NON-FOOD SAFETY CONSUMER PROTECTION TASKS

Objectives

After completing this module, you will be able:

- 1. Identify the statutes, regulations and primary directives that relate to non-food safety consumer protection responsibilities.
- 2. Explain what to do when noncompliance is observed with the Non-Food Safety Consumer Protection Tasks.
- 3. Explain the regulatory requirements for products that are subject to standards of identity.
- 4. Explain the purpose of the Non-Food Safety Consumer Protection Tasks.

Resource Materials

- Federal Meat Inspection Act (FMIA)
- Poultry Product Inspection Act (PPIA)
- 9 CFR Parts 301, 313, 316, 317, 318, 319, 327, 381 Subpart P, 412,424, 441, 442, and 500
- FSIS PHIS Directive 5000.1, "Verifying an Establishment's Food Safety System"
- FSIS Directive 6120.1, "Finished Product Standards Program for the New Line Speed Inspection System and the Streamlined Inspection System"
- FSIS Directive 6700.1 "Retained Water in Raw Meat and Poultry Products"
- FSIS Directive 6810.1, "Grademark Labeling on Meat and Poultry Product"
- FSIS Directive 7000.1 "Verification of Non-Food Safety Consumer Protection Regulatory Requirements"
- FSIS Directive 7000.2, "Experimental and Sample Product Policy"
- FSIS Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products"
- FSIS Directive 7124.1, "Standards of Identity or Composition—Use of Cooked or Cured Product"
- FSIS Directive 7160.1, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery Systems"

- FSIS Directive 7160.2, "'Meat" Prepared Using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems"
- FSIS Directive 7160.3, "Advanced Meat Recovery Using Beef Vertebral Raw Materials"
- FSIS Directive 7220.1, "Food Labeling Division Policy Memoranda" (Policy Memos 42, 44A, 57A, 66C, and 84A) (<u>FSIS Label Policy Memoranda (usda.gov)</u>)
- FSIS Directive 7221.1, "Prior Labeling Approval"
- FSIS Directive 7235.1, "Mandatory Safe Handling Statements on Labeling of Raw and Partially Cooked Meat and Poultry Products"
- FSIS Directive 7237.1, "Labeling of Ingredients"
- FSIS Directive 7270.1, "Sampling and Testing Procedures for Raw Poultry Products Labeled "Fresh"
- FSIS Directive 7620.3, "Processing Inspector's Calculation Handbook"
- FSIS Directive 8080.1, Recall of Meat and Poultry Products, including Attachment 1, "Product Recall Guidelines for Firms."
- Food Standards and Labeling Policy Book (<u>Food Standards and Labeling Policy Book (usda.gov)</u>)
- Labeling Compliance Guideline (July, 2020)
- NBS Handbook 133
- NIST Handbook 44

Training

- C024, Labeling DL0514
- C028, Net Weights DL0512
- C029, Processing Determinations DL0515
 (CDs available through CEDL in Outlook, and AgLearn)

Introduction

In this module, we'll be covering your responsibilities related to the statutes, regulations, and directives that cover the regulatory requirements for what is called the Non-Food Safety Consumer Protection (NFSCP), also known as "Other Consumer Protection" or "OCP" tasks. These requirements pertain to the quality rather than the safety of the products produced. These requirements relate to IPP responsibilities for ensuring that products are wholesome; are properly marked, labeled, and packaged; and are not economically adulterated or contain components that while not actually unsafe are undesirable.

The highest priority in FSIS is protecting public health and food safety. The Agency directs that inspection program personnel (IPP) focus on food safety first, followed by food security (when specific heightened security threat condition is declared), and yet still verify compliance with requirements that provide non-food safety protection to consumers extended by the FMIA and PPIA. The NFSCP duties are the ones that are covered by Other Consumer Protection tasks to verify that the establishments are complying with regulatory requirements designed to protect the consumer in ways other than ensuring food safety.

Statutes

Let's start by reviewing the statutes in the Federal Meat Inspection Act (FMIA) related to NFSCP requirements. The term "misbranded" is defined in 21 U.S.C. 601(n) of the FMIA. There are twelve parts to this definition. Misbranded is defined in the FMIA as a meat product that:

- Part (1), has labeling which is false or misleading.
- Part (2), is offered for sale under the name of another food.
- Part (3), is an imitation of another food.
- Part (4), has a container that is misleading.
- Part (5), has a label that fails to show the name and place of business that produced the product, or fails to contain an accurate statement of the quantity of the contents of the meat product.
- Part (6), contains a label that is missing required information.
- Part (7), has a label that purports that it was produced in a manner that follows a standard of identity, but the product does not conform to those standards.
- Part (8), does the amount of product in the container fall below the fill standard.
- Part (9), contains ingredients that are not represented on the label by common names of the food.
- Part (10), makes special dietary claims but does not list the corresponding dietary properties and information required on the label.
- Part (11), contains artificial flavoring, coloring, or chemical preservatives that are not listed on the label.
- Part (12), requires some type of handling for a wholesome condition to be maintained but the label fails to contain that information.

The terms "label" and "labeling" are also defined in the FMIA as follows.

