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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 304, 305, 327, 335, 381, and 500

[Docket No. 95–025F]

RIN 0583–AC34

Rules of Practice

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its rules of practice that apply to Agency enforcement actions. FSIS is defining each type of enforcement action that it may take, the conditions under which it is likely to take each of these actions, and the procedures that it will follow in doing so. This rule is part of FSIS's ongoing effort to consolidate, streamline, and clarify the meat and poultry product inspection regulations.

EFFECTIVE DATE: This rule is effective January 25, 2000.

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SUPPLEMENTARY INFORMATION:

Background

Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), the Secretary of Agriculture is charged with the responsibility of protecting the public health by assuring that meat and poultry products distributed in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. To accomplish this objective, the statutes require the Secretary to administer a comprehensive inspection program which includes examining live animals prior to slaughter, inspecting all carcasses to be used for human food, and inspecting facilities where meat and poultry products are produced or stored. FSIS has broad authority to issue regulations to carry out the provisions of the FMIA and PPIA, including authority to prescribe the terms and conditions under which inspection will be provided and maintained and pursuant to which the marks of inspection will be applied.

An establishment's failure to comply with regulatory requirements can result in the Agency's inability to determine that products are not adulterated as required by the inspection statutes. Accordingly, FSIS may find it necessary to take action to prevent the production and shipment of product until the Agency is assured that there is compliance with the statutes and their implementing regulations. For example, FSIS can refuse to grant an application for inspection. It can take regulatory control actions to retain product, to reject equipment or facilities, to slow or stop lines, or to refuse to allow the processing of specifically identified product. The Agency may refuse to allow the marks of inspection to be applied to products or suspend inspection by interrupting the assignment of program employees to all or part of an establishment. FSIS also can withdraw inspection or rescind or refuse to approve markings, labels, or containers.

FSIS takes these types of actions when an establishment fails to: (1) develop and implement a HACCP plan or operate in accordance with 9 CFR Part 417; (2) develop, implement, and maintain Sanitation Standard Operating Procedures (Sanitation SOP's) in accordance with 9 CFR Part 416; (3) conduct generic *E. coli* testing in accordance with 9 CFR 310.25(a) or 381.45(a); (4) comply with the *Salmonella* performance standard requirements prescribed in sections 9 CFR 310.25(b) or 381.94(b); (5) maintain sanitary conditions; (6) humanely slaughter livestock; or (7) destroy condemned product. FSIS also takes these actions when an applicant for inspection, a recipient of inspection, or anyone responsibly connected with the applicant or recipient is unfit to engage in business because of prior criminal convictions, or when establishment personnel assault, intimidate, or interfere with Federal inspection service.

When FSIS refuses to grant an application for inspection, seeks to withdraw inspection, or refuses to approve markings, labels, or containers, the Agency initiates an administrative action under USDA's ''Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes'' (7 CFR subtitle A, part 1, subpart H), as supplemented by FSIS's own ''Rules of Practice,'' which have been set out in 9 CFR part 335 for meat or part 381, subpart W, for poultry and are now replaced by 9 CFR part 500. FSIS's supplemental rules of practice also provide for the withholding of the marks of inspection and the suspension of inspection.

When public health is a concern, FSIS immediately suspends inspection until the problem is corrected. FSIS refuses to mark product as ''inspected and passed'' or retains an establishment's meat or poultry products if the Agency determines that meat or poultry products are adulterated or cannot determine, as required by the statutes, that those products are not adulterated. Such actions typically are discontinued when the adulterated products have been destroyed or properly controlled, or when the deficiencies or noncompliances are corrected satisfactorily. The current supplemental rules also provide for an opportunity to address and correct problems before the Agency files a formal administrative complaint to suspend or withdraw an establishment's grant of inspection.

On January 12, 1998, FSIS issued a proposed rule (63 FR 1797) to reorganize and revise its supplemental rules of practice to better ensure that its enforcement procedures are fair; to eliminate redundancy; to identify the situations that may lead FSIS to take enforcement action which may include refusing to grant or withholding the marks of inspection and suspending or withdrawing inspection; and to establish the procedures FSIS would follow in taking such actions.

Comments

FSIS received 64 comments in response to the proposed rule. Although the commenters supported the consolidation and streamlining of the

rules of practice, they raised concerns about the actual proposed revisions to the regulations. The following is a discussion of the commenters' issues.

