ducks or geese and, therefore, will shift their testing program to ducks or geese. Seven of these establishments will have to conduct more testing because they will not be very low volume establishments based on their duck or goose production. The eighth establishment will shift from a very low volume establishment that slaughters chickens to a very low volume establishment that slaughters ducks, and it and will not incur any additional costs.

In summary, under this final rule, 14 establishments will test ducks or geese. Two of these establishments will be very low volume establishments. All 14

poultry slaughter establishments affected by this final rule were included in the Pathogen Reduction/HACCP FRIA as very low volume poultry slaughter establishments, that is, annual chicken slaughter under 440,000 and annual turkey slaughter under 60,000. The methodology applied in the FRIA started with all 306 poultry slaughter establishments (FY 1993 ADRS data) in the Agency's Enhanced Economic Database. FSIS calculated the costs for 208 establishments processing more than 440,000 chickens annually and the costs for 48 establishments processing more than 60,000 turkeys annually. FSIS treated the remaining 50 poultry slaughter establishments as very low volume establishments.

This methodology most likely overestimated costs; more recent FY 1995 ADRS data include six poultry slaughter establishments processing ducks and/or geese exclusively. This cost analysis separates the costs already addressed and the incremental costs of basing sampling frequency upon duck and geese production. The costs already addressed that are actually costs of this final rule include the cost of six sampling plans at \$640 per plan or

\$3,840; training in aseptic sampling for five establishments at \$403 per establishment or \$2,015; sample collection and analysis costs for 156 (6 multiplied by 26) samples per year at a cost of \$24 per sample or \$3,744; and recording and record review costs of \$175. Using duck and geese production levels from FY 1995, five of the six establishments slaughtering only ducks and geese will have to collect and analyze an additional 2,281 samples per year at an annual cost of \$54,744. The recording and reviewing costs for 2,281 samples will be \$2,553 annually. The other establishment is a very low volume establishment.

As discussed above, there are seven establishments that are currently required to test for chickens or turkeys as very low volume establishments, but will have to conduct more analyses under this final rule because they will not be very low volume establishments based on their duck or goose production. These seven establishments will have to collect and analyze an additional 3,769 samples annually at a cost of \$90,456. Recording and review costs at five minutes per sample will total \$4,218 per year.

The total cost for extending testing to ducks, geese, and guineas includes a one-time cost of \$5,855 for training and sampling plan development and an

annual recurring sampling and recording cost of \$155,890. The cost for requiring generic *E. coli* sampling in establishments that slaughter ducks,

geese, and guineas are summarized in Table 2.

TABLE 2: COSTS FOR IMPLEMENTING GENERIC E. COLI SAMPLING PROGRAMS FOR DUCK, GOOSE, AND GUINEA ESTABLISHMENTS

Production category	Number of establishments	Training for aseptic sampling	Sampling plan development	Sample collection and analysis (recurring)	Recording and review (recurring)
Ducks and Geese only-Costs Included in FRIA .....	6	\$2,015	\$3,840	\$3,744	\$175
Ducks and Geese only-Costs not previously accounted for .....	15	.....	.....	54,744	2,553
Establishments Currently Required to test Chickens or Turkeys ..	7	.....	.....	90,456	4,218
<b>Total .....</b>	<b>13</b>	<b>2,015</b>	<b>3,840</b>	<b>148,944</b>	<b>6,946</b>

<sup>1</sup> Included in the 6 above.

**Overall Summary of Cost Analysis**

This final rule will extend mandatory generic *E. coli* sampling requirements to 25 federally inspected establishments, 11 that slaughter sheep and goats exclusively, eight that slaughter equines, and six that currently slaughter only ducks and/or geese. The nonrecurring up-front cost for these establishments will total \$23,657. The annual recurring cost for collecting and analyzing 10,999 samples and recording and reviewing results for these 25 establishments will be \$276,286. There are 31 establishments that currently test cattle, swine, chickens or turkeys that will have to increase their testing programs by 6,697 samples. The increase in annual 28 recurring costs for these 31 establishments will be \$168,223.

The costs summarized in Tables 1 and 2 are maximum costs because the final rule will allow for establishments operating under a validated HACCP system to use sampling frequencies other than those specified in this final rule if the alternative sampling frequency is an integral part of the establishment's HACCP plan. The cost estimates in Tables 1 and 2 do not account for possible reductions in sampling frequencies.

**Executive Order 12988**

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Because this rule is final, (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**

Abstract: As part of microbiological testing, each slaughter establishment

will be required to develop written procedures outlining specimen collection and handling. The slaughter establishments will be responsible for entering the results into a statistical process control chart or table. The data and chart will be available for review by FSIS upon request.

Estimate of Burden: Agency subject matter experts estimate that it will take 25 hours for establishments to develop a microbial sampling and analysis plan. It will take an estimated 17.5 minutes to collect samples and 5 minutes per sample to enter data into charts, and then review and file the information.

This final rule will require 25 federally inspected establishments to develop sampling plans. FSIS estimates that each plan will require 25 hours to develop. Plan development for 25 establishments will require 625 burden hours. Fifty-six establishments will be required to collect samples and to record new or additional test results. These 56 establishments will be required to collect and record and review the results of 17,696 analyses, annually. To collect samples at 17.5 minutes per sample, 5,161 burden hours will be required. It will take 1,475 burden hours at 5 minutes per result to record and review results.

