

Introduction to the Course

Objectives

After completing this module, students will be able to:

1. Explain the purpose of the Non-Food Safety Consumer Protection requirements.
2. Identify the primary statutes, regulations, directives and tools that relate to Non-Food Safety Consumer Protection (NFSCP) responsibilities.
3. Distinguish between the meaning of economic adulteration and misbranding.
4. Explain the meaning of the terms restricted ingredients and standard of identity.
5. Describe the requirements being verified when performing the five NFSCP tasks.
6. Describe the circumstance for conducting a directed NFSCP task.
7. Describe the IPP actions when product is economically adulterated, when product is misbranded, and when there is repetitive noncompliance.
8. Describe the enforcement action to be taken when repetitive noncompliance is found involving the same process or product.

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 6810.1, “Grademark Labeling on Meat and Poultry Product”
- FSIS Directive 7000.1 “Verification of Non-Food Safety Consumer Protection Regulatory Requirements”
- 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 7220.1, “Food Labeling Division Policy Memoranda” (Policy Memos 57A and 84A)
(www.fsis.usda.gov/OPPDE/larc/Policies/Policy_Memos_082005.pdf)

- 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 7620.3, “Processing Inspector’s Calculation Handbook”
- Food Standards and Labeling Policy Book
(www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf)
- Labeling Compliance Guideline (November, 2013)

Training

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

The mission of the Food Safety and Inspection Service (FSIS) is to assure that meat, meat food, poultry, poultry food, and egg products distributed in interstate commerce are wholesome, not adulterated, and properly marked, labeled, and packaged (not misbranded). FSIS enforces the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA) and the regulations implementing these laws. FSIS Directives and FSIS Notices provide inspection program personnel (IPP) with specific instructions to help them enforce the laws and regulations.

The highest priority in FSIS is protecting public health and food safety. The Agency directs IPP to focus on food safety and food security (when specific heightened security threat condition is declared). Nevertheless, FSIS must continue to verify that establishments that produce meat, poultry and egg products comply with the statutory and regulatory requirements that do not address food safety. These statutory and regulatory requirements are referred to as Non-Food Safety Consumer Protection (NFSCP) or Other Consumer Protection (OCP) requirements. NFSCP regulatory requirements ensure that meat, poultry and egg products distributed to consumers are wholesome and not economically adulterated or misbranded.

Statutory Authority

Economic Adulteration

The FMIA identifies statutory provisions that provide non-food safety protection for consumers. The first requirement is that carcasses, carcass parts, meat, and meat food products distributed to consumers cannot be adulterated. The term “adulterated” is

defined in 21 U.S.C. 601(m) of the FMIA. 601(m) identifies nine circumstances (m 1-9) in which a carcass, carcass part, meat or meat food product is adulterated.

The eighth circumstance (m 8) addresses consumer protection from economically adulterated products:

601 (m)(8)

The term adulterated applies to a meat or poultry food product:

if any valuable constituent has been in whole or in part omitted or abstracted there from; or if any substance has been substituted, wholly or in part; or if damage or inferiority has been concealed in any manner; or if any substance has been added or mixed 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.

When a meat food product such as hamburger has added water or a higher fat content than allowed, the product is economically adulterated. In either of these cases, a valuable constituent (lean beef) has been omitted or water or fat has been added (substituted) in place of lean beef that reduces the product's quality or value.

The same economic adulteration definition appears 21 U.S.C. 453(g) of the PPIA and 21 U.S.C. 1033(a) of the EPIA.

Misbranded

The second requirement is that carcasses, carcass parts, meat, and meat food products distributed to consumers must be properly marked, labeled and packaged. When a carcass, carcass part, meat, or meat food product is not properly marked, labeled and packaged, it is misbranded. The term "misbranded" is defined in 21 U.S.C. 601(n) of the FMIA. 601(n) identifies twelve circumstances (n 1-12) in which a carcass, carcass part, meat or meat food product is misbranded.

A carcass, part thereof, meat or meat food product is misbranded when it(s):

- n(1), has labeling that is false or misleading.
- n(2), is offered for sale under the name of another food.
- n(3), is an imitation of another food.
- n(4), has a container that is misleading.

