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Precautionary allergen labelling: perspectives from key stakeholder groups

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Abstract

Precautionary allergen labelling (PAL) was introduced by the food industry to help manage and communicate the possibility of reaction from the unintended presence of allergens in foods. However, in its current form, PAL is counter-productive for consumers with food allergies. This review aims to summarise the perspectives of all the key stakeholders (including clinicians, patients, food industry and regulators), with the aim of defining common health protection and risk minimisation goals. The lack of agreed reference doses, has resulted in inconsistent application of PAL by the food industry and in levels of contamination that prompt withdrawal action by enforcement officers. So there is a poor relationship between the presence or absence of PAL and actual reaction risk. This has led to a loss of trust in PAL, reducing the ability of consumers with food allergies to make informed choices. The result has been reduced avoidance, reduced quality of life and increased risk-taking by consumers who often ignore PAL. All contributing stakeholders agree that PAL must reflect actual risk. PAL should be transparent and consistent with rules underpinning decision-making process being communicated clearly to all stakeholders. The use of PAL should indicate the possible, unintended presence of an allergen in a consumed portion of a food product at or above any proposed action level. This will require combined work by all stakeholders to ensure everyone understands the approach, and its limitations. Consumers with food allergy then need to be educated to undertake individualised risk assessments in relation to any PAL present.

Introduction

Food allergy is a significant problem worldwide affecting up to 4% of children and up to 3% of adults (1,2) (Box 1). It is associated with considerable physical and psychological morbidity (3). Currently there is no therapy in routine clinical use (4,5,6,7). Management of food allergy therefore requires avoidance of the trigger food and rescue therapy where indicated (4). Accurate and comprehensible
information about the presence of allergens in food and drink products is central to successful avoidance.

According to previous European Union (EU) legislation, the presence of any of 14 allergens as ingredients in pre-packed food must be declared. The EU Food Information for Consumers (EC Regulation No. 1169/2011) required this mandatory disclosure to be extended to include non-prepacked foods from December 2014. Many food producers use precautionary allergen labelling (PAL) (e.g. “may contain …..”) to alert consumers to the possible unintended presence of allergens. The use of PAL is voluntary, and not covered specifically by existing legislation although it has been argued that general food safety law applies. All stakeholders have an interest in accurate and understandable PAL (8). Stakeholders have different motivations and the poor understanding of each other’s positions has resulted in a lack of consensus. The result is PAL that frequently does not provide consumers with sufficient information to make rational decisions about the risks of having an allergic reaction to a food.

Aims and methods

This paper is a review undertaken by the multidisciplinary team from the EU iFAAM project: Integrated Approaches to Food Allergen and Allergy Risk Management. The paper aims to summarise the perspectives of all the key stakeholders, with the objective of defining common health protection and risk minimisation goals.

The iFAAM project includes clinicians, dieticians, patient groups, psychologist, food scientists, food industry, auditors and regulators. These groups were therefore invited, as the key stakeholders, to participate in the review. Literature reviews were undertaken by each stakeholder group to inform their initial positions. Consensus was then achieved through discussion at a series of face to face and electronic meetings and electronic discussions. This consensus aims to develop an approach to PAL that optimises the safety and quality of life of the allergic consumer, while taking into account the complex issues involved in managing food allergens in the food manufacturing, retailing and catering sectors. Consensus could only not be reached on one point, this is described in the text. Finally we used a thematic approach to summarise the key important issues across the stakeholders.

Perspective of consumers with food allergy

What does PAL mean to consumers with food allergy?

