



**Public Health**  
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**HENRY & STARK COUNTY HEALTH DEPARTMENTS**  
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**FOOD ALLERGEN LABELING**

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

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. FALCPA addresses the labeling of all packaged foods regulated by the FDA. Foods that are made from two or more ingredients must declare the common or usual name of each ingredient contained in the food (21 CFR 101.4(a)(1)). 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>

**What is a "major food allergen?"**

Under FALCPA, a "major food allergen" is an ingredient that is one of the following nine foods or food groups or an ingredient that Contains protein derived from one of the following: **milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans and sesame** 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.



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

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.

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

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.

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

Yes. 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.

## Allergen Labeling (provisions and examples)

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

The allergen's food source must be declared at least once on the food label in one of two ways.

The name of the food source of a major food allergen must appear in **ONE** of the two ways below:

- In parentheses following the name of the ingredient.  
Examples: “lecithin (soy),” “flour (wheat),” and “whey (milk)”
- Immediately after or next to the list of ingredients in a “contains” statement.  
Example: “Contains wheat, milk, and soy.”

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.

Examples of **three** ways that allergens can be declared on a mock candy bar. In the first candy bar, milk and soy are declared as part of the common or usual name of the ingredients, but wheat, egg, and peanut are not, so they are declared in parenthesis after the common or usual name of the ingredient. In the second example, instead of declaring the allergens in parenthesis like in the first candy bar, the major food allergens are declared in the Contains statement. In the third example, in the ingredient list, wheat and milk are clearly declared and egg is declared in parenthesis next to ovalbumin, and consumers are made aware that the natural flavor is made from peanuts.



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

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,



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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.

**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?**

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.

### **Foods Not Subject To FALCPA**

**Are there any foods exempt from FALCPA labeling requirements?**

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 Section 203 for details on how to request allergen labeling exemptions.

**Are molluscan shellfish considered a major food allergen under FALCPA?**

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.

**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)”?**

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).

**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)?**

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.”

**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?”**

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 Name of Treenuts	
Almond	Heartnut
Beech nut	Hickory Nut
Brazil nut	Lichee Nut
Butternut	Macadamia Nut/Bush Nut
Cashew	Pecan
Chestnut (Chinese, American, European, Seguin)	Pine Nut/Pinon Nut
Chinquapin	Pistachio
Coconut	Sheanut
Filbert/hazelnut	Walnut (English, Persian, Black, Japanese, California)
Ginko nut	

**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)?**

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? May synonyms for the term “soybean” be used to satisfy the labeling requirements of FALCPA?**

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”).