

RULES OF PRACTICE

Objectives

To demonstrate mastery of Rules of Practice, the trainee will

- 1) Define the following terms
 - a) inspection
 - b) enforcement
 - c) compliance
 - d) due process
 - e) Rules of Practice
 - f) regulatory control action
 - g) withholding
 - h) suspension
 - i) Notice of Intended Enforcement Action
 - j) abeyance
- 2) Identify circumstances where prior notice of enforcement action is not required
- 3) Identify circumstances where prior notice of enforcement action is required
- 4) Identify the appeals process

Overview

The goal of FSIS is to protect public health by maximizing compliance with laws and regulations governing the production of meat and poultry products. The food-producing establishment has the responsibility to comply with the regulations and to produce a safe and wholesome food product. FSIS has the responsibility to verify that the establishment meets regulatory requirements. You ensure that establishments adhere to food safety regulations by conducting inspection verification activities and taking enforcement action when needed to ensure food safety compliance.

Let's clarify the meaning of some of these terms. **Inspection** includes all actions the Agency may take to examine the establishment and its processes, products, and systems. **Enforcement actions** are those the Agency takes when an inspector determines that the establishment's plans and systems are not in compliance with laws and regulations. There is a range of enforcement actions that FSIS uses. Some examples of enforcement actions are regulatory control actions such as slowing or stopping the slaughter line, rejecting equipment or processing locations, or retaining product; withholding actions; or the suspension of inspection. We will discuss these actions in more detail later in this module.

The **Rules of Practice**, 9 CFR 500, are FSIS's enforcement regulations. **Compliance** means that the establishment's processes are working properly in accordance with the laws and regulations.

Establishments have the right to do business and are guaranteed due process of law. The Constitution guarantees that the government cannot take away a person's basic rights to 'life, liberty or property, without due process of law.' "***Due process rights***" means that a fair "*process*" or proceeding, must take place before the government interferes with an individual's property or actions. This process might include notifications, hearings, or other activities. By following the Rules of Practice regulations, 9 CFR 500, FSIS assures that appropriate due process takes place.

As you perform your official duties, it is important to **balance the plant's right to do business with FSIS's obligation to protect the public's right to safe food**. Plants have a right to expect that FSIS will be fair and consistent, provide details about enforcement concerns, promptly respond to appeals, and provide the opportunity for correction. The Rules of Practice provide FSIS officials with the tools to ensure compliance by plants producing meat and poultry products, and the processes for FSIS to control product or stop production when plants fail to meet HACCP and other food safety requirements.

The Rules of Practice were published so that establishments will know the types of enforcement actions FSIS takes, and the processes FSIS uses to accomplish those actions. They notify plant management of their right to appeal enforcement decisions made by inspection program personnel. They also notify plant management that if FSIS suspends inspection the establishment may request a hearing.

It's important to remember that the Rules of Practice are regulations. Just as the establishment has to follow regulations in producing safe product, FSIS has to follow rules in the way we take action on violations we find. The Rules of Practice are regulations that USDA has adopted that apply to inspection personnel.

In this training, we will focus on the parts of the Rules of Practice regulations that apply to inspection verification activities. It is important for you to understand the Rules of Practice, so that you can do your job properly. The agency expects every inspection program employee to follow the Rules of Practice when you take any enforcement action as part of your regulatory duties. The rules of practice are explained in FSIS Directive 5000.1, Chapter IV - Enforcement.

**Rules of Practice
Part 500**

Sec. 500.1
Definitions

Sec. 500.2
Regulatory Control Action

Sec. 500.3
Withholding/Suspension
Without Prior Notification

Sec. 500.5(a)
Notification



Sec. 500.4
Withholding/Suspension
With Prior Notification

Sec. 500.5(b)
Notification



Sec 500.6
Withdrawal of Inspection

Sec 500.7
Refusal to Grant
Inspection

Sec 500.8
Rescinding or Refusing
Approval of Labels

Rules of Practice Regulation

Sec. 500.1 Definitions.

There are three types of enforcement actions defined in the regulation. (Note that material taken directly from the regulations will be set off in indentations.)

9 CFR 500.1 (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.

Regulatory control action is most commonly used by in-plant inspection personnel. This term refers to any action that inspection personnel take to control product or processes. Inspection personnel use regulatory control actions to identify regulatory noncompliance and prevent the movement of the product or use of the equipment or facility until the noncompliance has been corrected. A common example is the application of the FSIS reject/retain tag.

