

## Food Ingredients of Public Health Concern

### Objectives

1. List the “Big 8” food allergens.
2. List examples of food ingredients to which some individuals are intolerant.
3. Distinguish between food allergy and food intolerance.
4. Describe establishment responsibilities for controlling ingredients of public health concern.
5. Identify situations that could lead to cross-contact with a food allergen.
6. Identify situations that could lead to mislabeling of a product containing an ingredient of public health concern.
7. Distinguish between labeling requirements and voluntary labeling declarations for ingredients of public health concern.
8. Explain when an establishment can include factual statements about a product’s processing environment on the product label.
9. Describe how to perform and document the Big 8 Formulation Verification task.
10. Describe additional labeling concerns that should prompt IPP to perform a directed General Labeling task and document general labeling noncompliance.

### Reference

FSIS Directive 7230.1, *Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common (“Big 8”) Food Allergens*

### Introduction

Formulations of many meat and poultry products may include ingredients that pose a health risk to individuals who are allergic or otherwise intolerant to such ingredients. Food allergens are of particular health concern; however, FSIS is equally concerned about all foods or food ingredients that may cause adverse health effects in individuals intolerant to certain ingredients. FSIS has long maintained the need for adequate in-plant ingredient controls and appropriate labeling of all ingredients by common or usual name. Nevertheless, there have been far too many meat and poultry product recalls due to the non-declaration of ingredients of public health concern on product labels.

In this module, we discuss the significance of food allergens and other food and color additives of public health concern. We will discuss establishment responsibilities regarding adequate control of food allergens and other ingredients of public health concern and accurate labeling of products containing food allergens or other ingredients of public health concern. We will also cover the work methods IPP use to verify that an establishment is meeting these responsibilities and the actions taken by IPP when an establishment fails to meet these important public health responsibilities.

**NOTE:** FSIS *has not* established a comprehensive list of ingredients to which consumers have reported adverse reactions, and this handout should not be taken to represent a comprehensive list. Attachment 1 to FSIS Directive 7230.1 lists examples of ingredients and products that may be derived from the Big 8 food allergens. Several of the Additional Resources listed at the end of this handout provide similar information to help consumers in identifying allergenic ingredients in foods and may be useful to IPP.

## Food Allergies

Some individuals suffer from food allergies, which are immune responses to certain food ingredients. These ingredients, called **food allergens**, are harmless to most people. However, some people have a hypersensitive immune system that responds aggressively when exposed to even trace amounts of the allergenic ingredient. It is the immune system's aggressive response that is harmful, not a direct harmful effect from the ingredient itself. Symptoms of food allergies can include a tingling sensation in the mouth, swelling of the tongue and throat, difficulty in breathing, hives, vomiting, abdominal cramps, diarrhea, a decrease in blood pressure, loss of consciousness, and, in severe cases, death. Severe, life-threatening allergic responses are called anaphylactic reactions.

The FDA has defined the eight foods below and any ingredients that contain protein derived from these eight foods as major food allergens:

- Milk
- Eggs
- Fish (e.g., bass, cod, or flounder)
- Crustacean shellfish (e.g., crab, lobster, or shrimp)
- Tree nuts (e.g., almonds, pecans, or walnuts)
- Peanuts
- Wheat
- Soybeans

These are often referred to as the “Big 8” food allergens, because they account for approximately 90% of food allergies. Within the “Big 8,” the two products that account for most food allergies are peanuts and crustacean shellfish.

According to the FDA, millions of Americans suffer from food allergies each year. Many reactions are mild and likely go unreported. However, food allergies can cause severe, life-threatening reactions. The FDA estimates that food allergies result in 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths each year. While reactions can be treated, there is no cure for food allergies. Consumers with a food allergy must try to prevent reactions by strict avoidance of foods containing the allergen. To do so, these consumers rely on accurate labeling of food products.

For most known food allergens, there is no conclusive scientific evidence that can be used to establish a minimum threshold level necessary for a food allergen to cause an adverse reaction. For any sensitive individual, though, an allergic reaction is potentially catastrophic. Consequently, in most cases, the presence of an undeclared substance that is a known allergen, in even a trace amounts, could pose a significant public health risk.

## Food Intolerances

Some individuals may be intolerant of certain food additives and color additives. Food intolerances are often confused with allergic reactions, but the adverse effects of food intolerances do not involve the same immunological mechanisms as an allergic reaction. Food intolerances generally do not result in life-threatening reactions like food allergies; however, they are still of public health significance, and FSIS is equally concerned about all food ingredients that may cause adverse health effects.

