Further Processing and Labeling Inspection Course Student Handout

May 2024

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01 - Introduction to the Further Processing and Labeling Course

Objectives

After completion of this module, the student will be able to:

1. Explain the purpose of the Non-Food Safety Consumer Protection (NFSCP) requirements.
2. Identify the primary statutes, regulations, directives, and tools that relate to 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.

This module provides the big picture of what will be covered in this course. It will provide the basis and general overview touching on statutory authority, definitions, regulatory references and a discussion of the inspection verification tasks.

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

adulterated. The same information appears in 21 U.S.C. 453(g) of the PPIA ((g)(1) – (g)(8)) and 21 U.S.C. 1033(a) of the EPIA ((a)(1) – (a)(8)).

Misbranded

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)(1) – 601(n)(12) identifies twelve circumstances in which a carcass, carcass part, meat or meat food product is misbranded. The same information appears in 21 U.S.C. 453(h) of the PPIA ((h)(1) – (h)(12)) and 21 U.S.C. 1033(l) of the EPIA.

Label/Labeling

The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article. The term "labeling" means all labels and other written, printed, or graphic matter upon any article or accompanying the article. These terms can be found in 21 U.S.C. 601(o) and (p).

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, identifies food fit 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) and FSIS Directive 7120.1. 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.

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

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
- Meets requirements for restricted ingredients

Restricted ingredients (RIs) are non-meat ingredients, such as curing agents or antioxidants. They are direct food additives that have a regulatory limit established in 9 CFR 424.21. This regulation continues in Directive 7120.1 "Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products," which is updated quarterly. In general, the establishment **may** add the ingredient to the product's formula in any amount up to its regulatory limit. We will also learn that some products require certain RIs and amounts to meet their standard of identity.

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. Standards of identity are established in FSIS regulations and in the Food Standards and Labeling Policy Book for many meat and poultry products. For example, standards of identity for meat products can be found in 9 CFR 319 and in 9 CFR 381 Subpart P for poultry products.

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**.

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.

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

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. 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.

IPP are not to perform directed NFSCP tasks unless they observe conditions or activities while performing a food safety verification task that gives them a reason to suspect that product has not met NFSCP regulatory requirements. Laboratory testing is used when it is the only means available to determine regulatory compliance.

Compliance with the NFSCP regulations is on per lot basis and the establishment's control of the process being assessed such as applying accurate labeling to product, applying added solutions to product, applying an accurate net weight statement and/or formulating products to meet their standard of identities. Notify establishment management orally and then in writing with an NR when there is noncompliance. When uncertain, discuss the situation with your supervisor.

Examples of economic adulteration include meat or poultry components used above the maximum limit, water used above the maximum limit, and restricted ingredients used above the maximum limit. Examples of misbranding include the minimum amount of meat or poultry component not added, a required ingredient not added, and an ingredient that is not allowed is added. These lists are not inclusive.

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.

02 - General Labeling

Objectives

After completing this module, the student will be able to:

1. Define the following terms:
    - Immediate container
    - Generic labeling
    - Label
    - Sketch labeling
    - Principal display panel (PDP)
    - Shipping container

2. Identify the eight mandatory features of an immediate container label.

3. Identify the mandatory features that must be shown on shipping containers.

4. Identify the two types of labeling approvals granted by the Labeling and Program Delivery Staff (LPDS).

5. Identify the product name labeling requirements for raw meat and poultry products that contain added solutions.

6. Identify the product name and cooking instruction labeling requirements for mechanically tenderized raw beef products.

7. Describe how to perform the General Labeling inspection task.

Labeling Regulatory Requirements

Labeling regulatory requirements for **meat** products appear in Part 317—Labeling, Marking Devices, and Containers. Labeling regulatory requirements for **poultry** products appear in Part 381 - Poultry Products Inspection Regulations, Subpart N - Labeling and Containers. This segment of the module will specifically address the requirements in Subpart A of Part 317 of the regulations. The section of the poultry inspection regulations that references the same or similar requirements is identified in brackets at the end of pertinent paragraphs.

§317.2(a) - A label within the meaning of this part shall mean a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the ***immediate container*** *(not including package liners) of any product.*

Before use, labels require approval, either **generic approval** (when applicable) or by LPDS (**sketch approval** for certain products and **temporary approval**), 9CFR 412.

§317.1—Labels required; supervision by program employee.

§317.1(a)—When, in an official establishment, any inspected and passed product is placed in any receptacle or covering constituting an immediate container, there shall be affixed to such container a label as described in §317.2 [§381.115]

§301.2 identifies an ***immediate container*** as the receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

Products, such as whole or half carcasses or carcass parts, bearing the required, legible marks of inspection may be removed from the official establishment without further restriction. Once an official establishment places any inspected and passed product into any receptacle (carton, box, etc.) or covering (wrapper, plastic bag, etc.) constituting an immediate container, a label that complies with the regulations, must be affixed to it prior to it leaving the establishment.

Some coverings or immediate containers don't have to have a label affixed to them. These exceptions are identified in §317.1(a)(1) through (6). For example, properly marked products enclosed in uncolored, transparent coverings, such as cellophane, do not have to be labeled if the markings are clearly legible through the covering. The coverings cannot have any printed or graphic material on them.

Note: In some cases, the shipping container becomes the immediate container (e.g., when product units are bulk packed and not individually wrapped and labeled) and must then bear a label with all the required features (far left slide).

§301.2 identifies a ***shipping container*** as the outside container (box, bag barrel, crate or other receptacle) containing or wholly or partly enclosing any product packed in one or more immediate containers. In some cases, the shipping container becomes the immediate container (e.g., when product units are bulk packed and not individually wrapped and labeled) and must then bear a label with all the required features.

§317.1(c) - No covering or other container which bears or is to bear a label shall be filled, in whole or in part, except with product which has been inspected and passed in compliance with the regulations in this subchapter, which is not adulterated and which is strictly in accordance with the statements on the label. No such container shall be filled, in whole or in part, and no label shall be affixed thereto, except under supervision of a Program employee. [§381.136]

Only inspected and passed product that meets all regulatory requirements, is unadulterated, and has an accurate label may be packaged. Packaging and labeling operations can only be performed under the supervision of an IPP. Under the supervision of the IPP only means that he or she is on duty. The IPP does not need to continually oversee the filling and labeling of packages or containers.

Unlabeled Protective Coverings

From the Food Standards and Labeling Policy Book, ***PROTECTIVE COVERINGS (MEAT):*** *Processed or Prepared Product - Immediate containers, e.g., bags, cardboard cartons, tray packs, and film bags enclosing processed or prepared product can be considered protective coverings and exempt from the marking and labeling requirements if placed in a shipping container which meets all mandatory labeling requirements of an immediate container. This does not exempt the mandatory identification and marking which is specifically required on the immediate container of cooked beef (9 CFR 318.17). In addition, the shipping container must be clearly marked "Packed for Institutional Use" or an equally descriptive statement of intended limited distribution. Unlabeled product may not be removed from shipping containers for further distribution nor displayed or offered for sale.*

Unprocessed Meat Cuts - Transparent film bags enclosing individual meat cuts in an unprocessed state can be considered protective coverings and exempt from the marking and labeling requirements if placed in a shipping container which meets all mandatory labeling of an

immediate container. These unlabeled meat cuts may only be removed from the shipping container for resale and further distribution to retailers, hotels, restaurants, and similar institutions if the product itself or the film bag bears a clearly legible official mark of inspection and the establishment number.

See: Policy Memo 090B dated December 18, 1990

***PROTECTIVE COVERINGS (POULTRY):** Under provision of the Poultry Products Inspection Act, protective coverings may be exempt from labeling requirements for immediate containers. Under certain circumstances, some protective coverings are considered immediate containers; under different circumstances, they are regarded only as protective product coverings.*

When plastic film bags, cardboard cartons, etc., are used for protecting poultry sold for export or to institutions, e.g., hotels, restaurants, and hospitals (where the contents are consumed on the premises), they are exempt from the mandatory labeling of immediate containers, provided the shipping container meets all the labeling requirements for an immediate container. Such product may not be diverted to retail channels and displayed for sale or be sold to household consumers unless they bear all labeling features required for immediate containers. See: 9 CFR 381.65(p)

§317.2 - Labels: definition; required features.

Label Definition

*§317.2(a) - A label within the meaning of this part shall mean a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the **immediate container** (not including package liners) of any product.*

§301.2 Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article. and §381.1 Label. This term applies to any display of written, printed, or graphic matter upon any article or the immediate container (not including package liners) of any article.

Placement of Mandatory Label Information

§317.2(b) - Any word, statement, or other information required by this part to appear on the label must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. [§381.116(a)]

All mandatory information must appear on the label's **principal display panel**, except as otherwise permitted in 9 CFR 317.2 and 9 CFR 381.116. Except for products exported to foreign countries or distributed solely to Puerto Rico, the required information **must be** printed in the **English** language.

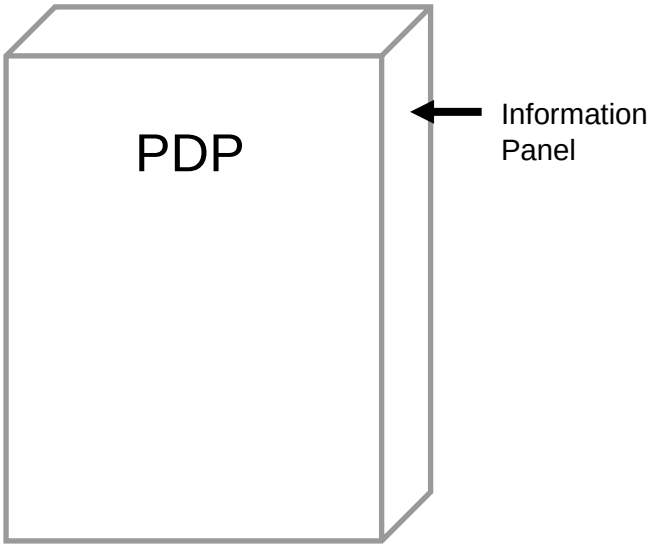
*§317.2(d)—The **principal display panel** shall be the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part and part 319 of this subchapter with clarity and*

conspicuousness and without obscuring of such information by designs or vignettes or crowding. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. [§381.116(b)]

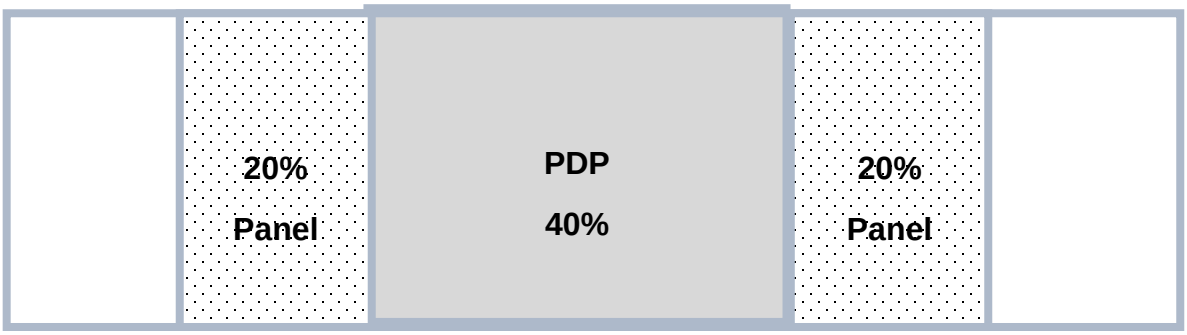
Principal display panels have specific size requirements to accommodate the mandatory information (features). The size requirements for the principal display panel for the various shapes of containers or packages are identified in §317.2(d)(1) though (3) and 381.116(b)(1) through (3). There are two PDP size layouts for cylindrical containers given in the regulations. For any other container shape (e.g., shrink wrapped hams), the PDP must be 40% of the total surface of the container or package. A **vignette** is a picture or illustration on a container or package label that describes the content of the container or package or represents the product as sold or as served.

Additional panels where certain mandatory label information may be shown in lieu of showing it on the principal display panel are identified in 9 CFR 317.2 and 9 CFR 381.116. For example, the ingredients statement, signature line, and/or nutritional facts may be placed together to form the **information panel**. Certain mandatory features may also be displayed on the **front riser panel** of a frozen food cartons and the 20% panel of a cylindrical container. A **cylindrical container's 20% panel** description and location is identified in 317.2(d)(2)(ii) and 381.116(b)(2)(ii). This panel is reserved for certain mandatory label information also identified in 317.2(d)(2)(ii) and 381.116(b)(2)(ii). **317.2(f)(2)** On containers of frozen dinners, entrees, pizzas, and similar consumer packaged products in cartons the ingredient statement may be placed on the front riser panel: *Provided,* That the words "see ingredients" followed immediately by an arrow is placed on the principal display panel immediately above the location of such statement without intervening print or designs.

Information Panel

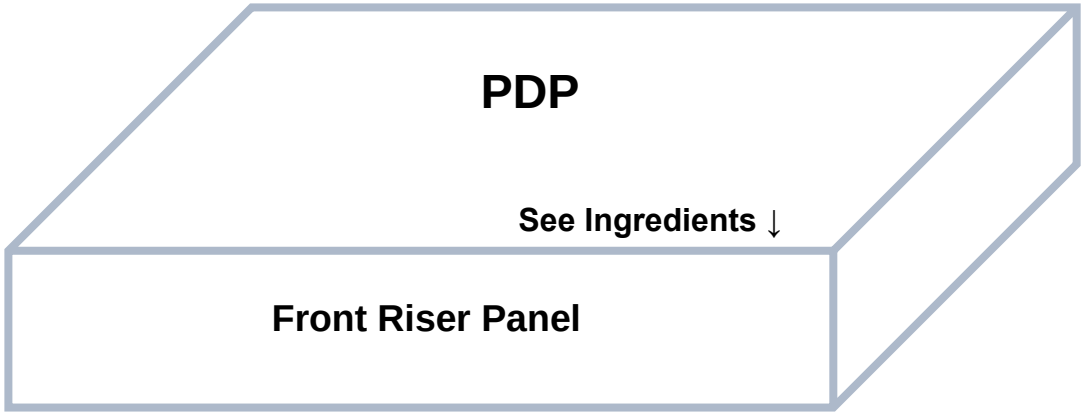


20% Panel on a Cylindrical Container



Either to the left or right of the PDP

Front Riser Panel



Information Panel

According to §317.2(m)(1), the information panel is the first surface to the right of the principal display panel (with some exceptions) is a particular location on the package or container other than the principal display panel. It may be formed by placing certain mandatory features together. The arrangement of these mandatory label features can be on a horizontal plane, vertical plane, or a combination of the two. §381.116(c)(1) has a slightly different definition. It is that part of the label that is the first surface to the right of the PDP as observed by an individual facing the PDP with some exceptions in 9 CFR 381.116(c)(1)(i-iii).

§317.2(m)(1) The information panel is that part of a label that is the first surface to the right of the principal display panel as observed by an individual facing the principal display panel, with the following exceptions: (i) If the first surface to the right of the principal display panel is too small to accommodate the required information or is otherwise unusable label space, e.g., folded flaps, tear strips, opening flaps, heat-sealed flaps, the next panel to the right of this part of the label may be used; (ii) If the package has one or more alternate principal display panels, the information panel is to the right of any principal display panel; (iii) If the top of the container

is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

Information panel configurations: **Combination plane** (e.g., nutrition panel shown vertically with the ingredients statement and signature line to the right which is horizontal), **Vertical plane** (e.g., the nutrition panel, ingredients statement, and signature line are all contiguous vertically without intervening information).

Mandatory Features of a Label

Up to eight features may be required on an ***immediate container*** label. The eight mandatory features are identified in the table in Attachment 1.

Quick overview of label features: Required on the PDP: product name, handling statement, net weight statement, and the inspection legend. May be on either the PDP or the information panel: ingredients statement, signature line, nutrition panel. May be anywhere on package: safe handling instructions and the establishment number. See below for more details about each.

Name of the Product

§317.2(c)(1)—The name of the product, which in the case of a product which purports to be or is represented as a product which a definition and standard of identity or composition is prescribed in part 319…shall be the name of the food specified in the standard, and in the case of any other product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation as prescribe in paragraph (e) of this section… [§381.117(a)]

Fresh pork sausage (§319.141), Italian sausage (§319.145) and frankfurters (319.180(a)) are examples of products that have standards of identity we will cover in this course. Ground beef is another meat product that has a standard of identity (§319.15(a)). Pork Shoulder and Beef Rib Eye Steak are common and usual names. "Sloppy Joe" is a fanciful name and must be qualified with the descriptive name "barbecue sauce with (species)".

Product names must be prominently shown on the principal display panel.

Raw Meat and Poultry Products Containing Added Solutions Descriptive Designations (if applicable)

§317.2(e)(2) - The product name for a raw meat product that contains added solution and does not meet a standard of identity in 9 CFR part 319 must contain a descriptive designation that includes:

(i) The percentage of added solution (total weight of the solution ingredients divided by the weight of the raw meat without solution or any other added ingredients multiplied by 100). The percentage of added solution must appear as a number (such as, 15, 20, 30) and the percent symbol (%). The percentage of added solution may be declared by the words ``containing'' or ``contains'' (such as, ``contains 15% added solution of water and salt,'' or ``containing 15% added solution of water and teriyaki sauce'').

The word “contain” or “contains” is not required. Other words that may be used in the descriptive designation include “added,” “with,” or “up to”, “injected,” or “flavored.” The word “solution” is not required in the descriptive designation as long as the added ingredients are included. The words “marinated” and “basted” may be used in the descriptive designation without restriction to the level of solution. All ingredients that make up the solution, including water if that is the liquid used in the formula, must be declared in the descriptive designation.

(ii) The common or usual name of all individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight.

(iii) When the descriptive designation includes all ingredients in the solution, a separate ingredients statement is not required on the label. When the descriptive designation includes multi-ingredient components and the ingredients of the component are not declared in the descriptive designation, all ingredients in the product must be declared in a separate ingredients statement on the label as required in Sec. 317.2(c)(2) and (f).

A multi-ingredient component is an ingredient added to the formula that itself is made up of two or more ingredients, for example, seasoning (salt and spices) or soy sauce (water, soybeans, wheat).

(iv) The product name and the descriptive designation must be printed in a single easy-to-read type style and color and must appear on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than one-third (\1/3\) the size of the largest letter.

(v) The word ``enhanced'' cannot be used in the product name. [381.117(h)]

This rule applies to:

- raw meat or poultry products where added solution increases the raw weight of the meat or poultry by any amount, for example, chicken with 2% solution of water and potassium lactate
- products where solution has been incorporated into raw meat or poultry through any method, for example, marinating, basting, injection, vacuum tumbling, and
- raw products with added solution going to Food Service, HRI, and retail

The regulation does not apply to cooked product or products with a standard of identity where added liquid ingredients comply with the standard.

The product name and descriptive designation may appear on more than one line provided there is no intervening text or graphics. The font sizes may be different provided they meet the 1/3rd size requirement.

Mechanically Tenderized Beef Product Name and Cooking Instructions (if applicable)

§317.2(e)(3) - Product name and required validated cooking instructions for needle- or blade-tenderized beef products.

(i) Unless the product is destined to be fully cooked or to receive another full lethality treatment at an official establishment, the product name for a raw or partially cooked beef product that has been mechanically tenderized, whether by needle or by blade, must contain the term

‘‘mechanically tenderized,’’ ‘‘needle tenderized,’’ or ‘‘blade tenderized,’’ as a descriptive designation and an accurate description of the beef component.

(ii) The product name must appear in a single easy-to-read type style and color and on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than 1⁄3 the size of the largest letter.

(iii) The labels on raw or partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions must contain validated cooking instructions, including the cooking method, that inform consumers that these products need to be cooked to a specified minimum internal temperature, whether the product needs to be held for a specified time at that temperature or higher before consumption to ensure that potential pathogens are destroyed throughout the product, and a statement that the internal temperature should be measured by a thermometer. These validated cooking instructions may appear anywhere on the label.

- **Products covered:**
    - Needle- or blade-tenderized raw beef products destined for household consumers, hotels, restaurants, or similar institutions (HRI)
- **Products not covered:**
    - Non-intact beef products that are clearly non-intact (e.g., ground beef patties, hamburger patties, beef patties)
    - Beef products tenderized by other than needle/blade, such as pounding or cubing, which visibly changes the appearance of the product, e.g., cubed beef steak
    - Fully cooked beef products and those destined to another Federal establishment for a full lethality treatment
    - Raw or partially cooked products labeled as “Corned Beef” that have been mechanically tenderized (including through injection of a solution)
    - Raw mechanically tenderized beef products that are less than 1/8” thick, such as, beef bacon or carne asada, or raw mechanically tenderized beef products that are diced, such as stew meat
- **Labels must bear:**
    - The descriptive designation “mechanically tenderized,” “blade tenderized,” or “needle tenderized” and an accurate description of the beef component in the product name; and in close proximity; w/o intervening text or graphic
    - All words in the descriptive designation be in the same style, color, and on a single-color contrasting background
    - Upper and lower case allowed; however, the smallest letter must be at least 1/3 the size of the largest letter
    - Validated cooking instructions for subject products destined for household consumers, hotels, restaurants, or similar institutions
- **Validated Cooking Instructions would address:**
    - A cooking method, (e.g., grill or bake)

- Usually includes cooking time(s), (e.g., bake 1 hour, grill 5 minutes on each side)
- That these products need to be cooked to a specified minimum internal temperature,
- Whether these products need to be held for a specified time at that temperature or higher before consumption, i.e., dwell time or rest time, to ensure that potential pathogens are destroyed throughout the product, and
- A statement that the internal temperature should be measured by a thermometer

Mechanically Tenderized Beef Labeling Workshop

You have scheduled a General Labeling task and selected the label for a raw mechanically tenderized beef flank steak destined for household consumers, hotels, restaurants, or similar institutions.

KEEP REFRIGERATED

Beef Flank Steak

Smoke Flavor Added

Mechanically Tenderized

Containing Up to 15 percent of a Solution

Nutrition Facts
Serving Size 1 Piece (142g)/5oz.
Servings Per Container 4

Amount Per Serving	
Calories 290	Calories from Fat 190
	% Daily Value*
Total Fat 16g	**25%**
Saturated Fat 8g	**40%**
Trans Fat 0g	
Cholesterol 75mg	**25%**
Sodium 440mg	**18%**
Total Carbohydrate 1g	**0%**
Dietary Fiber 0g	**0%**
Sugars 1g	
Protein 24g	
Vitamin A 0% •	*Vitamin C 8%*
Calcium 2% •	*Iron 15%*

*Percent Daily Values are based on a 2,000 calorie diet.

Cooking Instructions:
To ensure adequate cooking, grill 5 minutes over medium heat. Then flip over and grill an additional 5 minutes.

Ingredients: Beef flank steak, water, salt, spices, sodium phosphate

Meat Company 501 Main St,
Beltsville, MD 00000

NET WEIGHT: 20 OZ (1.25 LB)

U.S. INSPECTED AND PASSED BY DEPARTM ENT OF AGRICULTURE EST. 38

1. What is your first name?
2. What is your last name?

3. Does the label comply with §317.2(e)(3) of the regulations?

    a. Yes
    b. No

4. Does the designation “Mechanically Tenderized” need to be part of the product name?

    a. Yes
    b. No

5. What is incorrect regarding the color of the background of the descriptive designation?

    a. Nothing, there is no regulation regarding color of the background
    b. The background is not a single color and contrasting
    c. It should be white.

6. Does the label comply with the §317.2(e)(2) of the regulations?

    a. Yes
    b. No

7. Is the product misbranded?

    a. Yes
    b. No

Net weight statement (if needed).

§317.2(c)(4)—An accurate statement of the net quantity of contents as prescribed in paragraph (h) of this section…[§381.121(a)]

As stated in §317.2(h)(1) through (5), the net weight statement must:

- **Appear on the principal display panel** in a conspicuous and easily legible boldface print or type in distinct contrast to other material on the container.

- Not be false or misleading and shall express an accurate statement of the quantity of contents exclusive of wrappers and packing materials.

- Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices will be recognized. Variations from stated quantity of contents shall be as provided in §442.2. The statement shall not include any term qualifying a unit of weight, measure, or count such as “jumbo quart,” “full gallon,” “giant quart,” “when packed,” “minimum,” or words of similar importance.

- Appear in the lower 30 percent portion of the principal display panel, unless otherwise exempt in the regulations. The statement may appear in more than one line. §317.2(h)(3)

- The term "Net Weight" or "Net Wt." refers to contents in terms of weight. "Net Content" refers to fluid measure.

- The net weight statement shall not include any term qualifying a unit of weight, measure or count, e.g., “jumbo quart,” “full gallon,” “when packed,” or “minimum.”

- Be expressed in terms of Avoirdupois weight (US system) or liquid measure (when 100% liquid). Per §317.2(h)(4), a ¾ pound retail package would be labeled “Net Wt. 12 oz.” except for random weight which may use “lb.” as the unit even when the weight is less than one pound per §317.2(h)(5).

- Type size, see §317.2(h)(6), the minimum type size is based on the size of the PDP, sizes range from 1/16th inch to ½ inch. The ratio of the height to the width of the type, see §317.2(h)(7).

- Spacing, see §317.2(h)(8) - Spacing above and below by the height of the letter “N” and to the left and right by twice the width of the lettering.

For Random weight packages, see §317.2(h)(5),(9)&(11). A random weight "consumer size package’’ is one of a lot, shipment or delivery of packages of the same product, with varying weights and with no fixed weight pattern (381.121(c)(10)).

Inspection Legend and Establishment Number

§317.2(c)(5)—An official inspection legend and…the number of the official establishment, in the form required by part 312 of this subchapter. [§381.123(a)(b)]
Labels on all products shall show an official inspection legend as illustrated in §312.2, §352.7, or §381.96 of the regulations. The inspection legend shall be in the exact form and arrangement as shown in the examples. It may be of any size, provided it is sufficient, and any color as long as it is conspicuous and readily legible. The proportions of letter size and boldness must be as illustrated in the regulations.

The legend must be located on the principal display panel or on the 20% panel of a cylindrical container.

As stated in §317.2(i), the establishment number may be located inside or outside of the inspection legend. The establishment number may be located anywhere on the exterior of the container or its labeling.

From the Food Standards and Labeling Policy Book, ***INSPECTION LEGENDS (DUAL)*** - *Products consisting of mixed meat and poultry ingredients shall bear either the official meat inspection legend or poultry legend, depending on which ingredients are present in the greater amounts. If meat or poultry ingredients exist in equal proportions, either official legend may be used. If meat and poultry ingredients exist in exact proportions and both appear in the product name, the official legend must reflect the ingredient appearing first in the product name.*

Containers of products intended for sale to household consumers can bear only the official mark of inspection of the product enclosed. Containers of products intended for distribution to other than the retail trade may bear both the official meat inspection legend and the official poultry products inspection legend.

Handling Statement (if needed)

§317.2(k) - Packaged products which require special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: "Keep Refrigerated," "Keep Frozen," "Perishable Keep Under Refrigeration," or such similar statement as the Administrator may approve in specific cases. Products that are distributed frozen during distribution and thawed prior to or during display for sale at retail shall bear the statement on the shipping container: "Keep Frozen." The consumer-size containers for such products shall bear the statement "Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated."

Ingredients Statement (if needed)

§317.2(c)(2) - If a product is fabricated from two or more ingredients, the word "ingredients" followed by a list of ingredients as prescribed in paragraph (f) of this section… [§381.118(a)]

The word “ingredients” must be spelled out, never abbreviated. The ingredients must be listed by their common and usual name in descending order of predominance according to the amounts used in the product’s preparation. There are a few exceptions.

Spices (e.g. mustard, pepper, etc.) and flavorings (e.g., oleoresin of black pepper, garlic oil, etc.) as defined in §317.2(f)(i) may be listed as “spice” or “flavoring” as appropriate in the ingredients statement. For instance, spices, spice extractives, essential oils, oleoresins, onion powder, garlic powder, celery powder, onion juice, and garlic juice may be listed as flavorings but flavorings (e.g., oleoresins, essential oils, etc.) cannot be listed as spices in the ingredients statement.

Ingredients present in individual amounts of 2% or less may be listed in other than descending order of predominance if:

- Such ingredients are listed by their common or usual name at the end of the ingredients statement; and

- Such ingredients are preceded by a quantifying statement such as "contains ___ percent of ___," or "less than ___ percent of ___." The blank before the word "percent" shall be filled with a threshold level of 2% (or less, as appropriate, e.g., 1.5%, 1%, or 0.5%). No ingredient subject to the quantifying statement may be present in an amount greater than the stated threshold. Such ingredients may be adjusted in the formulation without changing the label if the adjusted amount complies with §318.7(c)(4) or §381.147(f)(4) and does not exceed the stated threshold level.

Note: For some products an ingredients statement can be substituted with a “Cured with statement.” The label states “Cured with water, salt, sodium phosphate…….” The meat is left out and just includes **all** of the other ingredients. We see this with bacon, corned beef, ham, and other cured products.

The ingredient statement must be located on either the principal display panel, information panel, 20% panel of a cylindrical container, or the front riser panel of a frozen food carton when the phrase “see ingredients ↓” is on the PDP immediately above the location of the ingredients statement without intervening print or designs.

Signature Line

§317.2(c)(3)—The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared, as prescribed in paragraph (g) of this section… [§381.122]

The name and place of business of the product’s manufacturer, packer, or distributor is known as the signature line. The place of business shall be shown on the label by city, state, and zip code when the business is listed in a telephone or city directory (Note: an online directory does not meet this criteria); and if not listed in such a directory, the place of business shall also show the street address. The signature line must be located on either the principal display panel, information panel, 20% panel of a cylindrical container, or the front riser panel of a frozen food

carton. When the product is prepared by one company and distributed by a different company, phrases like “prepared for…” or “distributed by” must precede the name and business address.

Safe handling instructions (if needed)

§317.2(l)—Safe handling instructions shall be provided for: all meat and meat products… or that do not meet the requirements contained in §318.17, or that have not undergone other processing that would render them ready-to-eat; and all comminuted meat patties not heat processed in a manner that conforms to the time and temperature combinations in the Table for Permitted Heat-Processing Temperature/Time Combinations for Fully Cooked Patties in §318.23… [§381.125(b)].

Product that will be further processed at another official establishment and products that are for export only are exempt from the safe handling requirements.

The safe handling instructions may be located anywhere on the outside of an immediate container.

Nutrition Facts Panel (unless an exemption applies)

§317.300 - (a) Nutrition labeling must be provided for all meat and meat food products intended for human consumption and offered for sale, except single-ingredient, raw meat products that are not ground or chopped meat products described in §317.301 and are not major cuts of single-ingredient, raw meat products identified in §317.344, unless the product is exempted under §317.400. Nutrition labeling must be provided for the major cuts of single-ingredient, raw meat products identified in §317.344, either in accordance with the provisions of §317.309 for nutrition labels, or in accordance with the provisions of §317.345 for point-of-purchase materials, except as exempted under §317.400. For all other products for which nutrition labeling is required, including ground or chopped meat products described in §317.301, nutrition labeling must be provided in accordance with the provisions of §317.309; except as exempted under §317.400.

FSIS requires nutrition labeling of the top 40 major cuts of single-ingredient, raw meat and poultry products (as defined in §317.344 and §381.444). This nutrition labeling must be on labels or at point-of-purchase, unless an exemption applies, however, the small business exemption specifically is not applicable to these cuts. FSIS also requires nutrition labels on all ground or chopped meat and poultry products as defined in §317.301 and §381.401 respectively, with or without added seasonings, unless an exemption applies. In addition, when a ground or chopped product does not meet the regulatory criteria to be labeled “low fat" (317.362(b)), a lean percentage statement may be included on the label or in labeling as long as a statement of the fat percentage that meets the specified criteria also is displayed on the label or in labeling when in compliance with §317.362(f) or §381.462(f).

Note: Ground and chopped product does not include products such as sausage, meatballs, beef patties. The “ground/chopped” products only includes products named “ground beef,” “hamburger,” “ground pork,” “ground chicken,” “ground turkey,” “chopped beef,” etc.

Nutrition labeling information may be shown on the principal display panel, on the information panel, or anywhere on the immediate container. There are exceptions for gift packs or when packaging doesn’t allow for sufficient space (§317.302 or §381.402).

Establishments may voluntarily provide nutrition labeling for single ingredient, raw meat and poultry products that are not one of the top 40 major cuts and are encouraged to do so.

The regulations in §317.302 exempt products produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information. There are two criteria for exemption, 1) less than 500 employees **AND** 2) less than 100,000 pounds of a specific product formula/nutrition profile per year. When calculating the total pounds of a formula, both retail and custom exempt with all pack sizes are included. For example, an establishment has a ground beef 70/30 formula. This formula is sold in bulk, as patties, in various retail sized packages, under various brand names, for HRI, some retail exempt, and some as custom exempt. All of this ground beef 70/30 is counted together for the total pounds per year. Each specific product formula/nutrition profile will need to be evaluated for the small business exemption and both criteria need to be met for that product labeling to be exempt from bearing the nutrition facts panel. It is possible for popular products manufactured in quantities larger than 100,000 pounds per year to be exempt but other products with production lower than 100,000 pounds per year to be exempt even though they are manufactured in the same establishment.

Mandatory Features for Shipping Containers

Shipping containers must bear the following mandatory features:

- Inspection legend [316.13(a)] and establishment number [317.2(i)]
- Handling statement (if needed) [317.2(k)]
- Net weight statement (if needed) [317.2(h)(9)(i)]

The establishment number may be located outside the inspection legend or elsewhere on the exterior of the container or its labeling if shown in a prominent and legible manner in a size sufficient to ensure easy visibility and recognition and accompanied by the prefix “EST.”

Note: The shipping container must bear a net weight statement per 381.121(a) and the following statements: "Tare weight of consumer package ___ oz." (weighed to nearest 1/8 ounce or less), and the "Net wt.” to be marked on consumer packages prior to display and sale" when retail random weight poultry products without the net weight statement are in the shipping container.

§412.1 - Labeling approval.

§412.1(a) No final label may be used on any product unless the label has been submitted for approval to the FSIS Labeling and Program Delivery Staff, accompanied by FSIS Form 7234–1, Application for Approval of Labels, Marking, and Devices, and approved by such staff, except for generically approved labels authorized for use in §412.2. The management of the official establishment or establishment certified under a foreign inspection system, in accordance with parts 327 and 381, subpart T, must maintain a copy of all labels used, in accordance with parts 320 and 381, subpart Q, of this chapter. Such records must be made available to any duly authorized representative of the Secretary upon request.

No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to FSIS except for generically approved labels authorized for

use in 9 CFR 412.2. A sketch label is a printer's proof or the equivalent which clearly shows all labeling features, including the size, and location.

FSIS requires the submission of labeling applications for the following four categories:

1. Labels for products produced under religious exemption (9 CFR 412.1(c)(1))
2. [Reserved]
3. Labels with special statements and claims (9 CFR 412.1(c)(3))
4. Labels for temporary approval (9 CFR 412.1(c)(4)). Under certain conditions, LPDS may grant a temporary approval for the use of a final label that may be deficient in some particular requirement for up to 180 calendar days.

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

The requirements for generically approved labels is covered in §412.2. IPP do not generically approve labels. Establishments do not generically approve labels. Generically approved labels are considered to be approved by FSIS provided that the label meets the criteria listed in §412.2(b). "Approved by FSIS" refers to compliance with the FSIS 9 CFR regulations, it does not mean that the labels have been submitted to Labeling and Program Delivery Staff (LPDS).

Labeling Record

The responsibility of ensuring that generic labeling complies with regulatory requirements rests with the establishment. The establishment is responsible for creating the generic labeling record and is required to keep a copy of all generic labeling and related information in its files. A corporate headquarters may create and maintain the labeling files for their associated establishments. When labeling records are needed, the IPP may request the labeling records from the assigned establishment. The labeling records are required to be made available to the requesting IPP within 24 hours (FSIS Directive 7221.1).

There is no specific format for a generic labeling record, however, it is required to include all information in FSIS Form 7234-1 that would be provided to LPDS as if they were submitting for sketch approval. Some establishments choose to use the FSIS 7234-1 form since they are familiar with the form, and it is a reminder of what information is needed in the labeling record, but they could provide all required information in another format. The labeling record should also include the final printed labeling that will be used on the finished packaged product and any supporting information that may be needed to verify that labeling is truthful and not misleading. Some companies choose to number their generic approvals as a way to track them internally, but there is no FSIS requirement to do so.

§317.8 - False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

§317.8(a) - No product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling. No product shall be wholly or partly enclosed in any wrapper, packaging, or other container that is so made, formed, or filled as to be misleading. [§381.129(a)(b)]

The product or its packaging material may not bear any false or misleading label, marking or labeling. No written or graphic material on the product label or in its marking or labeling may convey a false impression or give a false indication of contents. A product's packaging material color, design or kind may not be misleading. Product that bears false or misleading marking or labeling is misbranded.

§317.8(b)(1)-(40) list requirements that product labels and containers must comply with to prevent them from having a false or misleading feature.

General Label Review Workshop

You are a CSI covering a very small wiener processing establishment located in Cut and Shoot, Texas. It employs two people and produces one product (New York Wieners in ½ lb. packages) that conforms to the standard of identity in §319.180. The production volume has averaged 1,800 pounds per week over the past 2 years. Today, you have scheduled a General Labeling task and decide to verify whether the label (below) being applied to a lot of wieners complies with regulatory requirements.