1. FSIS Authority

Several commenters asserted that an establishment's failure to meet the *Salmonella* performance standards, to carry out and meet generic *E. coli* testing requirements, or to prevent a HACCP system failure would not provide an adequate basis to suspend or seek withdrawal of inspection. They contend that the FMIA and PPIA authorize FSIS to remove inspectors only when an establishment fails to follow sanitary practices, refuses to destroy condemned carcasses, fails to comply with the Humane Slaughter Act, or is convicted in a criminal proceeding.

FSIS disagrees with this assessment of the Agency's authority. Under the FMIA and the PPIA, FSIS is charged with the duty and the responsibility to protect the public health by developing and implementing an effective, comprehensive, and scientifically valid inspection system that will ensure that meat and poultry products are wholesome, not adulterated, and properly marked, labeled, and packaged. FSIS is required by these statutes to carry out continuous inspection of slaughter and processing operations at Federal establishments and to make the affirmative determination that the meat and poultry products produced at those establishments are wholesome and not adulterated prior to marking the products as ''inspected and passed.''

FSIS has specified, through regulations, the conditions under which meat and poultry products must be produced [the HACCP/Pathogen Reduction regulations]. These regulations are essential, integral components of the FMIA and PPIA inspection system, and the failure, inability, or unwillingness of an establishment to comply with these food safety regulations effectively precludes FSIS from making the statutorily-mandated determination that meat and poultry products are wholesome, not adulterated, and entitled to bear the legend ''inspected and passed.'' The inspection system provided for in the FMIA and PPIA is a continuous and real-time inspection program that, by its very nature, requires real-time and continuous inspection determinations. It is clear that the FMIA and the PPIA contemplate and authorize the Agency to take prompt and, if necessary, immediate action to carry out its public health responsibility to ensure that only products that are marked ''inspected and passed'' are shipped in commerce. It is the Agency view, therefore, that compliance with FSIS's food safety regulations, including the HACCP/Pathogen Reduction regulations, is a necessary predicate for inspection services and for the application of the marks of inspection under the FMIA and the PPIA, and that FSIS has inherent authority to withhold the marks, to suspend inspection services, and to withdraw inspection when these requirements are not satisfied.

In addition, FSIS is required to prescribe the rules and regulations for sanitation, with which slaughter and processing establishments must comply. The term ''sanitation'' is comprehensive and encompasses the array of procedures, practices, and controls employed by establishments to ensure that the products they produce are wholesome and not adulterated. Sanitation obviously includes procedures for the cleaning of equipment and facilities; proper sanitation also encompasses practices for ensuring the acceptability of incoming products and ingredients, proper product handling and preparation practices, controlling condemned product, and properly storing product. It is also FSIS's view that the SSOP requirements, the HACCP regulations, the *Salmonella* performance standards, and the generic *E. coli* testing requirements are material components of an effective sanitation program that is sufficient to meet the requirements of the FMIA and PPIA. For example, *E. coli* testing is prescribed in the HACCP/Pathogen Reduction regulations to verify that the establishment is employing sanitary dressing procedures to prevent the fecal contamination of carcasses. Also, the *Salmonella* performance standards were adopted to ensure that an establishment's procedures, practices, and controls, as embodied in its HACCP plans, are working properly. The Agency has ample statutory authority to withhold, suspend, or seek withdrawal, in accord with the facts of any particular case, when the Agency's sanitation requirements are not satisfied.

2. Due Process: Notice and Opportunity To Achieve Compliance

Commenters also raised concerns that the proposed rules did not provide adequate due process protections for establishments. The commenters argued, for example, that the taking of withholding actions by inspectors, and the resulting interruption of plant operations, without providing the establishment with notice of the deficiencies and an opportunity to demonstrate or achieve compliance is unreasonable and contrary to applicable law. Commenters underscored this point with particular focus on HACCP regulation noncompliances, contending that notice and opportunity to establish compliance were essential in such cases before taking withholding or suspension actions.

Some commenters believed that the proposed rules of practice were inconsistent with other FSIS regulations and policies related to the suspension of inspection. They cited, for example, the Quality Control (QC) regulations and the Progressive Enforcement Action program. Under these regulations and policies, in situations not involving the preparation and distribution of adulterated product, establishments were provided an opportunity to achieve compliance before FSIS terminated a QC program or imposed progressive sanctions.