*Respondents:* Livestock and poultry product establishments.

*Estimated Number of Respondents:* 56.

*Estimated Number of Responses per Respondents:* 18,402.

*Estimated Total Annual Burden on Respondents:* 7,261 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, 300 12th Street, SW, Room 109, Washington, DC 20250-3700.

**List of Subjects**

9 CFR Part 310

Meat Inspection, Microbial testing.

9 CFR Part 381

Poultry and poultry products, Microbial testing.

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

**PART 310—POST MORTEM INSPECTION**

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

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

2. Section 310.25 is amended by revising the section heading, the first sentence of paragraph (a)(1) introductory text, paragraphs (a)(2)(ii), (a)(2)(iii), and the first sentence of (a)(2)(v)(A) to read as follows:

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

(a) \* \* \*  
 (1) Each official establishment that slaughters livestock must test for *Escherichia coli* Biotype 1 (*E. coli*)

\* \* \*  
 \* \* \* \* \*

(2) \* \* \*  
 (ii) Sample collection. The establishment must collect samples from all chilled livestock carcasses, except those boned before chilling (hot-boned), which must be sampled after the final wash. Samples must be collected in the following manner:

(A) For cattle, establishments must sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments must take samples by sponging from

inside the flank, inside the brisket, and inside the rump.

(B) For sheep, goat, horse, mule, or other equine carcasses, establishments must sponge from the flank, brisket and rump, except for hide-on carcasses, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump.

(C) For swine carcasses, establishments must sponge or excise tissue from the ham, belly and jowl areas.

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

(A) Cattle, sheep, goats, horses, mules, and other equines: 1 test per 300 carcasses, but a minimum of one sample during each week of operation.

(B) Swine: 1 test per 1,000 carcasses, but a minimum of one sample during each week of operation.

\* \* \* \* \*

(v) \* \* \*

(A) Very low volume establishments annually slaughter no more than 6,000 cattle, 6,000 sheep, 6,000 goats, 6,000

horses, mules, or other equines, 20,000 swine, or a combination of livestock not exceeding 6,000 cattle and 20,000 total of all livestock. \* \* \*

\* \* \* \* \*

**PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS**

3. 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**

4. Section 381.94 is amended by revising paragraph (a)(2)(iii), the first and second sentence of paragraph (a)(2)(v)(A), and table 1 in paragraph (a)(5)(i) as follows:

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

(a) \* \* \*

(2) \* \* \*

(iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to

the establishment's volume of production at the following rates:

(A) Chickens: 1 sample per 22,000 carcasses, but a minimum of one sample during each week of operation.

(B) Turkeys, Ducks, Geese, and Guineas: 1 sample per 3,000 carcasses, but a minimum of one sample during each week of operation.

\* \* \* \* \*

(v) \* \* \*

(A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas or a combination of all types of poultry not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments that slaughter turkeys, ducks, geese, or guineas in the largest number must collect at least one sample during each 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.

\* \* \* \* \*

(5) \* \* \*

(i) \* \* \*

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 .....	1 100	1 1,000	13	3
Turkeys .....	* NA	* NA	* NA	* NA
Ducks .....	* NA	* NA	* NA	* NA
Geese .....	* NA	* NA	* NA	* NA
Guineas .....	* NA	* NA	* NA	* NA

1 CFU/ml.

\* Values will be added upon completion of data collection programs.

\* \* \* \* \*

Done at Washington, DC, on: November 18, 1999.

**Thomas J. Billy,**  
Administrator.

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**FEDERAL RESERVE SYSTEM**

**12 CFR Part 201**

[Regulation A]

**Extensions of Credit by Federal Reserve Banks; Change in Discount Rate**

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Final rule.

**SUMMARY:** The Board of Governors has amended its Regulation A on Extensions of Credit by Federal Reserve Banks to reflect its approval of an increase in the basic discount rate at each Federal Reserve Bank. The Board acted on requests submitted by the Boards of Directors of the twelve Federal Reserve Banks.

**DATES:** The amendments to part 201 (Regulation A) were effective November 16, 1999. The rate changes for adjustment credit were effective on the dates specified in 12 CFR 201.51.

**FOR FURTHER INFORMATION CONTACT:** Jennifer J. Johnson, Secretary of the Board, at (202) 452-3259; for users of Telecommunications Device for the Deaf

(TDD), contact Diane Jenkins, at (202) 452-3544, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

**SUPPLEMENTARY INFORMATION:** Pursuant to the authority of sections 10(b), 13, 14, 19, et al., of the Federal Reserve Act, the Board has amended its Regulation A (12 CFR part 201) to incorporate changes in discount rates on Federal Reserve Bank extensions of credit. The discount rates are the interest rates charged to depository institutions when they borrow from their district Reserve Banks.

The "basic discount rate" is a fixed rate charged by Reserve Banks for adjustment credit and, at the Reserve Banks' discretion, for extended credit. In increasing the basic discount rate