PART 500—RULES OF PRACTICE

Sec.

AUTHORITY: 21 U.S.C. 451–470, 601–695, 1031–1056; 7 U.S.C. 450, 1901–1906; (33 U.S.C. 1251 *et seq.*); 7 CFR 2.18, 2.53.

SOURCE: 64 FR 66546, Nov. 29, 1999, unless otherwise noted.

§ 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; and (d) An establishment subject to Federal inspection or facility receiving voluntary inspection services under the regulations is ''adversely affected'' when that person has a legally cognizable interest, and the decision or action has caused or is substantially likely to cause injury to that interest.

[64 FR 66546, Nov. 29, 1999, as amended at 87 FR 63424, Oct. 19, 2022]

§ 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 §§ 306.5, 381.35, and 590.310 of this chapter.

[64 FR 66546, Nov. 29, 1999, as amended at 85 FR 68672, Oct. 29, 2020; 85 FR 81340, Dec. 16, 2020]

§ 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, 21 U.S.C. 602, or 21 U.S.C. 1033;

(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, or egg product, that has been found to be adulterated and that has not been reprocessed, in accordance with part 314 or part 381, subpart L, or part 590 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.

[64 FR 66546, Nov. 29, 1999, as amended at 85 FR 68673, Oct. 29, 2020; 85 FR 81340, Dec. 16, 2020]

§ 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 §§ 416.2–416.8 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, 381.35, and 590.310 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, 381.35, and 590.310 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.

[64 FR 66546, Nov. 29, 1999, as amended at 85 FR 68673, Oct. 29, 2020; 85 FR 81340, Dec. 16, 2020]

§ 500.6 Withdrawal of inspection.

(a)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:

(1) An establishment produced and shipped adulterated product;

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

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

(4) An establishment did not maintain sanitary conditions;

(5) 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;

(6) [Reserved]

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

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

(9) 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, section 18(a) of the PPIA, or section 18 of the EPIA.

(b) [Reserved]

[64 FR 66546, Nov. 29, 1999, as amended at 79 FR 49637, Aug. 21, 2014; 85 FR 68673, Oct. 29, 2020; 85 FR 81340, Dec. 16, 2020]

§ 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, subpart H of part 381, part 416, or part 590 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.

[64 FR 66546, Nov. 29, 1999, as amended at 85 FR 68673, Oct. 29, 2020; 85 FR 81340, Dec. 16, 2020]

§ 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, poultry, or egg product, under section 7 of the FMIA, under section 8 of the PPIA, or under sections 7 or 14 of the EPIA.

(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, poultry, or egg 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.

[64 FR 66546, Nov. 29, 1999, as amended at 85 FR 68673, Oct. 29, 2020; 85 FR 81340, Dec. 16, 2020]

§ 500.9 Procedures for the filing of appeals.

(a) Any establishment subject to Federal inspection or facility under voluntary inspection and adversely affected by a decision or action of an inspector or other Agency employee related to an inspection activity mandated under the FMIA, PPIA, or EPIA or related to voluntary reimbursable inspection services allowed under the AMA may appeal the decision or action. Initial appeals of an applicable decision or action, as well as subsequent appeals of denied appeals through final Agency action, must be made within 30 calendar days after receipt of written notification of the contested decision or action. Appeals may be supported by any argument or evidence that the appellant may wish to offer as to why the contested decision or action should be reconsidered.

(b) Any initial appeal of a decision or action of an inspector or other Agency employee must be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal.

[87 FR 63424, Oct. 19, 2022]