

§ 500.4

9 CFR Ch. III (1–11 Edition)

§ 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 non-compliances;

(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 non-compliances;

(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.