- FMIA 601(o) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article.
- FMIA 601(p) The term "labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

Section 607 of the FMIA covers labeling, marking, and container requirements. Section 607(e) states that when there is reason to believe the marking or labeling or container is false or misleading, FSIS has the authority to withhold its use until it is modified so that it is no longer false or misleading.

There are similar provisions in the poultry statutes. The Poultry Products Inspection Act (PPIA) 453 (h) contains similar definitions of "misbranded" and 457 contains labeling and container standards.

Regulations

The regulations related to the NFSCP requirements are extensive and detailed. We will review the highlights of some of the key NFSCP regulations for meat and poultry products. The new 9 CFR 418 recall regulations are addressed later in this section.

General labeling requirements for meat products

Let's start with some of the key regulations related to meat products. 9 CFR 317 outline all of the regulatory requirements including labeling, marking devices, and containers. 9 CFR 317.1 states that labels are required for containers of meat products.

9 CFR 317.2 outlines the required features of labels for meat products. Some of the basic requirements include:

- The label must list the name of the product and ingredients.
- The name and place of business of the manufacturer must be shown.
- It must contain an accurate statement of the net weight or quantity.
- The label must not be false or misleading.
- It must list any handling (refrigeration) of the product that is required in order to maintain the product in a wholesome condition.

 There are also very specific requirements for safe handling instructions for raw or not ready-to-eat meat and meat products.

9 CFR 412.1 contains the requirements related to labeling approval. One of the key statements is that no final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to FSIS except for generically approved labels authorized for use in 9 CFR 412.2. Currently, the organizational unit responsible for handling the approval of labels is the Labeling and Program Delivery Staff (LPDS), Office of Policy and Program Development. A sketch label is a printers proof or the equivalent which clearly shows all labeling features, including the size, and location. The LPDS may grant a temporary approval that extends up to 180 calendar days. If the label is to be applied directly to a meat carcass, make sure that the type of ink the establishment uses complies with 9 CFR 312 and 316, which states they must be legible and of harmless material. FSIS requires the submission of labeling applications for the following:

- Labels for temporary approval (9 CFR 412.1(c)(4)),
- Labels for products produced under religious exemption (9 CFR 412.1(c)(1)),
- Labels for products for export with labeling deviations (9 CFR 412.1(c)(2)),
 and
- Labels with special statements and claims (9 CFR 412.1(c)(3))

9 CFR 412.2 covers generically approved labels. IPP do not generically approve labels. Establishments do not generically approve labels. Generically approved labels are approved by FSIS if the label meets the criteria listed in 9 CFR 412.2(b). Therefore, a label that meets one of the conditions of being a generically approved, does not have to be submitted to FSIS for further approval. Some generically approved labels Include labeling for:

- Products that have a standard specified, such as a standard of identity (identifies the kind and amount of meat required in that product; e.g., hot dogs).
- A product, such as steak, that has a single ingredient. There can be no special claims on these generically approved labels.
- Containers of products sold under government contract specifications, such as those sold for the school lunch program.
- Consumer test products which are not intended for sale.

• Any label that was previously approved as a sketch by FSIS qualifies to be used without any further approval.

As mentioned earlier, there are many more details regarding the regulatory requirements for labeling meat products. For example, there are extensive requirements related to nutritional labeling. These are found in 9CFR 317.300-317.400. Nutritional labeling is currently required for all meat products intended for human consumption except for those that are single ingredient, raw products, such as steaks. However, nutritional labeling may be provided for these products on a voluntary basis. We will not review these requirements in general, but you should take time to review the regulations and become familiar with them, as from time to time, you will need to verify that the establishment is complying with these requirements.

Later in this module we will review some of the basic requirements for labeling related to products that have standards of identity. But first, let's review some of the basic regulatory requirements of general labeling for poultry products.

General labeling requirements for poultry products

Just as there are a number of regulatory requirements related to the labeling of meat products, there are also a number related to poultry products. They are found in 9 CFR Subpart N of regulation 381, from 381.115 through 381.144. Here are a few of the key parts.

- 9 CFR 381.115 Require the containers of poultry products to be labeled.
- 9 CFR 381.118 Covers the requirement for ingredients statements for poultry products.
- 9 CFR 381.119 States that artificial flavoring or coloring must be declared on labels of poultry products.
- 9 CFR 381.120 States that antioxidants, chemical preservatives, and other additives must be declared on the labels of poultry products.
- 9 CFR 381.121 Requires that the label shows the quantity of the contents of the product.
- 9 CFR 381.122 Requires that the label identifies the product manufacturer, packer or distributor.
- 9 CFR 381.124 States that dietary food claims must be matched with appropriate details on the label.
- 9 CFR 381.125 Requires that if poultry products require special handling to maintain a wholesome condition, these handling requirements must be listed on the label.
- 9 CFR 381.130 States that false or misleading label are not permitted for poultry products.

9 CFR 381.132 - Describes the labeling approval process.

9 CFR 381.133 – Covers the requirements related to generically approved labeling. Just as was true for meat products, those products for which a standard of identity exists are eligible for generically approved labels.

Standards of identity

Now, let's review some of the regulatory requirements for products that are subject to standards of identity. The "Definitions and Standards of Identity or Composition" regulations for meat and poultry products are found in 9 CFR 319 and 9 CFR 381 Subpart P, respectively.

