

## Inspection Responsibilities

### Objectives

After completing this module, students will be able to:

1. Apply inspection methodology to determine when to write a noncompliance report.
2. Take appropriate actions when product is economically adulterated or misbranded.
3. Describe the IPP actions when there is repetitive noncompliance.

### Resource Materials

- 9 CFR Parts 500
- FSIS Directive 7000.1 “Verification of Non-Food Safety Consumer Protection Regulatory Requirements”

### Verification Methodology for NFSCP Tasks

NFSCP tasks are performed to verify that meat, poultry, and egg products distributed to consumers are not economically adulterated or misbranded. As with other inspection tasks, IPP are to schedule the tasks on the dates most appropriate for performing the particular verification task.

FSIS Directive 7000.1 provides IPP with guidance for verifying that an official establishment complies with consumer protection regulatory requirements that are not related to food safety. An attachment in this directive identifies each PHIS NFSCP verification task, verification instructions for the task, regulatory references, and guidance documents.

Before performing the NFSCP task, IPP are to review the regulatory requirements associated with the scheduled task listed in the attachment of FSIS Directive 7000.1. While performing the task, IPP use a thought process when verifying NFSCP regulatory requirements that includes:

- **Gathering** factual information;
- **Assessing** the information gathered; and
- **Determining** regulatory compliance

When a NFSCP task is performed, IPP may gather information by conducting one or more of the following verification activities as appropriate for the task and product produced.

- Observing the formulation of the product
- Verifying the accuracy of product's labeling
- Observing processing procedures
- Reviewing establishment records [9 CFR 320.1(b)(11) and 381.117(b)(6)]
- Examining product
- Checking product identification, condition and temperature
- Performing a variety of other in-plant (hands-on) measurements, such as weighing ingredients, and calculating RI amounts

When product is involved in the verification, IPP randomly select product to examine that accurately represents the production lot. One of the best ways to ensure an unbiased selection of product to examine is to randomly select a time for the examination. There are no designated sampling plans or sample sizes that IPP must use when examining product. IPP examine a sufficient amount of product (e.g., a batch or subgroup of 10 or 20 pieces of product) to determine whether the lot complies with the NFSCP regulatory requirements.

IPP should use the available tools to perform any of the necessary calculations to verify the NFSCP regulatory requirements when performing the NFSCP tasks:

- FSIS Directive 7620.3, Processing Inspectors' Calculation Handbook
- The Calculation Aid located on every IPP's computer in FSIS Applications

## **Documentation and Enforcement**

IPP assess all the information gathered and determine compliance by comparing what was observed to the relevant regulatory requirements. Compliance with most of the NFSCP requirements is based on production lots and assessing the establishment's control of the process (e.g., applying accurate labeling, applying added solutions to products, or adding ingredients or meat and poultry components that meet the product's standard of identity). Before making a determination that the establishment's process is out of control, IPP consider all available sources of information (e.g., establishment

records, and/or monitoring or testing results). IPP may exercise additional discretion when the establish has an effective quality control (QC) program (See Attachment An establishment is not required to develop and implement process control procedures but it may to ensure its process is within normal variation or under control. These control procedures may be a very detailed written statistically based quality control (QC) program with a specific sample size and sampling frequency, control limits, recordkeeping practices, and corrective actions if the control limits are exceeded. Even if an establishment has process control procedures in place or a written QC program, it is not regulatory noncompliance if the establishment does not follow the procedures or the program. In addition, establishments are not required to make their QC programs or NFSCP verification records available for FSIS review.

If an establishment shares its QC program and/or documentation with FSIS, the IPP should review the establishment's written program/procedure to become familiar with the sample or subgroup size, sampling frequency, control limits, recordkeeping practices, and the actions taken if the control limits are exceeded. The IPP should also observe establishment employees performing the procedures listed in the QC program or other control procedures to determine if they are conducted as written. When the establishment follows the provisions of the QC program or performs process control checks, IPP should consider this information when determining if the establishment is maintaining control of its process and meeting the regulatory requirements. IPP should also consider the variation in the process when determining compliance. If IPP have concerns about the QC program or a large variation in the process, the Frontline Supervisor (FLS) should be consulted for guidance and instruction with noncompliance determinations and recommendations regarding the actions to take to ensure compliance. The Policy Development Staff (PDS) is also available to provide additional technical and policy information to assist IPP.

If an establishment does not have process control procedures in place or a written QC program, or does not make the QC program and records available to IPP, an inspection result that exceeds maximum regulatory limit, falls below a regulatory minimum limit or does not meet any other NFSCP regulatory requirement represents noncompliance.

IPP are to consider any relevant factors when determining the amount of noncompliant product involved. Factors to be considered include factual information such as the establishment's lot identification procedures, receiving records, and production records, as well as those facts that can be reasonably ascertained based on the average amount of product produced per shift or per production line. When necessary, IPP consult with their supervisor for assistance in determining the extent of product involvement.

When noncompliance is found, IPP take the appropriate regulatory control actions, such as retention of product, rejection of equipment or facilities, stopping lines, or refusing to allow the processing of specifically identified product (9 CFR 500.1(a), if it is determined that misbranded or economically adulterated product would otherwise enter commerce or be shipped from the establishment. Additionally, FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes, or forms of any container for use with any meat or poultry product per 9 CFR 500.8. If it is determined that economically adulterated or misbranded product has entered commerce, FSIS may implement recall procedures.

IPP should associate the NRs when noncompliances are related to the same process (e.g., the application of solutions to meat and poultry products) as described in FSIS Directive 5000.1 and are to notify the District Office (DO) through supervisory channels when establishment management is unwilling or unable to take necessary steps to re-establish control of its process necessary to meet regulatory requirements.

The DO may notify the establishment in writing that the repetitive noncompliances may lead to a regulatory control action (9 CFR 500.1-3) that would affect the entire production of the product in question because product may be economically adulterated or misbranded. Whenever a regulatory control action is taken, such action will remain in place until the DO receives written assurances from the establishment indicating what procedures the establishment has instituted to regain and maintain process control. The DO will make a determination whether those procedures appear to correct the problem. Additionally, to determine the effectiveness of the actions, IPP will verify that the establishment's corrective actions are adequate and are operating as described in the establishment's response.

The DO may notify the Office of Investigation, Enforcement, and Audit (OIEA) Regional Manager if there is a reason to believe that NFSCP noncompliances involve the shipment of economically adulterated or misbranded product or criminal intent to defraud the consumer.