FSIS is mindful that withholding the marks of inspection and suspending inspection services are significant enforcement actions to be taken only after careful evaluation of the facts and circumstances. At the same time, as discussed above, it is FSIS's statutory responsibility and duty to protect public health by maintaining an inspection system that will ensure that meat and poultry products produced and shipped in commerce are wholesome and not adulterated. FSIS agrees that fundamental fairness requires that appropriate due process be accorded establishments in connection with enforcement actions under the FMIA and PPIA. FSIS believes that the proposed rules of practice, as modified and specified in this document will, in fact, protect the due process rights of all establishments.

As we make clear in this final rule, FSIS will continue to provide notice and an opportunity to demonstrate or achieve compliance in situations where the violations and deficiencies disclosed by inspection or investigation do not, in the Agency's view, present a public health concern that requires immediate action. Where, however, noncompliance with the requirements of the acts and regulations indicates that continued production and shipment of product do pose, in the Agency's view, an imminent threat to public health, FSIS will take immediate action. Accordingly, section 500.3 of the rules of practice sets out the conditions under which FSIS may withhold the marks of inspection or suspend inspection without prior written notification and section 500.4 sets out the conditions under which FSIS may withhold the marks of inspection or suspend

inspection after providing prior written notification.

Commenters also argued that FSIS's noncompliance records (NRs) should not be deemed adequate to notify an establishment of the Agency's determination that there has been a ''system failure.''

It is FSIS's view that NRs do constitute valid and effective notice to an establishment that the establishment has not maintained regulatory compliance. An NR informs the establishment of the specific deficiency involved and on its face invites the establishment to respond to the finding and to present in writing its immediate and further planned corrective actions. The NR also specifically notes the right to appeal the inspector's finding and potential regulatory consequences of the NR.

When an NR is issued, it is incumbent upon the establishment to evaluate the NR carefully and to act upon and respond to it promptly and effectively. In particular, it is important that establishments address the NRs related to a HACCP plan noncompliance because such NRs may indicate that the plan is not working properly and should be reassessed. Accordingly, FSIS believes that should the Agency determine that it is necessary to withhold the marks of inspection or to suspend inspection because of multiple or recurring noncompliances, evidenced by NRs, the establishment will have been given appropriate notice as well as ample opportunity to demonstrate or achieve compliance.

Nonetheless, in cases where FSIS has determined that multiple or recurring noncompliances warrant the withholding of the marks of inspection or suspension of inspection, this final rule provides for written notification to the establishment before withholding or suspending inspection when the circumstances do not pose an imminent threat to public health.

Therefore, in response to the comments, FSIS is revising the regulatory language used in the proposed rule. This final rule lists the types of enforcement actions that the Agency may take and identifies the circumstances under which each action may be taken. This final rule also clarifies the procedures FSIS will follow to provide, when appropriate, prior notification to establishments.

Section 500.1 defines a ''regulatory control action,'' ''withholding action,'' and ''suspension.'' A regulatory control action is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product. A withholding action is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all products in the establishment or product produced by a particular process. A suspension is an interruption of the assignment of program employees to all or part of an establishment.

Section 500.2 states that FSIS may take a regulatory control action because of insanitary conditions or practices, product adulteration or misbranding, conditions that preclude FSIS from determining that product is not adulterated or misbranded, or inhumane handling or slaughtering of livestock. These control actions are necessary, indeed essential, in-plant enforcement tools for inspectors to use in cases where the noncompliance is willful or involves public health, interest, or safety. Typically, regulatory control actions involve specific amounts of product or generally well-defined deficiencies such as crushed and open cartons or malfunctioning equipment. If FSIS takes a regulatory control action, it will immediately notify the establishment orally or in writing of the action and of the basis for the action. An establishment may appeal a regulatory control action, as provided in 9 CFR 306.5 and 381.35.

Withholding actions are generally more significant than regulatory control actions and affect a larger part of an establishment or the establishment's processes. In most cases, in-plant inspection personnel take these actions because of systemic problems, such as HACCP plan inadequacies. Typically, the actions necessary to correct the problem that resulted in a withholding action are more complex than those necessary to resolve a problem that resulted in a regulatory control action and are likely to require an establishment to accomplish a HACCP plan reassessment and make any necessary plan modification or to revise its Sanitation SOP.

A suspension of inspection is likely to have an even more significant impact on an establishment than a withholding action. Typically, an FSIS District Manager or Agency official at a higher level suspends inspection after an establishment fails to correct a situation involving a withholding action, or when the nature of the noncompliances are such that the corrective action, such as HACCP plan reassessment or changes in the establishment's operation, may take a significant amount of time to implement.

