

VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS
CONSUMER PROTECTION AND FOOD SAFETY
Meat Inspection Service
MONTPELIER, VT
Anson Tebbetts, Secretary



MIS DIRECTIVE

Adopted from FSIS Directive 7230.1 Rev 2

7230.1
Rev 2

12/15/18

ONGOING VERIFICATION OF PRODUCT FORMULATION AND LABELING TARGETING THE EIGHT MOST COMMON (“BIG 8”) FOOD ALLERGENS

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) for performing the “Big 8” Formulation Verification task in the Public Health Information System (PHIS). IPP verify that establishments are accurately controlling and labeling the eight most common (“Big 8”) food allergens in meat and poultry establishments. These allergens are designated as “major food allergens” by the Food and Drug Administration’s (FDA) [Food Allergen Labeling and Consumer Protection Act \(FALCPA\) of 2004](#).
KEY POINTS:

II. REASON FOR REISSUANCE

This directive should:

1. Emphasize that the “Big 8” Formulation Verification task is a Priority 3 task;
2. Emphasize the public health importance of verifying control of “Big 8” allergens in establishments;
3. Incorporate a shorter questionnaire;
4. Make IPP aware that the answer to the new Question 1 in the shorter questionnaire will generate a field in the Establishment Profile Report that indicates whether “Big 8” allergens are used in product formulation at the establishment; and
5. Add information about cold-pressed and highly refined oils in **Attachment 1**;

III. BACKGROUND

A. A food allergy is a potentially serious response to consuming certain foods or food additives. For those who are sensitive, a reaction can occur within minutes or hours, and symptoms can range from mild to life-threatening. Each year in the United States, it is estimated that anaphylaxis (an extreme allergic reaction) to food results in 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths. There is no cure for food allergies.

B. Starting in 2008, there has been a sustained increase in the number of recalls of FSIS-regulated products that contain undeclared allergens and food ingredients of public health concern.

C. The “Big 8” food allergens account for approximately 90 percent of all food allergy reactions. The “Big 8” food allergens are:

1. Wheat;
2. Crustacean shellfish (e.g. crab, lobster, shrimp, etc.);
3. Eggs;
4. Fish;
5. Peanuts;
6. Milk;
7. Tree nuts (e.g. almonds, pecans, walnuts, etc.); and
8. Soybeans.

D. Ingredients of public health concern include the “Big 8” allergens as well as additives that may cause food intolerance, such as sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG).

E. FSIS analyses of previous issuances and recalls connected to undeclared allergens and ingredients of public health concern revealed that many occurred because of changes in ingredient suppliers, products in the wrong package or with misprinted labels, or changes to product or ingredient formulation.

F. An FSIS analysis of recalls also revealed incidents that occurred when a meat or poultry product came in contact with an undeclared allergenic ingredient that was not directly 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 containing soy lecithin and is not properly declaring the soy lecithin on labeling.

G. When an establishment ships product into commerce with an undeclared allergen, its food safety system has failed. For an establishment producing meat or poultry products, the establishment has either failed to address the chemical (allergen) food safety hazard in its Hazard Analysis and Critical Control Point (HACCP) plan, failed to support the decisions made in its hazard analysis, or failed to effectively implement the controls to support the decisions made in the hazard analysis.

H. It is important that establishments have preventive measures or controls to address undeclared food allergens. When “Big 8” food allergens or other ingredients of public health concern are not properly declared, FSIS may request a voluntary recall. (Refer to [FSIS Directive 8080.1](#), *Recall of Meat and Poultry Products*, for additional information on recall procedures.)

I. This directive applies to meat and poultry product establishments that produce products other than single ingredient products in the following HACCP categories:

1. Raw – non-intact;
2. Raw – intact;
3. Thermally processed commercially sterile;
4. Not heat treated, shelf stable;
5. Heat treated shelf stable;

6. Fully cooked not shelf stable;
7. Heat treated not fully cooked not shelf stable; and
8. Secondary inhibitors not shelf stable.