- n(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.
- n(6), contains a label that is missing required information.
- n(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.
- n(8), amount in the container falls below the fill standard.
- n(9), contains ingredients that are not represented on the label by the common and usual name of the ingredient.
- n(10), has special dietary claims but does not list the corresponding dietary properties and information required on the label.
- n(11), contains artificial flavoring, coloring, or chemical preservatives that are not listed on the label.
- n(12), requires some type of handling for a wholesome condition to be maintained but the label fails to contain that information.

Many of the misbranding definitions identify the term label or labeling. Hence, the terms “label” and “labeling” are also defined in the 21 U.S.C. 601 of the FMIA as follows.

- 601(o) – The term “label” means a display of written, printed, or graphic matter upon the immediate container of any article.
- 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 such as a bill of lading or receipt.

The same misbranding, label and labeling definitions appear 21 U.S.C. 453(h) and 453(s) of the PPIA, respectively.

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

There are similar provisions for labeling and containers in the 21 U.S. C. 457 of the PPIA and 21 U.S.C. 1036 of the EPIA.

Regulations and Policies

The regulations that provide non-food safety protection to consumers are extensive and detailed. However, the same statutory provisions for adulteration and misbranding, as well as the definition of a label and labeling can be found in 9 CFR 301.2 and 9 CFR 381.1.

Regulations and policies also outline the approved ingredients which can be used in or on food products. These documents may dictate the amount of ingredients allowed in or on a product, and the purpose for which the ingredient can be used. Food and Drug Administration (FDA) regulations, 21 CFR Subchapter B, identify all approved food for human consumption. 21 CFR Subchapter B Parts 172-184 address direct and indirect food additives, and Parts 73, 74, 81, 82 address color additives. These regulations are incorporated into FSIS regulations by reference in 9 CFR 424.21(b)(2). FSIS determines the suitability of ingredients to be added to meat and poultry products, specifically, and they are listed in 9 CFR 424.21 and updated quarterly in FSIS Directive 7120.1. While FSIS no longer issues official policy through Policy Memos, and many have been cancelled or rescinded, there are Policy Memos that remain active and relevant. These have been incorporated into the Food Standards and Labeling Policy Book.

Some products have standards of identity. These regulatory standards in 9 CFR 319 and 381 Subpart P, dictate the ingredients, preparation and/or processing of the product in order for it to bear that name on its label. Product standards are also set by the Food Standards and Labeling Policy Book. We will talk more about Standards of Identity as we look at the Labeling Product Standards Task.

In the regulations, 9 CFR 442.1 prescribes the procedures to be followed for determining net weight compliance and prescribes the reasonable variations from the declared net weight on the labels of immediate containers of products in accordance with 9 CFR 317.2(c)(4), 317.2(h) and 381.121. FSIS uses the NIST Handbook 44 and the NIST Handbook 133 standards as the basis for verifying net weights and these documents have been incorporated into regulation by reference.

Non-Food Safety Consumer Protection Tasks

In this training, we will be teaching you how to verify non-food safety consumer protection regulations using five tasks:

General Labeling
Labeling Product Standards
Percent Yield/Shrink
X% Solution
Net Weight

See Attachment 1 for a chart of all the NFSCP Tasks.

General Labeling Task

When performing the General Labeling Task, IPP are to verify compliance with the labeling regulations, ensuring that the required label

- Is affixed to the immediate container and contains all the required information (mandatory features)
- Has an accurate ingredients statement
- Identifies any proteinaceous substances such as allergens
- Verify restricted ingredients

Restricted ingredients (RIs) are non-meat ingredients, such as curing agents or antioxidants. They are direct food additives and have a maximum amount allowed in the finished product. The maximum amount is established in the regulations in 9 CFR 424.21 and is updated quarterly in Directive 7120.1 - Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products. The establishment MAY add the ingredient to the product's formula in any amount up to its regulatory limit. When this limit is exceeded the additive becomes an economic adulterant. The product is being prepared in a manner that deceives the consumer by concealing inferiority and by causing the product to be of a different quality. When a restricted ingredient is used, IPP must verify it is being used within the regulatory limit. This verification will include reviewing formulation records, watching the establishment formulating the product and performing calculations, as needed, to determine compliance.

