

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

7230.1
Revision 3

1/16/24

ONGOING VERIFICATION OF PRODUCT FORMULATION AND LABELING TARGETING THE NINE MOST COMMON (“BIG 9”) FOOD ALLERGENS

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) for performing the “Big 9” Formulation Verification task in the Public Health Information System (PHIS). IPP verify that establishments are accurately controlling and labeling the nine most common (“Big 9”) food allergens in meat (including *Siluriformes* products), poultry, and egg products 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](#) and [Food Allergy Safety, Treatment, Education, and Research Act \(FASTER Act\) of 2021](#). FSIS is reissuing this directive in its entirety to add sesame as the ninth major food allergen, clarify that the milk allergen is “cow’s milk,” and include an additional example for soy products.

II. CANCELLATION

FSIS Directive 7230.1, Revision 2, *Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common (“Big 8”) Food Allergens*, 9/26/18

III. BACKGROUND

A. Effective Jan. 1, 2023, the FASTER Act expanded the definition of a “major food allergen” to include sesame. Therefore, the “Big 9” food allergens account for approximately 90 percent of all food allergy reactions. The “Big 9” food allergens are:

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

DISTRIBUTION: Electronic

OPI: OPPD

B. FSIS analyses of previous instructions to the field and establishment voluntary recalls of product connected to undeclared allergens revealed that misbranding usually occurred due to changes in ingredient suppliers, products in the wrong package or with misprinted labels, or changes to a product or ingredient formulation.

C. An FSIS analysis of establishment voluntary recalls revealed products with other misbranding issues also failed to include allergens on the product label when a meat or poultry product came in contact with an undeclared allergenic ingredient that was not directly added to the product.

D. When an establishment ships product into commerce with an undeclared allergen, its food safety system has failed to control the chemical hazards associated with allergens. 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.

E. It is important that establishments have preventive measures or controls in place to address undeclared food allergens. When “Big 9” food allergens or other ingredients are not properly declared, FSIS may request the establishment voluntarily recall the affected product (refer to [FSIS Directive 8080.1](#), *Recall of Meat and Poultry Products*, for additional information on recall procedures).

F. This directive applies to meat and poultry product establishments that produce products other than single ingredient products or those that have a combination of only meat or poultry ingredients. 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. Product with secondary inhibitors not shelf stable.

IV. IPP RESPONSIBILITIES

A. IPP are to inform the establishment at the next weekly meeting following issuance of Revision 3, that the Establishment Profile Report has been updated to identify whether “Big 9” allergens are used in product formulations based on the response to Question 1 in the task questionnaire.

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

1. Verify in advance of the meeting 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 with the establishment any products that contain any of the “Big 9” food allergens. Refer them to Attachment 1, which 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 9” 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 V.B. of this directive; and
4. Inform establishment management that FSIS allergen and labeling guidelines are available [online](#), which may assist them in assessing their own allergen program.

C. IPP are to conduct the assigned “Big 9” Formulation Verification task and document findings in PHIS as directed in Section VI of this directive.

V. TIMING OF VERIFICATION ACTIVITIES

A. Each meat, poultry, or egg products establishment that produces product in the HACCP categories listed in Section III. F. of this directive will continue to be assigned a routine “Big 9” Formulation Verification task in PHIS on a monthly basis.

B. If IPP receive the “Big 9” Formulation Verification task in establishments that produce single ingredient products or they only combine various species of meat or poultry products, they are to cancel the task per [FSIS Directive 13000.1](#), *Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)*. Refer to [FSIS 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.

C. In addition to the routine “Big 9” Formulation Verification task, IPP may schedule a directed “Big 9” Formulation Verification task more frequently in an establishment if there are indicators of an increased risk of undeclared allergens. IPP are to discuss these concerns with their immediate supervisor and frontline supervisor (FLS) and select the reason for the directed task as appropriate. IPP are to consider the situations below when considering whether they need to schedule additional “Big 9” Formulation Verification tasks:

1. A recall by the establishment related to “Big 9” 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 Noncompliance Records (NRs), and HACCP NRs for meat and poultry establishments, related to allergens, ingredients of public health concern, or other undeclared ingredients;
4. A history of labeling NRs for the establishment; or
5. Recent product formulation changes, adjustments to ingredients, supplier changes, or new products added by the establishment.