Some people experience gastrointestinal disturbance when they drink milk. Often, the gastrointestinal disturbance is not an allergic reaction to milk proteins but rather intolerance to **lactose**, a sugar molecule in milk and milk products. People intolerant to lactose are generally deficient in lactase, the enzyme that breaks down lactose in the intestinal tract. As people get older, their lactase levels tend to decline. In individuals with insufficient levels of lactase, bacteria in the intestine break down lactose, which produces gas, bloating, cramping, and sometimes diarrhea. It is not just whole milk that is the problem for these individuals, as a variety of food products may contain milk derivatives that contain lactose.

**Sulfites**, including sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite, have been used as food preservatives. One of the main uses of sulfiting agents is to prevent browning of processed fruits, vegetables, and shellfish. Sulfites are not used directly on meat or poultry products, but other ingredients added to meat or poultry products may contain sulfites.

People who have an intolerance to sulfites can experience symptoms including chest tightness, hives, stomach cramps, diarrhea, and breathing problems. The underlying mechanisms for sulfite intolerance are not completely understood. For some individuals, though, the sensitivity to sulfites may be an allergic type of response. People with asthma appear to be at an increased risk of having asthma symptoms following exposure to sulfites.

The presence of sulfiting agents must be declared on the label if their concentration in the finished meat or poultry food product is 10 ppm or higher. However, some finished meat and poultry food products may be comprised of multiple separate components, e.g., potatoes or apple cobbler in a frozen dinner. For these products, if a separate component contains 10 ppm or more sulfiting agents, the sulfiting agents must be declared even though the total product contains less than 10 ppm of sulfiting agents. When sulfiting agents are required to be declared on a label, they must be (1) declared by their specific name or as "sulfiting agents", and (2) listed in the ingredients statement in order of predominance or at the end of the ingredients statement with the statement, "This Product Contains Sulfiting Agents" (or the specific name of the sulfite compound).

**FD&C Yellow No. 5**, or **tartrazine**, has been used as a color additive in a variety of food products. Some consumers appear to have an intolerance to tartrazine. In these consumers, tartrazine may cause symptoms similar to an allergic reaction, i.e., hives and swelling, but the reaction is not considered a true allergy. Tartrazine was also thought to be associated with the onset of asthma attacks, but more recent scientific evidence indicated tartrazine was an unlikely cause of asthma symptoms. To help protect people

who may be intolerant to tartrazine, the FDA requires that any food for human use that contains Yellow No. 5 must specifically declare it as an ingredient.

**Monosodium Glutamate (MSG)** is included as a flavor enhancer in a number of meat and poultry products. Some individuals have reported headaches, chest tightness, nausea, diarrhea, and sweating following consumption of products containing MSG. There is scientific debate over whether MSG causes adverse health effects in individuals. Nonetheless, given the significant consumer concern about this ingredient, FSIS urges companies to ensure that its use is properly declared in labeling.

**Gluten** is the protein found in cereal grains, including wheat, barley, rye, and oats. It is what helps give dough its elasticity. Some individuals have a condition known as **celiac disease**, which is essentially an intolerance to gluten. Although it is not an allergic reaction, it does involve immunological mechanisms that result in inflammation and damage to the lining of the small intestine. Persons with celiac disease experience fatigue, bloating, cramping, chronic diarrhea, and nutrient malabsorption. FSIS permits statements highlighting the presence of certain gluten containing ingredients. If an establishment wishes to make a special claim that a meat or poultry product is gluten-free, then it must be able to support that special claim.

**Nitrate** and **nitrites** are different compounds, both of which are composed of nitrogen and oxygen. They are used as curing agents in many meat and poultry products, including hotdogs, bologna, salami, and other processed meats. These compounds contribute to the characteristic cured flavor and reddish-pink color of cured products. They are also important in inhibiting the growth of *Clostridium* spp. These compounds may cause headaches and hives in some people. In excessive amounts, nitrate or nitrite can be toxic. In addition to labeling requirements, the amount of nitrite or nitrate added to a product is restricted by regulation.

Some products that traditionally include nitrite or nitrate can be manufactured without the use of added nitrite or nitrate. Such products are formulated to only include naturally occurring sources of nitrite or nitrate, such as celery juice powder, parsley, cherry powder, beet powder, spinach, or sea salt. Such products must be labeled appropriately. For example, an "uncured" bacon product should include a declaration such as "Uncured Bacon, No Nitrates or Nitrites added except those naturally occurring in \_\_\_\_" on the product label. In addition, such products generally must bear the statement "Not Preserved, Keep Refrigerated Below 40°F At All Times," as the naturally occurring sources of nitrite or nitrate do not inhibit the outgrowth of *Clostridium* spp. to the same extent as the highly purified chemical forms. Exceptions to this refrigeration handling statement would be finished products that have been dried according to other requirements or that contain a sufficient amount of salt to achieve an internal brine concentration of 10% or more.