Net Wt. ½ lb.

Perishable, Store below Room Temperature

New York *Brand*

Wieners

INGRED: BEEF AND PORK, WATER, SALT, DEXTROSE, SUGAR, MUSTARD, PAPRIKA, SPICES, SPICE EXTRACTIVES, MONOSODIUM GLUTAMATE, SODIUM ASCORBATE, SODIUM NITRITE.

WORTHLESS MEATERY
GIG 'EM, TX

INSPECTED FOR WHOLESOMENESS BY U.S. DEPARTMENT OF AGRICULTURE P-42

Please select the best answer to the questions below.

1. What is your first name?
2. What is your last name?

3. What is incorrect with the Ingredient Statement?

   a. Nothing
   b. The word "Ingredients" needs to be spelled out
   c. It is not listed in order of predominance

4. Of the following choices, what is incorrect with the Net Weight Statement?

a. It should be in ounces
b. Nothing
c. It should be written in blue ink

5. Is the Handling Statement correct?
    a. Yes
    b. No

6. What is missing from the Signature Line? (Select all that Apply)

    a. The Zip Code
    b. The name of the firm that produced the product
    c. The state the product was produced in
    d. Either “Prepared for” or “Distributed By”
    e. Establishment Phone Number

7. Is the Inspection Legend correct?

    a. Yes
    b. No

§317.16 - Labeling and containers of custom prepared products.

*Products that are custom prepared…must be **packaged immediately** after preparation and **must be labeled**…with the words "**Not for Sale"** in lettering not less than three-eighth inch in height.*

Custom prepared product must be properly labeled and have a prominent "Not for Sale" statement. The establishment may include additional labeling on custom prepared products, or their containers provided it is not false or misleading.

Performing the General Labeling Task

Inspection program personnel perform this task to verify general labeling regulatory requirements and determine if the label accurately reflects the finished product.

General Labeling Requirements

Verifying that the general labeling requirements involves:

- observing the application of the label or labeling,
- selecting labels and labeling for review, and
- reviewing the establishment's labeling records

When IPP observe the packaging and labeling operations, they ensure that immediate containers of meat and poultry products have a label attached to them and that shipping containers bear the required information.

When IPP select and review the label/labeling applied to the container or package, they determine if:

- the label contains the mandatory features and other required information such as a qualifying statement or descriptive designation, and
- any printing or colors on the label and packaging material gives a false impression or does not meet specific formatting criteria

Product is misbranded if its label is missing a required feature, qualifying statement, or descriptive designation or is anyway false or misleading.

When IPP review the establishment's labeling file, they determine if the:

- label is on file and either met the generic approval requirements or was sketch approved by LPDS,
- label required sketch approval by LPDS and if so, the sketch is attached to the final label,
- label is being used beyond the expiration date if it has been granted a temporary approval by LPDS, and
- product's formulation (if applicable) and processing procedures are attached to or accompany the label/labeling.

If IPP find noncompliance, they issue an NR and take the appropriate action necessary to ensure misbranded product does not enter commerce.

Label Accurately Reflects the Product

Determining that the label accurately reflects the finished product involves reviewing the product's formulation record and observing its actual preparation and, in some cases, performing formula calculations.

When IPP perform this task, they should select one or more batches of product at formulation and verify ingredient amounts comply with the formula on file and that no undeclared ingredients are added or declared ingredients are omitted.

The verification may involve:

- observing pre-weighed ingredients for proper identification and weights, or
- observing establishment employees weighing ingredients or
- actually, weighing pre-weighed ingredients to determine if the weight on the container is accurate.

An ingredient added at a different level than indicated in the product formula could affect the ingredient order of predominance on the label. The product is misbranded if a declared ingredient is omitted, an ingredient is added but not declared on the label, or the ingredient order of predominance is not accurate. Depending on the type of undeclared ingredient (e.g., an allergen) that is added to the product, it may be either adulterated or misbranded or both.

The regulations and many product standards of identity allow the establishment to add various ingredients to the formula of certain meat and poultry products.

Some meat and poultry components used in the formulation may have regulatory limits. Some nonmeat ingredients have a specified maximum amount or percentage allowed in the product. These nonmeat ingredients are called **restricted ingredients**. The establishment **MAY** add the component or ingredient in any amount up to its permitted limit.

If the product is formulated with a meat or poultry component with a regulatory limit or with a restricted ingredient, the IPP should select one or more batches of product during formulation. They should determine the amount or percentage of the meat or poultry component and/or the amount of one or more restricted ingredients used in the formula. The IPP verifies that the:

- percentage of meat or poultry component meets the regulatory limit,
- restricted ingredient is allowed in the product, and
- the amount of the restricted ingredient added to the product does not exceed the regulatory limit.

Verifying meat and poultry components or restricted ingredients are in compliance with regulatory limits usually requires the IPP to perform a formula calculation.

When meat or poultry components or restricted ingredients are added at levels in excess of their maximum regulatory limit, they become economic adulterants.

If IPP find noncompliance, they issue an NR and take the appropriate action necessary to ensure adulterated or misbranded product does not enter commerce.

Labeling Summary Workshop

You are a CSI with a small raw ground beef product establishment on your assignment. The establishment produces ground beef, hamburger, and beef patties. The standards of identity for these products are provided at the end of the workshop.

The establishment has one HACCP plan under the Raw Product Non-Intact HACCP category. The company has 50 employees and produces about 50,000 lbs. of raw ground beef products a week. It operates two continuous production lines 8 hours a day, 5 days a week. The establishment has determined one day's production of a raw beef product is a lot.

The ground beef patties are 100% beef and produced using a two-step grinding method. The hamburger patties and beef patties have non-meat ingredients added at the blending step. The process of producing these patties involves a coarse grind, mixing and blending the meat and ingredients, and a final grind. Ingredients added to the hamburger patties include salt, seasonings and corn syrup. Ingredients added to the beef patties include salt, dried onions, flavorings, soy flour and water. The company does not rework broken or misshaped patties and it does not accept returned products. The patties are distributed in shelf ready 36-ounce trays or bulk packed in 20 lb. boxes.

The General Labeling task appears on your task schedule today.

You make your way to the production floor and ask the production supervisor what raw beef products are being produced. She states that tray packed beef patties are being produced on both lines. You review the labels, product formulation, and production procedures for the beef patties on file in the production supervisor's office.

You decide to verify product formulation. You observe the following ingredients added to the large blender on line 1 and line 2.

300.0 lb. 60/40 Beef Trimmings
85.0 lb. Water
60.0 lb. Soy Flour
25.0 lb. Flavorings
17.5 lb. Dried Onions
12.5 lb. Salt

You follow the product through the process. At the packaging step for line one, you observe the label/labeling being placed on the trays (immediate container) and the shipping container markings.

The label below is being placed on the top of the tray and the safe handing instructions below are placed on the bottom of the tray. This is the only labeling applied to the trays.

Homestyle Beef Patties

Keep Frozen

Ingredients: Beef, Soy Flour, Water, Flavorings, Dried Onions and Salt.

U.S. INSPECTED AND PASSED BY DEPARTM ENT OF AGRICULTURE EST. 38

UPC

Packed by: ABC Packing House
Anytown NC, 12345

Safe Handling Instructions

This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

Keep refrigerated or frozen. Thaw in refrigerator or microwave.

Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.

Cook thoroughly.

Keep hot foods hot. Refrigerate leftovers immediately or discard.

The shipping container has the inspection legend on it in the upper right corner. This is the only printed information on the outside of the box.

At the packaging step for line two, you observe the following label/labeling being placed on the trays (immediate container) and the shipping container markings.

The label below is being placed on the top of the tray and the safe handing instructions illustrated above are placed on the bottom of the tray. This is the only labeling applied to the trays. The shipping container for these trays has the inspection legend on it in the upper right corner. This is the only printed information on the outside of the box.

Keep Frozen

Blue Ribbon Ground Beef Patties

100% Beef

U.S.
INSPECTED
AND PASSED BY
DEPARTM ENT OF
AGRICULTURE
EST. 38

UPC

Packed by: ABC Packing House
Anytown NC, 12345

Net Wt. 36 oz. (2.25 Lb.)

1. What is your first name?
2. What is your last name?

3. Based on the review of the product formulation and the labeling applied to the immediate containers and shipping containers, has the establishment produced misbranded product?

    a. Yes
    b. No

4. Based on the review of the product formulation and the labeling applied to the immediate containers and shipping containers, has the establishment produced adulterated product?

    a. Yes
    b. No

5. Is there a food safety hazard associated with the production of the product?

    a. Yes
    b. No

Workshop Reference Materials

Product Standards

FSIS regulations prescribe standards of identity, or composition, for many meat and poultry products. Standards of identity set specific requirements for a product's make-up. For instance, 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 allowed in the product,
- the maximum percentage of a specific meat or poultry ingredient such as beef cheek meat or Mechanically Separated (Species)
- ingredients that are allowed or expected in the product, and
- any ingredient that is not allowed in the product.
- Non-meat ingredients that have a maximum percentage allowed in the finished product are called restricted ingredients. The establishment MAY add the ingredient in any amount up to its permitted limit. When restricted ingredients are added at levels in excess of the regulatory limit, they become adulterants.

319.15 Miscellaneous beef products.

(a) Chopped beef, ground beef, ''Chopped Beef'' or ''Ground Beef'' shall consist of chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. When beef cheek meat (trimmed beef cheeks) is used in the preparation of chopped or ground beef, the amount of such cheek meat shall be limited to 25 percent; and if in excess of natural proportions, its presence shall be declared on the label, in the ingredient statement required by § 317.2 of this subchapter, if any, and otherwise contiguous to the name of the product.

(b) Hamburger. ''Hamburger'' shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasoning, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of hamburger only in accordance with the conditions prescribed in paragraph (a) of this section.

(c) Beef patties. ''Beef Patties'' shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasonings. Binders or extenders, mechanically Separated (Species) used in accordance with § 319.6, and/or partially defatted beef fatty tissue may be used without added water or with added water only in amounts such that the product characteristics are essentially that of a meat patty.

Attachment 1: FSIS Directive 7221.1 Table 1 Required Label Features

Feature	Reference	Location	Applies to
Product Name	9 CFR 317.2(c)(1) or 381.117	Principal display panel	All products
Inspection Legend and Establishment Number*	9 CFR 317.2(c)(5) or 381.123	Principal display panel, or 20% panel of a cylindrical container	All products
Handling Statement (e.g. "Keep Frozen")	9 CFR 317.2(k) or 381.125(a)	Principal display panel	Products requiring special handling to maintain wholesomeness
Net Weight Statement	9 CFR 317.2(h) or 381.121	Principal display panel	Product sold at retail, unless the net weight is applied at retail
Ingredients Statement**	9 CFR 317.2(f) or 381.118	Principal display panel, Information panel, 20% panel of a cylindrical container, or Front riser panel of a frozen food carton	Products with multiple ingredients
Name and Place of Business of the Manufacturer, Packer, or Distributor	9 CFR 317.2(g) or 381.122	Principal display panel, Information panel, 20% panel of a cylindrical container, or Front riser panel of a frozen food carton	All products
Nutrition Facts Panel	by 9 CFR 317.300 or 381.400	Principal display panel or Information panel	Products not exempted by 9 CFR 317.400 or 381.500
Safe Handling Instructions	9 CFR 317.2(l) or 381.125(b)	Anywhere on the immediate container	Products with a not-ready-to-eat meat or poultry component

*NOTE: As stated in §317.2(i), the establishment number may be located inside or outside of the inspection legend. The establishment number may be located anywhere on the exterior of the container or its labeling; for example, it may be located on the end of a can if it is prominent, legible, and accompanied by the prefix "Est". The establishment number may be located off the exterior of the container when there is a statement identifying the location of the number; for example, "Est. No. on clip" is printed on a bag containing product.

**NOTE: All ingredients used in the product must be listed in the ingredients statement. Product is considered adulterated if an allergen is not listed in the ingredients statement. IPP are to contact their supervisor for guidance if at any time they have reason to believe that product failing to declare one of the "big 9" allergens [wheat, crustacean shellfish (e.g. crab, lobster, shrimp), eggs, fish, peanuts, milk, tree nuts (e.g. almonds, pecans, walnuts), soybeans and sesame] or other ingredients of public health concern has entered commerce. FSIS ingredient and allergen compliance guidelines are available online.

03 - Net Weight

Objectives

After completing this module, the student will be able to:

1. Define the following terms:
   - Net Weight
   - Drained Weight
   - Tare Weight
   - Labeled Weight
   - Standard Weight
   - Gross Weight
   - Random Weight
   - Inspection Lot
   - Package Error
   - Total Package Error
   - Maximum Allowable Variation (MAV)

2. Describe the steps for verifying net weight.

3. Describe the criteria for passing an inspection lot.

4. Determine whether an inspection lot passes or fails.

Introduction

Meat and poultry establishments must assure that the net weight statement on a label is not false or misleading and expresses an accurate statement of the quantity of contents. Since absolute accuracy is virtually impossible, FSIS net weight regulations allow “reasonable” variations from labeled weight.

Terminology

Net weight -The weight of the packaged product remaining after the deduction for tare weight. It is the weight of the nutritious content in the container suitable for food. For added solution products, e.g., chicken with X% solution of, the solution is part of the nutritious content.

Drained weight -The weight of the solids in the container when packed in non-nutritious media.

Tare weight -The weight of the container, box, wrapper or other packaging material. It is always excluded from gross weight when determining the actual net weight.

Gross weight - the total weight of the nutritious substance (the food) inside the packaging (which is the “net weight”) plus the weight of all the packaging (the tare weight).

Labeled weight - The net weight declared on the label.

Standard weight packages - Packages or containers that contain a predetermined amount of product and have identical net weight declarations, e.g., the full net weight statement is pre-printed on labeling, such as, Net Wt. 8 oz.

Random weight packages - Packages or containers that contain a varying amount of product and will not have identical net weight declarations, e.g., each package is weighed, and the specific net weight is written into a printed open net weight statement, such as, Net Wt. _____LBS, another example is when a scale generates an individual price/weight sticker to apply to the package. Note: the unit of measure for random weight packages may be in pounds (lb.) even when the weight of the package is less than one pound, §317.2(h)(5).

Directive 7000.1, *Verification of Non-Food Safety Consumer Protection Regulatory Requirements*, identifies the regulations, references, and verification activities for performing the Net Weight task.

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
Labeling - Net Weights	9 CFR §442.1, §442.2, §442.3, §442.4, §442.5	NIST Handbook 133 NIST Handbook 44 * FSIS inspectors are to use these handbooks as the definitive references for determinations of net weight compliance. Sections identified in §442.2(b) of NIST Handbook 133 should Not be used.	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.

Net Weight Inspection Verification Task

Prior to performing a net weight verification activity, IPP should review the requirements in NIST Handbook 44 and then will verify net weight following the procedures in NIST Handbook 133. NIST Handbooks 44 and 133 are the definitive references for determinations of net wet compliance that IPP are to use.

Scales

IPP must ensure the scales are of sufficient size, solidly supported, level and accurate. The scales are to be certified by the state or local government's weights and measures authority or from a registered or licensed individual at least once per calendar year. The valid certification is to be displayed on or near the scale.

NOTE: Sections identified in §442.2(b) of NIST Handbook 133 should NOT be used.

Steps to Determine Net Weight

1. Determine the number of containers or packages in the inspection lot.

Inspection lot - A collection of identically labeled packages or containers from the same production shift available for inspection at one time. The IPP determines the inspection lot. The inspection lot passes or fails as a result of net weight testing.

IPP should define which packages are to be tested as well as determine the size of the inspection lot. An *inspection lot* is defined as a collection of identically labeled packages or containers from the same production shift available for inspection at one time. Enforcement action can only be taken on the packages contained in the lot that has been defined.

Lots may be made up of either standard or random weight packages. "**Standard packages**" are those with identical net content declarations such as containers of meat sauce in 2 L bottles and 5 lb2.26 kg packages of chicken breasts. "**Random packages**" are those with differing or no fixed pattern of weight, such as packages of meat, poultry or cat.

2. Select a Sampling Plan.

Table 2-2. Sampling Plans for Category B (for Use in USDA-Inspected Meat and Poultry Plants Only)			
1	2	3	4
Inspection Lot Size	Sample Size	Initial Tare Sample Size	Number of Packages Allowed to Exceed the MAVs in Table 2-9
250 or Fewer	10	2	0
251 or More	30	5	0

IPP should use "Category B" sampling plans only to test meat and poultry products that are subject to USDA/FSIS regulatory requirements at the point-of-pack locations. Refer to second column of Table 2-2 Sampling Plans for Category B from NIST Handbook 133.

3. Record the inspection data.

All information collected should be recorded. There is no regulation or policy stating that there is a specific type of form that should be utilized to document the inspection data. It may be more practical to write the information in a notebook vs a form. **See Attachment 2.**

IPP must become familiar with the required information needed to officially determine if net weight is in compliance. There are minimum requirements for the information that should be collected to verify net weight compliance. Each state may alter the forms slightly as long as the minimum NIST criteria are met. The IPP should attach any additional notes, worksheets, etc. as needed.

4. Select the random sample.

Testing a "sample" of packages from a lot instead of every package in a shipment is efficient, but the test results have a "sampling variability" that must be corrected before determining if the lot passes or fails. A randomly selected sample is necessary to ensure statistical validity and reliable data. This is accomplished by using random numbers to determine which packages are chosen for inspection. Improper collection of sample packages can lead to bias and unreliable results. Appendix B of NIST Handbook 133 provides Random Number Tables and describes various ways to use the tables to randomly select packages within the inspection lot.

5. Randomly collect a tare sample and determine the average tare weight.

- See Column 3 of NIST Handbook 133 Table 2-2 Sampling Plan for Category B to determine the Initial Tare Sample Size based on the Inspection Lot Size
- If available, unused dry packaging may be used to determine the tare weight
- When packages are opened to determine the tare weight, use the first 2 (or 5) randomly selected packages of the Inspection Lot in order that they were selected to determine the dry tare weight.
- Weigh each set of packaging materials in the tare sample
- Add the weights together
- Divide the total tare weight by the sets of packaging material in the tare sample

NOTE: When the average tare weight is exactly half of a scale division, round the value up to the next scale division (e.g. If the scale units are 1 gram and tare 1=19 g and tare 2=20 g, round the 19.5 g average up to 20g). Additional rounding examples are in Attachment 1 at the end of the module.

6. Determine:

Nominal Gross Weight: Add the Average Tare Weight (as determined in step 5 above) to the labeled weight to determine the Nominal Gross Weight. Make sure you use the same units of measure for both values and that matches the units of measure of the scale being used.
(average tare weight + labeled weight) = nominal gross weight

Package error: The difference between the gross weight (the weight of each individual sample package that includes the food product and the packaging weight) and the nominal gross weight.
(gross weight of the sample – nominal gross weight) = package error

-/+ Package error: When the nominal gross weight weighs more than the gross weight the sample package weighs less than what the label declares and is recorded as a negative (-) package error under the - column. When the nominal gross weight weighs less than the gross weight the sample package weighs more than what the label declares and is recorded as a positive (+) package error under the + column.

Dimensionless Units

If desired, the package error may be expressed as “plus” or “minus” dimensionless unit by dividing the package error by the scale graduation. This method eliminates leading zeros and the units of measure and results in whole numbers. In the slide example, we were weighing in 0.001 lb. increments, so the unit of measure is 0.001 lb. By dividing + 0.038 lb. by .001 lbs., instead of recording 0.038 lb. in the plus column, record the error as “38” in the plus column. The second package error is -0.003 lb. and would be recorded as “3” in the negative column, and so on.

Total Package Error: The sum of all of the individual package errors.

–	+
1.	38
2.	12
3.	8
4.	4
5. 3	
6. 2	
7.	12
8. 3	
9.	4
10. 1	
Total: 9	Total: 78
Total Package Error: +69	

Maximum Allowable Variation (MAV): The maximum amount the actual net weight of an individual package or container may be under its labeled weight. It represents the maximum underweight or short weight a package can be and still be considered "reasonable" under good manufacturing processes. The MAV is provided in NIST Handbook 133 Table 2-9.

Table 2-9. U.S. Department of Agriculture, Meat and Poultry Groups and Lower Limits for Individual Packages (Maximum Allowable Variations)

Definition of Group and Labeled Quantity		Lower Limit for Individual Weights (MAVs)
Homogenous Fluid When Filled (e.g., baby food or containers of lard)	All Other Products	
Less than 85 g or 3 oz		10% of labeled quantity
85 g or more to 453 g 3 oz or more to 16 oz		7.1 g 0.016 lb (0.25 oz)
More than 453 g More than 16 oz	85 g or more to 198 g 3 oz to 7 oz	14.2 g 0.031 lb (0.5 oz)
	More than 198 g to 1.36 kg 7 oz to 48 oz	28.3 g 0.062 lb (1 oz)
	More than 1.36 kg to 4.53 kg More than 48 oz to 160 oz	42.5 g 0.094 lb (1.5 oz)
	More than 4.53 kg More than 160 oz	1 % of labeled quantity

7. Apply the decision criteria to determine net weight compliance.

Decision criteria: The rules for determining whether the inspection lot complies with the net weight requirements. The net weight test results must meet **BOTH** criteria.

- The total package error (sum of the individual package errors) is equal to or greater than zero;

  AND

- No individual minus package error can exceed the MAV.

8. Take appropriate action based on net weight testing results.

9 CFR 442.5 specifies that a lot tested in *an official establishment* and found not to comply with net weight requirements may be reprocessed and must be reweighed and remarked. A lot tested *outside an official establishment* must be reweighed and remarked with a proper weight statement.

Attachment 1:

Tare Rounding Examples

Tare Weights	Scale Graduation	Average Tare Weight	Rounded Tare Value
0.14 & 0.17 lb.	0.01 lb.	0.155 lb.	0.16 lb.
5/32 & 8/32 oz	1/32 oz	6.5/32 oz	7/32 oz
0.20 & 0.25 lb.	0.05 lb.	0.225 lb.	0.25 lb.
5.06 & 5.15 g	0.01 g	5.105 g	5.11 g

ATTACHMENT 2:

NET WEIGHT WORKSHEET

DATE	ESTABLISHMENT NO.	SCALE DIVISION	AVERAGE TARE WT.	GROUP NO.	MAV *(Lower Limit)*
LOT SIZE	SAMPLE SIZE	PRODUCT AND CONTAINER CODE:			LABELED WEIGHT

STANDARD WEIGHTS *(10 or 30 sample size)*

UNIT	+	-
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
TOTAL + 'S AND -'S *(10 weights)*		
TOTAL ERROR + 'S AND -'S *(10 wts.)*		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
TOTAL + 'S AND -'S *(30 weights)*		
TOTAL ERROR + 'S AND -'S *(30 wts.)*		

CATCH WEIGHTS *(10 or 30 sample size)*

UNIT	LABEL WEIGHT	ACTUAL WEIGHT	+	-
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
TOTAL + 'S AND -'S *(10 weights)*				
TOTAL ERROR + 'S AND -'S *(10 weights)*				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
TOTAL + 'S AND -'S *(30 weights)*				
TOTAL ERROR + 'S AND -'S *(30 weights)*				

PASS / FAIL DECISION CRITERIA

MAV CRITERIA: Is any single minus (-) unit greater than the MAV?

☐ YES - Lot Fails ☐ NO - Check Total Error

TOTAL ERROR CRITERIA: Is the total error equal to or greater than zero

☐ YES - Lot is Acceptable ☐ NO - Lot Fails

FSIS FORM 7240-1 (7/91) REPLACES FSIS FORM 7240-1 (3/86), WHICH IS OBSOLETE.

Date: *January 20, 2010*	**Random Package Report – Example**		Sampling Plan: ☑ A ☐ B	Report Number: 17
Location (name, address): *L&O Market MacCorkle Ave. Charleston, WV 25171*	**Product/Brand Identity:** *Ground Chuck* **Lot Codes:** *1, 19, 99*		**Manufacturer:** *Meat Dept. - L&O Market*	**Container Description:** *2S Tray w/soaker and plastic wrap*

1. Labeled Quantity: (Enter weight for each package in Column 1 below.)	2. Unit of Measure: *0.001 lb*	3. MAV: (Look up the MAV for each package with a minus error (−), convert it to dimensionless units and enter this value in the Box 4 column below.)	5. Inspection Lot Size: *23*	6. Sample Size (n): *12*
7. Initial Tare Sample Size: *2*	8. Number of MAVs Allowed: *0*	9. Range of Package Errors (Rc): *10*	10. Range of Tare Weights (Rt): *1*	11. Rc/Rt: (Box 9 ÷ Box 10 =) *10*	12. Total No. of Tare Samples: *2*

13. Avg. Tare Wt: *0.020 lb* ☑ Used Dry Tare ☐ Wet Tare ☐ Unused Dry Tare	13a. ☐ Tare Correction ☐ Moisture Allowance ☑ Not Applicable	14. Nominal Gross Wt: (Labeled Wt + Box 13 − Box 13a =) *Label Wt + 0.020 lb*

	Pkg 1	Pkg 2	Pkg 3	Pkg 4	Pkg 5	Pkg 6	Pkg 7	Pkg 8	Pkg 9	Pkg 10
a. Gross Wt	*1.852 lb*	*1.223 lb*								
b. Tare Wt	*0.020 lb*	*0.021 lb*								
c. Net Wt	*1.832 lb*	*1.202 lb*								
d. Package Error	*−18*	*−8*								

	Product Description, Lot Code, Unit Price	Money Errors −	Money Errors +	Column 1 Labeled Net Weight	Package Errors −	Package Errors +	4. MAV Dimension-less Units
1.	*Ground Chuck – 1, 19, 99 – $1.79 per lb*			*1.85 lb*	*18*		
2.				*1.21 lb*	*7*		
3.				*1.56 lb*	*8*		
4.				*1.98 lb*	*14*		
5.		*$ 0.04*		*1.07 lb*	*23*		*44*
6.				*1.55 lb*	*16*		
7.				*1.02 lb*	*2*		
8.		*$ 0.04*		*1.44 lb*	*25*		*56*
9.				*1.33 lb*	*16*		
10.				*2.03 lb*	*20*		*70*
11.				*1.73 lb*	*14*		
12.				*1.16 lb*	*11*		
13.							
14.							
15.							
16.							
				Totals	*−174*		

15. Total Error: *− 174*	16. Number of unreasonable minus (−) errors: (Compare each package error with the MAV in Column 4.) *0*	17. Is Box 16 greater than Box 8? ☐ Yes, lot fails ☑ No, go to Box 18	18. Avg. error in dimensionless units: (Box 15 ÷ Box 6 =) *− 14.5*	19. Avg. error in labeled units: (Box 18 × Box 2 =) *− 0.014 lb*

20. Does Box 18 = Zero (0) or Plus (+)? ☐ Yes, lot passes, go to Box 25 ☑ No, go to Box 21	21. Compute Sample Standard Deviation: *6.721*	22. Sample Correction Factor: *0.635*	23. Compute Sample Error Limit: (Box 21 × Box 22 =) *4.267*

24. Disregarding the signs, is Box 18 larger than Box 23? ☑ Yes, lot fails, go to Box 25 ☐ No, lot passes, go to Box 25	25. Disposition of Inspection Lot: ☐ Approved ☑ Rejected
Comments	**Official's Signature:**
	Acknowledgement of Report:

Table 2-2. Sampling Plans for Category B (for Use in USDA-Inspected Meat and Poultry Plants Only)			
1	2	3	4
Inspection Lot Size	Sample Size	Initial Tare Sample Size	Number of Packages Allowed to Exceed the MAVs in Table 2-9
250 or Fewer	10	2	0
251 or More	30	5	0

Table 2-9. U. S. Department of Agriculture, Meat and Poultry Groups and Lower Limits for Individual Packages (Maximum Allowable Variations)		
Definition of Group and Labeled Quantity		Lower Limit for Individual Weights (MAVs)
Homogenous Fluid When Filled (e.g., baby food or containers of lard)	All Other Products	
Less than 85 g or 3 oz		10% of labeled quantity
85 g or more to 453 g 3 oz or more to 16oz		7.1 g 0.016 lb (0.25 oz)
More than 453 g More than 16 oz	85g or more to 198 g 3 oz to 7 oz	14.2 g 0.031 lb (0.5 oz)
	More than 198 g to 1.36 kg 7 oz to 48 oz	28.3 g 0.062 lb (1 oz)
	More than 1.36 kg to 4.53 kg More than 48 oz to 160 oz	42.5 g 0.094 lb (1.5 oz)
	More than 4.53 kg More than 160 oz	1 % of labeled quantity

Scenario 1: You are in an establishment producing raw, non-intact beef product producing packages of ground chuck. You decide your inspection lot is 237 packages. The unit of measure for the certified scale being used is 0.001 lb.

1. What is your first name?
2. What is your last name?
3. What is the sample size of the packages that you should examine?

   a. 30
   b. 10
   c. 2
   d. 5

4. What is the initial tare sample size?

   a. 30
   b. 10
   c. 2
   d. 5

The sample tare weights were 0.020 lb. and 0.021 lb.

5. What is the Average Tare Weight?

   a. 0.022 lb.
   b. 0.21 lb.
   c. 02 lb.
   d. 0.021 lb.

Scenario 2: You are in an establishment producing 5 lb. packages of raw, frozen chicken breasts. There are 243 packages in the inspection lot. The unit of measure for the certified scale being used is 0.001 lb.

6. What is the sample size of the packages that you should examine?
   a. 30
   b. 10
   c. 2
   d. 5

7. What is the initial tare sample size?

   a. 30
   b. 10
   c. 2
   d. 5

Tare weights sampled 0.072 and 0.073

8. What is the average tare weight?

   a. 0.73
   b. 0.073
   c. 0.72
   d. 0.072

9. What was the total package error?

   a. 30
   b. 10
   c. 2
   d. 5

10. Did the lot meet the MAV criteria?

a. Yes
b. No

11. Did the lot pass?

a. Yes
b. No

Gross weight (lb.)	Labeled Net Weight (lb.)	Nominal Gross Weight (lb.)	Package Error
5.098	5.000	5.073	25
5.095	5.000	5.073	22
5.079	5.000	5.073	6
4.998	5.000	5.073	-75
5.088	5.000	5.073	15
5.083	5.000	5.073	10
5.071	5.000	5.073	-2
5.089	5.000	5.073	16
5.092	5.000	5.073	19
5.067	5.000	5.073	-6

Scenario 3: You are in an establishment producing 8 oz. (226 g) individually packaged frozen beef burritos. Your inspection lot is 1600 packages. The unit of measure for the certified scale in use is .1 grams. You weigh two complete sets of the packaging material. One set weighs 2.2 g and the other set weighs 2.2 g. The scale graduation is 0.1g. You then complete your task, converting to dimensionless units.

12. What is the sample size of the packages you should examine?

a. 30
b. 10
c. 2
d. 5

13. What was the total package error?

a. - 1388
b. + 1388
c. - 1269
d. + 1269

14. Did the lot meet the MAV criteria?

a. Yes
b. No

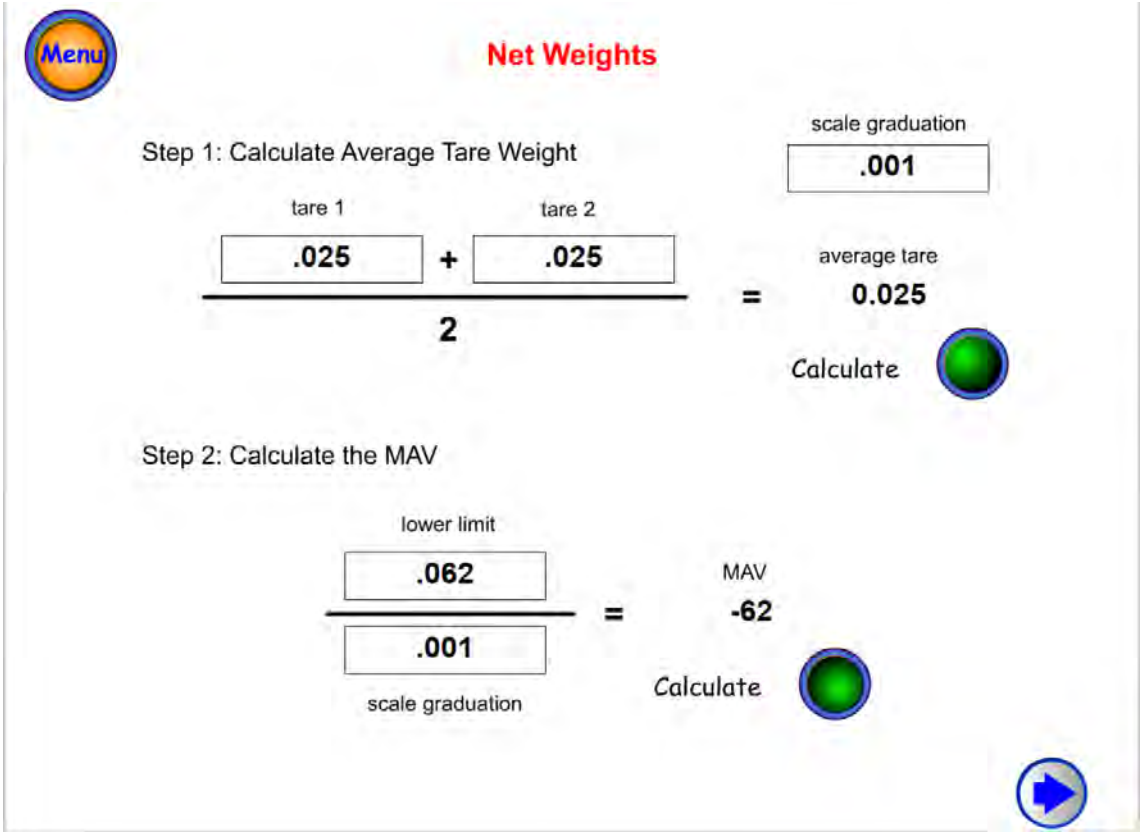
15. Did the lot pass?

