



## Managing Allergen Risks in Processed Foods

### A growing allergen problem

Food allergies are an increasing health problem in the US. According to the Centers for Disease Control (CDC), food allergy rates among children rose to 6 percent in 2012.

Allergic reactions are hypersensitive immune reactions that can range in severity. Symptoms typically appear from within a few minutes to two hours after the food is eaten.

Responses can range from minor irritation, such as hives, to swelling, coughing, vomiting, diarrhea, dizziness, difficulty breathing, loss of consciousness, anaphylactic shock, and death.

Reactions vary from person to person, as does the level of allergen needed to cause a reaction.

### 8 major allergens

The FDA recognizes eight major food allergens, which together account for over 90% of documented food allergies in the US:

- Milk | Eggs | Fish | Crustacean shellfish
- Wheat | Soybeans | Tree nuts | Peanuts

Labels must show common names as defined in the [FDA's Guidance for Industry](#). Know also that allergen classifications may not be intuitive. For example, coconut is classified as a tree nut. Consult the Guidance for more information.

Different countries recognize different allergens—for example, Canada recognizes 10 allergens. If you export, check relevant food laws.

### Allergen derivatives

Ingredients derived from major food allergens may also be allergenic and must be labeled accordingly. For example, whey is derived from milk. Allergenic food ingredients are listed in a fact sheet produced by Wisconsin's Dept. of Agriculture, Trade & Consumer Protection: <http://datcp.wi.gov/uploads/Food/pdf/derivatives.pdf>.

### Mandatory allergen labeling

The FDA mandated labeling of allergens in 2004 with the Food Allergen Labeling & Consumer Protection Act (FALCPA).

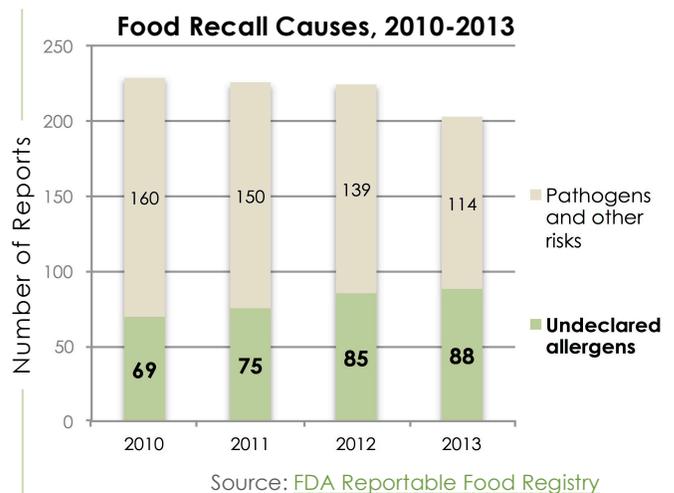
**Labels of foods that contain major food allergens in any amount must declare their presence.** Labels must include ingredients that are allergens themselves (e.g., milk) **and** declare allergens in ingredients that are components of the ingredients (e.g., chocolate chips that contain milk).

See the [FDA's Guidance for Industry](#) on FALCPA.

### Food recalls

Food product recalls are costly to conduct. The consequent erosion in consumer confidence is difficult for a processor to recover from.

Undeclared allergens (allergens that are not properly declared on a food product label) accounted for half of the FDA's food recalls at the end of 2014. FDA reports of undeclared allergens are increasing.



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## Allergen control plans

Allergen control plans establish a systematic way of identifying and managing allergens throughout the manufacturing process, from incoming supplies through shipments of finished product.

Plans include (but are not limited to) the following steps.\*

- Label incoming ingredients that contain allergens, and store them separately.
- Ensure that suppliers document allergens in ingredients and update information.
- Check ingredients when switching suppliers. A different formulation may contain a new allergen.
- Schedule processing runs, establish product flow, and manage tools and equipment to prevent cross-contact.
- Manage reworked product to identify and control product containing allergens.
- Establish traffic patterns, air flow, and equipment maintenance procedures to prevent cross-contamination.
- Ensure labeling and packaging processes that keep consumers fully informed.
- Design the facility, equipment, and cleaning procedures to maximize accessibility and facilitate sanitation.
- Train staff on allergen awareness, control and consequences of not following protocols.
- Review and evaluate the allergen control plan regularly.

\* List adapted from "[Components of an Effective Allergen Control Plan: A Framework for Food Processors](#)," published by the [Food Allergy Research & Resource Program at the University of Nebraska-Lincoln](#).

## State review of allergen labeling

Some state food safety regulatory agencies review product labels for compliance with FDA requirements and assist with requirements, terminology, and format.

*Organic Processing Institute Fact Sheets are fully vetted with experienced professionals from the fields of food processing and regulation. Inquiries about Fact Sheet content can be directed to OPI staff at [info@organicprocessinginstitute.org](mailto:info@organicprocessinginstitute.org).*

## Cottage food ("Pickle Bill") products

Many states have enacted laws that exempt some homemade food products from licensing under specific circumstances.

**However, the labels of these "cottage food products" must still declare major allergens that the products contain.**

## Shared-use kitchens & allergens

Allergen-free production in a shared-use kitchen requires complete separation between allergen-free and other areas.

When separation is not possible, product labels must include allergen statements. Kitchen clients should expect to furnish a list of allergens in their products to kitchen managers.

## Supplemental statements

Even if allergens are not present in a product, risk of allergen contamination may be present, such as when equipment is shared. Processors are responsible for all finished product. Consider supplemental statements in these instances.

EXAMPLE:

*This product was processed on machinery that was used to process products containing (list allergens).*

Supplemental statements **are not a substitute** for good manufacturing practices that prevent contamination.

## RESOURCES

[Food Allergy Research & Resource Program \(FARRP\), University of Nebraska-Lincoln](#)

[FARRP's "Components of an Effective Allergen Control Plan: A Framework for Food Processors" Writing and Implementing an Allergen Control Plan](#). *Food Safety Magazine*, Dec. 2003–Jan. 2004

[Food Allergy Research & Education](#)

FDA • [Guidance for Industry: Questions and Answers Regarding Food Allergens](#)

• [Food Allergen Labeling and Consumer Protection Act of 2004](#) (full regulation)