**NOTE:** FD&C coloring agents, like Red No. 3 and Red No. 40, are often added to cure mixes as a tint to distinguish nitrite from salt. FSIS policy has always been that since the coloring agent does not function as a color additive in the meat or poultry product, it is considered to be incidental and does not require declaration on the product label.

## Establishment Responsibilities

As part of conducting its hazard analysis, it is the responsibility of the establishment to research all ingredients used in the production of its products and determine if an ingredient may trigger food allergies in sensitive individuals. FSIS expects establishments to employ appropriate food safety procedures (i.e., HACCP plans, Sanitation SOPs, or other prerequisite programs) for ensuring that ingredient addition appropriately matches the product formula and that all ingredients are properly disclosed on the product label.

The establishment must implement measures necessary to: (1) prevent cross-contact between products, equipment, and utensils that do and do not contain allergens and (2) assure accurate label declarations on products that do contain allergens. Any food safety system procedures designed to control allergens must be effectively implemented on an ongoing basis to ensure adequate control.

Avoiding cross-contact between products containing a food allergen and those that do not is critically important. Cross-contact could result from inadequate control or inappropriate use of ingredients of public health concern. **Situations that might allow for cross-contact to occur include the establishment failing to:**

- Check ingredient containers for damage at receiving to prevent allergen contamination within the establishment;
- Implement a program to ensure proper identification and control of allergenic ingredients, allergen containing products, and allergen containers through receiving, weighing, formulation, and packaging;
- Ensure effective sanitation measures are in place to address the potential for cross-contact when producing multiple products with different formulations;
- Implement adequate sanitation procedures for cleaning of utensils and equipment used in formulating and processing both products containing an allergen and products without allergens;
- Train employees on the appropriate use of ingredients and the need to be especially careful when working with allergens;
- Appropriately identify/store products to be reworked that contain an allergen; or
- Manufacture a product in accordance with the intended product formulation.

In addition to inadequate controls to prevent cross-contact, accidental application of inaccurate labels to properly formulated products could pose a threat to consumers sensitive to any ingredients in the formulation. **Examples of how inaccurate labeling of a product can occur include the establishment failing to:**

- Declare ingredients listed in the product formula on the product label by common or usual name;
- Change labels when changing over from one product formulation to another;
- Review the labels on incoming non-meat/non-poultry ingredient mixes at receiving for changes;
- Discard obsolete labels after a change in product formulation;
- Review newly-printed labels to ensure accuracy;
- Control labels for products with similar appearance but different ingredients to ensure application of the correct label (e.g., storing mixed bundles of labels for

similar products with different ingredient formulas which could lead to a mix-up of labels);

- Maintain adequate production controls over a product that contains an allergenic ingredient and is intended for rework, allowing it to be reworked into a product not labeled to contain that ingredient; or
- Declare an allergen that was indirectly added to the product. An example would be an establishment that is producing product on a food contact surface sprayed with a non-stick coating (a release agent intended to prevent product from adhering to the food contact surface) containing soy lecithin and is not properly declaring the soy lecithin on its finished product label. Note that substances used as release agents on surfaces, including grills, loaf pans, cutters, or other hard surfaces, are generally considered to be processing aids and are not required to be declared in the ingredients statement on the meat or poultry product label. However, if a particular release agent contains a known allergen, such as soy lecithin, official establishments must list the allergenic ingredient in the ingredients statement on the product label. Many cooking sprays (e.g., PAM®) used as release agents will contain soy lecithin as an emulsifier. Some may contain other allergenic ingredients as well.

**NOTE:** It is always the responsibility of each official establishment to determine and support the safety of all chemical substances used in its process, including all non-meat/non-poultry food ingredients and processing aids. However, the following information may be helpful when IPP review an establishment's hazard analysis and supporting documentation regarding the use of highly refined edible oils.

1. Highly refined edible oils, such as soybean oil and peanut oil, are the result of processing that involves de-gumming, neutralizing, bleaching, and deodorizing extracted oils. This refining improves the quality of plant-based oils by removing a variety of undesirable chemicals, imparting a uniform color, and eliminating undesired odors. A benefit of refining edible oils is that the process renders them virtually free of allergenic proteins according to the Institute of Shortening and Edible Oils. Scientific studies indicate that refined edible oils are safe for the food-allergic population to consume. In contrast, mechanical or "cold press" extraction of oils from plant materials may not remove all protein; however, cold-pressed oils are rarely used.
2. Allergen-containing products cooked or par-fried in highly refined edible oils may leave traces of allergenic proteins behind in the oil. Establishments that reuse the same oil to cook or par-fry a variety of products should consider the potential hazard such reuse might pose to food-allergic consumers.