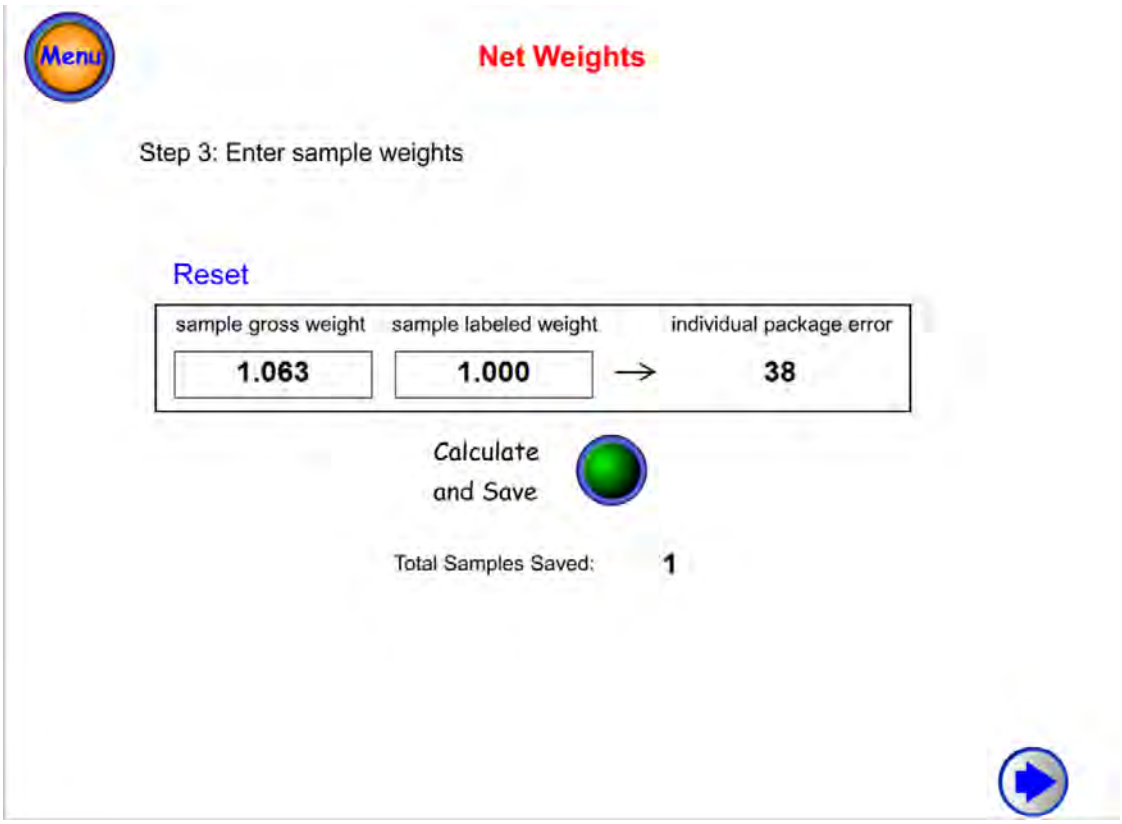
    a. Yes
    b. No

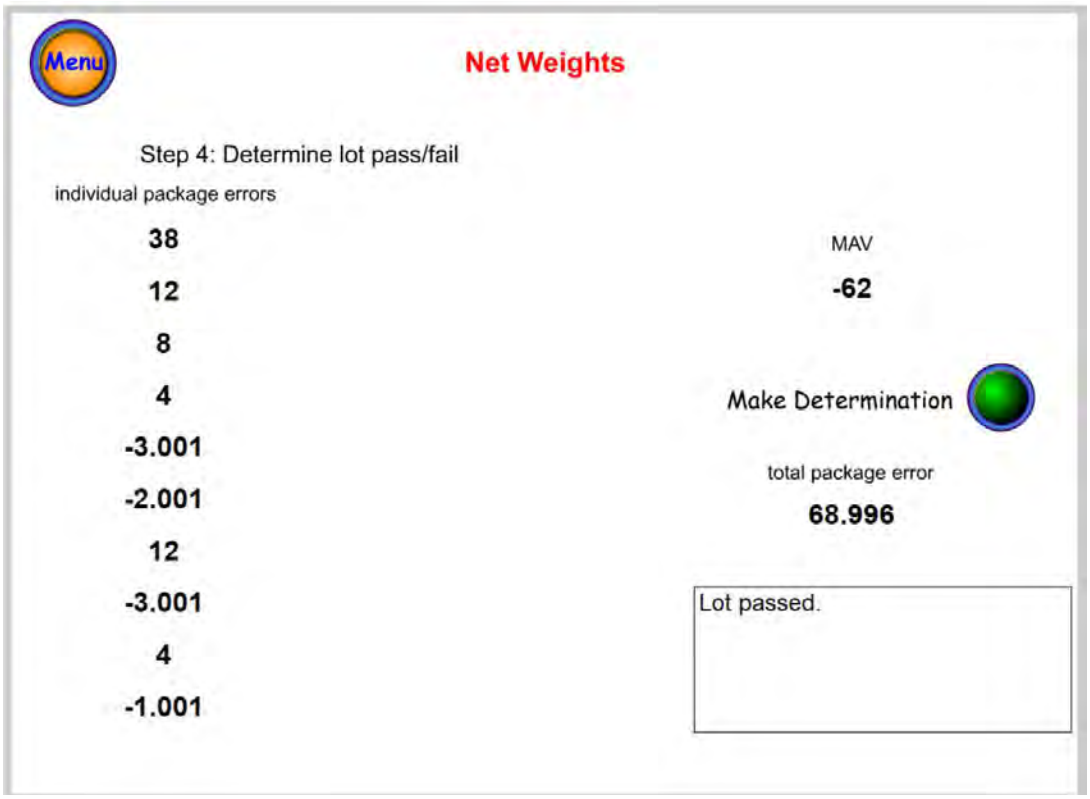
Gross Weight (g)	Labeled Net Weight (g)	Nominal Gross Weight	Package Error
238.6	226	228.2	104
234.4	226	228.2	62
228.8	226	228.2	6
245	226	228.2	168
231.1	226	228.2	29
236.2	226	228.2	80
224.4	226	228.2	-38
232.7	226	228.2	45
238.5	226	228.2	103
220.4	226	228.2	-78
241.1	226	228.2	129
232.5	226	228.2	43
234.6	226	228.2	64
232.2	226	228.2	40
232.6	226	228.2	44
230.9	226	228.2	27
236.8	226	228.2	86
240.5	226	228.2	123
242.2	226	228.2	140
233	226	228.2	48
234.4	226	228.2	62
200.2	226	228.2	-280
242.9	226	228.2	147
238.8	226	228.2	106
244.2	226	228.2	160
232.9	226	228.2	60
198.4	226	228.2	-298
238.2	226	228.2	100
230.7	226	228.2	25
236.3	226	228.2	81

Example Using the Calculation Aid

Access the Calculation Aid as follows: Start Menu > FSIS Applications > Calculation Aid > Select Net Weights




Menu
Net Weights
Step 3: Enter sample weights
Reset
sample gross weight
sample labeled weight
individual package error
1.063
1.000
38
Calculate and Save
Total Samples Saved:
1


Menu
Net Weights
Step 4: Determine lot pass/fail
individual package errors
38
12
8
4
-3.001
-2.001
12
-3.001
4
-1.001
MAV
-62
Make Determination
total package error
68.996
Lot passed.

3.5 - Solving for an Unknown Value

Introduction

This section gives a simplified explanation of how to solve the basic equations used to determine the amount of restricted ingredients permitted in federally inspected product. Occasionally, there may be an equation in which you have one unknown value. We will show you how to mathematically solve these equations.

Generic Model

To algebraically isolate an unknown value to one side of the equation and have all the known values or constants on the other, identical functions need to be performed on both sides of the equation.

The following ppm formula will be used to illustrate the generic model.

$$\text{ppm (parts per million)} = \frac{\text{lbs. Restricted Ingredient (RI)} \times \text{\% Pump} \times 1{,}000{,}000}{\text{lbs. Pickle}}$$

If all the values in the equation are known except the pounds of RI, isolate the pounds of RI (which is X) on one side of the equation and solve for it.

$$\frac{X \times \text{\% Pump} \times 1{,}000{,}000}{\text{lbs. Pickle}} = \text{ppm}$$

Solving for an unknown value is also called solving for X. When you have an unknown value, it is assigned a letter, generally X. So, Solving for an Unknown value and solving for X are used interchangeably.

When solving for X, the goal is to isolate it or get it by itself on one side of an equation.

There are a couple things to note.

1. In order to cancel a constant or known value from one side the of the equation, you perform what is known as an inverse operation. Which means you do the opposite. For example, if one side of an equation divides by 3, you would have to multiply by 3 to cancel out the division.

2. Equations are equal on both sides, so the value on one side of the equal sign (=) is the same value that is on the other side. So, if you do something to one side of the equation, you need to do it to the other side. Continuing with the previous example, if we multiply by 3 on one side of the equation, you will also need to multiply by 3 on the other side.

Using our example equation, our unknown value or X is the lbs. of Restricted Ingredients (RI).

$$\text{ppm} = \frac{\mathbf{X} \times \text{\% Pump} \times 1{,}000{,}000}{\text{lbs. Pickle}}$$

Our new equation has X in the place of lbs. of RI.

We ultimately need to isolate X, but there are several steps we need to take in order to do that.

First, we need to dispense with the denominator in the equation or the lbs. of pickle. It is a division, so we need to multiply by lbs. of pickle. Remember, what we do to one side of an equation, we also must do on the other side.

$$(\text{lbs. Pickle} \times) \ \text{ppm} = \frac{\mathbf{X} \times \text{\% Pump} \times 1{,}000{,}000}{\text{lbs. Pickle}} \ (\times \text{lbs. Pickle})$$

When you multiply and divide by the same value of one side of an equation, they cancel each other out.

$$(\text{lbs. Pickle x})\ \text{ppm} = \frac{\mathbf{X} \times \%\ \text{Pump} \times 1{,}000{,}000\ \cancel{(\times \text{lbs. Pickle})}}{\cancel{\text{lbs. Pickle}}}$$

And that gives us a new equation.

$$\text{ppm} \times \text{lbs. Pickle} = \mathbf{X} \times \%\ \text{Pump} \times 1{,}000{,}000$$

We still do not have X isolated. In order to do that we now need to divide by (% Pump x 1,000,000) to cancel out the multiplication. Remembering what you do on one side of an equation, you have to do on the other side, so we need to do this on both sides.

$$\frac{\text{ppm} \times \text{lbs. Pickle}}{(\%\ \text{Pump} \times 1{,}000{,}000)} = \frac{\mathbf{X} \times \%\ \text{Pump} \times 1{,}000{,}000}{(\%\ \text{Pump} \times 1{,}000{,}000)}$$

Again, when you multiply and divide by the same value on one side of an equation, they cancel each other out.

$$\frac{\text{ppm} \times \text{lbs. Pickle}}{(\%\ \text{Pump} \times 1{,}000{,}000)} = \frac{\mathbf{X}\ \cancel{\times \%\ \text{Pump} \times 1{,}000{,}000}}{\cancel{(\%\ \text{Pump} \times 1{,}000{,}000)}}$$

Which gives us another new equation.

$$\mathbf{X} = \frac{\text{ppm} \times \text{lbs. Pickle}}{\%\ \text{Pump} \times 1{,}000{,}000}$$

Then you plug and play. Otherwise known as solving the equation or solving for X. This same procedure is used to isolate X to one side of any equation.

Example 1

There is a pickle solution that weighs 1000 lbs. and 1.75 lbs. of nitrite was added to the solution. If we plug those numbers into our equation, we find the only value we do not have is the maximum % pump. So, we need to solve for maximum % pump or X is maximum % pump allowed.

$$200\ \text{ppm nitrite} = \frac{1.75\ \text{lbs.} \times \mathbf{X} \times 1{,}000{,}000}{1000\ \text{lbs.}}$$

First, we will need to alleviate the denominator or 1000 lbs. We do this by multiplying by 1000 lbs. on both sides of the equation because, once again, what we do on one side of an equation, we need to do to the other.

$$1000\text{lbs.} \times 200\ \text{ppm nitrite} = \frac{1.75\ \text{lbs.} \times \mathbf{X} \times 1{,}000{,}000}{1000\ \text{lbs.}} \times 1000\ \text{lbs.}$$

Again, when you multiply and divide by the same value on one side of an equation, they cancel each other out.

$$1000\text{lbs.} \times 200\ \text{ppm nitrite} = \frac{1.75\ \text{lbs.} \times \mathbf{X} \times 1{,}000{,}000\ \cancel{\times 1000\ \text{lbs.}}}{\cancel{1000\ \text{lbs.}}}$$

Which gives us a new equation.

$$1000\ \text{lbs.} \times 200\ \text{ppm nitrite} = 1.75\ \text{lbs.} \times \mathbf{X} \times 1{,}000{,}000$$

We still do not have X isolated. In order to do that we now need to divide by (1.75 lbs. x 1,000,000) to cancel out the multiplication. Keeping in mind, what you do on one side of an equation, you have to do on the other side, so we need to do this on both sides.

$$\frac{1000\text{lbs. x } 200\text{ ppm nitrite}}{(1.75\text{ lbs. x } 1{,}000{,}000)} = \frac{1.75\text{ lbs. x } \mathbf{X} \text{ x } 1{,}000{,}000}{(1.75\text{ lbs. x } 1{,}000{,}000)}$$

Again, when you multiply and divide by the same value on one side of an equation, they cancel each other out.

$$\frac{1000\text{lbs. x } 200\text{ ppm nitrite}}{(1.75\text{ lbs. x } 1{,}000{,}000)} = \frac{\cancel{1.75\text{ lbs. x }} \mathbf{X} \cancel{\text{ x } 1{,}000{,}000}}{\cancel{(1.75\text{ lbs. x } 1{,}000{,}000)}}$$

Which gives us another new equation.

$$\frac{1000\text{lbs. x } 200\text{ ppm nitrite}}{(1.75\text{ lbs. x } 1{,}000{,}000)} = \mathbf{X}$$

Then you solve the equation or Solve for X.

$$\frac{200 \times 1{,}000}{1.75 \times 1{,}000{,}000} = \mathbf{X}$$

$$\frac{200{,}000}{1{,}750{,}000} = \mathbf{X}$$

$$0.1142 = \mathbf{X}$$

Finally, multiply 0.1142 by 100 to convert to a percent and 11.42% is the maximum percent pump.

Example 2

The establishment has a written procedure that calls for 12% pump and has a pickle solution weighing 950 lbs. They use a cure mix that is 6.25% nitrite added to the solution. We need to solve for maximum amount of cure mix allowed.

$$200\text{ ppm nitrite} = \frac{\mathbf{X} \text{ x } 0.12 \text{ x } 1{,}000{,}000}{950\text{ lbs.}}$$

First, we need to alleviate the denominator, so we multiply by 950 lbs., keeping in mind, what we do on one side of an equation, we need to do on the other side.

$$950\text{ lbs. x } 200\text{ ppm nitrite} = \frac{\mathbf{X} \text{ x } 0.12 \text{ x } 1{,}000{,}000}{950\text{ lbs.}} \text{ x } 950\text{ lbs.}$$

And again, when you multiply and divide by the same value on one side of an equation, they cancel each other out.

$$950\text{ lbs. x } 200\text{ ppm nitrite} = \frac{\mathbf{X} \text{ x } 0.12 \text{ x } 1{,}000{,}000}{\cancel{950\text{ lbs.}}} \cancel{\text{ x } 950\text{ lbs.}}$$

Which gives us a new equation.

$$200\text{ ppm nitrite x } 950\text{ lbs.} = \mathbf{X} \text{ x } 0.12 \text{ x } 1{,}000{,}000$$

We still do not have X isolated. In order to do that we now need to divide by (0.12 x 1,000,000). Remember, what you do on one side of an equation, you have to do on the other side, so we need to do this on both sides.

$$\frac{950\text{ lbs. x } 200\text{ ppm nitrite}}{(0.12 \text{ x } 1{,}000{,}000)} = \frac{\mathbf{X} \text{ x } 0.12 \text{ x } 1{,}000{,}000}{(0.12 \text{ x } 1{,}000{,}000)}$$

Again, when you multiply and divide by the same value on one side of an equation, they cancel each other out.

$$\frac{950 \text{ lbs. x } 200 \text{ ppm nitrite}}{(0.12 \text{ x } 1{,}000{,}000)} = \mathbf{X} \ \frac{\text{~~x 0.12 x 1,000,000~~}}{\text{~~(0.12 x 1,000,000)~~}}$$

Which gives us another new equation.

$$\frac{950 \text{ lbs. x } 200 \text{ ppm nitrite}}{(0.12 \text{ x } 1{,}000{,}000)} = \mathbf{X}$$

We now need to simplify the numbers, so we perform the multiplication in the numerator and the denominator.

$$\mathbf{X} = \frac{190{,}000}{120{,}000}$$

Then we divide the numerator by the denominator.

X = 1.58 lbs.

We have solved for X, but we are not finished. We found out that 1.58 lbs. of nitrite are allowed, but the cure mix is only 6.25% nitrite, so we now need to figure out how much mix can be used. We do this by dividing lbs. of nitrite by 6.25% or .0625 (which is 6.25% written as a decimal).

1.58 lbs. nitrite ÷ 0.0625 = lbs. of cure mix allowed

OR

$$\frac{1.58 \text{ lbs. nitrite}}{6.25\ \%}$$

= **25.28 lbs.** of cure mix allowed in the pickle solution

04 - Sausage Operations

Objectives

1. Define terminology used in sausage operations.
2. Identify four criteria required of a sausage product additive.
3. Understand how restricted ingredients are classified, their minimum or maximum permitted limits, and conditions of use.
4. Identify the four classes of sausage products and two types of loaf.
5. Understand the sausage production process.
6. Understand the significance of emulsion development in cooked sausage products.
7. Identify the types and characteristics of sausage product casings.
8. Verify non-food safety consumer protection (NFSCP) by:
    - Conducting General Product Labeling tasks for all sausage products.
    - Conducting Labeling - Product Standards tasks for sausage products with a standard of identity or required product ingredients.
    - Performing accurate calculations to determine amounts of restricted ingredients and any meat or poultry components required in sausage products.
    - Understanding FSIS procedures for scheduling NFSCP product samples.

Sausage is one of the world's oldest forms of processed food. The word "sausage" is derived from the Latin word "salsus," which means to salt or to preserve meat. Along with unique customs, skills, and recipes, people from different regions brought to America many different sausage flavors, textures, and shapes. Certain types of sausages (e.g., wiener from Vienna, Austria; frankfurter from Frankfurt, Germany; Genoa salami from Genoa, Italy) are allowed under 9 CFR 317.8(b)(1) to use geographic names based on their origin.

Sausage (9 CFR Part 319, Subparts E, F, G, I, J, L; Part 381, Subpart N, P) is defined as a coarse or finely **comminuted** (i.e., reduced in size by grinding and/or chopping) meat food product. Sausage is prepared from one or more kinds of raw or frozen meat, meat and meat byproducts, and may contain poultry, poultry byproducts, and/or mechanically separated meat or poultry. Sausages may be raw or cooked, contain various amounts of water, are typically seasoned with condimental substances, and may be fresh (i.e., uncured) or cured.

9 CFR 319.140 addresses sausage in general and includes fresh sausage prepared from one or more kinds of meat or meat byproducts. **Meat** (§301.2) is defined as the part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat. Meat includes beef cheek and head meat, beef heart meat, exclusive of the heart cap (i.e., cardiac muscle trimmed from the ventricular wall), and skinned pork jowls. Meat also includes skeletal muscle tissue from advanced meat recovery (AMR) systems if specific §318.24 requirements are met. Meat does not include muscle found in the lips, snout, or ears. **Meat byproduct** (§301.2) is any part capable of use as human food, other than meat, which has been derived from one or more cattle, sheep, swine, or goats. Examples of meat byproducts, also referred to as "variety meat," include livers, stomachs and tripe (i.e., first or second stomach of a cow); pork snouts; whole livestock hearts, tongues, lips, weasands, and spleens; ear muscle tissue; partially defatted pork fatty tissue (PDPFT); partially defatted beef fatty tissue (PDBFT), and fat. Meat byproducts must be declared in the product label ingredients statement by common or usual name. For example,

if livestock blood is used in a sausage product, 9 CFR 317.8(b)(31) requires the ingredients statement to declare the specific kind of blood used (e.g., “swine blood”) in addition to including the term “blood” in the product name.

Poultry (§381.118) is the deboned white and dark meat, including other edible parts such as skin and fat not to exceed natural proportions as defined in 9 CFR 381.168). For cooked sausages, **poultry meat** (§319.180(g)) is deboned chicken and/or turkey meat without skin or added fat, while **poultry byproduct** (§381.2(c)) is any poultry skin, fat, gizzard, heart, or liver. Poultry byproducts must be declared in the product label ingredients statement by common or usual name.

Mechanically separated species (MSS) identified in §319.5 refers to the skeletal muscle that has been mechanically separated and removed from the bones of livestock carcasses and parts, excluding beef. **Mechanically separated kind of poultry** (MSK or MSKP) is any product resulting from the mechanical separation and removal of most of the bone from the attached skeletal tissue of poultry carcasses and parts, that may or may not contain skin with attached fat (§381.173 - 174). The result of mechanical separation is a finely comminuted product with paste-like form and consistency (“batter”). Certain standardized products in 9 CFR Part 319 that have a maximum fat content limit may use MSS up to 20% of the meat and poultry product portion of the product’s meat block. All of the meat, poultry, and/or meat or poultry byproduct components in the product formulation comprise the **meat block**.

Additives

9 CFR 320.1(b)(10) and 9 CFR 381.175(b)(6) requires establishments to maintain sausage formula records to help document compliance with meat and poultry regulations. This includes the use of ingredients which are commonly referred to as additives. In sausage, an **additive** is any safe ingredient other than the meat or poultry components. An acceptable food additive must be:

1) Safe and suitable.

2) Not detract from the product or promote deception.

3) Serve a useful purpose or benefit the consumer.

4) Lend itself to inspectional and/or analytical control.

FSIS and FDA share responsibility for ensuring food additive safety while the industry supports and controls the use of additives. For example, **water** and/or **ice**, one of the most common ingredients added to a sausage product formulation, helps control product temperature, aids in mixing or blending other additives, facilitates casing stuffing, and improves product texture and yield. Water/ice used in food formulas must meet the Environmental Protection Agency’s National Primary Drinking Water regulations (40 CFR Part 141) to be considered safe and suitable. To prevent economic deception, water is limited in certain standardized products. Added water is limited to **3% of the total ingredients** (excluding the weight of water or ice added to the formulation) in raw fresh (i.e., uncured) or cured meat sausage (9 CFR 319.140), uncooked smoked pork sausage (§319.160), and when certain standardized names used on the label of raw or cooked products are required to meet a standard of identity prior to cooking (e.g., “pork sausage” (§319.141), “beef sausage” (§319.142), “breakfast sausage” (§319.143), “whole

hog sausage" (§319.144), and "Italian sausage" (§319.145)). For cooked meat sausage products subject to 9 CFR 319.140, added water is limited to **10% of the finished product weight** unless other stated. Hotdogs, franks, etc. subject to 9 CFR 319.180 and cheesefurters in §319.181 are limited to no more than a 40% combination of water and fat, provided that the fat content does not exceed 30%. Poultry sausages bearing the poultry mark of inspection have no added water limits. If necessary, compliance with added water regulatory limits in cooked sausages is verified through FSIS laboratory analysis and with supervisory approval for sampling; otherwise, the amount of water added during formulation is monitored and measured by meter, weight, or volume, then the water content is determined through formula calculations.

Seasoning is a general term used to describe ingredients that give food products their unique tastes and flavors. Seasonings are considered to be condimental ingredients that must always be sublisted in the ingredients statement. Seasoning often make up less than 2% of the total product formulation, are usually self-limiting (i.e., adding too much ingredient is not a food safety concern but makes the product unpalatable), and may have bacteriostatic properties. Seasonings include salt, spices, flavorings, sweeteners, and other ingredients such as lactic acid starter cultures, which give many types of sausages their characteristic tangy taste.

Salt contributes to flavor, solubilizes, and releases muscle fiber proteins, prevents fat separation during cooking, binds water to improve product yield, texture, and palatability, suppresses bacterial growth, and extends product shelf-life. 1

Spice, which functions primarily as seasoning rather that nutrition, refers to any aromatic vegetable substance in whole, broken, or ground form, other than onions, garlic, and celery, where no portion of the volatile or flavoring principle has been removed (§317.2(f)(1)(i)(A) and §381.118(c)(1)). As examples, black pepper, nutmeg, dry mustard, and sage could each be identified by their common or usual name or referred to collectively in the ingredients statement as "spices," "flavoring," "flavor," "natural flavor," or "natural flavoring." **Paprika**, which adds color and makes meat look brighter red, may not be permitted in many raw sausage products unless an exception has been made in the regulations or FSLPB. When paprika is used in a sausage product formulation, it must be listed in the ingredients statement as paprika, "spices and color," "spices and color (includes paprika)," "flavoring and color" or "flavoring and color (includes paprika)," or similar language that addresses natural flavoring and color versions of these options. When paprika is permitted, the product name may also require a qualifier (e.g., "coated with paprika," "artificially colored," or "colored with paprika"). Annatto and turmeric are also coloring ingredients that have similar requirements as paprika.

Flavoring, whose primary function is taste rather than nutrition, include essential oils, oleoresins, (a mixture of resin and essential or fatty oil), and other flavoring constituents derived from a spice, any other edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products. Flavorings in §317.2(f)(1)(i)(B) and §381.118(c)(2) include powdered garlic, powdered onion, celery powder, oleoresin of black pepper, rosemary extract, and spices which may be identified in the ingredients statement by their common or usual name or collectively as "flavor", "flavoring", "flavor", "natural flavor" or "natural flavoring." Oleoresin of paprika, turmeric extract, and annatto extract may be identified by their common or usual name or as "flavoring and color" or "flavoring and color (includes..)," or similar statement addressing natural flavoring and color versions of these options.

NOTE: A frequently asked question is the difference between a spice and a flavoring? A spice is a seasoning agent obtained from whole, broken, or ground vegetable substances other than onions, garlic, and celery. A flavoring adds taste or flavor and is derived from a spice or other

edible parts of plants, animals, eggs, dairy products, or fermented products. While all spices may be called natural flavoring, not all natural flavoring can be called spices.

Sweeteners and **sugars** (e.g., sugar (sucrose), dextrose) are the primary food source for the lactic acid- producing bacteria starter cultures that drive the fermentation process and contribute to a characteristic tangy flavor in sausage. Malt syrup and sorbitol, which are not as sweet as sugar, are restricted in cured meat sausages and not permitted in poultry products. Sweeteners add flavor, counteract the harshness of salt, increase water retention, and improve casing peelability.

Restricted Ingredients

Restricted ingredients are approved for use in sausage products for the purposes indicated, within the stated limits, and under other conditions specified in 9 CFR Parts 318, 319, 381, and §424.21(c). Restricted ingredients, other than flavorings designated in §381.118(c)(1) and (2), must be declared in the ingredient statement by the common or usual name.

Some sausages have a standard of identity that usually include regulatory limits on restricted ingredients, such as ≤35% fat content in Italian sausage or ≤3% water in raw sausage at the time of formulation. In such cases, the establishment must have some means of measuring and calculating the actual amount of restricted ingredient added to the formulation in order to determine if the product meets its standard of identity. Establishments that do not measure the amount of restricted ingredient added using their instrumentation (e.g., fat content) must have some other supportable method for verifying the product meets the regulatory standards. Failure to meet the standard of identity is a noncompliance in addition to the label being false and misleading.

Antioxidants are food additives that prevent oxidative rancidity by inhibiting the development of undesirable chemical compounds that contribute to "off" odors and flavors. The most common antioxidants used in sausages are BHA (butylated hydroxyanisole), BHT (butylated hydroxytoluene), propyl gallate, tocopherol, and tertiary butylhydroquinone (TBHQ). Antioxidants in fresh sausage are limited to = 0.01% individually and 0.02% in combination on the basis of the actual product fat content at the time of formulation. If permitted, tocopherol is limited to 0.03% and may not be used in combination with other antioxidants. The maximum level of antioxidant is different for dry sausage, e.g., BHA is limited to 0.006% in combination with other antioxidants for use in meat. The amount of antioxidants permitted in sausage products is based on the fat content at the time of formulation.

To ensure the amount of added antioxidants do not exceed regulatory limits, many establishments identify a product’s formulation target fat that may be used for antioxidant calculations. Since the target fat limit should not exceed any maximum regulatory fat limits required by an applicable standard of identity (e.g., Italian sausage, pork sausage, etc.), the amount of antioxidants and synergist added to the formulation based on the target fat content would be in compliance. Even if the incoming meat ingredients varied in actual fat content, the target fat level is likely to be met during product formulation as long as the establishment does not exceed the regulatory limit. However, if less fat is used in the actual formula than indicated by the target fat content, Inspection Program Personnel (IPP) would need to take steps to verify that the actual amount of fat added to the product at the time of formulation did not exceed the fat content regulatory limit.

NOTE: An antioxidant (e.g., BHA, BHT, or TBHQ) can never be added to a product in an amount greater than its individual limit, even in combination with other antioxidants.

Synergists are used to increase antioxidant effectiveness. Most antioxidants used are in a mix or compound containing a carrier, two or more individual antioxidants, and possibly a synergist. Any meat sausage product that is permitted to contain antioxidants may contain citric acid as a synergist in amounts not to exceed 0.01% based on fat content. Fresh pork sausage products may contain no more than 0.02% monoglyceride citrate or monoisopropyl citrate as synergists.

NOTE: It is not necessary to calculate for each antioxidant that is part of a mixture. Only one antioxidant calculation is necessary when the following rules are applied:

(1) If no individual antioxidant or synergist is 50% or more of the total antioxidants in the mix, calculate the *total of all antioxidants* using the .02% limit.

(2) If one individual antioxidant or synergist is 50% or more of the total antioxidants, calculate for *that individual antioxidant or synergist* using the .01% limit.

Binders and **extenders** may be used individually or collectively in certain sausages to improve product sensory characteristics (e.g., texture, juiciness, flavor), sliceability, and yield. Most binders and extenders permitted in sausage are allowed at a maximum level of 3.5% of the finished product weight. However, isolated soy protein and sodium caseinate are limited to 2% due to a high protein content. Some binders, such as sodium caseinate, nonfat dry milk, soy flour, isolated soy protein, and soy protein concentrate, are allergenic.

NOTE: Only untextured soy products are approved for use sausages. Textured soy products are highly processed and not approved for use in sausage products.

Phosphates, which are not permitted in raw sausage products, increase water retention (i.e., water binding capacity) and reduce shrinkage by controlling moisture loss in cooked sausages during further processing. Comminuted meat and poultry products may contain 0.5% phosphates in the total or final product.

Antimicrobial agents (e.g., sodium lactate/diacetate or other organic salts) may be added to sausage formulations as either flavoring agents or to inhibit microbial growth. When these ingredients are added to sausage formulas, the establishment is responsible for identifying in the labeling records their intended purpose and IPP would verify this information.

Cures and **curing agents**, which will be discussed in more detail in the Cured Meat and Poultry Product training module, are added to develop the flavor, color, and extend the shelf life of sausages such as semi-dry and dry sausages. Cure agents such as **sodium or potassium nitrite**, and less commonly sodium or potassium nitrate, have bacteriostatic properties that inhibit or suppress the growth of Clostridia spp. and other spoilage microorganisms in addition to antioxidant effects. The amount of cure permitted in sausage products is based on the meat block **green weight** (i.e., the weight of the meat and/or poultry components prior to processing). Cured bacon is not included in the sausage product meat block when calculating curing agent or cure accelerator ingredient regulatory limits.

The nitrites in curing agents combine with the muscle pigment *myoglobin,* an iron- and oxygen-binding protein, to form the characteristic pink-red color and develop the cured meat sausage flavor that cannot be reproduced with other ingredients. Nitrite is actually converted (“reduced”)

by bacteria in the meat or poultry to form nitric oxide, which reacts with the myoglobin. If nitrate is used as source for nitrite, it must first be reduced to nitrite, which is then further reduced to nitric oxide. This nitrate reduction process is very difficult to control and slows the development of the cured color because the nitrate conversion rate and amount of nitrite formed is dependent on environmental factors (e.g., temperature, moisture content, salt content, pH) and the numbers of nitrate-reducing bacteria present in the sausage mixture.

Curing agents are typically added in very low concentrations to sausage products through a cure mix or curing compound that is pre-mixed with other ingredients (e.g., salt, sugar, corn syrup solids, monosodium glutamate, etc.). The use of nitrites and nitrates must be carefully controlled because these ingredients can be toxic to humans at very high levels. Nitrites and mixtures containing them must be kept securely under the care of a responsible establishment employee. Containers containing a cure mix (e.g., Prague powder) must indicate the percentage of nitrite and/or nitrate in the mixture. Most curing compounds are tinted with FD&C Red #3 dye as an identification aid. Such compounds must be labeled to identify the dye, but no reference to the coloring is required on a sausage product label because the small amount used would not affect product color.

Many establishments now add naturally occurring sources of sodium nitrate and nitrite (e.g., celery powder, beet juice, sea salt) to cooked sausage formulations. Natural sources of nitrite and nitrate are not approved as curing agents but are sufficient to develop and maintain the pink coloring. FSIS has determined that using **natural sources of nitrite** along with a natural source of ascorbate (e.g., cherry powder, beet juice) is approved for antimicrobial use because this combination has been determined to control *C. botulinum* growth. To control the growth of *Clostridia* spp., establishments should add at least 100 ppm ingoing nitrite from the natural source along with at least 250 ppm of ingoing ascorbate from a natural source at safe and suitable levels as outlined in §424.21(c) and FSIS Directive 7120.1. Natural sources of nitrite/nitrate combined with a natural source of ascorbate are not currently approved for use with a cure accelerator.

Certain sausage products that are required or expected to be cured (e.g., hot dogs or pepperoni) but are formulated with natural sources of nitrite instead of synthetic curing agents identified in §424.21(c) must be labeled as "uncured." In addition, the label must contain the statement "no nitrates or nitrites added" qualified by the statement "except for those naturally occurring in [name of natural source of nitrite such as celery powder]." Unless the pH is 4.6 or below or the water activity is .92 or less, these sausage products must also bear “Not Preserved— Keep Refrigerated Below 40°F at All Times” in easy to read lettering adjacent to and at least one-half the size of the product name.

Cure accelerators (e.g., sodium ascorbate, sodium erythorbate) increase the effectiveness of nitrite, help speed up color development, and stabilize cure color. Cure accelerators may only be used in association with approved curing agents.

FOOD INGREDIENTS EXERCISE

Answer the following questions using Module 4 Sausage Operations information in the student notebook.

1. What is your first name? (online only)
2. What is your last name? (online only)

3. What are the four criteria required for an additive to be allowed in a sausage product?

    a. Safe and suitable
    b. Does not detract from the product or promote deception
    c. Cost effective
    d. Serves a useful purpose or benefits the consumer
    e. No regulatory limit
    f. Lends itself to inspectional and/or analytical control

4. A spice may be listed in a label ingredients statement as spice, flavor, flavoring, or by common or usual name, and a flavoring may be listed in an ingredients statement as flavor or flavoring, by common and usual name, but cannot be listed as spice. True or False?

    a. True
    b. False

5. When an antioxidant is permitted in a fresh sausage, the percentage allowed is based on the weight of the _____ .

    a. meat block
    b. fat content
    c. finished product
    d. entire weight of the ingredients, excluding the weight of water or ice used

6. Water or ice may be used in the preparation of raw sausage products in an amount not to exceed what percentage of the total ingredients?

    a. 1 %
    b. 3 %
    c. 10 %
    d. 15 %

7. For most cooked sausages, added water may be no more than what percentage of the finished product?

    a. 1 %
    b. 3 %
    c. 10 %
    d. 15 %

Sausage Classes and Types

Fresh sausage (§319.141-145) does not contain curing agents unless otherwise permitted (e.g., Italian sausage). 9 CFR 317.8(b)(6) does not permit the term “fresh” to be used on a sausage product label if it contains any sodium nitrate/nitrite, potassium nitrate/nitrite, or has been salted for preservation. **Uncooked, smoked pork sausage** (§319.160) is also not cured and obtains its distinct flavors and aromas from the smoking process. **Cooked sausages** such as frankfurters, franks, hotdogs, wieners, viennas, bologna, knockwurst, and similar products (§319.180-182) are cured, semisolid sausages prepared from one or more kinds of comminuted meat or poultry. Cooked sausages are permitted to contain phosphates and may gain distinct flavors from added nitrite curing agents and aromas if smoked. Cooked sausages are typically stuffed into a semi-permeable or impermeable casing or stainless-steel mold, then cooked in either a heating unit or hot water bath.

Semidry and **dry sausages** (FSLPB) are fermented by lactic acid-producing bacteria or directly acidified. Semi-dry (e.g., summer, Genoa) and dry sausages (e.g., salami, pepperoni) may be uncooked, cooked, or smoked. All semidry and dry sausages undergo a controlled air drying process (“product stabilization”). Sausages with a standard of identity for which nitrate or nitrite is permitted may also be prepared without nitrate or nitrite. Such sausage products (§319.2) must be labeled with the term ‘‘uncured’’ as part of the product name.

Many establishments that produce cooked sausages also produce **specific loaf** (§319, Subpart K) and **nonspecific loaf** (§319, Subpart L), which are addressed in this training module. Specific and nonspecific loaf, which are not sausage products, are similarly processed comminuted, emulsified, semisolid products made from seasoned and cured raw or cooked meat or poultry.

Sausage Standard of Identity

Some sausage products are produced under a specified name or **standard of identity** identified in 9 CFR Part 319 and the Food Standards Labeling and Policy Book (FSLPB). Be aware when working with sausage products that the specific order of the product name is critical in determining which standard of identity may be applicable. For example, “uncooked smoked pork sausage” follows §319.160, but “uncooked pork smoked sausage” follows §319.140, and “uncooked pork sausage” follows §319.141. Additional requirements for sausage product labeling are identified in §317.8.

Fresh pork sausage (§319.141) only contains fresh or frozen pork and no byproducts. Fresh pork sausage may contain mechanically separated pork up to 20% of the meat block, no more than 50% fat content in the finished product, and 3% or less added water. Antioxidants are allowed, but binders and extenders are not permitted.

The term “country style” may be used for **fresh country style pork sausage** when labeled in accordance with 9 CFR 317.8(b)(2). In addition to following the basic §319.140 requirements for fresh pork sausage, sausage labeled “country” or “farm” style are only permitted to contain sugar as the sweetening agent and natural spices (i.e., no oleoresins, spice extractives, or essential oils). Any sausage product labeled “country” or “farm” style must be prepared in the same way and have the same characteristics as in the country or farm.

Fresh beef sausage (§319.142) may contain fresh or frozen beef with no byproducts, binders, and extenders, no more than 30% fat content in finished product, and up to 3% added water. Antioxidants are permitted, but mechanically separated beef is inedible and not allowed.

Breakfast sausage (§319.143) may contain fresh or frozen meat, fresh or frozen meat and meat byproducts, binders, and extenders up to 3.5% (or 2%), up to 50% fat content in finished product, and no more than 3% added water. Mechanically separated species up to 20% of the meat block and antioxidants are also permitted.

Whole hog sausage (§319.144, FSLPB) is prepared fresh and/or frozen meat from swine in proportions normal to a single carcass (i.e., two hams, two shoulders, one heart, one belly, one tongue, two cheeks, etc. per carcass). Mechanically separated pork produced in natural proportions from a single hog is allowed. Whole hog sausage may contain added water not to exceed 3% of the total ingredients and no more than 50% fat content in the finished product. Antioxidants are permitted but binders and extenders are not.