Withholding actions withhold the marks of inspection. Such actions may be taken against product produced by a particular process or all products in the plant. Withholding is a more severe enforcement action than a regulatory control action, because it can affect a larger part of an establishment or establishment processes. The decision to take an immediate withholding action can be made by whomever is in charge for FSIS at the establishment (for example, the IIC or designee), the frontline supervisor; or the District Office (DO).

Suspension refers to the interruption in the assignment of inspection personnel to the plant. A suspension of inspection also has a severe impact on an establishment. A suspension is usually in effect for a much longer duration of time than a withholding action. Because a federally inspected establishment cannot legally apply marks of inspection to product without an assigned inspector, this action stops all production, or it can be applied to a specific production process. For example, FSIS may suspend all inspection at a beef slaughter and processing plant. The decision to suspend inspection is made at the District Office, or higher level of authority.

There are several other types of enforcement actions that we will cover later, including withdrawal of a Federal grant of inspection, rescinding or refusing approval of marks, and refusal to grant inspection.

Sec. 500.2 Regulatory control action.

This regulation lists provisions for a regulatory control action.

9 CFR 500.2 (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 Secs. 306.5 and 381.35 of this chapter.

Regulatory control actions are taken when there is danger of adulterated, contaminated, misbranded, or hazardous product leaving the plant. Examples of such circumstances include:

- **Insanitary conditions** likely to result in contamination of product, such as a piece of equipment that contains residue from the previous day's production found during pre-op inspection.
- **Product adulteration**, such as condensation dripping directly into a bin of meat.
- **Conditions in the plant that prevent an inspector from deciding that product is not adulterated**, such as intensity of light being not adequate to determine whether product is adulterated.

Regulatory control actions are taken in **situations that require immediate correction**. It is not necessary to notify the establishment in advance. Once the action is taken, however, the Rules of Practice regulations require that the inspection personnel taking the action immediately notify plant management. This can be done orally or in writing. The written notification will be a noncompliance record (NR). The NR documents the noncompliance, and the description should include any FSIS reject/retain tag numbers issued.

The regulations also specify that the establishment has the right to appeal a regulatory control action to the next level of FSIS supervision.

Sec. 500.3 Withholding action or suspension without prior notification.

The Rules of Practice regulation also identifies situations where FSIS may take withholding or suspension actions without giving the plant prior notification. Withholding the marks of inspection and suspending inspection services are significant enforcement actions and are taken only after careful evaluation of the facts and circumstances.

<p>9 CFR 500.3 (a) FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:</p> <ul style="list-style-type: none">(1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 601;(2) The establishment does not have a HACCP plan as specified in Sec. 417.2 of this chapter;(3) The establishment does not have Sanitation Standard Operating Procedures as specified in Secs. 416.11-416.12 of this chapter;(4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;...

In most cases, in-plant personnel take these enforcement actions because the situation involves an imminent threat to public health. FSIS can immediately take a withholding action or suspension without giving the plant prior notification in order to protect the public health, but inspection program personnel must be able to document the imminent threat to public health. If FSIS takes a withholding action or imposes a suspension without providing prior notification, the establishment must be notified orally and then, as promptly as the circumstances permit, in writing. As stated earlier, the decision to take a withholding action can be made by the IIC or designee, the Frontline Supervisor, or the DO, whereas the decision to suspend is made only at the DO level or higher.

FSIS may also take enforcement action without prior notification if the plant has violated the terms of a regulatory control action, has threatened or intimidated an FSIS employee, did not destroy condemned product, or handled animals inhumanely.

Sec. 500.4 Withholding action or suspension with prior notification.

If a withholding or suspension action is based on any reason other than those listed in §500.3, FSIS must provide the plant written notice before taking the action.

9 CFR 500.4 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 Sec. 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 Secs. 416.13 through 416.16 of this chapter;
- (c) The establishment has not maintained sanitary conditions as prescribed in Secs. 416.2-416.6 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 Sec. 310.25(a) or Sec. 381.94(a) of this chapter;
- (e) The establishment did not meet the *Salmonella* performance standard requirements prescribed in Sec. 310.25(b) or Sec. 381.94(b) of this chapter.

