Non-Food Safety Consumer Protection Regulatory Requirements — FSIS Directive 7000.1

OBJECTIVES

After completing this module, you will be able:

1. Identify the statutes and regulations that relate to non-food safety consumer protection responsibilities.
2. Describe how to conduct the 04 procedures appropriately.
3. Describe how to conduct the 05 procedures appropriately.
4. Explain what to do when noncompliance is observed.
5. Describe what to do when there are multiple noncompliances.

RESOURCE MATERIALS

- Federal Meat Inspection Act (FMIA)
- Poultry Product Inspection Act (PPIA)
- FSIS Directive 7000.1- “Verification of Non-Food Safety Consumer Protection Regulatory Requirements”
- 9 CFR Parts 301, 313, 316, 317, 318, 319, 327, 381 Subpart P, 424, 441, and 500
- FSIS Directive 5000.1, Revision 2, Amendment 1, “Verifying an Establishment’s Food Safety System”
- FSIS Directive 5400.5, Attachment 5, “Inspection System Activities”
- FSIS Directive 6120.1, “Finished Product Standards Program for the New Line Speed Inspection System and the Streamlined Inspection System”
- FSIS Directive 6700.1 Amendment 1, "Retained Water in Raw Meat and Poultry Products"
- FSIS Directive 6810.1, “Grademark Labeling on Meat and Poultry Product”
- FSIS Directive 6900.1, Revision 1, “Humane Handling of Disabled Livestock”
- FSIS Directive 6900.2, “Humane Handling and Slaughter of Livestock”
- FSIS Directive 7000.2, “Experimental and Sample Product Policy”
- FSIS Directive 7120.1 Amendment 13, “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 7140.1, “Questions and Answers Relating to Ingredients that may be Designated as Flavors, Flavorings, Natural Flavorings in the Ingredients Statement on the Labels of Meat and Poultry Products”
- 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, Revision 1, “Advanced Meat Recovery Using Beef Vertebral Raw Materials”
- FSIS Directive 7220.1, Revision 3, “Policy Memoranda”
- FSIS Directive 7221.1, Amendment 1, “Prior Labeling Approval”

- FSIS Directive 7222.1, “Inspection Requirements for Food and Nutrition Service In-plant Control Programs”
- FSIS Directive 7235.1, “Mandatory Safe Handling Statements on Labeling of Raw and Partially Cooked Meat and Poultry Products”
- FSIS Directive 7237.1, Revision 1, Amendment 1,“Labeling of Ingredients”
- FSIS Directive 7270.1, Revision 1, “Sampling and Testing Procedures for Raw Poultry Products Labeled “Fresh’”
- FSIS Directive 7355.1, Revision 2 “Use of Seals for Program Samples and Other Applications”
- FSIS Directive 7620.3, “Processing Inspector’s Calculation Handbook”
- FSIS Directive 8080.1, Revision 4, Amendment 3, “Recall of Meat and Poultry Products”; FSIS 8080.1, Rev. 4, Amendment 1 (7/29/04)
- FSIS Directive 10,200.1 “Accessing Laboratory Sample Information via LEARN”
- FSIS Directive 10,210.1, Amendment 6, “ Unified Sampling Form”
- FSIS Directive 10,520.1, Revision 1, “Pumped Bacon Sampling Program — Nitrosamine Analysis”
- Part 3, Section 3, “Import Inspection Manual of Procedures for the Species Verification Testing Program”
- Policy Memos 42, 44A, 57A, 66C, and 84A (http://www.fsis.usda.gov/OPPDE/larc/Policies/Policy_Memos_082005.pdf)
- Food Standards and Labeling Policy Book (http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf)
- NBS Handbook 133
- NIST Handbook 44 (http://museum.nist.gov/object.asp?ObjID=55)

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, or NFSCP. These requirements relate to economic adulteration and misbranding of products other than food safety. Additional information may be obtained from the Training CD developed by FSIS Center for Learning.

FSIS’ highest priorities are protecting public health and food safety. The Agency is ensuring 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 Inspection System Procedures (ISP) 04 and 05B to verify that the establishments are complying with regulatory requirements designed to protect the consumer in ways other than ensuring food safety. The Agency is issuing new ISP description for all 04 and 05B procedures, except 04C02, Humane Handling (inspection program personnel are to follow Dir. 6900.1, Rev.1, and 6900.2, Rev.1). FSIS has retired procedure code 04C01, and therefore, IPP are not to use it.

