

Food Allergy: Labelling and exposure risks

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ABSTRACT

In the United States, food allergen labeling is regulated by the U.S. Food and Drug Administration with the implementation of the Food Allergen Labeling and Consumer Protection Act in 2006 that requires packaged foods to clearly indicate the presence of any milk, egg, peanut, tree nuts, wheat, soybeans, fish, and crustacean shellfish. Educating patients and their families how to read food labels includes reading the ingredients list as well as the declaration statement that begins with "Contains." In addition, there is widespread use of precautionary advisory labeling, and patients should be counseled that these precautionary statements are not mandatory and not regulated and, therefore, do not necessarily identify foods with allergen contamination. An allergic reaction to undeclared food allergens as well as complacency with label reading, including precautionary advisory statements, remains a relevant risk for patients with food allergy.

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Along with carrying an epinephrine autoinjector and strict avoidance (see Food Allergy Management section¹), food-label reading is a key educational step communicated to those with a food allergy diagnosis. The responsibility of food-label reading initially lies with the caregivers of children too young to read and identify their food allergens. As children age and become developmentally able, the counseling for food-label reading, as well as decisions and management of their disease, is transitioned to them. Food-label reading is an essential skill to keep patients safe because buying processed and packaged foods is a common part of a consumer's diet. Food allergy label reading requires not only being familiar with the mandated labeling requirements but also how to read the label and its specific allergen declarations. Families must be made aware that not all allergens are listed and that precautionary advisory labeling (PAL) is not regulated. This can lead to misconceptions about the safety of the products with and without labeling. Because undeclared food allergen remains the highest reported category to the Reportable Food Registry (RFR), we must continue to be vigilant in educating our patients about the accidental exposure risks in processed and packaged foods.

FOOD LABELING REQUIREMENTS

Passed in 2004 and implemented in 2006, the Food Allergen Labeling and Consumer Protection Act (FALCPA)² requires that the labels of all packaged foods regulated by the U.S. Food and Drug Administration (FDA) declare the presence of any of the eight common "major" food allergens: milk, egg, peanut, tree nuts, wheat, soybeans, fish, and crustacean shellfish. FALCPA also requires disclosure of the type of tree nut, fish, or crustacean shellfish. On food labels, the allergen will be declared in one of two ways (Fig. 1):

1. The name of the allergen will be listed in plain English in parentheses after the food source ingredient, *e.g.*, casein (milk), lecithin (soy).
2. Underneath the ingredient list, the word "Contains" is printed, followed by the allergen ingredient.

Companies may label their product both ways, such as in Fig. 1. We encourage families to not only look at the "Contains" statement but also to look at the ingredient list, especially in instances in which their allergen(s) is not one of the major eight allergens. Of note, molluscan shellfish such as oysters, clams, mussels, or scallops are not included. Also, although the most recent Food Labeling Modernization Act of 2018 (<https://www.congress.gov/bill/115th-congress/house-bill/5425/text>) seeks to make sesame the ninth major food allergen listed, the bill has not yet been passed. It is important to encourage all patients with food allergy (whether or not their allergen is in the top eight) to read the entire label because companies may choose to declare the ingredient only in the ingredient list rather than the more obvious "Contains" statement.

Patients also must be conscious of the different food-labeling requirements when they travel outside of the country. In Canada, the list of foods required on

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Nutrition Facts	
19 servings per container	
Serving size	14 pieces (30g)
Amount Per Serving	
Calories	100
	<small>% Daily Value*</small>
Total Fat 5g	6%
Saturated Fat 2g	10%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 100mg	4%
Total Carbohydrate 15g	5%
Dietary Fiber 3g	11%
Total Sugars 10g	
Includes 8g Added Sugars	16%
Protein 2g	4%
<small>Not a significant source of vitamin D, calcium, iron, and potassium</small>	
<small>*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.</small>	
Ingredients: Enriched flour (wheat flour, malted barley, niacin, iron, thiamin mononitrate, riboflavin, folic acid) sugar, sunflower oil, eggs, whey (milk), vanilla, natural and artificial flavoring, salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy)	
Contains: wheat, egg, milk, soy	

Figure 1. Sample label with Food Allergen Labeling and Consumer Protection Act (FALCPA) disclosures.

