



FOOD ALLERGEN LABELING

referencing

“A food Labeling Guide – Guidance for Industry – January 2013”

U.S. Department of health & Human services

Food & Drug Administration

Center for Food Safety & Applied Nutrition

General Information

F1. What is the Food Allergen Labeling and Consumer Protection Act of 2004?

Answer: The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (or Title II of Public Law 108-282) is a law that was enacted in August 2004. Among other issues, FALCPA addresses the labeling of all packaged foods regulated by the FDA. We recommend that producers of meat products, poultry products, and egg products, which are regulated by the U.S. Department of Agriculture (USDA), contact appropriate USDA agency staff regarding the labeling of such products. Also see Information about Food Allergens for more information about the agency's food allergen activities and related guidance documents that address additional FALCPA questions and answers.

<http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/default.htm>

F2. What is a “major food allergen?”

Answer: Under FALCPA, a “major food allergen” is an ingredient that is one of the following eight foods or food groups or an ingredient that contains protein derived from one of them:

- a. milk
- b. egg
- c. fish
- d. Crustacean shellfish
- e. tree nuts
- f. wheat
- g. peanuts
- h. soybeans

Although more than 160 foods have been identified to cause food allergies in sensitive individuals, the “major food allergens” account for 90 percent of all food allergies. Allergens other than the major food allergens are not subject to FALCPA labeling requirements.

F3. When did the labeling requirements of the FALCPA become effective for packaged foods sold in the United States?

Answer: All packaged foods regulated by FDA under the FD&C Act that are labeled on or after January 1, 2006, must comply with FALCPA's food allergen labeling requirements.

F4. Are flavors, colors, and incidental additives subject to FALCPA labeling requirements?

Answer: Yes. FALCPA labeling requirements apply to foods that are made with any ingredient, including flavorings, colorings, or incidental additives (e.g., processing aids), that is or contains a major food allergen.

F5. Do retail and foodservice establishments have to comply with FALCPA's labeling requirements?

Answer: FALCPA's labeling requirements extend to foods packaged by a retail or foodservice establishment that are offered for human consumption. However, FALCPA's labeling requirements do not apply to foods provided by a retail food establishment that are placed in a wrapper or container in response to a consumer's order - such as the paper or box used to convey a sandwich that has been prepared in response to a consumer's order.

Foods Not Subject To FALCPA

F6. Are there any foods exempt from FALCPA labeling requirements?

Answer: Yes. Under FALCPA, raw agricultural commodities (generally fresh fruits and vegetables) are exempt as are highly refined oils derived from one of the eight major food allergens and any ingredient derived from such highly refined oil. In addition, FALCPA provides mechanisms by which a manufacturer may request that a food ingredient may be exempt from FALCPA's labeling requirements. See FALCPA Section 203 for details on how to request allergen labeling exemptions.

<http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106187.htm>

F7. Are molluscan shellfish considered a major food allergen under FALCPA?

Answer: No. Under FALCPA, molluscan shellfish (e.g., such as oysters, clams, mussels, or scallops) are not major food allergens. However, Crustacean shellfish (e.g., crab, lobster, or shrimp), and ingredients that contain protein derived from Crustacean shellfish, are major food allergens.

F8. Does FALCPA provide any specific direction for declaring the Presence of ingredients from the three food groups that are designated as “major food allergens (i.e., tree nuts, fish, and Crustacean shellfish)”?

Answer: Yes. FALCPA requires that in the case of tree nuts, the specific type of nut must be declared (e.g., almonds, pecans, or walnuts). The species must be declared for fish (e.g., bass, flounder, or cod) and Crustacean shellfish (crab, lobster, or shrimp).

F9. Under section 403(w)(1) of the FD&C Act, a major food allergen must be declared using the name of the food source from which the major Food allergen is derived. Section 403(w)(2) of the FD&C Act provides that, in the case of fish or Crustacean shellfish, the term “name of the food source from which the major food allergen is derived” means the “species” of fish or Crustacean shellfish. What is the “species” of fish or Crustacean shellfish for purposes of section 403(w)(2)?