PAL is meant to inform consumers with food allergy about a significant risk of reacting to a product. Many consumers erroneously believe that PAL is regulated and mandatory. Such a view drives consumer beliefs that variations in PAL statements reflect a hierarchy of risk of reaction; for example, “may contain” indicating a higher risk than “may contain traces” (9,10). This has recently been confirmed in a multinational survey conducted by the Patient Organisation Committee of the European Academy of Allergy and Clinical Immunology and the international Food Allergy and Anaphylaxis Alliance (iFAAAA, (personal communication, Sabine Schnadt; Figure 1)). However the reality is that there is no relationship between the risk of contamination and the wording employed (11). Furthermore, there is a perception that PAL refers to unintended presence of allergen which is
either consistently present in the products or present only in “trace” amounts (Figure 1). So, when a product with a PAL does not cause a reaction, consumers may feel that the product is ‘safe’ or they can tolerate traces of that allergen (9). This can lead to unintended risky behaviour when consumers continue to freely consume the product. Confusion can also arise when manufacturers introduce PAL on a product; some consumers may consider the change has been made purely for liability reasons to protect the food manufacturer and so ignore the warning (9). All this creates confusion, mistrust and ultimately anxiety. Consequently it is difficult for consumers with food allergy to make an informed choice as to whether or not they should be eating specific products (Figure 2).

What do consumers consider to be the issues?

The use of PAL is seen as inconsistent and not transparent (11; Box 2). This perception is not helped by a poor understanding of PAL statements by many consumers and some healthcare professionals (HCP) who advise them. Consumers with food allergies respond by being very selective in their food purchases which gives rise to extra costs, anxiety and impaired quality of life (13). The proliferation of PAL, together with its appearance on unexpected products, has led to a loss of credibility and reduced observance by consumers (10,14,15). There is a clear relationship between the extent to which PAL is used and the extent to which it is observed by consumers (16) (Figure 3). Since risk perception is individual, observance may differ for parents, children, adolescents and adults.

What do consumers feel could be done better?

Consumers with allergies need to be able to trust PAL and so our patients group representatives felt that PAL should be regulated and have consistent uniform wording placed next to the ingredient list. Where appropriate, there should be a clear indication that a product has undergone an adequate risk assessment and is unlikely to pose an appreciable risk for a consumer with a food allergy. Regulation on when to use PAL should be based on agreed reference doses which are now being developed (Box 1). These can form a basis on which action levels (Box 1) can be calculated to protect consumers (Figure 4). Though consumers want to make “safe” food choices, they understand - with appropriate explanation - that it will be impossible to reduce risk to zero. A good communication strategy is critical to conveying the concept and meaning of reference doses and action levels to patients and other stakeholders, including HCPs.

**Healthcare professionals’ perspective**

What do healthcare professionals understand by PAL?

Recently, UK-based HCPs with a professional interest in allergy were surveyed about PAL (17). Only one-third would advise patients with tree nut allergy to avoid all foods with PAL relating to tree nuts. More stringent avoidance advice was provided with co-existent asthma, prior anaphylaxis or previous reaction to a tiny amount of allergen. Many HCPs interpreted some statements as conveying a lower risk of containing an allergen (e.g. “made in an environment”) compared to more direct statements which explicitly mention “may contain...” (17). HCPs working as allergy specialists were less likely to recommend stringent avoidance (17). This perhaps reflects an awareness that
consumers with allergies find PAL frustrating (18,19) with HCPs endeavouring to educate them to use PAL as part of a realistic risk management approach.

What do healthcare professionals see as the issues?

The major issue is to provide clear guidance to patients as to how they can avoid their trigger food (Box 2). This is a challenge with the absence of uniformity in labelling text, ambiguity over true allergen content and actual risk of reaction. The available evidence suggests that most foods with PAL do not contain sufficient allergen to trigger reactions, although the risk is not negligible (20,21). Likewise, some foods without PAL contain sufficient allergen to trigger a reaction (10,22). Many allergic patients ignore PAL (19,23) and may interpret ‘tolerance’ of products with PAL as a sign of a more ‘mild’ food allergy; this can result in increased risk-taking. HCPs need to be able to train their patients on how to utilise PAL as part of their own risk management strategy. This includes identifying patients with very high risk profiles, perhaps due to low personal thresholds for reaction or co-existing diseases (e.g. poorly controlled asthma), as they will need to utilise a different risk management behaviour.

