SPECIAL GUEST EDITOR SECTION: FOOD ALLERGENS MANAGEMENT

Challenges and Path Forward on Mandatory Allergen Labeling and Voluntary Precautionary Allergen Labeling for a Global Company

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For food manufacturers, the label on a food package is a tool meant to alert consumers to the presence of specific allergens, allowing consumers to make informed decisions and not unnecessarily limit their food choices. Mandatory allergen labeling is used when the allergen is an intentionally added ingredient, whereas voluntary allergen labeling is used when the presence of the allergen is unintentional and may be in the finished product as a result of cross-contact. In a globalized economy, ensuring food safety is a growing challenge for manufacturers. When ingredients and technologies are sourced worldwide from multiple business partners, complexity rises, which can increase the chance for errors, leading to potential harm. Threshold science, Voluntary Incidental Trace Allergen Labelling (VITAL) reference doses, fit-for-purpose analytical technology, and common sense enable us to optimize allergen management for the benefit of allergic consumers. This is a good strategy because all stakeholders share the common goal of making foods safe and wholesome for all. Herein, we recommend that (*1*) senior management make science-based thresholds a priority for both regulatory authorities and the food industry; (*2*) VITAL 2.0 be adopted as a risk assessment and risk management tool for precautionary allergen labeling (PAL); (*3*) a standardized message for PAL, i.e., "may contain *x*," be used to make it easily understandable to allergic consumers so they can make informed food choices; and (*4*) validated fit-for-purpose allergen methods be used to meet analytical needs. This is an opportunity for us to speak with one voice and demonstrate that food safety is not a competitive issue, but a shared responsibility. This approach could significantly improve allergic consumers' lives.

Food allergies are a serious food safety issue. Managing food allergens is essential in today's food industry. As the unique treatment of food allergies is strict avoidance, correct allergen information on product labels can mean the difference between life and death for individuals with food allergies. It is well established that food allergy is a common health issue in industrialized countries. It affects people of all ages, but infants and young children are particularly impacted because introduction of solid foods starts in infancy and immunologic tolerance develops during childhood.

The prevalence of food allergy has increased globally during the past 10–20 years without a known cause (1, 2). Food allergy is estimated to affect more than 1–2% and <10% of the global population (3). The majority of these statistics refer to immunoglobulin E (IgE)-mediated allergic manifestations that can be reproduced with short-term observations of acute allergenic responses. Other food-related allergic manifestations, which are often non-IgE mediated or mixed humoral and cellular immune responses, such as allergic proctocolitis or food protein-related atopic dermatitis (eczema), have a much higher prevalence.

The prevalence of adverse reactions to food in the United States in 2014 was estimated to be 5% for adults and 8% for children, an increase from 2006 estimates, which were 3–4 and 6%, respectively. Reports over the last decade indicate that the incidence of food-induced hospitalizations in the United States has increased from 0.6 to 1.3 per 1000 patients (4–6). Deaths from anaphylaxis are rare, but occur most commonly in children, teens, and young adults. Food allergy can be morbid and costly. It has been estimated to cost the United States almost $25 billion annually.

Food allergy also has a negative impact on the quality of life (QOL) of allergic consumers and their care providers. Several QOL studies among food allergy patients established that stress and anxiety are associated with continuous allergen avoidance and the looming threat of anaphylaxis. Indeed, recent oral immunotherapy and oral food challenges have been associated with improved QOL among both allergic consumers and their care providers (7). Still, today, there is no definitive cure for food allergy. Dietary avoidance and management of accidental reactions remain the cornerstone of public health (8).