NOTE: If an establishment produces a product that is only comprised of various species of meat or poultry (e.g., a mixture of beef and pork which contains no other ingredients) then IPP are not to perform the “Big 8” Formulation Verification task.

V. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. IPP are to inform the establishment at the next weekly meeting that the Establishment Profile Report now indicates whether “Big 8” allergens are used in product formulations based on the response to Question 1 in the task questionnaire.

B. When there are potential regulatory concerns, and with all new establishments, IPP are to meet with establishment management to discuss the items in the Background (Section IV) of this directive. IPP are to:

1. Verify whether the establishment has developed and implemented preventive or control measures within its HACCP plan, Sanitation Standard Operating Procedures, or other prerequisite program to address allergens;
2. Discuss whether the establishment produces any products that contain any of the “Big 8” food allergens. **Attachment 1** lists examples of ingredients and products that may be derived from or contain these food allergens;
3. Inform establishment management that IPP will continue to verify that the establishment’s labels match its product formulations during an ongoing “Big 8” Formulation Verification task occurring at a monthly frequency. IPP are to schedule additional verification tasks (directed) in response to FSIS concerns in accordance with Section VI.B. of this directive; and
4. Inform establishment management that FSIS allergen and labeling compliance guidelines are available [online](#), which may assist them in assessing their own allergen program.

C. IPP are to conduct the assigned “Big 8” Formulation Verification task and document findings in PHIS as directed in Section VII of this directive.

VI. TIMING OF VERIFICATION ACTIVITIES

A. Each meat and poultry establishment that produces product in the HACCP categories listed in Section IV. I. of this directive and each egg products plant per Section IV. J. will continue to be assigned a directed “Big 8” Formulation Verification task in PHIS on a monthly basis.

NOTE: If IPP receive the “Big 8” Formulation Verification task in establishments that produce single ingredient products (e.g., only grind beef) or they only combine various species of meat or poultry products (e.g., a mixture of beef and pork which contains no other ingredients), they are to cancel the task per [Directive 13000.1](#), *Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)*. Please refer to [Directive 5300.1](#), *Managing the Establishment Profile in the Public Health Information System (PHIS)* for information on how to view or edit the establishment task list in the PHIS profile.

B. IPP may schedule the “Big 8 Formulation Verification” task more frequently in an establishment if there are indicators of an increased risk of undeclared allergens and ingredients of public health concern. IPP

are to discuss the circumstances that are causing concerns with their supervisor before scheduling additional tasks. IPP are to consider the situations below when determining whether they need to schedule additional tasks:

1. A recall by the establishment related to “Big 8” allergens, ingredients of public health concern, or other undeclared ingredients;
2. Consumer complaints linked to the establishment related to allergens, ingredients of public health concern, or other undeclared ingredients;
3. A history of sanitation Non-compliance Records (NRs), and HACCP NRs for meat and poultry establishments, related to allergens, ingredients of public health concern, or other undeclared ingredients;
4. Labeling NRs for the establishment; or
5. Recent product formulation changes, adjustments to ingredients, supplier changes, or new products added by the establishment.

NOTE: IPP are to contact their supervisor for guidance if at any time they have reason to believe product bearing labels that fail to declare one of the “Big 8” food allergens or other ingredients of public health concern has entered commerce (refer to VT Directive 8080.1).