D. IPP are to contact their immediate supervisor and FLS for guidance if at any time they have reason to believe product bearing labels that fail to declare one of the “Big 9” food allergens has entered commerce (refer to [FSIS Directive 8080.1](#)).

VI. “BIG 9” FORMULATION VERIFICATION TASK

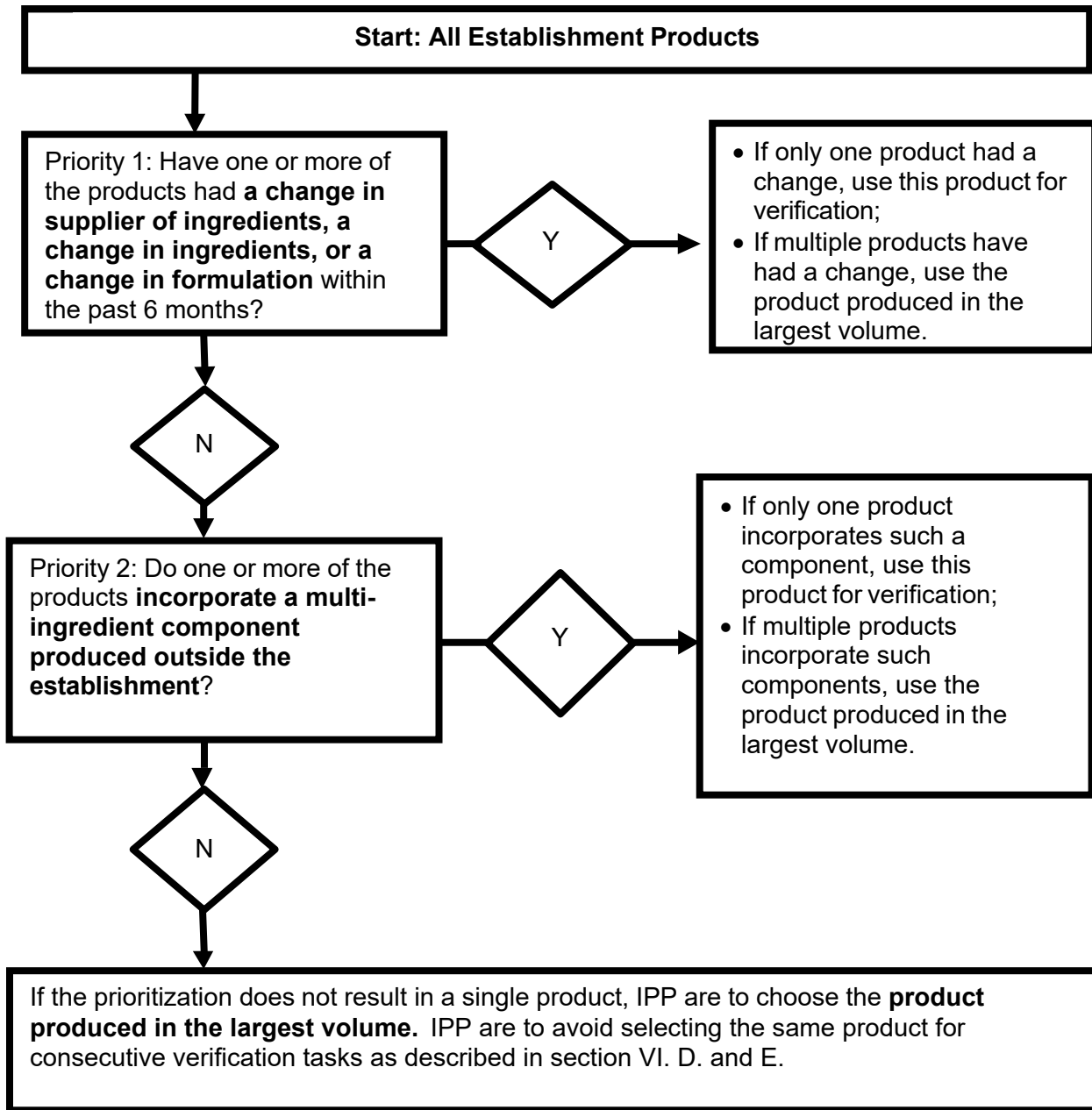
A. IPP are to perform the “Big 9” Formulation Verification task at the frequency assigned in PHIS.