What could be done better from the healthcare professionals’ perspective?

The wording and presentation of PAL needs to be uniform and justified in terms of level of risk. This would aid the education of patients and their carers to make safe food choices. The application of PAL needs to be evidence-based so that the statements reflect actual risk of an allergic reaction. There was a view in our HCP stakeholder group that regulation will be needed to enforce this (21). However, such changes will be ineffective if HCPs involved in managing patients with food allergy are not educated in their interpretation and able to train patients to utilise them correctly within their personalised risk perception.

The psychologists’ perspective

Both quantitative and qualitative findings suggest that food allergy has a significant impact on quality of life of patients and their families in terms of social, dietary and psychological factors (24-31). ‘Rules’ and restrictions ostensibly apply to food but because food is such an integral part of everyday life, these restrictions extend far beyond mealtimes.

What do psychologists consider to be the issues?

Inconsistency in application of PAL statements by food producers and in advice given by HCPs makes PAL a significant source of uncertainty (Box 2). Uncertainty has a direct effect on perception of control and trust, and indirect effects on emotional adjustment, social interaction, coping strategies and quality of life (27,28,32-34). Furthermore, the perception that PAL is used as a ‘safety net’ by manufacturers can lead, in a search for control, to increased consumer anxiety. This can lead to avoidance of birthday parties, groups of people, and restaurants or risk-taking behaviour, such as disregarding all PAL (Figure 5). Some of the strongest and most adverse impacts on health-related quality of life relate to social and dietary restrictions, including fear of new foods, new people and new places (27,29,30,35). In Italy, 20% of young children with food allergy have never attended a birthday party (34). Data from an ongoing Food Allergy Research and Resource Program (FARRP) study involving an online survey and focus group interviews with over 500 parents, teenagers and
adults and clinicians from Ireland, the UK, and the US, suggested that aligning PAL statements with level of risk would greatly enhance patients’ management of food allergy by allowing them to make informed decisions (36) (Fig 4). The majority of parents, teens and young adults agreed that it would be ‘very useful’ if ‘there was some level or hierarchy of risk implied by labelling’ linked to current labelling practice.

What do psychologists feel could be done better?

HCPs need to ensure that patients and their carers understand PAL and how risk can be managed. We know from previous research that practical interventions can reduce uncertainty and improve quality of life (27,28,34,37-39) by allowing families to feel more in control of their lives, their diets, and their allergy. For the same reasons, harmonised reference doses and action levels governing the use of PAL statements could reduce uncertainty and improve quality of life (36).

In terms of ‘acceptability’, research has also shown that a lack of ‘meaningful communication’ (32) between stakeholders to be a major barrier to successful implementation of any new technology. In the FARRP study, lack of awareness, confusion, and ‘talking past each other’ are reported as significant barriers to translating the science of ‘thresholds’ into real world applications, such as product labelling (36) (Figure 6). Integrating perspectives from HCPs, food industry and families is required to develop coherent, meaningful, and creative communication strategies that work, that will be accepted, and that can be conveyed clearly. A regulatory framework needs to be sufficiently flexible to remain relevant to consumers and to facilitate new research and technology.

The analytical and food scientists’ perspectives

What do PAL mean to analytical and food scientists?

Analysts and food scientists should provide the analytical information needed to underpin PAL. Several analytical surveys have documented that only a small percentage of products with PAL for peanuts contain detectable peanut residues. Products without PAL sometimes possess similar levels. The relationship between presence or absence of other allergens in food products and use of PAL is also poor (10,20,22,40-44). Collectively, these findings might suggest that PAL is being both over- and under-applied by the food industry so that the presence or absence of a PAL is not related to the actual risk of an allergic reaction (Figure 1).

What are the issues?

The poor association between the use of a PAL and the actual risks of reaction probably reflects the lack of public health authority guidance on risk assessment for such labelling decisions (Box 2). Ideally, PAL would only be used when food companies cannot guarantee to a defined degree the absence of unintended allergens to a level that could be harmful to consumers with food allergy (45).

