



ALLERGEN LABELING ON FOOD PRODUCTS

Disaster Preparedness for Food Businesses

The Food Allergen Labeling and Consumer Protection Act (FALCPA), which took effect on January 1, 2006, requires food manufacturers to use common names to identify major allergens. Allergen declaration is required on products regulated by the Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and state regulatory authorities (e.g., Mississippi Department of Agriculture and Commerce, Mississippi State Department of Health, Mississippi Department of Marine Resources). Additionally, FALCPA's labeling requirements extend to cottage food products and foods packaged by retail or foodservice establishments.

Food allergies are a serious public health concern that affects adults and children of all ages. Food allergies affect 32 million Americans and are reportedly increasing in prevalence. There is no cure for food allergies. True food allergies are immune-mediated systemic allergic reactions to certain foods that can cause serious illness or death. Although more than 160 foods have been identified to cause food allergies in sensitive individuals, the "big eight" most common food allergens account for 90 percent of all food allergies. In the U.S., only these eight most common food allergens are subject to FALCPA labeling requirements.

MAJOR FOOD ALLERGENS

In the United States, there are eight major food allergens, also known as the "big eight." These eight foods and their components (including major ingredient sub-ingredients) are considered to be major food allergens under FALCPA and must be declared on food product labels. Note that major food allergens (as discussed on pages 20–24 of the [FDA Labeling Guide](#)), even if they are present only in trace amounts, must be declared. They include:

1. Milk
2. Eggs
3. Fish
The specific species of fish must be declared (e.g., bass, cod, flounder). See [Guidance for Industry: The Seafood List](#).
4. Crustacean Shellfish
The specific species must be declared (e.g., crab, lobster, shrimp). See [Guidance for Industry: The Seafood List](#).
5. Tree Nuts
The specific type of nut must be declared (e.g., almonds, pecans, walnuts). See [Guidance for Industry: Questions and Answers Regarding Food Allergens](#) (scroll down for a list of tree nuts).
6. Wheat
7. Peanuts
8. Soy

LABELING

If your food product contains any of the major eight food allergens, they must be declared on the product label. Here, we will look at sugar cookies as an example using the ingredients listed below. Ingredients must be listed in descending order of predominance by weight, meaning the ingredient that is used the most by weight is listed first, next most used is listed as second, and so forth.



Ingredient	Sub-ingredients
Enriched flour	wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid
Sugar	
Partially hydrogenated cottonseed oil	
High fructose corn syrup	
Whey	
Eggs	
Vanilla	
Natural and artificial flavoring	
Salt	
Leavening	sodium acid pyrophosphate, monocalcium phosphate
Lecithin	
Mono- and diglycerides	

You have two options for listing allergens on product labels.

Option 1. Include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major food allergen does not appear elsewhere in the ingredient statement for another allergenic ingredient. *In the sugar cookie example, wheat, milk, eggs, and soy are specifically stated and listed within the ingredients, so an additional "contains" statement is not required.*

OR

Option 2. Place the word "Contains," followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in a type size that is no smaller than that used for the ingredient list.

Nutrition Facts

Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin, mononitrate, riboflavin, folic acid), sugar, partially hydrogenated cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring, salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono- and diglycerides.

Any Cookie Company
College Park, MD 20740

Nutrition Facts

Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin, mononitrate, riboflavin, folic acid), sugar, partially hydrogenated cottonseed oil, high fructose corn syrup, whey, eggs, vanilla, natural and artificial flavoring, salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin, mono- and diglycerides.

Contains: Wheat, Milk, Egg and Soy.

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FOOD RECALLS

There are three recall classes for food products, and they are categorized according to the level of hazard involved (Table 1). Undeclared allergens are one of the leading causes of food recalls in the United States in both FDA- and USDA-regulated products. Undeclared allergens are a Class I recall, which means they are required to be recalled due to the seriousness of the hazard.

Table 1. Recall classification.

Class I	Dangerous or defective products that predictably could cause serious health problems or death. Examples include: food found to contain botulinum toxin, food with undeclared allergens , a label mix-up on a lifesaving drug, or a defective artificial heart valve.
Class II	Products that might cause a temporary health problem, or pose only a slight threat of a serious nature. Example: a drug that is under-strength but that is not used to treat life-threatening situations.
Class III	Products that are unlikely to cause any adverse health reaction but that violate FDA or USDA labeling or manufacturing laws. Examples include: a minor container defect or lack of English labeling on a retail food.