### **Label Declarations**

The fact that some individuals have allergies or intolerances to certain foods and food ingredients emphasizes the importance of accurate, informative product labeling. Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), all ingredients used to formulate meat or poultry products generally must be declared in the ingredients statement on the product label. A product is misbranded under the FMIA or PPIA when it contains ingredients that are permitted but not declared on product labeling. Therefore, the general expectation is that, with few exceptions, all ingredients should be declared on the labeling of meat and poultry products. FSIS guidance for

many years has been that ingredients of public health concern should always be declared in the ingredients statement.

FSIS regulations require that any ingredient be declared only by its common or usual name in the ingredients statement. In addition to accurately declaring product ingredients, though, FSIS supports the use of **voluntary statements** on labels to alert people who have sensitivities or intolerances to the presence of specific ingredients. For example, a label statement like, “Contains: milk, wheat gluten, soy” would alert consumers to these ingredients of public health concern. FSIS further supports identifying the source of a specific ingredient in a parenthetical statement. For example, a product label might specify, “Contains sodium caseinate (from milk)” to alert milk allergic consumers that the ingredient is derived from milk.

In limited situations, the Labeling and Program Delivery Staff (LPDS) of FSIS does permit the use of **factual labeling statements about a product’s manufacturing environment** such as, “Produced in a plant that uses peanuts,” or “**may contain statements** like, “may contain peanuts,” on meat and poultry product labeling. However, the use of a factual statement about a product’s manufacturing environment or a “may contain” statement should only be used in cases when an establishment can show that GMPs and Sanitation SOPs cannot reasonably be expected to effectively eliminate the possibility of cross-contact of products with ingredients of public health concern. The Agency believes the indiscriminate use of such elective statements does not promote good manufacturing practices under a HACCP system and is not helpful to consumers (that is, they are not an acceptable substitute for adequate HACCP plans, SSOPs, GMPs, etc.). Consequently, the use of such statements may only be used in cases where establishments show that adequate Sanitation SOPs cannot effectively eliminate the potential for cross-contact. LPDS evaluates and approves factual labeling statements on a case-by-case basis.

#### **FACTUAL LABELING STATEMENT EXAMPLE:**

*An official establishment uses chopped peanuts in making a dry, Thai-style meat sauce mix. During operations, it is necessary for the processing environment to remain dry; thus, the production equipment cannot be washed with water or other fluids. In this instance, peanut dust may become airborne and unavoidably contaminate other meat or poultry products manufactured in the same production area. In such situations, a statement about the manufacturing environment, as described above, or the use of a “may contain (name of allergenic ingredient)” statement has been approved by LPDS. However, this type of statement is not acceptable where it is used as a replacement for poor Sanitation SOPs, i.e., the potential for cross-contact because an establishment fails to adequately wash equipment between the production of different products.*

FSIS will also consider any non-misleading symbols, statements, or logos to inform consumers of the presence of ingredients of public health concern in meat or poultry products. An establishment may submit such a request to the Agency as a policy inquiry but not as label-approval submission.

All ingredients listed on labels of incoming food and food ingredients (e.g., multi-ingredient products such as soy sauce and bread) must be listed on labels of the meat and poultry products in which they are used as ingredients, unless FSIS has determined

that a particular use of an ingredient is consistent with the FDA's definition of a processing aid or incidental additive. All the ingredients listed in a "may contain" or "produced in a facility" statement must be listed on the final label except in situations where the establishment contacts the supplier of the component and addresses the statement in its hazard analysis. Specifically, all the ingredients in a "may contain" or "produced in a facility" statement may not need to be listed on the final label if the official establishment: (1) contacts the supplier and confirms, preferably in writing, that the statement is a cautionary statement, and no such ingredient is in the product; and (2) includes a written statement in its hazard analysis documentation to support why the "may contain" or "produced in a facility" statement is not carried forward to the finished meat or poultry product label.