The determination to take withholding or suspension actions against the establishment requires that the Agency has compiled extensive information and analyzed it carefully. It is only reasonable to provide the establishment with this information in advance of any action. This gives the establishment an opportunity to provide a response to the notification, to point out any factual errors made by the Agency, identify scientific or technical disagreements, and articulate differing interpretations of regulatory requirements. Often these enforcement actions are based on repetitive noncompliance, such as systemic problems with the SSOP or HACCP systems. It is critical that inspection personnel properly document and, when appropriate, show a pattern of noncompliance and the failure of the establishment's corrective and preventive actions.

The purpose of prior notification is to provide the establishment with due process rights as required by USDA regulations and the U.S. Constitution. The establishment is provided an opportunity to respond and to demonstrate compliance before FSIS takes the enforcement action when the circumstances do not pose an imminent threat to public health.

Sec. 500.5 Notification, appeals, and actions held in abeyance.

9 CFR 500.5 (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 Secs. 306.5 and 381.35 of this chapter.

(b) The prior notification provided for in Sec. 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 Secs. 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.

Notice of Intended Enforcement (NOIE)

If the IIC believes that a withholding or suspension seems to be warranted, he or she discusses the noncompliance situation with the Frontline Supervisor and the District Office, and requests that an NOIE be issued to the establishment. An NOIE is issued for noncompliances that do not pose an imminent threat to public health, but, that may warrant a withholding or suspension if not corrected. The Notice of Intended Enforcement (NOIE) will be issued to the plant by the District Manager (DM).

A NOIE provides notification to an establishment that there is a basis for FSIS to withhold the marks of inspection or to suspend inspection. The NOIE must contain specific information including the action FSIS intends to take and the effective date of the action, the reason for the proposed action, and the operations, products, or processes affected. The NOIE provides the establishment an opportunity to present immediate corrective action and further planned preventive action. The NOIE also notifies the establishment that it has three business days to contest the basis for the proposed enforcement action or to demonstrate how compliance has been or will be achieved. This means that in the absence of a response from the establishment which includes the information requested, FSIS will take an enforcement action in three days.

When the DM receives the establishment's response to an NOIE, he or she will evaluate it and then decide whether inspection should be withheld or suspended. The DM determines whether the establishment's proposed action plan addresses the problem and, if effectively implemented, will ensure regulatory requirements are met. The DM will consider the establishment's history when determining whether the establishment is likely to implement its proposed actions effectively. DMs may contact staff members from the Technical Service Center and other agency offices for assistance in making decisions.

Upon assessing and evaluating the establishment's response, the DM may decide to:¹

- a. accept the establishment's plan,
- b. implement the appropriate enforcement action, or
- c. defer his or her decision.

a. Under what circumstances would a DM accept the establishment's response?

If the establishment responds within the specified time frame, has demonstrated that compliance has already been achieved, or provides a description of acceptable corrective and preventive actions from which the DM can determine that compliance will be achieved upon implementation, the DM can

- accept the response,
- notify the establishment of the decision,
- ensure that the establishment implements the corrective and preventive actions in a timely manner, and
- close the matter with a **Letter of Information (LOI)** to the establishment.

The DM will also include a **verification plan**, which will explain FSIS's plans for verifying the proposed actions.

¹ From FSIS Directive 5000.1

b. Under what circumstances could a DM implement an enforcement action?

If the establishment does not respond or, based on the assessment and evaluation of all pertinent information, the DM finds that compliance cannot or will not be achieved upon implementation, the DM will implement the enforcement action. In those instances involving

i. withholding actions, the DM instructs the IIC to impose the withholding action and notifies the establishment as specified in the regulations. The DM's notification must include the basis for his or her decision.

ii. suspension actions, the DM instructs the IIC to suspend inspection and notifies the establishment as specified in the regulations. The DM's written notification to the establishment, the **Notice of Suspension**, will include the basis for his or her decision.

c. Under what circumstances can a DM defer an enforcement decision?

1. A DM may defer an enforcement decision when he or she has substantial reason to believe that the establishment's proposed corrective and preventive action are adequate to eliminate the noncompliance but lacks the substantive and supporting evidence that he or she needs to make a definite decision. For example, a plant may submit an apparently adequate proposed plan and have a good history of executing its HACCP plan, but not include sufficient documentation to enable the DM to determine that the proposed plan, once executed, will prevent recurrence. In this situation, a DM may choose to defer the enforcement decision and allow the establishment to implement the plan until it can be determined whether the plan is effective. The DM will make a decision on the adequacy of the preventive action as soon as sufficient information becomes available. The DM will notify the establishment in writing, with a **Notice of Deferral**, about the reasons that the decision has been deferred. The DM will also include a verification plan, which will explain FSIS's plans for verifying the proposed actions.