Italian sausage (§319.145) is fresh, uncured raw sausage that has a standard of identity. Italian sausage must contain at least 85% meat or meat and fat, no more than 35% fat in the finished product, and no more than 3% added water. Products named "Italian sausage" must be prepared from pork, or pork and pork fat. Required ingredients that characterize the flavor of Italian sausage includes fennel and/or anise, salt, and dry pepper (e.g., black pepper, red pepper, white pepper, etc.). It is permitted to contain paprika under its standard of identity. While Italian sausage is classified as a fresh sausage, regulations allow for product name alternatives to be used when the product is cooked and/or cured (e.g., raw and cured product would be named "cured Italian sausage;' cooked product would be named "cooked Italian sausage"). When beef or veal are used with pork, the pork must make up the majority of the meat block and the product name would be changed accordingly (e.g., "Italian sausage with beef"). If beef or veal with or without beef fat or veal fat replaced all of the pork and pork fat in the meat block, that product name would also change accordingly (e.g., "Beef Italian sausage")

Bratwurst, chorizo, and **linguica** are other fresh sausages identified by standards of identity in the FSLPB. When Bratwurst and Linguica are cured the term "cured" is required in the product name on the label (i.e., "Cured Bratwurst," "cured Linguica"). Chorizo sausage may be fresh, cured, cooked, dried or semi dry but does not require changes to the product name, i.e., all red meat versions may be called "chorizo." Fresh and/or raw chorizo and linguica are permitted to contain paprika as an ingredient per the FSLPB and also §424.23(a)(2). All three of these sausages follow basic requirements in §319.140 with additional requirements in the FSLPB.

NOTE: Although the FSLPB states that wine is credited as added water, FSIS considers that less than 2% wine and vinegar added to chorizo as flavoring and does not include either ingredient in added water calculations. When wine or vinegar are added at 2% or more of the total formula, the characterizing ingredient must be included in the product name (e.g., "chorizo with wine" or "chorizo with vinegar") and the sausage standard would need to be met.

NOTE: Sausages with vegetables/fruits and sausages with cheese are addressed in the FSLPB ("SAUSAGE TYPE PRODUCTS WITH FRUITS AND VEGETABLES" and "SAUSAGE CONTAINING CHEESE"). When unexpected characterizing ingredients are used in the formula, the product name will need to identify such ingredient (e.g., "Bratwurst with Cheese") and the formula will need to meet the applicable sausage standard, excluding the identified characterizing ingredient.

Fresh poultry sausage must be labeled to indicate the kind of poultry (e.g., “Turkey Sausage”) and meet other regulatory requirements in §319.140, except that added water and fat content limits are not applied to fresh poultry sausage. If red meat ingredients are added to poultry sausage, the red meat ingredient needs to be included in the product name, e.g., “chicken sausage with pork fat added” when the red meat ingredient is 20% or less of the total meat block or e.g., “chicken and pork sausage” when the red meat ingredient is more than 20% of the total meat block. Products labeled “Italian Turkey Sausage” must have a meat block with only the kind of poultry identified in the product name and must also meet the basic regulatory requirements in §319.145, excluding the fat and water limitations.

Cooked and/or **smoked sausage** products are produced under a standard of identity. 9 CFR 319.140 includes **Polish sausage** and **cotto salami**. These sausages are usually coarsely ground, may contain no more than 10% water based on the finished cooked weight, have no regulatory limit for fat, may contain binders/extenders up to 3.5% (or 2%) as permitted in §424.21(c) and the FSLPB, and may contain MSS.

Frankfurters, franks, furters, hotdogs, wieners, viennas, bologna, garlic bologna, knockwurst, and similar products such as mettwurst and teawurst are identified in §319.180. Cheesefurters and similar products are addressed in §319.181. The cooked meat sausages listed in §319.180 may contain raw or cooked poultry meat and/or mechanically separated poultry without skin, kidneys, and sex glands up to 15% of the total ingredients, excluding water. These products are limited to no more than 30% fat and may contain up to 40% fat in combination with added water. They may contain binders/extenders up to 3.5% (or 2%) as permitted in §424.21(c). Comminuted, semisolid, seasoned, and cured sausages containing raw meat byproducts, or raw or cooked poultry products, must be labeled with the phrase ‘‘with byproducts’’ or ‘‘with variety meats’’ in the product name.

Braunschweiger (§319.182(a)) is a type of sausage that may be made from fresh, cured, and/or frozen pork, beef, and/or veal, and at least 30% pork, beef, and/or veal liver computed on the fresh weight of the liver. It may also include pork and/or beef fat. Binders/extenders and MSS are permitted, and the product may be smoked. Water is limited to 10% or less in the finished product. When made from a single species, the product name may reflect the species (e.g., if only beef, beef fat, and beef liver were used, the name would be “beef Braunschweiger”). **Liverwurst** (§319.182(b)) is a type of sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30% liver from any amenable species (pork, beef, veal, sheep, goat) computed on the fresh weight of the liver. It may also include pork and/or beef byproducts. Binders/extenders and MSS are permitted but the product cannot be smoked. When made from a single species, the product name may reflect the species (e.g., if only pork, pork byproducts, and pork liver were used, the name would be “pork liverwurst”).

Sausage Products Containing Both Livestock and Poultry Ingredients (FSLPB) - The labeling of non-standardized cooked sausage products must comply with 9 CFR 319.180. Meat food products are those in which more than 50% of the livestock and poultry product portion consists of livestock ingredients. Cooked meat and poultry sausage products in which poultry ingredients constitute more than 15% of the total ingredients (excluding water) must have product names that indicate the species of livestock and kind(s) of poultry ingredients (e.g., example, “Beef and Turkey Frankfurter” or “Frankfurter Made From Beef and Turkey”).

Poultry sausage products contain more than 50% poultry of the livestock and poultry portions. If more than 20% of the total poultry and livestock ingredients consists of livestock, the product name must indicate the kind(s) of poultry and livestock species ingredients (e.g., “Turkey and

Beef Frankfurter," "Frankfurter Made From Turkey and Beef"). Cooked sausage products that contain livestock ingredients at 20% or less of the total poultry and livestock ingredients must have product names that are appropriately qualified to indicate the inclusion of livestock ingredients (e.g., "Turkey Frankfurter - Pork Added or - With Pork"). The product names of cooked sausage products containing no livestock ingredients must designate the kind(s) of poultry ingredients (e.g., "Turkey Frankfurter"). Cooked sausage products containing more than 50% meat ingredients would carry the red meat legend, while those containing more than 50% poultry ingredients would carry the poultry legend.

Specific loaf (§319.260-261 and FSLPB) and **nonspecific loaf** (§319.280-281 and FSLPB) are formulated similar to sausage. These products are made with comminuted meat, meat and meat byproducts or poultry components (including MSKP), and nonmeat ingredients such as added water, various spices, and flavorings. Binders and extenders are permitted in specific and non-specific loaf unless otherwise indicated in §424.21(c) or the FSLPB. Specific and nonspecific loaf may contain ingredients such as pickles, olives, or pimentos, are stuffed into a casing or mold, then cooked. Specific loaf has a standard of identity and must include the meat and poultry species in the product name (e.g., corned beef loaf, baked pork and chicken loaf, pork olive loaf, etc.). If poultry specific loaf contains more than 20% total livestock ingredients, the product name must be descriptively labeled to indicate the presence of the livestock ingredients (e.g., "Olive Loaf made with Chicken and Pork"). Nonspecific loaf has no standard of identity and may be labeled with either a descriptive name that identifies characterizing components and/or ingredients, or a fanciful or coined name with the ingredients statement contiguous to the product name. Examples of nonspecific loaf include "Olive Loaf" and "Pickle Loaf."

Sausage Preparation

Meat and poultry used in fresh sausage may be produced within the establishment during de-boning operations (e.g., whole hog pork sausage producers) or come from outside suppliers. Non-meat ingredients and packaging materials are almost always outsourced. Many processors rely on formal agreements with suppliers to ensure consistent product is received, including written purchase specifications that include quality aspects, such as the lean-to-fat ration in trimmings. For preblended or proprietary mixes, the establishment must provide an explicit breakdown of the ingredients and ensure that the ingredients are declared on the fresh sausage finished label.

Establishments are required under §320.1(b)(10) and §381.175(b)(6) to have on file any labeling records, product formulas, processing procedures, and additional documentation to support that products meet §412.1 labeling requirements. Establishments should **weigh** and **identify** individual ingredients according to the formula to create a consistent product batch and also ensure that the ingredients are accurately represented on the fresh sausage product finished label. Labels of spice or seasoning blends typically provide instructions for how much mixture to use for a specific amount of meat or poultry (e.g., one package seasoning mix per 100 lb. of meat). Restricted ingredients, some of which are allergenic, should be stored in separate containers for single batch formulas.

Meat and poultry components used in the formulation of raw and fresh sausages are comminuted through **chopping, grinding, flaking**, or a combination of methods. The comminuted meat and poultry is then mixed or blended with additives to achieve a uniform distribution of meat particles, fat, spices, flavorings, antioxidants, water, and other ingredients. The comminuted mixture may be stuffed into casings or chubs, shaped into skinless links, or

formed into patties. The finished raw or cooked and/or smoked sausage products are packaged, labeled, and typically passed through metal detection before storage and distribution. Establishments must ensure that all ingredients, including those in proprietary mixtures, are properly used and accurately declared on the finished product label by common or usual name.

Cooked Sausage Preparation

Cooked sausage products, which may or may not be cured, may combine meat and poultry components, mechanically separated species, water, and nonmeat ingredients to form a paste or emulsion. A mix of raw meat and/or poultry with appropriate water binding characteristics and nonmeat ingredients is essential to forming an **emulsion**. Emulsions may breakdown from too much added fat, over chopping of the meat and/or poultry mixture, increased mixture temperature, high acid content, low pH, or too rapid heating to a high temperature.

The emulsified sausage mixture may be stuffed into one of three types of **casings**. Natural, artificial, or collagen casings can be used to hold the semisolid meat and/or poultry sausage batter until the proteins can coagulate and harden during cooking to form the sausage. A **natural casing** is an animal casing derived from various sections of viscera. These must be inspected for condition and nodules, then thoroughly flushed and rinsed before use. For sausages encased in natural casings made from a different species than the encased meat or poultry, 9 CFR §317.8(b)(37) requires the casing type be listed on the product label. Fibrous, saran, and hydrocellulose **artificial casings** are strong, easy to handle, permeable to smoke and moisture, storable in a dry nonrefrigerated area, and are available in various sizes and shapes. Most artificial casings are typically inedible and must be removed prior to consumption. However, many establishments now use alginate film, which is applied as a liquid to the formed sausage batter. When placed in a calcium bath, the alginate forms a solid structure to produce a stable and edible artificial sausage casing. **Collagen casings** are derived or “regenerated” from a natural constituent of hides that has been chemically processed and extruded to form an edible protein casing. If the species of meat in the collagen casing is different than the species of meat in the sausage, §317.8(b)(38) requires the product label to identify the species used for the casing.

Rework is the re-routing of partially or fully processed product into a new batch or formulation with the same or similar ingredients. Product may be reworked due to emulsion residue, product breakage (“blow outs”), broken, irregular, or end slices, smoked meats, returns, etc. Rework must be wholesome, unadulterated, and not violate a standard of identity, change the order of predominance of ingredients, or perceptibly affect normal product characteristics. Rework may be used in cooked sausage and meat loaf without limitation, but establishments typically limit rework to 10% or less because it has no binding capabilities. Sausage products in edible collagen casings may be used in similar finely comminuted products without need for peeling. Finished cooked sausage in natural casings made from bungs, middles, beef rounds, bladders, or stomachs must be stripped of the casings before use. Also, natural casings of any type that break during stuffing operations should not be included in emulsions. The new product may have similar but different ingredients, but all ingredients in the rework must be declared in the new product’s ingredients statement. For the purpose of calculating restricted ingredients, IPP must not include the weight of the rework product since it has already met the requirements for restricted amounts at the time of its formulation and is only used as a filler product.

Stuffed sausage products are typically produced by stuffing the raw sausage emulsion into a casing, then pinching or twisting the casing to create a link. Some stuffed sausage products

may be smoked with non-resinous hardwoods, which has been shown to inhibit bacterial growth, enhance flavor, and increase shelf life. Other stuffed sausage products may be subjected to a **lethality** process. Whether stuffed sausage products are fully cooked, fermented, and/or smoked, the establishment must monitor and control time and temperature lethality parameters to ensure microorganisms of concern are either eliminated or reduced to acceptable levels. Humidity may also need to be controlled, but the heat resistance of pathogens is not affected when sausages are cooked in casings because almost all semi-permeable or impermeable product casings will prevent or inhibit moisture loss. Following the cooking and/or smoking lethality step, the cooling process (i.e., **stabilization**) begins. Rapidly cooling the cooked sausages to an internal temperature of ≤40°F will control the outgrowth of spore-forming pathogens that may have survived the lethality process. The chilled cooked sausage product may have casings removed in a machine called a peeler. After **peeling,** the cooked sausage product may be sliced and is often packaged in labeled plastic packaging for **distribution** to retail stores, hotels, and restaurants.

NOTE: Refer to FSIS Appendix A for product lethality guidelines and FSIS Appendix B for product stabilization guidelines.

PHIS Labeling Verification Tasks

IPP are to verify establishment compliance with non-food safety regulatory requirements and ensure that product labels accurately reflect the finished product. A meat or poultry product is considered misbranded when its label is false or misleading, or the label is missing a required feature, qualifying statement, descriptive designation, or if it contains special statements or claims without LPDS approval. IPP should only perform unscheduled non-food safety consumer protection verification tasks if conditions or activities observed cause them to suspect that the establishment is not meeting non-food safety regulatory requirements. Conversely, if IPP identify a food safety concern while conducting a non-food safety consumer protection verification task, they should first perform the food safety procedure as an unscheduled procedure, taking any enforcement actions necessary, then complete the non-food safety verification activity. IPP perform labeling verification tasks as instructed in FSIS Directive 7000.1, with FSIS Directive 7620.3 and the FSLPB available as additional resources.

NOTE: Labels with special statements and claims may require sketch approval by LPDS as required in 9 CFR 412.1(c)(3). Labels with claims that designate an ingredient as certified “organic” under the Agricultural Marketing Service (AMS) National Organic Program, geographic landmarks displayed on a product label (e.g., foreign country flag, monument, or map), and negative claims that identify the absence of certain ingredients or types of ingredients (e.g., “No MSG Added”, “Gluten Free”) are acceptable under generic label approval.

The **General Labeling task** is performed in establishments that prepare meat or poultry products, including sausages that bear a label. The **Labeling-Products Standards task** is performed for sausage products with a standard of identity (i.e., sausage products required to have minimum amounts of meat or edible portion of the animal (e.g., liver), or when specific ingredients are required.

Labeling Compliance

IPP will schedule and perform the General Labeling and Labeling-Products Standards tasks on the dates most appropriate. IPP will gather and assess the necessary information to determine that product label approvals are on file and accurately reflect the finished product, all required label information and graphics are represented, no declared ingredients are omitted or undeclared ingredients added, and the establishment's labeling procedures are adequate. Compliance verification activities include observing establishment product formulations, verifying label accuracy, 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 to verify that restricted ingredients in product formulations do not exceed regulatory limits.

Using the GAD Thought Process, IPP are to consider all relevant factors when determining if a product fails to meet a non-food safety regulatory requirement. Activities to be considered include reviewing establishment records and labels, lot identification procedures, receiving records, production records, and any details that can reasonably be determined based on average production parameters. When verifying or ingredient statement compliance, IPP should observe product preparation and compare these findings to their review information and the approved label. IPP with any questions or concerns should consult their supervisor for assistance.

General Labeling Task

IPP are to conduct the General Labeling Task to the verify that the establishment is producing product in compliance with 9 CFR. This task is performed by comparing the product to the relevant regulatory requirements and determining whether:

1. The finished product label contains all required information.

2. The ingredients statement is accurate and all ingredients are listed in descending order of predominance.

3. The label ingredients statement declares any allergenic or proteinaceous substances used.

4. The label is used on appropriate product.

5. A label approval is on file.

6. The product defect levels are consistent with applicable standards.

Labeling - Product Standards Task

IPP are to use the Labeling - Product Standards task to determine whether some sausage products with specific standards meet regulatory compliance. IPP perform the Labeling - Product standards tasks by comparing an appropriate product to its regulatory relevant requirements. This will likely include performing calculations to determine the amounts of

specific ingredients added (e.g., percent fat, percent water, curing agents, etc.). IPP should verify that the product selected for Labeling - Product Standards task:

1. Meets product requirements specified in the applicable standard of identity.

2. Contains restricted ingredients used only in accordance with regulatory requirements.

3. Has ingredients accurately declared on the product label in descending order of predominance.

4. Product net weight is accurately reflected on its label.

Labeling Noncompliance

IPP will examine products to determine if product standards, net weight standards, ingredient or component regulatory minimum or maximum limits, or product defects meet regulatory requirements. There is regulatory noncompliance when a product exceeds any of the maximum limits, falls below the minimum requirements, or fails to meet any of the other non-food safety regulatory requirements. However, IPP should only examine product when assigned the task or if there is reason to believe that product regulatory requirements are not met. In addition, IPP are not required to verify all products and there are no designated sampling plans or sample sizes used in examining products to assure that non-food safety regulatory requirements are met. Instead, IPP will determine whether a product complies with regulations 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 should investigate whether issues in the process will cause all packages to exceed the net weight requirements rather than issuing the establishment an NR. Similarly, if the product is economically adulterated or misbranded, IPP may withhold production (e.g., withhold use of the product label) until ingredient suitability and the product's label accuracy can be determined. IPP are to issue the establishment an NR only if they determine the processes are out of control, resulting in economically adulterated or misbranded product. If IPP are unable to verify finished product formulation and composition without laboratory testing, they should inform establishment management when samples are collected for FSIS analysis and the reason why in order to give the establishment the option to hold all product represented by the sample pending sample results. IPP would issue the establishment an NR only if the sample results indicated that the product did not meet regulatory compliance.

Fresh Sausage Verification Task Examples

Calculations frequently used to verify compliance for limited and restricted ingredients in fresh sausage product formulas include added water, fat content, antioxidants, synergists, binders and extenders, mechanically separated species, cure agents, and cure accelerators.

Calculation Considerations

The calculation methods taught in this course have been used for years and are supported by Directive 7620.3, "Processing Inspectors' Calculations Handbook." IPP may use other methods

as long as it will return the correct answer. For calculations, it is acceptable to round the final answer to 2 decimal points. Decimals from 0.1 - 0.4 are rounded down while 0.5 -0.9 are rounded up. The one exception to this rounding rule is to always round down limited and restricted ingredients to avoid adding too much of that ingredient.

Added Water Verification Calculations

Step 1) Using information from the formula, on the left side of the equations below, subtract the weight of added water in the batch from the total weight of the batch. This determines the actual amount of water used. On the right side, subtract the regulatory maximum percent of water allowed – this is the 'perfect' amount of water. The right and left side calculations are independent calculations, do not try to force or manipulate the values to equal each other since that is not the purpose of each side of the calculation. The result on the left tells us the weight of the actual formula without any added water, while the result on the right tells us that the 'perfect' formula would have 97% ingredients left over that are not water.

lb. batch weight	[100% batch weight]
- lb. added water	[- 3% water regulatory limit]
lb. formula weight	[97% batch weight, w/o 3% added water]

NOTE: In many of these added ingredient calculations, the percentage of ingredients remaining in the formula must be determined. In addition to subtracting the weight of the ingredient to be verified from the product's total batch weight, some restricted ingredient verification calculations will also subtract the percent regulatory limit of that restricted ingredient from 100% of the total batch weight or applicable component. Th resulting value provides the percentage of other ingredients remaining in the product formulation, which can then be used as a variable factor in calculating regulatory limits for some restricted ingredients.

Step 2) Divide the formula weight (without added water) by the percent of the ingredients remaining in the batch (i.e., 97%). The result is how much the fresh sausage batch would 'ideally' or 'perfectly' weigh (i.e., 100% calculated weight) if all other ingredients were the same and exactly 3% maximum water was added to the product formulation.

___ lb. formula wt. ÷ .97 [97% batch weight] = ____ lb. [100% calculated weight w/3% water]

NOTE: The term "per cent" means for one part out of every hundred, on the basis of a whole divided into 100 equal parts. When dividing by a percentage, the percent value is expressed as a decimal that represents the number of parts per 100 (e.g., 97% = .97; 93.5% = .935).

Step 3) To determine the maximum amount of water permitted, subtract the formula weight from the calculated weight, which represents the product batch weight with exactly 3% added water.

___ lb. 100% calculated weight	[97% ingredients with exactly 3% added water]
- ___ lb. formula weight	[97% ingredients without added water]
___ lb. maximum water permitted	[3% regulatory limit]

If the amount of added water documented in Step 1 is greater than the maximum permitted water calculated in Step 3, the amount of added water would not be in compliance.

Antioxidant Verification Calculations

Antioxidants are permitted for use in some fresh sausage products based on that product's fat content. If known, the establishment's target fat content should be used to calculate the maximum amount of antioxidants allowed in sausage products. This fat target would be such that if it was exceeded, the antioxidant regulatory limit would still be met. In other words, the establishment could add more fat to the formula with less than the maximum amount of antioxidant, but adding less fat to the formula would result in too antioxidant for the amount of target fat. If the establishment has not identified a target fat, IPP must calculate the fat content based on the meat or poultry ingredients used in the product's formulation. Regardless, establishments must have some means to verify they meet or exceed the target, such as a measurement derived from a laboratory fat analysis.

The following antioxidant example demonstrates how to calculate the fat content based on the actual amount of meat or poultry ingredients used or if the establishment has not identified a target fat content.

Step 1) Determine the total amount of fat in the formulation by multiplying the weight of each meat and poultry component by its percent fat.

__ lb. meat/poultry component	[may be multiple components]
× __ % fat	[% fat content supported by establishment]
__ lb. added fat	[total added fat in meat/poultry component]

Step 2) (optional) If there are multiple meat and poultry components, repeat Step 1 to total the amount of added fat in each meat and/or poultry component to determine the total fat content in the product formulation.

__ lb. Component 1 fat +__ lb. Component 2 fat +__ lb. Component 3 … = __ lb. total added fat

Step 3) Add all the percentages of antioxidants (and synergists if necessary) to determine if the percent of any one antioxidant is 50% or more of the total combined antioxidants in the mix or compound.

____ % Antioxidant A
____ % Antioxidant B
+____ % Antioxidant C (if necessary)
____ % total antioxidants x 0.50 = 50% calculated total of antioxidants

Next, compare the calculated 50% total antioxidants to the individual amounts of each antioxidant and synergist in the product formulation to determine if any of those ingredients is equal to or more than 50% of the total.

Step 4) Determine the antioxidant regulatory limit by multiplying the weight of total fat by the percent of antioxidant permitted in the formulation using the following rules from Directive 7620.3:

- If no antioxidant or synergist is 50% or more of the total antioxidants, multiply the total fat by .02% to solve for the total of all antioxidants permitted in the mix.
- If one antioxidant or synergist is 50% or more of the total antioxidants, multiply by .01% to solve for that individual antioxidant or synergist.

___ lb. total fat
x .0001 (or .0002) [.01% if one antiox./syn. ≥50%; .02% if no antiox./syn.≥50% combined]
___ lb. [individual antioxidant/synergist or total antioxidants regulatory limit]

NOTE: The amount of each antioxidant or synergist in a compound or mix is to be considered when determining if one of these ingredients constitutes 50% or more of the total antioxidants and synergists. If an individual synergist makes up 50% or more of the total, its regulatory limit is determined by multiplying the amount of that synergist by .01%. However, synergists determined to be less than 50% of the total antioxidants and synergists are not included in total antioxidant calculations. If no antioxidant or synergist is 50% or more of the total, then the regulatory limit for total antioxidants is determined by multiplying the total amount of antioxidants by .02%.

Step 5) Determine the amount of antioxidants permitted in the formula by dividing the weight of individual or total antioxidants by the percent of antioxidant or total antioxidants in the compound or mix.

When using the limit of 0.01% in Step 4, solve for *individual* antioxidant or synergist using the 50% total antioxidants calculated in Step 3):

____ lb. antiox./syn. ÷ ____ % individual antiox./syn. = ____ lb. max. antiox./syn. permitted

NOTE: If Step 4 required the limit of 0.02%, the calculation to solve for *total* antioxidants is lb. total antioxidants ÷ % total antioxidants = lb. max. antioxidant mix permitted.

To convert pounds of antioxidant mix to ounces:

____ lb. maximum antioxidant mix × 16 [ounces] = oz. max. antioxidant mix permitted

Water, Binder and Extender Verification Calculations

Step 1) Using information from the raw product formula, on the left side subtract the actual amounts of water, binders and extenders from the total batch weight. On the right side, subtract the percent regulatory limits of 3% for added water (from §319.140) and 3.5% for binders and extenders (§424.21(c). The left side calculation in this example will display the weight of the actual batch without any water or binders/extenders. The right side calculation will show what the remaining 93.5% ingredients in this example's 'ideal' or 'perfect' formula would weigh without any added water or binders and extenders.

___ lb. batch weight [100% batch weight]
- ___ lb. added water [- 3% water regulatory limit]
- ___ lb. binders and extenders [- 3.5% added binder regulatory limit]
___ lb. formula weight [93.5% batch weight, less water and binder]

Step 2) Divide the formula weight from the left side calculation by the percent of the ingredients remaining in the 'ideal' or 'perfect' batch (e.g., 93.5%) to determine the 100% calculated weight. The 100% calculated weight is the weight the batch would weigh if, all other ingredients remaining the same, it contained exactly 3% added water and exactly 3.5% binders and extenders.

___ lb. formula wt. ÷ .935 [93.5%] = ___ lb. [100% calculated wt. with 3% water, 3.5% B&E]

Steps 3) Multiply the 100% calculated weight by the 3% regulatory limit for added to determine the maximum amount of added water allowed in the product formula.

___ lb. 100% calculated weight
× .03 [3% water regulatory limit]
lb. maximum added water permitted

Step 4) Multiply the calculated weight by the 3.5% regulatory limit for binders and extenders to determine the maximum amount of binders and extenders permitted in the product formula.

___ lb. 100% calculated weight
×.035 [3.5% binders and extenders regulatory limit]
____ lb. maximum binders and extenders permitted

Mechanically Separated Species Verification Calculations

Sausage products may be permitted under 9 CFR Part 319, Subparts E and G, to contain no more than 20% mechanically separate species (MSS) in the total meat block.

In Step 1, using information from the formula, on the left side subtract the weight of the MSS from the total meat block. On the right, subtract the regulatory limit for the percent of MSS permitted. The left side calculation shows the weight of the meat block without any MSS. The right side displays what the 'ideal' or 'perfect' formula would weigh with 80% of the meat block and no MSS.

___ lb. batch meat block [100% batch meat block]
- lb. added MSS [- 20% MSS regulatory limit]
___ lb. meat components [80% meat block formula, less 20% MSS]

Step 2) Divide the meat components weight (from the left side calculation) by the percentage of meat block remaining from the 'ideal' or 'perfect' batch (from the right side calculation) to determine the 100% calculated meat block weight with exactly 20% MSS.

____ lb. meat components ÷ .80 [80% MB] = ____ lb. [100% calculated MB w/20% MSS]

Step 3) Multiply the weight of the 100% calculated meat block by the 20% MSS regulatory limit to determine the amount of MSS permitted in the formula without including a qualifying statement in the product label's standard of identity name.

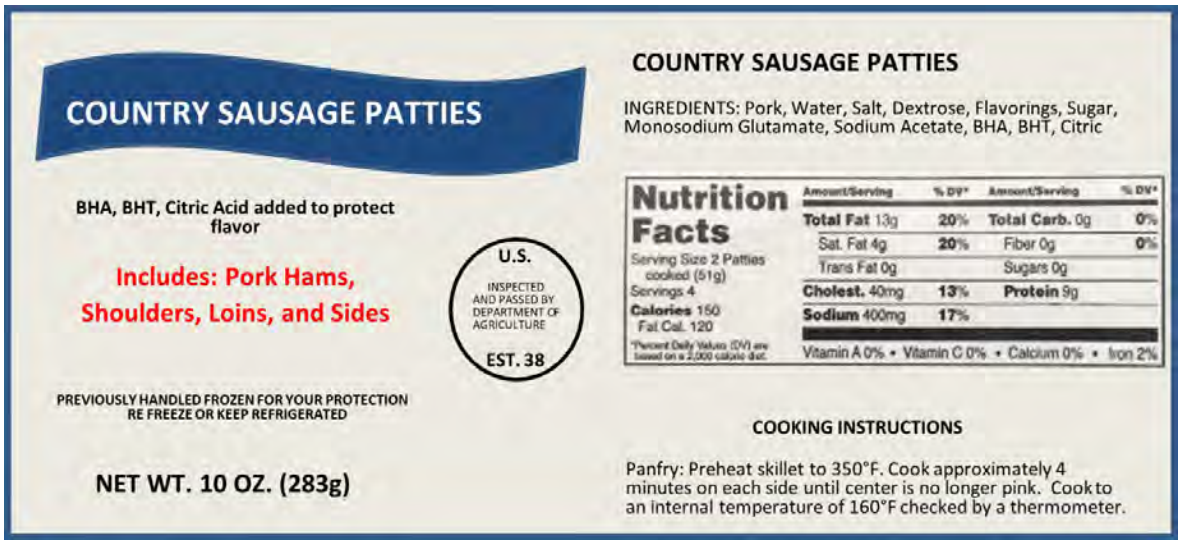
____ lb. [100% calculated meat block]
× .20 [20% MSS regulatory limit]
____ lb. maximum MSS permitted

Another way to determine the amount of MSS permitted is to subtract the weight of the meat components (left side calculation, Step 1) from the 100% calculated meat block (in Step 2).

____ lb. calculated meat block [100% calculated MB in Step 2]
- ____ lb. meat components [left side of calculation, Step 1]
____ lb. maximum MSS permitted

Fresh Sausage Verification Calculations: Example 1 - Fresh Country Sausage Patties

A CSI has the General Labeling task on the schedule today. The establishment is making fresh country sausage patties and tray packing them. The CSI observes the label below being applied to the film wrapped trays.



They observe the following sausage patty formula posted near the blenders in the processing room. They also observes the pre-weighed ingredients for one batch. The ingredient weights and names agree with the posted formula. The labeling record does not indicate a minimum target fat level.

Country Sausage Formula

Regular pork trimmings (60% fat)	280 lb.
Pork hams, loins, shoulders, sides (30% fat)	160 lb.
Water	18 lb.
Hunts Fresh Sausage Seasoning Mix	10 lb.
Sugar	2 lb.
Total batch weight	**470 lb.**

In the production office, the CSI finds the same label and formula in the establishment's label file as above. She also finds attached to the formula the following additional information for the seasoning mix:

"Directions: Use one bag seasoning mix for each 470 pound batch of sausage patties."

Salt	5 lb.
Dextrose	2 lb.
Black pepper	1 lb.
Sage	12 oz.
Nutmeg	9 oz.
MSG	7 oz.
Sodium Acetate	3 oz.
Antioxidant Mix	1 oz.
Total seasoning mix	10 lb.

The establishment has a Letter of Guarantee from the seasoning mix manufacturer stating that an antioxidant mix included in the seasoning mix contains BHA, BHT, and citric acid. It lists the following ingredients and percentages: BHA (butylated hydroxyl anisole; antioxidant) = 30%; BHT (butylated hydroxytoluene; antioxidant) = 10%; citric acid (synergist) = 10%; and a salt carrier = 50%. When used according to directions, the seasoning mix complies with antioxidant regulatory requirements.

The CSI needs to verify the following requirements in this product formula:

1. Does the added water comply with the added water limit for this type of product?

2. What is the amount of total fat in the product formulation?

3. Is the antioxidant in compliance with the regulatory limit in this type of product?

Added Water Verification Calculations

Given: Total amount of the ingredients = 470 pounds.

Step 1) On the left side, using the values from the formula, subtract the percentage of water permitted from the formula batch weight. On the right side, subtract the regulatory maximum percent of water allowed. The left side calculation determines the weight of the batch without any water added. The right side calculation shows what the 'ideal' or 'perfect' formula weight would be for the remaining 97% of the ingredients with no added water.

470 lb.	[100% batch weight]
- 18 lb.	[- 3% water limitation]
452 lb.	[97% formula weight, less added water]

Step 2) Divide the 97% formula weight without any water (answer from the left side calculation in Step 1) by the percent remaining in the 'perfect' formula (the answer from the right side calculation in Step 1) after the ingredient in question is removed (e.g., 97% with 3% water

removed). The answer to Step 2 tells us how much the 'perfect' batch would weigh if it contained exactly 3% added water at the regulatory maximum, i.e., the 100% calculated weight.

452 lb. ÷ 0.97 = 465.97 lb. [100% calculated weight with 3% water regulatory limit]

Step 3) Subtract the formula weight less added water (the answer from the left side calculation in Step 1) from the 100% calculated weight (with 3% maximum water at the regulatory limit – the answer from Step 2).

465.97 lb.	[100% calculated weight]
- 452.00 lb.	[formula weight without any water added]
13.97 lb.	[3% water regulatory limit]

Added water is not in compliance because the 18 lbs. of water added to the formula exceeds 13.97 lbs., which is the 3% regulatory limit for added water permitted for the fresh sausage patties. The CSI should retain all sausage patties produced from the beginning of the shift and any other lots of sausage patties produced using the same formula that are still in the establishment.

Fat Content / Antioxidant Verification Calculations

Review the contents of the antioxidant/synergist mixture and verify the percentage of each ingredient. Information attached to the label in the establishment's labeling file states that BHA = 30%, BHT = 10%, citric acid = 10%, and salt carrier = 50%.

NOTE: Antioxidants (e.g., BHA, BHT, and propyl gallate) and synergists (e.g., citric acid) limitations in raw sausage are 0.01% individually or 0.02% in combination based on total fat content. Tocopherols are limited to 0.03% and may not be used in combination with other antioxidants.

Given: Fat content = 280 lb. regular pork trimmings containing 60% fat and 160 lb. pork hams, shoulders, loins, and sides containing 30% fat.

Step 1) Determine the amount of fat added in the meat portion of the formula. A target fat content is not provided.

280 lb.	[pork trimmings]
× 0.60	[60% fat content]
168 lb.	[total fat]

160 lb.	[pork hams, shoulders, loins, sides]
× 0.30	[30% fat content]
48 lb.	[total fat]

Step 2) Determine the total fat content in the product formula.

168 lb. + 48 lb. = 216 lb. total fat added

Given: The amount of antioxidant compound in the seasoning mix = 1.0 oz.

Step 3) Determine the total percentage of antioxidants in the antioxidant compound or mix that has the antioxidants, synergist, and a carrier).

30% BHA
+ 10% BHT
40% total antioxidants X 0.50 = 20% [50% of the antioxidant total; BHA = 30%]

Step 4) If one antioxidant or synergist in the mix is 50% or more of the total antioxidants, multiply total added fat by 0.0001 (0.01%) to determine the maximum permitted amount of that individual antioxidant or synergist. If no antioxidant or synergist is 50% or more of the total antioxidants, multiply total added fat by 0.0002 (0.02%) to determine the total combined amount of antioxidants permitted.

In this example, the antioxidant total is 40% of the compound, and 50% of that total is 20%. The BHA at 30% of the antioxidant compound/mix is more than 50% of the total antioxidants, so the regulatory limit of 0.01% is used to solve for the amount of the BHA alone.

216 lb.	[total fat added]
× 0.0001	[0.01% - 30% BHA >50% of total antioxidants]
0.0216 lb.	[maximum BHA antioxidant permitted]

Step 5) To determine the maximum amount of antioxidant compound permitted, divide the maximum amount of antioxidant permitted by the percentage of that specific antioxidant in the mix. Then, convert pounds into ounces since the formula in this example stated the ounces of antioxidant mix used.

0.0216 lb. [BHA permitted] ÷ .30 [30% BHA] = 0.072 lb. maximum antioxidant mix permitted

Converting to ounces:

0.072 lb. × 16 [oz. per lb.] = 1.15 oz. maximum antioxidant mix permitted

The antioxidant compound is in compliance because 1 oz. is used in the product formulation and 1.15 oz. is the maximum amount permitted.

Fresh Sausage Verification Calculations: Example 2 - Breakfast Sausage

A CSI has the General Labeling task scheduled today. The establishment is making fresh breakfast sausage links and packaging them in trays with label below being applied to the trays.

Ingredients: Pork, mechanically separated pork, water, soy flour, salt, natural flavorings, sugar. Stuffed in collagen casings. Contains soy.

The CSI observes the following breakfast sausage formula posted near the blenders in the processing room.

Breakfast Sausage Formula

Pork (30% fat)	210 lb. (Fat target = 50%)
Skinned pork jowls (88% fat)	187 lb.
Mechanically separated pork (30% fat)	50 lb.
Water and ice	20 lb.
Soy flour	15 lb.
Salt	8 lb.
Sugar	5 lb.
Natural Flavorings	5 lb.
Total batch weight	**500 lb.**

NOTE: When verifying total fat content, some establishments identify a “fat target” in the product formulation that is more restrictive than the total fat regulatory limit. If the actual amount of total fat added to the product batch is calculated to be more than the fat target but does not exceed the total added fat regulatory limit, there would be no noncompliance for fat content.

The CSI wants to verify compliance for:

1. Water – 3% maximum in the total formula at the time of formulation
2. Extenders and binders – soy flour is limited to 3.5% of the total formulation
3. Mechanically separated pork (MSS) – is limited to 20% of the total meat block

Water, Binder and Extender Verification Calculations

Added water is limited to 3% and binders and extenders used in this formula are limited to 3.5% of total ingredients.