VII. “BIG 8 FORMULATION VERIFICATION” TASK

A. IPP are to perform the “Big 8” Formulation Verification task at a monthly frequency.

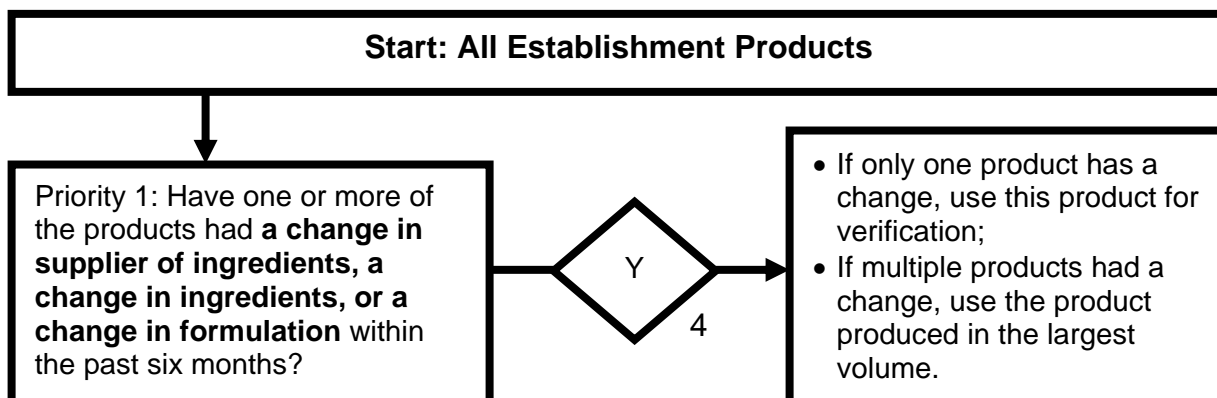
B. IPP are to schedule the “Big 8” Formulation Verification task in advance and determine which products will be produced on that date.

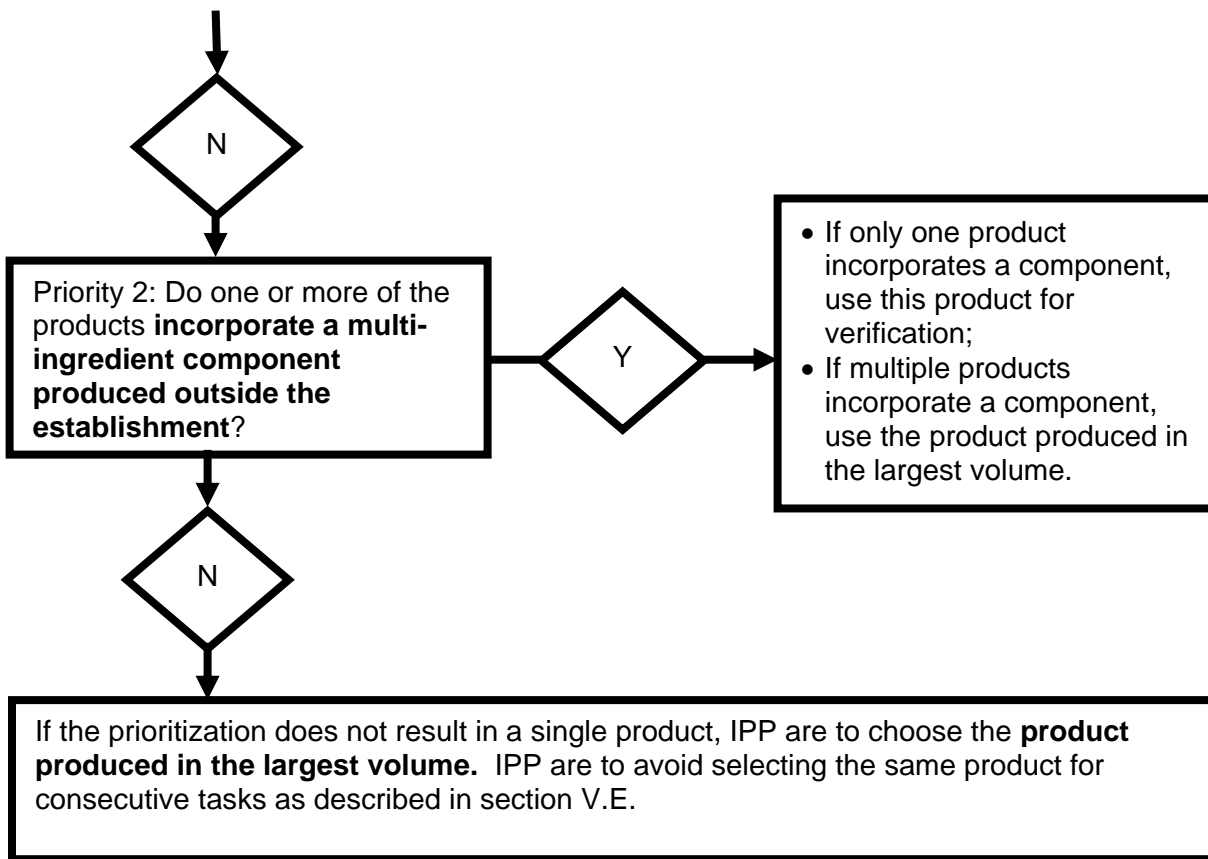
C. IPP are to select one product, which may or may not contain an allergen, for the “Big 8” Formulation Verification task. IPP in establishments and plants with multiple shifts are to complete the verification task on each shift.

