

clarifying that policy in the regulations. Therefore, this rule should have no impact on entities whether they are large or small.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### Regulatory Reform

This action is part of the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals.

#### List of Subjects in 9 CFR Part 130

Animals, Birds, Diagnostic reagents, Exports, Imports, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Tests.

Accordingly, 9 CFR part 130 is amended as follows:

#### PART 130—USER FEES

1. The authority citation for part 130 continues to read as follows:

**Authority:** 5 U.S.C. 5542; 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 7 CFR 2.22, 2.80, and 371.2(d).

#### § 130.20 [Amended]

2. Section 130.20 is amended by removing paragraph (d) and redesignating paragraph (e) as paragraph (d).

3. A new § 130.49 is added to read as follows.

#### § 130.49 Exemptions.

(a) *Veterinary diagnostics.* User fees for veterinary diagnostic services, including, but not limited to, tests and diagnostic reagents specified in §§ 130.14 through 130.18, are not charged under the following conditions:

(1) When veterinary diagnostic services are provided in connection with Federal programs to control or eradicate diseases or pests of livestock or poultry in the United States (program diseases);

(2) When veterinary diagnostic services are provided in support of zoonotic disease surveillance when the Administrator has determined that there is a significant threat to human health; and

(3) When veterinary diagnostic reagents are distributed within the United States for testing for foreign animal diseases.

(b) [Reserved].

Done in Washington, DC, this 7th day of November 1997.

**Charles Schwalbe,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

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## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

#### 9 CFR Parts 310, 381, and 417

[Docket No. 97-056DF]

RIN 0583-AC40

#### Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems—Sample Collection—Technical Amendments and Corrections: Direct Final Rule

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

**ACTION:** Direct 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. In response to worker safety concerns, FSIS will permit samples collected for generic *E. coli* testing of turkeys to be collected by sponging two sites. Samples may still be collected by the whole bird rinse procedure (shaking turkeys in a bag containing a buffer solution). FSIS will also permit chickens and turkeys to be taken from the end of the slaughter line if it is impracticable to take a whole bird from the end of the chilling process.

Additionally, FSIS is amending the regulations to add the performance standard for *Salmonella* in fresh pork sausage, which was unavailable at the time the rule was published, and correct a minor editorial oversight.

**DATES:** This rule will be effective on January 13, 1998, unless adverse or critical comments are received on or before December 15, 1997. If adverse or critical comments within the scope of the rulemaking are received, FSIS will issue timely notice in the **Federal Register**.

**ADDRESSES:** Send an original and two copies of adverse written comments within the scope of the rulemaking to: FSIS Docket Clerk, DOCKET # 97-056DF, Room 102, Cotton Annex, 300 12th Street, SW, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700. Reference materials cited in this docket will be available for public inspection in the FSIS Docket Room from 8:30 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 final rule required all slaughter establishments to test for generic *E. coli* at a frequency based on production volume to verify that plants are meeting the established performance criteria. In the preamble to the final rule, FSIS solicited comments and information on a number of technical issues concerning the protocols for generic *E. coli* testing and announced that conferences would be held to discuss these issues.

The first conference was held on September 12 and 13, 1996. Participants discussed issues such as testing frequency, sampling procedures, and revision of the testing protocol to better account for differing establishment characteristics. In light of these comments, FSIS published the May 13, 1997, final rule "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems—Technical Amendments and Corrections" (62 FR 26211). The final rule made some changes to the *E. coli* testing requirements.

On May 8, 1997, FSIS held a follow-up conference "Technical Conference: Review of *E. coli* Testing." A panel of

industry and academia representatives made presentations about the on-going generic *E. coli* verification testing by establishments and discussed their observations and views. In response to information provided at the conference, FSIS is amending the sample collection procedures for turkeys and allowing flexibility for the collection of poultry to be sampled.

Currently, turkeys randomly selected for sampling must be rinsed in a buffer solution. The rinsing technique involves shaking a whole turkey carcass in a bag containing the buffer solution. Prior to the meeting, FSIS was aware of concerns regarding this process. At the meeting, commenters raised the issue and presented data that supports an alternative means of sample collection.

The primary concern regarding the current sampling technique for turkeys is the physical difficulty of shaking large turkeys (i.e., those that are 15 to 20 pounds). Also, some commenters have stated that the size of the turkeys makes it difficult to prevent sample contamination when the buffer solution is decanted from the sampling bag into the sample bottle for transportation to the laboratory. At the conference, data was presented which indicated that a sponging technique is more practical, and provides accurate and reliable results for microbiological sampling.

FSIS agrees that shaking turkeys in the bag may be difficult for individuals taking the sample and that sample contamination may occur. Because of the lack of data in support of an alternative method, FSIS has not previously adopted another sample collection method for turkeys. However, after reviewing the data presented at the conference, FSIS has determined that a sponge method for the collection of turkey samples is effective. Therefore, FSIS will amend the Pathogen Reduction/HACCP final rule to permit establishments to sample turkeys by sponging the back and thigh or to continue using the whole bird rinse procedure.

Data collected using the sponge technique will be evaluated using statistical process control techniques as required in the May 13, 1997, technical amendments final rule. FSIS has begun to develop m/M criteria for turkey samples collected by the sponge method and will release data from this baseline quarterly so that establishments can use them for statistical process control techniques. FSIS also is in the process of developing m/M criteria for cattle and swine samples collected by the sponge method. The results from FSIS's first quarter of the study is as follows: for cattle m=negative and M=1; for swine m=.1 and M=100.