Answer: A declaration of the “species” of fish or Crustacean shellfish for purposes of complying with Section 403(w)(2) should be made using the acceptable market name provided in FDA's The Seafood List. The Seafood List is a compilation of existing acceptable market names for imported and domestically available seafood. We note, however, that if a “Contains” statement is used to declare the source of the fish or Crustacean shellfish, we would not object to just the type of fish or Crustacean shellfish being used, e.g., “Contains salmon” or “Contains trout.”

F10. Section 201(qq) of the FD&C Act defines the term “major food allergen” to include “tree nuts.” In addition to the three examples provided in section 201(qq) (almonds, pecans, and walnuts), what nuts are considered “tree nuts?”

Answer: The following are considered “tree nuts” for purposes of section 201(qq). The name listed as “common or usual name” should be used to declare the specific type of nut as required by section 403(w)(2).

Common or usual name

Scientific name

Almond	Prunus dulcis (Rosaceae)
Beech nut	Fagus spp. (Fagaceae)
Brazil nut	Bertholletia excelsa (Lecythidaceae)
Butternut	Juglans cinerea (Juglandaceae)
Cashew	Anacardium occidentale (Anacardiaceae)
Chestnut (Chinese, American, European, Seguin)	Castanea spp. (Fagaceae)
Chinquapin	Castanea pumila (Fagaceae)
Coconut	Cocos nucifera L. (Arecaceae (alt. Palmae))
Filbert/hazelnut	Corylus spp. (Betulaceae)
Ginko nut	Ginkgo biloba L. (Ginkgoaceae)
Hickory nut	Carya spp. (Juglandaceae)
Lichee nut	Litchi chinensis Sonn. (Sapindaceae)
Macadamia nut/Bush nut	Macadamia spp. (Proteaceae)
Pecan	Carya illinoensis (Juglandaceae)
Pine nut/Pinon nut	Pinus spp. (Pineaceae)
Pistachio	Pistacia vera L. (Anacardiaceae)
Sheanut	Vitellaria paradoxa C.F. Gaertn. (Sapotaceae)
Walnut (English, Persian, Black, Japanese, California), Heartnut	Juglans spp. (Juglandaceae)

The foregoing list reflects FDA's current best judgment as to those nuts that are “tree nuts” within the meaning of Section 201(qq). In order to be comprehensive, this list employs broad scientific categories that may include a species that currently has no food use. The fact that a species falls within a scientific category on this list does not mean that the species is appropriate for food use. FDA further advises that, as with any guidance, the list may be revised consistent with the process for revising guidance documents in our regulation on good guidance practices in 21 CFR 10.115

F11. Section 201(qq) of the FD&C Act includes “wheat” in the definition of major food allergen. What is considered “wheat” for purposes of Section 201(qq)?

Answer: The term “wheat” in Section 201(qq) means any species in the genus Triticum. Thus, for the purposes of Section 201(qq), wheat would include grains such as common wheat (Triticum aestivum L.), durum wheat (Triticum durum Desf.), club wheat (Triticum compactum Host.), spelt (Triticum spelta L.), semolina (Triticum durum Desf.), Einkorn (Triticum monococcum L. subsp. Monococcum), emmer (Triticum turgidum L. subsp. dicoccon (Schrank) Thell.), kamut (Triticum polonicum L.), and triticale (x Triticosecale ssp. Wittm.).

F12. May singular terms be substituted for the plural terms “peanuts,” “soybeans” and the different types of “tree nuts” (e.g., almonds, pecans, or walnuts), and may synonyms for the term “soybean” be used to satisfy the labeling requirements of FALCPA?