The Agency is making changes in the verification procedures that relates to these other protections to ensure that they align with FSIS’ responsibilities and priorities.

STATUTES

Federal Meat Inspection Act (FMIA)

Let's start by reviewing the statutes 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), the amount of product in the container falls 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(b) states: labels must be "in distinctly legible form." Section 607(c) states that misleading or false labeling is to be avoided. It also indicates articles that are subject to standards of identity must be consistent with those standards when they apply to the article. Section 607(d) states, "No article subject to this subchapter shall be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted". 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.

Poultry Products Inspection Act (PPIA)

There are similar provisions related to the definition of the term "misbranding" in the PPIA. Here's an overview.

- PPIA 453(h) – Definition of "misbranded" with 12 provisions.

- PPIA 457 – Labeling and container standards. There are four parts to this section:

  (a) Must bear legible labels
  (b) Must comply with definitions and standards of identity; and fill of container
  (c) Must not be sold under false labeling or misleading size
  (d) Label may be withheld until modified so that it is not misleading or false.

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. You will need to review the regulations on your own to become familiar with them in more detail, as we will not cover all aspects that you need to know during this training program.

General 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. Currently, there are forty two regulations related to NFSCP requirements for meat products, and some of these regulations have a number of subparts.

9 CFR 317.1 states that labels are required for containers of meat products. There are a few exceptions which are outlined in the regulation.

9 CFR 317.2 outlines the required features of labels for meat products. Here are some of the basic requirements. The label must list the name of the product and ingredients used in the production of the product. The name and place of business of the manufacturer must be shown on the label. It must also contain an accurate statement of the net quantity of the contents of the product. Just as was stated in the statutes, the label must not be false or misleading. It must list any handling of the product that is required in order to maintain the product in a wholesome condition. There are also some very specific requirements for safe handling instructions for meat and meat products.

9 CFR 317.4 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. Currently, the organizational unit responsible for handling the approval of labels is the Labeling and Consumer Protection Staff (LCPS), Office of Policy, Program and Employee

Development. A sketch label is a printers proof or the equivalent which clearly shows all labeling features, including the size, location, and final color of the label. The LCPS 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.

9 CFR 317.5 covers generically approved labels. When a label meets one of the conditions of being a generically approved label, it does not have to be submitted to FSIS for further approval. 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 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. Let's review a few of the key parts. As we walk through these, you'll see that they are very similar to the regulations that we reviewed for meat products. They also match the same principles contained in the statutes that we reviewed. Here are some highlights.

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 CFR381.124 – 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. This process is the same as the one for meat products.

9 CFR 381.133 – Covers the requirements related to generically approve 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. Remember those products can use generic labels. 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. We won't cover each of the products outlined in the regulations in detail but you need to review these regulations and become familiar with the requirements associated with each product that is produced in the establishment where you are assigned.

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 products 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 very few, if any ingredients or preparation, to products such as cooked sausage that may have a number of ingredients and may go through a variety of steps in preparation. Remember that we covered some of the processing steps when we introduced you to the regulated industry. For example, Subpart B (—Raw Meat Products) covers the following products: chopped and ground beef, hamburger, beef patties, fabricated steak, and partially defatted beef and pork fatty tissue. In Subpart D (—Cured Meats, Unsmoked and Smoked) some products such as cured pork products, the regulations relate to the list of ingredients on the label, such as binders, and the percent of water added. Also, for some products, there are protein fat free (PFF) percentage regulatory requirements; in other products Mechanically Separated

(Species) Product may be used in accordance with §319.6. The regulations also specify that smoking must be done with approved nonresinous materials (§319.160). Furthermore, there are definitions in the regulations of each of these types of products. For example, in Subpart L (—Meat Specialties, Puddings and Nonspecific Loaves), there is a very specific definition of the meat product bockwurst that includes details of the formulation of the product. Subpart M (—Canned, Frozen, or Dehydrated Meat Food Products) contains a very specific definition for "hash".