NOTE: IPP in establishments with multiple shifts are to coordinate with each other to avoid selecting the same product for a “Big 8” Formulation Verification task.

D. IPP are not to select the same product for consecutive “Big 8” Formulation Verification tasks and are to, where possible, to first select products that have not been selected previously for this task; exceptions would include repeating the tasks for products associated with a change in supplier, change in ingredients, change in formulation, or if the establishment produces a very limited number of products.

E. If the establishment produces more than one product, IPP are to use the following product flow chart to prioritize a product for the “Big 8” Formulation Verification task. IPP are to apply the prioritization flow chart to all products and eligible establishments as per Section IV.I. of this directive regardless of whether they produce 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).

F. IPP are to obtain the selected product formulation from the establishment after completing the prioritization process. The product formulation is to be specific to the actual product, not a general formula.

1. 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 381.180.

G. IPP are to perform the "Big 8" Formulation Verification task using a record review and observation component for the production of the product selected using the product prioritization flow chart in this section of this directive. IPP are to verify that:

1. All ingredients used in the production of the product are present on the product formulation record (through Record Review and Observation);

2. All ingredients in the product formulation are declared in the ingredients statement on the product label by common or usual name in descending order of predominance and that the appropriate label is applied to the product (through Record Review and Observation); and

3. The applied label is consistent with the establishment's label approval on file (through Record Review).

NOTE: IPP can use the list of common ingredients and foods in **Attachment 1** of this directive for help in identifying "Big 8" allergens.

H. IPP are to answer specific questions related to the "Big 8" Formulation Verification task in PHIS. These questions are located on the "additional info" tab of the task. See **Attachment 2** of this directive for questions, answer choices, and related guidance. IPP are to be aware that if they select one or more of the "Big 8" allergens in response to Question 1, the Establishment Profile Report will automatically populate this field within 30 days of completing the task to reflect that the establishment or plant uses "Big 8" allergens in its product formulation.

NOTE: IPP are not required to, nor able to, edit the "Big 8" allergens field in the Establishment Profile Report.

I. IPP are to perform direct observation to verify that all ingredients used in a product formulation are appropriately declared on the final meat, poultry, or egg product labels.

1. IPP are to verify that all ingredients listed on the labels of incoming food and food ingredients (e.g., multi-ingredient components such as sauces or seasoning packets) are listed on the labels of the meat, poultry, or egg products in which they are used.

a. Ingredients classified as spices and flavoring may be declared under the general declaration of "spices" or "flavoring";

b. Except under limited circumstances, the label does not need to declare substances that FSIS has determined meet the definition of a processing aid or incidental additive. However, processing aids or incidental additives derived from allergens (e.g., soy) and ingredients of public health concern are exceptions and must be declared on labels; and