Section 500.3 states that FSIS may take a withholding or suspension action without providing the establishment prior notification because the establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602; the establishment does not have a HACCP plan as specified in section 417.2 of the regulations; the establishment does not have Sanitation SOPs as specified in sections 416.11–416.12 of the regulations; sanitary conditions are such that any products in the establishment are or would be rendered adulterated; an establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; the establishment violated the terms of a regulatory control action; or the establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, in accordance with 9 CFR part 314 or part 381, subpart L, within three days of notification. FSIS also may impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely.

Section 500.4 states that FSIS may take a withholding action or impose a suspension after the Agency provides an establishment prior notification and the opportunity to demonstrate or achieve compliance because the HACCP system is inadequate, as specified in 9 CFR 417.6, due to multiple or recurring noncompliances; the Sanitation SOPs have not been properly implemented or maintained as specified in 9 CFR 416.13–16; the establishment has not maintained sanitary conditions as prescribed in 9 CFR 416.2–416.8 due to multiple or recurring noncompliances; the establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results in accordance with 9 CFR 310.25(a) or 381.94(a); or the establishment did not comply with the *Salmonella* performance standard requirements prescribed in 9 CFR 310.25(b) or 381.94(b).

Section 500.5 states that if FSIS takes a withholding action or imposes a suspension without prior written notification, the Agency will notify the establishment orally and, as promptly as circumstances permit, in writing. The written notification will provide the effective date of the action, reasons for the action, products or processes affected by the action, opportunity for the establishment to present immediate corrective action and further planned preventive action, and the appeals procedures. This section also addresses the prior notification provided for in section 500.4. This prior notification will state the type of action that may be

taken; describe the reason for the proposed action; identify the products or processes affected by the proposed action; advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has been or will be achieved; and advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.

The provisions in section 500.5 also reiterate that an establishment may appeal the withholding action or suspension, as provided in section 9 CFR 306.5 and 381.35. Also, this section provides that if FSIS suspends inspection and does not hold the suspension action in abeyance, the establishment may request a hearing pursuant to the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H. Upon such request, the Administrator will file a complaint that will include a request for an expedited hearing.

Section 500.6 addresses withdrawal of inspection, and section 500.7 addresses refusal of inspection. These provisions are substantially unchanged from the January 1998 proposal. When FSIS withdraws or refuses inspection, the Agency initiates an administrative action under USDA's Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes (7 CFR subtitle A, part 1, subpart H). Also, FSIS made no significant changes, other than renumbering the sections, to the provisions that relate to rescinding or refusing approval of marks, labels, and containers, (section 500.8) and refusing or withdrawing inspection for applicants or recipients unfit to engage in business (sections 500.6 and 500.7).

3. Appropriateness of Other Aspects of the Regulations

Some commenters suggested that FSIS should better explain the Agency's practice of allowing an establishment to operate while under a suspension if the establishment presents adequate written assurances that corrective actions are being implemented.

It has been FSIS's experience that some establishments, upon being notified that the Agency intends to suspend inspection, offer a plan to address the circumstances that caused FSIS to issue the notification. In these cases, FSIS has concluded that, even though the basis for a suspension existed, it was appropriate to hold the suspension in abeyance and to allow the establishment to continue to operate under its proposed corrective and preventive actions.

Section 500.5(e) states that FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.

Some commenters suggested that there should be a third-party review of an establishment's response to the notification of the Agency's intent to take an enforcement action, and that this third party should make the decision on whether the enforcement action is warranted.

FSIS concluded that such third-party review is not appropriate under the meat and poultry inspection statutes. The Agency is required to make the determination that the statutes and regulations have been complied with, and that the products produced meet the statutory requirements. The suggested procedure is clearly inconsistent with the statutory authority and plan embodied in the FMIA and PPIA and would be impractical and contrary to the public interest.

A number of commenters raised concerns about FSIS's appeal policy. Some recommended provisions for alternative dispute resolution instead of an administrative hearing before an Administrative Law Judge in cases where there is a scientific dispute. Under the provisions submitted by the commenters, the Agency would create a standing panel of expert advisors to be called upon on an as needed basis. The establishment and the Agency would be permitted to call witnesses and present relevant evidence, especially scientific evidence, to the panel. The panel's decision along with any dissenting views would be written and shared with the establishment and the Agency. The Administrator, as the ultimate decisionmaker for the government, would give the panel's decision due consideration. Other commenters suggested that FSIS establish a special appeals resolution team in the Technical Service Center to which all appeals from inspection decisions would automatically be sent. Some commenters urged FSIS to specify how long it will take to resolve appeals, to allow establishments to continue operating while an appeal of an FSIS decision to suspend or withdraw inspection is pending, except in the event of an ''imminent hazard to health,'' and to reimburse regulated establishments for losses during ''down time'' when they win an appeal from an inspection decision.