Step 1) On the left side, using the values from the formula, subtract the pounds of the water and binder that were added from the batch weight. On the right side, subtract the regulatory maximum for water (which is 3%) and subtract the regulatory maximum for the binders and extenders (which for soy flour is 3.5%). The answer to the left side calculation tells us the weight of the formula without and water or binders/extenders added. The answer on the right side tells us that the 'perfect' formula without any water or binders would have 93.5% ingredients left over.

500 lb.	[100% batch weight]
- 20 lb.	[3% added water regulatory limit]
- 15 lb.	[3.5% binder regulatory limit]
465 lb.	[93.5% formula weight, less water and soy flour]

Step 2) Divide the formula weight without any water or binders and extenders (the answer to the left side calculation) by the percentage of the 'perfect' batch remaining (i.e., 93.5%) (the answer to the right side calculation). The answer to Step 2 tells us how much the 'perfect' batch would weigh if exactly 3% maximum of water and exactly 3.5% binders and extenders (3.5% for soy flour) were added, i.e., the 100% calculated weight.

465 lb. ÷ 0.935 [93.5%] = 497.32 lb. [100% calculated weight w/3% added water, 3.5% binder]

Step 3) Multiply the 100% calculated weight (the answer in Step 2) by the maximum water regulatory percentage limit to determine the maximum amount permitted.

497.3 lb.	[100% calculated weight]
× 0.03	[3% water permitted]
14.9 lb.	[water regulatory limit]

Added water is not in compliance because the maximum amount of water permitted is 14.9 lb. but 20 lb. was added.

Step 4) Multiply the 100% calculated weight by the binder regulatory percentage limit to determine the maximum amount permitted.

497.3 lb.	[100% calculated weight]
× 0.035	[3.5% binder and extenders permitted]
17.4 lb.	[soy flour regulatory limit]

Soy flour is in compliance because 15 lb. was added and 17.4 lbs. is maximum amount permitted.

Mechanically Separated Pork Verification Calculations

20% MSS is permitted based on the total meat and meat byproduct portion (meat block) of the formula.

Step 1) Determine the weight of the meat block in the formula. On the left side calculation, subtract the amount of MSS (pork) from the total meat block used in the formula, then subtract the regulatory maximum percent of MSS permitted from the right side calculation.

210 lb.	Pork
187 lb.	Pork jowls
50 lb.	MSS (pork)
447 lb.	Total

447 lb.	[100% meat block]
- 50 lb.	[MSS (pork)]
397 lb.	[80% of meat block, without 20% regulatory limit for MSS]

The left side calculation shows that the meat block weighs 397 pounds without any MSS. The right side calculation tells us that the 'perfect' meat block without any MSS at all would have 80% of the meat block left over.

Step 2) Divide the meat block weight with no MSS by the percentage of the meat block remaining (i.e., 80%). The result is a 100% calculated meat block, which is what the 'perfect' meat block would weigh with exactly 20% MSS.

397 lb. ÷ 0.80 [80%] = 496.25 lb. [100% calculated meat block weight with 20% MSS added]

Step 3) Multiply the 100% calculated meat block weight by the regulatory limit for MSS (i.e., 20%) to determine the maximum amount of MSS permitted in the formula.

496.25 lb.	[100% calculated meat block weight]
x 0.2	[20% MSS limit]
99.25 lb.	[MSS permitted]

MSS (pork) is in compliance because 50 lb. is being used in the formula and 99.25 lb. is the maximum amount permitted.

FRESH SAUSAGE WORKSHOP

Using the methods outlined in this handout, answer the questions related to the following fresh sausage formula and perform the required calculations. If you need help, contact your instructor.

A CSI is assigned to an establishment that produces several types of pork sausage and Italian sausage. The Labeling - Products Standards and General Labeling tasks are on the PHIS task calendar for today. They assign the tasks, then proceed to the processing room and observe that both processing lines are in operation today. At the end of line one, Italian sausage stuffed into natural casings is being tray packed and placed in cardboard shipping containers. The CSI verifies that the shipping containers have an inspection legend and handling statement ("keep refrigerated"). The label below is being applied to the film wrapped trays.

Ingredients: Pork, water, corn syrup, green peppers, and less than 2% of the following: salt, spices, paprika, dextrose, monosodium glutamate, flavoring, BHA, propyl gallate, citric acid

The CSI takes one label from the roll of labels and asks the production supervisor to show then the formula for the Italian sausage. The supervisor opens a binder at his work bench and shows the following formula.

Italian Sausage Batch Formula

Pork trimmings (20% fat)	285 lb.	*(Fat content target = 34%)*
Pork jowls, skinned (85% fat)	155 lb.	
Spice and Seasoning mix*	14 lb.	
Water	13 lb.	
Corn syrup	10 lb.	
Green peppers	10 lb.	
Salt	6 lb.	
Paprika	4 lb.	
Dehydrated parsley	3 lb.	
Total batch weight	**500 lb**.	

*Spice and Seasoning Mix - 14 lb.

Fennel = 3 lb.
MSG = 3 lb.
Dextrose = 3 lb.
Cumin = 2 lb. 7.75 oz.
Black pepper = 2 lb. 7.0 oz.
Antioxidant mix = 1.25 oz. (20% BHA, 15% propyl gallate, 15% citric acid, 50% salt)

The CSI writes down the meat block, water, antioxidant mix weights, and fat percentages for the meat ingredients from the formula in their field notebook and takes the label to the government office. There they review the standard of identity for Italian sausage in §319.145.

For the Labeling - Product Standards task, the CSI performs the necessary calculations to answer the following questions.

1. *What is your first name? (online only)*
2. *What is your last name? (online only)*

3. Do the seasoning ingredients in the product meet the standard of identity for Italian sausage?

    a. Yes
    b. No

4. Does the product contain the required amount of meat or meat and fat combination?

    a. Yes
    b. No

04B01 - % Meat or Poultry
(single component product)

$$\frac{\text{meat/poultry in the formula}}{\text{batch weight}} \times 100 = \text{\% meat/poultry in the formula}$$

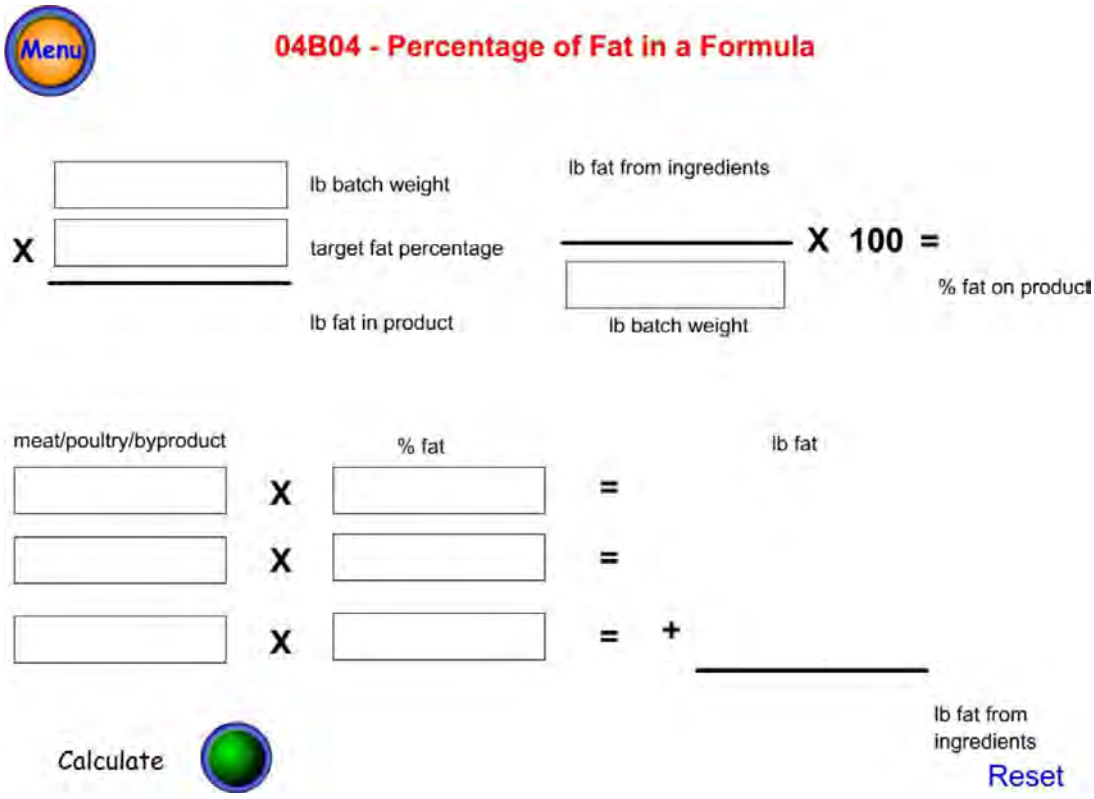
Calculate 

Reset

As part of the General Labeling task, the CSI compared the ingredients statement on the label brought from the packaging area to the formula in the binder. The CSI verifies that all ingredients were listed by their common and usual name in descending order of predominance and the label contained all of the mandatory features and required information. Next, the CSI proceeds to the QC office and verifies that the selected label is on file with the establishment and the processing procedures and formula are attached. The CSI determines that formula in the file is the same formula they observed on the processing floor. The CSI proceeds to the spice room, where they observe pre-weighed non-meat ingredients in plastic bags for 2 batches of the Italian sausage. The CSI asks establishment personnel to weigh the spice and seasoning mixture, salt, and paprika for one of the batches. The CSI verifies the weights recorded on the bags are accurate and agrees with the product formula. The CSI looks at the label on the container of antioxidant mix, documents the ingredients and percentages, and returns to the government office to perform the calculations necessary to answer the following questions.

5. What is the fat content of the Italian sausage formula?

    a. 30.8%
    b. 35%
    c. 37.75%
    d. 54.65%



6. Is the fat content in the Italian sausage in compliance with the standard of identity?

    a. Yes
    b. No

7. Is the antioxidant mix in compliance with the actual product formulation for Italian sausage?

    a. Yes
    b. No

Back

04B04 - Maximum Antioxidant Mix Allowed

(raw product e.g., meatballs)

Add-up antioxidants

Example: BHA 25%
BHT 20%
+ Propyl gallate 10%
Total Percent 55%

[ ] lb batch weight

x [ ] percentage fat in product, e.g. 25%

lb fat

x [ ] antioxidant restricted limit

maximum lb antioxidant allowed

[ ] total antioxidant percent, e.g. 55%

=

lb antioxidant mix allowed

When no individual antioxidant or synergist is more than half of the total antioxidant percentage, use .0002 (.02%) as the restricted limit.

x 16 =

lb antioxidant mix allowed

oz antioxidant mix allowed

Calculate

Reset

Cooked Sausage Verification Task Examples

Calculations frequently used to verify compliance for limited and restricted ingredients in cooked sausage product formulas includes binders and extenders, phosphates, mechanically separated kind of poultry, and fresh liver.

Projected Finished Weight Verification Calculations

Projected finished weight (PFW) can be used to verify phosphates, binders and extenders compliance in cooked sausage products. The PFW is more accurate than measuring the amount of water added to the sausage formulation.

Step 1) On the left side, using values from the formula, subtract from the raw sausage formulation batch weight any rework and the respective weights of added water, binders and extenders, and phosphates. On the right side, subtract the percent regulatory limits for the water, binders and extenders, and phosphates.

____ lb. batch weight	[100% batch weight]
- ____ lb. rework	[rework]
- ____ lb. water	[- 10% water regulatory limit]
- ____ lb. binders and extenders	[- 3.5% B&E regulatory limit]
- ____ lb. phosphates	[- 0.5% phosphate regulatory limit]
____ lb. formula weight	[86% formula weight]

Step 2) Divide the formula weight (from the left side in Step 1) by the percent of ingredients remaining in the 'ideal' or 'perfect' formula (from the right side in Step 1) to determine the projected finished weight.

____ lb. formula wt. ÷ .86 [86% formula wt.] = ___ lb. [projected finished weight (PFW)]

Step 3) Multiply the PFW by the 3.5% (or 2%) regulatory limit for binders and extenders to determine the maximum amount of binders and extenders permitted in the batch.

____ lb. PFW
× .035 [3.5% (or 2%) binders and extenders regulatory limit]
____ lb. maximum binders and extenders permitted

Step 4) Multiply the PFW by the 0.5% regulatory limit for phosphates to determine the maximum amount of phosphates permitted in the batch.

____ lb. PFW
× .005 [0.5% phosphate regulatory limit]
____ lb. maximum phosphate permitted

NOTE: The percent water or fat content in a finished cooked sausage can only be verified for noncompliance based on laboratory analysis.

Mechanically Separated Kind of Poultry (MSKP) Verification Calculations

If permitted, the meat block of cooked sausage products under §319.180(a) may contain no more than 15% mechanically separated kind of poultry of the total ingredients, excluding water, without including a qualifying statement on the finished product label.

Step 1) On the left side, deduct the added water weight and the MSKP from the batch weight. On the right side, subtract the 15% regulatory limit from the batch weight. DO NOT ASSIGN OR SUBTRACT A PERCENTAGE OF WATER IN THIS CALCULATION!

____ lb. batch weight	[100% batch weight]
- ____ lb. added water	[exclude added water, do not assign a %]
- ____ lb. MSKP	[-15% MSKP regulatory limit]
____ lb. formula weight	[85% formula weight, less water and MSKP]

Step 2) Divide the formula weight (left side calculation) by the precent of ingredients remaining in the formula weight (right side calculation).

____ lb. formula weight ÷ .85 = ____ lb. 100% calculated weight [w/ 15% MSKP]

Step 3) Subtract the formula weight without MSKP (left side answer in Step 1) from the 100% calculated weight with MSKP (answer in Step 2) to determine the amount of mechanically separated chicken permitted in the batch.

____ lb. 100% calculated weight
- ____ lb. formula weight
____ lb. MSKP permitted

Fresh Liver Verification Calculations

Cooked liver sausage products produced under §319.182 must contain a minimum of 30% fresh liver computed on the weight of the fresh livers.

Step 1) On the left side, deduct the weight of the fresh livers from the batch weight. On the right side, deduct the minimum percentage of liver required by the regulations.

____ lb. batch weight.	[100% batch weight]
- ____ lb. fresh liver	[- 30% fresh liver regulatory minimum]
- ____ lb. formula weight	[70% formula weight, less 30% livers]

Step 2) Divide the formula weight (left side in Step 1) by the percent of the remaining ingredients in the batch (right side in Step 1).

____ lb. formula weight ÷ .70 = ____ lb. [100% calculated weight w/ 30% minimum fresh livers]

Step 3) Subtract the formula weight from the formulated weight to determine the minimum amount of fresh livers required in this batch.

____ lb. [100% calculated weight with 30% fresh liver]
- ____ lb. formula weight without fresh liver
____ lb. minimum liver required

NOTE: There is no calculation aid for liver.

Cooked Sausage Verification Example

The establishment has the following bologna formula on file. The Projected Finished Weight (PFW), also known as the Calculated Finished Weight (CFW), must be determined in order to verify that binders, extenders, and phosphates are in compliance.

Bologna Formula

Beef	250 lb.	
Pork	250 lb.	
Water and ice	70 lb.	(Finished Product Target = 10% Water, 30% Fat)
Rework	50 lb.	
NFDM (nonfat dry milk)	18 lb.	
Salt	5 lb.	
Flavorings	4 lb.	
Sodium phosphates	2 lb.	10.5 oz.
Sodium erythorbate		4.25 oz.
Sodium nitrite		1.25 oz.
Total batch weight	**650 lb.**	

The amount of nonfat dry milk (NFDM) binder and the amount of sodium phosphate documented in the formula must be calculated to determine if they are in compliance.

Binders and Phosphates Verification Calculations

NOTE: The PFW (or CFW) or always includes the maximum targeted water. Once the CSI determines a product's PFW, the weight can be used to calculate the maximum amount of phosphates, binders and extenders permitted in each formula. *REMEMBER TO ALWAYS REMOVE REWORK FROM INGREDIENT VERIFICATION CALCULATIONS!*

Step 1) Subtract from the batch weight any rework, the weight and percentage of the targeted added water, and restricted ingredient(s) that have regulatory limits based on the PFW.

650 lb.	[batch weight]
- 50 lb.	[rework]
600 lb.	[100% batch weight, less rework]

600 lb.	[100% batch weight]
- 70 lb.	[- 10% water]
530 lb.	[90% batch weight]

530 lb. [90% batch weight]
- 18 lb. [- 3.5% NFDM]
512 lb. [86.5% batch weight]

512 lb. [86.5% batch weight]
- 2.65 lb. [- 0.5% phosphate]
509.35 lb. [86.0% formula weight]

Step 2) Divide the formula weight (from the left side calculation) by the percentage of the total remaining batch (from the right side calculation) to determine the projected finished weight (PFW).

509.35 lb. ÷ 0.86 [86.0%] = 592.26 lb. PFW [with 10% water, 3.5% NFDM, 0.5% phosphate]

Step 3) Multiply the PFW by binders and extenders regulatory limit of 3.5% to determine the maximum amount of NFDM permitted.

592.26 lb. [PFW]
× 0.035 [3.5% binder limit]
20.72 lb. [NFDM permitted]

The binders and extenders are in compliance because 18 lb. of NFDM was added and 20.72 lb. is permitted.

Step 4) Multiply the PFW by the phosphates regulatory limit of 0.5% to determine the maximum amount of sodium phosphate permitted.

592.26 lb. [PFW]
× 0.005 [0.5% phosphate limit]
2.96 lb. [sodium phosphate permitted]

Sodium phosphate is in compliance because the 2.65 lb. used is less than the maximum permitted amount of 2.96 lb.

Cooked Sausage Example - Mechanically Separated Kind of Poultry

An establishment processes a cooked meat and poultry sausage product that is labeled as "Frank's Furters." A CSI assigned a Labeling - Product Standards Task has reviewed the product formulation on file. The CSI observed that the batch weight is 800 lb., which includes 115 lb. of added water and 90 lb. of mechanically separated chicken. The CSI obtained a product label and observed that poultry is declared on the label as an ingredient in the correct order of predominance. The CSI wants to verify that the amount of MSKP in the product formulation is in compliance with product labeled as "Frank's Furters."

9 CFR 319.180(a) states that cooked poultry meat and/or mechanically separated kind of poultry in product labeled as furter is permitted if it does not exceed 15% of the total ingredients, excluding water. The FSLPB states for non-standardized cooked sausage products containing both livestock and poultry ingredients that cooked sausage product containing more than 15% poultry in the total ingredients (excluding water) must indicate in the product name the species of livestock and kind(s) of poultry ingredients (e.g., "Beef and Turkey Furter," "Furter Made from Beef and Turkey").

The CSI uses the following calculations to verify compliance with the amount of mechanically separated chicken in a cooked furter product formulation that does not include a qualifying statement on the label.

Step 1) Exclude the added water and subtract the MSKP from the batch weight to determine the formula weight.

800 lb.	[100% batch weight]
- 115 lb.	[- exclude water - DO NOT SUBTRACT A PERCENTAGE]
- 90 lb.	[- 15% MSKP regulatory limit]
595 lb.	[85% formula weight]

Step 2) Divide the formula weight (in Step 1) by the percent of the batch weight remaining (in Step 1).

595 lb. ÷ .85 = 700 lb. [100% calculated weight, with 15% MSKP regulatory limit]

Step 3) Subtract the formula weight (in Step 1) from the 100% calculated weight to determine the amount of MSKP permitted without a qualifying statement included on the product label.

700 lb.	[100% formulated weight]
- 595 lb.	[85% formula weight]
105 lb.	[MSKP permitted]

The "Frank's Furters" label is in compliance because 105 lb. of MSKP is the 15% regulatory limit permitted without including a qualifying statement and 90 lb. is added.

Liver Sausage Verification Example (§319.182)

After reviewing the following liver sausage product formula, the CSI wants to determine if the amount of fresh liver in the product formulation meets the 30% minimum regulatory limit.

Braunschweiger Formula

Skinless pork jowls	250 b.
Pork livers	100 lb.
Water	17 lb.
Salt	8 lb.
Corn syrup	4 lb.
Sodium lactate	3 lb.
Dried onions	3 lb.
Sodium diacetate	2 lb.
Dextrose	1 lb. 7.6 oz.
Flavorings	1 lb. 7.6 oz.
Sodium nitrite	0.80 oz.
Total batch weight	**390 lb.**

Step 1) Using values from the formula, on the left side subtract the liver weight from the batch weight. On the right side, subtract the minimum percentage of liver required.

390 lb. batch	[100% batch weight]
- 100 lb. liver	[- 30% minimum liver required]
290 lb. formula weight	[70% formula weight, less fresh liver]

Step 2) Divide the formula weight (left side in Step 1) by the percent of the batch weight remaining (right side in Step 1).

290 lb. ÷ 0.70 [70%] = 414.28 lb. [100% calculated wt. w/30% minimum liver regulatory limit]

Step 3) Subtract the formula weight (left side in Step 1) from the 100% calculated weight (in Step 2).

414.28 lb.	[100% calculated weight]
- 290 lb.	[70% formula weight without fresh liver]
124.28 lb.	[minimum fresh liver regulatory limit]

This Braunschweiger formula is not in compliance because a minimum of 124.28 lb. of fresh liver is required to meet the product standard of identify but only 100 lb. was added in the formula.

NOTE: Be aware that simply adding additional liver to this formula may not be adequate to ensure compliance with other ingredients. Additional ingredient calculations may be necessary.

COOKED SAUSAGE WORKSHOP – EXAMPLES 1 AND 2

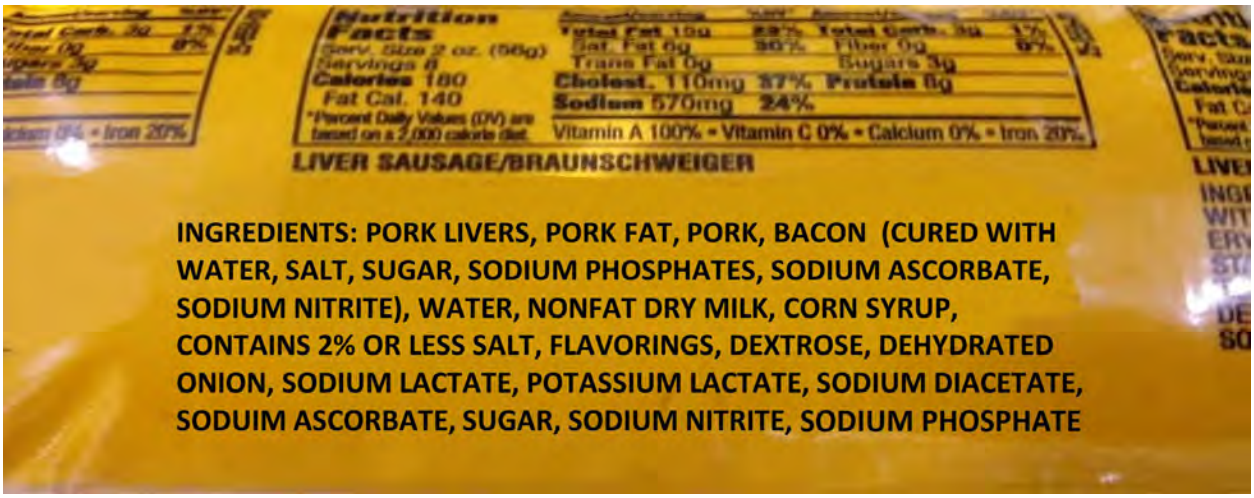
Using the methods outlined in this handout, answer the questions related to the following cooked sausage formulas and perform the required calculations. If you need help, contact your instructor.

Example 1

A CSI is assigned to an establishment that produces several types of cooked and smoked sausages, cooked sausages, and non-specific loaf. The General Labeling and Labeling - Products Standards tasks are on the PHIS task calendar for today. They assign the tasks, then proceed to the processing room.

The establishment is stuffing Braunschweiger sausage into impervious saran casings (sticks) and cooking them in water. The CSI observes notice staged, properly identified, pre-weighed ingredients for a batch of the Braunschweiger sausage in plastic totes and brown bags on a rack next to the large blender. They have the production supervisor weigh the sodium nitrite, sodium ascorbate, and nonfat dry milk (NFDM), then record the weights in their field notebook. The CSI proceeds to the grinding area and observes the meat components staged in stainless steel totes for a batch of the Braunschweiger sausage. They have the production supervisor weigh the pork livers, then record the weight of the livers in their notebook.

The CSI enters the ready-to-eat product packaging room and observes that the establishment is slicing the Braunschweiger sticks into 1 lb. portions and shrink wrapping the portions in plastic film that has the labeling printed on it. They take a piece of plastic film with the following labeling on it from the end of the packaging line.



The CSI proceeds to the production office and asks the production supervisor to show them the formula for the Braunschweiger sausage being produced today. The supervisor shows the following formula.

Braunschweiger Formula

Pork livers	150 lb.
Pork fat	150 lb.
Skinned pork jowls	75 lb.
Bacon (cured)	53 lb.
Rework	25 lb.
Water	20 lb.
Nonfat dry milk (NFDM)	16 lb.
Corn syrup	11 lb.
Salt	7 lb. 14 oz.
Flavorings*	6 lb.
Potassium lactate	3 lb.
Sodium lactate	2 lb.
Dehydrated onion	2 lb.
Dextrose	1 lb. 12 oz.
Sodium diacetate	1 lb.
Sugar	14 oz.
Sodium ascorbate	4 oz.
Sodium nitrite	2 oz.
Sodium phosphate	2 oz.
Total Batch	**525 lb. batch weight**

*Flavorings (6 lb.)
White pepper = 2 lb.
Marjoram = 2 lb.
Mace = 1 lb. 12 oz.
Ground cloves = 4 oz.

The CSI reviews the labeling on the plastic film wrap and verifies that all mandatory labeling features and required information are on it. They compare the sodium nitrite, sodium ascorbate,

and liver weights documented in their notebook with the weights in the formula. They determine the ingredient weights recorded in their notebook are the same as the ingredient weights in the formula. The CSI compares the ingredients statement on the plastic film wrap with the product formula to answer the following questions.

1. *What is your first name? (online only)*
2. *What is your last name? (online only)*

3. Identify the meat byproduct(s) used in the formula.

    a. Pork livers
    b. Pork fat
    c. Skinned pork jowls
    d. Bacon

4. Is the ingredients statement in compliance with the standard of identity for Braunschweiger?

    a. Yes
    b. No

The CSI proceeds to the government office to perform the calculations necessary to answer the following Labeling - Product Standards task questions.

5. Does the Braunschweiger formula contain the required amount of fresh liver?

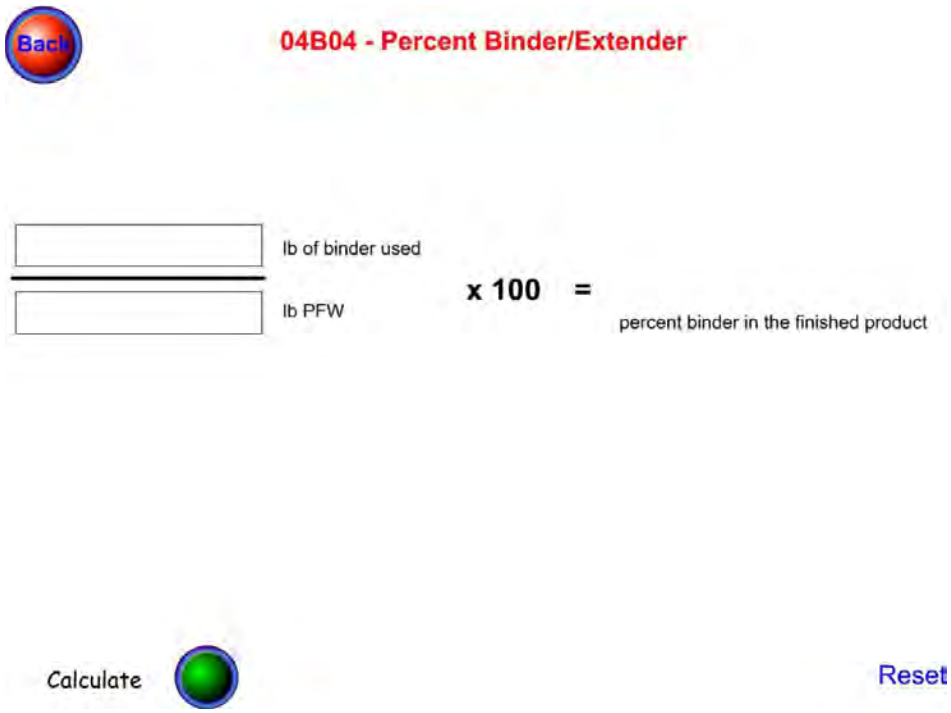
    a. Yes
    b. No

The CSI continues performing the calculations necessary to answer the following General Labeling task questions.

NOTE: ***For the following calculation only***, determine binder and extender compliance by using the formula batch weight, less rework, instead of calculating the PFW. Since this product is cooked in an impervious casing, less than 10% added water would normally be included because there would be no cook shrink expected. If the 10% added water regulatory limit was used in determining the PFW for this product, the calculated PFW would actually be greater than the batch weight.

6. Is the amount of nonfat dry milk (NFDM) added to the formulation in compliance?

    a. Yes
    b. No



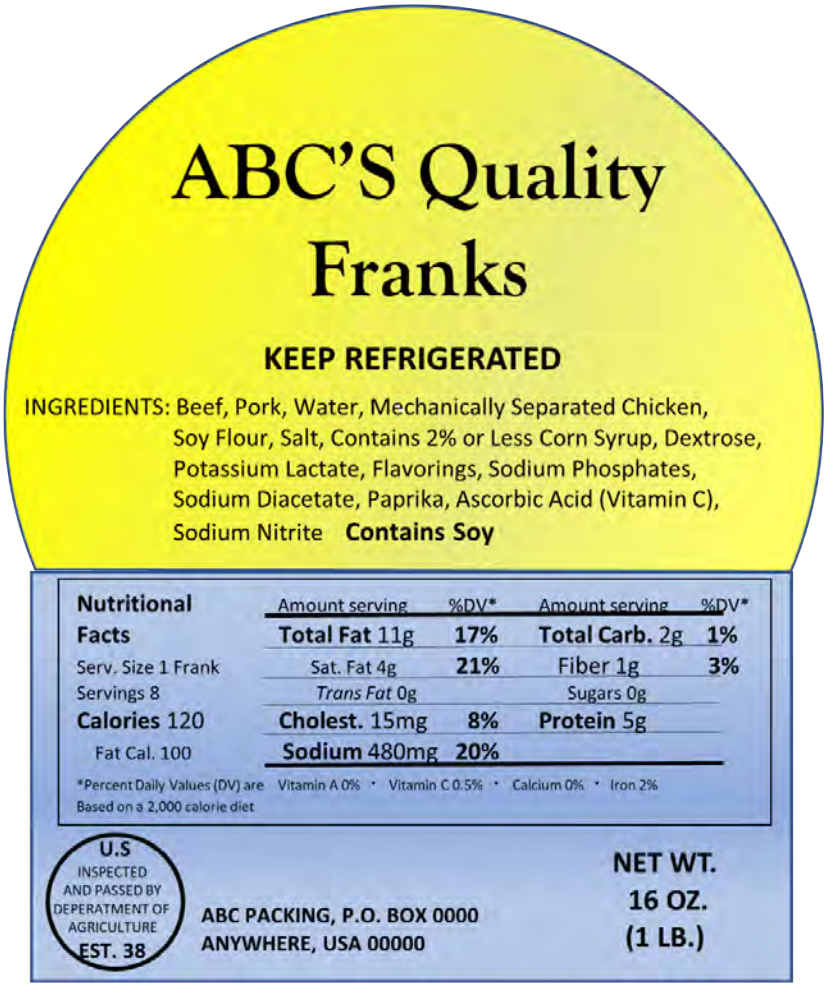
7. Is the product name “Braunschweiger” in compliance with the standard of identity for a liver sausage based on the ingredients used in the formula?

   a. Yes
   b. No

Example 2

A CSI is assigned to an establishment that produces several types of cooked and smoked sausages, cooked sausages, and non-specific loaf. They assign the General Labeling task on the PHIS task calendar for today. The CSI begins start the task by proceeding to the packaging room. The establishment is packaging 8 per lb. franks in pre-labeled plastic film in the ready-to-eat (RTE) product packaging room.

The CSI collects from the end the packaging line a discarded film with the pre-printed label shown below.



The CSI proceeds to the production office and verifies label on the plastic film is on file and the processing procedures and formula are attached to it. They record the ingredients and weights from the formula in their field notebook, then proceed to the production room.

The establishment has a continuous system for producing small diameter cooked sausages. The raw sausages in casings are on loaded on metal trees, moved to a cooking and chilling tunnel for processing, and the finished sausage are taken to the RTE product packaging room.

The CSI observes the staged, properly identified, pre-weighed ingredients for a batch of franks in plastic totes and brown bags on a rack next to the large blender. They have the production

supervisor weigh the sodium nitrite, ascorbic acid, and soy flour. They then compare the weights to the weights from the formula recorded in their field notebook and verify the weights are the same. The CSI proceeds to the grinding area and observes the meat and poultry components are staged in stainless steel totes for a batch of frankfurters. They have the production supervisor weigh the mechanically separated chicken and compare the weight on the scale to the weight of the mechanically separated chicken in their notebook. They verify the weights are the same.

The CSI asks the sausage foreman to show the formula for the frank. He opens a binder at his work bench and shows the CSI the following formula.

Quality Franks Formula

Beef (boneless cow meat)	250 lb.	
Pork trimmings	200 lb.	*(Finished Product Target = 30% fat)*
MS chicken	100 lb.	
Water and ice	120 lb.	*(Finished Product Target = 10% water)*
Frank rework (like product)	50 lb.	
Soy flour	22 lb.	
Salt	15 lb.	
Corn syrup	11 lb. 12 oz.	
Dextrose	8 lb.	
Potassium lactate	7 lb.	
Flavorings	7 lb.	
Sodium diacetate	4 lb.	
Sodium phosphates	3 lb.	
Curing mix	1 lb. 6 oz.	*(6.25% nitrite salt carrier)*
Paprika	10 oz.	
Ascorbic acid	4 oz.	
Total Batch Weight	**800 lb.**	

The CSI compares the weights recorded in their field notebook with the weights in the above formula and verified the ingredients and weights used in production are the same as the ingredients and weights in the formula on file. The CSI then compares the ingredients statement on the frank label being applied to product to the frank formula on file. The CSI verifies that the ingredients were listed by their common and usual name in descending order of predominance. They also verified that the mandatory features and required information were on the label.

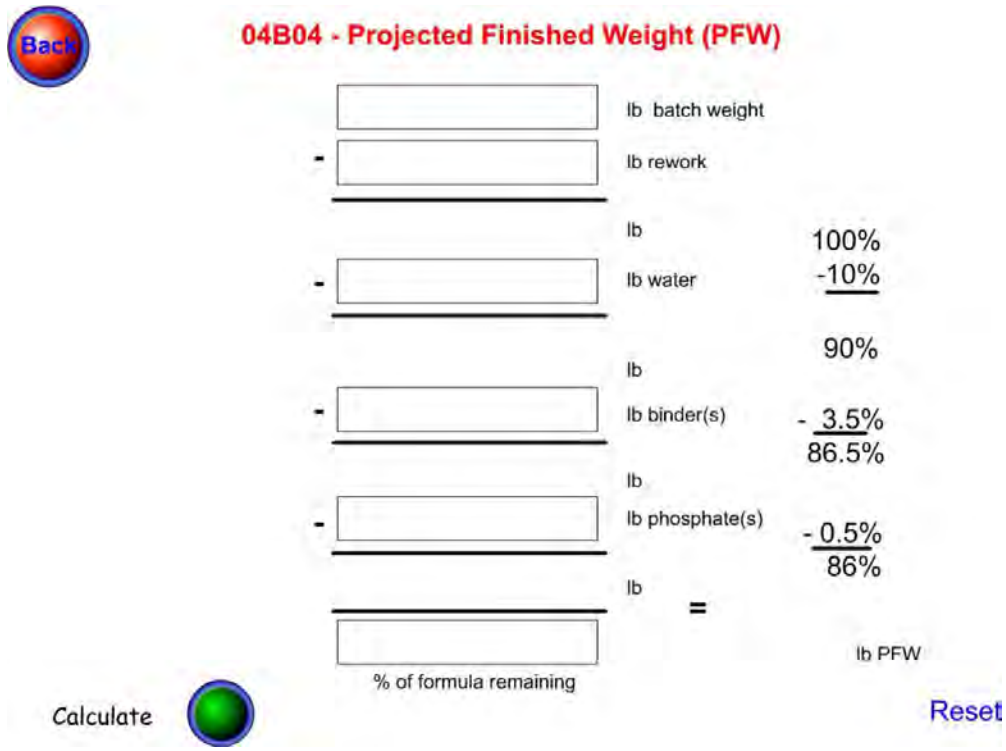
The CSI proceeds to the government office and performs the calculations necessary to answer the following questions.