- c. Releasing agents used to prevent sticking of foods to food contact surfaces are not considered processing aids or incidental additives. The label must declare releasing agents containing food allergens (e.g., soy).
2. IPP are to verify that all of the ingredients listed in a “may contain” or “produced in a facility” statement on incoming food and food ingredients are listed on the final product label, except in situations where the establishment contacts the supplier of the component and addresses the statement. Establishments producing meat and poultry products would address the statement in the hazard analysis. Specifically, all the ingredients in a “may contain” or “produced in a facility” statement of a purchased ingredient need not be listed on the final label if the official establishment:
 - a. Contacts the supplier and confirms in writing that the statement is a cautionary statement, and no such ingredient is in the product; and
 - b. 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.

VIII. “BIG 8 FORMULATION VERIFICATION” NONCOMPLIANCE

A. IPP are to record any noncompliance identified on an NR according to [FSIS Directive 5000.1](#). IPP are to notify their supervisor if they identify a noncompliance during the verification.

B. If IPP find an undeclared allergen, they are to cite **both** the relevant hazard analysis **and** labeling regulations. Examples of potential noncompliances are:

1. Hazard analysis:

- a. If during the course of conducting the verification task, IPP find that a meat or poultry product contains an undeclared allergen, and the establishment has not identified the allergen or allergen containing ingredient as a chemical hazard in its hazard analysis, IPP are to document the noncompliance in an NR. IPP are to cite [9 CFR 417.2\(a\)\(1\)](#) as the relevant regulation because the establishment failed to address a chemical food safety hazard in its process. IPP are also to verify that the establishment has implemented corrective actions that meet the requirements of [9 CFR 417.3\(b\)](#) in response to the unforeseen hazard and are to document noncompliance in an NR;
- b. If during the course of conducting the verification task, IPP find that a meat or poultry product contains an undeclared allergen, and the establishment has identified the allergen as a chemical hazard in its hazard analysis and determined it is not reasonably likely to occur (NRLTO) as a result of a prerequisite program, there is noncompliance with [9 CFR 417.2\(a\)\(1\)](#) and [417.5\(a\)\(1\)](#) because there is evidence that the prerequisite program may not effectively prevent the chemical hazard from being reasonably likely to occur (RLTO). IPP are also to verify that the establishment has implemented corrective actions that meet the requirements of [9 CFR 417.3\(b\)](#) and [417.3\(c\)](#) and, if it does not, IPP are to document noncompliance in an NR;
- c. If during the course of conducting the verification task, IPP find that a meat or poultry product contains an undeclared allergen, and the establishment has identified that

ingredient as a chemical hazard in its hazard analysis and has determined that it is RLTO, IPP are to document noncompliance in an NR citing [9 CFR 417.2\(c\)\(4\)](#). IPP are to do so because they observed a deviation from the critical limit that was not identified through the establishment's monitoring procedure. IPP are also to verify that the establishment has implemented corrective actions that meet the requirements of [9 CFR 417.3\(a\)](#) and [417.3\(c\)](#) and are to document any noncompliance with these requirements in an NR.

NOTE: IPP are to 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. Refer to [FSIS Directive 5000.6, Performance of the Hazard Analysis Verification \(HAV\) Task](#), for additional information regarding the performance of the HAV. IPP are to discuss their concerns with their supervisor if they believe a directed HAV task is needed.

2. Labeling: If during the course of conducting the verification task, IPP find that a meat or poultry product contains one of the "Big 8" allergens that is not declared on the final label, IPP are to document a food safety labeling noncompliance in an NR. The noncompliance is to be documented under the "Big 8" Formulation Verification task citing [9 CFR 317.2](#), [381.118](#), or [590.411\(c\)\(1\)](#) as the relevant labeling regulations.