Unfortunately, application of analytical methods currently presents challenges (46) and these may have driven the food industry toward more widespread use of PAL. Enzyme-linked immunosorbent assays (ELISAs) are the favoured analytical approach for the food industry because they can detect
allergen residues in a highly specific and sensitive manner (47). Commercial ELISA kits exist for many of the priority allergenic foods but questions remain about their reliability with most kits not being validated according to the consensus approach (48). For example, a recent international study demonstrated that only one egg kit accurately determined egg protein at 3 mg.kg\(^{-1}\) and only one milk (casein) kit accurately determined milk at 6 and 15 mg.kg\(^{-1}\) (49). No consensus approach exists yet for the validation of the frequently used lateral flow ELISA devices (50). ELISA methods are often evaluated by spike and recovery approaches (specific amount of allergen added to food product and this compared to results from ELISA) but there are few data relating to the influence of food processing methods on quantification (51). Food processing affects the reliability of analytical data, for example peanut and milk are harder to detect after baking (52,53). The development of confirmatory methods, such as mass spectrometry, are needed (54). When mixing is not uniform, sampling may be an added difficulty as relatively high levels of allergens may be detectable in just a few units of a production batch (55). Also, particulate allergens, such as nuts, will be non-uniformly dispersed. All these issues may influence the confidence in analytical allergen data and lead food companies to use PAL even in the absence of analytical findings of detectable allergen residues.

What could be done better?

Quantitative risk assessment (QRA) is emerging as an approach that can be used to predict the potential risk of reaction associated with allergen residues in foods (43,56,57). QRA can be used to predict the expected number of reactions in foods with PAL (42,43). QRA requires inputs from threshold dose distributions for specific allergenic foods, consumption level distributions for specific foods and analytical data on the food product under consideration. While guidance on management thresholds has yet to emerge from public health authorities, dose distributions have been derived for 11 priority allergenic foods, based on which reference doses have been proposed for application of PAL statements (58,59). These reference doses form the basis for the Allergen Bureau of Australia & New Zealand Voluntary Incidental Trace Allergen Labelling (VITAL\(^{®}\)) 2.0 programme (58,59). QRA is currently rarely used by the food industry and must be expanded to make PAL more transparent, consistent and meaningful to food allergic consumers. Guidance from regulatory authorities to the food industry in this regard would speed the adoption of this approach. As part of this process, prospective data should be gathered to ensure that the derived action levels work in real life.

The food industry’s perspective

What does PAL mean to the food industry?

Food allergy is a relative newcomer to the food safety risks that the food industry has to manage having been recognised only during the 1990s. Food manufacture is a complex process involving a large number of ingredients and raw materials and the sequential use of the same equipment for different products. Cleaning and manufacturing protocols cannot completely remove carryover of allergen from one product to the next. Development of PAL was the food industry’s response to this
situation, fulfilling both risk management and risk communication roles. The risk management element of PAL is crucially dependent on their effectiveness in communicating risk.

What does the food industry consider to be the issues with PAL?

The food industry recognises that PAL has spread to such an extent that the majority of products in some categories (e.g., chocolate, biscuits) carry precautionary statements (41) (Box 2). This potentially reduces food choices for consumers with food allergies. Use of PAL is voluntary and both its application, and the associated level of risk of unintended allergen presence, can also be very inconsistent across industry. Small and medium food businesses (SMEs) sometimes may not use PAL because of a lack of knowledge and awareness (60) while others frequently over-utilise PAL. This is a major issue as they contribute a significant proportion of the food supply in most countries and a large proportion of supplies to large companies. This situation may worsen with the extension of allergen labelling to non-pre-packed foods from December 2014.

What could the food industry do better?