**NOTE:** Some of the chemicals mentioned in this handout may be classified as "**generally recognized as safe**" (**GRAS**) compounds. A GRAS food additive is generally recognized, among qualified experts, as having been shown to be safe under the conditions of its intended use. You may wonder why any GRAS ingredients would be of public health concern. All ingredients used in meat and poultry products are required to be safe. The designation of a particular food ingredient as GRAS relates to a determination that the ingredient is safe for human consumption. However, it is not the safety of the substance itself that is the problem. This module focuses on concern over the addition of ingredients reported to cause adverse health effects in some individuals and an establishment's failure to properly declare those ingredients on the product label. It is important to remember that establishments must consider all potential chemical food safety hazards in their hazard analyses, including ingredients that are GRAS substances.

### **Inspection Program Personnel Responsibilities**

Obviously, it is important that establishments have preventive measures and controls to address all potential chemical hazards, including food allergens and other ingredients of public health concern. If a meat or poultry establishment ships product containing an undeclared allergen into commerce, then its food safety system has failed. The establishment may have failed to address the allergen as a potential chemical food safety hazard in its hazard analysis, failed to support the decisions made in the hazard analysis, or failed to effectively implement controls supporting the decisions made in the hazard analysis.

As mentioned earlier, numerous recalls have occurred due to undeclared allergens. FSIS analyses of recalls connected to undeclared allergens have revealed that many occurred due to reasons including:

- Changes in ingredient suppliers.
- Suppliers changing ingredient formulations.
- Finished meat or poultry products in the wrong package.
- Misprinted labels applied to finished meat or poultry products.
- Changes to the ingredient formulation of meat or poultry products without a corresponding change in the labeled ingredients.
- A meat or poultry product coming into contact with an undeclared allergenic ingredient not directly added to the product.

It is vitally important for IPP to always be vigilant with regard to establishments' preventive measures and controls for allergens and other ingredients of public health concern. Multiple inspection tasks may be relevant to verifying that an establishment's food safety system meets regulatory requirements with regard to allergens and other ingredients of public health concern, including the HAV task, the HACCP Verification tasks, the Review Establishment Data task, Pre-operational and Operational SSOP tasks, the General Labeling task, and the Big 8 Formulation Verification task. They will issue a Noncompliance Record (NR) under the appropriate inspection task when the establishment:

- Fails to address a potential chemical food safety hazard in its process.
- Fails to implement its Sanitation SOPs or other prerequisite programs adequately to support a decision that a chemical food safety hazard is not likely to occur.
- Does not have adequate documentation on file to support decisions made in its hazard analysis for hazards that are not reasonably likely to occur.
- Fails to appropriately declare any allergen or other ingredient of public health concern on the product label.

### **The Big 8 Formulation Verification Task**

Now, we will focus on the Big 8 Formulation Verification task, which provides IPP with a method for verifying that establishments are accurately controlling and labeling the eight most common food allergens. The Big 8 Formulation Verification task methodology is described in **FSIS Directive 7230.1**. Performing the task will involve reviewing records, observing production processes, and responding to specific task-related questions in PHIS.