The labeling module will cover specific labeling and marking regulatory requirements and the inspection methods IPP use to verify that establishments are in compliance.

Labeling Product Standards Task

When performing the Labeling Product Standards Task, IPP are to verify compliance with the regulations and standards for products that have a standard of identity (as previously mentioned). FSIS regulations and policies prescribe standards of identity, or composition, for many meat and poultry products. Product standards are established to ensure that consumer expectations are met when they purchase a product that is labeled with a particular name (e.g., fresh pork sausage, bologna, chicken pot pie) and help to ensure fair competition among producers making products with the same name. Standards of identity set specific requirements for a product's recipe or formulation.

The regulations that establish standards of identity or composition for meat food products can be found in 9 CFR Part 319. The regulations that establish standards of identity and composition for poultry and poultry food products can be found in 9 CFR 381 Subpart P. A more detailed list of regulations can be found in Attachment 2. As previously mentioned, in addition to the regulations, FSIS also enforces the standards set out in the Food Standards and Policy Labeling Book.

If the product doesn't contain the minimum amount of meat or poultry component, or a required ingredient, or contains an ingredient that is not permitted, the product's label would be false or misleading, and therefore the product is misbranded.

Percent Yield/Shrink Task

As part of their standard of identity, some products (such as some cured products) have established limits for increased weight after processing expressed as gain or yield. Some products must decrease in weight after processing, with a minimum shrink requirement (such as ham or bacon). These required percentages are verified by calculations when performing the Percent Yield/Shrink Task.

X Percent Solution Task

When performing the X Percent Solution Task, IPP are verifying the label truthfulness pertaining to the percentage of added solution which has been declared on the label. IPP calculate the percentage added by formulation and comparing the result to the amount on the label.

Net Weights Task

The Net Weights Task is performed to ensure establishments are properly representing on the label the amount of product in the container. Net Weight calculations allow for some variation, but IPP perform this task to verify regulatory compliance.

Inspection Responsibilities

The Public Health Information System (PHIS) assigns NFSCP tasks to the establishment's task lists based on the product information recorded in the establishment profile. NFSCP tasks are performed to verify that meat, poultry, and egg products distributed to consumers are not economically adulterated or misbranded. As with other inspection tasks, IPP are to schedule the tasks on the dates most appropriate and verify the regulatory requirement using the GAD Thought Process – Gather information, Assess the information and Determine compliance. FSIS Directive 7000.1 provides guidance for verifying NFSCP regulations.

While performing NFSCP tasks, IPP may uncover concerns related to an establishment's food safety system, such as the Sanitation SOP or the HACCP plan. When this occurs, IPP should perform the appropriate food safety inspection task as a directed task following the instructions in FSIS Directive 5000.1. For example, if an IPP is performing the general labeling verification task and discovers that the establishment has formulated a product with an allergen or other ingredient of public health concern without properly declaring the ingredient on the label, the IPP should pursue the food safety aspects of this finding by scheduling and performing the appropriate directed HACCP verification task.

IPP are not to perform directed NFSCP verification tasks unless, during the performance of food safety verification activities (e.g., HACCP or Big 8 Allergen Formulation verification task), they observe conditions or activities that cause them to suspect that the establishment is not meeting NFSCP regulatory requirements. If, following a preliminary assessment of such information, IPP have reason to believe that non-compliant product is being or has been produced, they are to perform a directed NFSCP verification task. In PHIS, IPP should document a brief explanation of why the directed NFSCP task was performed in Findings tab of the Inspection Results page.

Sample Collection

Compliance with the NFSCP regulatory requirements is verified when the meat or poultry food product is formulated, processed, or prepared. Routine sampling for verifying NFSCP regulatory requirements is not cost effective when these requirements can be verified at the time the product is formulated. See Attachment 3 for more information on NFSCP Sampling.

Documentation and Enforcement

IPP assess all the information gathered and determine compliance by comparing what was observed to the relevant regulatory requirements. Compliance with most of the NFSCP requirements is based on production lots and assessing the establishment's control of the process (e.g., applying accurate labeling, applying added solutions to products, or adding ingredients or meat and poultry components that meet the product's standard of identity. Before making a determination that the establishment's process is out of control, IPP consider all available sources of information (e.g., establishment records, and/or monitoring or testing results). IPP may exercise additional discretion when the establish has an effective quality control (QC) program.