package labeling is extended to include some seeds, such as sesame and mustard as well as molluscan shellfish and sulfites (a preservative).³ In Europe, this list is even more comprehensive; the European Union's Food Information for Consumers defines a list of 14 foods as priority allergens: cereals that contain gluten, eggs, peanuts, soybeans, milk (including lactose), nuts, celery (including celeriac), mustard, sesame, sulfur dioxide and/or sulfites, lupin, fish, crustaceans, and mollusks.⁴ This is in great contrast to the only eight major foods designated by the FDA in the United States. However, in Japan, food labeling is required only for seven ingredients: eggs, milk, wheat, buckwheat, peanuts, shrimp, and crab.⁵

HOW TO READ A LABEL FOR FOOD ALLERGY

When reviewing how to read a food label to identify food allergens, it is important to review with patients and their families the different labeling methods used as listed above. We encourage families to practice this skill until it becomes second nature. An important resource to provide patients is the Food Allergy and Research Education organization's "Food Allergy Field Guide,"⁶ a packet of information that can be provided to patients newly diagnosed with food allergies. The "Understanding Food Labels" section details FALCPA requirements, labeling methods, and reviews frequently asked questions about food labeling. We also note to the patient that ingredients can be listed in

unfamiliar terms, such as lactose, whey, and casein for milk, or lysozyme and globulin for egg. There are also comprehensive lists available for the different ingredient names for allergenic foods listed in the Food Allergy and Research Education Field Guide⁶ under the "Tips for Avoiding Your Allergen" section. Patients are advised strict avoidance of food with any presence of an allergen listed (with the exception of baked milk or egg if listed as the third ingredient or lower in "dry" goods, provided the patient has reached tolerance of the baked antigen⁷).

Reviewing labels and packaging each time that an item is purchased is of utmost importance because manufacturers may change ingredients unbeknownst to patients and add relevant allergens. In this case, a product that families have been buying and eating safely for years may now confer danger. It is also important to note that although FALCPA covers packaged foods, vitamins and dietary supplements, infant formula and foods, and medical foods, it does not include restaurant or bakery items. Some establishments voluntarily clearly disclose food allergens on the menu, but this practice remains uncommon and unregulated. Patients and families, therefore, must rely on being forthcoming about their food allergies with bakery and restaurant staff, and engage in detailed, food allergy-specific conversations with those staff to remain safe when eating out.

PRECAUTIONARY LABELING AND ITS PITFALLS

Despite the improvements in labeling for common food allergens, food-label reading and evaluating the risk of allergen exposure remain frustrating for patients, their families, and practitioners alike. A common question concerns clarification with regard to the PAL. The three most popular forms of PAL statements used are "may contain [allergen]," "manufactured on shared equipment with [allergen]," and "manufactured in the same facility with [allergen]."⁸ This precautionary labeling is not required by the FDA but rather is a voluntary label placed by food manufacturers. There is evidence that there is no factual difference among each of these three statements as pertains to level or likelihood of contamination.⁹ For example, peanut content was studied in foods with different PAL statements, with residues found in 2 of 51 "may contain" products, 3 of 57 "shared equipment" products, and 7 of 68 "shared facility" products.⁹ For milk, contamination was found in 60.7% of the products (17/28) with "may contain," 33.3% of the products (10/30) with "shared equipment," and 28.6% of the products (6/21) with "shared facility."¹⁰

Further confounding patients is that the use of precautionary labels is extensive, with one study showing that, of a product data base of 20,241 items, 17% contained

advisory labels. Chocolate candy and cookies were among the most common foods to use these labels, with up to 50% having a PAL statement.¹¹ Although FALCPA requires disclosure of the type of tree nut, shellfish, or fish ingredient, this disclosure is not required for PAL. This leads to ambiguity of a label that states “may contain tree nuts” when the potential contaminant is limited to walnut for example.¹¹ There are even different legislative allowances of PAL statements in different countries, with Japan and Switzerland forbidding the practice, whereas the European Union, Australia, New Zealand, and Canada allow it without regulation, similar to the United States.¹²

Although PAL is becoming more widespread, patients and their families are increasingly ignoring the statements and consuming these foods, with a study done on 6684 participants that demonstrated that up to 41.1% of the respondents reported buying foods that used PAL in the United States, and up to 36.5% in Canada.⁹ Respondents were least likely to buy foods that used “may contain allergen” labeling (12.3%) but, as detailed previously, the other precautionary statements do not necessarily present less risk. One of the most common misconceptions about precautionary labeling is that it is required by law¹³; it is important to discuss with patients that this indeed is not true. The usefulness of PAL, therefore, is limited due to the ambiguity of statements as well as the lack of regulation of these designations.

