

## Review



# Global Perspectives on Allergen Labeling: Harmonization of Regulations and Practices

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## ABSTRACT

The prevention of allergic reactions relies on avoiding allergenic foods making it crucial to accurately label products and provide clear information to customers.

The “Big Eight” allergenic foods (milk, eggs, peanuts, tree nuts, shellfish, fish, soybeans, and wheat) recommended by the Codex Alimentarius form the basis of the global allergy labeling system. Nevertheless, countries worldwide have developed their own labeling systems tailored to their unique dietary habits and allergy prevalence. With the increase in global food trade and allergy rates, inconsistent international food allergy labeling can jeopardize consumer safety and confuse manufacturers. This review provides a comprehensive overview of the Big Eight allergenic foods and a comparative analysis of allergen labeling regulations across various global regions. It highlights the need for internationally consistent labeling standards, and harmonized approaches for precautionary allergen labeling as well as emphasizes global efforts to enhance the identification of allergenic foods. Furthermore, this review aims to enhance global food safety management, promote international cooperation, and help consumers make informed food choices.

**Keywords:** Food allergy; food labeling; management; allergen regulation; allergen labelling, cross reactivity

## INTRODUCTION

Food allergies are defined as adverse health effects resulting from a specific immune response to a particular food, which consistently occurs upon exposure.<sup>1</sup> These allergies manifest as a spectrum of immune responses, ranging from mild gastrointestinal discomfort to severe anaphylactic shocks. The prevalence of food allergies is estimated to range from 1%–4% in adults and 4%–8% in children.<sup>2</sup> Despite the increasing global prevalence of food allergies,<sup>3,4</sup> the primary approach to preventing symptom exacerbation remains the avoidance of allergenic foods.<sup>5</sup> Therefore, the top priority in food allergy safety management for most countries is to establish a labeling system that provides precise information, enabling individuals with allergies to avoid allergenic foods.

The Codex Alimentarius recommends the disclosure of the “Big Eight” allergens, which have high prevalence rates and significant cross-reactivity: milk, eggs, peanuts, tree nuts,

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shellfish, fish, soybeans, and wheat.<sup>6</sup> The Big Eight have established the foundation for global allergen labeling standards. Many countries, including China, Egypt, India, Mexico, and Vietnam, have integrated these standards into their national regulations.<sup>7</sup> However, the specific foods requiring mandatory labeling can vary significantly by country, influenced by local dietary habits and the prevalence of particular allergies within those populations. In response to these regional dietary specificities and the prevalence of local allergens, several countries have developed enhanced labeling systems tailored to their unique needs.

With the expansion of global food trade, there is a growing need for harmonized international standards to ensure the safety of consumers with food allergies worldwide.<sup>8</sup> Allergen labeling must comply with the specific regulatory requirements of each country, ensuring that both domestically produced and imported foods adhere to the labeling standards mandated by the respective national regulations. However, inconsistent allergen labeling practices across countries pose a serious risk to consumers and create significant challenges for manufacturers navigating international trade. For international travelers, the variation in allergen labeling may lead to confusion, increasing the risk of accidental exposure. Meanwhile, for exporters and manufacturers, the need for frequent label modifications complicates production processes and regulatory compliance, potentially resulting in increased costs. In the United States (US), approximately 70 food recalls related to allergenic foods occur annually, while in Europe, approximately 100 alerts are issued each year through the Rapid Alert System for Food and Feed due to undeclared allergenic foods.<sup>9</sup> Given that 1 in 6 of these incidents results in adverse effects on consumer health, this represents a significant public health concern.<sup>10</sup> Therefore, the establishment of internationally harmonized standards is crucial to ensure the accurate labeling of allergenic foods and effectively safeguard consumer health.

This review aimed to demonstrate the allergenic properties and symptoms associated with the Big Eight foods, compare allergen labeling systems and safety management practices globally, and identify other potential priority allergenic foods. Furthermore, the review aimed to propose advanced and internationally harmonized labeling standards by identifying areas for improvement in current labeling practices.

## THE BIG EIGHT ALLERGENIC FOODS: CHARACTERISTICS AND CLINICAL IMPLICATIONS

The Big Eight allergens account for approximately 90% of all food allergy reactions, due to their high prevalence and anaphylaxis rates.<sup>11</sup> These allergens encompass a diverse range of allergenic proteins, and even within the same food category, variations in source can lead to differences in allergenic composition and labeling terminology (**Table 1**). Consequently, the Big Eight allergens are mandated for labeling in most countries worldwide to ensure effective allergy management. To clarify the rationale behind their selection and management on an international scale, this section provides a comprehensive review of the prevalence and clinical characteristics of each allergen.

### Milk

Milk is available in various forms and is essential for the functional properties of many foods in the food industry. However, milk allergy is one of the most prevalent food allergies in early childhood and can persist into adulthood in some cases. It is estimated that the prevalence