Remember that in this section of the training we are covering the labeling requirements related to these products. There are food safety requirements for these products as well. You will learn about the food safety requirements when you attend the Food Safety Regulatory Essentials (FSRE) training.
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)

9 CFR 381 Subpart P covers the labeling requirements for poultry products that have standards of identity. Again, if the establishment you are assigned produces any of these types of products, you must familiarize yourself with the specific regulations, as from time to time you will be performing procedures to verify that these products comply with the labeling requirements. Let's walk through a few of these requirements briefly. 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 cover 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:

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)

VERIFICATION METHODOLOGY FOR NON-FOOD SAFETY ISP CODES

If you are assigned to a large plant, the inspection procedures for verifying that the establishment complies with the NFSCP requirements will be performed by a Consumer Safety Inspector (CSI) that you supervise. You may perform the 04 and 05B procedures when you are acting in a relief capacity for the CSI. If you are assigned to work in establishments that are small or very small, you may perform these duties yourself. In either case, you need to know the details of how to perform the procedures. So, we will cover how to perform the procedures as if you were doing them yourself.

FSIS Directive 7000.1 provides instructions for how you are to perform verification procedures related to NFSCP requirements. While performing NFSCP procedures, it is possible that you may uncover concerns related to an establishment's food safety systems, such as the SSOP or HACCP plan. When this occurs, you should perform the food safety procedure as an unscheduled procedure and take any necessary enforcement actions. For example, if you are performing a routine labeling verification procedure and discover that the establishment has issued an ingredient of public health concern without properly declaring the ingredient, you should pursue the food safety aspects of the findings and performed any warranted, unscheduled food safety procedure as instructed in FSIS Directive 5000.1, Revision 2 Amendment 1.

Inspection program personnel are not to perform unscheduled NFSCP 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 an unscheduled verification procedure and a thorough evaluation. Whenever an unscheduled verification procedure is specified, a pop-up dialogue screen will appear in the PBIS on-line reporting system. Using the dialogue screen, provide a brief explanation of why you believe an unscheduled procedure is warranted.

Performing the 04 procedures (all 04A and 04B codes, and 04C03 and 04C04 codes)

NOTE: Procedure code 04C01 has been retired and is no longer used.

When the Performance Based Inspection System (PBIS) schedules one of these NFSCP procedures per one of the above codes, you are to perform the appropriate verification procedures by:

- observing establishment product formulation, verifying the accuracy of labeling;
- observing preparation or processing procedures;
- reviewing establishment records;
- examining product;
- checking product identification, condition and temperature;
- or performing a variety of other in-plant measurements, testing and calculations;
- observe slaughter practices

Inspection personnel need only examine product when they have reason to believe that product does not meet regulatory requirements. However, 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, nor are IPP to examine all products. They examine 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 exceeds its net weight, IPP are to investigate whether there have been problems in the process that will cause all packages to exceed the net weight requirements.

When you verify (under 04C) the condition of inspected and passed product, verify product identification, and evaluate the product condition. That includes the product temperature and storage. After such an assessment, you should be able to determine the extent of the verification procedures that you may need to perform. Where effective establishment processing controls are evident, only limited verification activity may be necessary. You should, in these cases, direct the inspection to those parts of the processing operation that are not covered by an establishment's control procedures. You do not need to count individual defects to make a judgment on a finished production lot. The condition of product should be clearly evident and sufficient to allow inspection personnel to render a judgment that the product is not adulterated.

Verification activities under 04A and 04B (Formulation and Labeling)

Verify that the establishment is producing product in compliance with the appropriate 9CFR reference (see Attachment 1 of Directive 7000.1) and determine whether the product complies with the regulations by comparing the product to the relevant regulatory requirements.

So, what should you be looking for when you observe product formulation?

- Verify that the product meets requirements that are specified in the applicable standards of identity.
- Verify that all ingredients have been added in amounts that come within the maximum or minimum level specified in the applicable standard.
- Verify all ingredients used in formulating the product are accurately declared on the label in descending order of predominance and any proteinaceous substances used in the formulation are declared in the ingredient statement.
- Verify that the product defects level are consistent with applicable standards.
- Observe establishment activities.
- Review establishment records.