The credibility of PAL, and therefore its value as a risk management tool, will only be restored if it communicates a clear and consistent message about risk regarding amount of allergen present in a food and the resulting risk of an allergic reaction. Additionally, the absence of a PAL should imply a clear and agreed level of safety. This can only be achieved by adoption of a common standard across the food industry, including suppliers of ingredients and retailers. It needs to be clearly explained and communicated to consumers and other stakeholders, and preferably endorsed, or at least supported, by food safety authorities. The VITAL® 2.0 programme is an example of such an approach (58, 59) and utilised “may be present” to distinguish itself from other PAL labelling. There is though a need for a label to indicate that a manufacturer has utilised a risk assessment tool such as VITAL, especially when no PAL is needed. To be effective, small and medium food operators, which represent the majority of food businesses, need to be targeted with specific food safety programmes as has happened in the US (61).

The auditors’ perspective

What does PAL mean to auditors

Many food-businesses are certified to an external food safety and quality management standard (e.g., 22000:2005; http://www.iso.org) with processes being audited to them. These standards either address issues relating to food allergen management generically in a similar manner to other chemical, physical or microbiological hazards or make specific provision for their management as found in standards which meet the requirements of the Global Food Safety Initiative (www.mygfsi.com) (62). A common requirement of these standards is that food safety management systems should be informed by risk analysis. Risk analysis itself has three components: assessment, management and communication. As an aspect of risk communication and management, PAL would fall within the scope of any audit. An auditor would look for evidence to demonstrate that the decision to use PAL was justified and that the wording does not misinform. So, food businesses must
demonstrably adopt best practice in terms of food allergen management (63) as well as the decision making process in determining the need for and nature of any PAL (64).

What do the auditors consider to be the issues?

Determining whether the risk of unintended allergen presence warrants a PAL is a major issue. Food safety standards and codes of practice are generic in nature and ignore risk perception; so different food businesses may make opposite decisions about the need for a PAL for the same risk of reaction (Box 2). The wording of PAL is also an issue particularly when third-party manufacturers are involved in producing products. Such an example would therefore not be expected to fall within the scope of the BRC Standard (62).

What could be done better?

A quality system auditor’s fundamental role is to determine compliance with a particular standard. In terms of the actual risk assessment process, auditors will need to see evidence of a reasoned approach to the risk analysis underpinning a decision whether or not use PAL. Risk assessments will require both a clear definition of the food business’s policy as to what level of risk would trigger PAL, and the reasoning underpinning the risk assessment. They therefore have to be food-business specific and informed by industrial best practice (e.g. Allergen Bureau (www.allergenbureau.net/), 65). In most jurisdictions, the wording of PAL is effectively at the discretion of the food business and so the degree to which an auditor can determine compliance with a standard is dependent on whether or not the product is to be sold under the business’s own brand or is manufactured on behalf of another. For the auditor, the situation would be made simpler if PAL was governed by legislation.

The regulatory risk assessors’ perspective

What do regulators understand by PAL?

PAL has been used to communicate to the consumer that allergens could be present as a result of unintended allergen presence. However, food manufacturers and regulators know that the allergen is not always present in the finished product nor is it necessarily present at a consistent level throughout the batch, production run or even product. In some countries regulatory agencies (e.g. Food Standards Agency, UK; Danish Veterinary and Food Administration) have advised businesses that PAL should only be applied following a thorough risk assessment rather than as an automatic default position.

What do regulators see as the issues?

There is no specific European legal provision which determines when PAL should be applied. EU regulation 178/2002 on the general requirements of food law, states that food must not be placed on the market if it is “injurious to health”. However, the amount of an allergen which is considered to be injurious to health is an area of uncertainty and inconsistency due to the lack of a consensus
on agreed reference doses on which action levels can be based to drive labelling decisions. The published reference doses for VITAL are a start but we need to know more about how the dose distributions that underlie these doses vary between countries, regions and populations plus whether they are modified by extrinsic factors. If these have an important impact, reference doses will need to be re-calculated to achieve the agreed level of safety. So this area continues therefore to be a major issue facing regulators (Box 2). Additionally there is a lack of confidence in the sensitivity and robustness of analytical methods used to monitor against any given level and consistency in the reporting of results. In the absence of agreed reference doses and consistency in reporting results, there is an inconsistent application of PAL and enforcement actions.