Allergic Reactions and Allergen Recalls

Hazardous exposure to undeclared allergens in packaged food products is an unfortunate reality for food-allergic consumers and an enormous challenge for food manufacturers. Undeclared allergens are the leading cause of food recalls in developed countries and a serious health concern for allergic consumers worldwide. In 2012, the analysis of 2005–2008 U.S. Food and

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Drug Administration (FDA) data showed allergen recalls occurred at a frequency of 64–87 per year and totaled 302 recalls, affecting 551 different products. Among the allergen recalls, undeclared milk is the most frequently reported cause of recalls and is also responsible for the most adverse reactions associated with allergen recalls. About one in six product recalls due to an undeclared allergen result in adverse health consequences (9). Similar data are reported for 2013 (10). In Europe, the number of Rapid Alert System for Food and Feed (RASFF) notifications due to undeclared allergens has also increased in past years, with 70–85 notifications between 2012 and 2014, peaking in 2015 (137 notifications) and decreasing slightly in 2016 (113 notifications). With exception of sulfites, milk is again the most frequent cause of RASFF notification (11).

In a more globalized economy, ensuring an allergen control plan (ACP) is effective is becoming increasingly difficult and time consuming for food manufacturers. When ingredients and technologies are sourced worldwide from different suppliers, ACP complexity rises exponentially, leading to a potential for increased error. This will be discussed later.

Societal Needs

Consumers with a food allergy rely on accurate allergen information on the labels of the packaged foods they consume to meet their nutritional needs and be safe. Hence, the labeling of both intentional and unintentional allergenic foods is an important public health intervention that helps consumers avoid potentially allergenic foods. Although mandatory allergen labeling provides clear information about intentional allergens, precautionary allergen labeling (PAL) for the presence of unintentional allergens is undefined, mostly unregulated, and confusing to consumers. It is generally recognized by all stakeholders that the current PAL system is not effective at informing consumers about the actual risks from food allergens in the food.

Mandatory allergen-labeling requirements have been around for many years in both developed and developing countries, yet recalls of unlabeled allergens but not cross-contact allergens occur every day worldwide. Currently, the U.S. Food Safety Modernization Act identifies allergens as a hazard that is reasonably likely to occur in food manufacturing operations. The act requires food manufacturers to develop an ACP. A properly executed Hazard Analysis and Critical Control Point (HACCP)-based ACP ensures allergens are properly labeled. In the European Union (EU), general rules for the control of hazards are defined in Regulation (EC) No. 852/2004, which covers the hygiene of foodstuffs. These rules must prevent, eliminate, or reduce to acceptable levels the hazards of concern, but the hazards are not explicitly named, thus requiring food business operators know which major food allergens need risk management.

Although the food industry's goal is obviously to prevent that a consumer with a food allergy experience an allergic reaction after consuming a packaged food product, achieving this goal in reality can be very challenging due to the complexity of common farming practices, global trade, transportation, storage, shared equipment, and the system of distribution. From a food industry perspective, four general approaches can be used to minimize the risk of a reaction from an allergenic food: (*1*) Remove allergens that have no functional effects from product recipes; (*2*) declare the allergen on the product label as an ingredient when it is intentionally added, irrespective of the amount; (*3*) implement preventive ACP to minimize allergen cross-contamination; and (*4*) use PAL to inform the consumer about a potential risk when necessary.

For years, consumer groups and the food industry have asked regulatory bodies and healthcare providers for clear and consistent guidelines for the managing of food allergens, especially for more clarity in PAL, which is voluntary in nature. Although many government and nongovernmental organizations provide tools, guidelines, and policies, their implementation and enforcement varies greatly across the United States, Europe, and other jurisdictions. Moreover, policies and guidelines may not be keeping pace with the science.

In 2017, the National Academies of Sciences Committee on Food Allergies (12), representing all stakeholders, recommended the following:

- The FDA make its decisions about labeling exemptions for major allergenic ingredients based on a quantitative risk assessment framework.
- The FDA and U.S. Department of Agriculture (USDA) work cooperatively to replace the PAL system for low-level allergen contaminants with a new risk-based labeling approach, such as the Voluntary Incidental Trace Allergen Labelling (VITAL) program used in Australia and New Zealand.
- The FDA and USDA should establish reference doses (thresholds) for allergenic foods, when possible.
- With reference doses, foods should be subjected to PAL only when exposure would result in doses above the reference dose level.
- The FDA should restrict allowable PAL statements to one phrase.
- The FDA and USDA should educate consumers and health care providers on the meaning of PAL statements.