**Table 1.** The Big Eight allergens and its indication on labeling statements

Food	Sources	Major allergen proteins	Words used to denote allergen presence on labeling statements
Milk	Cow, buffalo, sheep, and goats	Casein proteins ( $\alpha$ -s1-casein, $\alpha$ -s2-casein, $\beta$ -casein, and $\gamma$ -casein) and whey proteins ( $\beta$ -lactoglobulin, $\alpha$ -lactalbumin, bovine serum albumin, lactoferrins, transferrins, and immunoglobulins).	Milk, milk derivatives, milk solids, milk powder, milk proteins, casein, whey, lactose, caseinate, lactoglobulin, lactoferrin, and rennet casein, butter, and ghee.
Eggs	Chicken, goose, duck, and turkey	Ovalbumin, ovomucoid, ovotransferrin, lysozyme, and alpha-livetin.	Egg, egg white, egg yolk, egg powder, egg solids, albumin, ovalbumin, lysozyme, egg lecithin, globulin, transferrin, mucin, mucoid, and apovitelline.
Peanut	Groundnut	Seed-storage protein (Ara h 1, 2, 3, 4, and 6), birch pollen homology (Ara h 8), lipid-transfer protein (Ara h 9), oleosin (Ara h 10, 16, and 17), and defensin (Ara h 11, 12, 13, 14, and 15).	Peanut, peanut protein, peanut butter, peanut starch, peanut oil, and peanut flour, peanut paste, peanut extract, and peanut pieces.
Tree nuts	Hazelnut, walnut, pecan, almond, cashew, pistachio, Brazil nut, and macadamia nut	2S albumin, non-specific lipid transfer proteins, vicilin, legumin, Bet v 1-like protein, profilin, and oleosin.	Labeled with their botanical names and derivatives of most tree nuts.
Shellfish	Crustaceans (crab, lobster, shrimp, and prawns) and mollusks (oyster, mussel, abalone, and clam)	Tropomyosin, parvalbumins, enolase, aldolase, vitellogenin, and gelatin.	Crustaceans, crab, lobster, shrimp, prawns, mollusks, abalone, clams, mussels, oysters, and their extractives.
Fish	Cod, herring, mackerel, salmon, swordfish, salmon, tilapia, and tuna	Enolase, aldolase, $\beta$ -parvalbumin, parvalbumin, vitellogenin, and tropomyosin.	Fish, fish fillets, fish sauces, seafood mixes, fish parts, split fish, fish oil, and marine oil.
Soybean	Soybean	Defensin (Gly m 2), profilin (Gly m 3), $\beta$ -conglycinin (Gly m 5), glycinin (Gly m 6), and 2S albumin (Gly m 8).	Nuts, granules of soybean, soybean oil, soy lecithin, soy flour, soy milk, suffixes of soy, sauce, and albumin.
Wheat	Wheat and grains	$\omega$ -gliadin (Tri a 19), $\gamma$ -gliadin (Tri a 20), $\alpha/\beta$ -gliadin (Tri a 21), HMW-glutenin (Tri a 26), and LMW-glutenin (Tri a 36).	Wheat, flour, cereal, gluten, lecithin, wheat granules, common wheat, club wheat, and botanical names of wheat varieties.

of food allergies in infants and young children is approximately 2%–3%, with the diagnosed prevalence of cow's milk allergy in the general population, including adults, reaching around 0.9%.<sup>12</sup> Cow's milk protein primarily consists of 80% casein proteins ( $\alpha$ -s1-casein,  $\alpha$ -s2-casein,  $\beta$ -casein, and  $\gamma$ -casein) and 20% whey proteins ( $\beta$ -lactoglobulin,  $\alpha$ -lactalbumin, bovine serum albumin, lactoferrins, transferrins, and immunoglobulins).<sup>13</sup> Common cross-reactants include egg, soy, and peanut-based food products, and cross-reactivity can occur among milks from different mammals such as buffalo, sheep, and goats.<sup>14</sup>

### Eggs

Egg allergy is one of the most prevalent food allergies, with self-reported prevalence ranging from 0.51%–1.0% in adults and 0.64%–1.23% in children and adolescents.<sup>15</sup> While typically seen in childhood, some individuals may continue to experience egg allergy symptoms into adulthood, increasing the risk of fatal reactions. According to the National Health and Nutrition Examination Survey in US, sensitization to eggs is 3.4% in children aged 6 and older and 14.2% in children under 6 years old.<sup>16</sup>

Common allergens found in egg white include ovalbumin, ovomucoid, conalbumin, and lysozyme enzymes, whereas the egg yolk contains vitellus, alpha-livetin, and apoprotein B. The primary allergenic proteins responsible for triggering symptoms are ovalbumin, ovomucoid, and conalbumin. Furthermore, alpha-livetin is a major allergen associated with cross-reactivity.<sup>17</sup> Due to the homologous structure of proteins in chicken eggs and other avian eggs, the body may recognize these proteins as allergens, leading to cross-reactivity.<sup>14</sup>

### Peanut

Peanut allergy is a common food allergy in children that often persists into adulthood. The prevalence of peanut allergy has shown a dramatic increase in the Western world over the

past few decades. For instance, in the US and Canada, the diagnosed prevalence of peanut allergy is approximately 2% of the population, whereas in the United Kingdom (UK), 7.8 million people were sensitized to peanuts between 2001 and 2005.<sup>18</sup>

Peanut allergy is primarily immunoglobulin E (IgE)-mediated and typically results in immediate reactions. The major peanut allergens identified are seed-storage proteins (Ara h 1, 2, 3, 4, and 6), birch pollen homology (Ara h 8), lipid-transfer protein (Ara h 9), oleosin (Ara h 10, 16, and 17), and defensin (Ara h 11, 12, 13, 14, and 15).<sup>18,19</sup> Some of these proteins are essential due to their clinical cross-reactivity with tree nuts, leading to reactions in 20% to 60% of cases.<sup>20</sup>