Meat - The requirements in 9 CFR 319.1 cover the general labeling and preparation of standardized meat products. This regulation states that products for which standards of identity exist must have a label showing the product name and ingredients statement and other information as appropriate. The 9 CFR 319.15-319.881 (Subparts B through U) cover the specific requirements for various meat products – from raw products that have only a few ingredients, to products such as cooked sausage that may have a number of ingredients and may go through numerous processing steps.

Here's an outline of all the regulations covering the definitions and standards of identity or composition (Part 319) for **meat** products:

Subpart A – General

Subpart B – Raw meat products

Subpart C - Cooked meats

Subpart D - Cured meat, unsmoked and smoked

Subpart E – Sausage generally: fresh sausage

Subpart F – Uncooked, smoked sausage

Subpart G – Cooked sausage

Subpart K - Luncheon meat, loaves, jellied products

Subpart L - Meat specialties, puddings, nonspecific loaves

Subpart M – Canned, frozen, dehydrated meat food products

Subpart N – Meat food entrée products, pies, and turnovers

Subpart O – Meat snacks, hors d'oeuvres, pizza, and specialty items

Subpart P – Fats, oils, shortenings

Subpart Q - Meat soups, soup mixes, broths, stocks, extracts

Subpart R – Meat salads and meat spreads

Subpart U – Miscellaneous (breaded and liver meat products)

Poultry - 9 CFR 381 Subpart P covers the labeling requirements for poultry products that have standards of identity. 9 CFR 381.156 covers the requirements for using terms such as light or dark meat on a label containing poultry products. Similar to the regulations related to meat products, these regulations covering poultry products specify percent of poultry light/dark meat required for the product to meet the standard, and in some cases the type of ingredients required/allowed, such as binders or extenders.

Here are the 9 CFR §381 Subpart P regulations covering the standards of identity for **poultry** products:

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381.155 – General
381.156 – Poultry meat content standards for certain poultry products
381.157 - Canned boned poultry and baby or geriatric food
381.158 – Poultry dinners (frozen) and pies
381.159 - Poultry rolls
381.160 – (Kind) burgers; (Kind) patties
381.161 – "(Kind) A La Kiev"
381.162 – "(Kind) steak or fillet"
381.163 - "(Kind) baked" or "(Kind) roasted"
381.164 - "(Kind) barbecued"
381.165 – "(Kind) barbecued prepared with moist heat
381.166 - Breaded products
381.167 – Other poultry dishes and specialty items
381.168 – Maximum percent of skin in certain poultry products
381.169 - Ready-to-cook poultry products to which solutions are added
381.170 – Standards for kind and classes, and for cuts of raw poultry
381.171 – Definitions and standards for "Turkey Ham"
381.173 – Mechanically Separated (Kind of Poultry)
381.174 – Limitations with respect to use of Mechanically Separated (Kind
of Poultry)
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Verification Methodology for Non-Food Safety Tasks

FSIS Directive 7000.1 provides general instructions for how IPP are to perform specific verification task related to non-food safety requirements. The PHIS system will assign other consumer protection tasks to establishment task lists based on the product information recorded in the establishment profile. As with

other tasks, IPP are to schedule the tasks on the dates most appropriate for performing the particular verification task.

Perform the appropriate verification procedures by:

- Observing establishment product formulation,
- Verifying the accuracy of labeling,
- Observing processing procedures,
- Reviewing establishment records,
- Examining product,
- Checking product identification, condition and temperature,
- Performing a variety of other in-plant measurements, testing and calculations, or
- Observing slaughter practices.

There are no designated sampling plans or sample sizes that IPP are to use when examining products to assure that the products meet non-food safety regulatory requirements. Examine sufficient amount of product to determine whether the product complies with regulatory requirements, such as product standards, net weight standards, regulatory maximum or minimum limits of ingredients or components, or product defects. Inspection program personnel are to determine whether product complies with the regulation based on production lots or process controls rather than on individual units of product. For example, if one package of product fails to meet its net weight, IPP are to investigate whether there have been problems in the process that will cause all packages to fail the net weight requirements.

When examining product, verify product identification and evaluate the product condition, including product temperature and storage. Where effective establishment processing controls are evident, only limited verification activity may be necessary.

While performing these procedures, it is possible that you may uncover concerns related to an establishment's food safety systems, such as the Sanitation SOP or HACCP plan. When this occurs, you should perform the food safety inspection task as a directed procedure and take any necessary enforcement actions. For example, if you are performing a routine labeling verification procedure and discover that the establishment has included an ingredient of public health concern in product formulation without properly declaring the ingredient on the label, you should pursue the food safety aspects

of the findings and perform a directed food safety procedure as instructed in FSIS PHIS Directive 5000.1.

Inspection program personnel are not to perform directed non-food safety verification procedures unless, during the performance of food safety verification activities, they observe conditions or activities that cause them to suspect that the establishment is not meeting non-food safety regulatory requirements. If, following a preliminary assessment of such information, you have reason to believe that non-compliant product is being or has been produced perform a directed verification procedure and a thorough evaluation. In PHIS, document a brief explanation of why the directed task was performed.

Specific Tasks

Now, let's walk through each of the NFSCP tasks.

Percent Yield/Shrink/Gain

When performing this task, you'll verify the requirements associated with percent yield/shrink/gain.

