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Worldwide Food Allergy Labeling and Detection of Allergens in Processed Foods

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Abstract

The labeling of allergenic foods is an important public health measure to assist food-allergic consumers in avoiding foods that can cause allergic reactions. The regulatory framework for such labeling depends upon the selection of priority allergenic foods, which vary among countries. Most countries include milk, eggs, fish, crustacean shellfish, peanuts, tree nuts, soybeans, and cereal sources of gluten on the priority allergenic foods list, as recommended by the Codex Alimentarius Commission. However, a variety of other foods appear on the priority lists of some countries but not on others. Sesame seeds, molluscan shellfish, buckwheat, and mustard are identified in two or more countries. In most countries, all ingredients derived from these priority allergen sources must also be declared on labels by source. However, exemptions exist for some ingredients in some countries but not in others. Detection methods are critical for the enforcement of allergen labeling regulations and for the investigation of allergic reactions in the community by public health officials. The development of detection methods has advanced considerably over the past several decades and will be briefly reviewed in this chapter. Because of the

emphasis on labeling and the development of detection methods, the ingredient statement on packaged food labels now contains more information than ever before to assist food-allergic consumers. © 2015 S. Karger AG, Basel

Introduction

IgE-mediated food allergies are recognized as an important worldwide public health issue. The prevalence of food allergies and the identity of the most common allergenic foods differ between countries, and avoidance diets remain the primary approach to the prevention of reactions. The ingredient statement on the label of packaged foods is a key source of information for allergic consumers wishing to avoid specific allergenic foods. However, many of the most serious allergic reactions occur in restaurants and other foodservice establishments, where full-label disclosure of ingredients is typically not practiced.

Methods for the detection of allergenic food residues are needed for the regulatory enforce-

ment of labeling regulations. In this chapter, we will review worldwide labeling approaches and briefly comment on detection methods that can be used to enforce those regulations.

Labeling of Allergenic Foods

An excellent and thorough review of worldwide labeling regulations was recently published and is highly recommended as an additional resource [1]. Many countries have implemented laws, regulations or standards for food allergen labeling. These measures typically focus on a list of priority allergenic foods. The foods on such lists vary around the world, leading to key differences in labeling laws and regulations.

Historically, many countries had general food labeling laws and regulations that served to protect food-allergic consumers. These general food labeling laws and regulations required that ingredients deliberately used in the formulations of the foods should be declared on an ingredient list on the package label. However, many exemptions and exceptions existed. The declaration of the sources of some ingredients was not required, and other ingredients were declared using technical terms, e.g. casein, which did not directly reveal the true source. Thus, food-allergic consumers found that allergens were often 'hidden' in packaged food products. Furthermore, they had to learn to identify ingredient terms, such as casein, that indicated the presence of specific allergenic foods.

More clarity in the labeling of allergenic foods began to emerge with guidance from the Codex Alimentarius Commission (CAC), an organization formed jointly by the Food and Agricultural Organization (FAO) and the World Health Organization to develop food standards and guidelines that would be recognized worldwide. The CAC first turned its attention to the labeling of food allergens in 1993 when a working paper on food allergens was developed by the Nordic countries. A FAO Technical Consultation was formed in 1995

and led to the development of a list of priority allergenic foods (table 1) that were adopted by the CAC in 1999. The CAC list of priority allergenic foods serves as guidance to all countries, but individual countries have the option to adopt this list or to modify the list as they might choose.

Since one of us (SLT) was a member of the original 1995 FAO consultation, several comments are appropriate regarding the approaches used by the assembled experts to develop the priority list of allergenic foods that was ultimately adopted by the CAC. In 1995, the level of published information regarding the comparative prevalence of allergies to specific foods was rather limited, largely due to pediatric populations of allergic individuals. Data on adults and on the prevalence of specific food allergies in the general population were lacking. Accordingly, expert judgment was used, in part, to develop the priority list adopted by the CAC in 1999. The main criterion used by the expert panel was comparative prevalence, although the differential severity of certain allergenic foods was also recognized. On this basis, milk, egg, fish, crustacean shellfish, peanut, soybean, tree nuts, and cereal grain sources of gluten were considered priority allergens. The FAO group also considered celiac disease, intolerances, and sensitivity reactions, in addition to IgE-mediated food allergies. Thus, gluten was included because of its association with celiac disease, and sulfites were included because of the documented severity of sulfite-induced asthma.