### Tree nuts

Tree nut allergy has emerged as a major concern in the realm of food allergies due to its lifelong risk and prevalence.<sup>20</sup> Common tree nuts include almonds, walnuts, cashews, hazelnuts, pecans, pistachios, macadamia nuts, and Brazil nuts. The prevalence of tree nut allergy, based on self-reported data, ranges from 0.05% to 4.9% of the population. This allergy is more prevalent in Western countries and Europe, while it is relatively lower in Asia.<sup>21</sup>

Compared to other food allergies, IgE-mediated reactions to tree nuts are associated with a high risk of fatal food allergy-induced anaphylaxis.<sup>22</sup> Proteins responsible for tree nut allergies include 2S albumins, nonspecific lipid-transfer proteins, vicilin, legumins, oleosin, Bet v 1-like proteins, and profilin.<sup>23</sup> These allergens are present in most tree nuts, and due to their high sequence homology, there is a significant possibility for cross-reactivity between nuts and seeds.<sup>21</sup>

### Shellfish

Shellfish are categorized into 2 classes: crustaceans and mollusks. Allergies triggered by the crustacean group (including prawns, crabs, lobsters, and shrimps) and the mollusks group (including oysters, mussels, abalones, and clams) are mainly IgE-mediated reactions and are more prevalent in adults than in children. The global prevalence of these allergies is estimated to be up to 2.5%, with higher rates observed in regions where seafood consumption is common.<sup>20,24</sup>

Shellfish allergy commonly provokes severe anaphylaxis in both children and adults.<sup>25</sup> Shellfish allergens, including tropomyosin, arginine kinase, myosin light chain, sarcoplasmic calcium-binding protein, troponin, triose phosphate isomerase, and paramyosin, are characterized by low molecular weight, water solubility, heat stability, and acidic isoelectric point.<sup>25</sup> Tropomyosin is considered a panallergen due to its clinical cross-reactivity between crustaceans and mollusks, with amino acid sequence identities ranging from 88% to 100%.<sup>24</sup> Additionally, studies have shown sequence identity of 78% to 98% in tropomyosin between shellfish and mites, cockroaches, and parasites, resulting in cross-reactivity.<sup>20</sup>

### Fish

Fish allergies are relatively common, with a survey-based prevalence of nearly 7% in children and 0.12% to 2.7% in adults.<sup>26,27</sup> Approximately 40% of adults with fish allergies experience these conditions as lifelong issues. The major fish allergens that trigger IgE-mediated symptoms include parvalbumin, fish gelatin, enolase, aldolase, vitellogenin, and tropomyosin. These allergens are present in the muscle, skin, and bones of various fish species.<sup>13</sup> Among them, parvalbumin, the most well-known fish allergen, is particularly

abundant in cod, carp, salmon, tuna, and mackerel.<sup>28,29</sup> Enolase and aldolase, identified as clinically relevant allergens, are commonly found in cod and tuna.<sup>30</sup> Vitellogenin, a known allergen in fish roe, has been identified in caviar from various fish. Additionally, tropomyosin has been implicated in allergic reactions to cod, albacore tuna, swordfish, and hake.<sup>30,31</sup> Clinical cross-reactivity has been observed among various fish species, including those from different taxonomic families, and some studies have also reported cross-reactivity between fish and shellfish, as well as between fish and chicken meat.<sup>27</sup>

### Soybeans

Soybeans are a rich source of protein, fatty acids, minerals, and fiber and have been a staple in human diets for centuries. Soybeans, belonging to the legume family, have been recognized as a major allergen for children. Studies have shown varying prevalence rates of soybean allergy, estimated at approximately 0.5% in the general population and 0.4% in children.<sup>32</sup> Over 33 soybean allergens have been identified, including proteins from various superfamilies such as the prolamin superfamily, cupin superfamily, profilin, Bet v 10-like superfamilies, defensins, and oleosin.<sup>32</sup> Fortunately, the rate of clinically relevant cross-reactivity to the legume family is lower compared to other allergenic foods. Studies have shown similarities between soybean and peanut allergens through protein sequence comparison, epitope mapping, and molecular modeling. However, the reported range of clinically relevant cross-reactivity is between 6.5% and 15%.<sup>33</sup>

### Wheat

Wheat is one of the most cultivated crops globally, serving as a primary food source for over a third of the world's population.<sup>34</sup> Despite its nutritional value, wheat contains allergens that can pose health risks to humans. The prevalence of wheat allergy is increasing worldwide, affecting an estimated 0.4% of the global population, with rates as high as 3.6% among children in Europe and northern China.<sup>35</sup>

Major wheat proteins, including albumin, globulin, glutenin, and gliadin, can trigger allergic reactions.<sup>35</sup> Gluten consumption can induce IgE-mediated allergic reactions, with symptoms ranging from mild discomfort to severe reactions depending on the amount ingested.<sup>14</sup> Common allergic reactions to wheat include rashes, dermatitis, skin redness, throat irritation, digestive problems such as abdominal pain, vomiting, and diarrhea, and anaphylaxis in severe cases.<sup>14</sup> Wheat may also cross-react with other grains like barley and rice due to their shared cereal family classification.<sup>36</sup>

## COMPARATIVE ANALYSIS OF INTERNATIONAL ALLERGENIC FOOD LABELING REGULATIONS

Globally, food allergen labeling systems typically mandate the disclosure of allergens when intentionally added as ingredients. However, precautionary allergen labeling (PAL) is permitted in cases of potential cross-contamination in shared production facilities to mitigate risks. This approach aims to prevent allergic reactions and enable individuals with food allergies to make safe and informed dietary choices.<sup>8</sup>

Notably, countries such as the US, Canada, Argentina, Brazil, the European Union, the UK, Japan, Korea, Australia, New Zealand, and South Africa not only follow the Big Eight allergen labeling but have also expanded their regulations to encompass additional allergens relevant

to their populations (**Table 2**). This review summarized the food labeling regulations and policies of each country to understand how they manage food allergy safety (**Table 3**).