Examples of products: bacon, BBQ meats, roasts beef, corned beef, cured beef tongue, country ham, etc.

Regulations: 319.80; 319.81; 319.100; 319.101; 319.102; 319.103; 319.106; 319.107; 424.21 (c)

Directive: 7620.3

When performing the task select an appropriate product and verify compliance with regulatory requirements by reviewing establishment records and labels, calculating the % yield or shrink, and comparing the result with the appropriate regulatory requirement. You may also verify compliance by weighing a sample of product before and after the appropriate step in the process (pumping, cooking, chilling, curing, drying, etc.), calculating the % yield, shrink or gain, and comparing the result with the appropriate regulatory requirement.

X% Solution Labeled Products

You will verify the requirements associated with added solution only for X percent solution labeled products. This procedure relates to the regulations regarding false or misleading labeling or practices, because you are verifying that the percent of a solution added to a product does not exceed the regulatory requirements.

Examples of products: cured pork products, ham patties, chopped ham, ready-to-cook poultry products, turkey ham, corned beef, beef brisket, etc

Regulations: 317.2 (c); 317.8; 381.129, 381.169, 319.104, and 319.105 (in these regulations, the sections that apply are those covering X% label products)

Directive: 7620.3

FSIS Issuances: Policy Memos 57A, "Labeling Turkey Ham Products Containing Added Substances"

Policy Memos 42, "Labeling of Raw Bone-in Poultry Products Containing Solutions"

Policy Memos 44A, "Labeling of Raw Boneless Poultry Products Containing Solutions"

Policy Memos 66C, "Uncooked Red Meat Products Containing Added Substances"

Policy Memos 84A, "Cooked Red Meat Products Containing Added Substances"

When performing this task select an appropriate product and verify compliance with X% labeling requirements by reviewing establishment records and labels, calculating the % added solution and comparing the results with the X% labeling declaration. You may also verify compliance by weighing a sample of product before and after the appropriate step in the process (pumping, curing, drying, etc.), calculating the % added solution, and comparing the result with the X% labeling declaration.

MSP/MSKP/PDBFT/PDPFT/AMR products

You will verify one of the requirements depending on the type of product that is being produced: Mechanically Separated Pork (MSP), Mechanically Separated Kind of Poultry (MSKP), Partially Defatted Beef Fatty Tissue (PDBFT), and Partially Defatted Pork Fatty Tissue (PDPFT), and Advanced Meat Recovery (AMR) products.

Regulations: 319.5; 319.15; 319.29; 318.24; 381.173

Directives: 7160.1; 7160.2; 7160.3, Rev. 1

When performing this task select an appropriate product and verify compliance by reviewing establishment records and labels, or by observing the preparation of products, and comparing the findings to the standards listed in the regulations. Also, take samples as directed.

To verify compliance:

- check product identification, condition, temperature, holding time/temperature;
- examine bones (for example, two intact portions of bones) before and after the meat recovery systems in order to observe condition and conformation;
- review establishment laboratory results and compare findings with the appropriate regulatory standard, and
- collect samples as directed.

Batter/Breading

You will verify the requirements associated with batter and breading.

Examples of products: breaded products, breaded patties, breaded meat cuts, fritters

Regulations: 319.880; 381.166

Directives: 7220.1; 7620.3

Here's what you should do when performing this task. Select an appropriate product and verify compliance with the batter and breading

regulatory requirements by reviewing establishment records to calculate final % batter/breading and comparing the findings to the standards listed in the regulations. You may also verify compliance by performing batter and breading pickup tests on one or more subgroups (according to the plant's QC programs) or batches of the product.

Labeling - Product Standards

You will verify the requirements for product standards.

Examples of products: miscellaneous beef products, sausage, frankfurters, luncheon meats, chili con carne, meat stews, tamales, and others (see Directive 7000.1)

Regulations: 319.15; 319.140-145; 319.160; 319.180-182; 319.260-261; 319.280-281; 319.300-313; 319.500; 319.700-703; 319.720-721; 319.760-762; 319.881; 381.156-168; 381.170-171.

Directives: 7220.1, Rev. 3; 7620.3

When performing this task select an appropriate product and verify compliance by reviewing establishment records and labels, or observing the preparation of products and comparing the findings to the appropriate regulatory standards. To verify some regulatory requirements, calculations will need to be performed to determine specified components, such as %fat, or %water.

Child Nutrition (CN)/Grade Labeling/Declared Count/Vignette

You will verify the requirements related to false or misleading labeling or practices, including specific prohibitions and requirements for labels and containers, and wording on labels of immediate containers.

Examples of products: All types of products

Regulations: 317.2; 317.8; 381.116

Directives: 6810.1; 7222.1

When performing this task select product and verify that the labeling is used on appropriate product and that there is a label approval on file. Remember that products for which there is a standard of identity can use generically approved labels.

Net weights

You will verify the requirements related to net weights whether the containers are catch weight or bear a stated net content.

Examples of products: All types of products that carry a net weight statement.

Regulations: 442.1-442.5

References: NBS Handbook 133 and NIST Handbook 44

Note: FSIS has determined that both handbooks mentioned above should be used as the definitive references for determinations of net weight compliance.