As stated in the proposed rule, FSIS is committed to providing establishments with appropriate notice and an effective opportunity to appeal withholding actions and suspensions of inspection. It recognizes the need for timely resolution of all such appeals. The Agency intends to develop regulations to address how appeals are handled. However, since there were no proposed regulations on appeals included in the proposed rules of practice, establishing such rules in this document is outside the scope of this rulemaking. FSIS plans to issue a proposed rulemaking related to the appeals process at a later date.

Until new regulations on appeals are in place, appeals will continue to be heard through the ''chain-of-command'' process, which is incorporated into FSIS's existing regulations (9 CFR 306.5 and 381.35). In an attempt to ensure the timely review of appeals, FSIS issued FSIS Notice 14–98 on April 20, 1998. This notice explains FSIS's policy regarding the appeal of inspection findings and decisions. It also established the Inspection Appeals Tracking System (IATS) report which the Agency uses to help ensure a timely response to appeals.

Some commenters stated that FSIS should not delete the provisions in section 335.13. In this regulation, FSIS stated that it will notify an establishment of what actions are necessary to correct an insanitary condition and of the time within which corrections must be made.

It is an establishment's responsibility to identify problems and to determine how best to correct them. Section 335.13 appeared by its terms to place the burden for devising and correcting insanitary conditions on the Agency. Such regulations are not consistent with the Pathogen Reduction/HACCP approach. The Agency will identify problems when an establishment fails to do so, but it is the establishment's responsibility to identify problems on a continuing basis and to identify, select, and implement effective action to correct noncompliances. FSIS will verify that establishments have taken the necessary corrective actions. Accordingly, FSIS is removing section 335.13.

Commenters also questioned the elimination of section 335.40, ''Present Your Views (PYV)'' provisions, which allow establishments believed to have violated the FMIA an opportunity to present their views to the Agency regarding an alleged criminal violation before FSIS refers the violation to the Department of Justice for prosecution. The commenters pointed out that the PYV provisions are a statutory entitlement for poultry processors, and that by rescinding the regulations, the

Agency is backing away from equity between meat and poultry.

After consideration of these comments, FSIS has reconsidered its proposal and will not remove Part 335, Subpart E.

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 made a determination 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).

There are no direct costs or benefits associated with this final rule. Costs and benefits are related to the regulatory actions, not the proceedings. At the present time, there is no way to predict whether industry ''down time'' will increase or decrease under these revised rules of practice. To the extent that resolution of disputes in a timely and efficient manner will be facilitated by these rules, there are potential benefits to consumers, industry, and the government. When disputes are related to public health issues, FSIS may reduce health risks to consumers by stopping an establishment's operations until the problem has been resolved.

There are also costs to industry associated with actions that suspend production operations.

Executive Order 12988

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

Paperwork Requirements

This final rule does not include any new paperwork requirements.

Additional Public Notification

In an effort to better ensure that minorities, women, and persons with disabilities are made aware of this final rule, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update.

FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at *http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** Notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information with a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Office of Congressional and Public Affairs, at (202) 720–5704.

List of Subjects

9 CFR Part 304

Meat inspection.

9 CFR Part 305

Meat inspection.

9 CFR Part 327

Imports, Meat inspection.

9 CFR Part 381

Poultry and poultry products.

9 CFR Part 500

Rules of practice.

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

PART 304—APPLICATION FOR INSPECTION; GRANT OF INSPECTION

1. The authority citation for part 304 continues to read as follows:

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

2. Part 304 is amended by revising the heading to read as set forth above, and amending § 304.2 by removing paragraphs (c) and (e), redesignating paragraph (d) as paragraph (c), and revising the last sentence of paragraph (b) to read as follows:

* * * * *

§ 304.2 Information to be provided.

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(b) * * * Any application for inspection may be refused in accordance with the rules of practice in part 500 of this chapter.