B. IPP are to determine which products will be produced on the date they have planned and scheduled the routine task.

C. IPP are to select one product, which they perceive may or may not contain an allergen, for the “Big 9” Formulation Verification task. IPP in establishments with multiple shifts are to complete the verification task on each shift and are to coordinate with each other to avoid selecting the same product for a “Big 9” Formulation Verification task.

D. IPP are not to select the same product for consecutive “Big 9” Formulation Verification tasks and are to, where possible, 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. IPP are to apply the prioritization flow chart to all products and eligible establishments as per Section III.F. of this directive regardless of whether they produce products containing a “Big 9” 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 formulation for the product selected for the task from the establishment after completing the product prioritization and selection process. The product formulation is to be specific to the actual product, not a general formula.

1. Meat, poultry and egg 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](#), [381.180](#), and [9 CFR 590.411](#).

G. IPP are to perform the “Big 9” Formulation Verification task using the 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).

H. IPP are to use the list of common ingredients and foods in Attachment 1 of this directive for help in identifying “Big 9” allergens.

I. IPP are to answer specific questions related to the “Big 9” Formulation Verification task in PHIS. These questions can be accessed from the “questionnaire” 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 9” 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 uses “Big 9” allergens in its product formulation.

J. IPP are not required to, nor able to, edit the “Big 9” allergens field in the Establishment Profile Report.

K. 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, substances that would normally be considered processing aids or incidental additives that are derived from allergens (e.g., soy) are exceptions and must be declared on labels; and

- c. As a rule, releasing agents applied to food contact surfaces used to prevent sticking of foods are considered processing aids. However, the label must declare the releasing agents that contain food allergens (e.g., soy) in the ingredients statement.

NOTE: [21 U.S.C. 343\(w\)\(6\)](#) provides for a petition process administered by FDA by which companies may request exemption for the declaration requirement for processing aids that contain food allergens. To date, only soy lecithin release agents produced by Archer Daniels Midland and Solae have been exempted from declaration. All other soy lecithin products must be declared by common and usual name in the ingredient statement. If IPP are unsure if an ingredient meets the definition of a processing aid, incidental additive or release agent or if an ingredient used as a processing aid, incidental additive or release agent is required to be declared in the ingredients statement on the product label, they should submit a question to the Labeling and Program Delivery Staff via [askFSIS](#).

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 conducts both of the following:
 - 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.

VII. “BIG 9” FORMULATION VERIFICATION NONCOMPLIANCE

A. IPP are to record any noncompliance identified on an NR according to [FSIS Directive 5000.1, Verifying an Establishment’s Food Safety System](#). IPP in egg products establishments are to follow the instructions in [FSIS Directive 5030.1, Labeling and Import Verification in an Official Egg Products Plant](#).

B. If IPP identify an undeclared allergen, they are to cite both the relevant hazard analysis and labeling regulations. IPP are to notify their immediate supervisor if they identify a noncompliance during the “Big 9” Formulation Verification task. Examples of potential noncompliance that warrant the issuance of a NR are:

1. Hazard Analysis:
 - a. If during the course of conducting the verification task, IPP find that a meat, poultry or egg 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 a 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 a NR;

- b. If during the course of conducting the verification task, IPP find that a meat, poultry or egg 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 a NR;
- c. If during the course of conducting the verification task, IPP find that a meat, poultry or egg 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 a 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 a NR.

C. IPP are to consider what their verification 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 Task](#), for additional information regarding the performance of the HAV. IPP are to contact their FLS if they believe a directed HAV task is needed.

1. Labeling: If during the course of conducting the verification task, IPP find that a meat, poultry, or egg product contains one of the "Big 9" 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 9" Formulation Verification task citing [9 CFR 317.2](#), [381.118](#), or [590.411\(c\)\(1\)](#) as the relevant labeling regulations.

D. If IPP detect other labeling issues, they are to describe and document their findings. For example, if IPP find that product contains an ingredient other than one of the "Big 9" allergens, and that the 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 in an NR citing [9 CFR 317.2](#), [381.118](#), or [590.411\(c\)\(1\)](#) as the relevant regulation. IPP are to discuss their concerns with their FLS if they believe misbranding has occurred. Inspectors should note that while the "Big 9" allergens are the most common allergenic foods, people may have adverse reactions to other substances as well. Consumption of some ingredients, such as sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG), may result in an adverse reaction in certain susceptible individuals, yet they are not considered allergens.