When performing this task select an appropriate retail-sized packaged product and verify net weight regulatory requirements by reviewing establishment records and conducting net weight/drained weight checks, scale calibration checks (certification and accuracy), and calculating average tare weights. For QC inspection verification, follow the QC program requirements after first evaluating the program to ensure that following the program results in compliance with net weight regulatory requirements.

General Labeling

The General Labeling task applies to all products that bear a label. For example, it includes verifying the requirements related to standards of identity.

Example of products: All products

Regulations: 316; 317; 318; 319; 327.10(d); 327.26; 381; 412, 424.21;

441.10

Directives: 6700.1; 7120.1; 7235.1; 7270.1; 7620.3

When performing this procedure select an appropriate product and verify that the label contains all required information, the ingredients statement is accurate (i.e., that all ingredients are listed in descending order of predominance and any proteinaceous substances used in the formulation are declared in the ingredients statement), restricted ingredients are used as per regulatory requirements, the label is used on appropriate product, and that there is a label approval on file. When verifying restricted ingredient requirements or ingredients statement compliance, observe the establishment formulating product and compare to the approved label.

NOTE: Proteinaceous substances can cause adverse reactions (i.e., allergic and non-allergic) in certain individuals, and therefore, such substances are of a food safety concern if not clearly declared in the ingredients statement.

When verifying imported products verify that the establishment meets the regulatory requirements for pre-stamping.

Livestock Finished Product Standards

The Livestock Finished Product Standards task applies to carcasses, boneless meat, returned products, product reconditioning, reinspection, retention, and disposal of meat products at official establishments; and to requirements concerning procedures, ingredients, and other articles used in preparation of products.

Examples of products: boneless meat, meat carcasses, pork skins for popping

Regulations: 318.2; 318.5; 318.6

When performing this task select an appropriate product/procedure and verify these regulatory requirements by reviewing establishment records and/or observe plant performance of activities. You may perform direct examination of the product, if warranted, to verify that the product is not economically adulterated or misbranded, per 9CFR 318.2(b).

Poultry Finished Product Standards

The Poultry Finished Product Standards task covers finished product standards, rework/reprocess/salvage products, poultry carcasses, poultry products and other articles entering or at official establishments, examination and other requirements, returned products, and good commercial practices for poultry slaughter.

Regulations: 381.1; 381.76; 381.78; 381.84; 381.86; 381.9(b); 381.145; 381.65(b)

When performing this procedure verify compliance by performing:

- Pre-chill FPS tests
- Post-chill FPS tests
- Reinspection of carcasses and giblet
- Inspection of returned products
- Inspection of rework products
- Observation of product condition
- Observation of slaughter practices

Sample Collection for Non-Food Safety Verification

Inspection program personnel may perform directed non-food safety sampling activities when they observe conditions or activities that cause them to suspect that the establishment is not meeting non-food safety regulatory requirements and testing is the only means available to determine noncompliance, for example, a finished product in which formulation cannot be verified without laboratory testing. When IPP believe a Collector Generated sample is warranted, notify the supervisor by e-mail explaining why a Collector Generated sample is warranted and obtain approval before proceeding. In PHIS, add a sample request task to the task calendar for the date of sampling, using the most appropriate project code.

When inspection program personnel take a sample of product, they should notify establishment management. This will provide management the option to hold all product represented by the sample, pending the sample results.

When IPP collect samples for **species** testing, they are to collect at least one pound of product and put it in a plastic bag supplied by the laboratory. If the product is in a natural casing, IPP are to collect a sample just prior to stuffing.

IPP complete all requested information in PHIS on the Sample Management screens, submit the form to the laboratory electronically, and print the sample form to include with the sample.

IPP are to attach product label showing an ingredient statement to the printed sample form before packing the sample. Also, they are to follow all instructions previously discussed for sealing, packing, and shipping the sample.

Sample results will be reported on the LIMS-Direct intranet site for receipt information and sample results. For species adulteration concerns, the laboratory will test the product against a panel of species anti-sera. Species results that correlate with the ingredient statement are reported as "Acceptable", and species results that indicate a species not declared on the ingredient statement is present, or one of the species on the ingredient statement is not present, are reported as "Not Acceptable".

Enforcement

Product compliance determinations are made based on non-food safety regulatory requirements, including product standards, net weight standards, regulatory minimum or maximum limits of ingredients or components, or product defects. If product is found to exceed any of the maximum limits, falls below the minimum requirements, or fails to meet any of the other regulatory requirements, there is noncompliance. As mentioned before, determinations of noncompliance should be based on production lots or process controls rather than on individual units of product. Use professional judgment and consult with your supervisor for assistance when necessary. Notify the establishment management immediately when noncompliance is found. Inspection program personnel are to issue NRs when they determine the process are out of control, resulting in economically adulterated or misbranded product.

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, consult with the supervisor for assistance in determining the extent of product involvement.

When noncompliance is found, 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 will expect establishments to implement recall procedures.

Repeated Noncompliances - Inspection program personnel should associate the NRs when noncompliances are from the same cause, as described in FSIS PHIS Directive 5000.1 and are to notify the District Office (DO) through supervisory channels when plant management is unwilling to meet regulatory requirements. The DO may notify the establishment in writing that the repeat 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 to meet regulatory requirements. 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 Compliance and Investigations Division if there is a reason to believe that non-food safety noncompliances involve the shipment of economically adulterated or misbranded product or criminal intent to defraud the consumer.