2. If the DM determines that the establishment's plan is adequate, the DM will accept the response, notify the establishment of the decision, ensure that the establishment implements the corrective and preventive actions in a timely manner, and close the matter with a Letter of Information to the establishment.

3. If, at any time, during a period of deferment, the establishment fails to adhere to the proposed action plan, and the DM determines that an enforcement action is warranted, the DM will instruct the IIC to either impose a withholding action or effect the suspension. The DM will immediately notify the establishment management of this decision and the basis for it.

Notice of Suspension Held In Abeyance

There are circumstances when the DM has suspended inspection, and then may subsequently decide to hold that suspension in abeyance as specified in 9 CFR 500.5. ***Suspension held in abeyance*** means that the suspension is temporarily lifted, and the plant is allowed to operate under conditions agreed upon by FSIS and the establishment.

Under what circumstances could the DM hold a suspension in abeyance?

1. When a DM has suspended inspection, he or she may subsequently decide to hold that suspension in abeyance if

a. the establishment presents a plan that demonstrates that the establishment has designed corrective and preventive actions that meet the appropriate regulatory requirements and appears adequate to eliminate the noncompliance; and

b. it is necessary to allow the establishment to operate after implementing these corrective and preventive actions so that FSIS can determine whether the establishment is able to adequately execute the plan. The DM will not hold a suspension in abeyance until the corrective and preventive actions are implemented. The establishment will be notified in writing about the reasons for this decision with a Notice of Suspension Held in Abeyance. This letter will also explain FSIS's plans for verifying the corrective and preventive actions, and a copy of the FSIS Verification Plan will be included. The suspension is closed, or ended, with a Letter of Warning.

2. If the establishment has a history of failing to meet the criteria discussed above, the DM may decide not to accept the establishment's plan.

3. If the DM decides to put the suspension in abeyance, and the establishment fails to either meet regulatory requirements or maintain regulatory compliance, during the abeyance period, the DM may lift the abeyance and put the suspension back in effect. This is called a reinstatement of suspension. If this occurs, the DM will instruct the IIC to suspend inspection and immediately notify the establishment management. The establishment will be provided a written ***Notice of Reinstatement of Suspension*** which explains the basis of this decision.

Note: When the CSI rotates into a new assignment or is assigned to an establishment for the first time, he or she should familiarize him/herself with previous noncompliance issues and any enforcement action that may have been taken against the establishment. He or she should contact the Frontline Supervisor (FLS) or EIAO if additional information is needed. The FLS or EIAO should discuss with the newly assigned CSI the corrective and preventive

measures taken by the establishment for noncompliances in the last 90 days and inform him or her of any enforcement action that has been deferred or if a suspension has been held in abeyance at the establishment. The FLS or EIAO should explain the Agency's expectations for verifying the effectiveness of the corrective and preventive measures identified in the verification plan that were proffered by the establishment and what led to the to the decision to defer the enforcement action or hold the suspension in abeyance.

Appeal Process

FSIS regulations, 9 CFR 306.5 and 9 CFR 381.35, provide plants with the opportunity to appeal any inspection decision. An appeal is part of a plant's due process according to the Rules of Practice. If FSIS program personnel issue an NR, the plant can appeal the whole decision or part of the decision. Any enforcement action taken in accordance with the Rules of Practice, 9 CFR 500, may also be appealed.

A plant should file an appeal without fear of retaliation. FSIS encourages plants to appeal decisions they believe are unfair or are not consistent with applicable standards. The appeal process is a mechanism for ensuring that any disagreements between plant managers and FSIS program personnel are reviewed.

