

Answers to Frequently Asked Questions About FALCPA

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The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 was passed to ensure that individuals, particularly parents of children with food allergies and others providing food to those children, could easily and accurately identify food ingredients that may cause allergic reactions. Under FALCPA, allergen declarations must be written in plain English. The answers to frequently asked questions about FALCPA appear below.

1. What labeling changes are going to result from the new law?

FALCPA requires that allergens contained in food products be declared in plain English in one of two ways:

- (1) By placing 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 no smaller than that used for the list of ingredients (e.g., “Contains milk and wheat”); or
- (2) By placing the common or usual name of the allergen in the list of ingredients followed in parentheses by the name of the food source from which the allergen is derived (e.g., “natural flavoring [eggs, soy]”).

The name of the allergen needs to appear only once in the ingredient statement. For example, a product that contains both milk and a milk-derived ingredient, such as whey, would be labeled as follows: “milk, sodium caseinate, whey” or “natural flavor (milk), sodium caseinate, whey.”

In the case of nuts and seafood, the law requires that the specific type of nut (e.g., walnut, almond, cashew) or species of fish (e.g., cod, tuna) or shellfish (shrimp, lobster) be specified.

2. When does FALCPA go into effect?

The law applies to food products that are labeled on or after January 1, 2006. Food products manufactured and labeled prior to this time can continue to be shipped by food companies and some will be found on retail shelves after January 1, 2006. Food products that are labeled prior to January 1, 2006, may be found in stores for months and possibly a year or longer, depending on the product’s expiration date.

3. Is there a penalty for noncompliance?

Yes. A company will be subject to the civil and criminal penalty provisions of the Federal Food, Drug, and Cosmetic Act if one of the company’s packaged food products does not comply with the FALCPA labeling requirements. In addition, food products containing undeclared allergens will likely be subject to recall.

4. Why does this act affect only certain allergens?

More than 160 foods have been identified in the scientific literature as triggering food allergies. When drafting the language of FALCPA, Congress limited the labeling requirements to the eight “major food allergens,” which account for 90% of all food allergies in the United States. These

eight foods or food groups are milk, egg, fish (e.g., bass, flounder, cod), crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, pecans, walnuts), wheat, peanuts, and soybeans or an ingredient that contains a protein derived from one of these foods.

While other allergens are not subject to FALCPA's labeling requirements, these allergens and ingredients derived from these allergens must be declared in ingredient statements. Importantly, if you are allergic to an allergen other than one of the Big 8 major allergens (such as sesame seeds or poppy seeds), your allergen is not required to be identified in the "Contains ____" statement that will appear on some packages — you must read the full ingredient statement.

5. If a manufacturer chooses to list "contains," may I assume it includes all allergens and just tell my in-laws to read the "contains" section?

FALCPA requires companies to use *either* (but not both) a "Contains ____" statement or to use common English names embedded in the ingredient statement. Regardless of which format a company chooses, it must include all of the eight major allergens that are present in the food. We recommend that food-allergic individuals and their caregivers review both the ingredient statement and any "Contains ." statement.

6. Do manufacturers need to remove products without plain language once the new labeling law comes into effect?

No.

7. How can I tell if a label meets FALCPA standards?

During this transition period, there is no way to determine whether the food is labeled in accordance with FALCPA. You may want to contact a manufacturer directly to obtain specific information about a particular product.

8. Does FALCPA apply to local companies making local store brands?

The law applies to all food products regulated by the FDA that are required to have ingredient statements. While the FDA technically only has jurisdiction over products that are introduced into interstate commerce, it is difficult to imagine a product that is manufactured locally that would not be subject to the FDA's jurisdiction. Notwithstanding the FDA's broad interpretation of "interstate" commerce, it is possible that locally made foods may not be in full compliance with the FDA labeling requirements, including FALCPA. You should carefully read the ingredient statements of all foods and contact the manufacturer if you have questions.

9. If a product that allergic persons have been tolerating for years now (with the new labeling laws) declares an allergen, do you simply stop giving it to them?

Only you and your doctor can determine whether you should eat a certain food. You should not assume, however, that you can continue to eat a food simply because you could eat it safely in the past. The food formulation may have been changed, the manufacturer may have received new information indicating that a major allergen may now be present in the food, or the manufacturer may be adding the name of the major allergen because FALCPA does not contain an exemption for major allergens that may be present in small quantities thought to be inconsequential. It is impossible to know which is the case. The safest course is to avoid any food that declares the major allergen.