What do regulators consider could be done better?

Internationally agreed reference doses need to be derived from the distribution of individual allergen threshold doses in the allergic population to determine action levels below which PAL will not need to be used. These should inform decisions by regulators during the handling of food allergen incidents. Once there are agreed allergen reference doses, regulators will need to consider how businesses should best communicate to consumers that a risk assessment has been conducted and its outcome. Consideration of the most appropriate phrases is required, both where the level of contamination is above the threshold and a warning is needed and, as importantly, that a risk assessment has concluded that contamination levels are below a set action level. Communication needs to be consistent and meaningful. Educating healthcare professionals and allergic consumers is critical to explaining the outcomes of such risk assessments. The message would be that there is an acceptably low risk of a reaction and, should a reaction occur there will only be mild clinical manifestations.

Summary of the stakeholders’ perspectives

PAL was introduced by the food industry to help manage and communicate the risk of reaction from the unintended presence of allergens in foods. All stakeholders now agree that, in its current form, PAL is counter-productive for consumers with food allergies. The problem with PAL can be traced back to the lack of agreed quantitative reference doses from which action levels can be developed (Box 2). The problem is exacerbated by limitations associated with the current analytical methods for detecting allergens in food products and the diversity of PAL terminology. This means that there is an unreliable relationship between the presence or absence of PAL and actual risk of reaction among consumers with food allergy. The variable advice given by HCPs about PAL makes sense within this context. For consumers with food allergies, there has been a loss of credibility, trust, and ability to facilitate an informed choice with regards to PAL. This has important negative impacts giving rise to poor confidence in coping; low perception of control; reduced observance of avoidance strategies; reduced quality of life; and increased risk by consumers who learn to disregard PAL. All stakeholders agreed that this situation needs to be urgently addressed.

There is a general stakeholder consensus on how the situation could be improved with our present knowledge (Box 2). PAL must reflect actual risk. A PAL should indicate the likely unintended presence
of an allergen in a consumed portion of a food product that is at or above a reference dose. The absence of PAL should imply a clear level of safety. PAL should be based on agreed reference doses, although there are currently deficiencies in the data for all the key allergens and how intrinsic and extrinsic factors may modulate the reference dose. PAL should also have transparent reasoning, workings and rules underpinning any decision making process, this must be communicated clearly to all stakeholders. All agree that the application of PAL should be consistent across food products, with most stakeholders favouring a regulatory framework. The alternative view is that a voluntary approach would be more flexible, allowing advice to be modified as we see the results of the initial advice and our understanding improves. A compromise might be to introduce a regulatory framework that is sufficiently flexible to remain relevant to consumers and to facilitate new research and technology, as well as enable rapid implementation of new findings. The latter may include a combination of legislation to standardise certain aspects (e.g. phraseology) with a voluntary framework for specific methods of analysis.

For this new approach to work, it must be communicated effectively to all stakeholders, with appropriate education and training to ensure consistent implementation and correct understanding to best inform individual risk assessments (7). Such a risk-based PAL system would allow most consumers with food allergies to eat foods without PAL with a high degree of safety. An ‘informed risk’ based approach can help to increase a sense of control and trust, increase effective communication among all stakeholders, and reduce uncertainty. The authors of this paper hope that the ideas contained therein will foster ongoing discussion from many different perspectives in order to reach some form of consensus that will benefit all.

Key gaps and recommendations for research

There are still key areas of uncertainty in this area (Box 3)(66). Data able to support definition of reference doses have been defined for some allergens, they are needed for others and data are still lacking regarding how they may be modulated by host-related and extrinsic factors. Prospective data on the utility of actions in real life are also required. Better analytical techniques are needed to reliably detect in products allergens in excess of the action levels. There are challenges in interpreting what a reference doses might mean at the level of individual patients. We do not know to what extent inter- and intra-patient variability in threshold for reaction or exposure to co-factors will impact on the safety of food products for consumers with food allergy in the absence of a PAL. Lastly, we need to develop better ways of educating consumers with food allergy to undertake individualised risk assessment in the light of correctly applied PALs and assess how this impacts on their quality of life.