The appeal process follows the Office of Field Operations (OFO) chain of command. The chain of command ensures that program employees most familiar with the appeal facts evaluate the appeal first to minimize response time. The chain of command also allows a plant to appeal to the next highest level if unsatisfied with an appeal outcome. The OFO chain of command is:

1. Program employee who made the finding (e.g. CSI, Public Health Veterinarian (PHV), Inspector in Charge (IIC))
2. PHV IIC or Mini-Circuit Supervisor
3. Frontline Supervisor (FLS)
4. District Manager (DM)
5. Executive Associate for Regulatory Operations
6. OFO Assistant Administrator
7. FSIS Administrator

Note: The formal appeal process starts with the immediate supervisor of the employee making the enforcement finding or decision, e.g., #2 above. FSIS recommends that the establishment request that the employee who made the finding or decision reconsider his or her finding or decision before starting the appeal. Although §381.35 indicates that the establishment has 48 hours from the time the decision was made to appeal, **there is no time limit** for the establishment to appeal an enforcement decision. FSIS recommends that the establishment make the appeal in a timely manner.

Sec. 500.6 Withdrawal of inspection.

9 CFR 500.6 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 Sec. 310.25(a) or Sec. 381.94(a) of this chapter;
- (f) An establishment did not comply with the Salmonella performance standard requirements as prescribed in Secs. 310.25(b) and 381.94(b) of this chapter;...

Withdrawal of the grant of inspection is the most severe enforcement action that can be taken against an official establishment. Withdrawal terminates the grant of inspection. Once that happens, no portion of the plant can operate as a FSIS federally inspected establishment.

Withdrawal actions can be the culmination of a lengthy process. Plants that have been subjected to withholding actions and suspensions can eventually be subject to withdrawal if operations are not returned to compliance, or if the situation is severe. The final decision to withdraw the grant of inspection is made at the Administrator's level.

Sec. 500.7 Refusal to grant inspection.

There are several reasons why the Agency may refuse to approve a grant of inspection to an applicant.

9 CFR 500.7 (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;...

FSIS has the authority to **refuse** to approve a grant of inspection. When FSIS decides not to approve a grant of inspection, the establishment cannot operate as a Federal meat, poultry, or egg products processing facility. Some examples of situations when FSIS would refuse to grant Federal inspection are when the establishment does not have a HACCP plan or Sanitation SOPs.

Sec. 500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.

FSIS may rescind and refuse to grant approval for false or misleading marks, labels, or containers for use with any meat or poultry product. These decisions are made at the Administrator's level, and the plant must be given written notice.

9 CFR 500.8 (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...

References

FSIS Directive 5000.1, Revision 3, Chapter IV

Exercises

Using the module and FSIS Directive 5000.1, answer the following questions.

1. Describe each term:

Compliance

Due process

Regulatory control action

Withholding

Suspension

2. a. Who is authorized to take regulatory control action?

b. Is prior notification of regulatory control action required?

c. How is the establishment informed of regulatory control action?

d. How is a regulatory control action documented?

8. Please indicate true or false for each of the following statements.

a. Using a tag to reject an area of a processing room is an example of a regulatory control action.

True

False

b. An establishment may appeal any regulatory control action.

True

False

c. Recurring insanitary conditions is a circumstance in which FSIS would take a withholding action without giving prior notice.

True

False

9. Sort the following actions into the most logical chronological progression of events, by putting the number 1, 2, 3, or 4 in front of the statement.

- FSIS provides the establishment a Notice of Deferral explaining that the decision whether to suspend has been deferred
- The establishment fails to maintain sanitary conditions due to multiple or recurring noncompliances
- The establishment provides a written response which contains proposed corrective and preventive actions
- FSIS provides the establishment with an NOIE

10a. Is there a time limit to initiate an appeal?

b. Who does the appeal first go to?

Appendix 1 - Rules of Practice Regulations

PART 500--RULES OF PRACTICE

Sec. 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.

Sec. 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 Secs. 306.5 and 381.35 of this chapter.

Sec. 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 Sec. 417.2 of this chapter;
- (3) The establishment does not have Sanitation Standard Operating Procedures as specified in Secs. 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.

Sec. 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 Sec. 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 Secs. 416.13 through 416.16 of this chapter;

(c) The establishment has not maintained sanitary conditions as prescribed in Secs. 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 Sec. 310.25(a) or Sec. 381.94(a) of this chapter;

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

Sec. 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 Secs. 306.5 and 381.35 of this chapter.

(b) The prior notification provided for in Sec. 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 Secs. 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.

Sec. 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 Sec. 310.25(a) or Sec. 381.94(a) of this chapter;
- (f) An establishment did not comply with the Salmonella performance standard requirements as prescribed in Secs. 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.

Sec. 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.

Sec. 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.