**Table 2.** International comparison of mandatory allergen labeling requirements

Food	Codex*	United States	Canada	European Union	United Kingdom	Australia and New Zealand	Japan	Korea	Argentina	Brazil†	South Africa
Milk	+	+	+	+	+	+	+	+	+	+	+
Eggs	+	+	+	+	+	+	+	+	+	+	+
Peanut	+	+	+	+	+	+	+	+	+	+	+
Tree nuts	+	+	+	+	+	+	+‡	+§	+	+	+
Shellfish	+	+	+	+	+	+	+‡	+§	+	+	+
Fish	+	+	+	+	+	+		+§	+	+	+
Soybean	+	+	+	+	+	+		+	+	+	+
Wheat/cereals	+	+	+	+	+	+	+‡	+§	+	+	+
Sesame		+	+	+	+	+					
Mustard			+	+	+						
Triticale			+								
Celery				+	+						
Lupin				+	+	+					

\*Countries adhering to Codex standards include many in Latin America, Africa, and Asia: China, Colombia, Cuba, Egypt, Venezuela, Hong Kong, India, Indonesia, Malaysia, Mexico, Philippines, Morocco, and Vietnam.

†Brazil additionally includes natural latex.

‡Tree nuts include only walnuts. Shellfish includes only shrimp and crab. Additionally, in Japan, buckwheat is mandatory to label. These foods are required to be labeled, with an additional 20 foods recommended for labeling.

§Fish includes only mackerel. Shellfish includes only shrimp, crab, squid, oysters, abalone, and mussels. Tree nuts include only walnuts and pine nuts.

Additionally, Korea requires labeling for buckwheat, pork, peaches, tomatoes, chicken, and beef.

||Shellfish includes only crustaceans, with the inclusion of mollusks being unclear.

**Table 3.** Global allergen labeling regulations and implementation

Country	Allergen labeling practices
Codex	<ul style="list-style-type: none"> <li>- Mandatory allergen labeling is required for pre-packaged foods, with ingredients listed in descending order of weight.</li> <li>- Allergens should be clearly identified within the ingredient list or separately.</li> </ul>
United States	<ul style="list-style-type: none"> <li>- All packaged foods manufactured domestically or imported under FDA regulation must comply with allergen labeling.</li> <li>- Allergens are indicated in parentheses within the ingredient list (e.g., "lecithin (soy), flour (wheat)") or in a separate "Contains" statement.</li> <li>- Specific allergen names (e.g., "cod," "shrimp," "almond") must be used instead of general categories (e.g., "fish," "crustaceans," "tree nuts").</li> </ul>
Canada	<ul style="list-style-type: none"> <li>- All pre-packaged foods containing priority allergens, gluten sources, or sulfites must use prescribed source names.</li> <li>- Allergens must be highlighted either in the ingredient list or in a separate "Contains" statement on the same panel.</li> </ul>
European Union	<ul style="list-style-type: none"> <li>- Allergenic ingredients must be labeled for all consumer foods.</li> <li>- In the ingredient list, allergens must be highlighted (e.g., bold, different font, or background color) to distinguish them from other ingredients.</li> </ul>
United Kingdom	<ul style="list-style-type: none"> <li>- Food businesses must provide allergen information for pre-packaged and non-prepackaged foods.</li> <li>- Allergen names must be emphasized in the ingredient list and displayed in English, with a minimum font size of 1.2 mm.</li> </ul>
Australia and New Zealand	<ul style="list-style-type: none"> <li>- Packaged retail foods must declare allergens and derivatives in both the ingredient list and a separate allergen summary statement using prescribed names.</li> </ul>
Japan	<ul style="list-style-type: none"> <li>- Processed foods and additives containing allergens must be labeled.</li> <li>- Ingredients and additives that include specific allergens must be individually listed. If individual labeling is not feasible, a grouped declaration is allowed.</li> <li>- Individual labeling: Allergens must be specified immediately after the ingredient name in parentheses (e.g., "flour (wheat)").</li> <li>- Grouped labeling: If multiple allergens are present, a concluding statement such as "(Contains ○○ and ○○)" is used at the end of the ingredient list.</li> </ul>
Korea	<ul style="list-style-type: none"> <li>- Labels must include a dedicated allergen section near the ingredient list, clearly separated from the background.</li> <li>- All allergens present must be listed, regardless of quantity.</li> </ul>
Argentina	<ul style="list-style-type: none"> <li>- Pre-packaged food labels must be clear and understandable to consumers.</li> <li>- Ingredients must be listed in Spanish or Portuguese with clear allergen declarations.</li> </ul>
Brazil	<ul style="list-style-type: none"> <li>- Allergenic foods, ingredients, and additives must be declared using standardized phrases such as "Alérgicos: Contém (common allergen name)" or "Alérgicos: Contém derivados de (derived from common allergen name)."</li> <li>- For crustaceans, the specific species name must also be included.</li> </ul>
South Africa	<ul style="list-style-type: none"> <li>- Ingredients must be listed in descending order of mass.</li> <li>- Common allergens must be explicitly declared either in parentheses within the ingredient list or in a separate "Contains" statement.</li> </ul>

FDA, Food and Drug Administration.