Examples of Noncompliance Situations

 IPP find that a carcass in the cooler has a large and heavy blood clot that would increase the weight of the carcass in such a way to reduce its quality, and the establishment has failed to address the situation. The blood clot is an example of an "inferiority that has been concealed" because it could not be seen until the carcass was chilled.

- IPP find that after the boning process the boneless product does not represent "boneless meat" because the number of bone fragments, and the establishment has failed to address the situation. (Labeling – Product Standards)
- Raw corned beef exceeds the % added solution stated on the label (X% Added Solution task).
- Finding 1.2 % bone solids content for Mechanically Separated Poultry (MSP task) which exceeds the bone solids allowed.
- Batter/breading was higher than allowed based on product standards, for example, 32% for breaded chicken breast (Batter/Breading task).
- Smoked bacon failed to return to green weight-102% yield (%Yield/Shrink task).
- Under-weight product (product does not accurately contain the net weight stated on the label).
- Product does not meet requirements that are specified in the applicable standard of identity for the product, for example, product labeled "ground beef" which contains more than 30% fat (Labeling – Product Standards).

Workshop: Other Consumer Protection Tasks

Choose the best answer:

- 1. Which of the following represents the definition of the term "misbranded" in the Statutes?
 - a. A product with labeling that is false or misleading.
 - b. A product with a label that does not show the name and place of business that produced the product.
 - c. A product that is subject to standards of identity but was not produced to follow those standards.
 - d. All of the above.
- 2. Which of the following is **NOT** true about labeling approval?
 - a. Sketch labels must show the size, location, and final color of the label
 - b. Temporary approval of labels may be granted.
 - c. A single ingredient product with no special claims must have label approval.
 - d. Some labels have generic approval.
- 3. Which of the following represents what you should do when performing Other Consumer Protection tasks?
 - a. Observe establishment product formulation, labeling, packaging, preparation, and processing procedures.
 - b. Examine product and review establishment records.
 - c. Check product identification, condition and temperature.
 - d. Perform a variety of in-plant measurements, testing and calculations.
 - e. All of the above.

- 4. When observing product formulation, you should do which of the following?
 - a. Verify product formulation and compliance with permitted amounts of restricted ingredients.
 - b. Verify all ingredients used in formulating the product are listed on the label in descending order of predominance and any proteinaceous substances used in the formulation are declared in the ingredient statement.
 - c. Verify compliance with standards of identity and composition regulatory requirements.
 - d. All of the above
- 5. Which one of the following should you do when establishment processing controls appear to be effective?
 - a. Count defects.
 - b. Direct your attention to establishment records.
 - c. Direct your attention to areas in the process not covered by establishment controls.
 - d. Review product formulation.
- 6. It is appropriate to perform directed NFSCP verification tasks when you suspect regulatory requirements are not being met.
 - a. TRUE
 - b. FALSE
- 7. Make determinations of noncompliance based on an individual unit of product.
 - a. TRUE
 - b. FALSE

- 8. What should you do when noncompliance with an NFSCP requirement is found?
 - a. Issue an NR.
 - b. Notify the establishment orally of the finding.
 - c. Determine the amount of noncompliant product involved.
 - d. Take appropriate regulatory control actions if without such action a misbranded or economically adulterated product would be shipped from the establishment.
 - e. All of the above.
- 9. When performing the %Yield/Shrink/Gain to verify compliance with regulatory requirements, you should do which of the following?
 - a. Select an appropriate product.
 - b. Review establishment records and labels.
 - c. Calculate % yield, gain, or shrink and compare result with regulatory compliance.
 - d. Be familiar with the regulatory requirements.
 - e. All of the above
- 10. For %Yield/Shrink/Gain, you verify compliance by weighing a sample of product before and after the appropriate step in the process (pumping, cooking, chilling, curing, drying, etc.), calculating the % yield, gain, or shrink, and comparing the result with the appropriate regulatory requirement.
 - a. TRUE
 - b. FALSE
- 11. What should you do when performing the X% Solution Labeled Products task to verify compliance with regulatory requirements?
 - a. Select an appropriate product for verification.
 - b. Review establishment records and labels, calculating the % added solution and comparing the results with the X% labeling declaration.
 - c. Weigh a sample of product before and after the appropriate step in the process (pumping, curing, drying, etc.), calculating the % added solution, and comparing the result with the X% labeling declaration.
 - d. All of the above.