Proteinaceous substances can trigger food sensitivities or allergies in certain individuals and therefore, such substances are of a food safety concern if they are not clearly declared in the ingredients statement. The eight most common food allergens that have become a serious issue for the food industry include milk, eggs, fish, crustacean shellfish (e.g., shrimp), peanuts, tree nuts (almonds, walnuts, etc.), soybeans, and wheat. The U.S. Department of Agriculture considers the above mentioned undeclared allergens, with the exception of wheat, as the basis for Class I or II recalls which have potential for severe health consequences. The Recall Committee is responsible in making the decision for which recall classification the undeclared allergen will fall under based on their assessment of the product in question. Following are a few examples of products with undeclared ingredients that triggered a recall. Recently, there were two products that were retrieved from market under Class I classification. One of them was deli franks which may have contained dry milk, and the other product was soup with meatballs and chicken which contained cheese as the undeclared ingredient. Under Class II classification, the product “Steak for Country Frying-Fully Cooked Cubed Steaks” was recalled from the market due to undeclared “buttermilk blend” in the ingredient statement on the carton.

What should you do when verifying the NFSCP requirements related to labeling?

- Review the establishment’s labeling records including any supporting documentation such as letters from FSIS, temporary approvals, etc.
- Determine whether labeling is approved in accordance with appropriate regulations, i.e., either approved as a sketch by the FSIS LCPS, or generically approved in accordance 9 CFR §317.5 or §381.133.
- Verify that the required features are present on the labels.
- Verify that the net weight of the product is accurately reflected on its label.
- Verify that the labels are not false or misleading.
- Verify that the correct labels are applied to products.

<u>Verification activities under 04C03 (Livestock Product Examination)</u>

Under 04C03, IPP are to verify that the establishment complies with 9 CFR 318.2, 318.5, and 318.6. The IPP are no longer to perform activities known as livestock carcass re-inspection, boneless meat re-inspection, and other product re-inspection duties to verify compliance with the relevant regulations. Instead, IPP only are to examine product that may have undergone a significant change after it was inspected and passed (e.g., chilled in the cooler or boned). In other words, the IPP should be able to determine the

extent of the procedures needed based on conditions observed in the establishment. Where effective establishment processing controls are evident (i.e., the establishment has procedure in place to examine incoming product for acceptability, uses control programs to monitor product processing, and such controls and procedures are documented), the IPP will limit non-food safety verification activities. In these cases the IPP will direct their inspection to those parts of the processing operation that the establishment does not cover by control procedures. The IPP need not count individual defects to make a judgment on a finished production lot but 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 condition of the product should be clearly evident and sufficient to allow inspection personnel to determine that the product is in compliance. As mentioned earlier, determinations of acceptability should be based on production lots and process controls rather than on individual units of product.

The purpose of the product examination is to determine whether standards are being met and the product meets the conditions as set out in the Act: "…any valuable constituent has been in whole or part omitted or abstracted there from; or any substance has been substituted, wholly or in part thereof, or if damage or inferiority has been concealed in any manner; or if any substance has been added to the product or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is" (21 U.S.C. 601(m) (8)).

In addition, IPP may also observe establishment's quality control programs and review associated records to verify whether the establishment meets regulatory requirements.

Inspection program personnel should consult with their Frontline Supervisor (FLS) for assistance, when necessary, in determining noncompliance. The Policy Development Division (PDD) (formerly Technical Service Center (TSC)) will provide additional guidance to assist with determining noncompliance.

Examples of noncompliance situations:

- IPPS 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.

  Note: 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.

Verification activities under 04C04 (Poultry Product Examination)

The 04C04 procedure is used to verify that the establishment complies with the relevant regulations for poultry finished product standards (FPS), Giblet Acceptable Quality Levels, rework product standards, inspection of received products and returned products, and good commercial practices (GCP) for slaughter. Inspection program personnel inspect raw or unprocessed poultry products under the 04C04 procedure. In

addition, the 04C04 procedure is used to verify conformance with GCP for poultry slaughter that comply with 9 CFR 381.65 (b), i.e., thorough bleeding of carcasses, ensuring that breathing has stop prior to scalding, and that blood from the killing operation is confined to a relatively small area.