In 2015, a German working group on food allergy drew similar conclusions: "The reference doses proposed should, for the present, form the basis for the establishment of threshold values for unintended presence of allergens. The vast majority of allergic individuals (99 or 95%, respectively) would benefit if the determined reference doses were implemented, as in the VITAL concept. The use of PAL should be carried out exclusively on the basis of evidence-based allergen risk assessment" (13).

Labeling

For food manufacturers, the label on a food package is a tool that alerts consumers to the presence of specific allergens so consumers can make informed decisions about the level of risk they are willing to take and not limit their food choices. There are two types of labeling and they serve two distinct purposes: (*1*) Mandatory labeling is used when the allergen is intentionally added as an ingredient to a product, and (*2*) voluntary labeling is used when the inadvertent or unintentional allergen is found in the finished product as a result of cross-contact.

Global Regulatory Allergen-Labeling Requirements

To help consumers with food allergen avoidance, the U.S. Food Labeling and Consumer Protection Act was enacted in 2004, mandating major allergens be identified in plain language (e.g., "milk" instead of "casein") on food labels if the food allergen

Table 1. International allergen regulations by country as compiled by the Food Allergy Research and Resource Program (30)

International allergens	United States	Canada	European Union	Australia/New Zealand	Hong Kong	China	Japan[a]	Korea	Taiwan	Argentina	Bolivia	Brazil	Chile	Colombia	Costa Rica	Cuba	Mexico	Nicaragua	South Africa	Venezuela
Shellfish	X	X	X	X	X	X	X[b]	X[b]	X[c]	X	X	X	X	X	X	X	X	X	X	X
Egg	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Fish	X	X	X	X	X	X		X[d]		X	X	X	X	X	X	X	X	X	X	X
Milk	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Peanut	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Soy	X	X	X	X	X	X		X		X	X	X	X	X	X	X	X	X	X	X
Tree nuts	X	X	X	X	X	X				X	X	X	X	X	X	X	X	X	X	X
Wheat	X	X	X	X		X	X	X			X	X		X	X	X		X	X	X
Cereals with gluten		X	X	X	X	X				X	X	X	X	X	X	X	X	X		X
Buckwheat						X	X	X												
Celery			X																	
Lupine			X	X																
Molluscan shellfish		X	X	X		X													X	
Mustard		X	X																	
Sesame		X	X	X																
Sulfites, mg/kg	≥10	≥10[e]	≥10	≥10	≥10					≥10	≥10	X	≥10	≥10	≥10	≥10	≥10	≥10		≥10
Bee pollen/ propolis				X																
Royal jelly				X																
Mango									X											
Peach								X												
Pork								X												
Tomato								X												
Latex (natural rubber)												X								

[a] Voluntary labeling recommended for abalone, mackerel, squid, salmon, salmon roe, cashew, walnut, matsutake, sesame, soybean, yam, apple, banana, kiwi fruit, orange, peach, beef, chicken, gelatin, and pork.

[b] Crab, shrimp, and prawn.

[c] Crab and shrimp.

[d] Mackerel.

[e] Or directly added.

Table 2. VITAL reference doses (25)

Allergen	Peanut	Milk	Egg	Tree nuts	Soy	Wheat	Mustard	Lupine	Sesame	Crustacean shellfish
Reference dose, mg protein[a]	0.2	0.1	0.03	0.1	1	1	0.05	4	0.2	10

[a] The reference dose is defined as the milligram protein level (total protein from an allergenic food) below which only the most sensitive individuals (between 1 and 5%, depending on the quality of the data set available) of the allergic population are likely to experience an adverse reaction.

was an intended ingredient, unless it is exempted. Similarly, in the EU, current Consumer Information Regulation No. 1169/2011 (the allergens are in Annex II, No. 1169/2011) covers prepackaged and non-prepackaged goods (e.g., from bakeries, catering outlets, etc.), requiring manufacturers to declare all ingredients present in prepackaged and non-prepackaged foods sold in the EU, with some exemptions. This directive has been amended a number of times with regard to allergens. Because allergen-labeling regulations have been enacted for many years, implementation is straightforward when current good manufacturing practices (GMPs) are observed. For convenience, the international allergen labeling regulations are shown in Table 1.