8. Is the amount of binder added in compliance?

    a. Yes
    b. No

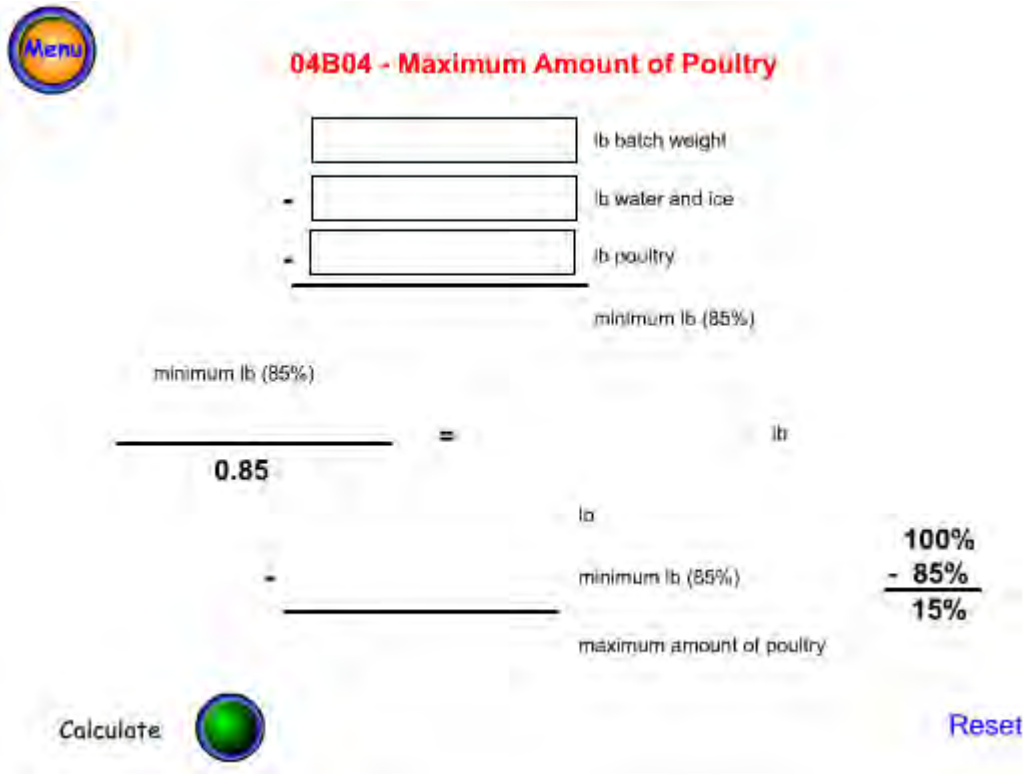
9. Is the amount of sodium phosphate added in compliance?

    a. Yes
    b. No



10. Is the amount of mechanically separated chicken in compliance?

    a. Yes
    b. No



9 CFR 424.21(c) Excerpt

Antioxidants and oxygen interceptors	Ascorbyl palmitate	To retard rancidity	Margarine or oleomargarine	0.02 percent (by wt. of finished product) individually or in combination with other antioxidants approved for use in margarine.
	.....do	Dry sausage	0.003 based on total weight	0.006 percent in combination with other antioxidants for use in meat.
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs	0.01 percent based on fat content	0.02 percent in combination with other antioxidants for use in meat, based on fat content.
	.....do	Various poultry products	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry) based on fat content.	
	BHT (butylated hydroxytoluene)	.....do	Dry sausage	0.003 percent based on total weight 0.006 percent in combination with other antioxidants for use in meat.
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs	0.01 percent based on fat content	0.02 percent in combination with other antioxidants for use in meat, based on fat content.
	.....do	Various poultry products	0.01 percent based on fat content (0.02 percent in	

			combination with any other antioxidant for use in poultry) based on fat content.	
	Propyl gallate	.....do	Dry sausage	0.003 percent based on total weight 0.006 percent in combination with other antioxidants for use in meat.
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs	0.01 percent based on fat content	0.02 percent in combination with other antioxidants for use in meat, based on fat content.
	Tocopherols	.....do	Dry sausage, semidry sausage, dried meats, uncooked or cooked fresh sausage made with beef and/or pork, uncooked or cooked Italian sausage products, uncooked or cooked meatballs, uncooked or cooked meat pizza toppings, brown and serve sausages, pregrilled beef patties, and restructured meats	Not to exceed 0.03 percent based on fat content. Not used in combination with other antioxidants.
Binders and Extenders	A mixture of sodium alginate, calcium carbonate, lactic acid, and calcium lactate	To bind poultry pieces	Ground and formed raw or cooked poultry pieces	Sodium alginate not more than 0.8 percent, calcium carbonate not more than 0.15 percent; lactic acid and calcium lactate, in combination, not more than 0.6 percent of product formulation. Added mixture may not exceed 1.55 percent of product at formulation. The

				mixture must be added in dry form.
	Bread	To bind and extend product	Bockwurst	3.5 percent individually or collectively with other binders for use in meat.
	Cereal	To bind and extend product	Sausages as provided in 9 CFR Part 319, bockwurst	3.5 percent individually or collectively with other binders for use in meat.
	Dried milk	.....do	Sausages as provided for in 9 CFR Part 319	3.5 percent individually or collectively with other binders for use in meat
	Dried skim milk, calcium reduced	.....do	Sausages as provided in 9 CFR 9 CFR Part 319	Do.
	Enzyme (rennet) treated with calcium reduced dried skim milk and calcium lactate	.....do	Sausages as provided for in 9 CFR Part 319	3.5 percent total finished product (calcium lactate required at rate of 10 percent of binder.)
		.....do	Imitation sausages; nonspecific loaves; soups, stews (meat only) and various poultry products	Sufficient for purpose in accordance with 21 CFR 172.5 (calcium lactate required at a rate of 10 percent of binder).
	Enzyme (rennet) treated with sodium caseinate and calcium lactate	.....do	Imitation sausages; nonspecific loaves; soups, stews (meat only) and various poultry products	Sufficient for purpose in accordance with 21 CFR 172.5 (calcium lactate required at a rate of 25 percent of binder).
	Isolated soy protein	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst	2 percent.
		.....do	Imitation sausages; nonspecific loaves; soups; stews (meat only) and various poultry products	Sufficient for purpose in accordance with 21 CFR 172.5.
	Sodium caseinate	To bind and extend product	Imitation sausages, nonspecific loaves, soups, stews (meat only)	Sufficient for purpose in accordance with 21 CFR 182.1748 and 21 CFR 172.5.

		.....do	Sausages as provided for in 9 CFR Part 319	2 percent in accordance with 21 CFR 182.1748.
	Soy flour	.....do	Sausages as provided for in 9 CFR Part 319, bockwurst	3.5 percent individually or collectively with other binders and extenders for use in meat.
	Soy protein concentrate	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst	3.5 percent individually or collectively with other binders and extenders for use in meat.

05 - Cured Meat and Poultry Product Operations

Objectives

1. Describe how to perform the % Yield/Shrink task.
2. Describe how to perform the General Labeling task.
3. Calculate the maximum amount of curing agent, curing accelerator, and phosphate allowed, when given a formula, and determine if these restricted ingredients are in compliance.
4. Calculate the volume of a tank, when given the dimensions of a tank.
5. Compute parts per million of restricted ingredients in cured meat products at the time of pumping to determine compliance.
6. Calculate parts per million allowed for each restricted ingredient approved for use in bacon products.
7. Calculate the yield of cured pork bellies when given finished weight and green weight numbers.
8. Calculate the percent shrink for dry cured pork products.

Curing Methods

There are three general methods of curing, with a number of variations for each method. These methods are pickle curing, dry curing, and dry salt curing.

Dry curing is the application of salt alone; salt, nitrate, and/or nitrite; or salt, nitrate, and/or nitrite with sugar directly to the surface of the meat. Meat subjected to this curing method cannot be injected with, or immersed in, a cure solution.

Dry salt curing is modification of the dry curing method, which includes the same mixtures in dry curing, except that product may be injected with cure solution directly into the muscle tissue (not through the circulatory system). Just prior to being covered with the dry mix, the meat may be momentarily moistened to facilitate salt penetration.

Pickle curing includes the use of a cure solution that could be prepared with a:

- brine solution (water and salt);
- pickle solution (water, salt, nitrate and/or nitrite); or
- sweet pickle solution (water, salt, nitrate and/or nitrite, and a sugar).

*** NOTE:** Other ingredients could also be added to enhance flavor. Binders are permitted in certain PFF cured pork products in §319.104 in accordance with §424.21(c), e.g., “ham with natural juices”, “ham water added”, and “ham and water product X% of weight is added ingredients.” Binders are not permitted in bacon, “ham” or other cured pork products without adjusting the product name to identify the binders, e.g., “bacon and binder product.”

Product covered with pickle solution for any length of time should be checked by the IPP to assure the amount of added solution does not affect the establishment’s procedural controls. After mixing, a pickle solution should be continually agitated to assure a uniform blend of the curing agents and to prevent ingredients such phosphates from precipitating out of the pickle.

Cure solutions are often reused. When a cure solution is reused, it should be filtered to keep it clear, free of sediment, and prevent decomposition. The IPP should check the filter to ensure that it is in good repair and removing meat residue and sediment.

NFSCP PHIS Tasks

The proper inspection tasks used to verify the cured meat and poultry product regulatory requirements may not always be readily apparent. Below are two commonly used tasks for the products covered in this module: 1) General Labeling Verification Task, and 2) % Yield/Shrink Verification Task.

Performing the General Labeling Task

Before starting the task, review the applicable regulations and review the steps for performing the task. Use professional knowledge, good judgement and begin your (**GAD**) process. Inspection program personnel perform this task to verify general labeling regulatory requirements and determine if the label accurately reflects the finished product for the cured meat and poultry products. Restricted Ingredients regulatory requirements should also be verified while performing this task.

General Labeling Requirements

Select the Label - Select a label to verify that is being applied to a product on the day that the task is being implemented. Check the label to verify that all mandatory features required in 9CFR 317.2 are present; product names include qualifying statements and/or descriptive designations if necessary; that label does not include any false or misleading information, etc. You will verify that the product is not misbranded by use of the label.

NOTE: Product is misbranded if its label is missing a required feature, qualifying statement, or descriptive designation or is anyway false or misleading.

A product is misbranded, if:

- a declared ingredient is omitted,
- an ingredient is added but not declared on the label, or
- the ingredient order of predominance is not accurate.

Labeling file – Determine if the label approval is on file (sketch, temporary, or generic per §412.1); if sketch approval is required by §412.1 verify that the label has LPDS approval; if a temporary approval (which requires LPDS approval) is being used verify that the expiration date is still valid; verify that the product being made follows the formula and processing procedures in the label approval. In order to do this, you will need to request to see that the label approval is on file for review; the establishment is required to provide this information upon request.

NOTE: If a noncompliance is found, IPP should issue an NR and take the appropriate action necessary to ensure misbranded product does not enter commerce.

Label Accurately Reflects the Product

Determining that the label accurately reflects the finished product involves:

- reviewing the product's formulation record,
- observing its actual preparation and, in some cases,
- performing formula calculations.

Steps for performing the General Labeling task:

1. select one or more batches of product at formulation
2. verify ingredient amounts comply with the formula on file
3. verify that no undeclared ingredients are added or declared ingredients are omitted from the finished product.

The verification process may involve:

1. observing pre-weighed ingredients for proper identification and weights, or
2. observing establishment employees weighing ingredients, or
3. actually, weighing pre-weighed ingredients to determine if the weight on the container is accurate.

NOTE: An ingredient added at a different level than indicated in the product formula could affect the ingredient order of predominance on the label.

Once the formula process for the curing solution preparation has been observed, verify that the label does not have false or misleading information, that the ingredients are correctly listed in the ingredients statement and that they are in descending order of predominance.

Restricted ingredients

The regulations and many product standards of identity allow the establishment to add various ingredients to the formula of certain meat and poultry products. Some meat and poultry components used in the formulation may have regulatory limits. Some nonmeat ingredients have a specified maximum amount or percentage allowed in the product. These nonmeat ingredients are called restricted ingredients. The establishment ***MAY*** add the component or ingredient in any amount up to its permitted limit. IPP will perform calculations when restricted ingredients are used, e.g., nitrite, cure accelerators, phosphates, etc.

If the product is formulated with a meat or poultry component with a regulatory limit or with a restricted ingredient, the IPP should select one or more batches of product during formulation. They should determine the amount or percentage of the meat or poultry component and/or the amount one or more restricted ingredients used in the formula. The IPP verifies that the:

- percentage of meat or poultry component meets the regulatory limit,
- restricted ingredient is allowed in the product, and
- the amount of the restricted ingredient added to the product does not exceed the regulatory limit.

Verifying meat and poultry components or restricted ingredients are in compliance with regulatory limits usually requires the IPP to perform a formula calculation. When meat or poultry components or restricted ingredients are added at levels in excess of their maximum regulatory limit, they become economic adulterants.

If IPP find noncompliance, they issue an NR and take the appropriate action necessary to ensure adulterated or misbranded product does not enter commerce.

Performing the %Yield/Shrink Task

Inspection program personnel (IPP) perform the percent yield/shrink task in establishments that are preparing meat or poultry cuts, parts and products with added solutions at levels that do not require the product's label to be qualified with a statement to indicate the percent of the solution

and ingredients added to the product. When the product's label is qualified with a percentage, it is verified using the X% solution task. We will discuss this in the next module.

The added solution, product shrink, and yield verification determinations are performed on one or more **subgroups** (samples) of product or on entire batches of product.

When performing this task, IPP:

- select an appropriate product (has to be one that the product name does not require an added solution statement) and
- verify compliance with regulatory requirements, by:
  - reviewing establishment records and labels,
  - weighing appropriate amount of meat or poultry,
  - calculating the % added solution, gain, pump or pickup, yield or shrink, and
  - comparing the result with the appropriate regulatory requirement, the establishments records, and product label.

In addition, inspection program personnel should weigh a sample of product before and after (IPP should weigh the same product/pieces) the appropriate step in the process (i.e., pumping, cooking, chilling, curing, drying, etc.); then calculate the % yield or shrink, and compare the result with the appropriate regulatory requirement, the establishment records, and the product label.

To calculate the % yield, shrink:

- Weigh a subgroup (sample) of product before and after the appropriate step in the process (pumping, injecting, dipping, cooking, chilling, or drying).
  - There is not a specified number of pieces of product that must make up a subgroup. The number of pieces selected and weighed should be representative of the lot size. For example, the IPP may select 20 or 30 pieces of meat or poultry and have them weighed before the solution is applied (green weight) and 20 or 30 pieces after the appropriate processing step, e.g., pumping, immersion, or cooking and chilling, and have them weighed (finished weight).
  - Actual % pump or pick-up – the actual amount of solution above green weight that is in the meat or poultry without allowing a drain time.
  - Effective % pump or pick-up – the amount of solution above green weight that remains in the meat or poultry after allowing a specified drain time.
  - Restricted ingredient calculations will be based on whether or not the company includes a drain time in their processing procedures, if not, then the actual % pump is used.
- After the subgroup or batch weights (green and finished weights) are obtained, the IPP must perform a calculation to verify that the added solution or the product's yield or shrink complies with the product's standard of identity or regulatory requirement.

Note: Shrink and yield determinations should be conducted on entire lots of product. However, in many instances it is not feasible to perform shrink and yield tests with the entire weight of the lot (inspection personnel time constraints or extremely large lot size). Therefore, weighing a large enough portion (subgroup sample) to represent the lot would be acceptable.

Restricted Ingredients

This section includes information on ingredients and the limitations for their use in curing compounds and curing solutions that are to be applied in or on meat and meat food products and poultry and poultry food products. It also covers mathematical calculations to determine compliance for the following restricted ingredients:

- Curing agents and curing compounds,
- Curing accelerators, and
- Phosphates

Note: In the establishment, FSIS Directive 7620.3, Processing Inspectors' Calculations Handbook can be used to assist you. Restricted ingredients are verified using the General Labeling Task.

IPP may use two methods to determine curing agent, curing compound, curing accelerator or phosphate compliance.

1. Determine ingoing parts per million of cure agent, cure accelerator or phosphate in pickle formula then compare their result against the ingoing amount allowed by the regulations. If the calculated ingoing amount is equal to or less than the amount allowed by regulation, the product is in compliance.

2. Determine the maximum amount of the cure agent, cure compound, cure accelerator or phosphate allowed in the formula and then compare their calculated result to the amount that is actually being used in the formula. If the amount used in the pickle formula is equal to or less than the maximum amount allowed, the product is in compliance.

Limits for restricted ingredients (RI) permitted in pickle cured meat and poultry products are expressed in terms of ounces (oz) or pounds (lb.) per gallons of pickle solution, or as percentages (%) in the Table of Approved Substances in section 9 CFR 424.21(c) and FSIS Directive 7120.1. The same limits may be expressed in parts per million (ppm) which are more convenient units for verifying food additive compliance. The conversion of curing agent and accelerator weight limits, and the phosphate percentage limit to parts per million (ppm) limits is shown in **Table I.**

Note: When nitrate and nitrite are used in combination, the limits are calculated separately and the permitted maximum (weight or ppm) of each may be used.

TABLE 1

Conversion of Restricted Ingredient Weight or Percentage Limitations to PP limitations

Cure Agent Limits in Regulations	Converted to Maximum PPM Limit General PPM Equation for Pickled Product: $\text{ppm} = \frac{\text{lb RI} \times \text{\% pump} \times 1{,}000{,}000}{\text{lb of pickle}}$ If 1-gallon pickle weighs 10 lb (wt. base when regulations were written), then 100 gallons weighs 1000 lb.
Nitrite 2 lb to 100 gallons of pickle at 10% pump	$\frac{2 \text{ lb} \times 10\ (10\%) \times 1{,}000{,}000}{1000 \text{ lb}} = 200$ ppm
Nitrate 7 lb to 100 gallons of pickle at 10% pump	$\frac{7 \text{ lb} \times 10\ (10\%) \times 1{,}000{,}000}{1000 \text{ lb}} = 700$ ppm
Note: When nitrite and nitrate are used in combination, the limits are calculated separately and the permitted maximum (weight or ppm) of each may be used.	
Cure Accelerators in Regulations	**Converted to ppm**
Ascorbic Acid and Erythorbic Acid 75 oz to 100-gal pickle at 10% pump	If 1 gal pickle weighs 10 lb, then 100-gal pickle weigh 1000 lb. 75 oz. = 75/16 = 4.687 lb
Ascorbate and Erythorbate	$\frac{4.687 \times 0.10 \times 1{,}000{,}000}{1000} = 469$ ppm
87.5 oz to 100-gal pickle at 10% pump	87.5 oz = 87.5 oz/16 = 5.468 lb $\frac{5.468 \times 0.10 \times 1{,}000{,}000}{1000} = 547$ ppm
Phosphates in Regulations	**Converted to ppm**
Used to decrease cooked out juices: 5 percent of phosphate in pickle at 10% pump (meat regulations)	5% in pickle = 5 lb in 100 lb $\frac{5 \times 0.10 \times 1{,}000{,}000}{100} = 5000$ ppm
0.5% of total product (poultry regulations)	5000 ppm = 0.005 = 0.5%
0.5% of phosphate in product (meat regulations)	5000 ppm = 0.005 = 0.5%
Used to protect flavor: 0.5% of total product (meat regulations)	5000 ppm = 0.005 = 0.5%

Curing Agent (Nitrite and Nitrate) Compliance Determinations

Table II lists the maximum parts per million (ppm) for each of the four curing agents permitted in products, based on the curing method used. The limits vary among curing methods because the methods differ in the efficiency with which the curing agent is brought in contact with the meat and/or poultry. Limits for nitrite/nitrate combinations and combination procedures (such as pumping and dry curing) are addressed in the Processing Inspectors' Calculation Handbook.

TABLE II
Maximum Ingoing Nitrite and Nitrate Limits (in PPM) for Meat and Poultry Products*

Curing Agent	Curing Method			
	Immersion Cured	Massaged or Pumped	Comminuted	Dry Cured
Sodium Nitrite	200	200	156	625
Potassium Nitrite	200	200	156	625
Sodium Nitrate	700	700	1718	2187
Potassium Nitrate	700	700	1718	2187

* There are more stringent limits for curing agents in bacon to reduce the formation of nitrosamines. For this same reason, nitrate is no longer permitted in any bacon (pumped and/or massaged, dry cured, or immersion cured).

The amount of ingoing nitrite or nitrate used in pumped, massaged, injected, or immersion-cured products, such as hams, poultry breasts, poultry rolls, corned beef, etc., is based on the green weight of the meat and/or poultry used in the product formulation.

The green weight is the weight of the meat and/or poultry (e.g., ham, chicken breast, pork belly, beef brisket or pork trim for sausage) prior to processing (such as grinding and adding ingredients, pumping with a solution, adding batter and breading, cooking, or drying). Nothing has been added or removed from the meat and/or poultry.

Curing Accelerator Compliance Determinations

Cure accelerators speed up the color development (color fixing) of cured products by accelerating the chemical conversion of nitrite to nitric oxide. In addition, cure accelerators aid in keeping myoglobin (muscle pigment) in the reduced state so that it can readily combine with nitric oxide to form nitric oxide myoglobin. Since cure accelerators aid the curing agents in cure color development, they may only be used in combination with the curing agents.

Ascorbic/Erythorbic Acid:

- 75 oz to 100 gallons of pickle at 10% pump or 469 ppm maximum.

Ascorbate/Erythorbate:

- 87.5 lb. to 100 gallons of pickle at 10% pump or 547 ppm maximum (except or bacon).

Table III lists the permitted maximums for accelerators used alone **and** in combination in the curing of pumped, massaged, and immersed meat or poultry products other than bacon. Maximums for sodium ascorbate and sodium erythorbate (isoascorbate) in bacon are given on page 15 of this handout.

TABLE III
Maximum Ingoing Cure Accelerators (in PPM)
for Meat and Poultry Products

Cure Accelerator	Maximum Limit
Ascorbic Acid	469 ppm*
Erythorbic Acid	469 ppm*
Sodium Ascorbate	547 ppm*
Sodium Erythorbate (isoascorbate)	547 ppm*
Citric Acid or Sodium Citrate	may replace up to half of any one of the above
	*Except in bacon

The amount of ingoing cure accelerators used in cured, pickled products, such as ham, corned beef, turkey ham, etc., is based on the ***green weight of the meat and/or poultry and/or meat/poultry byproducts*** used in the product formulation.

All the methods for calculating nitrite and nitrate amounts also apply in the calculation of cure accelerator amounts. Different limits apply, depending upon which cure accelerator is used as shown in Table III.

Phosphate Compliance Determinations

Phosphates are frequently added to curing solutions and cured product formulations because of the numerous beneficial effects they have in meat and poultry curing. Phosphates increase the water retention (water binding capacity) of the meat and poultry, which reduces the shrinkage (moisture loss) and purge (cook-out) of pickle-cured products during further processing. The improved water binding results from the reaction of the phosphate ions with the meat and poultry proteins. Phosphates also improve the sensory characteristics of the product (texture, juiciness, and tenderness), improve the stability and uniformity of the cure color, and suppress the development of rancidity in cured products. Phosphates tend to precipitate out of pickle if not agitated.

Phosphates are permitted in meat and poultry products, unless otherwise prohibited by the regulations, to reduce the amount of cooked-out juices. Phosphates in pickle-cured meat products such as ham, corned beef, and bacon are limited to 5% in a pickle at a 10% pump level. Phosphates in pickle-cured poultry products such as turkey ham are limited to .5% in the total product. Both limits are equivalent to 5000 ppm. For pickle cured meat products, the maximum ingoing phosphate limit is based on the green weight of the meat or meat byproduct in the product formulation. Calculations for phosphate(s) are the same as those for nitrite and cure accelerators in pickle-cured meat products.

Pickle Solution Compliance Determinations

Firstly, when the pickle is measured by volume, not weight;

- determine its weight by multiplying the number of gallons of water by 8.33 (the weight in pounds of a gallon of water) and adding the actual weight of the other ingredients.

Next, if two parts of the equation are known, the third can be calculated by:

- substituting the known values using the following calculation equation:

$$\text{ppm (parts per million)} = \frac{\text{lb. Restricted Ingredient (RI)} \times \text{\% Pump}}{\text{lb. Pickle}} \times 1{,}000{,}000$$

Example Problems

1. Solving for Ingoing RI parts per million (ppm)

An establishment's written procedure calls for 10% pump, 100 gal of pickle weighing 1,000 lb., and 2 lb. of sodium nitrite.

("X") = unknown

$$X = \frac{2 \times 0.1 \times 1{,}000{,}000}{1{,}000}$$

$$X = \frac{200{,}000}{1{,}000}$$

X = 200 ppm ingoing nitrite

Note: *Ingoing parts per million for cure accelerators and phosphate (meat product only) are determined using the same method except the weight of the cure accelerator or phosphate would be substituted into the equation for the weight of nitrite.*

2. Solving for maximum percent pump

Pickle "A" contains 1 lb. 12 oz of nitrite for 1,000 lb. What percent of pump is permitted?

Calculation: Convert 1 lb. 12 oz to 1.75 lb. nitrite allowed at 200 ppm

$$200 = \frac{1.75 \times X \times 1{,}000{,}000}{1{,}000}$$

In this instance, all the known values are moved to the left side of the equation, leaving "X" on the right and keeping it in the numerator. To transfer a value from one side of the equation to the other, it is simply moved to the numerator on the other.

$$\frac{200 \times 1{,}000}{1.75 \times 1{,}000{,}000} = X$$

$$\frac{200{,}000}{1{,}750{,}000} = X$$

$$0.1142 = X$$

11.42% maximum % pump allowed

3. Solving for maximum amount of restricted ingredient

Establishment 38 is using a cure mix with 6.25% nitrite. The establishment is planning to pump hams at 12% using a pickle solution. How much cure mix can the establ;ishment use per 100 gallons of pickle at this level of pump if the pickle weight is 9.5lb. per gallon?

Calculation: $200 = \frac{X \times 0.12 \times 1,000,000}{950}$

In this instance, all the known values are moved to the left of the equation, leaving "X" on the right where it is the numerator.

$$\frac{200 \times 950}{0.12 \times 1,000,000} = X$$

$\frac{190,000}{120,000}$ = 1.58 lb. nitrite allowed per 100 gallons of curing solution

Special Note: To find the amount of cure mix allowed, IPP divide the amount of nitrite allowed (in this case 1.58lb.) by the percent nitrite in the mixture (in this case 6.25% nitrite).

$\frac{1.58}{.0625}$ = 25.28 lb. of pickle solution allowed in each 100 gallons of pickle

4. Determining the volume of a container

Pickle tank "C" is a rectangular tank with these dimensions:

Length = 60 inches; Width = 48 inches; Height = 48 inches

How many gallons will it hold when **completely filled***?*

Special Note: *There are 231 cubic inches in a gallon and 7.48 gallons in a cubic foot.*

ANSWER: $V = \frac{LWH}{231}$

$$V = \frac{60 \times 48 \times 48}{231}$$

$$V = 598.44 \text{ gal}$$

Special Note: *When calculating for restricted ingredients, the tanks are usually never filled to the brim. Therefore, IPP may calculate for the gallons per inch of depth and multiply the gallons per inch by the height in inches that the tank will be filled to find the total volume.*

5. Determining volume in a partially filled tank

Pickle tank "D" is a rectangular tank with these dimensions:

Length = 65 inches; Width = 60 inches; Height = 48 inches

How many inches from the top would 600-gal measure in this tank?

ANSWER: *V = 65" × 60" × 48"*

$$V = \frac{187200}{231}$$

V = 810.39 gallons

$$V = \frac{810.39\ gal}{48\ in}$$

V per inch in height = 16.88 gal

H = 600 gal ÷ 16.88 in

H = 35.55 inches in tank

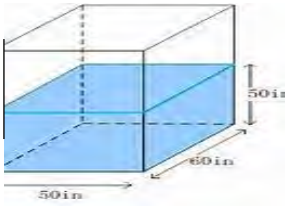
H = 48 in − 35.55 in

H = 12.54 inches or 12.5 inches from the top of the tank

Volume Determinations

The volume of a rectangular or square container is determined by multiplying **length** x **width** x **height**. When determining volume, you may need to do a calculation based on the size of the continuer and the amount of solution in it before performing a calculation to determine volume. The container holding solution may not be full. Calculations must be performed on the actual solution volume not the container volume to be accurate. Cylindrical volume will be calculated differently.

Formula: **V= Lx W x H**



Cylinder volume formula:

$V = \pi \times r^2 \times h$

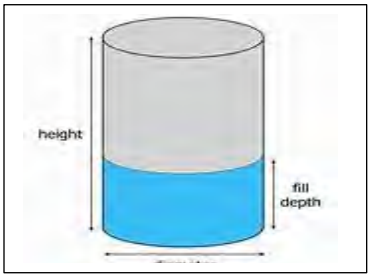
π = pi or 3.14

r^2= radius squared

h = height

*(note: the radius is one-half of the diameter)

**(note: radius squared is the radius multiplied by Itself, r x r)



Cure Agent and Cure Accelerator Determination Workshop

Curing Problem Scenario 1

There is a General Labeling task scheduled on the task calendar today. The establishment's production sheet indicates that the boneless ham water added product is being prepared today. You go to the production office and review that procedure. The Boneless Ham Water Added procedure indicates that the pickle solution is prepared in a 200-gallon batch. A gallon of pickle weighs 10 lb. The target pump is 14%.

The restricted ingredients used in the pickle formula:

Phosphate—72 lb.
Nitrate—8 lb.
Nitrite—2 lb. 10 oz.
Sodium Ascorbate—5 lb.

In the pickle preparing room, you find the Boneless Ham Water Added procedure posted above the pickle tank. It is the same procedure you observed in the production office. You find the tank used for mixing this pickle has these dimensions:

length = 40"; width = 40"; height = 30"

There is a 200-gallon mark located 3" from the top of the tank.

Note: There are 231 cubic inches in a gallon

Workshop Questions

3. What is the volume of the pickle in the tank? (What are your general concern(s) in relation to the restricted ingredient levels? Would you expect the levels in this volume of solution to be higher or lower than in 200 gallons?)

a. 187.01 gallons
b. 207.79 gallons
c. 205.71 gallons

4. Is the mark on the tank correct?

a. Yes
b. No

5. Phosphate – calculate the ingoing PPM based on 200 gallons of pickle

a. 5040 ppm
b. 5400 ppm
c. 50.40 ppm

6. Nitrate – calculate the ingoing PPM based on 200 gallons of pickle

a. 560 ppm
b. 56 ppm
c. 5.6 ppm

7. Nitrite – calculate the ingoing PPM based on 200 gallons of pickle

a. 183.75 ppm
b. 1.83 ppm
c. 18.37 ppm

8. Ascorbate – calculate the ingoing PPM based on 200 gallons of pickle

a. 350 ppm
b. 35 ppm
c. 3500 ppm

Calculate the ingoing PPM for nitrite based on the gallons of pickle from question.

9. Nitrite

a. 196.52 ppm
b. 19.65 ppm
c. 1.96 ppm

10. Did these calculations support your concern(s) from the previous question?

a. Yes
b. No

11. Based on the pickle formula (200 gallons), was the regulatory limit exceeded for any of the restricted ingredients?

a. Yes
b. No

Curing Problem Scenario 2

The General Labeling task is on the task calendar today. The establishment's written procedure states that the beef brisket pickle solution is prepared in an 860-gallon curing vat. The total ingredients (including water) weigh 8,586 lb. The pump target is 12%.

(Note: The cure ingredients are combined in a curing compound.)

The cure compound label states:

Sodium nitrite	23%
Sodium erythorbate	25%
Salt carrier	52%
Total	100%

12. What is the maximum amount of curing compound permitted in this pickle formula?

a. 62.21 lb.
b. 6.221 lb.
c. 622.1 lb.

Curing Problem 3

13. How many gallons are contained in a cylindrical drum filled to within two inches of the top with pickle if the drum dimensions are 24" (diameter) X 30" (height)?

$V = \pi r^2 h$ $\pi = 3.14$ r^2 = radius h = height V= volume

Note: There are 231 cubic inches in a gallon

a. 54.8 gallons
b. 548 gallons
c. 5.48 gallons

How much nitrite, nitrate, and ascorbic acid could be used if the establishment wants to pump 15%? (A gallon of pickle weighs 9.68 pounds.)

14. Nitrite

a. 0.70 lb.
b. 70 lb.
c. 7.0 lb.

15. Nítrate

a. 2.47 lb.
b. 247 lb.
c. 24.7 lb.

16. Ascorbic Acid

a. 1.65 lb.
b. 165 lb.
c. 16.5 lb.

Added Solution and Shrink Determinations

Several meat food products and turkey ham have specific regulatory limits for the amount of water that can be added or picked-up from a curing solution. Inspection program personnel must perform pump or pick-up determinations to verify that the amount of solution added to the product is in accordance with the regulations, the establishment's written procedures, or product label. IPP also perform the % Yield/Shrink task to verify that the product's finished weight meets the regulatory requirement prior to packaging.

This section includes examples and/or practice problems designed to assist IPP in:

Performing percent added solution (pump/pick-up) determinations;
Maximum percent pump/Maximum amount of added solution (gain, pump or pick-up)
Performing product shrink determinations on the finished product
Performing cooking/smoking/cooler shrink determinations.
Interpreting processing procedure charts; and
Calculating maximum amounts of restricted ingredients allowed.

Percentage of Added Solution (Gain in the Calculation Aid) Determination

Calculation Equation for Raw Products

$$\frac{\text{(pumped, treated, or massaged) weight - green weight}}{\text{green weight}} \times 100 = \%\ \text{pump/pick-up/added solution}$$

Note: Pumped weight, treated weight, or massaged weight can be in inserted into the above equation depending upon the method in which the solution is applied, e.g., treated weight is used when the product is dipped or submerged in the solution; pumped weight is used when the solution is injected into the cut.

Note: The green weight is the weight of the meat and/or poultry prior to processing (such as adding ingredients, pumping with a solution, cooking, or drying)

Calculation Method

IPP can use the steps in the table below to compare a product's green weight with its pumped, treated, or massaged weight and determine the percent added solution.

STEP		EXAMPLE
1	Determine the green weight of a given number of pieces of fresh (unpumped, untreated, etc.) meat or poultry or an amount of fresh (unpumped, untreated, etc.) meat or poultry product that will represent the lot.	Fifteen beef briskets to be pickle- cured weigh 227.6 lb.
2	If a drain time is listed in the establishment's written procedure, allow the pumped/treated product to drain for the specified time period and then weigh. If no drain time is listed, take the weight directly after pumping.	After *pumping*, the *same* fifteen beef briskets weigh 271.1 lb.
3	Subtract the green weight from the pumped or treated weight to obtain the pounds of added solution.	271.1 lb – 227.6 lb 43.5 lb of solution
4	Divide the pounds added solution by the green weight.	43.5 lb ÷ 227.6 lb = 0.1911
5	Convert the decimal answer into the percentage of added solution by multiplying by 100.	0.1911 × 100 = 19.11% added solution. In this case 19.11% could also be referred to as the *effective* percent pump (if product is drained) or *actual* percent pump (if product is not drained).

Comments

If the beef briskets in the above example were targeted to have a 17% pump had a 19.11% effective or actual pump, there is regulatory noncompliance. If the establishment can demonstrate with records (e.g., its own added solution tests during the shift and previous shifts) that the added curing solution is consistently or routinely 17% (as declared on the label) or below, then there is no noncompliance. On the other hand, if the establishment cannot demonstrate that the added curing solution is consistently or routinely 17% (as declared on the label) or below (i.e., has no data or records), then the IPP would retain the lot of beef briskets until the briskets drain to 17% percent added solution. If a consistent pattern of over pumping (indicates lack of process control) is identified, then the IPP shall request that establishment management update its written procedure to reflect the effective or actual pumping percentage. Any pumping above the establishment's target pump but below the maximum solution allowed in the product should be discussed at the weekly meeting. The establishment response needs to be documented in the MOI. When applicable, the 20% range is determined as, (X% declared on the label x 0.8 for the lower limit) – (X% declared on the label x 1.2 for the upper limit).

If the IPP determined the amount of curing solution added to the raw beef briskets in the example above was 21% (i.e., above the FSIS allowance of 20% which for 17% declared on the label is 20.4% maximum), the IPP would document this as a noncompliance.

Note to IPP- The amount declared on the label is the limit for the actual/effective pump.

If an establishment does not have a history of over-pumping and it was not intentionally targeting an amount of added solution above what is declared on the label, the agency has allowed a 20% variance. The variance is not to be used all the time it is only for occasional unusual circumstances.

Additional Added Solution Example Calculations

A pump test shows 30 fresh, uncured hams had a green weight of 450 pounds; the same 30 pumped hams had a weight of 510 pounds. The procedure indicates 16% target pump.

What percent added solution does this test show?

Answer: 510 – 450 = 60 lb.
60 ÷ 450 = 0.133 or 13.3%

If a consistent pattern of under pumping is identified, then the IPP should request that management adjust the procedure to reflect the actual pumping percentage. Pumping equipment is checked for accuracy daily by the establishment and should be spot checked by the IPP. The under pumping should be discussed at the weekly meeting and the establishment's response documented in the MOI.

A second test was conducted on 25 pork hams. The procedure indicates a 19% effective pump.

Pumped weight = 260 lb.; Green weight = 210 lb.

What is the percentage of added solution?

Answer: 260 – 210 = 50 lb. of solution

50 ÷ 210 = 0.2380 or 23.80%

Note: The IPP should request that the establishment demonstrate that these hams are in compliance with the minimum PFF value in the table in 9 CFR 319.104 after they are cooked and accurately labeled because they have been over pumped by 4.8%. IPP should also verify the amount of ingoing restricted ingredients are in compliance using the 23.8% effective pump. This finding should also be discussed at the weekly meeting and the establishment's response documented in the MOI.