10. With new food labeling, how do we know if an allergen has always been there, and has been safe, or if it is a new added ingredient?

As explained above, there is no way to know this information without contacting the manufacturer.

11. Soy lecithin is safe for my child. Lately I've seen some labels that include soy in the allergen statement, but soy lecithin is the only soy ingredient in the list of all ingredients. Can I assume the soy lecithin is the reason, or could it also have an unsafe soy ingredient?

You cannot assume that soy lecithin is the only soy ingredient in the product. FALCPA does not require each ingredient derived from a major allergen to be identified with a common English name — it only requires the common English name to appear once. In this particular situation, it is possible that soy lecithin may be the only soy-derived ingredient in the product, but it is also possible that the food could contain another soy-derived ingredient.

12. Will products after January 2006 have to label if the product is made on the same lines as peanuts or other allergens or remove the need for "May Contain" statements?

No. FALCPA does not establish standards for the use of "May contain ____" or other advisory labeling statements or address the use of shared lines. FALCPA does, however, require the FDA to issue a report to Congress on this issue.

13. Will FALCPA stop discrepancies between the list of ingredients and the kosher symbol? I had a box of crackers with a "D" kosher symbol, but when I called the manufacturer, it told me there is no dairy in the product. What should I believe?

Kosher labeling cannot be used as a guide to determine whether a product does or does not contain milk.

14. Will FALCPA apply to imported foods?

FALCPA applies to all packaged foods (except meat, poultry, and certain egg products) sold in the United States, whether they are manufactured in the United States or manufactured abroad and imported into the United States.

15. Will FALCPA apply to meat or alcoholic beverages?

No. FALCPA does not apply to the labeling of products regulated by the U.S. Department of Agriculture (USDA), such as meat and poultry products, or to the labeling of products regulated by the Alcohol Tobacco Tax and Trade Bureau (ATTB), such as distilled spirits, wine, and beer. Both the USDA and the ATTB have indicated an interest in amending their regulations to harmonize their labeling requirements with FALCPA. For now, meat and poultry products and alcoholic beverages will not be subject to allergen labeling requirements on January 1, 2006.

16. How will the term "dairy-free" be used under FALCPA?

The FDA regulations authorize the use of "nondairy" but do not specifically address the labeling of "dairy-free." FALCPA does not change the requirements for the use of "nondairy," and this terminology will continue to appear on products that contain caseinates as ingredients. The caseinates must be listed in the ingredient statement with a parenthetical such as "(a milk derivative)."

17. I heard there will be a petition process whereby, if a company can prove that there is not enough allergen to produce a reaction, the ingredient does not have to be on the label.

The law provides three ways of obtaining an exemption from labeling a major food allergen:

- (1) There is a statutory exemption for all highly refined oils.
- (2) A premarket notification may be filed when (i) scientific evidence establishes that the food ingredient does not contain allergenic protein or (ii) the FDA has made a determination through the food additive approval process that the ingredient does not cause an allergic response that poses a risk to human health.
- (3) A petition may be filed requesting an exemption for an ingredient derived from a major food allergen, demonstrating that the ingredient does not cause an allergic response that poses a risk to human health.

18. Why would a company not want to label a common allergen?

The primary purpose of the law is to provide food-allergic individuals with understandable and accurate information about the content of food products, so they can choose from a variety of foods that do not pose a risk from allergic reactions.

There are ingredients that can be derived from major allergens that may contain extremely small levels of allergenic protein. When the level of allergenic protein is present at these low levels, it is believed that the food-allergic individual should be able to safely eat the food. By way of example, there are clinical studies demonstrating that highly refined oils can be safely consumed by food-allergic individuals, even though these oils may contain very small levels of protein. Congress exempted highly refined oils from the allergen labeling requirements.

In the absence of an exemption, there may be a significant increase in allergen labeling. Peanuts, soy, and wheat could be declared on many products that contain a grain flour because of cross contact on the farm. There also may be a significant increase in the number of packages that label "soy" from soy lecithin. Soy lecithin is used in the baking industry because it prevents baked goods from sticking to pans, belts, and other food contact surfaces.

A company may want to avoid labeling for an allergen that is used at very low levels because it will unnecessarily limit a food-allergic individual's already restricted diet.

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