Precautionary Allergen Labeling (PAL)

Existing regulations in most countries focus on intentionally added ingredients as described above. However, greater public health concerns exist regarding the potential that residues of allergenic foods may occur inadvertently as the result of cross-contact due to common food industry practices, such as the use of shared equipment. Such practices can result in the presence of detectable levels of allergen residues in various foods.

PAL is useful if it conveys accurate and easily understandable information to the consumer relating to potential cross-contamination. Although PAL is used in many marketplaces, current PAL bears little relationship to actual risk. Surveys of products both with and without PAL indicate that many products having PAL do not contain detectable allergen levels, whereas some products without PAL do contain detectable allergen levels (14–19). There is little wonder as to why more than 50% of allergic consumers have been routinely ignoring precautionary labeling (16, 20). Studies show more people will eat products declaring "produced in the same facility" than ones that state "may contain," and they are less likely to consume products that state "made on the same equipment." This shows that consumers are making decisions based on self-determined risk assessment and risk management (16), and consumer preferences for PAL are not considered (21).

In a survey of consumer products, the majority of the products that tested positive that had allergen concentrations above the VITAL action level that would trigger PAL declarations were found in products both with and without PAL (22). In combination with consumer risk-taking behavior, this study highlights the need for the food industry and regulators to adopt a transparent, harmonized risk-based approach for the communication of the risk associated with potential cross-contact that could occur in a processing facility.

Clearly, consensus guidelines should be developed for the application of PAL to the label based on actual health risk and those action levels adopted by regulators. Such guidelines would lead to a decrease in the occurrence of allergic reactions while maximizing the QOL of individuals with a food allergy.

Imagine if PAL were regulated based on scientific evidence of allergen threshold levels and if action levels were defined and recognized by regulatory bodies. Then, food manufacturers could confidently determine whether the packaged food needs to declare the inadvertent presence of cross-contact allergens when their GMP and ACP control measures cannot adequately mitigate the health risk. Risk assessors on the HACCP team could perform risk assessment with reasonable certainty no harm in mind. The consumers could make purchase decisions, trusting that the information on the food label protects them from allergic reactions. When a harmonized threshold-based PAL approach is adopted by the majority of food manufacturers, proliferation of PAL will decrease. These are just a few of the foreseeable benefits that society deserves and is currently lacking.

Threshold or Action Level Concept

Consumer confusion and fear regarding the use of PAL continues to hinder the food industry's efforts to protect allergic consumers. As previously mentioned, products with PAL do not necessarily contain significant amounts of allergen, yet have proliferated the marketplace in recent years. Armed with recognized threshold information, risk managers can take necessary actions based on safety evidence that protects public health in an expedited manner, allowing us to solve tomorrow's crisis today.

A VITAL risk assessment tool to ensure our food is safe is already in existence. Although the VITAL reference doses mentioned below, Table 2, were established several years ago by an international scientific expert panel, they are not yet recognized by regulatory agencies. The endorsement of reference doses by public health authorities would enhance the impact of such an approach. It is foreseeable that the food industry will shift to a more proactive approach and adopt this science and data-based VITAL reference doses as the threshold or action level to determine whether a PAL should be used or not. It will enhance industry's focus on public health protection and set aside issues that are not of concern. This VITAL risk assessment is based on the best currently available scientific and clinical evidence and, at present, offers the best approach to protecting sensitive consumers and providing them with information.