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PART 305—OFFICIAL NUMBERS; INAUGURATION OF INSPECTION; WITHDRAWAL OF INSPECTION; REPORTS OF VIOLATION

3. The authority citation for part 305 continues to read as follows:

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

§ 305.5 [Removed]

4. Part 305 is amended by removing § 305.5.

PART 327—IMPORTED PRODUCTS

5. The authority citation for part 327 continues to read as follows:

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

6. Section 327.6 is amended by removing the last four sentences in paragraph (f) and adding in their place one sentence to read as follows:

§ 327.6 Products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers

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(f) * * * Any application for inspection under this section may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

PART 335—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE FEDERAL MEAT INSPECTION ACT

§§ 335.1–335.32 (Subparts A—D [Removed]

7. Part 335 Subparts A through D (§§ 335.1–335.32) are removed. Subpart E—Criminal Violations is redesignated as Subpart A.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

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

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

9. Section 381.21 is amended by removing paragraphs (a), (b), and (c); redesignating paragraph (d) as (b); and adding a new paragraph (a) to read as follows:

§ 381.21 Refusal of inspection.

(a) Any application for inspection in accordance with this part may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

* * * * *

§ 381.29 [Removed]

10. Part 381 is amended by removing § 381.29.

§§ 381.230–381.236 (Subparts VI) [Removed]

11. Part 381 is amended by removing Subpart W (§§ 381.230—381.236).

SUBCHAPTER E—REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

12. Subchapter E is amended by adding a new Part 500 to read as follows:

PART 500—RULES OF PRACTICE

Sec.

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

§ 500.1 Definitions.

(a) A ''regulatory control action'' is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

(b) A ''withholding action'' is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.

(c) A ''suspension'' is an interruption in the assignment of program employees to all or part of an establishment.

§ 500.2 Regulatory control action.

(a) FSIS may take a regulatory control action because of:

(1) Insanitary conditions or practices;

(2) Product adulteration or misbranding;

(3) Conditions that preclude FSIS from determining that product is not adulterated or misbranded; or

(4) Inhumane handling or slaughtering of livestock.

(b) If a regulatory control action is taken, the program employee will immediately notify the establishment orally or in writing of the action and the basis for the action.

(c) An establishment may appeal a regulatory control action, as provided in sections 306.5 and 381.35 of this chapter.

§ 500.3 Withholding action or suspension without prior notification.

(a) FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:

(1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602;

(2) The establishment does not have a HACCP plan as specified in § 417.2 of this chapter;

(3) The establishment does not have Sanitation Standard Operating Procedures as specified in §§ 416.11–416.12 of this chapter;

(4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;

(5) The establishment violated the terms of a regulatory control action;

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

(7) The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, in accordance with part 314 or part 381, subpart L, of this chapter within three days of notification.

(b) FSIS also may impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely.

§ 500.4 Withholding action or suspension with prior notification.

FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:

(a) The HACCP system is inadequate, as specified in § 417.6 of this chapter, due to multiple or recurring noncompliances;

(b) The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§ 416.13 through 416.16 of this chapter;

(c) The establishment has not maintained sanitary conditions as prescribed in § § 416.2 through 416.8 of this chapter due to multiple or recurring noncompliances;

(d) The establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results in accordance with §§ 310.25(a) or 381.94(a) of this chapter;

(e) The establishment did not meet the *Salmonella* performance standard requirements prescribed in §§ 310.25(b) or 381.94(b) of this chapter.

§ 500.5 Notification, appeals, and actions held in abeyance

(a) If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:

(1) State the effective date of the action(s),

(2) Describe the reasons for the action(s),

(3) Identify the products or processes affected by the action(s),

(4) Provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and

(5) Advise the establishment that it may appeal the action as provided in §§ 306.5 and 381.35 of this chapter.

(b) The prior notification provided for in § 500.4 of this part will:

(1) State the type of action that FSIS may take;

(2) Describe the reason for the proposed action;

(3) Identify the products or processes affected by the proposed action;

(4) Advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has been or will be achieved; and

(5) Advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.

(c) An establishment may appeal the withholding action or suspension, as provided in §§ 306.5 and 381.35 of this chapter.

(d) If FSIS suspends inspection and does not hold the suspension action in abeyance as provided in paragraph (e) of this section, the establishment may request a hearing pursuant to the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H. Upon such request, the Administrator will file a complaint that will include a request for an expedited hearing.

(e) FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.

§ 500.6 Withdrawal of inspection.

The FSIS Administrator may file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H because:

(a) An establishment produced and shipped adulterated product;

(b) An establishment did not have or maintain a HACCP plan in accordance with part 417 of this chapter;

(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]

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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.