## US

In the USA, it is estimated that at least 10.8% of adults (over 26 million individuals) have food allergies, resulting in approximately 30,000 emergency department visits and 150 fatalities annually due to food allergy reactions.<sup>37,38</sup> The US Food and Drug Administration enforces the Food Allergen Labeling and Consumer Protection Act of 2004, which mandates that food labels clearly identify the presence of any of the Big Eight allergenic foods: milk, eggs, fish, crustacean, shellfish, tree nuts, peanuts, wheat and soybean.

Nevertheless, there have been numerous reports of sesame allergy in addition to the 8 major allergenic foods, with research indicating that IgE-mediated sesame allergy likely affects at least 1 million children and adults in the US, highlighting the need for its regulation.<sup>39</sup> Consequently, on April 23, 2021, the Food Allergy Safety, Treatment, Education, and Research Act designated sesame as the ninth major allergenic food.<sup>11</sup> According to these regulations, food produced or imported into the US must clearly indicate the presence of any of the 9 major allergenic foods or their derived proteins on product labels for easy recognition by consumers. Additionally, for tree nuts (such as almonds, pecans, and walnuts), fish (such as bass, flounder, and cod), and crustacean shellfish (such as crab, lobster, and shrimp), the specific species must be identified on the label to provide detailed information.

In the US, major allergenic foods introduced through cross-contamination do not require mandatory labeling, and there are no obligatory regulations for precautionary allergen statements. Some manufacturers voluntarily include advisory warnings like "may contain" or "produced in a facility to alert consumers to potential allergenic food presence," but these warnings are not legally required.

## Canada

In Canada, it has been reported that more than 3 million Canadians have at least one food allergy, with over 600,000 children under 18 affected by food allergies.<sup>40</sup> Health Canada and the Canadian Food Inspection Agency have identified eggs, milk, mustard, peanuts, crustaceans, mollusks, fish, sesame seeds, soy, sulfites, tree nuts (including almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts), wheat, and triticale as priority allergenic foods. This list is similar to the Big Eight allergenic foods but includes mustard, sesame seeds, sulfites, and triticale. According to the Food and Drug Regulations, if priority allergenic foods, gluten sources (barley, oats, rye, triticale, and wheat), or sulfites ( $\geq 10$  ppm total  $\text{SO}_2$ ) are present in a food product, they must be clearly labeled using their common names for easy recognition by consumers.<sup>41</sup>

Canadian manufacturers may include PAL, such as "may contain," but Health Canada does not mandate these statements. Food companies can choose to include "may contain" warnings at their discretion, as long as the statements are accurate and not misleading. The Canadian government advises consumers not to rely solely on precautionary statements to assess risk and to avoid making assumptions based on these labels.<sup>42</sup>

## European Union (EU)

According to the World Allergy Organization, an estimated 11 to 26 million individuals in Europe are affected by food allergies.<sup>43</sup> The EU Regulation No 1169/2011 mandates that information on allergenic foods such as cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulfites ( $\geq 10$  ppm total  $\text{SO}_2$ ), lupin, and mollusks, as well as products derived from these foods, must be clearly

distinguishable on product labels.<sup>44</sup> This regulation includes the Big Eight allergenic foods, along with celery, mustard, sesame seeds, and lupin. In Europe, the self-reported prevalence of celery allergy is 5.5%, while mustard and sesame allergies are reported at 3% and 0%–1.5%, respectively.<sup>45</sup> Although clear evidence supporting their inclusion in mandatory labeling regulations is limited, their increasing prevalence and country-specific dietary characteristics appear to have contributed to their addition.

In accordance with the regulation, the name of the allergenic food or product must be emphasized on the label through a typeset to distinguish it from other ingredients. Additionally, when a product contains nuts, the specific type of nut must be specified. If the name of the food already indicates the allergenic ingredient, additional allergen information can be omitted. The EU does not mandate PAL for unintended cross-contamination, leaving this decision to individual manufacturers.<sup>46</sup>

### UK

It is estimated that approximately 6% of the adult population in the UK has a clinically confirmed food allergy, totaling around 2.4 million adults.<sup>47</sup> The UK's Food Information for Consumers Regulation specifies the requirements for allergen labeling. The regulation mandates the declaration of the following allergenic foods on food labels: celery, cereals containing gluten, crustaceans, eggs, fish, lupin, milk, mollusks, nuts, peanuts, sesame seeds, soybeans, and sulfites ( $\geq 10$  ppm total  $\text{SO}_2$ ).

In the UK, the method of allergen labeling varies based on the type of food product. Foods are categorized into prepacked foods, nonprepacked foods, and prepacked foods for direct sale (such as sandwiches and salads).<sup>48</sup> For prepacked foods, the packaging must list ingredients, with allergenic foods highlighted each time they appear. For nonprepacked foods, allergen information must be provided separately for items containing any of the 14 allergenic foods. Prepacked foods for direct sale, packaged on the same premises where they are sold, require a full ingredient list on the packaging, with allergenic foods clearly emphasized.