VITAL

The labeling of allergenic packaged foods is an important public health measure to assist consumers with a food allergy in avoiding potentially allergenic foods. The current precautionary labeling system for allergenic foods is not effective at informing consumers about risks from food allergens in the food for the previously mentioned reasons.

The Allergen Bureau of Australia and New Zealand has recommended establishing reference doses based on statistical dose-distribution modeling to support the VITAL program (23, 24). VITAL is a voluntary program aimed at the food industry so they can provide a scientific basis for precautionary labeling decisions (25). As of today, VITAL has not yet been endorsed by any public health authority.

The VITAL program and reference doses have been subjected to extensive peer review (23, 24) and are recognized by several international authorities as defining a sound level of risk when applying precautionary allergen statements. VITAL action levels to define labeling outcomes are determined by using a reference dose and a reference amount in a typical eating occasion. The process needs to be transparent. Transparency creates trust between our services and consumers.

Analytical Needs and Challenges

Inaccurate allergen detection hinders the validity of allergen risk management for the food industry and enforcement actions by regulatory authorities. ELISA, PCR, and MS can be used to detect food allergens, but there are quantification problems with all three. ELISA is currently the most commonly applied technique, and, although it can detect the presence of most allergens in foods, it struggles with recovery and accurate quantification. In addition, results generated from different test kits are not comparable. The principal pitfalls are a lack of (*1*) recognized standard reference materials for some allergens; (*2*) a recognized standard sampling plan; and (*3*) a recognized reference method, with the exception of gluten. The AOAC INTERNATIONAL allergen community is involved and helps provide solutions to analytical challenges, e.g., in collaboration with the MoniQA Association and National Institute of Standards and Technology in the development of reference materials and has established a working group to develop community guidance for a harmonized sampling protocol.

Continuous improvements in analytical methods, equipment, and detection capability may drive the sensitivity of the method down to the subclinical level. This may create a public perception of risk rather than an actual food safety risk. Public perception and media attention can generate pressure that initiates management activities of specific allergens. As a result, the mere identification of an allergen at trace levels may be perceived as a health risk even though it does not present an actual concern to the allergic population. This can result in hazard-based rather than risk-based management of food safety (26). Risk-based food safety and health standards drive innovation and improve QOL. Zero risk is neither achievable nor scientifically or clinically relevant.

Allergen-Testing Market Trend

The global food allergen-testing market is projected to grow 6.8% by 2022, reaching U.S. $760 million, according to ref. 27. The market is driven by labeling compliance in various food industries, growing allergic reactions in consumers, consumer complaints, recalls, implementation of regulations, and the international trade of food materials. The main technologies are covered below.

ELISA

ELISA is commonly used to determine food allergens in food products because this technology offers low detection limits, high analytic selectivity, and simple application, and it is economical. For these reasons, its use is expected to grow.

However, a significant number of ELISAs have produced erroneous results, especially when applied to highly processed food. Some ELISA methods offer extraction solutions containing a surfactant and a reductant to enhance the solubility of the analyte protein in highly processed food to yield more reliable results.

Lateral-Flow Device (LFD)

Allergen management in food companies is becoming increasingly important. HACCP concepts are mandatory in food-producing firms and are the best approach to control allergens in food-manufacturing facilities. Segregation upon receipt, storage of allergenic ingredients, and equipment cleaning verification are important control points. Halting a production line until a test result is received from the laboratory is not an option. Therefore, test systems that are performed on-site and deliver results quickly are required. LFDs fill this niche.