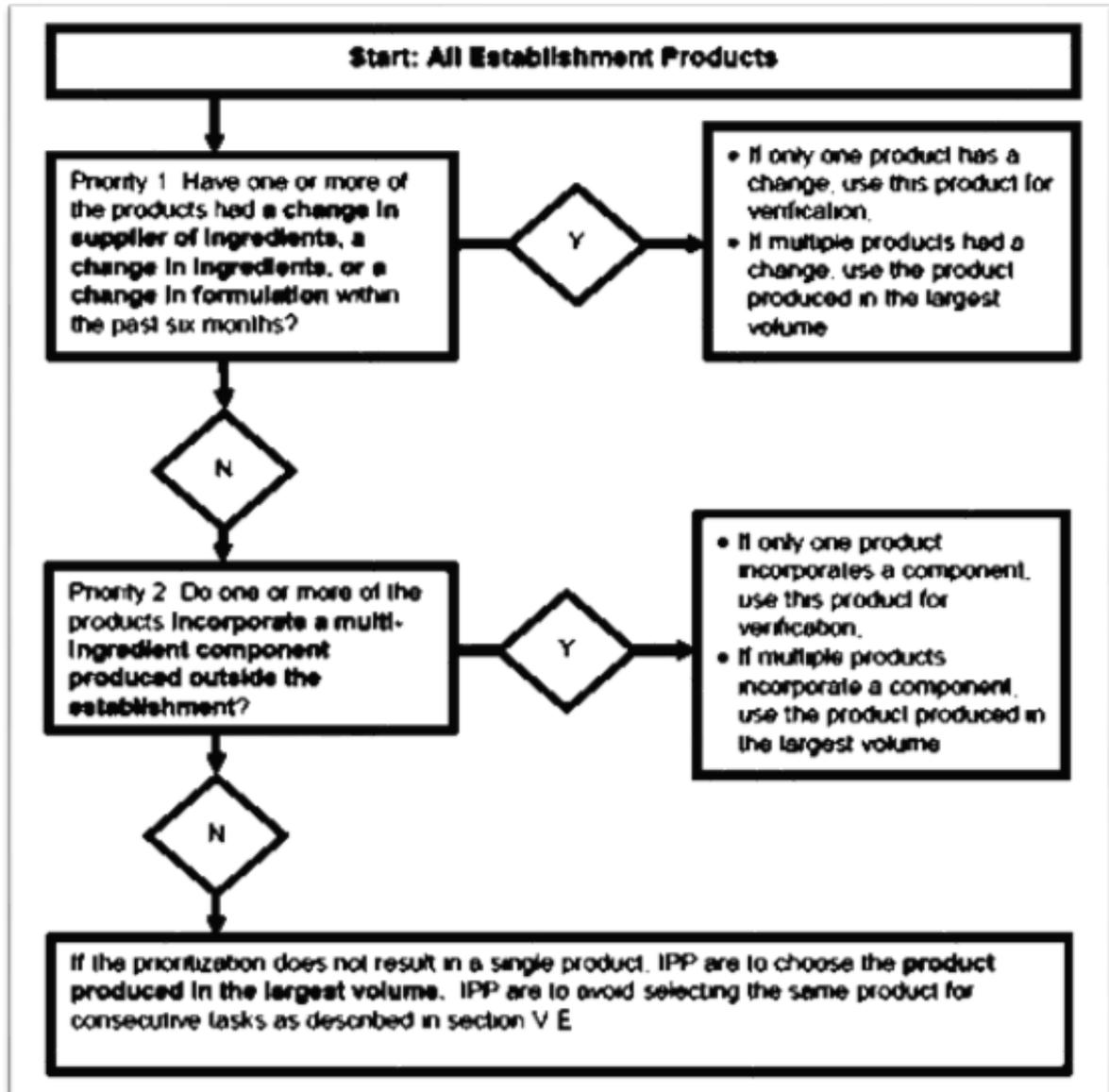
IPP assigned to establishments that produce products in any of the HACCP processing categories **other than slaughter** must determine whether the establishment produces any products that **may contain** any of the Big 8 food allergens. If IPP determine the establishment does produce any products that may contain any of the Big 8 food allergens, they should review the preventive and control measures developed by the establishment and verify that such measures are being effectively implemented, including that product labels are consistent with product formulation records. Note that, depending on its processes and decisions made in its hazard analysis, an establishment's preventive and control measures to address allergens may be within its HACCP plan, its Sanitation SOPs, and/or in a prerequisite program.

**NOTE:** If the Big 8 Formulation Verification task does not apply to the operations in a given establishment according to the criteria in FSIS Directive 7230.1, IPP are to find the task on the Establishment Profile/Inspection Tasks page for that establishment and disable the task. Refer to FSIS Directive 13,000.1 for instructions on disabling an inspection task when it does not apply to an establishment.

For establishments in which the task is relevant, a **routine** Big 8 Formulation Verification task will appear monthly on the Establishment Task List as a Priority 3 task in PHIS. In establishments with multiple shifts, IPP will perform the routine verification task on each shift. Big 8 Formulation Verification tasks may be performed more frequently as **directed** tasks if there are any indications of increased risk of undeclared allergens in the establishment. For example, the production of a new product, changes in product

formulation, sanitation NRs related to allergen control, or other labeling NRs, may be indication of increased risk of undeclared allergens. **IPP are to discuss the circumstances and their concerns of increased risk of undeclared allergens with their supervisor and Frontline Supervisor before scheduling additional Big 8 Formulation Verification tasks as directed tasks.**

When performing the routine Big 8 Formulation Verification task, IPP must first schedule the task in advance and determine which products will be produced on that date. Next, they must select a product for the task. This requires coordinating with IPP on the other shift, if applicable, to avoid selecting the same product for a task. IPP must also avoid selecting the same product for consecutive tasks without first attempting to select products that have not been selected previously, unless there has been a change in supplier, change in ingredients, change in formulation, or the establishment produces a very limited number of products. In establishments that produce more than one product, IPP are to use the chart on the next page to prioritize a product for the verification task. **IPP are to apply the priority list to all products in an eligible establishment, whether or not the establishment produces products containing a “Big 8” allergen.**



**NOTE:** Examples of multi-ingredient components include sauces, condiments such as ketchup or mustard, seasoning packets, flavorings, spice mixes, soup bases, or other combinations of two or more ingredients that are mixed together (in this case, outside of the establishment).