Subsequently, an International Life Sciences Institute-Europe Task Force on Food Allergy took a more in-depth look at foods that merited placement on the priority allergenic foods list [2]. The criteria used by this group included clinical evidence of an allergic reaction through double-blind, placebo-controlled food challenge and published evidence of severe and/or fatal anaphylactic reactions. Data on prevalence were considered insufficient. This task force determined that the priority list should include milk, egg, fish, crustacean shellfish, peanut, soy, tree nuts, wheat,

Table 1. Priority allergenic food lists

	Codex Alimentarius Commission	U.S.	EU	Canada	Australia/ New Zealand	Japan	Korea
Milk	X	X	X	X	X	X	X
Eggs	X	X	X	X	X	X	X
Peanut	X	X	X	X	X	X	X
Gluten	X		X	X	X		
Wheat	X	X	X	X	X	X ^a	X ^b
Crustacea	X	X	X	X	X	X ^a	X ^b
Fish	X	X	X	X	X		X ^b
Soybean	X	X	X	X	X		X
Tree nuts	X	X	X	X	X		
Sesame seed			X	X	X		
Molluscs			X	X			
Mustard			X	X			
Celery			X				
Lupine			X				
Buckwheat						X	X
Other						X ^a	X ^b

^a Japan: Shrimp and crab are the only Crustacea on the list. Grains include wheat and buckwheat but not other cereal sources of gluten. Other includes foods that are on a recommended but not required labeling list including salmon, salmon roe, mackerel, abalone, squid, beef, pork, chicken, soybean, orange, kiwi, banana, peach, apple, yam, gelatin, matsutake mushroom and walnut.

^b Korea: Shrimp and crab are the only Crustacea on the list. Grains include wheat and buckwheat but not other cereal sources of gluten. Other includes peach, pork and tomato.

and sesame seed. Several subsequent groups within International Life Sciences Institute-Europe have continued to develop criteria for the selection of allergenic foods of public health significance [3, 4]. The criteria have since been expanded to include prevalence, severity and potency.

The increase in awareness of the public health significance of food allergies began to occur on a worldwide basis at the same time when CAC was considering the adoption of the priority list of allergenic foods. The priority list released by the CAC in 1999 has been adopted by numerous countries and, as noted in table 1, those 8 foods or food groups are represented on the vast majority of the priority food allergen lists that are recognized by specific countries. However, several countries decided to include additional foods in their priority allergen lists. As thoroughly re-

viewed elsewhere [1], the regulatory framework for the labeling of allergenic foods differs from country to country. The basis for the inclusion of additional foods on the priority lists for specific countries has not been clearly delineated in most cases, and the role of scientific criteria in these judgments appears to be secondary in many cases. Although the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures recognizes the 1999 CAC list, the existence of different priority lists in various parts of the world can lead to trade disputes and consumer confusion.

The first priority list of allergenic foods for the EU was established by the European Parliament and the Council through Directive 2003/89. This list was apparently created from the deliberations of the EU Parliament, but the criteria for inclusion

of foods on the list were not clearly stated. In addition to the 8 foods or food groups from the CAC list, this initial EU list included sesame seed, mustard, and celery. Subsequently, the EU priority list of allergenic foods was updated with the release of the European Parliament and the Council through Directive 2007/68. At that time, molluscan shellfish and lupine were added to the EU list of priority allergenic foods. The European Commission apparently used the opinion of the European Food Safety Authority (EFSA) Scientific Panel on Dietetic Products, Nutrition, and Allergies on molluscan shellfish and lupine allergies to reach this decision [5, 6]. For lupine, the decision appeared to be based upon the recognition that some peanut-allergic individuals will experience allergic reactions upon ingestion of lupine.

The U.S. Congress passed the Food Allergen Labeling and Consumer Protection Act (FALCPA) in 2004. FALCPA established a list of priority allergenic foods (table 1) that was quite similar to the 1999 CAC list. The only exception was that FALCPA specifically identified wheat as a cause of food allergies and did not recognize other grain sources of gluten.