Maximum Percent (Gain, Pump or Pick-up) Determination

To verify that the level of ingoing restricted ingredients (curing agents, cure accelerators, phosphates, etc.) in a pickle formula are in compliance, IPP can determine the maximum % pump for each restricted ingredient and compare it to the targeted % pump. The listed target % pump shall never be greater than the maximum % pump allowed for any restricted ingredient in the solution. To verify restricted ingredient compliance at the time of pumping, the effective or actual % pump must be compared to the maximum % pump allowed for the pickle solution.

Calculation Equation for Maximum Percent (Gain, Pump, or Pick-up)

$$\frac{\text{lb. restricted ingredient} \times \% \text{ pump} \times 1{,}000{,}000}{\text{lb. pickle}} = \text{ppm}$$

Calculation Method

IPP may use the steps in the following table to determine the maximum percent pump allowed for each restricted ingredient in a pickle or curing solution.

STEP		EXAMPLE
1	Determine the weight of the nitrite added to the pickle solution, the total weight of the pickle solution, and the target percent pump from the label transmittal form or the establishment's written procedure record/chart. *If any two of these quantities are known, the third can be calculated by substituting the known values into the equation.*	Pickle Formula Water 1310.00 lb. Salt 132.00 lb. Dextrose 18.00 lb. Phosphate 35.00 lb. Sodium Erythorbate 3.25 lb. Sodium Nitrite 1.75 lb. Total 1500.00 lb. Beef briskets are pumped with 16% solution.
2	Enter the weight of the nitrite, the weight of the pickle solution, and the ppm limit for nitrite (200 ppm) into the equation and solve for ***n***, the maximum percent pump.	We have 1.75 lb. of nitrite in 1500 lb. of solution that is to be pumped into beef briskets at a targeted level of 16%. However, what would be the maximum % pump allowed in the event the establishment exceeded the target % pump? $200 = \frac{1.75 \times n \times 1{,}000{,}000}{1500}$ $n = \frac{200 \times 1500}{1.75 \times 1{,}000{,}000} = 0.1714$
3	Convert the decimal answer into the percent pump by multiplying by 100.	0.1714 × 100 = 17.14 % is the maximum pump % level for nitrite. Since the target % pump is 16%, this processing procedure would produce beef briskets in compliance for ingoing nitrite.

If the weights and maximum permitted levels (in ppm) of phosphate and sodium erythorbate were substituted into the table on the previous page, the IPP would obtain a maximum % pump of 21.42% for phosphate and 25.24% for sodium erythorbate. Although three different maximum % pump levels exist for this pickle solution, 17.14% would be the maximum % pump level allowed for this solution because the ingoing nitrite limit would be exceeded at any % pump greater than 17.14%.

As stated before, restricted ingredient compliance must be verified at the time of pumping. Verifying at this point helps assure that the pumping machine is in proper adjustment and draining procedures are followed. This can be done by determining the effective or actual % pump and comparing it with the maximum % pump for the pickle solution. For example, if the beef briskets on the previous example were pumped with the pickle solution in Step 1 in the table on the previous page, they would be out of compliance for ingoing nitrite because the

effective or actual % pump (19.11%) is greater than the maximum % pump (17.14%) for the pickle solution.

Each restricted ingredient's compliance at the time of pumping could also be verified by inserting its weight, the effective or actual % pump, and the weight of the pickle solution into the equation in Step 2 of the table on page 39 and solving for ppm.

Maximum Amount of Added Solution (Gain) Allowed Determination

Beef cuts or beef briskets dipped or submerged into or injected with pickle solutions *may not* have more than the 10% or 20% solution added to them in accordance with regulations.

Calculation method

The steps in the table below will assist IPP in determining the maximum amount (pounds) of added solution.

STEP		EXAMPLE
1	Multiply the green weight of the meat or poultry to be pumped/treated by the amount of solution allowed -- 10% (.10) or 20% (.20).	Ten beef tongues treated with a pickle cure Ten tongues weigh 38 lb. 38 lb. × .10 (10%) 3.8 lb. of solution permitted
2	Add the untreated (green) weight and the solution permitted to get the total maximum weight of the treated product.	38.0 lb. + 3.8 lb. 41.8 lb. would be the maximum amount the ten tongues could weigh after being treated.

Finished Product Shrink and Cooking/Cooling Shrink Determinations

After processing, some products must weigh a certain percentage less than the green weight of the fresh meat cut. IPP are responsible for verifying the shrinkage of various cured meat products. For example, **dry-cured hams and pork shoulders** must **shrink a minimum of 18%**--9 CFR 319.106(b)(7). IPP may also verify that the establishment is following its written processing procedures as required.

Use the equation on the next page to verify the percent shrink compliance of dry cured hams and pork shoulders. This equation may also be used to determine the shrink for other meat food products that are required to have specific amount of shrink, e.g., bacon bits and barbecued meat.

Calculation Equation for Percent Shrink

$$\frac{\text{green weight meat or poultry - finished weight}}{\text{green weight meat or poultry}} \times 100 = \%\ \text{shrink}$$

Note: Finished weight is the weight of the meat and/or poultry plus the weight of any ingredients added during processing minus the weight loss (shrink) from smoking, cooking, cooling, or drying.

The steps in the table below should be used when IPP want to find a finished product's percent shrink.

STEP		EXAMPLE
1	Determine the green weight of the meat.	Dry-Cured Pork Shoulders Pork shoulders 500 lb
2	Determine the weight of the product after processing (cooking, drying, etc.).	After the specified curing and drying period, the pork shoulders weigh 395 lb
3	Subtract the weight of the product after processing (finished weight) from the green weight of the meat to find the amount the product shrunk.	500 lb - 395 lb 105 lb
4	Divide the number of pounds the product has shrunk by the green weight of the meat.	105 lb ÷ 500 lb = 0.21
5	Convert the decimal answer into the percentage of shrink by multiplying by 100.	0.21 × 100 = 21% shrink (in compliance). The weight of the pork shoulders is at least 18% less than the fresh uncured (green) weight of the pork shoulders

Cook and Chill Shrink Determinations

The establishment must adhere to its written procedures, e.g., solution formulation, cooking and chilling time, temperature and humidity, and cook and chill shrinks. Smokehouse instrument charts should be checked periodically against a known accurate thermometer to determine the accuracy of the recording devices. When an establishment is producing a PFF controlled cured pork product and does not meet the target shrinks, the product may not be accurately labeled, e.g., ham natural juices versus ham water added versus ham X% of weight is added ingredients. Likewise, if an establishment is producing cooked cured beef product or cooked turkey ham and does not meet the target shrinks, the finished product weight may exceed the original (green) weight of the beef cut or thigh meat prior to curing, i.e., the product yield is more than 100%. Cooked corned beef products and turkey ham, whose weights after cooking exceed the weights of the fresh uncured beef or thigh meat, must be descriptively labeled to indicate the presence and the amount of the additional substances, e.g., “Corned Beef Containing 15% Solution” or “Turkey Ham, Cured Turkey Thigh Meat 25% Added Water.”

Use the following equation to determine the percent cook shrink or chill shrink of cooked bacon bellies, PFF-controlled cured pork products, cured beef products, and turkey ham.
Calculation Equation for Cooking and Chilling Shrink

$$\frac{\text{weight in (smokehouse/oven/cooler) - weight out (smokehouse/oven/cooler)}}{\text{weight in (smokehouse/oven/cooler)}} \times 100 = \%\ \text{shrink}$$

The steps in the following table should be used when IPP want to determine the percentage of cook or chill shrink.

STEP		EXAMPLE
1	Determine the weight of the product (less tare) going into the smokehouse, oven, cooler, etc.	1000 lb. of turkey thigh meat
2	Determine the weight of the product (less tare) coming out of the smokehouse, oven, cooler, etc.	927 lb of Turkey Ham after cooking and smoking
3	Subtract the weight coming out from the weight going in to find the amount of product shrink.	1000 lb 927 lb 73 lb
4	Divide the number of pounds shrunk by the product weight going into the smokehouse, oven, cooler, etc.	73 lb ÷ 1000 lb = 0.073
5	Convert this decimal answer into the percentage of shrink by multiplying by 100.	0.073 × 100 = 7.3% cook shrink

Additional Example Shrink Calculations

The establishment may record or periodically monitor the cooking shrink.

Cooking Shrink Example

The weight of 60 hams on a smokehouse tree going into a smokehouse is 990 lb. The hams have been pumped at 14%. The same tree coming out of the smokehouse weighed 910 lb. What is the percentage of smokehouse shrink?

$$\frac{990 - 910}{990} \times 100 \qquad 80 \div 990 = 0.0808 \text{ or } 8\% \text{ shrink}$$

Similar to the cooking shrink, the establishment may monitor cooler shrink.

Cooler Shrink Example

The weight of 60 hams on a smokehouse tree (hot weight) going into the cooler is 910 lb. The weight of the same 60 hams after the minimum chill time is 895 lb.

$$\frac{910 - 895}{910} \times 100 \qquad 15 \div 910 = .0164 \text{ or } 1.6\% \text{ shrink}$$

Note: When shrinks targets listed in the establishment's written procedure are exceeded, the IPP should discuss this finding at the weekly meeting and document the establishment's response in the MOI. If the establishment has a history or pattern of not meeting the target cooking and chilling shrinks, the IPP should request that the establishment update the written

processing procedure. When the product is cooked corned beef or turkey ham, the IPP should also determine if the corned beef product or turkey ham returned to the weight of the fresh briskets or turkey thigh meat (green weight). When the product is a PFF-controlled product, the IPP should request that the establishment demonstrate that the product is truthfully labeled, e.g., the minimum PFF value in §319.104 is met for qualifying statement in the product name (ham natural juices, ham water added, or ham X%..., etc.)

Added Solution and Shrink Calculation Workshop

The chart below is a written cured ham example processing procedure for establishment 38. Review the information in the chart and answer the questions.

Processing Procedures for Cured, Cooked, and/or Smoked Ham

STYLE Fully Cooked
EST. # 38 PRODUCT Bone-in Ham with Natural Juices Weight Ranges 14/16

PICKLE FORMULA			USUAL PROCEDURES	
100-Gal Pickle weighing 1000 lb	LB	% PUMP		
SALT	92.5		% PUMP	16
CORN SYRUP	40		LB. PRESSURE	60
WATER 100 GAL	833		SPEED	—
PHOSPHATE	30		BEGIN S.H. TEMP.	140° F
NITRITE	1.25		TIME	2 hours
ASCORBATE	3.25		MIDDLE S.H. TEMP.	160° F
			TIME	2 hours
			FINISH S.H. TEMP.	180° F
			TIME	8 hours
			TOTAL S.H. TIME	12 hours
			INT. FINISH F°	152° F
			% S.H. SHRINK	12%
			% COOLER SHRINK	2%
			S.H. HUMIDITY	70
TOTALS	1000.0		COOLER TIME	24 hours

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PROCEDURE REVIEW

DATE	PUMP TEST			SMOKEHOUSE PERIODS						SHRINK			
	GREEN WT	PUMPED WT	% PUMP	FIRST		SECOND		FINISH		SMOKEHOUSE		COOLER	
				TIME	F°	TIME	F°	TIME	F°	HOT WT	%	CHILL	%
2/15	455	528	16.0	1:55	140	2:20	162	8:00	182	472 lb	10.94	458 lb	2.96
2/23	420	486	15.7	2:00	140	2:00	160	8:00	180	432 lb	11.83	422 lb	2.31

Calculate the maximum percent of pump permitted for each restricted ingredient and compare your answers to the procedure chart.

3. Phosphate

   a. 16.66%
   b. 166%
   c. 1.66%

4. Nitrite

a. 16%
b. 160%
c. 1.6%

5. Ascorbate

a. 16.83%
b. 168.3%
c. 1.68%

6. Is the % of pump indicated on the procedure chart acceptable?

a. Yes
b. No

Calculate the pump tests using the procedure chart above and compare your answers.

7. Test dated 2/15

a. 16.04 % pump
b. 1.60 % pump
c. 160.4 % pump

8. Test dated 2/23

a. 15.71 % pump
b. 157.1 % pump
c. 1.57 % pump

Added Solution and Shrink Problems

The % Yield/Shrink task is on the task calendar today. The establishment is producing product labeled Corned Beef Brisket. The target pump on the establishment's written procedure for the beef briskets is 18%. There is a 30-minute drain time for the pumping procedure. The establishment has data indicating that it does % added solution (pump) checks once a month. You select a stainless-steel bin with several corned beef briskets (approximately 90) and follow the establishment to the scale and have them weighed. After the weight of the bin is removed, the beef briskets weigh 895 lb. green. You accompany the bin of beef briskets to the pumping machine and observe them being pumped with a curing solution. You place a U.S Retained tag on the bin with the pumped briskets and write pump test on the tag. Thirty minutes later you return to the processing room and have the bin moved to the scale and weighed. After the weight of the bin is removed, the beef briskets weigh 1,105 lb. pumped. Are the briskets in compliance?

9. Calculate _____ % pump (added solution)

a. 23.46 % pump
b. 234.6 % pump
c. 2.35 % pump

10. Are the briskets in compliance?

a. Yes
b. No

The % Yield/Shrink task is on the task calendar today. The establishment is producing product labeled Country Style Bone-in Hams. The Bone-in hams are place on stainless steel rack and covered with the salt, curing agents, spices, etc. Each rack holds 80 hams. After the hams are placed on the racks but before the dry curing ingredients applied to them, you have the establishment weigh a single rack of hams. The hams weigh 1,280 lb. You place a U.S Retained tag on the rack with the uncured hams and write shrink test on the tag. The establishment begins covering the hams with the dry curing ingredients. Each time the establishment overhauls the hams (adds new dry curing ingredients) they notify you. After 45 days they notify you they are going to hang the hams on tree and move them to the drying (ripening) room. You observe the hams transferred from the rack to a tree and you transfer the U.S. Retained tag to the tree. After another 155 days the establishment informs that they want to remove the hams from drying room and package and label them. While on the way to the packaging room, you have the establishment weigh the hams on the tree. After the weight of the tree is removed, the finished hams weigh 1,042 lb.

11. Calculate_____% shrink

a. 18.59 %
b. 1.86 %
c. 185.9 %

12. Are the hams in compliance?

a. Yes
b. No

Bacon Processing

This section includes information on bacon manufacturing and IPP verifications activities including bacon restricted ingredients and bacon yield determinations. The establishment is responsible for controlling bacon manufacturing to assure that the finished product is in compliance with FSIS Regulations §318.2, §319.107, and §424.22. Calculation examples are provided for reference purposes.

Introduction

Because of problems associated with nitrosamine formation in bacon, FSIS regulations, section 424.22(b) (1) prescribe the regulatory amounts of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) to be used in pumped and massaged bacon. For the immersion curing and dry curing of bacon, maximum amounts of sodium and potassium nitrite are prescribed in section 424.22(b)(2) and (3) of the regulations.

Establishment management must develop written pickle formulas and processing procedures for preparing bacon (9 CFR 320.1(b)(10))and 381.175(b)(6)). The pickle formula and targeted percent pump or pick-up or cure mixture must ensure that the restricted ingredient limits listed below are met.

Regardless of the curing method used, restricted ingredient calculations for bacon are based on the green weight of the skinless belly. For rind-on bacon, e.g., where the skin is sold as part of the finished product, a restricted ingredient conversion calculation is necessary. Nitrate is no longer permitted in any curing method for bacon.

Restricted Ingredient Limits

Pumped and/or Massaged Bacon (rind-off): These bellies are injected with a cure solution or a cure solution is added to them by massaging or tumbling. Pumped and/or massaged bacon must contain 120 ppm ingoing sodium nitrite (or 148 ppm potassium nitrite).

550 ppm ingoing sodium ascorbate or sodium erythorbate (isoascorbate) is required in pumped and massaged bacon, in addition to any prescribed amount of nitrite.

Note: When determining pumped and/or massaged product compliance with the nitrite and ascorbate (or erythorbate) limits, the Agency allows a plus or minus 20% ppm allowance at the time of injecting or massaging due to variables in pumping procedures, draining, purge, etc.

For example: 20% = 0.20, thus 0.20 × 120 ppm nitrite = 24 ppm

120 ppm	120 ppm
- 24 ppm	+ 24 ppm
96 ppm minimum nitrite	144 ppm maximum nitrite

The same calculation can be done for ascorbate or erythorbate (440 ppm minimum, 660 ppm maximum).

The additional solution added to the product from the higher effective or actual % pump than the establishment's target % pump would be considered negligible because the finished product weight must return to green weight.

Note: The 20% variation is only for actual pump test and is not to be used when determining pickle formulas or % pump for the establishment's written procedure.

Immersion Cured Bacon (rind-off): These bellies may be place in a pickle solution containing salt, nitrite, and flavoring. A maximum of 120 ppm of nitrite or equivalent of potassium nitrite (148 ppm) can be used in immersion cured bacon.

Note: The calculation method for nitrite in immersion cured bacon is the same as that for nitrite in other immersion cured products.

Dry Cured Bacon (rind-off): These bellies are cured by covering them with a pre-measured amount of cure mixture. A maximum of 200 ppm of nitrite or equivalent of potassium nitrite (246 ppm) can be used in dry cured bacon.

Note: The calculation method for nitrite in dry cured bacon is the same as that for nitrite in other dry cured products.

Bacon labeled "Dry Cured" may not be injected with, or immersed in, a curing solution.
Bacon labeled "Dry Salt Cured" may contain a curing solution injected directly into the tissues but not through the circulatory system. It is then covered with dry curing mixtures.

Pumped, Massaged, Immersion Cured, or Dry Cured Bacon (rind-on): The maximum limit for ingoing nitrite and sodium ascorbate or sodium erythorbate must be adjusted if bacon is prepared from pork bellies with attached skin (rind-on). A pork belly's weight is comprised of approximately 10 percent skin. Since the skin retains practically no cure solution or cure agent, the maximum ingoing nitrite and sodium ascorbate or erythorbate limits must be reduced by 10 percent. For example, the maximum ingoing limit for nitrite and sodium ascorbate or erythorbate for pumped pork bellies with attached skin would be 108 ppm [120 ppm − 12 ppm (120 × .10)] and 495 ppm [550 ppm − 55 ppm (550 × .10)], respectively.

Written Bacon Processing Procedure Ingoing Restricted Ingredient Determination

Calculation Equations

The equation for determining nitrite compliance in a proposed pumped or massaged bacon processing procedure is:

$$\frac{\text{lb. nitrite} \times \%\ \text{pump} \times 1{,}000{,}000}{\text{lb. pickle}} = \text{ppm}$$

In pumped and/or massaged bacon, this equation can be used to determine:

The permitted weight of nitrite allowed, if you know the weight of the pickle solution and the target percent pump to be used.

The minimum weight of the pickle solution that can be made, if you know the weight of the nitrite and the target percent pump to be used.

The maximum percent pump, if you know the weight of the nitrite and the weight of the pickle solution.

Whether or not a procedure will be in compliance with the regulations, if you know the weight of the nitrite, the weight of the pickle solution, and the target percent pump to be used.

To determine nitrite compliance based on the effective or actual % pump, you can use the equation above by replacing the target pump with the effective or actual % pump.

Note: You can use the calculation above in conjunction with the % Gain formula (shown below, which calculates the percent gain/pick-up) to verify amount of RI at the time of pumping.

$$\frac{\text{(pumped or treated) weight} - \text{green weight}}{\text{green weight}} \times 100 = \%\ \text{pump or pick-up}$$

Alternatively, you could use the following variations to the equation on the previous page:

$$\frac{\text{lb. nitrite} \times 1{,}000{,}000}{\text{lb. pickle}} = \text{ppm nitrite in the pickle}$$

ppm nitrite in the pickle × effective or actual % pump = ppm nitrite in the bacon

IPP can use the steps in following table to determine if a proposed bacon processing procedure will produce product in compliance with the regulations.

STEP		EXAMPLE
1	Determine the weight of the nitrite added to the pickle solution, the total weight of the pickle solution, and the target % pump from the establishment's written procedure.	Pickle Formula Water 1996.3 lb. Salt 302.2 lb. Sugar 156.2 lb. Sodium Phosphate 31.3 lb. Sodium Erythorbate 11.5 lb. Sodium Nitrite 2.5 lb. Total 2500 lb. *Target pump is 12%*
2	If all three factors are known, one can just solve for ***ppm*** and compare the answer with the regulation to determine if the procedure produces bacon in compliance. ***Note:*** *The ingoing ppm of sodium erythorbate and sodium phosphate can be determined by replacing the pounds of nitrite with the pounds of sodium erythorbate and sodium phosphate and performing the mathematics.*	We have 2.5 lb. of nitrite and want to make 2500 lb. of pickle and pump at a level of 12%. Is this in compliance? $n = \frac{2.5 \times 0.12 \times 1{,}000{,}000}{2500}$ n = 120 ppm nitrite (in compliance)

Ingoing Nitrite at the Time of Pumping Determination

Example 1

IPP can use the steps in the following table to determine if bacon is in compliance at the time of pumping and/or massaging. The pickle formula in the table above will be used as the example in this table.

STEP		EXAMPLE
1	Multiply the weight of the sodium nitrite by 1,000,000.	2.5 lb. sodium nitrite × 1,000,000 = 2,500,000 ppm nitrite.
2	Divide this figure by the weight of the pickle solution.	2,500,000 ÷ 2,500 = 1000 ppm nitrite in the pickle solution.
3	Multiply this figure by effective or actual % pump to obtain ppm. Refer to the How to Determine the Percentage of Added Solution section previously discussed in this handout to learn how to determine the effective or actual % pump.	1000 ppm × 0.096 (9.6 % effective pump) = 96 ppm ingoing nitrite in the pork bellies. Product ***is*** in compliance with the 20% ppm allowance.

Example 2

Establishment 38 has a vat of uncured (green) bellies weighing 1,635 pounds. After pumping and draining the vat of bellies weighs 1,782 pounds. The establishment's written bacon production procedure calls for using 1.2 lb. of sodium nitrite in a pickle weighing 1,000 lb. and a 10% pump.

Step 1: *Determine effective % of pump (use the added solution equation)*

1,782 (treated wt) – 1,635 (green wt) = 147 ÷ 1,635 (green wt) = 0.0899 × 100 = 8.99% pump or 9.0% pump

Step 2: *Determine ppm of ingoing nitrite based on effective or actual % of pump (use the ppm equation from Table 1)*

$$ppm = \frac{1.2\ lb. \times 0.09 \times 1{,}000{,}000}{1{,}000\ lb.} = 108\ ppm$$ *(above 96 ppm which is the 20% variation)*

The establishment's process produces bacon that is in compliance for ingoing nitrite!

Bacon Yield Determination

In accordance 9 CFR 319.107, the weight of the pork bellies produced by pumping, immersion, massaging, or tumbling that are ready for slicing, packaging and labeling as "Bacon" must not exceed the green (fresh uncured) weight of the pork bellies. In other words, the weight of the cured pork bellies must return to green weight or their yield CANNOT be greater than 100%. FSIS does not routinely sample for added solution or ingredients; therefore, the determination of solution above the green weight is accomplished by the IPP's in-plant % yield tests. IPP assigned to a bacon producing establishments will verify that the bacon yield is in compliance when performing %Yield/Shrink task.

Bacon Yield Determination Method

Note: When determining yield and comparing green weight to pumped weight, it is not necessary to compare the same uncured pork bellies as long as a comparison is done on pork bellies produced under similar conditions and the subgroup (in this case all 100) are in the **same weight range**.

Step 1: Use a subgroup such as 50 uncured (green) pork bellies of the same weight range (e.g., 10-12 pounds). Normally bellies are skinned and trimmed prior to pumping.

Step 2: Determine total weight of 50 cured pork bellies that have:

- Completed the chilling cycle as described in the establishment's processing procedure.
- Previously undergone skinning/trimming prior to pumping.

If any trimming or removal of any portion of pork bellies occurs after pumping/massaging, the weight of these trimmings must be added when determining the finished weight.

Note: If the green weight must be calculated with the skin on, the finished weight figures must include the weight of the skin.

Calculation Equation

Determine the yield by inserting the green (fresh, uncured) weight pork bellies and the finished weight (cured bellies ready for slicing) into this equation:

$$\text{Percent yield} = \frac{\text{finished weight}}{\text{green weight}} \times 100$$

Note: Finished weight is the weight of the meat and/or poultry plus the weight of any ingredients added during processing minus the weight loss (shrink) from smoking, cooking, cooling or dying.

Bacon Yield Determination Example

Establishment 38 produces bacon. The IPP selects 50 chilled bellies from the cooler and has them weighed. The total green weight is 705 lb. The IPP selects 50 uncured bellies and has them weighed. The total finished weight is 717 lb.

The percent of yield is:

$$\frac{717 \text{ lb.}}{705 \text{ lb.}} \times 100 = 101.7\%$$

Remember that IPP are to determine whether product complies with the regulations based on production lots or process controls rather than on an individual % yield result. Although a % yield result of 101.7 is above 100% before concluding there is regulatory noncompliance, the IPP should determine if the establishment is routinely conducting % yield tests. If so, when the average of the establishment's recent yield results is 100% or less, then there is no regulatory noncompliance. However, when the establishment's yield results also indicate a pattern or history of producing bacon with a yield above 100% or the establishment is not routinely conducting bacon yield determinations, then the % yield result of 101.7 would be considered noncompliant.

*** If you incur this situation discuss with your supervisor before making a determination.

Bacon Calculations Workshop

Establishment 38 has recently expanded its production of cured product to include curing and slicing bacon. The establishments pickle formula and written processing procedure on file is provided below. The Labeling Product Standards task appears on the task calendar today. Review the establishments procedure chart and answer the questions related to the bacon processing procedure.

Processing Procedure for Smoked Bacon

STYLE Heat Treated
EST. # 38 PRODUCT Bacon Weight Ranges 10/12

BACON PICKLE FORMULA				USUAL PROCEDURES	
SKIN OFF X	SKIN ON ___	LB	OZS	% PUMP	12
WATER		1990.30		LB. PRESSURE	60
SALT		300.20		DRAIN TIME	30 minutes
SUGAR (DEXTROSE)		150.30		TIME IN SMOKE	7-7.5 hours
SODIUM PHOSPHATE		31.25		S.H. HUMIDITY	70-75%
NATURAL FLAVORINGS		14.00		SMOKEHOUSE TEMP	125-130°F
SODIUM ERYTHORBATE		11.45		BACON INTERNAL TEMP	126-128°F
SODIUM NITRITE		2.50		TIME HELD	1-7 Days
				% COOLER SHRINK	2-4%
TOTALS		2500			

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Based on the bacon pickle formula identified in the chart, calculate the ingoing parts per million (ppm) for:

3. Sodium erythorbate

    a. 549.6 ppm
    b. 54.96 ppm
    c. 5.49 ppm

4. Sodium nitrite

    a. 120 ppm
    b. 12 ppm
    c. 1200 ppm

The establishment is producing bacon using the processing procedure above, so you decide to proceed to the pumping machine and select 50 pork bellies from lot 1A1 (weight range 10-12 lb.). The 50 bellies weigh 545 lb. before pumping. After pumping, the same bellies weigh 604.5 lb.

5. The actual % of pump is:

    a. 10.9 %
    b. 1.09 %
    c. 109 %

NOTE: Base your calculations on the amount of sodium nitrite in the bacon pickle formula in the processing procedure above.

6. The ppm of ingoing nitrite (based on the actual pump) is:

a. 109 ppm
b. 10.9 ppm
c. 1.09 ppm

7. Will the pump procedure will produce bacon in that is compliance?

a. Yes
b. No

The % Yield/Shrink task appears on the task calendar today. You select 50 uncured pork bellies from lot 2B3 (12-14 lb. weight range). The 50 pork bellies weigh 635 lb. (green weight). Then you select 50 cured/smoked bellies from the cooler. These bellies range in weight from 12-14 lb. each, and weigh 649 lb. The establishment does not routinely perform and document bacon yield determinations.

8. The % yield is:

a. 102
b. 10.2
c. 1.02

9. Is the bacon in compliance with 9 CFR 319.107?

a. Yes
b. No

06 - Meat and Poultry Products with Added Solutions

Objectives

1. After completion of this module, the student will be able to:
2. Identify some enzyme tenderizers that are approved for use on meat or poultry cuts.
3. Describe how to perform the X percent (%) solution task.
4. Determine when there is noncompliance with the added solution regulatory requirements.
5. Given example problems, calculate the amount of a water-based solution (e.g. curing, marinating, or flavoring) added to both raw and cooked products to verify the percentage of solution in the product name designation is accurate and truthful.

Reference Material

9 CFR Parts 317 and 319
9 CFR 381 Subpart N and P
9 CFR Part 424
FSIS Directive 7000.1 and 7120.1
Food Standards and Labeling Policy Book
Processing Inspectors' Calculations Handbook 7620.3

Introduction

Water-based and oil-based solutions (curing, tenderizing, marinating, basting and flavoring) are added to raw meat and poultry cuts for several purposes. These solutions are added by pumping (injecting), tumbling, massaging, dipping, or immersing to impart favorable quality and sensory characteristics and add weight to the finished product. For instance, enzyme tenderizing solutions are often added to raw beef cuts from no-roll carcasses (i.e., a carcass that did not grade as prime or choice) or raw poultry cuts from mature birds to reduce the toughness of connective tissue in the cut. The proteolytic enzymes degrade several tissue proteins, including collagen and elastin, which are major constituents of connective tissue to improve tenderness. Curing solutions are added to meat and poultry cuts to impart specific color and flavoring, but they also serve to preserve the product for food safety and quality purposes. Marinating and basting solutions add unique flavors to the meat or poultry cut and also improve the texture of the cut.

Solutions may be added to raw bone-in or boneless meat and poultry cuts at various amounts unless such use is not allowed or otherwise restricted by FSIS policy or regulation. Some meat and poultry products have a standard of identity which identifies the amount of solution allowed in the product.

Added Solutions Requirements

The Food and Drug Administration (FDA) approves all food safe for human consumption. FSIS additionally has an approval process for determining food ingredients and additives safe and suitable for use in meat and poultry products (9 CFR 424.21 and Directive 7120.1). FSIS additionally determines standards of identity for some products through regulations or as outlined in the Food Standards and Labeling Policy Book. Under certain circumstances, when establishments add solutions to meat and poultry products, these solutions must be declared on the label.

Descriptive Designations - Raw Meat and Poultry Products

Raw (not heated or cooked) meat and poultry products with added solutions that do not meet their standard of identity and raw meat or poultry products with added solutions that do not have a standard of identity are subject to the Added Solutions final rule in 9 CFR 317.2(e)2 and 381.117(h). Since addition of solutions to meat or poultry products changes the nature of the product, the label needs to identify the percentage and composition of the solution. These regulations require establishments to inform the consumer that the raw product contains an added solution and make them aware of the ingredients in the solution. The standardized or common and usual name with a truthful descriptive designation distinguishes the product with the added solution from the standardized product.

In accordance with 9 CFR 317.2(e)2 and 381.117(h), establishments must ensure the product name (standardized or common and usual) on the label contains a descriptive designation that includes: 1) the percentage of added solution (which must appear as a number and the percent symbol (%), 2), a declaration that may use the words “containing" or “contains" (such as, “contains 15% added solution of water and salt,” or “containing 15% added solution of water and teriyaki sauce”), and 3) the common or usual name of all individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight. The product name and descriptive designation must be printed in a single easy-to-read type style and color, and must appear on a single-color contrasting background. The print may appear in upper- or lower-case letters with the lower-case letters not smaller than 1/3 the size of the largest letter. The product name may not include the word “enhanced.”

Raw corned beef, corned beef brisket, corned beef rounds, other corned beef cuts and cured beef tongue have standards of identity in 9 CFR 319.100-103. Corned beef brisket (§319.101) can contain no more than 20% added solution. Corned beef (§319.100), Corned beef rounds, other corned beef cuts (§319.100) and cured beef tongue (§319.103) can contain no more than 10% added solution. These products may contain up to the regulatory maximum percent curing solution (20% or 10%) without the presence of the solution being declared on the label. Verify these regulatory limits by calculation when you perform the %Yield/Shrink Task. When these beef products are treated with a solution at levels that exceed the regulatory limit, the presence and amount of the ingredients must be declared as part of the product name. The percentage of solution declared in the product name is the percentage of added solution above the green weight of the beef cut or part. “Corned Beef Contains Up to 35% of a Solution of Water, Salt, Natural Flavorings, Sodium Erythorbate, Garlic and Sodium Nitrite” would be an acceptable product name. Verify this percentage on the label using the X% Solution Task.

X% Solution Task

- IPP verify that the value inserted into the “X” is accurate for products labeled with a descriptive designation. For example. A descriptive designation could read, “Contains up to X% of ..”
- The contains statement would refer to solution which has been marinated, injected, pumped, etc.
- The X% solution task only verifies the label truthfulness as it pertains to the percent of added solution declared on the label.

For raw meat and poultry products, the percent added ingredients for the descriptive designation is determined by subtracting the fresh (green) weight of the article from the weight of the finished product, (e.g., after being pumped or treated), dividing by the fresh (green) weight, and multiplying by 100. “Pumped or treated” refers to any method used to increase the weight of the raw meat or poultry, e.g., tumbling, vacuum tumbling, massaging, marinating, injecting, and dipping.

The following formula is used to calculate the “X:”

$$\frac{[(\textit{pumped or treated) weight - green weight}]}{\textit{green weight}} \times 100 = \%\ \textit{added solution (ingredients)}$$

Note: This equation is also used to calculate %Gain, as it is expressed in the Calculation Aid.

X% Solution Labeled Meat and Poultry Products
Raw Product Example

Given - Product name on the label:

“Corned Beef Brisket, Contains Up to 25% of a Solution of Water, Salt, Sodium Phosphate, and Sodium Nitrite”

$$\frac{[(\textit{pumped or treated) weight - green weight}]}{\textit{green weight}} \times 100 = \%\ \textit{added solution (ingredients)}$$

Step 1: Weigh the beef briskets. The weight of a steel tub of fresh uncured beef briskets weighs (less the tare) 127.8 lb. This is the green weight.

Step 2: Weigh beef briskets after pumping. After pumping the same tub of beef briskets weighs (less the tare) 159.6 lb.

Step 3: Subtract the green weight from the pumped weight

$$\begin{array}{r} 159.6\ \text{lb.} \\ -\ 127.8\ \text{lb.} \\ \hline 31.8\ \text{lb.} \end{array}$$

Step 4: Divide weight difference by the green weight

$$31.8\ \text{lb.} \div 127.8\ \text{lb.} = 0.2488$$

Step 5: Convert the decimal answer to a %

$$\begin{array}{r} 0.2488 \\ \times\ 100 \\ \hline 24.88\% \end{array}$$

Since “up to 25%” added solution is declared in the descriptive designation in the product name, this product is in compliance.

Tenderized Raw Meat and Poultry Products

In some establishments, enzyme tenderizers, such as papain, bromelain, and Aspergillus oryzae (a mold) are used on meat and poultry cuts to degrade connective tissue proteins and improve the tenderness of the cut. They are applied to carcasses and cuts by direct application to the surface dipping, immersion or injection. The enzymes are activated when the meat or poultry cut is heated during cooking by the consumer. As the temperature rises, the enzymes are denatured and become inactive.

Tenderizing agents that may be applied to raw meat and poultry cuts and their regulatory limits are identified in 9 CFR 424.21(c) and in FSIS Directive 7120.1. The regulation states that a solution consisting of water and a proteolytic enzyme (e.g., papain) applied or injected into the tissue of a raw meat or poultry cut shall not result in a weight gain (solution pick-up or pump) of more than 3% above the weight of the untreated cut (green weight). When proteolytic enzymes are used on raw meat and poultry cuts, the qualifying statement "Tenderized with (Approved Enzyme)" must prominently appear on the label.

If an establishment produces a tenderized product with more than 3% added solution, it must have a descriptive designation for the amount above 3%. The percent solution reflected on the label for tenderizers is the actual percentage minus the 3% which is already allowed. For example, if the establishment added 20% of a flavoring and proteolytic enzyme solution to a meat or poultry cut, the name of the product must show that the product contains 17% added solution in a descriptive designation that meets the requirements in 9 CFR 317.2(e)(2) and 381.117(h). When a descriptive designation and the "Tenderized with (Approved Enzyme)" qualifying statement appear on the label, the "Tenderized with (Approved Enzyme)" may not intervene between the product name and descriptive designation. The product name may read: "Beef Skirt Steak, Contains Up To 17% Solution of Water, Natural Flavor, Salt, Spice, Sugar, Hydrolyzed Corn Protein, Spice Extract, Citric Acid, Sodium Lactate, Sodium Phosphate, Soybean oil, and Yeast Extract - Tenderized with Bromelain." The "tenderized" qualifying statement may be incorporated into the descriptive designation, for example, "Beef Skirt Steak Tenderized and Flavored with 17% Solution of Water, Natural Flavor, Salt, Spice, Sugar, Hydrolyzed Corn protein, Spice Extract, Citric Acid, Sodium Lactate, Sodium Phosphate, Soybean Oil, and Yeast Extract."