ALLERGENS IN INGREDIENTS

Allergens may be in several ingredients used in product formulations. It is important to review, assess, and include major ingredients and their sub-ingredients on product labels. Undeclared allergen recalls are often a result of new ingredients, new suppliers, misprinted labels, products in the wrong package, product reformulation, and ingredient reformulation.

Always read food labels carefully and watch for hidden allergens in your product ingredients. Hidden allergens are ingredients derived from or containing major food allergens with common names that may be unfamiliar to consumers. Table 2 lists foods associated with common allergens. Note: This is not a comprehensive list.

Table 2. Common foods and ingredients that may contain allergens.

Allergens	Common Foods and Ingredients	Allergens	Common Foods and Ingredients
Peanuts	Chili Chocolate Crumb toppings Graham cracker crust Hydrolyzed plant protein Hydrolyzed vegetable protein Mole sauce Peanut flavoring (natural and artificial) Fried foods Ethnic foods: African, Asian, Chinese, Indian, Indonesian, Thai, Vietnamese, Mexican	Milk	Almond butter Butter Calcium caseinate Casein/caseinate Lactose/lactoalbumin Margarine with milk solids Milk Milk chocolate Nonfat milk solids Sodium caseinate Whey
Tree nuts	Black walnut hull extract (flavoring) Natural nut extract Nut distillates/alcoholic extracts Nut oils (e.g., walnut oil, almond oil) Walnut hull extract (flavoring) Grated/shredded coconut	Eggs	Albumin Binder Coagulant Emulsifier Globulin Lecithin Livetin Lysozyme Mayonnaise Ovalbumin Ovamucin Ovovitelin Salad dressings (some) Vitelin
Wheat	Baking mixes (most) Crackers Cream sauces Enriched flour Farina Gravy Graham flour Modified food starch Salad dressings (some) Soy sauce Vegetable gum Vegetable starch		

Allergens	Common Foods and Ingredients
Fish	Barbecue sauce Caesar salad and Caesar dressing Bouillabaisse Caponata (eggplant relish) Imitation or artificial fish or shellfish (surimi, also known as "sea legs" or "sea sticks," is made from fish) Worcestershire sauce (anchovies)
Shellfish	Bouillabaisse Cuttlefish ink (crab or clam extract) Fish stock Glucosamine Seafood flavoring Imitation or artificial fish, crab, or lobster Surimi, also known as "sea legs" or "sea sticks," is made with fish, not shellfish.

Allergens	Common Foods and Ingredients
Soy	Margarines Meat substitutes Pan release (cooking spray) Soy Soybeans Soy flour/soy milk/soy nuts Soy protein isolate (can be found in many seasonings) Soy sauce Tamari (soy) sauce Tempeh Teriyaki sauce Texturized vegetable protein Tofu Vegetable gum Vegetable starch

*This is not a comprehensive list.

RESOURCES AND REFERENCES

Food and Drug Administration (FDA). Food Labeling Guide. <https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf>

Food and Drug Administration (FDA). Guidance for Industry: Questions and Answers Regarding Food Allergens (Edition 4). <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergens-edition-4>

Food and Drug Administration (FDA). Guidance for Industry: The Seafood List. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-seafood-list>

United States Department of Agriculture – Food Safety and Inspection Service (USDA FSIS). Compliance Guidelines Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling. <https://www.fsis.usda.gov/wps/wcm/connect/f9cbb0e9-6b4d-4132-ae27-53e0b52e840e/Allergens-Ingredients.pdf?MOD=AJPERES>

MSU EXTENSION PUBLICATIONS

P3545 *Labeling Mississippi Cottage Food Products*. <http://extension.msstate.edu/publications/labeling-mississippi-cottage-food-products>

P2920 *Basic Labeling Requirements for Food Products Entering Commerce*. <http://extension.msstate.edu/publications/publications/basic-labeling-requirements-for-food-products-entering-commerce>

P3542 *Developing a Food Recall Plan*. <http://extension.msstate.edu/publications/developing-food-recall-plan>

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By **Courtney A. Crist**, PhD, Assistant Extension Professor, Food Science, Nutrition, and Health Promotion.

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