

Rules Of Practice

EIAO Training



Objectives

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

- Describe what the Rules of Practice are and why FSIS must follow them.
- List the conditions when FSIS may take a suspension or withholding action:
 - without prior notice
 - with prior notice
- Describe the “due process” protections in the Rules of Practice.
- Describe what an “abeyance” is.
- Describe how to support an enforcement action using a supportable regulatory-statutory rationale.

Background

- Administrative Procedure Act (5 U.S.C. 551 - 559)
 - Law governing federal administrative agencies
 - Openness, fairness, and uniformity in administrative processes
 - Uniformity in rule making

Administrative Procedure Act

- Withdrawal, suspension, revocation or annulment of a license
- Written notice of the facts or conduct which may warrant the action
- Opportunity to demonstrate or achieve compliance
- Exceptions for willfulness or for public health, interest or safety

Due Process

- FSIS must comply with the APA in carrying out its food safety and administrative enforcement activities
- FSIS must provide details about compliance concerns and opportunity for correction
- FSIS may take immediate action for an imminent threat to public health or safety

FSIS Rules of Practice

- Define types of enforcement actions
- Conditions under which FSIS may act
- Procedures FSIS must follow
- Industry appeal and hearing rights



FSIS Rules of Practice - 9 CFR Part 500

- Effective January 25, 2000
 - 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

9 CFR 500.1 Definitions

- 3 Types of Enforcement Actions Defined
 - Regulatory Control Action
 - Withholding Action
 - Suspension

Regulatory Control Action

- Retention of product
- Rejection of equipment or facilities
- Slowing or stopping of lines
- Refusal to allow the processing of a specifically identified product

U.S.
 REJECTED

U.S.
 RETAINED

ITEM TAGGED AND LOCATION

REASON FOR TAGGING

TAG APPLIED BY DATE

REMARKS

PLANT/EST./EMPLOYEE NOTIFIED

Withholding

- Refusal to allow the marks to be applied to products
- May affect all product or product produced by a particular process



Suspension

- Interruption in the assignment of program employees to all or part of an establishment



9 CFR 500.2 Regulatory Control Actions

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

9 CFR 500.3 Withholding or Suspension without Prior Notice

- Produced and shipped adulterated product
- No SSOP or HACCP Plan
- Insanitary conditions
- Violated regulatory control action
- Inhumane slaughter or handling

9 CFR 500.4 Withholding or Suspension with Prior Notice

- SSOP/ HACCP system inadequate (multiple or recurring noncompliance)
- Sanitary conditions/sanitation performance standards (multiple or recurring noncompliance)
- Did not collect or analyze for *E. coli* Biotype 1

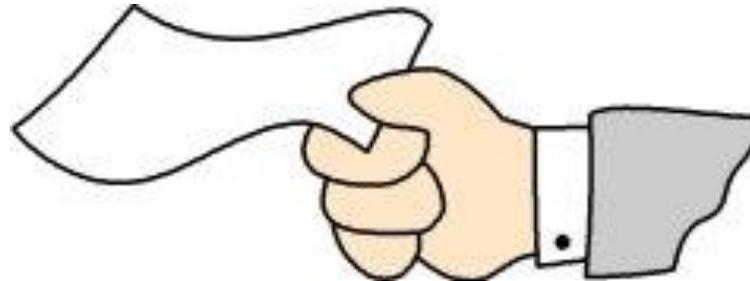
9 CFR 500.5(a) Notification

- If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and as promptly as circumstances permit in writing



Types of Written Notice

- Notice of Suspension/Withholding
- Notice of Intended Enforcement
- Notice of Deferral
- Additional Notification Letters



9 CFR 500.5(a)

Contents of Enforcement Letters

- Effective date of action
- Describe the reasons for the action
- Identify the product or process affected
- Provide establishment opportunity for corrective actions
- Advise of appeal process

9 CFR 500.5(b)

Notice of Intended Enforcement - NOIE

- Reason for action
- Identify product or processes affected
- Advise of right to contest basis or explain compliance
- Three days to respond to FSIS

Notice of Deferral

- Issued to establishment when proposed corrective actions seem adequate
- Establishment implements corrective actions
- Verification plan is included
- Close out with Letter of Warning

Additional Notification Letters

- Notice of Suspension Held in Abeyance
 - Allows establishment to operate after presenting corrective actions and preventive measures
- Notice of Reinstatement of Suspension
 - Failure of establishment to meet or maintain compliance
- Letter of Warning
 - Notification that enforcement action is closed

Due Process Protections



- Appeal Rights
- Opportunity For an Administrative Hearing

9 CFR 500.5 (c) Appeal Rights

- Establishment may appeal withholding or suspension action
- 9 CFR 306.5 and 381.35
 - Actions are appealed to next higher level of supervision



9 CFR 500.5(d) Hearing Rights

Establishments have a right to request a hearing when a suspension is put into effect



9 CFR 500.5(e) Abeyance

- Establishment has been suspended
- DM temporarily “lifts” suspension
- Establishment operates under conditions agreed by FSIS and establishment
- Notice of Suspension Held in Abeyance

9 CFR 500.6 Withdrawal of Grant

- Produced and shipped adulterated product
- Failure to have or maintain SSOP/HACCP plan
- Insanitary conditions
- Did not collect or analyze for E. coli Biotype 1
- Did not comply with Salmonella PS
- Inhumane handling or slaughter
- Assault, threat, intimidation, or interference
- Unfitness

9 CFR 500.7 Refusal to Grant Inspection

- No HACCP plan as required by part 417
- No SSOP as required by part 416
- Establishment has not demonstrated adequate sanitary conditions
- Establishment has not demonstrated that livestock will be handled and slaughtered humanely
- Unfitness of applicant

9 CFR 500.8

Rescinding or refusing labels/marks

- False or misleading marks, labels
- Forms or containers for use with meat or poultry products
- Decisions made at Administrator level

Statutory-Regulatory Exercise

- Example – an establishment has several associated NRs for condensation in exposed product areas, some included product contamination.
 - What would your thought process be if enforcement action were being considered?
 - Don't forget to include the Rules of Practice!

Rules of Practice Workshop

