

Rules of Practice

Objectives

Upon completion of this module the trainee will be able to:

1. Describe what the Rules of Practice are and why FSIS must follow them.
2. List the conditions under which FSIS may take a suspension or withholding action without prior notification.
3. List the conditions under which FSIS must give prior notice before taking a suspension or withholding action.
4. List the items that must be in a NOIE letter.
5. List the items that must be in a Letter of Suspension.
6. Describe the “due process” protections in the Rules of Practice.
7. Describe what “abeyance” is.

Introduction

Think about the activities we carry out in FSIS. These activities are conducted under the authority delegated by Congress to the Secretary of Agriculture and then to the Administrator and the entire agency. We carry out these activities to ensure the purpose of the statutes and mission of agency are met. In FSIS we promulgate regulations (legislative power), enforce laws (executive), and file complaints (judicial). We do all of this as an agency that is governed by administrative law.

Administrative Law

Administrative law is the body of law that governs the creation and operation of public regulatory agencies which includes the statutes (e.g., FMIA) and regulations that authorize agency action, and the regulations, orders, and adjudicative decisions created by agencies to fulfill their public mission. In the broad sense, administrative law is what we in FSIS do every day. The activities that we conduct each day in FSIS make sure that the goal of food safety is achieved under the authority we are given as an administrative agency.

Due Process

The same body of law that gives us certain authorities also prescribes certain parameters that we operate under, including the important one of providing plants with due process. Plants have a constitutional right to do business and to due process of law before we interfere with this right. Whenever an agency engages in any activity that affects the right to do business, it must afford due process. For FSIS, due process is

particularly significant when we are considering action that may impact an individual or company's business (e.g., suspending operations). FSIS has a legal responsibility to be fair and consistent in its activities, decisions and enforcement actions. FSIS must act within the scope of its authority and not in an arbitrary or capricious manner.

Administrative Procedures Act

The Administrative Procedures Act (APA) is a law that significantly impacts federal regulatory agencies. The purpose of the APA is to make the methods used by agencies more fair and consistent. The APA is:

- A fundamental law governing the processes, practices and proceedings of federal administrative agencies.
- Designed to give uniformity to rulemaking and adjudicative proceedings of federal administrative agencies.
- Designed to assure increased openness and fairness in the administrative process.

The APA provides due process and affects how FSIS carries out administrative enforcement actions. The APA has provisions for withdrawal/suspension of license, providing notice before taking action, and providing an opportunity for compliance. The APA provides an exception to this due process in that immediate action may be taken when public health and safety is imminently threatened.

FSIS must comply with the APA in carrying out its food safety and administrative enforcement activities. We must provide details about compliance concerns to the establishment and provide an opportunity for correction unless there is an imminent threat to public health or safety.

Administrative Enforcement and the Rules of Practice

Administrative enforcement actions which are taken by the District Office are generally viewed as informal agency actions in that we are not required to file a formal administrative complaint. However, because these actions affect individual and establishment business and property rights, even when action is temporary, we must provide due process and follow the legal requirements of the APA. The Rules of Practice (ROP) are regulations (9 CFR 500) that are designed to meet the legal requirements of the APA. These regulations provide the establishments with the due process rights provided by law. The ROP may be thought of as tools to maximize compliance with FSIS requirements and, at the same time, provide establishments with their legal rights.

It is important to remember that the Rules of Practice are regulations that FSIS must follow. Just as industry has to follow regulations in producing meat and poultry, we, as regulators, have to follow rules in the way we take action on violations we find. There are consequences when FSIS fails to follow the Rules of Practice the agency has set for itself. Just as there are consequences if industry members don't follow food safety regulations, there are consequences if we don't follow the rules that apply to us. We may be stopped from taking actions to protect consumers or we may incur liabilities for the agency.

The Rules of Practice became effective January 25, 2000 and are found in 9 CFR 500. They define the types of enforcement actions FSIS may take and the conditions under which FSIS may take the action, the procedures FSIS must follow in taking the action, and industry appeal and hearing rights.