In Canada, the original priority allergen list included molluscan shellfish and sesame seeds, in addition to the 8 foods or food groups on the 1999 CAC list. More recently, Canada has added mustard to its list. In Australia and New Zealand, the priority list (table 1) has been stable since its inception but includes sesame seeds as an addition to the 1999 CAC list.

Japan has a rather unique approach to its priority list, with a short mandatory labeling list and a longer recommended labeling list. The mandatory priority list is comprised of wheat, milk, eggs, peanut, buckwheat, and crustacean shellfish (table 1), and crab and shrimp are identified as the only crustacean shellfish of concern. Japan and Korea are the only countries that list buckwheat on their priority allergen lists. Buckwheat is known to cause frequent and occasionally severe allergies in Japan [7]. The recommended priority list in Japan

is extensive and includes several molluscan shellfish (abalone, squid), several fish (mackerel, salmon, and salmon roe), several fruits (orange, kiwi, peach, apple, banana), one tree nut (walnut), several meats (pork, chicken, beef), soybean, matsutake mushroom, yam, and gelatin. The basis for the Japanese priority list was a survey of allergy clinics in Japan, where the causative foods of over 1,500 cases of food allergy were compared [8].

As previously noted, many countries simply refer to the 1999 CAC list in their food labeling regulations. However, a few countries (Argentina, Switzerland, Ukraine) have adopted the EU regulatory framework instead [1].

The 1999 CAC priority list includes several food groups – tree nuts, fish and crustacean shellfish. In most countries, fish is used to include all species of finfish. As noted, in Japan, only mackerel and salmon are included on the recommended priority list for allergenic foods. Similarly, most countries include all species of shrimp, crab and lobster among the crustacean shellfish. In Japan, only crab and shrimp are included on the mandatory priority list for allergen labeling, and in several countries, including Canada, the labeling regulations refer only to shellfish and not specifically to crustacean shellfish or molluscan shellfish.

Greater differences occur among various countries in the recognition of various tree nuts as part of the group covered by the allergen labeling regulations. In Europe, the tree nuts group includes walnuts, pecans, cashews, pistachios, almonds, hazelnuts, Brazil nuts, and macadamia nuts. In Canada, these same 8 nuts are listed along with pine nuts. However, the U.S. Congress did not identify specific tree nuts that required mandatory labeling under the provisions of FALCPA. Subsequently, the U.S. Food and Drug Administration drafted a guidance document in October of 2006 that included a very long list of 19 tree nuts that would need to be specifically included on U.S. food labels. Unfortunately, this list includes several foods that are not tree nuts – coconut and litchi.

Ingredient Labeling and Exemptions

The wording of most regulatory approaches indicates that the food and any ingredients derived from those foods must be declared on the ingredient statements of packaged foods. Ingredients derived from allergenic sources vary widely with respect to the amount of protein (allergens) from the allergenic source [9]. Some such ingredients, including casein, whey, and gluten, contain substantial amounts of protein from the allergenic source. A few ingredients, such as fish gelatin, contain substantial protein from the allergenic source, but the protein fraction in the ingredient does not include much of the major allergen from the source [10]. Other ingredients from priority allergenic sources contain low to moderate levels of protein from the source. For example, food-grade lactose may contain as much as 1% milk protein; however, the amount of protein in lactose will depend upon the method of manufacture of this ingredient. Lactose with 1% milk protein likely has sufficient milk allergens to provoke allergic reactions. Still, other ingredients from priority allergenic sources contain no detectable protein or very low levels of detectable proteins. The best examples are highly refined oils from soybeans and peanuts. Other examples include soy lecithin, wheat starch, and several milk-derived flavors (butter oil, butter ester, butter acid, starter distillate).