The Agency does not have a list of what is considered approved GCPs for slaughter. Good commercial practices are determined by Industry. The National Chicken Council and a few other organizations have listed on their website what they consider GCPs. In many ways, the GCPs followed by a plant would be determined by the plant's production process.

Inspection program personnel verifying compliance with FPS are to use criteria as listed in the regulations. They should verify compliance by performing pre-chill FPS testing, post-chill FPS testing, reinspection of carcasses and giblets, inspection of returned products, inspection of rework products, and condition inspection of products in the establishment. Also, they are to perform the activities at the frequencies prescribed in 9 CFR 381.76. Each time inspection program personnel perform the FPS activities they are to record the activities in PBIS as unscheduled.

Sample collection for NFSCP verification (05B01)

When scheduled by PBIS, conduct sampling activities under the appropriate 05 ISP code. The non-food safety sampling verification is schedule under ISP code 05B01. Inspection program personnel may perform unscheduled non-food safety sampling activities when, 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 and testing is the only means available to determine noncompliance, e.g., finished product in which IPP cannot verify formulation and composition without laboratory testing. Whenever you believe an unscheduled sample is warranted, notify the FLS by e-mail explaining why you believe an unscheduled sample is warranted and receive his or her approval before proceeding.

When inspection program personnel perform any sampling they are to inform the establishment management when they are taking a sample and the reason why FSIS is analyzing the sample. This notification will afford establishment management the option to hold all product represented by the sample, pending the sample results.

Code 05B01 is the procedure code to be entered on the schedule when a non-food safety sample is collected. However, if the sample result indicates that the product does not comply with the regulations, the IPP document a Noncompliance Record (NR) under the appropriate ISP code, **not** 05B01.

Note: The Office of Public Health and Science (OPHS) directs food safety sampling. When directed by OPHS to perform food safety sampling, IPP should document the collection of the samples as an unscheduled procedure under code 05B02.

Please note that IPP will no longer receive the Species Identification Field Test (SIFT) kits to conduct in-plant tests to determine whether product contains a species that is not accurately declared on the product label. When IPP have concerns about the species in a product, they are to collect the sample as follow.

- When IPP collect samples for species testing, they are to collect at least one pound of product and put in a plastic bag supplied by the laboratory. If the product is in a natural casing, IPP are to collect a sample of the emulsion. Thereafter, IPP are to complete FSIS form 10,000-2 (form may be requested from Field Supply Center in Beltsville, MD) as follows:

  — Block 7 -- establishment number
  — Block 13 -- date sampled
  — Block 14 -- date mailed
  — Block 21 -- check 'species identification' box
  — Block 24 -- provide production lot sample and declared species
  — Block 25 -- inspector name (type or print)
  — Block 26 -- badge number

  - IPP are to attach product label showing an ingredient statement to the 10,000-2 Form. Also, they are to:

    — follow FSIS Directive 7355.1, Revision 2, "Use of Sample Seals for Laboratory Samples and Other Applications";
    — ship the samples to the Eastern Laboratory in an insulated shipping container;
    — use sufficient frozen gel packs to keep the sample cold, and
    — ship via overnight contact carrier, Monday thru Friday. For samples shipped on Fridays, be sure to mark Saturday delivery on package and include a Saturday delivery sticker on the box.

- The results will be on the LEARN intranet site (see FSIS Directive 10,200.1) for receipt information and sample results. The laboratory will test the product against a panel of species anti-sera, report species results that correlate with the ingredient statement as "Acceptable", and report species result that indicate a species **not** declared on the ingredient statement is present, or one of the species on the ingredient statement is **not** present as "Not Acceptable".

Enforcement

Product compliance determinations are made based on NFSCP regulatory requirements (see Attachment 1 in Directive 7000.1), 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 NFSCP regulatory requirements, there is regulatory 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 FLS for assistance when necessary.

Good commercial slaughter practices for poultry should be evaluated on a case by case basis. Inspection program personnel must use a logical thought process when determining if poultry are being treated in a manner consistent with GCPs. If birds have not stopped breathing prior to entering the scalding process or died otherwise than by slaughter, this would represent a failure to follow GCPs and the requirements of 381.65

(b) and 381.1 (b) (v). Carcasses and parts would be considered adulterated under the provisions of the PPIA.