The UK allows food manufacturers to voluntarily indicate the possibility of unintentional allergenic food contamination to help consumers make safe and informed food choices. However, excessive use of PAL can limit consumer choices and diminish the effectiveness of warnings for individuals with food allergies. Therefore, the UK acknowledges the risk of misuse and specifies that PAL should only be used after a risk assessment confirms the actual risk of cross-contact with allergenic foods in the supply chain and when the risk cannot be eliminated through risk management measures.<sup>49</sup>

### Australia and New Zealand

Australia and New Zealand have some of the highest rates of food allergies globally, affecting approximately 10% of infants, 4%–8% of children, and around 2% of adults.<sup>50</sup> The Australia New Zealand Food Standards Code, specifically Standard 1.2.3—Information Requirements—Warning Statements, Advisory Statements and Declarations, mandates the labeling of the following allergenic foods: sulfites ( $\geq 10$  ppm total  $\text{SO}_2$ ), gluten-containing cereals (barley, oats, and rye), wheat, tree nuts (almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio, and walnut), crustacea, egg, fish, lupin, milk, mollusk, peanuts, sesame seed, and soybean.<sup>51</sup> Accordingly, manufacturers are required to clearly label products containing these allergenic ingredients. Additionally, catering



businesses, including restaurants and other food service providers, must disclose allergen information to consumers when selling ready-to-eat products.

While the Australia New Zealand Food Standards Code does not regulate voluntary PAL, the Allergen Bureau of Australia and New Zealand recommends the Voluntary Incidental Trace Allergen Labeling (VITAL) program to help consumers make informed food choices.<sup>52</sup> The VITAL program establishes threshold levels for allergenic proteins based on clinical research, targeting the most sensitive individuals with food allergies.

In 2012, Australia analyzed the threshold levels of allergenic proteins for 11 allergenic foods using VITAL 2.0, identifying doses that could trigger allergic reactions in 1% of the population: 0.2 mg of peanut protein, 0.1 mg of milk, 0.03 mg of egg, and 0.1 mg of hazelnut.<sup>53</sup> Manufacturers use the allergen protein thresholds established by the VITAL program to quantitatively assess the risk of allergen cross-contamination during production. This program provides a science-based approach to evaluate the potential presence of unintentional allergenic foods, providing more intuitive information to consumers and playing a crucial role in safeguarding individuals with food allergies.

### Japan

According to a large-scale epidemiological study in Japan, the prevalence of food allergies is estimated to be 5%–10% among infants and 4.5% among school-aged children.<sup>54</sup> Japan was the first country to mandate food allergen labeling in 2002, categorizing allergen labeling requirements into mandatory and recommended categories under the Food Labeling Act and Food Labeling Standards.<sup>55</sup> The regulations mandate clear labeling of 8 high risk allergenic foods, including shrimp, crab, walnuts, wheat, buckwheat, eggs, milk, and peanuts. Additionally, 20 other foods are recommended for allergen labeling due to their lower but still significant risk of causing allergic reactions, such as almonds, abalone, squid, salmon roe, oranges, cashew nuts, kiwi, beef, sesame seeds, salmon, mackerel, soybeans, chicken, bananas, pork, matsutake mushrooms, peaches, yams, apples, and gelatin.<sup>56</sup>

In Japan, the use of the phrase "May Contain" to indicate potential allergenic food presence is strictly prohibited by law. If a food product contains 10 ppm or more of allergenic proteins per unit weight, mandatory allergen labeling is required regardless of intentional inclusion or cross-contamination.<sup>5</sup> Consequently, manufacturers must determine the necessity of allergen labeling using methods such as enzyme-linked immunosorbent assay, polymerase chain reaction, and western blot analysis.

### Korea

In Korea, the prevalence of current immediate-type food allergies among schoolchildren is estimated to be 4.06%, with food-induced anaphylaxis occurring at a rate of 0.97%.<sup>57</sup> Korea is known for its strict allergy regulations outlined in the Act on Labeling and Advertising of Foods. These regulations require clear labeling of foods containing allergenic ingredients, either as raw ingredients or extracted components, irrespective of the quantity. The allergenic ingredients include eggs, milk, buckwheat, peanuts, soybeans, wheat, mackerel, crab, shrimp, pork, peaches, tomatoes, sulfites ( $\geq 10$  ppm total  $\text{SO}_2$ ), walnuts, chicken, beef, squid, shellfish (including oysters, abalone, and mussels), and pine nuts.<sup>58</sup> Notably, Korea includes specific allergens such as buckwheat, beef, chicken, peach, pork, tomato, and pine nut, which are less commonly regulated in other countries, reflecting their prevalence as triggers of immediate-type food allergies among Korean children.<sup>59</sup>

Additionally, if allergenic and non-allergenic products are manufactured in the same facility or share equipment and storage processes, resulting in potential cross-contamination, precautionary statements must be included. These statements should warn of the possible presence of allergenic foods, such as "This product is manufactured in a facility that also processes (allergenic foods) or may contain (allergenic foods)".

### **Argentina**

Although epidemiological data on the overall prevalence of food allergy in Latin America are limited, a recent study estimated the diagnosed prevalence of food allergy in an Argentine pediatric population at 0.87%.<sup>60,61</sup> The allergenic foods requiring declaration in Argentina align with the Codex list, except for gluten-containing cereals, which are specifically defined as "wheat, rye, barley, oats, spelt, or their hybridized strains and products thereof. In Argentina, the use of PAL is permitted provided that manufacturers submit a Declaración Jurada, a sworn statement declaring that "despite adherence to good manufacturing practices (GMP), accidental contamination during the manufacturing process is possible. This statement is then evaluated by the Sanitary Authority, and its use is allowed only if its appropriateness is approved."<sup>62</sup>

### **Brazil**

The Brazilian Ministry of Health and the National Health Surveillance Agency have established regulations that specify allergenic foods, including wheat, rye, barley, oats, and their hybridized strains, crustaceans, eggs, fish, peanuts, soybeans, milk from all mammalian animals, almonds, hazelnuts, cashew nuts, Brazil nuts, macadamias, walnuts, pecan nuts, pistachio nuts, pine nuts, chestnuts, and natural latex.<sup>63</sup>

In Brazil, the use of PAL to warn of potential allergen cross-contamination is not prohibited by law. However, manufacturers must implement GMP at various production stages to identify and control the risk of cross-contamination with allergenic foods or their derivatives. Consequently, each company is required to develop, implement, and manage an allergen control program tailored to their operations and suppliers, ensuring proper allergen management and accurate product labeling.