In a few countries, selected ingredients are exempted from source labeling. The U.S. Congress exempted highly refined oils when it passed FALCPA. The U.S. also set up a regulatory process under FALCPA where food ingredient manufacturers could petition for source labeling exemptions. Recently, the use of specific soy lecithin ingredients manufactured by Solae, LLC (a division of DuPont) as a processing aid for use as a stick-release agent in bakeries has been granted the first source labeling exemption in the U.S. In the EU, the initial directive included an opportunity for companies to petition for source labeling

exemptions for specific ingredients derived from the priority allergens. The petitions were evaluated by the EFSA Panel of Dietetic Products, Nutrition and Allergies. Ultimately, based upon the recommendation of the EFSA Panel, several ingredients were exempted from source labeling requirements, although some were exempted only for specific uses (table 2). While the EU appears to have the most source labeling exemptions, the EU does not have a continuing process to seek further exemptions in a manner similar to that of the U.S. Australia and New Zealand have considered the necessity of labeling the fish origin of isinglass, an ingredient used in the clarification of alcoholic beverages, including wines. Isinglass is comprised of collagen derived from fish swim bladders and contains little detectable parvalbumin, the major fish allergen; it is therefore exempt from source labeling in the EU [11]. Currently, Australia and New Zealand are also not requiring the declaration of isinglass on labels of alcoholic beverages.

Advisory Labeling

The existing regulatory frameworks in various countries focus on intentionally added ingredients. However, residues of allergenic foods may also occur adventitiously as the result of common food industry practices, such as the use of shared equipment. Such practices can, on occasion, lead to potentially hazardous levels of allergenic residues. Increasingly, food companies in many countries (U.S., EU, Canada, Australia, New Zealand) are voluntarily providing consumers with advisory labeling statements to alert them to products that are at risk of contamination. Advisory labeling is not required in any country, but it is allowed for voluntary use by food companies in many countries. Many forms of advisory labeling are used worldwide. Some countries mandate certain forms of advisory labeling, while other countries allow the use of a variety of different

Table 2. Ingredients with source-labeling exemption in the EU

Wheat-based glucose syrups, including dextrose, and any products derived from such ingredients.
Wheat-based maltodextrins and any products derived from such ingredients.
Glucose syrups based on barley.
Cereals used for making distilled or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

Fish gelatin used as a carrier for vitamin or carotenoid preparations.
Fish gelatin or isinglass used as a fining agent in beer and wine.

Fully refined soybean oil and fat and any products derived from such ingredients.
Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources.
Vegetable oils derived from phytosterols and phytosterol esters from soybean sources.
Plant stanol esters produced from vegetable oil sterols from soybean sources.

Whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.
Lactitol.

Nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

Adapted from: European Commission. Directive 2007/68/EC, Official Journal of 28 November 2007, L 310, pp 11–14.

forms. For example, Canada uses ‘may contain x’, while the U.K. uses ‘not suitable for x allergy sufferers’. In the U.S., no standard form exists for advisory labeling, but three different formats predominate: (a) ‘may contain x’, (b) ‘manufactured on shared equipment with x’ and (c) ‘manufactured in shared facility with x’. Many companies who use such advisory labeling do so judiciously and only after assessing the potential risk. For these companies, there will always be some risk of an allergic reaction occurring in a consumer who ignores such labeling. In contrast, other companies appear to use advisory labeling more broadly, even in cases where the risk is virtually nonexistent. Overall, allergic consumers should never be advised to ignore advisory statements on package labels. Physicians should advise food-allergic patients to avoid products with advisory labeling statements because many such products represent an appreciable risk to such consumers.

In Australia, the Allergen Bureau of Australia was voluntarily formed by the food industry in an

attempt to curtail the widespread use of advisory labeling. As a result, the Allergen Bureau developed the Voluntary Incidental Trace Allergen Labeling (VITAL) program. Products at potential risk for allergen cross contact from the use of shared equipment or other practices are analyzed to determine the concentration levels of detectable allergen residues. These concentrations are used together with estimated consumption levels for the specific product in a VITAL Calculator (available on-line) to determine the estimated dose of allergenic protein that could be consumed. These doses are then compared to the Reference Doses that have been developed from clinical data on the distribution of individual threshold doses for individuals with specific food allergies. If the estimated consumption dose exceeds the Reference Dose, then advisory labeling is recommended. However, if the estimated consumption dose is below the Reference Dose, then advisory labeling is discouraged. The VITAL program can be reviewed at the website of the Allergen Bureau (www.allergenbureau.net/vital/vital).

