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## Information for Consumers: Food Allergen Labeling And Consumer Protection Act of 2004 Questions and Answers

The Food Allergen Labeling and Consumer Protection Act (FALCPA) will improve food labeling information for the millions of consumers who suffer from food allergies. The Act will be especially helpful to children who must learn to recognize the allergens they must avoid. (See [Food Allergen Labeling and Consumer Protection Act of 2004 \(Public Law 108-282, Title II\)](#)).

The following questions and answers will be useful in answering questions about FALCPA, food allergen labeling, gluten, and advice for consumers.

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**1. What is the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004?**

FALCPA is an amendment to the Federal Food, Drug, and Cosmetic Act and requires that the label of a food that contains an ingredient that is or contains protein from a "major food allergen" declare the presence of the allergen in the manner described by the law.

**2. Why did Congress pass this Act?**

Congress passed this Act to make it easier for food allergic consumers and their caregivers to identify and avoid foods that contain major food allergens. In fact, in a review of the foods of randomly selected manufacturers of baked goods, ice cream, and candy in Minnesota and Wisconsin in 1999, FDA found that 25 percent of sampled foods failed to list peanuts or eggs as ingredients on the food labels although the foods contained these allergens.

**3. When does FALCPA become effective?**

FALCPA applies to food products that are labeled on or after January 1, 2006.

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

FALCPA identifies eight foods or food groups as the major food allergens. They are milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, and soybeans.

**5. FALCPA identifies only 8 allergens. Aren't there more foods consumers are allergic to?**

Yes. More than 160 foods have been identified to cause food allergies in sensitive individuals. However, the eight major food allergens identified by FALCPA account for over 90 percent of all documented food allergies in the U.S. and represent the foods most likely to result in severe or life-threatening reactions.

**6. How serious are food allergies?**

It is estimated that 2 percent of adults and about 5 percent of infants and young children in the U.S. suffer from food allergies. Approximately 30,000 consumers require emergency room treatment and 150 Americans die each year because of allergic reactions to food.

**7. Does FALCPA apply to imported foods as well?**

FALCPA applies to both domestically manufactured and imported packaged foods that are subject to FDA regulation.

**8. FDA held public meetings on allergens and gluten; what were the outcomes of those meetings?**

FDA held two meetings. The first meeting, a Food Advisory Committee Meeting held in June 2005, evaluated FDA's draft report, "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food." See [Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food \(Draft Report\)](#). This draft report was written to help develop FDA's policy on food allergens and to implement FALCPA.

FDA held a second public meeting in August 2005 to obtain expert comment and consultation from stakeholders to help FDA develop a regulation to define and permit the voluntary use on food labeling of the term "gluten-free" ([Public Meeting On: Gluten-Free Food Labeling](#)). The meeting focused on food manufacturing, analytical methods, and consumer issues related to reduced levels of gluten in food. Information presented during and following the meeting provided FDA important and relevant data regarding current industry practices in the production of foods marketed as "gluten-free," challenges faced by manufacturers of "gluten-free" foods, and consumer perceptions and expectations of what "gluten-free" means to them. FDA is using this information to develop its proposal on the use of the term "gluten-free."

**9. Will FDA establish a threshold level for any allergen?**

FDA may consider a threshold level for one or more food allergens.

## **Labeling**

**10. How will food labels change as a result of FALCPA?**

FALCPA requires food manufacturers to label food products that contain an ingredient that is or contains protein from a major food allergen in one of two ways.

The first option for food manufacturers is to 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 allergen does not appear elsewhere in the ingredient statement. For example:



**Ingredients:** Enriched flour (**wheat** flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or 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 (emulsifier)

The second option is to 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 type size that is no smaller than the type size used for the list of ingredients. For example:

*Contains Wheat, Milk, Egg, and Soy*

**11. Will the ingredient list be specific about what type of tree nut, fish, or shellfish is in the product?**

FALCPA requires the type of tree nut (e.g., almonds, pecans, walnuts); the type of fish (e.g., bass, flounder, cod); and the type of Crustacean shellfish (e.g., crab, lobster, shrimp) to be declared.

**12. After January 1, 2006, will I still find products on the supermarket or grocery shelf without the improved labeling?**

Yes. FALCPA does not require food manufacturers or retailers to remove or relabel products from supermarket shelves that do not reflect the additional allergen labeling so long as the products were labeled before January 1, 2006. Therefore, FDA advises consumers with allergies to always read a product's ingredient statement in conjunction with any "contains" statement.

**13. Does FALCPA require the use of a "may contain" statement in any circumstance?**

No. Advisory statements are not required by FALCPA.

**14. Are flavors, colors, and food additives subject to the allergen labeling requirements?**

Yes. FALCPA requires that food manufacturers label food products that contain ingredients, including a flavoring, coloring, or incidental additive that are, or contain, a major food allergen using plain English to identify the allergens.

**15. Are there any foods exempt from the new 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.

**16. Can food manufacturers ask to have a product exempted from the new labeling requirements?**

Yes. FALCPA provides mechanisms by which a manufacturer may request that a food ingredient covered by FALCPA may be exempt from FALCPA's labeling requirements. An ingredient may be exempt if it does not cause an allergic response that poses a risk to human health or if it does not contain allergenic protein.