VIII. SUPERVISORY RESPONSIBILITIES

- A. Supervisors are to ensure that IPP have been trained and understand how to review labels and product formulations.
- B. The FLS may request or recommend a [Public Health Risk Evaluation, Food Safety Assessment](#), or possible enforcement action if the establishment has not effectively ensured that allergens and ingredients are properly used and declared, or if the FLS determines that the lack of controls raises concerns about the adequacy of the meat, poultry, and egg products establishments' food safety system.
- C. The FLS is to contact the district office promptly if IPP findings indicate that a product with undeclared allergens may have entered commerce so that, if needed, a preliminary inquiry for a recall can be initiated following the instructions in [FSIS Directive 8080.1](#).

IX. DATA ANALYSIS

The Office of Planning, Analysis and Risk Management will analyze PHIS data from this verification activity. FSIS will use these analyses to determine whether additional policy instructions are needed.

X. QUESTIONS

Refer questions regarding this notice to your supervisor or as needed to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, complete the [web form](#) and select Labeling as the Inquiry Type.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator
Office of Policy and Program Development

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 9” 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 9” 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
egg substitutes	noodles		

Additionally, eggs are sometimes found in the following foods:

baked goods	lecithin	marzipan	nougat
pasta	macaroni	marshmallows	

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	salad dressing	Worcestershire sauce
barbeque sauce	imitation fish/shellfish		

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 cow's milk (usually identified on the label as "milk") are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely

contain cow's 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 hydrosylate	Whey protein hydrosylate
casein hydrolysate	ghee	pudding	yogurt

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

**FDA did not find significant allergic concern if Dey/Engley (DE) broth is used on food-contact surfaces only.

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 9" 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 cheese	soy nuts	soybean
hydrolyzed soy protein	soy fiber	soy protein	(cold-pressed) soybean oil*
miso	soy flour	soy sauce	tamari
natto	soy grits	soy sprouts	tempeh
shoyu	soy ice cream	soy yogurt	textured vegetable protein

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

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. However, soy lecithin used for laboratory purposes (e.g., neutralizing buffered peptone water (nBPW)) is a laboratory grade, highly refined product that is processed to the extent that allergenic proteins are not present in detectable amounts.

9. Sesame

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

benne	sesame flour	sesame seed	sim sim
gingelly	sesame oil*	sesamol	tahini
gomasio	sesame paste	sesamum indicum	til
halvah	sesame salt	sesamolina	

*Highly refined sesame oil is exempt from being labeled as an allergen. However, the use of cold pressed or unrefined sesame oil is common for flavoring purposes, and FDA does not exempt these products from allergen labeling.

Additionally, sesame is sometimes found in the following foods:

Asian foods	sauces and marinades	hummus	processed meats and sausages
baked goods	falafel	margarine	Seasoning blends and spices
tempeh			

PHIS Questions for the “Big 9” Formulation Verification Task

Question 1: Which of the following “Big 9” allergens are included in products produced at the establishment (choose all that apply)?

Choices: Soy, milk, fish, shellfish, peanut, tree nuts, wheat, eggs, sesame, no “Big 9” allergens included in any product at this establishment

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

Question 2: Does the establishment use any components that have multiple ingredients that the establishment does not produce or mix onsite?

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 3: For the selected product, does the establishment have any labels (statements on the package) that bear a “negative” claim (e.g., no soy added) for one or more of the following “Big 9” allergens (choose all that apply)?

Choices: Soy, milk, fish, shellfish, peanut, tree nuts, wheat, eggs, sesame, no negative claims made

Question 4: For the selected product, did the establishment implement control measures within its HACCP Plan, Sanitation SOPs, prerequisite or other programs to prevent misbranding (for example, pre-shipment review check for mistakes on ingredient labeling)?

Choices: Yes, No

Question 5: For the selected product, did the establishment implement control measures within its HACCP Plan, Sanitation SOPs, pre-requisite or other programs to prevent allergen cross-contamination (for example, food allergens from one product getting into another product that doesn’t contain the allergen)?

Choices: Yes, No