After selecting a product, IPP are to obtain the specific product formulation (or recipe) for that product from the establishment. The establishment may consider its product formulation proprietary information; however, meat and poultry establishments are required to provide IPP accurate information on all procedures involved in product preparation, including product composition, for verification in accordance with 9 CFR 318.6 and 9 CFR 381.180.

IPP perform the Big 8 Formulation Verification task using a combination of the recordkeeping and review and observation inspection components for the production of the selected product. Performing the task involves:

1. Reviewing product formulation records and observing product formulation process steps to verify that all ingredients used in the production of the product are consistent with the intended product formulation.
2. Reviewing the product label to verify that all ingredients used in formulating the product are declared in the ingredients statement by common or usual name and in descending order of predominance. IPP should never assume that all ingredients used in a product formulation are appropriately declared on the final meat or poultry product labels.
3. Verifying the appropriate label is the label being applied to the product.
4. Verifying the applied label is consistent with the establishment's label approval on file.

**NOTE:** IPP can use the list of common ingredients and foods in Attachment 1 of FSIS Directive 7230.1 for help in identifying “Big 8” allergens.

Additional considerations regarding multi-ingredient seasonings or spices, processing aids or incidental additives, release agents, and “may contain” or “produced in a facility” statements on incoming food and food ingredients are outlined in FSIS Directive 7230.1.

As part of documenting the task in PHIS, IPP will respond to specific questions related to this task located on the “additional info” tab of the task documentation page. Attachment 2 of FSIS Directive 7230.1 provides more information regarding these questions.

### **Documenting Noncompliance with the Big 8 Formulation Verification Task**

Whenever IPP determine that a meat or poultry product contains one of the Big 8 allergens, but the establishment failed to declare the allergen in the ingredients statement on the product label, they are to document noncompliance on a Noncompliance Record in PHIS under the Big 8 Formulation Verification task. IPP will cite the relevant food safety regulation(s) and the appropriate labeling regulation (9 CFR 317.2(f) for products bearing the meat inspection legend or 9 CFR 381.118 for products bearing the poultry inspection legend). In addition, IPP must always notify their supervisor when they identify such noncompliance so that a recall request determination can be made.

### **NONCOMPLIANCE EXAMPLE 1**

*While performing a Big 8 Formulation Verification task, an inspector determined that a meat product contained an allergen the establishment had failed to declare in the ingredients statement on the product label. The inspector immediately notified establishment management. Further investigation revealed this occurred because the establishment did not recognize that its supplier of a marinade solution had recently altered the formulation of the marinade solution to include a soy-based ingredient. The establishment was able to provide records to support that all affected product was still under its control (i.e., no affected product had entered commerce). The inspector then contacted her Frontline Supervisor to inform him of her findings. The meat establishment had not considered the allergenic ingredient as a potential chemical hazard in its hazard analysis; therefore, the inspector cited 9 CFR 417.2(a)(1) on the Noncompliance Record. The inspector also cited 9 CFR 317.2(f) because the establishment failed to list all ingredients in the ingredients statement as required for a product bearing the meat*

*inspection legend. There was no previous noncompliance due to the same cause. The inspector completed the task after she verified the establishment had implemented and documented corrective actions in accordance with 9 CFR 417.3(b) and 9 CFR 417.3(c).*

## **NONCOMPLIANCE EXAMPLE 2**

*An establishment produced a variety of dry seasoned and marinated, raw poultry products. Some product formulations contained one or more allergens, and some did not. In its hazard analysis, the establishment concluded that allergens were not reasonably likely to occur on the basis of its allergen control prerequisite program. The allergen control program included operational and pre-operational Sanitation SOPs designed to prevent cross-contact with allergens, as well as a procedure for verifying label accuracy for each product at the packaging and labeling step. While performing a Big 8 Formulation Verification task, an inspector determined that a product containing an allergen was being labeled with a label for a similar product whose formulation did not include the allergenic ingredient; therefore, the ingredients statement did not include the name of the allergenic ingredient. The inspector took a regulatory control action by rejecting the packaging line to stop production of the adulterated and misbranded product. He also identified and retained affected product in the establishment's finished products cooler to prevent the product from being shipped. He immediately notified establishment management of the basis for the regulatory control actions. The establishment provided production records supporting that no affected product had been shipped. The inspector contacted his supervisor and informed her of his findings. Next, the inspector documented noncompliance with 9 CFR 417.2(a)(1) and 417.5(a)(1) because the establishment's prerequisite program failed to effectively prevent the chemical hazard from being reasonably likely to occur. In addition, he cited noncompliance with 9 CFR 381.118 because the establishment failed to list all ingredients in the ingredients statement as required for a product bearing the poultry inspection legend. The inspector followed up by verifying the establishment implemented and documented appropriate corrective actions in accordance with 9 CFR 417.3(b) and 417.3(c).*