When a descriptive designation and a product name qualifier (e.g., "Tenderized with Papain") appear on the label, the Tenderized with Papain may not intervene between the product name and descriptive designation. The qualifying statement and descriptive designation can be combined. For example, "Beef Skirt Steak Tenderized and Flavored with 7% Solution of water, salt, spices, and papain."

Performing the X% Solution Task (for tenderized product)

- IPP verify that the value inserted into the "X" is accurate for products labeled with a descriptive designation. For example. A descriptive designation could read, "Contains up to X% of..." For a tenderized product, the green weight has increased by more than 3% tenderizing solution.
- Weigh a subgroup of meat or poultry before the tenderizing solution is applied.
- Determine the maximum amount of tenderizing solution multiplying the green weight by 0.03 (3%)
- Weigh the same group of meat or poultry after tenderizing solution is applied

- Compare the treated subgroup weight to the maximum treated product
- Calculate the added solution using the formula then subtract 3%. This answer is the adjusted percentage that should be declared on the label.

X% Solution Labeled Meat and Poultry Products
Raw Product Example
Tenderizing Agents (Enzyme) Example

$$\frac{[(\textit{pumped or treated}) \textit{ weight - green weight}]}{\textit{green weight}} \times 100 = \%\ \textit{added solution (ingredients)}$$

Given - Product name on the label:

"Beef Skirt Steak Tenderized with Bromelain, Contains up to 15% Solution"
200 oz represents the green weight of the skirt steak. After treated with the tenderizer, the weight is 236 oz.

Step 1: 236 oz - 200 oz = 36 oz

Step 2: $\frac{36 \text{ oz}}{200 \text{ oz}} = 0.18 \times 100 = 18\%$

15% was declared on the label. Subtract the 3% allowed, 18%-3% = 15%. In Compliance.

Note: The % Yield/Shrink Task is performed to verify that the amount of tenderizing solution does not exceed 3% above green weight. The label would not have an X% declared. Instead, it would just have the product name qualifier, e.g., "tenderized with..." The same formula would be used to make this determination.

Meat and Poultry Products Treated with Added Enzyme Solutions - Workshop 1

1. First Name
2. Last Name

3. Which of the following enzyme is not approved for tenderizing meat and poultry cuts?

    a. protozoa
    b. Aspergillus oryzae
    c. bromelain

4. The maximum pick-up of solution used for tenderizing purposes is (without 20% allowance):

    a. 1%
    b. 2%
    c. 3%

5. The regulations do not require that proteolytic enzymes be approved if they tenderize the product.

    a. True
    b. False

6. Untreated boneless chicken breasts weigh 160 lb. How much can the boneless chicken breasts weigh after being treated with a tenderizing solution (without 20% allowance)?

    a. 160 lb.
    b. 164.8 lb.
    c. 170.2 lb.

7. An establishment produces a product labeled “Beef T-Bone Steak, Tenderized with Papain.” While performing the % Shrink/Yield task, the IPP randomly selected 10 beef T-bone steaks to conduct an added solution or pick-up test. The untreated steaks weigh 12 oz each. After the steaks are dipped in the enzyme solution, the same 10 steaks weigh 123.9 oz. The establishment does not implement a procedure for monitoring the amount moisture the meat and poultry cuts it tenderizes picks up. The percent solution pick-up is:

    a. 3.15%
    b. 3.25%
    c. Less than 3%

8. Based on the answer to the previous question, the IPP would:

    a. Attach a U.S. Retained tag to all tenderized Beef T-Bone Steaks produced on the shift until the establishment takes corrective action.
    b. Weigh additional sample units as another verification pick-up test.
    c. Allow product to move freely.

Cooked or Raw Cured Pork Products

Cooked and raw cured pork products covered by the cured pork products regulations (9 CFR 319.104 and 105) have labeling schemes for indicating the presence of added solutions in these products listed in the regulation. For example, the presence and amount of added ingredients must be declared as part of the product name, e.g., "Ham and Water Product-- X% of Weight is Added Ingredients." The percent of added ingredients in the finished product is inserted as the "X" value.

Cooked Poultry Products

Turkey ham cured and cooked has a standard of identity in 9 CFR 381.171 that requires the finished product weight to be no more than the original weight of the turkey thigh meat prior to curing. In accordance with the Food Standards and Labeling Policy Book (FSLPB), turkey ham weighing more than the original weight of the turkey thigh meat used prior to curing shall be descriptively labeled as "Turkey Ham," with words that specify the amount of the additional ingredients, e.g., "and X% Water," "With X% Water Added" or "Turkey Ham and Water Product X% of Weight is Added Ingredients". The ingredients of the added solution may be incorporated into the product name, e.g., "Turkey Ham and Water Product X% of Weight is Added Water, Salt, Dextrose, Sodium Phosphate, and Sodium Nitrite." The X is filled in with a percent determined by subtracting the original weight of the turkey thigh meat from the weight of the cooked finished product. "Turkey Ham, Cured Turkey Thigh Meat, 12% Water Added" is an example product name.

Added Solutions in Cooked Product

The FSLPB provides requirements for cooked red meat products containing added substances and labeling prominence guidelines for cured, cooked products with added substances that do not return to green weight.

Cooked Cured Beef and Pork Products

Cooked cured beef products and cooked cured pork products not addressed by the cured pork products regulation (9 CFR 319.104), that weigh more than the weight of the fresh uncured article (green weight), may be prepared if they are descriptively labeled to indicate the presence and amount of the added solution. Acceptable product names include: "Corned Beef and X% Water" or "Cured Pork and Water Product, X% of Weight is Added Ingredients," and "Beef Pastrami Contains Up to X% of a Solution." The ingredients of the solution may accompany the product name or appear in locations prescribed for ingredient statements. If product name qualifiers, such as "X% of Weight is Added Ingredients," are used, the labeling prominence guidelines used for cured pork products as found in 9 CFR 319.104(b) apply.

Cooked Uncured Meat Products

Labeling requirements for uncured meat products to which solutions are added to impart flavor and other sensory characteristics then are subsequently cooked. It does not apply to solutions containing ingredients used to extend a product, such as isolated soy protein (ISP) and carrageenan.

These products must be labeled to identify the amount and composition of solutions added. For a product to be truthfully labeled, a differentiation must be made from a cooked product (e.g.,

Cooked Beef) that has had no solution added to it from a cooked product labeled with the same name (e.g., Cooked Beef) that has had solution added. Remember, meat and poultry products with added solutions that are heat treated or cooked are not subject to the Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions final rule.

There are two allowable methods of providing descriptive labeling necessary to distinguish cooked meat products with added solutions from the traditional products without added solutions.

Establishments may choose either of two labeling methods:

Labeling Method 1

When solutions are added to uncured meat products prior to cooking and return to equal to or less than the green weight after cooking, words such as "seasoned" or "flavored," are to be used to reflect that solutions have been added, e.g., "Seasoned Cooked Beef." While solution has been added, all the solution has been “cooked out.” (Verify this requirement while performing the General Labeling Task.)

Labeling Method 2

Uncured meat products that weigh more than the green weight after cooking must be labeled with a product name qualifying statement indicating the amount of solution remaining after cooking, e.g., “Contains X% of a Solution.” The ingredients of the solution may accompany the qualifying statement or appear in locations prescribed for ingredient statements, e.g., “After cooking, Contains X% of a Seasoning Solution of Water…..” The qualifying statement must be at least one-fourth the size of the largest letter in the product name. If the ingredients of the solution accompany the qualifier, they must appear in print at least one-eighth the size of the most prominent letter in the product name.

For cooked products, the percent added solution for the label statement is determined by subtracting the fresh (green) weight of the article from the weight of the finished cooked product, (e.g., after injecting or marinating **and cooking**), dividing by the weight of the finished product, and multiplying by 100.

X% Solution Labeled Meat and Poultry Products - Cooked Product Example

$$\frac{\textit{[finished weight - green weight]}}{\textit{finished weight}} \times 100 = \%\ \textit{added solution}$$

Given - Product name on the label:

“Beef Pastrami Contains up to 10% of a Solution” in the product name on the label.

Step 1: Weigh beef top rounds. The weight of a stainless-steel vat of fresh uncured beef top rounds weighs (less the tare) 161.4 lb.

Step 2: Weigh the top rounds after cooking and chilling. The same beef top rounds finished weight is 178.7 lb. (less the tare).

Step 3: Subtract the green weight from the finished weight

178.7 lb.
− 161.4 lb.
17.3 lb.

Step 4: Divide weight difference by the finished weight

17.3 lb. ÷ 178.7.8 lb. = 0.0968

Step 5: Convert the decimal answer to a %

0.0968
× 100
9.68%

Since 10% added solution is declared in the containing statement. This product is in compliance.

NFSCP PHIS Tasks

Performing the X Percent (%) Solution Task

Inspection program personnel (IPP) perform the X percent (%) solution task in establishments that are producing meat or poultry cuts, parts, and products containing added solutions that are required to have the percent (X) of the solution identified in the product's name to be truthfully labeled.

When performing this task, IPP select an appropriate product and verify compliance with regulatory requirements by reviewing establishment records and labels, calculating the amount of solution added to the product and comparing the result with the regulatory requirement, when applicable. Compare the calculated amount of added solution with the X% declaration in the product's name.

IPP have the establishment weigh a subgroup (sample) or batch of product before and after the appropriate step in the process (pumping, injecting, dipping, or cooking and chilling). The number of pieces selected and weighed should be representative of the lot size. For example, the IPP may select 20 or 30 pieces of meat or poultry and have them weighed before the solution is applied (green weight) and 20 or 30 pieces after the appropriate processing step, e.g., pumping, dipping or cooking and chilling, and have them weighed (finished weight). After obtaining the subgroup weights (green and finished weights), perform a calculation to verify the percentage of solution (the value for the "X") in the product name is accurate and truthful.

To accurately determine the percent of the solution added to a **raw** product, IPP have to differentiate between an **actual** or **effective** percent pump or pickup. (This determination is not necessary for cooked products.)

The **actual percent pump or pick-up** is the amount (pounds) of a water-based or oil-based solution (curing, tenderizing, marinating, etc.) pumped or injected into or picked up by a piece of meat or poultry that ***is not*** held for a period of time and allowed to drain prior to being further processed. This is expressed as a percentage of the weight of the meat or poultry before it is pumped with the solution.

The **effective percent pump or pick-up** is the weight gained (expressed as a percent) by the meat or poultry **after draining** for the specified amount of time in the establishment's written procedure and represents the amount of reactive solution that remains in the product. Any reactive ingredients (nitrites, phosphates, enzymes, flavors, etc.) in the solution are thought to remain in solution during the drain time after pumping, rather than reacting immediately with the meat or poultry protein. Therefore, using the effective percent pump in calculations more accurately reflects the ingoing amount of solution and reactive ingredients.

Weighing the **same** pieces of meat or poultry weighed before and after the solution application is the most accurate way to determine the percent added solution.

Identification of the pieces of meat or poultry should be maintained. IPP may use another method to determine the percent added solution under certain circumstances, e.g., the scale and pumping or injecting apparatus are not in the same area or room. In this situation, IPP **may** select and have the pumped or treated pieces of meat or poultry weighed before selecting fresh unpumped or untreated pieces **provided** that the pieces **are uniform** in size and weight (e.g., lotted into 2-to-3 lb. weight ranges). The green weight is determined from different pieces of meat or poultry. All pieces selected must be in the same weight range.

Compliance Determinations

FSIS allows the added solution to be 20% above the X% solution declaration in the product name, before there is noncompliance, provided that the establishment does not have a history of (or is routinely) adding the solution above the percentage declared in the product name. For cured products with X% solution declarations, the establishment is allowed up to 20% solution above the percent declared in the product name, provided the establishment is not routinely adding solution above the percentage declared in the product name ***AND*** the added solution does not result in any restricted ingredient (e.g., cure agent) regulatory limit being exceeded.

The 20% solution allowance relates to the truthfulness of the X% in the product name and not for other regulatory limits or product standards of identity.

When the IPP's added solution or pick-up test reveals that the product has gained more than 3% tenderizing solution and there is no descriptive designation indicating the percent above 3% in the product name, he or she needs to determine if the establishment has data that demonstrates it is producing tenderized product in compliance with the regulatory limit. For instance, the establishment may be implementing a written program that includes conducting pick-up tests and the records show the process is still under control even though the IPP's pick-up test is over the regulatory limit. Normal variation in the process of tenderizing meat and poultry cuts may occasionally result in a solution pick-up test being over 3%. When the establishment does not have data that demonstrate control over the process of tenderizing meat and poultry cuts and the IPP's pick-up test exceeds the regulatory limit, the IPP should retain all of the product on hand from that shift's production.

Keep in mind that while many establishments have some type of quality control (QC) program, these are not required by regulation. IPP may exercise additional discretion when the establishment's program is effective, and this data can be used as additional records.

20% Allowance Example

Given:
A Turkey Breast Tenderloin label reads..."Contains 10% Solution..."

10 x .20 (20%) = 2%, thus 12% with the 20% allowance

Noncompliance

After performing the tasks, IPP are to use the GAD thought process to determine compliance.

Examples of Noncompliance:

- Label, solution formula or processing procedure is not on file.
- LPDS temporary approved label is used beyond the expiration date.
- Label requiring sketch approval by LPDS has not received sketch approval by LPDS
- Missing mandatory feature, e.g., safe handling instructions or handling statement.
- Missing product name qualifying statement
- Solution ingredients not listed in the descriptive designation
- Ingredients not listed in descending order of predominance in ether the descriptive designation and/or ingredients statement
- Inaccurate ingredients statement
- Any false or misleading information
- A RI ingredient, e.g., nitrite exceeds the maximum amount allowed
- The % solution declaration (X%) listed on the label is false or misleading (not truthful)

X% Solution Labeled Meat and Poultry Products Summary - Workshop 2

Using the methods outlined in this handout, perform the required calculation to verify the X% solution label declaration is accurate and the product name is truthful.

Scenario A

You are a CSI assigned to an establishment that adds water-based tenderizing and flavoring solutions to raw meat and poultry products. When you arrive at the establishment, you log-on to your computer and bring up the task calendar in PHIS. The X Percent (%) Solution task is on the task calendar for today. You start the X Percent (%) Solution task by proceeding to the processing room. You know this establishment has a history of exceeding the regulatory limit for this added solution, therefore they are not given a 20% allowance. The establishment is applying a tenderizing and flavoring solution to beef skirt steaks. After the solution is added to the skirt steaks, the treated beef skirt steaks are moved to the packaging room and vacuum packaged in a plastic film with the pre-printed label below.

The establishment uses a tumbler to mechanically agitate the tenderizing and flavoring solution into the beef skirt steaks. You notice beef skirt steaks in stainless steel containers and a plastic container of solution with the label staged next to the tumbler. You have the production supervisor move the stainless-steel containers and plastic container with the tenderizing/flavoring solution to the scale. After removing the tare weight of the containers, the beef skirt steaks weigh 199.5 lb. and the solution weighs 43 lb. The tumbler runs for 15 minutes, and the solution is completely absorbed, which makes the treated weight equal to the addition of the green weight and the weight of the solution.

1. First Name
2. Last Name

3. Calculate the percentage of solution added to the beef skirt steaks and select your answer.

    a. 21.55%
    b. 22.02%
    c. 17.00%

4. Is the X% solution label declaration in compliance?

    a. Yes
    b. No

Scenario B

You are a CSI assigned to an establishment that adds water-based flavoring solutions to raw beef cuts that are subsequently cooked to produce roast beef, cooked beef and beef pastrami. The cooked beef products do not return to green weight; thus, the finished beef products have an X% solution qualifying statement in the product name. When you arrive at the establishment, you log-on to your computer and bring up the task calendar in PHIS. The X Percent (%) Solution task is on the task calendar for today. You start the X Percent (%) Solution task by proceeding to the processing room. The establishment is pumping beef top rounds with a seasoning solution today. After the top rounds are cooked, they are sliced in the RTE product packaging room and the slices are vacuum packaged in 7 oz plastic trays that have the following label.

The establishment's processing procedures attached to the label indicates that the beef top rounds are weighed and grouped into 10 to 12 lb. or 12 to 14 lb. weight ranges. The top rounds are pumped with 30% of a flavoring/seasoning solution. The top rounds are cooked in an oven for 2 to 2.5 hours based on the weight range to an internal temperature 145 degrees Fahrenheit for 3 minutes. The cook shrink is 8 to 9% and the chiller shrink is 2 to 3%.

You have the production supervisor assist you in weighing 15 unpumped (green) top rounds from lot A2456. The 15 unpumped top rounds weigh 169.5 lb. The next day, before the top rounds are moved from the cooler to the RTE product room for slicing, you have the production supervisor assist you in weighing 15 cooked top rounds from lot A2456. These top rounds weigh 214.6 lb. The establishment does not routinely monitor the amount of solution remaining (or the "X" % on the label) for its finished cooked beef product. The 20% allowance is not given.

5. Calculate the percentage of solution remaining in the beef top rounds and select your answer.

   a. 26.60%
   b. 25.04 %
   c. 21.01 %

You review the MOIs for the establishment and find that the previous three added solution tests for this product were above the 20% declared on the product's label but were within the 20% solution allowance. Each time the IPP's added solution calculation was above the percentage declared in the product name (20%), the IPP discussed the added solution result with establishment management at the weekly meeting. Each time the establishment stated it would adjust the pumping procedure.

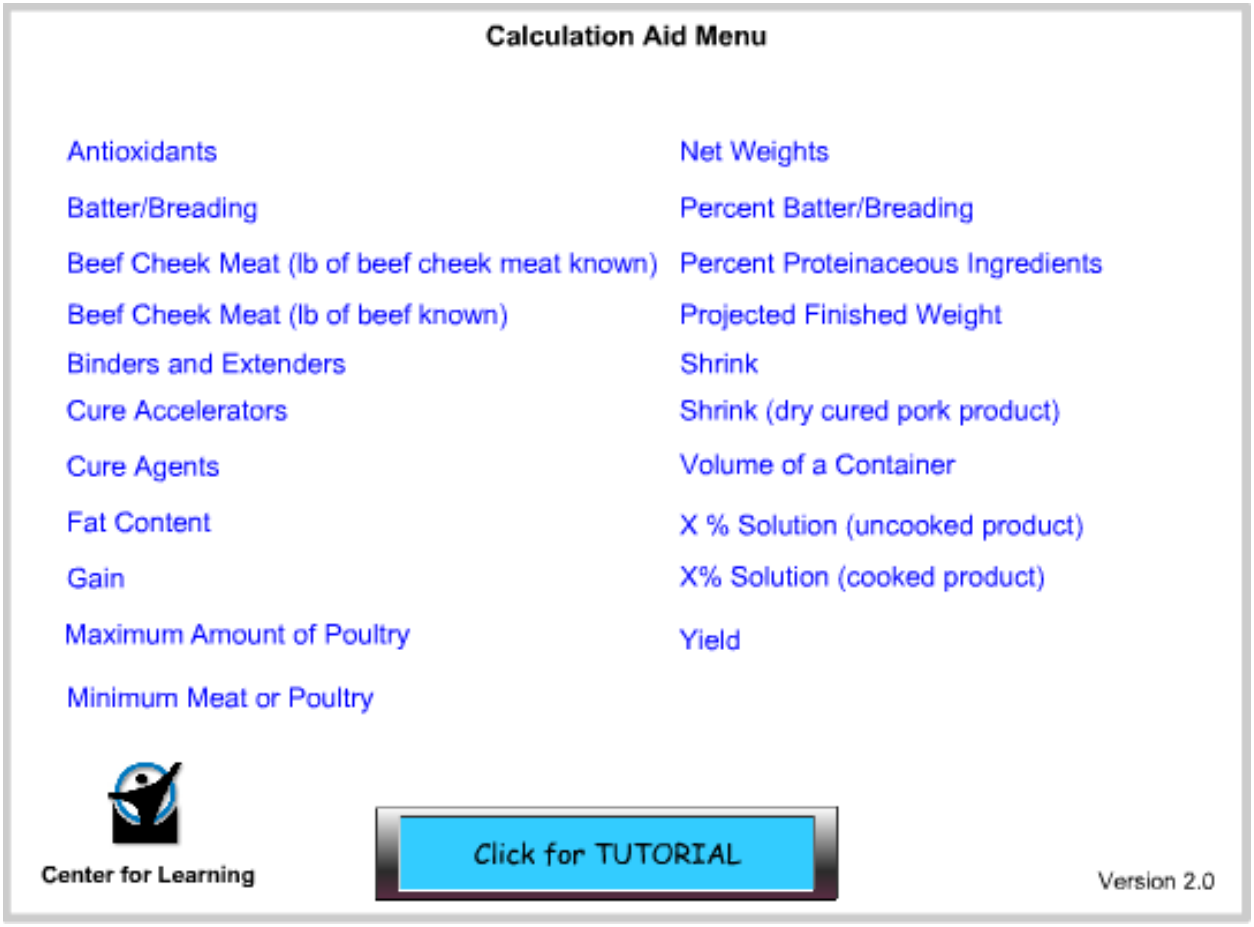
6. Based on the information you have gathered, is the establishment in compliance?

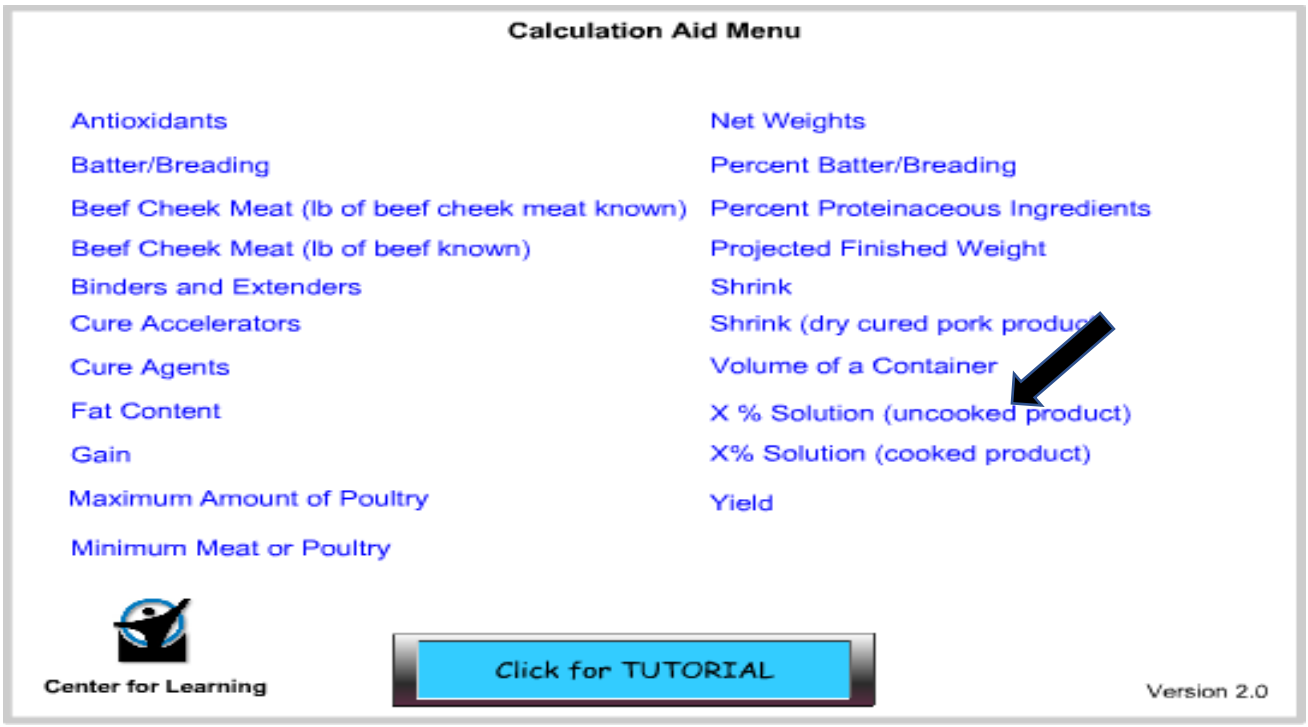
   a. Yes
   b. No

Attachment 1: Demonstrating the Use of the Calculation Aid

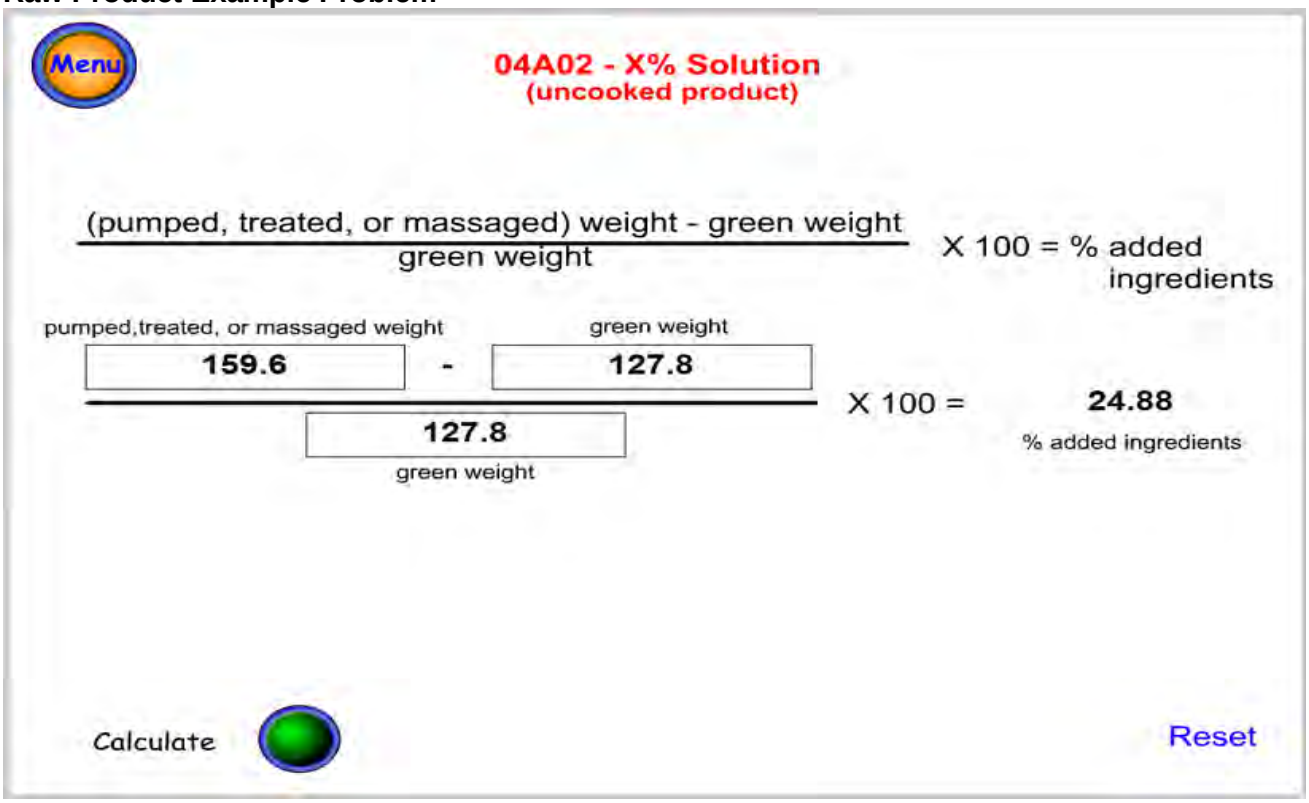
Accessing the Calculation Aid

Step 1: Click on the Start button (or Windows button) lower left corner computer screen
Step 2: Click on FSIS Applications
Step 3: Highlight and double click on Calculation aid in the menu

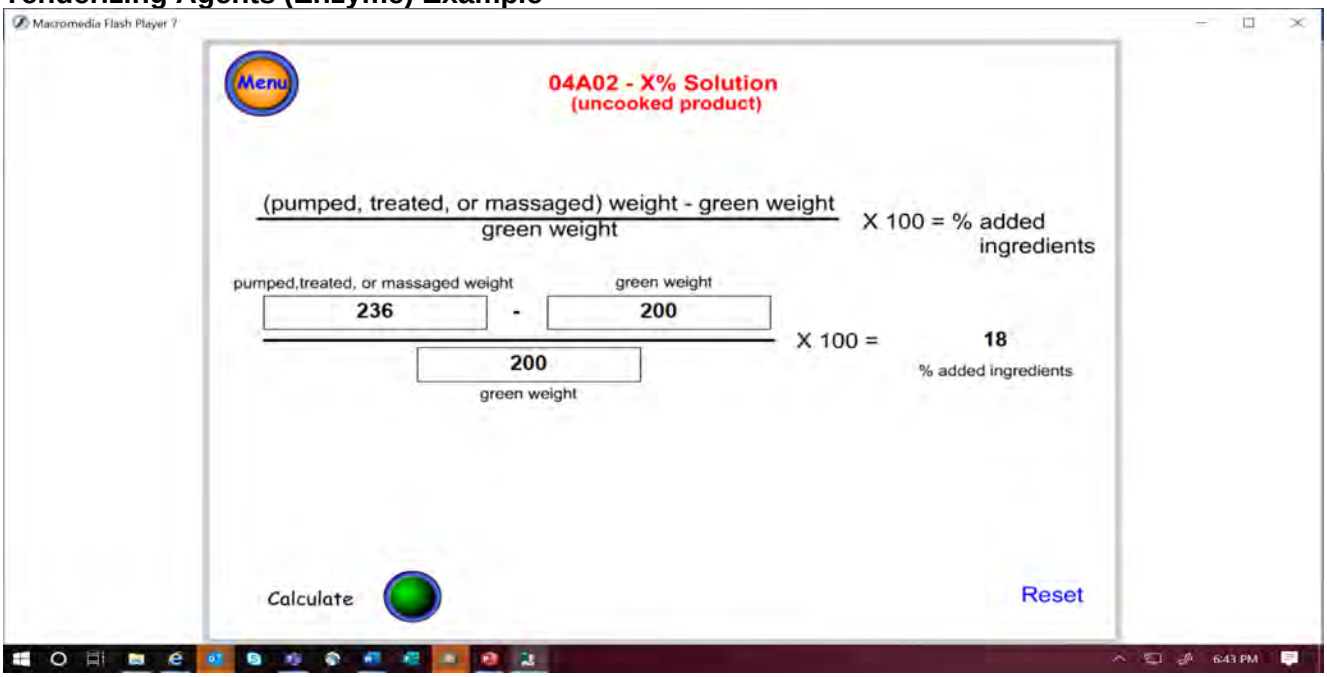




X% Solution Labeled Meat and Poultry Product
Raw Product Example Problem

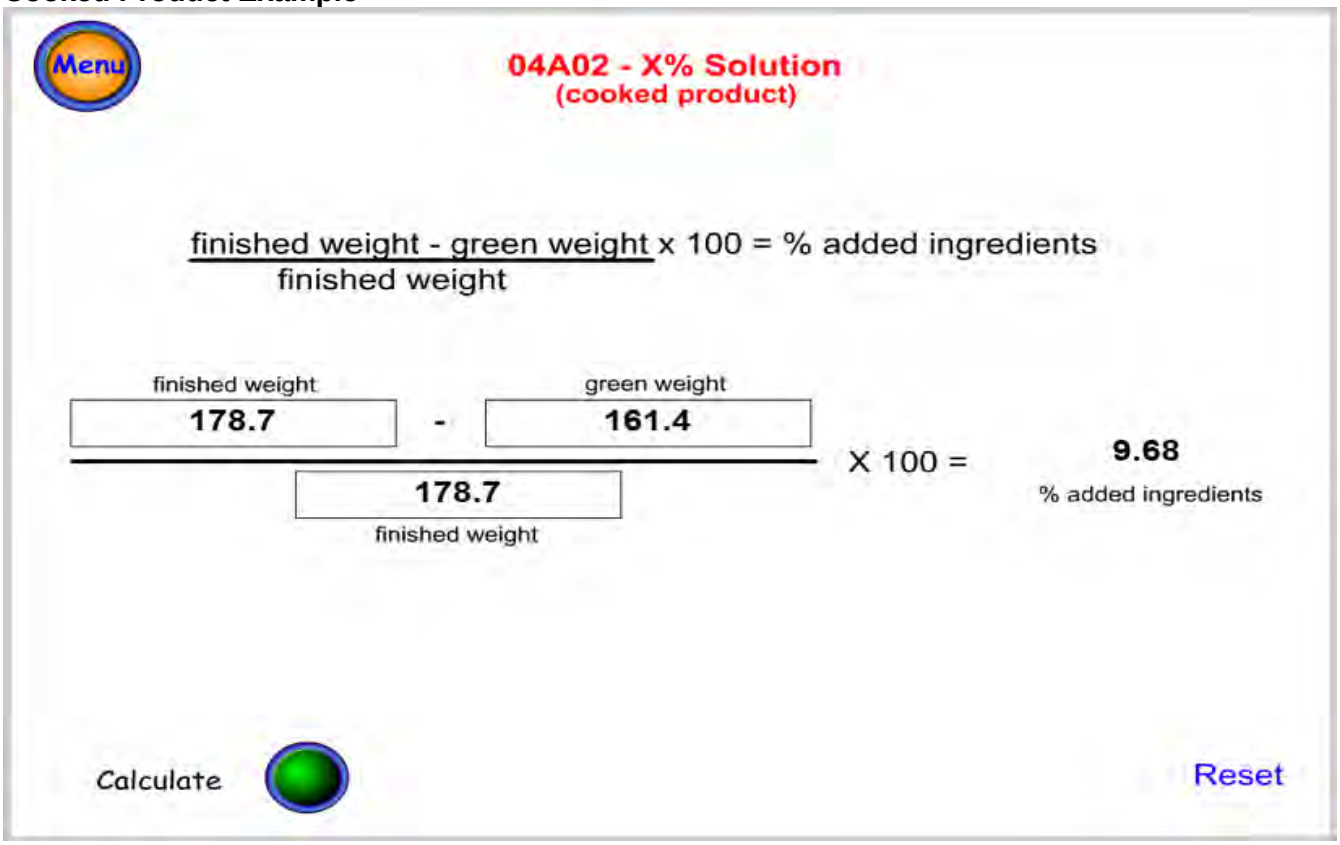


Tenderizing Agents (Enzyme) Example



X% Solution Labeled Meat and Poultry Product

Cooked Product Example



07 - Inspection Responsibilities

Objectives

After completion of this module, the student will be able to:

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

Verification Methodology for NFSCP Tasks

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

FSIS Directive 7000.1 provides IPP with guidance for verifying that an official establishment complies with consumer protection regulatory requirements that are not related to food safety. Attachment 1 in this directive identifies each PHIS NFSCP verification task, verification instructions for the task, regulatory references, and guidance documents.

Before performing the NFSCP task, IPP are to review the regulatory requirements associated with the scheduled task listed in the attachment of FSIS Directive 7000.1. Regulations can be viewed using the Regulations Tab on the Inspection Results Page in PHIS. Always use the GAD thought process.

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

- Observing the formulation of the product
- Observing processing procedures
- Examining product
- Reviewing establishment records [9 CFR 320.1(b)(10) and 381.117(b)(6)]
- Verifying the accuracy of product's labeling
- Checking product identification, condition and temperature
- Performing a variety of other in-plant (hands-on) measurements, such as weighing ingredients, and calculating RI amounts.

Products may have a standard of identity in the regulations or in the Foods Standards and Labeling Policy Book. Restricted ingredients are identified in 9 CFR 424.21 and FSIS Directive 7120.1. Calculations may be necessary to verify regulatory requirements. Available calculation tools for IPP include The Processing Inspector's Calculations Handbook (FSIS Directive 7620.3)

and the Calculation Aid available on IPP's computer. NIST Handbook 133 identifies the sample sizes for net weight compliance determination.

If IPP identify a food safety concern while performing a NFSCP task, they should perform the appropriate food safety task as a directed task and follow instructions from FSIS Directive 5000.1. Remember, IPP are not to perform directed NFSCP tasks unless they observe conditions or activities while performing a food safety verification task that gives them reason to suspect product has not met NFSCP regulatory requirements.

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, applying an accurate net weight statement, or adding ingredients or meat and poultry components that meet the product's standard of identity).

Documentation and Enforcement

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.

If the establishment has a QC program or control procedures, IPP should review sample size, sample frequency, control limits, recordkeeping practices, and the actions taken if the control limits are exceeded, observe employees implementing the procedures, and review establishment records. This information should be considered when determining if the establishment is maintaining control of its processes and meeting regulatory requirements.

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

IPP are to orally notify the establishment and issue an NR when verification results reveal that product is not in compliance with a NFSCP regulatory requirement. When noncompliance is found, IPP take the appropriate regulatory control actions, such as retention of product, rejection of equipment or facilities, stopping lines, or refusing to allow the processing of specifically identified product (9 CFR 500.1(a), if it is determined that misbranded or economically adulterated product would otherwise enter commerce or be shipped from the establishment. Additionally, FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes, or forms of any container for use with any meat or poultry product per 9 CFR 500.8. If it is

determined that economically adulterated or misbranded product has entered commerce, FSIS may implement recall procedures.

IPP should associate the NRs when noncompliances are related to the same process (e.g., the application of solutions to meat and poultry products) as described in FSIS Directive 5000.1. 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. The DO may notify the establishment in writing that the repetitive noncompliances may lead to a regulatory control action (9 CFR 500.1-3) that would affect the entire production of the product in question because product may be economically adulterated or misbranded.

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