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
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
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
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