Rules of Practice and Your Role
EIIO 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/equitable 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(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 (NOS)
- Notice of Intended Enforcement (NOIE)
- 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 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:
- 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