When noncompliance is found, IPP notify the establishment management immediately. IPP are to issue noncompliance records (NRs) when they determine the establishment's process is out of control, resulting in economically adulterated or misbranded product.

Examples of Noncompliance

- Raw corned beef exceeds the % added solution stated on the label (X Percent Solution task).
- Smoked bacon failed to return to green weight-102% yield. (%Yield/Shrink task).
- Underweight product i.e., packaged product does not meet the net weight stated on the label. (Labeling – Net Weights).
- 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).

IPP are to consider any relevant factors when determining the amount of noncompliant product involved.

IPP take the appropriate regulatory control actions according to the rules of practice, if misbranded or economically adulterated product would otherwise enter commerce or be shipped from the establishment.

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

Attachment 1: Non-Food Safety Consumer Protection Tasks Job Aid

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
<p>Percent Yield/Shrink</p>	<p>9 CFR §319.107, §319.80, §319.81, §319.100 -103, §319.106, §381.171, and §424.21(c)</p>	<p>Directive 7620.3 “Processing Inspectors’ Calculations Handbook” Chapters 11, 12 and 13</p>	<p>Verify certain products that have a specified %Yield/Shrink as part of their Standard of Identity are met and not misbranded.</p> <ol style="list-style-type: none"> 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, inspection program personnel are to: 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.
<p>X Percent (%) Solution</p>	<p>9 CFR §319.104*, §319.105*, §317.2(c), §317.2(e)(2) §317.8, §381.117(h)(1), and §381.129,</p> <p>*NOTE: Applies only to sections of 319.104 and 319.105 covering X% labeled products.</p>	<p>Food Standards and Labeling Policy Book Policy Memos 57A, 59, 84A</p> <p>Directive 7620.3 “Processing Inspectors’ Calculations Handbook” Chapter 10</p>	<p>Verify products that contain Percent (%) Added Solution meet regulatory standards and are not misbranded. *NOTE: Applies only to X% Labeled Products</p> <ol style="list-style-type: none"> 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.

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
<p>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS</p>	<p>9 CFR §318.24, §319.5, §319.15(e), §319.29, and §381.173</p>	<p>FSIS Directives 7160.1, 7160.2, 7160.3</p>	<p>Verify Mechanically Separated, Partially Defatted, and Advanced Meat Recovery Products meet regulatory requirements.</p> <ol style="list-style-type: none"> 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. <u>In addition, inspection program personnel are to take samples when necessary.</u> 3. Verify compliance, inspection program personnel should: <ol style="list-style-type: none"> a. check product identification, condition, temperature, and holding time/temperature. b. examine bones (for example, two intact portions of bones) before and after the meat recovery systems in order to observe condition and conformation. c. review establishment laboratory results and compare findings with the appropriate regulatory standard. d. take samples as necessary.
<p>Batter & Breeding</p>	<p>9 CFR §319.880 and §381.166</p>	<p>FSIS Directive 7620.3 Chapter 14, Directive 7220.1, Food Standards and Labeling Policy (FSLD) Book Policy Memo 089</p>	<p>Verify batter and breeding of applicable products meets regulatory requirements and product is not misbranded.</p> <ol style="list-style-type: none"> 1. Select an appropriate product, 2. Verify compliance with the batter and breeding regulatory requirements by reviewing establishment records to calculate final % batter/breeding, and comparing the findings to the standards listed in the regulations. <u>In addition, inspection program personnel are to:</u> 3. Verify compliance by performing batter and breeding pickup tests on one or more subgroups (according to the establishment's QC programs) or batches of the product.