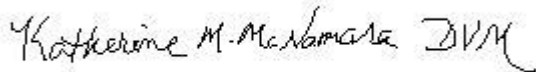
NOTE: If IPP detect additional labeling concerns, they are to describe and document the findings. For example, if IPP find that product contains an ingredient other than one of the "Big 8" allergens that is of public health concern, and that ingredient is not declared, or if the order of predominance of the ingredients on the label is incorrect, IPP are to schedule a directed General Labeling task and document a General Labeling noncompliance with 9 CFR 317.2, 381.118, or 590.411(c)(1) as the relevant regulation. IPP are to discuss their concerns with their supervisor if they believe misbranding has occurred.

VII. SUPERVISOR RESPONSIBILITIES

A. The supervisor is to ensure that IPP know how to review labels and product formulations.

B. A food safety assessment (FSA) or possible enforcement action may be recommended if the establishment has not effectively ensured that allergens and ingredients of public health concern are properly used and declared, or if the lack of controls raises concerns about the adequacy of the meat and poultry establishment's HACCP system.

VIII. QUESTIONS



Head of Service
VT Meat Inspection Service

Attachment 1

Allergenic Ingredients and Foods

[Food Allergy Research and Education](#) is a source of information regarding food allergies. One of their resources for consumers lists allergenic ingredients and foods that may contain allergenic ingredients. The list of ingredients and foods below can be used to help IPP identify “Big 8” allergens.

1. Wheat

Consumers allergic to wheat products are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain wheat.

bread crumbs	Farina	sprouted wheat	wheat gluten
bulgur	flour*	triticale	wheat grass
cereal extract	hydrolyzed wheat protein	vital wheat gluten	wheat malt
club wheat	Kamut	wheat	wheat protein isolate
couscous	matzoh/matzo, matzah/matza	wheat bran	wheat sprouts
cracker meal	Pasta	wheat bran hydrolysate	wheat starch
durum	Seitan	wheat durum	whole wheat berries
einkorn	semolina	wheat germ	
emmer	Spelt	wheat germ oil	

* all purpose, bread, cake, durum, enriched, graham, high gluten, high protein, instant, pastry, self-rising, soft wheat, steel ground, stone ground, whole wheat flour

Additionally, wheat is sometimes found in the following foods:

baking powders (particularly imported)	glucose syrup	starch	Worcestershire sauce
bouillon	soy sauce	surimi	

2. Crustacean Shellfish

Consumers allergic to crustacean shellfish are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products have these ingredients, they contain a “Big 8” allergen

barnacle	crawfish	lobster	shrimp
crab	Krill	prawns	

Additionally, crustacean shellfish are sometimes found in the following foods:

bouillabaisse	fish stock	imitation fish/shellfish	surimi
cuttlefish ink	glucosamine	seafood flavoring	

3. Eggs

Consumers allergic to eggs are advised to avoid foods that may contain these ingredients. If meat or poultry products contain any of these, they likely contain eggs.

albumin/albumen	egg white	lysozyme	ovalbumin
dried egg	egg yolk	mayonnaise	powdered eggs
egg solids	eggnog	meringue	surimi

Additionally, eggs are sometimes found in the following foods:

baked goods	lecithin	marzipan	nougat
egg substitutes	macaroni	marshmallows	pasta

4. Fish

It is generally recommended that consumers allergic to fish should avoid all fish. The most common kinds of fish that individuals are allergic to are salmon, tuna, and halibut.

Additionally, fish is sometimes found in the following foods:

Asian foods	bouillabaisse	meatloaf	Worcestershire sauce
barbeque sauce	imitation fish/shellfish	salad dressing	

5. Peanuts

Consumers allergic to peanuts are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain peanuts.

artificial nuts	ground nuts	nut meat	peanut flour
beer nuts	mixed nuts	nut pieces	peanut protein hydrolysate
goobers	monkey nuts	peanut butter	

Additionally, peanuts are sometimes found in the following foods:

African, Asian, Latin American foods	Chili	marzipan	
baked goods	egg rolls	mole sauce	
candy	enchilada sauce	nougat	

The FDA exempts highly refined peanut oil from being labeled as an allergen.