Answer: Yes. FDA believes that the singular terms “peanut,” and “soybean,” as well as the singular terms (e.g., almond, pecan, or walnut) for the different types of tree nuts are acceptable substitutes for the plural terms for these major food allergens for the purpose of satisfying the FALCPA labeling requirements. Also, the terms “soybean,” “soy,” and “soya” are reasonable synonyms for the common or usual Name “soybeans,” and any one of these terms may be used to identify the food source of the major food allergen “soybeans.” However, packaged foods that are made using “soybeans” as an ingredient or as a component of a multi-component ingredient (e.g., soy sauce or tofu) should continue to use the word “soybeans” as the appropriate common or usual name for this ingredient to identify properly the ingredient (e.g., “soy sauce (water, wheat, soybeans, salt)”).

FALCPA Labeling (provisions and examples)

F13. How must major food allergens be declared on food labels to comply with FALCPA?

Answer: FALCPA requires food manufacturers to label food products that are made with an ingredient that is a major food allergen in one of the ways shown below.

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

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.

OR

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.

Contains: wheat, Milk, Egg and soy.

Any Cookie company
College Park, MD 20740

F14. Are single ingredient foods that are major food allergens required to comply with FALCPA?

Answer: Yes. Single ingredient foods must comply with the allergen declaration requirements in Section 403(w)(1). A single ingredient food that is, or contains protein derived from milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans, may identify the food source in the name of the food (e.g., “all-purpose wheat flour”) or use the “Contains” statement format. FDA recommends that if a “Contains” statement format is used, the statement be placed immediately above the manufacturer, packer, or distributor statement. For single ingredient foods intended for further manufacturing where the “Contains” statement format is used, the statement should be placed on the PDP of the food.

F15. May a “Contains” statement on a food label provided in accordance with FALCPA list only the names of the food sources of the major Food allergens that are not already identified in the ingredient list for a packaged food?

Answer: No. If a “Contains” statement is used on a food label, the statement must include the names of the food sources of all major food allergens used as ingredients in the packaged food. For example, if “sodium caseinate,” “whey,” “egg yolks,” and “natural peanut flavor” are declared in a product’s ingredients list, any “Contains” Statement appearing on the label immediately after or adjacent to that statement is required to identify all three sources of the major food allergens present (e.g., “Contains milk, egg, peanuts”) in the same type (i.e., print or font) size as that used for the ingredient list.

F16. Is there more than one way to word a “Contains” statement used to declare the major food allergens in a packaged food?

Answer: Yes. The wording for a “Contains” statement may be limited to just stating the word “Contains” followed by the names of the food sources of all major food allergens that either are or are contained in ingredients used to make the packaged product. Alternatively, additional wording may be used for a “Contains” statement to more accurately describe the presence of any major food allergens, provided that the following three conditions are met:

- The word “Contains” with a capital “C” must be the first word used to begin a “Contains” statement. (The use of bolded text and punctuation within a “Contains” statement is optional.)
- The names of the food sources of the major food allergens declared on the food label must be the same as those specified in the FALCPA, except that the names of food sources may be expressed using singular terms versus plural terms (e.g., walnut versus walnuts) and the synonyms “soy” and “soya” may be substituted for the food source name “soybeans.”
- If included on a food label, the “Contains” statement must identify the names of the food sources for all major food allergens that either are in the food or are contained in ingredients of the food.

F16. Is there more than one way to word a “Contains” statement used to declare the major food allergens in a packaged food?

Answer: Yes. The wording for a “Contains” statement may be limited to just stating the word “Contains” followed by the names of the food sources of all major food allergens that either are or are contained in ingredients used to make the packaged product. Alternatively, additional wording may be used for a “Contains” statement to more accurately describe the presence of any major food allergens, provided that the following three conditions are met:

- The word “Contains” with a capital “C” must be the first word used to begin a “Contains” statement. (The use of bolded text and punctuation within a “Contains” statement is optional.)
- The names of the food sources of the major food allergens declared on the food label must be the same as those specified in the FALCPA, except that the names of food sources may be expressed using singular terms versus plural terms (e.g., walnut versus walnuts) and the synonyms “soy” and “soya” may be substituted for the food source name “soybeans.”
- If included on a food label, the “Contains” statement must identify the names of the food sources for all major food allergens that either are in the food or are contained in ingredients of the food.