Issue an NR (see FSIS Form 5400-4) when product is not in compliance with NFSCP regulatory requirement, and orally notify the establishment management of the finding. 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 FLS 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 (e.g., under-weight product, the product does not meet requirements that are specified in the applicable standard of identity for the product, etc.), would otherwise enter commerce (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.

Inspection program personnel are to issue NRs when they determine the process are out of control, resulting in economically adulterated or misbranded product. Inspection program personnel should link the NRs when noncompliances are from the same cause, as described in FSIS Directive 5000, Revision 2 Amendment 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 should notify the Regional Manager of the Compliance and Investigations Division whenever 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.

SPECIFIC NFSCP PROCEDURES

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

<u>04A01 - % Yield/Shrink/Gain</u>

When performing this procedure, 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 procedure 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.

04A02 – X% Solution Labeled Products (applies only to X% labeled products)

You will verify the requirements associated with X percent solution for 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, read- 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 procedure 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.

04A03 – 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 procedure 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.

04A04 – 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 procedure. 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.

04B01 – 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 procedure 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.

04B02 – 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 procedure 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.

04B03 – 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: 317.18-22; 381.121 (a-e)

References: NBS Handbook 133
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 procedure 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.

04B04 – General labeling

Procedure 04B04 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; 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.

04C02 − Humane Handling and Slaughter

Procedure 04C02 is the procedure for verifying humane handling and slaughter. We covered this in another section of the training.

04C03 – Livestock Product Examination

Procedure 04C03 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 procedure 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 (318.2b).

04C04 – Poultry Product Examination

Procedure 04C04 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; 381.91(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; and
- condition of products in the establishment.
- observation of slaughter practices

05B01 – Misbranding/Economic Adulteration Sampling, Directed and Unscheduled Sampling

Procedure 05B01 covers misbranding and economic adulteration sampling. It can be directed or unscheduled.

Examples of products: cooked sausage, Italian sausage, ground beef, hamburger, ground pork, pH controlled product, lard, and others

Regulations: 301.2; 318.9; 318.22; 318.24; 319; 319.5; 381.1; 381 Subpart P; 381.146; 381.173; 500.3

When performing this procedure randomly select an appropriate product for verification. Verify compliance by collecting, processing and mailing samples to the designated laboratory as scheduled, or when there is a reason to believe that product is not in compliance with regulatory requirements. Request permission to sample suspect product from the FLS and notify the establishment of the sampling.

Note: 05B02 covers food safety directed sampling which was covered in the FSRE class.

FSIS **Directive 7000.1 -Verification of NFSCP Regulatory Requirements — Workshop**

A. 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. If when performing an NFSCP procedure you uncover concerns related to an establishment’s SSOP or HACCP plan, you should:

    a. Perform an unscheduled 04 procedure.
    b. Perform an unscheduled food safety procedure.
    c. Perform an unscheduled 05 procedure.
    d. Contact the Policy Development Division (formerly Technical Service Center).

4. NFSCP duties cover which one of the following?

    a. HACCP verification
    b. economic adulteration
    c. SSOP verification
    d. food safety sampling

5. Which of the following represents what you should do when performing the 04 procedures?

    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.

6. When observing product formulation, you should do all of the following except:

   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 ascending 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. Observe establishment activities and review establishment records.

7. Is the following statement TRUE or FALSE?

   When verifying NFSCP requirements for labeling, you should determine whether labeling is approved in accordance with appropriate regulations, i.e., either approved as a sketch by the FSIS LCPS, or generically approved in accordance with 9 CFR 317.5 or 381.133.

   a. TRUE
   b. FALSE

8. 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.

9. Is the following statement TRUE or FALSE?

   It is appropriate to perform unscheduled NFSCP verification procedures when you suspect regulatory requirements are not being met?

   a. TRUE
   b. FALSE

10. Is the following statement TRUE or FALSE?

    It is not appropriate to perform unscheduled sampling unless you suspect regulatory requirements are not being met.

    a. TRUE
    b. FALSE

11. Which of the following must be done first if you believe collecting an unscheduled sample is warranted?

    a. Notify the FLS by e-mail explaining why the sample is warranted.
    b. Inform the DO before you take the sample.

c. Inform plant management before you take the sample.
d. Inform plant management of the type of analysis that will be done on the sample.
e. All of the above.