The ROP regulations are as follows:

- 500.1 Definitions
- 500.2 Regulatory Control Action
- 500.3 Suspension w/out prior notification
- 500.4 Suspension with prior notification
- 500.5 Notification and Procedures
- 500.6 Withdrawal of inspection
- 500.7 Refusal to grant inspection
- 500.8 Rescinding or refusing labels/marks

Enforcement Actions

500.1 Definitions

Regulatory control action: the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

Withholding action: the refusal to allow the marks of inspection to be applied to products. It may affect all product or product produced by a particular process.

Suspension: the interruption in the assignment of program employees to all or part of an establishment.

500.2 Regulatory Control Action

A regulatory control action may be taken under the following conditions:

- Insanitary conditions or practices
- Product adulteration or misbranding
- Conditions that preclude FSIS from determining that product is not adulterated or misbranded
- Inhumane handling or slaughtering

No prior notice is needed for a regulatory control action and the program employee immediately notifies the establishment orally or in writing of the action and the basis for action. The establishment may appeal pursuant to regulations.

500.3 Suspension w/out prior notification

A suspension or withholding action may be taken without prior notification if the establishment has:

- Produced and shipped adulterated product.
- No HACCP plan.
- No SSOP.
- Insanitary conditions.
- Violated a regulatory control action.
- Assaulted, threatened or intimidated inspection personnel.
- Inhumane slaughter or handling.
- Failed to destroy condemned carcass.

500.4 Suspension with prior notification

A suspension or withholding may be taken with prior notification if the:

- HACCP system is inadequate (due to multiple or recurring noncompliance).
- SSOP is inadequate (due to multiple or recurring noncompliance).
- Sanitary conditions/sanitation performance standards are not met (multiple or recurring noncompliance)
- *E. coli* testing (generic) is not performed.

500.5(b) Prior Notification

Prior notification is a letter called a Notice of Intended Enforcement Action (NOIE). It must contain the following items.

- State the type of action that FSIS may take
- Describe the reason for the proposed action
- Identify the products or processes affected
- Advise the establishment of their right to contest the basis for the proposed action or to demonstrate or achieve compliance
- Provide 3 days to respond (unless extended)

500.5(a) Notification of Action

If a suspension or withholding action is taken, the letter must contain the following items.

- State the effective date of the action
- Describe the reason(s) for the action
- Identify the products or processes affected
- Provide an opportunity to present corrective actions
- Advise the establishment that it may appeal or request a hearing

500.5(e) Abeyance

Once a suspension action is taken, FSIS may subsequently hold the suspension in abeyance to allow the establishment to operate under the conditions agreed to by FSIS and establishment. FSIS must monitor and verify plant implementation and effectiveness of corrective actions to support subsequent decisions to close out the action or to reinstate enforcement

Due Process Protections

Some of the more critical parts of the ROP are those that are designed to ensure that plants are provided with appropriate due process protections. In some instances, such as when there is no immediate food safety issue, this entails providing plants with notice and a chance to take corrective action prior to FSIS action.

Due process also entails providing rights or additional process after taking actions. This includes the right to appeal agency actions or the opportunity for a hearing. Under 9 CFR 306.5 and 381.35, the establishment may appeal a withholding or suspension action to the immediate supervisor of the employee taking the action. The ROP also give establishments the opportunity to request a hearing before an Administrative Law Judge (ALJ) when FSIS places a suspension in effect, shutting down plant operations.

500.6 Withdrawal of Grant of Inspection

FSIS may file an administrative complaint at the department level to withdraw a grant of inspection from an establishment if it:

- Produced and shipped adulterated product.
- Failed to have or maintain a HACCP plan.
- Failed to have or maintain an SSOP.
- Failed to maintain sanitary conditions.
- Failed to test for *E.coli*.
- Inhumanely slaughters or handles animals.
- Assaults, threatens, intimidates, or interferes with inspection personnel.
- Has a “responsibly connected” person that is “unfit” according to the Act.

500.7 Refusal to Grant Inspection

FSIS may refuse to grant inspection if the applicant has:

- No HACCP plan as required by part 417.
- No SSOP as required by part 416.
- Not demonstrated adequate sanitary conditions.
- Not demonstrated that livestock will be handled and slaughtered humanely.
- A “responsibly connected” person that is “unfit” according to the Act.

6. Describe the “due process” protections in the Rules of Practice.

7. Describe what “abeyance” is.