### **South Africa**

In South Africa, the following foods are designated as allergenic: eggs, cow's milk, crustaceans, mollusks, fish, peanuts, soybeans, tree nuts, and cereals.<sup>64</sup> Additionally, South African regulations mandate precautionary statements to warn consumers about potential cross-reactivity. For instance, if a food product contains lupin or lupin-derived ingredients, the label must include the statement: Allergenicity: Peanut-allergic individuals are at high risk of reacting to lupin present in this product.<sup>65</sup> Manufacturers in South Africa must establish an Allergen Control Plan (ACP) in accordance with the provided guidelines if there is a risk of cross-contamination. Precautionary labeling is only permitted after implementing appropriate ACP and GMP, and it cannot be used to bypass these measures.

## **DISCUSSION**

### **The necessity of continuous updates to the Big Eight allergen list**

In 2020, the Food and Agriculture Organization/World Health Organization convened the Expert Consultation on the Risk Assessment of Food Allergens.<sup>66</sup> The Expert Committee

evaluated the prevalence, severity, and potency of immune-mediated hypersensitivity for several allergenic foods beyond the Big Eight, including mollusks, mustard, celery, sesame, buckwheat, and lupin. The assessment highlighted sesame as a priority allergen, surpassing some foods already included in the Big Eight, such as Brazil nuts, macadamias, and pine nuts. These findings suggest that the Big Eight allergens may not always remain the most prevalent or severe allergens, and highlight the necessity for ongoing revisions to the list.

Furthermore, as novel foods become more prevalent, new potential allergens continue to emerge, necessitating consideration of these factors in regulatory updates. For instance, the growing consumption of edible insects as sustainable protein sources introduces allergenic proteins such as tropomyosin and arginine kinase into the food supply.<sup>67</sup> These proteins can trigger cross-reactivity with crustacean shellfish and dust mite allergens, posing significant risks to individuals with existing allergies to these substances.<sup>68</sup> To ensure consumer safety, regulatory frameworks must adapt by integrating emerging allergens through ongoing research and risk assessments.

### **Harmonizing allergenic food definitions across national regulations**

National regulations may refer to the same allergenic foods but with different meanings. For instance, in the case of milk and eggs, the US defines "milk" as milk from domesticated cows (21CFR131.110) and eggs as eggs from chickens (21CFR160.115). In contrast, EU regulations have broader definitions, where "egg" refers to eggs from all farmed birds and "milk" refers to milk from the mammary glands of farmed animals. Similarly, the classification of allergenic foods varies between countries. For example, while the US, Canada, and Korea classify pine nuts as tree nuts, the EU categorizes them as seeds. Additionally, some countries classify mollusks as fish.<sup>5</sup>

Differences in the scope of food definitions between countries can lead to confusion for businesses engaged in international trade and may fail to provide consumers with adequate information.<sup>8</sup> To address this issue, it is essential for national allergy regulations to clearly define food items and align these definitions with taxonomic standards to reduce confusion and ensure accurate consumer information.

### **Managing cross-reactivity in food allergen labeling**

Cross-reactivity in allergies can act as hidden allergens, triggering food allergy reactions even if the allergenic food is not explicitly listed on the product label. These cross-reactions occur due to the similarity between allergenic protein sequences, making it more likely for patients to exhibit symptoms when consuming foods within the same group. Most countries categorize food groups rather than specific foods for items with high cross-reactivity, such as nuts, shellfish, and fish. This classification helps prevent allergic incidents caused by shared proteins within the same food category.