## **NONCOMPLIANCE EXAMPLE 3**

*A further processing establishment produces a variety of partially-cooked and fully-cooked meat and poultry products. Many products produced by the establishment contain at least one allergenic ingredient. The establishment has operational and pre-operational Sanitation SOPs designed to prevent cross-contact. At the product rework step in each of its hazard analyses, they support that allergens are not reasonably likely to occur on the basis of a prerequisite program designed to ensure that any given batch of product identified for rework will be appropriately identified, stored in a manner to ensure no contact with different products held for rework, and only reworked into product with the same ingredients. In addition, it has identified that allergens are reasonably likely to occur at the finished product labeling in each of its hazard analyses. In each HACCP plan, there is a CCP at the finished product labeling step. The critical limit at this CCP is that all finished product packages must bear labels that accurately declare the allergenic ingredient(s) included in the product formulation. The monitoring procedure described for this CCP specifies that a QA technician will visually inspect labels applied to finished products to ensure the ingredients statement is consistent with each product's*

*formulation. The frequency of monitoring specifies that visual inspection of one label will be performed at the beginning of each production lot and of one label hourly until completion of each production lot. As part of conducting a Big 8 Formulation Verification task, an inspector identified a beef product whose formulation had recently been changed. Previously, the product formulation included a soy-based ingredient, but it had been changed to also include a peanut-based ingredient. After reviewing formulation records on this particular product, the inspector proceeded to the monitoring location for the CCP to review the finished product label. He noted that the label being applied at that time only included the soy-based ingredient. He immediately notified a production supervisor of the critical limit deviation. Further investigation revealed that, sometime after the establishment's last hourly monitoring check, another roll of preprinted labels had been retrieved from a storeroom. Unfortunately, all labels based on the old formulation had not yet been destroyed, and a production employee had inadvertently retrieved a roll of the old labels. The establishment was able to support that product affected by the critical limit deviation was restricted to only that produced since the last hourly monitoring check. The inspector notified his supervisor of the issue, documented noncompliance with 9 CFR 417.2(c)(4) and 9 CFR 317.2(f), and verified the establishment implemented and documented appropriate corrective actions in accordance with 9 CFR 417.3(a) and 417.3(c).*

**NOTE:** IPP are to always consider what their findings show about the overall effectiveness of the establishment's food safety system and take these findings into account during the performance of the next Hazard Analysis Verification (HAV) task. If IPP identify concerns when performing the Big 8 Formulation Verification task and believe a directed HAV task should be performed, they are to discuss those concerns with their supervisor.

### **Documenting Noncompliance for Other Undeclared Ingredients**

If IPP determine that a product contains an ingredient not declared in the ingredients statement, but that ingredient is not one of the Big 8 allergens, IPP are to schedule a directed General Labeling task and document General Labeling noncompliance with 9 CFR 317.2(f) for products bearing the meat inspection legend or 381.118 for products bearing the poultry inspection legend. Note that this instruction would apply to any ingredient that is not one of the Big 8 allergens, including other ingredients of public health concern discussed in this module.

### **Other Actions**

IPP may need to take regulatory control of product at the official establishment, if necessary, to prevent the product from entering commerce. IPP must always contact their FLS for guidance if at any time they have reason to believe any product bearing labels that fail to declare one of the "Big 8" food allergens or any other ingredient of public health concern has entered commerce. An immediate withholding action on the process may be necessary, and a product recall may be requested by the Recall Management and Technical Analysis Staff (refer to FSIS Directive 8080.1 for more information on recalls).

### **Additional Resources**

- **FSIS Compliance Guidelines - Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling November 2015**  
<https://www.fsis.usda.gov/sites/default/files/import/Allergens-Ingredients.pdf>
- **Additives in Meat and Poultry Products**  
<https://www.fsis.usda.gov/food-safety/safe-food-handling-and-preparation/food-safety-basics/additives-meat-and-poultry>
- **A Guide to Federal Food Labeling Requirements for Meat and Poultry**  
[https://www.fsis.usda.gov/sites/default/files/media\\_file/2021-07/Labeling\\_Requirements\\_Guide.pdf](https://www.fsis.usda.gov/sites/default/files/media_file/2021-07/Labeling_Requirements_Guide.pdf)
- **Allergens - Voluntary Labeling Statements**  
<https://www.fsis.usda.gov/guidelines/2013-0010>