12. Is the following statement TRUE or FALSE?

    Make determinations of noncompliance on individual units of product.

    a. TRUE
    b. FALSE

13. 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.

14. When noncompliance is found which of the following must be considered in determining the amount of noncompliant product involved in the noncompliance?

    a. The establishment's number of employees.
    b. Sampling records.
    c. Production records.
    d. None of the above.

15. All of the following are appropriate regulatory control actions to take if it appears that a product that is economically adulterated or misbranded will be shipped from the establishment except:

    a. Retention of product.
    b. Rejection of equipment or facilities.
    c. Stopping lines.
    d. Refusing to allow the processing of specifically identified product.
    e. Refusing to allow the plant manager to leave the establishment.

16. What should you do when there are repeated violations involving the same process and product and the establishment seems unable or unwilling to maintain regulatory compliance?

    a. Link the NRs.
    b. Notify the DO through supervisory channels.
    c. If a regulatory control action is taken, maintain that action 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.

d. Conduct any follow up verification activities as directed by the DO to ensure compliance.
e. All of the above.

17. When performing the 04A01 procedure to verify compliance with regulatory requirements, you should do all of the following except:

    a. Select an employee to accompany you.
    b. Select an appropriate product.
    c. Review establishment records and labels.
    d. Calculate % yield, gain, or shrink and compare result with regulatory compliance.
    e. Be familiar with the regulatory requirements.

18. Is the following statement TRUE or FALSE?

    For 04A01, 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, gain, or shrink, and comparing the result with the appropriate regulatory requirement.

    a. TRUE
    b. FALSE

19. What should you do when performing the 04A02 procedure 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.

20. What should you do when performing the 04A03 procedure 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.

21. When directed to take samples while performing the 04A03 procedure, you should do all of the following except:

    a. check product identification, condition, temperature, holding time/temperature
    b. compare your finding with the closest plant
    c. review establishment laboratory results and compare findings with the appropriate regulatory standard

d. examine bones (for example two intact portions of bones) before and after the meat recovery system to observe condition and conformation

22. Is the following statement TRUE or FALSE?

When performing the 04A04 procedure to verify compliance with regulatory requirements, it is not appropriate to perform batter and breading.

a. TRUE
b. FALSE

23. What should you do when performing the 04B01 procedure to verify compliance with regulatory requirements?

a. Select an appropriate product for verification.
b. 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.

24. What should you do when performing the 04B02 procedure to verify compliance with regulatory requirements?

a. Verify that labeling is used on appropriate product
b. Contact your supervisor prior to performing verification
c. Verify that there is a label approval on file at the TSC
d. Review all NRs

25. What should you do when performing the 04B03 procedure to verify compliance with regulatory requirements

a. Select an appropriate wholesale-sized product for verification.
b. 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.

26. When performing the 04B04 procedure 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 there is a label approval on file.
d. Verify that the label has been used at least twice.

27. What should you do when performing the 04C03 procedure to verify compliance with regulatory requirements?

    a. Select an appropriate product for verification.
    b. Review establishment records and/or observe plant performance of activities.
    c. You may perform direct examination of the product.
    d. All of the above.

28. What should you do when performing the 04C04 procedure to verify compliance with regulatory requirements

    a. only perform pre-chill and post-chill FPS testing
    b. perform reinspection of carcasses, giblets, and spleens
    c. return reworked product
    d. observes poultry slaughter practices.

B. Match the NFSCP procedure codes below with the type of requirements they are used to verify.

	NFSCP procedure	Requirements verified
____	1. 04A01	A. product standards
____	2. 04A02	B. general labeling
____	3. 04A03	C. % yield/shrink/gain
____	4. 04A04	D. CN/grade/declared count
____	5. 04B01	E. poultry product examination
____	6. 04B02	F. MSP/PDBFT/AMRS
____	7. 04B03	G. misbranding/economic adulteration sampling
____	8. 04B04	H. batter/breading
____	9. 04C03	I. carcass/boneless meat reinspection
____	10. 04C04	J. X% solution
____	11. 05B01	K. net weights