



Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Rules of Practice and Your Role

EIAO Training



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 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 in a fair and consistent manner
- 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

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



9 CFR 500.1 Definitions

- 3 Types of Enforcement Actions Defined
 - **Regulatory Control Action** – Retention of product, rejection of equipment or facilities, slowing or stopping the lines, or refusal to allow the processing of specifically identified product
 - **Withholding Action** – Refusal to allow the marks of inspection to be applied to products
 - **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 – Notifications, appeals, and actions held in abeyance

- Types of Written Notice:
 - Notice of Suspension/Withholding (NOS)
 - Notice of Intended Enforcement (NOIE)
 - Notice of Deferral
 - Additional Notification Letters



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



9 CFR 500.5(a) Contents of Enforcement Letters

- Effective date of action
- Describe the reasons for the action
- Identify the product or processes 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

9 CFR 500.5(c) Appeal Rights

Due Process protections give the right to the Establishment to:

- Appeal a 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

Due Process protections also give the right to the Establishment to request a hearing when a suspension is put into effect.



9 CFR 500.5(e) Abeyance

- Establishment has been suspended
 - The District Manager (DM) temporarily “lifts” the suspension
 - Establishment operates under conditions agreed by FSIS and the establishment
 - Notice of Suspension Held in Abeyance*
- * Means that the suspension is temporarily lifted

9 CFR 500.6 Withdrawal of the Grant of Inspection

- 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