- 12. What should you do when performing the MSP/MSKP/PDBFT/PDPFT/AMR task to verify compliance with regulatory requirements?
 - a. Call the DO prior to performing verification.
 - b. Review establishment safety records.
 - c. Observe the preparation of products and, compare the findings to the standards listed in the regulations.
 - d. None of the above.
- 13. What should you do when performing the Product Standards task to verify compliance with regulatory requirements?
 - a. Select an appropriate product for verification.
 - Review establishment records and labels, or observe the preparation of products and compare the findings to the appropriate regulatory standards.
 - c. For some regulatory requirements, perform calculations to determine specified components, such as % fat, or % water.
 - d. All of the above.
- 14. What should you do when performing the Net Weight task to verify compliance with regulatory requirements?
 - a. Select an appropriate wholesale-sized product for verification.
 - Review establishment records and conduct net weight/drained weight checks, scale certification and accuracy, or calculate average tare weight checks.
 - c. For QC inspection verification, follow HACCP requirements.
 - d. None of the above.
- 15. When performing the General Labeling task to verify compliance with regulatory requirements, you should do all of the following except:
 - a. Verify that the label contains all required information.
 - b. Verify that restricted ingredients are used as per regulatory requirements by observing the establishment formulating product and comparing it to the approved label.
 - c. Verify that the establishment has a label approval on file.
 - d. Verify that a copy of the label is on file in the inspection office.

Attachment: Other Consumer Protection Tasks Job Aid

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
Percent Yield/Shrink	9 CFR §319.107, §319.80, §319.81, §319.100, §319.101, §319.102, §319.103, §319.106, §424.21(c)	Directive 7620.3 "Processing Inspectors' Calculations Handbook" Chapters 11, 12, & 13; % gain, %shrink & %yield	Verify certain products that have a specified %Yield/Shrink as part of their Standard of Identity are met and not misbranded. 1. Select an appropriate product and 2. Verify compliance with regulatory requirements by reviewing establishment records and labels, calculating the % yield or shrink, and comparing the result with the appropriate regulatory requirement. In addition, 3. Verify compliance by weighing a sample of product before and after the appropriate step in the process calculating the % yield or shrink, and comparing the result with the appropriate regulatory requirement.
X Percent (%) Solution	9 CFR §319.104*, §319.105*, §381.129, §381.169, §317.2(c), §317.8 *NOTE: Applies only to sections of 319.104 and 319.105 covering X% labeled products.	Labeling Policy Book FLD Policy Memos 42, 44A, 57A, 59, 66C, 84A	Verify products that contain Percent (%) Added Solution meet regulatory standards and are not misbranded. *NOTE: Applies only to X% Labeled Products 1. Select an appropriate product and 2. Verify compliance with X% labeling requirements by reviewing establishment records and labels, calculating the % added solution and comparing the results with the X% labeling declaration. In addition, inspection program personnel are to. 3. Verify compliance by weighing a sample of product before and after the appropriate step in the process (i.e., pumping, curing, drying, etc.), calculating the % added solution, and comparing the result with the X% labeling declaration.
MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS	9 CFR §318.24, §319.5, §319.15(e), §319.29, §381.173	FSIS Directives 7160.1, 7160.2, 7160.3	Verify Mechanically Separated, Partially Defatted, and Advanced Meat Recovery Products meet regulatory requirements. 1. Select an appropriate product and 2. Verify compliance by reviewing establishment records and labels, or by observing the preparation of products, and comparing the findings to the standards listed in the regulations. In addition, inspection program personnel are to take samples as directed. 3. Verify compliance, inspection program personnel should: -check product identification, condition, temperature, and holding time/temperature. -examine bones (for example, two intact portions of bones) before and after the meat recovery systems in order to observe condition and conformation. -review establishment laboratory results and compare findings with the appropriate regulatory standard -take samples as directed.

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
Batter & Breading	9 CFR §319.880, §381.166	FSIS Directive 7620.3 Chapter 14, Directive 7220.1, Labeling Policy Book FLD Policy Memo 089	Verify batter and breading of applicable products meets regulatory requirements and product is not misbranded. 1. Select an appropriate product, 2. Verify compliance with the batter and breading regulatory requirements by reviewing establishment records to calculate final % batter/breading, and comparing the findings to the standards listed in the regulations. In addition, inspection program personnel are to: 3. Verify compliance by performing batter and breading pickup tests on one or more subgroups (according to the plant's QC programs) or batches of the product.
Livestock Finished Product Standards	9 CFR 310.22, 318.1, 318.2, 318.5, and 318.6	FSIS Directive 7000.1	 Verify Livestock products are wholesome and not adulterated. Verify compliance with the appropriate regulations and corresponding establishment quality control programs and records. IPP should observe to the extent possible the locations where the establishment's processing controls are evident. IPP need not count individual defects to make a judgment on a finished production lot. Inspection program personnel need to base determinations of product compliance by making determinations regarding product usability. The products should not pass inspection if defects are severe or numerous enough to affect the usability of the product. The purpose of product examination that inspection program personnel are to perform is to determine whether standards are being met. Determinations of acceptability should be based on production lots and process controls rather than on individual units of product. If necessary, IPP should consult with their Frontline Supervisor for assistance in determining noncompliance. The Technical Service Center (TSC) will provide additional guidance to assist with determining noncompliance.
Poultry Finished Product Standards			Verify poultry products are produced in a safe, wholesome manner and not misbranded.