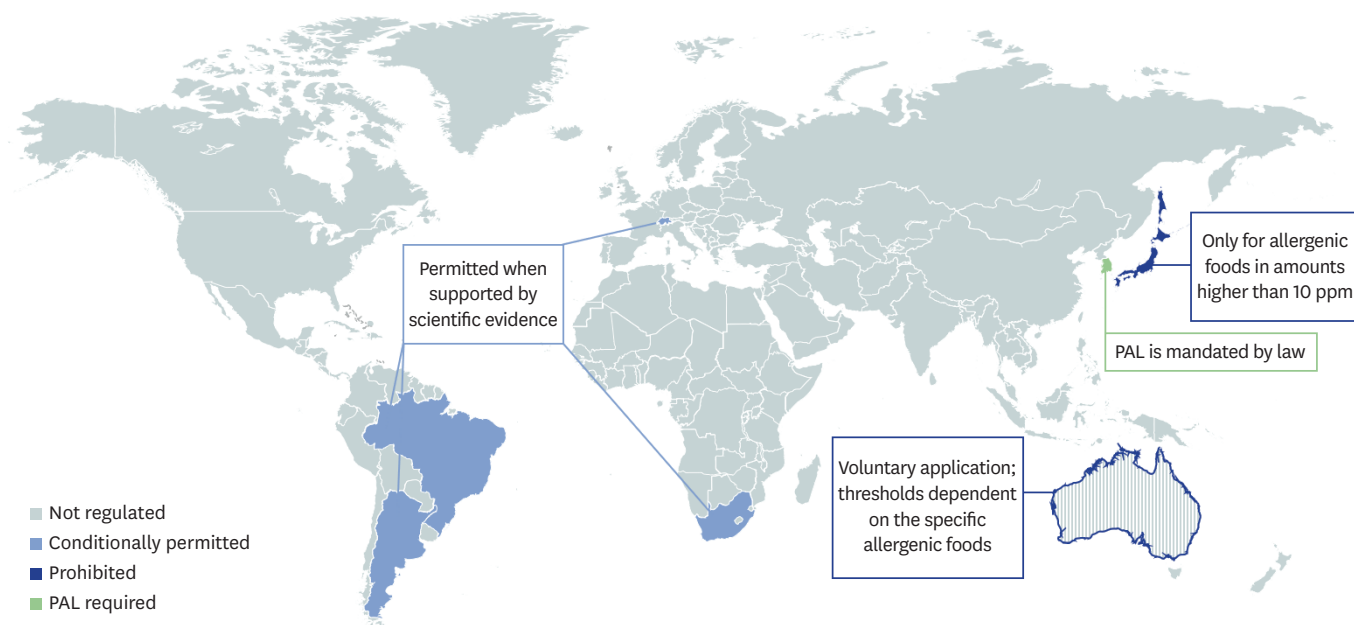
Nevertheless, some countries like Japan and Korea have regulations that specify certain individual foods within broader allergenic groups (e.g., walnuts and pine nuts for nuts, and mackerel for fish in Korea). Although these selections may vary based on national policies, there is room for improvement in terms of cross-reactivity and international harmonization. In the US, regulations require specific species to be listed when nuts, fish, or crustaceans are included, providing consumers with more comprehensive and accurate information without contradicting individual country policies. This approach can serve as a valuable reference for enhancing allergen labeling practices.

Nevertheless, these measures only indirectly safeguard against cross-reactions, highlighting the need for consumer-friendly information on cross-reactivity. For instance, South Africa mandates warning labels for the cross-reactivity between lupin and peanuts, offering a potential solution to this issue.

### Regulatory strategies and challenges for PAL

Many allergic reactions likely stem from undeclared allergens, but quantifying the risk remains challenging due to individual sensitivity, dose-response variability, and exposure frequency.<sup>69</sup> Nevertheless, a prospective cohort study by Blom *et al.*<sup>70</sup> involving 157 adults diagnosed with food allergies found that 46% (73 individuals) experienced accidental allergic reactions due to undeclared ingredients over 1 year. While variability in incident cases limits broad generalization, these findings indicate that cross-contamination may account for a significant proportion of food allergy incidents.

The primary goal of PAL is to prevent incidents caused by accidental allergenic food contamination. However, labeling all potential cross-contamination risks can lead to ambiguous information and significant uncertainty for consumers.<sup>71</sup> Most countries do not have specific regulations for PAL, leaving it up to manufacturers to decide (**Figure**). This lack of government guidance results in inconsistent labeling practices and can overwhelm consumers with excessive information, leading them to ignore allergy warnings.<sup>72</sup> Indeed, a 2006 survey in the US found that 42% of allergy sufferers ignored PAL warnings.<sup>73</sup> Furthermore, surveys conducted in the US and Canada in 2013 have revealed that 40% of consumers with food allergies purchased products labeled "manufactured in a facility that also processes," whereas only 11% bought products labeled "may contain."<sup>74</sup> This indicates that the impact of PAL on consumer behavior varies with the wording, and inappropriate PAL may fail to adequately warn allergic individuals.



**Figure.** Global comparison of PAL regulations.

Most countries do not have specific regulations for PAL. However, Switzerland, South Africa, Argentina, and Brazil only allow PAL if there is scientific evidence of cross-contamination. In Japan, PAL is prohibited by law, and allergenic foods that exceed 10 ppm must be labeled, regardless of intent. Although voluntary threshold labeling is not legally mandated in Australia and New Zealand, it is recommended. Notably, South Korea is the only country where PAL is mandated by law. PAL, precautionary allergen labeling.

Despite these challenges, PAL still plays a role in alerting consumers to potential allergen risks. Therefore, some countries allow PAL but require it to be based on scientific evidence (e.g., Argentina, Brazil, South Africa) to prevent its misuse as a substitute for Hazard Analysis and Critical Control Points, GMP, or ACP. Initiatives like Australia's VITAL and mandatory quantitative labeling standards in countries like Japan aim to provide clear information to consumers and could potentially replace PAL. However, the feasibility of implementing such frameworks globally and the cost-effectiveness of quantitatively detecting food allergens remain concerns. Therefore, a pragmatic regulatory approach for PAL may be to allow its use conditionally, only when there is scientific evidence of allergen contamination and established control measures, as seen in some countries at this time.

## CONCLUSION

As international trade expands, the import and export of food products across various countries, along with the complexity of distribution channels, also grows. Accurate product labeling is crucial for preventing food allergies, making it important to adhere to internationally agreed-upon standards for allergen labeling to some extent, despite variations in regulations and policies among countries. The "Big Eight" allergens identified by the Codex Alimentarius are among the most significant allergenic foods. However, with advancements in technology and a better understanding of allergies, it is necessary to reassess the existing standards. Regulations on labeling methods, such as highlighting allergens and using PAL, should aim to provide clear information to consumers and promote international harmonization.

The authors of this review anticipate that the recommendations presented will foster collaboration among international stakeholders to respect the choices of consumers with food allergies and enhance their safety. Implementing these proposals can ensure that consumers worldwide can make informed and safe food choices without the risk of allergic reactions, regardless of their location.

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