

The Consequences of Precautionary Allergen Labeling: Safe Haven or Unjustifiable Burden?



Katrina J. Allen, MD, PhD^{a,b}, and Steve L. Taylor, PhD^c *Melbourne, Victoria, Australia; and Lincoln, Neb*

Precautionary allergen labeling (PAL) also known as “may contain” labeling has been applied to many packaged food products around the world. PAL is a voluntary form of labeling whose original intent was to help ensure that packaged foods were as safe as possible for allergic consumers by alerting them to the possible presence of allergen residues resulting from the use of shared processing equipment, shared processing facilities, or other industry practices. However, the proliferation of PAL and the myriad of various phrasing used as PAL statements are confusing to consumers and serve to diminish their quality of life. Thus many allergic consumers are known to ignore PAL statements. Analytical surveys indicate that many PAL products contain no detectable allergen residues and are likely safe for allergic consumers. However, up to 8% of allergic consumers report having had reactions to the ingestion of PAL products. Clearly a better approach to labeling is needed that balances the health and safety considerations of allergic consumers with their desire to enjoy the widest possible array of foods available in the marketplace. This article presents an overview and discussion of the shortcomings of the current PAL system and explores why a new approach is required. © 2018 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2018;6:400-7)

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Patients with food allergies manage their condition by the complete avoidance of all foods that contain their causative allergen(s). Because food consumption is associated with variable risk in differing situations, these patients can experience a

diminished quality of life as they struggle to maintain a safe and effective allergen avoidance diet.¹ Food-allergic patients or their caregivers rely heavily on the ingredient declarations on packaged food products to determine safe food choices.² They are advised to avoid consumption of packaged foods that have mandated labels that declare the presence of the food that they are allergic to. Although this mandatory form of label declaration is pivotal to the safety of these patients, food-allergic consumers also face management of a second form of labeling called precautionary allergen labels (PAL). The use of PAL has become increasingly widespread in recent years. There are many questions raised by this second form of labeling because it is not currently regulated or standardized and some manufacturers employ them on an *ad hoc* basis. So what do PAL labels really mean? Do food-allergic patients really need to avoid all foods with PAL statements? Are products with PAL statements safe to eat? Are these statements required by regulation? Are they even helpful? Although well intentioned at the outset, there is emerging evidence that a rational approach to the interpretation of PAL statements is difficult for consumers and health care professionals alike. This article aims to explore the issues surrounding PAL statements and seeks to understand if there is a better path forward.

REGULATORY STATUS OF LABELING OF ALLERGENIC FOODS

A large number of countries have enacted legislation mandating the labeling of the most common allergenic foods on packages, but only when these foods or ingredients derived therefrom are used as intentional components of the formulation.³ Although the list of foods requiring mandatory labeling varies by country to some extent, peanuts, tree nuts, milk, eggs, crustacean shellfish, fish, soybeans, and cereal sources of gluten are found on the lists in most of these countries in accordance with recommendations first made by the Codex Alimentarius Commission in 1999.³

Previously, food labeling regulations permitted the undeclared use of certain intentional ingredients derived from allergenic foods if they had no technical or functional effect in the finished food product (defined as processing aid). Examples of processing aids would include the use of soy lecithin as a release agent to prevent baked goods from sticking to processing equipment or the addition of fining agents made from milk, egg, and fish to clarify beverages. In addition, certain ingredients derived from allergenic sources were allowed to be declared in collective terms such as “natural and artificial flavors” or “spices.” Finally, many ingredients were previously declared by a name that did not identify the food source such as casein or whey (milk) or semolina (wheat).

^aDepartment of Paediatrics, Murdoch Children’s Research Institute, The University of Melbourne, Melbourne, Victoria, Australia

^bDepartment of Allergy and Immunology, Royal Children’s Hospital, Parkville, Melbourne, Victoria, Australia

^cFood Allergy Research and Resource Program (FARRP), Department of Food Science and Technology, University of Nebraska, Lincoln, Neb

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Corresponding author: Steve L. Taylor, PhD, Food Allergy Research and Resource Program, Department of Food Science and Technology, University of Nebraska, 281 Food Innovation Center, 1901 N. 21st Street, Lincoln, NE 68588-6207. E-mail: staylor2@unl.edu.

