

FSMA Frequently Asked Questions: What Are the Allergen Labelling Requirements Under FSMA?

1. My business has to comply with FSMA's Good Manufacturing Practices rules, which include allergen labelling. How do I know if allergen labelling applies to me?

If your business makes or distributes a packaged food that is not a raw agricultural commodity, that food must have a label that lists the ingredients of the food and provides nutrition information. And if that food, or any ingredient in that food, includes proteins from any of the 'major eight' allergens, the presence of that allergen(s) must also be disclosed on the label.

2. What are the major eight allergens?

The following eight foods or food groups account for 90 percent of all food allergies, and so are classed as the 'major eight':

- Eggs
- Crustacean shellfish (shrimp, lobster, crab)
- Fish
- Milk
- Peanuts
- Soybeans
- Tree nuts
- Wheat

Any human food that contains at least one of these foods as an ingredient, or that contains protein derived from one of those foods, is subject to the allergen labelling requirements. For example:

- Whey is derived from milk and contains milk proteins, so any food with whey must have allergen information on its label.
- Lecithin, a food ingredient used as an emulsifier, is typically obtained from soybeans or eggs yolks; any food containing soy- or egg-derived lecithin must have allergen information on its label.

NOTE: Highly refined oils made from these eight foods **are not allergens** because the refining process removes the proteins. For example, highly refined soybean and peanut oils **do not** contain proteins, and so are not allergens. *This exception does not apply to oils that have not been highly-refined.*

NOTE: If a packaged food you produce or distribute **does not include any of these eight foods**, or proteins derived from them, **you are not required to include any allergen information** on its label.

3. My food contains one or more of these eight major allergens. How do I disclose them on the label?

You can disclose the presence of an allergen on the food label using either of two methods:

- a. **Placing what's known as a 'Contains statement'** next to the ingredient list that states all of the major eight allergen foods in your product. For instance, if you make pound cake, you would place a 'Contains eggs, milk, and wheat' statement next to the ingredient list.
NOTE: If using a 'Contains statement', the 'C' in 'contains' **must be capitalized**, and the statement **must be in the same or larger type size** as the text of the ingredient list.
- b. **Include the names of any allergens in the ingredient list.** If the allergen food is a source of an ingredient but the allergen source name itself does not appear in the ingredient list, then place that allergen food name in parenthesis following the common name of an ingredient that includes the



allergen source. For example, you would list 'butter (milk), flour (wheat), eggs' in the ingredient list for a pound cake.

[The FDA has published a detailed guide](#) for food makers and distributors that covers a wide range of federal food labelling laws, including allergen labelling. It provides further information on allergen disclosures for specific types of crustacean shellfish, fish, and tree nuts; allergen disclosures for single-ingredient foods made with a 'major eight' allergen; and formatting of allergen disclosure.

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