Commenters also expressed concern about the difficulty in taking whole birds from the end of the chilling process, after the drip line, because the birds on the drip line are often high off the ground and hard to reach. FSIS understands this concern. In the technical amendments final rule, FSIS provided establishments with the option of taking birds from the end of the slaughter line for carcasses that are hot-boned. With this rule, FSIS is amending the regulations to permit birds to be taken at the end of the slaughter line for carcasses, if sampling at the end of the drip line is impracticable.

In the pathogen reduction/HACCP final rule, FSIS stated that it was in the process of developing a *Salmonella* performance standard for fresh pork sausages. That work has been completed and the performance standard will be added to the regulations. The performance standard is 30% (percent positive for *Salmonella*), the number of samples tested (n) equals 53, and the maximum number of positives to achieve the standard (c) equals 18. The methodology used to develop this performance standard was the same as for the other ground products. To further explain how the performance standard was developed, FSIS is making available copies of the paper "Estimation of *Salmonella* Prevalence in 25-gram Portions of Fresh Ground Pork" in the FSIS Docket Room.

Lastly, FSIS is making a technical correction to 9 CFR 417.2(e). The section should reference the Poultry Products Inspection Act (PPIA) and the Federal Meat Inspection Act (FMIA). FSIS inadvertently omitted references to sections 21 U.S.C. 456 and 463 of the PPIA and only referenced sections 21 U.S.C. 608 and 621 of the FMIA. Therefore, references to the PPIA authority will be added to this section.

FSIS expects no adverse public reaction resulting from this change in regulatory language. Therefore, unless the Agency receives adverse or critical comments within the scope of this rulemaking, or a notice of intent to submit adverse comments within the scope of this rulemaking within 30 days, the action will become final 60 days after publication in the **Federal Register**. If adverse comments within the scope of the rulemaking are received, the final rulemaking notice will be withdrawn and a proposed rulemaking notice will be published. The proposed rulemaking notice will establish a comment period.

**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 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 amendment do not change the cost and benefit estimates and impact assessments presented in the FRIA.

**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.

**Final Rules**

**List of Subjects**

*9 CFR Part 310*

Meat inspection, Microbial testing.

*9 CFR Part 381*

Poultry and poultry products, Microbial testing.

For 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 Table 2 in paragraph (b)(1) to read as follows:

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

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

TABLE 2.—SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance standard (percent positive for Salmonella) <sup>a</sup>	Number of samples tested (n)	Maximum number of positives to achieve standard (c)
Steers/heifers .....	1.0	82	1
Cows/bulls .....	2.7	58	2
Ground beef .....	7.5	53	5
Hogs .....	8.7	55	6
Fresh pork sausages .....	30	53	18

<sup>a</sup> Performance Standards are FSIS's calculation of the national prevalence of *Salmonella* on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of *Salmonella* on raw products are available in the FSIS Docket Room.)

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**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)(ii) to read as follows:

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

(a) \* \* \*

(2) Sampling requirements.

(ii) *Sample collection.* A whole bird must be taken from the end of the chilling process. If this is impracticable, the whole bird can be taken from the end of the slaughter line. Samples must be collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird. Samples from turkeys also may be collected by sponging the carcass on the back and thigh.<sup>1</sup>

\* \* \* \* \*

**PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

3. The authority citation for part 417 continues to read as follows:

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

<sup>1</sup> A copy of FSIS's "Guidelines for *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments" and "FSIS Turkey Microbiological Procedures for Sponge Sample Collection and Methods of Analysis" are available for inspection in the FSIS Docket Room.

**§ 417.2 Hazard Analysis and HACCP Plan.**

4. Section 417.2 is amended by revising paragraph (e) to read as follows:

\* \* \* \* \*

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

Done at Washington, DC, on November 4, 1997.

**Thomas J. Billy,**  
*Administrator.*

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**DEPARTMENT OF AGRICULTURE  
Food Safety and Inspection Service  
9 CFR Parts 331 and 381**

[Docket No. 97-050F]

**Designation of the State of Florida Under the Federal Meat Inspection Act and the Poultry Products Inspection Act**

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

**ACTION:** Final rule.

**SUMMARY:** Representatives of the State of Florida have advised the Agency that, because of a lack of funding, the State of Florida will no longer continue administering its State meat and poultry inspection programs after November 30, 1997. The Food Safety and Inspection Service (FSIS) is mandated by law to assume the responsibility, previously held by the State of Florida, for administering the meat and poultry inspection programs with respect to operations and transactions within the

State of Florida. Therefore, in accordance with the law, the Secretary of Agriculture is designating the State of Florida to receive Federal inspection with respect to operations and transactions within the State, and FSIS is amending the Federal meat and poultry inspection regulations by adding Florida to the list of "designated" States.

**DATES:** This final rule will be effective on December 2, 1997.

**FOR FURTHER INFORMATION CONTACT:** Dr. William Leese, Director, Federal-State Relations Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700 at (202) 720-6313.

**SUPPLEMENTARY INFORMATION:**

**Background**

Under section 301 of the Federal Meat Inspection Act (FMIA) and section 5 of the Poultry Products Inspection Act (PPIA), a State may administer State meat and poultry inspection programs provided the State has developed and is effectively enforcing State meat and poultry inspection requirements at least equal to those imposed under titles I and IV of the FMIA and section 1-4, 6-10, and 12-22 of the PPIA (collectively referred to below as the titles). These titles contemplate continuous ongoing programs. When States can no longer effectively enforce meat and poultry inspection requirements at least equal to Federal requirements, then they must be "designated" by the Secretary to receive Federal inspection.

In accordance with the FMIA and PPIA, the Secretary had determined that the State of Florida had developed and was enforcing State meat and poultry inspection requirements for establishments at least equal to Federal meat and poultry inspection