Multiplex or Multianalyte System

ELISA and LFD methods are very sensitive and analyte-specific, requiring different assays to detect each food allergen. Using multianalyte profiling technology (e.g., xMAP), Cho et al. (28) developed a commercial bead-based multiplex assay using established antibodies for the simultaneous detection of 15 different food allergens plus gluten. The assay concurrently detects crustacean seafood, egg, gluten, milk, peanut, soy, and nine tree nuts (almond, Brazil nut, cashew, coconut, hazelnut, macadamia, pine nut, pistachio, and walnut). By simultaneously performing multiple tests for each analyte, this magnetic bead-based assay offers built-in confirmatory analyses without the need for additional resources. Although this technology provides an excellent alternative platform for allergen measurement, it is expected to have the same limitations as ELISA and LFD, including cross-reactivity, and is not commercially available yet. Official multilaboratory validation of the method is necessary before it can be adopted as a method of choice.

Other Technologies: PCR and MS

PCR-based methods have been successfully used for the detection of allergens, but no single assay is available that tests all major allergens. This approach also suffers from severe drawbacks: It detects proteinaceous allergen indirectly by amplifying small DNA fragments, assuming DNA presence guarantees also protein presence. The technology is not quantitative, and it is impossible to discriminate between egg or milk and corresponding tissue DNA from chicken or cow. Methods combining MS and LC [LC-tandem MS (MS/MS)] are the most promising nonimmunological approaches for the accurate quantitation of multiple allergens as well as gluten traces. Because LC-MS/MS is a relatively new technology, deficiencies similar to those occurring in ELISA can be expected and need to be elucidated. In addition, due to a requirement for expensive equipment, expertise, and time to obtain results (very time consuming), it is not widely used for routine analysis.

Analytical Devices for Consumers

In January 2017, a pocket-sized gluten sensor, the Nima (29), was made available to consumers. Nima determines whether a food contains gluten. It also quantifies a result when there is no fixed sample size. Currently, Nima detects either no gluten or gluten below 20 ppm with a smile icon and gluten found at or above 20 ppm with a wheat icon. The cut off is 20 ppm gluten. All Nima results are shared by consumers online in the Nima database. It is not known whether the data generated by Nima are comparable with AOAC *Official Methods*SM because there are no validation studies published in the scientific literature. Consequently, false-positives from this sensor may have a significant negative impact on the food industry, whereas false-negative results may impact the safety and QOL of celiac consumers.

Conclusions

In a globalized economy, ensuring safety is a growing challenge for manufacturers. When ingredients and technologies are sourced worldwide from multiple business partners, complexity rises and this can increase the chance for errors, leading to potential harm. For global firms, this can mean a proliferation of allergen cross-contact occasions and, ultimately, recalls of unsafe products if allergens are not managed properly. In fact, allergen recalls make headlines daily. Yet complexity can be managed. Safe and healthy food is possible for all if we, including the upstream supply chain, implement a robust risk management program, follow safe production policies, and execute safety and quality procedures within an organization. These processes need to be transparent. Transparency creates trust between our services and consumers. Furthermore, it is clear that interaction between thresholds and allergen analytical methods rather than each alone is the critical factor that contributes to successful allergen management to meet societal needs.

Threshold science, VITAL reference doses, the analytical community, and common sense enable us to optimize allergen management for the benefit of allergic consumers. This is a good strategy because all stakeholders share the common goal of making foods safe and wholesome for all.

Herein, we recommend the following: (*1*) Senior management make science-based thresholds a priority for both regulatory authorities and the food industry; (*2*) VITAL 2.0 be adopted as the risk assessment and risk management tool for PAL; (*3*) that a standardized message for PAL be used, such as "may contain *x*," making the message easily understandable to and useful for allergic consumers so they can make informed food choices; and (*4*) validated fit-for-purpose allergen methods be used to meet analytical needs.

These suggestions will deliver safe and healthy foods for all, reduce accidental allergic reactions in consumers as a result of adventitious presence of allergens, and reduce the enormous costs to food manufacturers. Safety is not a business advantage, but a right for all parties. It is our hope, as the authors of this review, that our paper facilitates further collaboration among all stakeholders in the implementation of science-based reference doses to define the action levels for PAL that will enable the food industry to improve the QOL of food-allergic consumers. If we embrace it, we can make the apparently impossible possible.

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