EXPOSURE RISKS

Appropriate education for families and patients includes reading the label on a packaged food each and every time. However, it is important to advise that a lack of allergen or advisory statement does not confer zero risk. The assumption that products will be labeled correctly has been proven to be incorrect, with undeclared food allergens being the highest reportable category to the RFR.² The FDA established the RFR, an electronic portal in which reportable food (defined as “an article of food/feed for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals”) can be reported for further investigation. Reports to the RFR can be made by registered food facilities that manufacture, process, pack, or hold food, whereas consumers and food retailers use a state assigned consumer complaint coordinator. The FDA has generated an annual report for 5 years since the RFR opened in 2009. In each annual report, undeclared food allergen remains the highest reported category and has been steadily increasing since inception. Undeclared food allergens represented 30.1% of reports in year 1 and have risen to 47% of reports in year 5.² Of the products reported, bakery

items (frequently, cookies, muffins, and cakes) were the most common culprits in all 5 years. Undeclared milk remains the most reported specific undeclared major food allergen found in bakery items as well as chocolate/candy categories.

A few studies evaluated the allergen content in both advisory-labeled foods and foods without any labels. One study assessed 401 foods, including advisory-labeled and undisclosed allergen labeled, and found detectable residues of allergenic food (egg, milk, or peanut) in 5.3% of advisory-labeled products and 1.9% of similar products without advisory statements.¹⁴ Among foods from small companies, 5.1% were contaminated compared with 0.75% from large companies.¹⁴ Extrapolating the actual rate of allergic reactions due to accidental food ingestion from contamination of packaged foods is difficult to quantify because the rate of unexpected allergic reaction to food in general is unknown.¹⁵ A study done in the European Union showed that, in a survey of patients with food allergy who had experienced an accidental food ingestion and subsequent reaction, 41% of the reactions were due to prepackaged foods. Of the food analyzed with an allergen detected, 18% had a PAL statement, whereas 20% of the inciting food had an allergen detected but neither ingredient nor a PAL statement was listed.¹⁶

Further complicating the matter, there is no specialist consensus on threshold doses for allergenic foods that may be clinically relevant and confer a real risk for patients. The Voluntary Incidental Trace Allergen Labeling 2.0 initiative¹⁷ in Australia has attempted to establish reference doses for 11 commonly allergenic foods, however, with data pooled from 55 studies of clinical oral food challenges. The proposed eliciting doses for an allergic reaction in the most sensitive 1% (the remaining 99% would not react at or less than this threshold) of the population were 0.2 mg of protein for peanut, 0.1 mg for cow’s milk, 0.03 mg for egg, and 0.1 mg for hazelnut.¹⁷ However, these threshold doses would be most useful if accepted internationally, with consistent labeling across all countries and when the allergen content is analyzed on all packaged foods. It is important to note that eliciting doses for patients are going to be variable, and patients with their families who work with an allergist will be better able to discern individualized thresholds.

Although immunotherapy is a foreseeable management option for peanut allergy (other sections of the primer^{18,19}), strict avoidance and carrying an epinephrine autoinjector (see other section of the primer¹) will remain key treatments of food allergy. We will need to continue to educate our patients on how to mitigate their risk of allergic reactions from accidental food ingestion; an important part of this is how to properly read food labels when available. Although we have resources, *e.g.*, FALCPA, that mandate accurate and reliable food labels, we should

encourage our patients to remain vigilant because there are still hazards for undeclared food contamination as well as misperceptions with regard to PAL statements. Education is a vital piece in helping manage food allergy with patients, including instructing how to read a food label and having conversations about what risks lie with consumption of manufactured foods.

CLINICAL PEARLS

- Patients must receive an appropriate education on how to correctly identify food allergens on labels of packaged foods. On nutrition labels in the United States, the allergen will be identified in plain English in the ingredient list and/or declared in a “Contains” statement placed underneath the list.
- It is advisable to patients and their families to remain vigilant with food-label reading, even with items previously tolerated, because of formulation changes that the food manufacturer may have undergone and variability in cross-contamination over time.
- Undeclared food allergen remains the most common reason to report a food through the FDA’s online portal, the RFR, with bakery items being the most common commodity and with milk being the most common undeclared allergen.
- PAL includes statements such as “may contain [allergen],” “manufactured on shared equipment with [allergen],” and “manufactured in the same facility with [allergen]”⁸; this precautionary labeling is not required by the FDA but rather is a voluntary label placed by food manufacturers; there is variability in PAL statements and their allergen content, although consumers assume there is not.⁹
- It is important to discuss with patients and their families that a lack of either a declared allergen or a PAL statement does not confer zero risk because a possibility of an undeclared allergen still exists.

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