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
Livestock Finished Product Standards	9 CFR §310.22, 310.11,, 310.14 310.18(b), 311.14, §318.1(a)(c), §318.2(a)(d), §318.5, and §318.6	FSIS Directive 7000.1	<p>Verify Livestock products are wholesome and not adulterated.</p> <ol style="list-style-type: none"> 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 Policy Development Staff (PDS) will provide additional guidance to assist with determining noncompliance.
Poultry Finished Product Standards	9 CFR §381.1, §381.76 §381.78, §381.84, §381.86, §381.87, §381.89 §381.91(a)(b), and §381.145	FSIS Directive 7000.1	<p>Verify poultry products are produced in a safe, wholesome manner and not misbranded by performing:</p> <ul style="list-style-type: none"> - pre-chill FPS testing, - post-chill FPS testing, - reinspection of carcasses and giblets, - inspection of returned products, - inspection of rework products, - condition inspection of products in establishment, and - observation of slaughter practices
Labeling - Product Standards	9 CFR §319.15, §319.140 - 145 §319.160, §319.180, §319.181, §319.182, §319.260, §319.261, §319.280, §319.281, §319.300 - 310, and §381.155 - 174	FSIS Directives 7620.3, 7220.1	<p>Select an appropriate product and</p> <ol style="list-style-type: none"> Verify compliance by reviewing establishment records and labels; or observe the preparation of products and compare the findings to the appropriate regulatory standards. Verify some regulatory requirements, by performing calculations to determine minimum meat or poultry components or required ingredients.

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
Child Nutrition/Grade Labeling/ Declared Count/Vignette	9 CFR §317.2, §317.8, and §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 §317.2 (c)(h)(i)(j), §381.121a – e, §442.1 - 442.5 and §541.7	NIST 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.
General Labeling	9 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, §541.2-5 and §541.7	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.

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
Collector Generated - Economic Verification Sampling	9 CFR §301.2, §381.1, §318.9, §381.1, and §381.146	FSIS Directives 10,210.1, 7355.1, 10,240.3, 10,520.1	<p>Sampling for misbranding/economic adulteration</p> <p>Economic Testing and Criteria <u>Randomly</u> select an appropriate product for verification. To <u>verify</u> compliance, inspection program personnel are to <u>select</u> and <u>process</u> samples and mail to the designated laboratory when there is reason to believe that product does not comply with regulatory requirements.</p> <p>Sampling Economic Testing and Criteria 1. <u>Verify</u> compliance by collecting, processing and mailing samples (bacon, species testing, advanced meat recovery products, mechanically-separated species, etc.) to the designated laboratory following instructions from the Frontline Supervisor or District Office, or Washington Headquarters.</p>
Custom Exempt	9 CFR §303.1(a)(ii)(iii)(iv), §316.16, §317.16, §320.1, §416.4(d) §416.13(b), §416.13(c) and §381.175		<p>Verify that custom exempt operations in official establishments meet regulatory requirements and do not impact inspected products or operations.</p> <p>Custom Exempt</p> <p>1. <u>Verify</u> the establishment is conducting custom 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.</p> <p>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:</p> <ul style="list-style-type: none"> • <u>Verify</u> that there is proper segregation of custom (uninspected) product from inspected product. • <u>Verify</u> that custom exempt products are properly identified and marked as "not for sale".

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
Retail Exempt	9 CFR §305.2(a), and §381.26		<p>Verify that retail exempt operations do not interfere with inspected products/operations</p> <p>Retail-exempt operations are separate and distinct (e.g., time/space) from the official establishment. Adequate procedures implemented 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 these requirements have not been met. This includes actions to ensure misbranded/mislabeled product(s) do not enter commerce.</p>
Other Inspection Requirements	<p>9CFR §307.2, §307.4(d), §307.7, §310.1, §310.2, §310.3, §310.4, §310.7, §310.11 §310.12, §310.14-16, §310.19, §311.29, §318.1, §318.2(a), §318.2(d), §318.3, §320.1 §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</p>	<p>FSIS Directives 5000.1 and 5220.1,</p>	<p>Verify other inspection requirements Other Requirements:</p> <ol style="list-style-type: none"> 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.

Attachment 2: Standards of Identity

A product standard may identify:

- the kind and percentage of meat or poultry required in the product
- the maximum percentage of a non-meat/non-poultry ingredient or added solution allowed in the product
- the maximum percentage of a specific meat or poultry ingredient
- ingredients that are allowed, required or expected in the product
- any ingredient that **is not** allowed in the product

9 CFR Part 319 - Meat and Meat food 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 - Poultry and Poultry food 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)

In addition to the regulations, FSIS also enforces the standards set out in the Food Standards and Policy Labeling Book.