**17. What does FDA require in order for a product to be exempt?**

FALCPA states that any person can petition the Secretary of Health and Human Services for an exemption either through a petition process or a notification process.

The petition process requires scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.

The notification process must include scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the production method specified in the notification) does not contain allergenic protein.

If either the petition or the notification is granted by the Secretary, the result is that the ingredient in question is not considered a "major food allergen" and is not subject to the labeling requirements.

**UPDATED** For a list of the notifications for exemptions FDA has received, see: [Inventory of Notifications Received under 21 U.S.C. 343\(w\)\(7\) for Exemptions from Food Allergen Labeling](#); for a list of the petitions for exemptions FDA has received, see: [Inventory of Petitions Received under 21 U.S.C. 343\(w\)\(6\) for Exemptions from Food Allergen Labeling](#).

**18. How will FDA make sure food manufacturers adhere to the new labeling regulations?**

As a part of its routine regulatory functions, FDA inspects a variety of packaged foods to ensure that they are properly labeled.

**19. What is cross-contact?**

Cross-contact is the inadvertent introduction of an allergen into a product. It is generally the result of environmental exposure during processing or handling, which may occur when multiple foods are produced in the same facility. It may occur due to use of the same processing line, through the misuse of rework, as the result of ineffective cleaning, or from the generation of dust or aerosols containing an allergen.

**20. Are mislabeled food products removed from the market?**

Yes. A food product that contains an undeclared allergen may be subject to recall. In addition, a food product that is not properly labeled may be misbranded and subject to seizure and removed from the market place.

The number of recalls due to undeclared allergens (8 of the most common allergens only) remained steady between 1999 and 2001. In 2002, recall actions nearly doubled, rising from 68 to 116. This rise may be attributed to the increased awareness of food allergies among consumers and manufacturers and increased attention from FDA inspectors to issues related to food allergy in manufacturing plants.

## **Gluten**

**21. Why is there a concern about gluten?**

Gluten describes a group of proteins found in certain grains (wheat, barley, and rye.) It is of concern because people with celiac disease cannot tolerate it. Celiac disease (also known as celiac sprue) is a chronic digestive disease that damages the small intestine and interferes with absorption of nutrients from food. Recent findings estimate that 2 million people in the U.S. have celiac disease or about 1 in 133 people.

**22. What does FALCPA require with regard to gluten?**

FALCPA requires FDA to issue a proposed rule that will define and permit the voluntary use of the term "gluten free" on the labeling of foods by August 2006 and a final rule no later than August 2008.

**23. What has FDA done in response to the FALCPA mandate?**

FDA held a public meeting in August 2005 to obtain expert comment and consultation from stakeholders to help FDA develop a regulation to define and permit the voluntary use on food labeling of the term "gluten-free" ([Public Meeting On: Gluten-Free Food Labeling](#)). The meeting focused on food manufacturing, analytical methods, and consumer issues related to reduced levels of gluten in food.

## **Advice for Consumers**

**24. How can I avoid foods to which I'm allergic?**

FDA advises consumers to work with health care providers to find out what food(s) can cause an allergic reaction. In addition, consumers who are allergic to major food allergens should read the ingredient statement on food products to determine if products contain a major allergen. A "Contains \_\_\_\_\_" statement, if present on a label, can also be used to determine if the food contains a major food allergen.

**25. But I don't understand what some of the terms mean. How will I know what they are?**

FALCPA was designed to improve food labeling information so that consumers who suffer from food allergies - especially children and their caregivers - will be able to recognize the presence of an ingredient that they must avoid. For example, if a product contains the milk-derived protein casein, the product's label would have to use the term "milk" in addition to the term "casein" so that those with milk allergies would clearly understand the presence of an allergen they need to avoid.

**26. What about food prepared in restaurants? How will I know that the food I ordered does not contain an ingredient to which I am allergic?**

FALCPA only applies to packaged FDA-regulated foods. However, FDA advises consumers who are allergic to particular foods to ask questions about ingredients and preparation when eating at restaurants or any place outside the consumer's home.

**27. How will FALCPA apply to foods purchased at bakeries, food kiosks at the mall, and carry out restaurants?**

FALCPA's labeling requirements extend to retail and food-service establishments that package, label, and offer products for human consumption. However, FALCPA's labeling requirements do not apply to foods that are placed in a wrapper or container in response to a consumer's order - such as the paper or box used to provide a sandwich ordered by a consumer.

**28. When will consumers see the food labels change?**

FALCPA applies to food products that are labeled on or after January 1, 2006, so FDA anticipates that consumers will begin to see new labels on or after that date. However, FDA cautions consumers that there will be a transition period of undetermined length after January 1, 2006, during which it is likely that consumers will see packaged food on store shelves

and in consumers' homes without the revised allergen labeling.

29. **Where can I find more information on food allergens?**

See the following websites for additional information on food allergens:

- Food and Drug Administration: [Information about Food Allergens](#)
- U.S. Department of Agriculture: [Food Safety and Inspection Service](#)
- The National Institute of Health: [National Institute of Allergies and Infectious Diseases](#)
- The National Library of Medicine: [MedlinePlus Food Allergy](#)

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[Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004](#) October 5, 2005

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[Food Allergens](#)

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