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Abbreviations used

CFR- Code of Federal Regulations

EU- European Union

FALCPA- Food Allergen Labeling and Consumer Protection Act

FDA- Food and Drug Administration

GMP- Good Manufacturing Practices

PAL- Precautionary allergen labels

VITAL- Voluntary Incidental Trace Allergen Labeling

This situation changed in many countries with the increased awareness of food allergies that began to occur in the mid-1990s. In the United States, the Food and Drug Administration (FDA) wrote an open letter to the food industry in 1996 indicating that food manufacturers must declare the allergenic source on the ingredient statement of any packaged food where a processing aid derived from a commonly allergenic source was used (www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens). Subsequently, allergen labeling regulations were enacted in the United States and many other countries to require that all ingredients derived from commonly allergenic sources be declared by the allergenic source on food labels unless regulatory authorities ruled them as exempt from source labeling requirements.³ Such exemptions are variable around the world, but the ingredients that are exempt in some countries (but perhaps not others) pose low, if any, risks to food-allergic consumers.⁴⁻⁷ In the United States, highly refined oils derived from peanuts or soybeans are exempt from source labeling as directed by Congress when they passed the Food Allergen Labeling and Consumer Protection Act (FALCPA). A petition process for source labeling exemptions was implemented in the United States with the passage of FALCPA, but thus far the U.S. FDA has only exempted certain uses of specific formulations of soy lecithin for use as stick-release agents on processing equipment when applied directly to the equipment. The European Union (EU) has established source labeling exemptions for several ingredients derived from commonly allergenic sources including cereal sources of gluten, nuts, and wheat used for making distillates or ethyl alcohol; soybean oil; tocopherols (vitamin E), phytosterols, and plant stanol esters made from soybeans; glucose syrups made from wheat and barley; dextrose and maltodextrin made from wheat; lactitol (from milk); fish gelatin as a carrier for vitamin or carotenoid preparations and fish gelatin or isinglass used as a fining agent for beer and wine (www.foodallergens.info/Legal/Labelling/Exemptions.html). Australia and New Zealand have exempted the following ingredients from source labeling: glucose syrup made from wheat, soybean oil, tocopherols and phytosterols made from soybeans, distilled ethyl alcohol from wheat or whey, and isinglass from fish used in clarification of wines (www.allergenbureau.net/new-allergen-labelling-exemptions-australia-new-zealand-example-industry-collaboration).

Although mandatory labeling of commonly allergenic foods aids food-allergic consumers, such labeling does not cover the unintended inclusion of allergens that can often occur because of cross-contact from the shared use of processing equipment (a common practice in the food industry) or agricultural com-ingling.⁸ Accordingly, the food industry has widely adopted the voluntary use of PAL to alert consumers to the possible unintended presence of allergens. PAL statements are not mandated by regulation, but their use is voluntarily allowed in most

TABLE I. Some phrases used in precautionary allergen labeling

Phrases
May contain "X"
"X" may be present
Not suitable for "X" allergy sufferers
Manufactured on shared equipment with "X"
Manufactured in a shared facility with "X"
Packaged in a shared facility with "X"
May contain the occasional nut
May contain any allergen not present in the ingredient statement
May contain allergens
Allergens may be present
Carefully baked in a nutty environment

countries. From a regulatory perspective, PAL statements must only meet the criteria that they should be truthful and not misleading (Code of Federal Regulations, Title 21, Part 101, Sec. 101.18—Misbranding of food).

PRECAUTIONARY ALLERGEN LABELING AND ITS USE BY THE FOOD INDUSTRY

The adoption of PAL also coincided with the increased awareness of food allergies by the food industry in the mid-1990s and the associated rise of both the prevalence and rates of hospital admissions for anaphylaxis to foods.⁹⁻¹¹ With no guidance from regulatory/public health agencies on threshold levels for allergenic foods, food companies increasingly chose to inform allergic consumers about the potential unintentional allergen presence by applying PAL statements. Increased usage of PAL ensued over the subsequent years with evidence in Australia that at least 65% of all edible packaged goods in a supermarket setting have some form of PAL labeling.¹² Because PAL is used voluntarily by the food industry, many different PAL phrases have appeared on package labels (Table I). In Australia, the mix of various PAL phrases has been quantified over the years with "may contain traces of" (29.0%), "may be present" (12.7%), and "made on the same production line" (12.1%) as the most common.^{12,13}

The food industry makes very frequent use of shared processing equipment and/or facilities across almost the entire range of food product categories.¹⁴ Smaller companies with a diverse range of product formulations often have to use shared equipment with more frequency than larger companies. Larger companies with very popular brands can sometimes devote a processing line to only 1 or a few highly related products. But a small gourmet chocolate manufacturer might well use shared equipment that processes milk, eggs, peanuts, tree nuts, wheat, and soybeans. As such it can be difficult to manage the control of cross-contact of these allergens—particularly when cleaning chocolate lines is a complex and tedious process.

The removal of residues of allergens from shared processing equipment surfaces can be quite difficult in some circumstances. The equipment can be large and disassembly for more effective cleaning can be time consuming. For some food categories, water cannot be used for cleaning. In bakery operations for example, the use of water would lead to mold growth and in chocolate processing, the use of water encourages the growth of pathogenic bacteria. Food residues can, on occasion, be difficult to remove because of stickiness (eg, peanut butter, chocolate) or the

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