Detection of Food Allergen Residues

The increased awareness of the public health implications of food allergies during the 1990s resulted in a need to develop analytical methods to detect residues of allergenic foods to allow enforcement of the labeling regulations described earlier in this chapter. Accordingly, many analytical methods have been developed over the past 20 years [12, 13]. This chapter will include a brief review of quantitative and qualitative immunoassay methods that detect proteins or allergens from food and are the most widely used methods by the food industry and public health authorities. However, polymerase chain reaction methods that detect DNA in food are also used, especially in cases where immunoassays are not available. Furthermore, mass spectrometry methods to detect protein residues are being intensively investigated but have not yet become widely used.

Quantitative Immunoassay Methods

The major quantitative method for the detection of food allergen residues is the enzyme-linked immunosorbent assay (ELISA), which has been widely commercialized. ELISAs allow a quantitative determination of the concentration of allergenic proteins in food products. ELISAs most typically use polyclonal antisera produced against a specific protein (e.g. casein) or a food extract (e.g. peanut). In the case of gluten, monoclonal antibodies are available and used in commercial kits. Commercial ELISA kits have been developed for most of the priority allergenic foods discussed previously, with the exceptions of fish and a few tree nuts (i.e. pecan, pistachio, macadamia nut, pine nut). These assays are highly specific, except in the case of very closely related foods, e.g. pecan would interfere with walnut detection, and pistachio would interfere with cashew detection. ELISAs are also quite sensitive and able to detect residues at low ppm concentrations ($\mu\text{g/g}$). ELISAs have several disadvantages.

The extraction of the protein residues can be altered by processing, especially by heat processing in dry systems, e.g. baking and deep-fat frying. In most cases, ELISAs detect intact proteins from food and are unable to detect hydrolyzed proteins, which are widespread food ingredients and can retain some allergenicity if incomplete hydrolysis is accomplished. In a few cases, competitive ELISAs have been developed to detect hydrolyzed proteins from specific foods. The only commercial competitive ELISA is for partially hydrolyzed gluten.

Qualitative Immunoassay Methods

Immunoassay methods can also be designed into qualitative lateral flow strips (LFSs), also known as lateral flow immunochromatographic assays or dipsticks. LFSs are widely used by the food industry to assess the cleanliness of shared processing equipment after sanitation. LFSs contain zones where antibodies are affixed to the solid matrix. Swab samples of equipment surfaces are wicked onto the strip and produce visible lines where antigen-antibody interactions occur. LFSs are inexpensive, rapid, and portable, and they do not require instrumentation and are extremely simple to perform. LFSs are specific and sensitive, but the results are qualitative; the usual detection limits are in the range of 5 ppm. Consequently, commercial LFSs are now widely used within the food industry and are available for a wide variety of priority allergenic foods.

Conclusion

A regulatory framework has been developed for labeling of allergenic foods in many parts of the world over the past 15 years. Labeling laws and regulations vary considerably among the various countries of the world, although most countries require the declaration of milk, eggs, fish, crustacean shellfish, peanuts, soybeans, tree nuts, and

cereal grain sources of gluten on packaged food products. Additional foods are included on priority lists in various parts of the world. No consistent basis has been developed for generating priority allergen lists, and thus, these lists do not appear to be based solely on a sound scientific basis. Even with the use of scientific information, opinions and actions could differ due to variable weighting of the importance of factors such as prevalence, severity and potency. The worldwide situation is made more complex by the variability in the implementation of requirements to use source labeling for ingredients derived from foods on the priority allergen lists. Some countries provide opportunities for exemptions from source labeling requirements for specific ingredients, and these exemptions are not consistent between countries. However, most countries do use scientific information to reach decisions regard-

ing source labeling exemptions. For the allergic consumer, the widespread use of unregulated advisory labeling also complicates their ability to interpret the risk for specific packaged food products.

Several methods exist for the detection of residues of allergenic foods, allowing public health officials to enforce labeling regulations. These methods can also provide food companies with data on allergen concentrations that are essential to risk assessment and decisions on the voluntary use of advisory labeling options. ELISA methods are currently favored for the analysis of allergen residues because they are specific for the detection of proteins from the allergenic source, sufficiently sensitive to protect allergic consumers, and available in rugged formats that allow quick determination of residue levels within food manufacturing facilities.

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