6. Milk

Consumers allergic to milk are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain milk.

butter	caseinates	half-and-half	recaldent
butter fat	cheese	lactalbumin	rennet casein
butter oil	cottage cheese	lactoferrin	sour cream
butter acid	cream	lactose	sour milk
butter ester	curds	lactulose	tagatose
buttermilk	custard	milk*	whey

casein	diacetyl	milk protein hydrolysate	whey protein hydrolysate
casein hydrolysate	ghee	pudding	yogurt

* *milk in all forms (including condensed, derivative, dry, evaporated, goat's milk and milk from other animals, low fat, malted, milkfat, nonfat, powder, protein, skimmed, solids, whole)*

Additionally, milk is sometimes found in the following foods:

artificial butter flavor	chocolate	margarine	sausages
baked goods	hot dogs	nisin	
bouillon	lactic acid starter culture and other bacterial cultures	nondairy products	
caramel candies	luncheon meat	nougat	

7. Tree Nuts

Consumers allergic to tree nuts are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain a “Big 8” allergen.

almond	coconut	Nangai nut	pili nut
artificial nuts	filbert/hazelnut	natural nut extract	pine nut
beechnut	gianduja	nut butters	pistachio
Brazil nut	ginkgo nut	nut meal	praline
butternut	hickory nut	nut paste	shea nut
cashew	litchi/lichee/lychee nut	nut pieces	walnut
chestnut	macadamia nut	pecan	
chinquapin	marzipan/almond paste	pesto	

Additionally, tree nuts are sometimes found in the following foods:

alcoholic extracts	black walnut hull extract	nut distillates	walnut hull extract
Asian foods	natural nut extract	nut oils	

8. Soybeans

Consumers allergic to soybeans are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain soybeans.

edamame	soy fiber	soy sprouts	tamari
miso	soy flour	soy yogurt	tempeh
natto	soy grits	soya	textured vegetable protein
shoyu	soy ice cream	soybean	tofu
soy albumin	soy milk	soy protein	
soy cheese	soy nuts	soy sauce	

* *FDA exempts highly refined soybean oil from being labeled as an allergen. However cold-pressed soybean oil, which is less commonly used, is not exempt from allergen labeling as it likely contains more residual protein.*

Additionally, soybeans are sometimes found in the following foods:

Asian foods	vegetable broth	vegetable starch	
soy lecithin*	vegetable gum	Worcestershire sauce	

** With the exception of a few specific products, FDA does not exempt soy lecithin from allergen labeling as it generally contains residual protein. The use of soy lecithin in non-stick sprays and coatings (i.e. releasing agents) has led to recalls of FSIS-regulated product when the soy was not properly declared.*

PHIS Questions for the “Big 8 Formulation Verification” Task

Question 1: Which of the following “Big 8” allergens are included in any product formulation at the establishment?

Choices: Soy, milk, fish, shellfish, peanut, tree nuts, wheat, eggs, none

NOTE: *IPP in egg products plants should include “eggs” in their response.*

Question 2: Has the establishment developed and implemented prevention or control measures within the HACCP plan, Sanitation SOPs, or other program to address allergens?

Choices: Yes-HACCP plan, Yes-Sanitation SOPs, Yes-Other Program, No

NOTE: *Check all choices that apply.*

Question 3: Does the establishment use a multi-ingredient component that is produced/mixed outside of the establishment?

Choices: Yes, No

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).*

Question 4: What is the product chosen for the verification activity?

Answer: *Please list the product name of the product chosen for verification based on the prioritization.*

Question 5: How many ingredients does the product chosen for the verification activity contain?

Choices: Less than 15, 15-30, More than 30

Question 6: Was the product formulation consistent with what was observed being used in production?

Choices: Yes, No

Question 7: Were all “Big 8” allergens present in the product formulation also declared on the product label being applied to the product?

Choices: Yes, No, Not Applicable

Question 8: Was the product label being applied to the product consistent with the label approval on file?

Choices: Yes, No