Attachment 3: Non-Food Safety Consumer Protection Sampling

IPP may submit a NFSCP sample for products that have a regulatory standard of identity defined in 9 CFR part 319 and 9 CFR 381.155 through 9 CFR 381.174. A NFSCP sample may be submitted **only** when IPP observe establishment operations, conditions, processing procedures, product formulations, activities, or records that cause them to suspect that a NFSCP regulatory requirement is not being met **AND** laboratory **testing** is the **only means** available to determine compliance.

Example 1

While performing the Labeling-Product Standards verification task, the IPP observes the addition of water to the formulation of a lot of hamburger. The standard of identity for hamburger (9 CFR 319.15(b)) states that hamburger shall not contain added water. The IPP has determined through direct observation that the hamburger has been economically adulterated with added water. There is no need to submit a sample to confirm the hamburger is economically adulterated with added water.

Example 2

The standard of identity for hamburger (9 CFR 319.15(b)) also states that hamburger shall not contain more than 30% fat. While performing the Labeling-Product Standards verification task, the IPP observes several empty beef trim combo bins next to the grinder used to prepare a lot of hamburger. About a third of the combo bins are labeled 80/20 beef trim. The rest of them are labeled 50/50 beef trim. The 50/50 beef trim is normally used in the preparation of beef patties which do not have a fat content limit. The establishment does not use a rapid fat analysis method to confirm the fat content of the hamburger. In this case, a sample may need to be submitted to verify that the hamburger is not economically adulterated, i.e., the fat content is not over 30%.

Example 3

The standard of identity for hamburger (9 CFR 319.15(b)) also states that hamburger shall consist of chopped fresh and/or frozen beef. While performing the Labeling-Product Standards verification task, the IPP observes several empty beef trim combo bins and one empty mutton combo bin next to the grinder used to prepare a lot of hamburger. The establishment uses mutton and beef trim to produce its breakfast sausage patties. The establishment did not produce breakfast sausage patties on the day the IPP conducted the task. In this case, a sample may need to be submitted to

verify that the hamburger is not economically adulterated and misbranded, i.e., a species substitution has made the product inferior (mutton versus beef) and the label is false and misleading (mutton not listed on the label).

A NFSCP sample falls under Collector Generated sampling. When IPP believe a Collector Generated NFSCP sample is warranted, IPP must get approval from their FLS before collecting and submitting a sample. If the FLS approves the sample request, IPP use the sample management left navigation menu in PHIS to add the task to the calendar using the most appropriate project code.

When IPP take the sample of product, they must notify establishment management and provide them with the reason for taking the sample, e.g., added water analysis, species determination, or fat content analysis. This notification gives management the option to hold all product represented by the sample, pending the sample results.

When IPP collect samples for **species** determination, 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. The natural casing may be from a different species than encased meat food product. For instance, a pork small intestine casing around a sausage meat food product made with beef. This could give a false positive result for pork.

IPP are to determine and record the percent of Group 2 protein contributing ingredients (refer to 9 CFR 318.22) in **the finished or projected finished product** on the sample form when submitting a sample of cooked sausage (9 CFR 319.140, 319.180, and 319.181) formulated with such ingredients to the laboratory for a possible added water violation. Group 2 protein contributing ingredients are ingredients of livestock or poultry origin that have been processed by hydrolysis, extraction, concentrating, or drying, or **any other ingredient** which contributes **protein**, such as ingredients of dairy, plant or yeast origin. Examples include: hydrolyzed pork skins, hydrolyzed plant protein, nonfat dry milk, milk protein hydrolyzate, autolyzed yeast extract, and beef extract. IPP should refer the Processing Inspectors' Calculations Handbook for instructions on how to calculate the percentage of Group 2 protein contributing ingredients in cooked sausages.

IPP must complete all requested information in PHIS on the Sample Management page screens, submit the form to the laboratory electronically, print the sample form, and include form with the sample. IPP are to attach a product label to the printed sample form showing the ingredient statement before packing the sample.

Sample receipt information and the results are reported on the LIMS-Direct intranet site. 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 in the ingredient statement is present, or one of the species on the ingredient statement is not present, are reported as "Not Acceptable".