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
Labeling - Product Standards	9 CFR §319.15, §319.140, §319.141, §319.142, §319.143, §319.145, §319.160, §319.180, §319.181, §319.260, §319.261, §319.261, §319.261, §319.281, §319.300, §319.301, §319.301, §319.302, §319.304, §319.305, §319.306, §319.307, §319.308, §319.309, §319.310	FSIS Directives 7620.3, 7220.1	Select an appropriate product and 1. Verify compliance by reviewing establishment records and labels; or observe the preparation of products and compare the findings to the appropriate regulatory standards. 2. Verify some regulatory requirements, by performing calculations to determine specified components, such as % fat, or % water.
Child Nutrition/Grade Labeling/ Declared Count/Vignette	9 CFR §317.2, §317.8, §381.116,	FSIS Directives 6810.1, 7222.1	Select product and 1. Verify that the product's label is correct and a label approval is on file
Labeling - Net Weights	9 CFR §317.18, §317.19, §317.20, §317.21, §317.22, §381.121a, §381.121b, §381.121c, §381.121d, §381.121e, §442.1-442.5	NBS Handbook 133 NIST Handbook 44 * FSIS inspectors are to use these handbooks as the definitive references for determinations of net weight compliance.	Select an appropriate retail-sized product and 1. Verify net weight regulatory requirements by reviewing establishment records and conducting net weight/drained weight, scale calibration, or tare weight checks. 2. Follow the QC program requirements after evaluating the program to ensure that following the program results in compliance with net weight regulatory requirements.

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
General Labeling	CFR Part 316, Part 317, Part 318, Part 319, §319.6 §327.10(d), §327.26, Part 381, §381.174, Part 412, §424.21, §441.10	FSIS Directives 7120.1, 7620.3, 7640.1, 6700.1, 7235.1, 7270.1, Revision 1	1. Verify that: a. the label contains all required information; b. the ingredients statement is accurate, (i.e., that all ingredients are listed in descending order of predominance); c. the label declares any proteinaceous substances* used in the ingredients statement; d. the establishment used restricted ingredients as per regulatory requirements; e. the label is used on appropriate product; and a label approval is on file. 2. Verify the establishment meets the regulatory requirements for pre-stamping of imported product. When verifying restricted ingredient requirements or ingredient statement compliance, inspection program personnel are to observe the establishment formulating product and compare to the approved label. * NOTE: Proteinaceous substances can cause adverse reactions (i.e., allergic and non-allergic) in certain individuals, and therefore, such substances are of a food safety concern if not clearly declared in the ingredients statement.
Economic Verification Sampling	9CFR §301.2, §381.1, §318.9, §381.1, §381.146	FSIS Directives 10,210.1, 7355.1, 10,240.3, 10,520.1	Directed sampling for economic wholesomeness issues. Misbranding/economic adulteration sampling, directed and unscheduled sampling Economic Testing and Criteria Randomly select an appropriate product for verification. To verify compliance, inspection program personnel are to select and process samples and mail to the designated laboratory as scheduled, or when there is reason to believe that product does not comply with regulatory requirements. Directed Sampling Economic Testing and Criteria 1. Verify compliance by collecting, processing and mailing samples (bacon, species testing, advanced meat recovery products, mechanically-separated species, etc.) to the designated laboratory, upon request from computer-generated instructions, or upon instructions from the Frontline Supervisor or District Office, or Washington Headquarters.

Task Name	9 CFR References	FSIS Issuance	Inspection Personnel Verification Activities
Custom Exempt	9CFR §303.1, §316.6, §317.6, §320.1, §381.10, §381.14, §381.15, §381.175	References FSIS Directive 5930.1 Revision 4	Verify that custom exempt operations in official establishments meet regulatory requirements and do not impact inspected products or operations. Custom Exempt/Retail Exempt 1. Verify the establishment is conducting custom-exempt/retail-exempt operations in accordance with all applicable regulatory requirements including time/space separation and adequate procedures to assure that product does not bear the mark of inspection. Actions are taken by the establishment or FSIS determines that the standards have not been met. This includes actions to ensure that misbranded/mislabeled products do not enter commerce. 2. The custom exempt task is performed by IPP to verify that custom exempt products (uninspected) are properly separated from inspected products in a manner that prohibits adulteration of products that bear the mark of inspection. The custom exempt task primarily involves two procedures: • Verify that there is proper segregation of custom (uninspected) product from inspected product. • Verify that custom exempt products are properly identified and marked as "not for sale".
Retail Exempt	9 CFR 303.1(d), 381.10(d)		Verify that retail exempt operations do not interfere with inspected products/operations The establishment is conducting retail-exempt operations in accordance with all applicable regulatory requirements including time/space separation and adequate procedures to assure that product does not bear the mark of inspection. Actions are taken by the establishment when either FSIS or the establishment determines that the standards have not been met. This includes actions to ensure misbranded/mislabeled product(s) do not enter commerce.
Other Inspection Requirements	9CFR §307.2, 307.4(d), 307.7, 310.1, , 310.2, 310.3, 310.4, 310.7, 318.3, 320.6, 381.36, 381.37(d), 381.67, 381.68, 381.71(a),381.76, 381.77, 381.91, 418.2, and 418.3	FSIS Directives 5000.1, 5220.1,	Verify other inspection requirements Other Requirements: 1. Verify inspection and Reprocessing Stations meet the criteria set forth in regulations to ensure they are adequate for the purpose and do not pose a public health hazard. 2. Verify that line speeds do not exceed regulatory limits. 3. Verify that efficient inspection can be performed on carcasses and parts. 4. Verify actions are taken by the establishment or FSIS determines that the standards have not been met. This includes actions to ensure that misbranded/mislabeled products do not enter commerce.