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Work Package 10 in improving food avoidance for consumers with food allergy through transparent precautionary allergen labelling.

Statement of contribution
Graham Roberts and Audrey DunnGalvin developed the concept, facilitated the writing and edited the manuscript. Anton Alldrick, Chun-Han Chan, René Crevel, Audrey DunnGalvin, Kate Grimshaw, Graham Roberts, Sabine Schnadt, Steve Taylor and Paul Turner all led the writing of specific sections. All the authors contributed to the development of the manuscript and approved the final version.

Conflict of interests
Katrina Allen is on the Board of the Ilhan Food Allergy Foundation, Australia and has received speakers honoraria from Abbozt, Danone, Pfizer and Alphapharm. Luca Bucchini has worked as a consultant for the food industry and one patient organisation. Audrey DunnGalvin is a co-investigator in the ORCA project, and is a consultant for FARRP. Geert F Houben is a consultant, senior scientist and manager for TNO, The Netherlands.Montserrat Fernandez-Rivas has no conflicts of interest. Kate Grimshaw is a consultant for FARRP and has provided scientific advice for Nutricia North America. Jonathan Hourihane has received threshold study funding from FARRP and other research funding from Danone. Astrid G. Kruizinga is a consultant and scientist for TNO, The Netherlands. Charlotte B. Madsen is a consultant for the Danish National Food Authority. Steve L Taylor is a consultant on food safety to ConAgra Foods and Kellogg Co., and a co-Director of the Food Allergy Research & Resource Program at the University of Nebraska, a food industry-funded consortium with more than 80 member companies. Graham Roberts is an executive committee member of EAACI and has provided scientific advice for Danone. Paul J Turner holds a Clinician Scientist Award from the UK Medical Research Council and is supported through the NIHR/Imperial Biomedical Research Centre.

Figure 1. Percentage of food allergic consumers that would "never" buy a product with precautionary allergen label according to the wording used
Data from a the global survey completed by the EAACI Patient Organisation Committee and the international Food Allergy and Anaphylaxis Alliance (iFAAA) on consumers’ perspective on allergen labelling and thresholds. Numbers participating in each country are shown in the legend. Personal communication, Sabine Schnadt.

Figure 2. Interpreting the presence / absence of “may contain...” statements?
Conceptual figure of possible interpretations of presence or absence of PAL for consumers with a food allergy. This means that the actual risk of a reaction cannot be assessed for the allergic consumer, when purchasing a product.
Figure 3. Conceptual representation of the relationship between the extent of PAL and its observance by consumers with food allergies

With a low reference dose where a large proportion of products have a PAL (dashed line), few consumers will observe the precautionary labelling (dotted line) giving a high risk (solid line) of allergic reaction from exposure to an unintended allergen. If a high reference dose is used, few products will have a PAL and a high proportion of consumers are likely to observe the labelling but because many products without a PAL are likely to contain sufficient unintended allergen to cause an allergic reaction, the risk will again be high. So an intermediate reference dose is required that balances the proportion of affected products and consumer behaviour.

Figure 4. ‘How useful would it be for you/your children/your patients/consumers if ‘there was some level or hierarchy of risk implied by labelling’

Illustration from DunnGalvin et al (36). Data from http://farrp.unl.edu/.

Figure 5. What do psychologists consider to be the issues?

Conceptual overview of psychological issues. The approach of patients and their care givers to food allergy is negatively impacted by (1) uncertainty about how much allergen is required to cause a reaction and how severe the reaction will be (top left) and (2) inconsistency in use and advice on the interpretation of PAL (top right). This is likely to result in reduced confidence in coping, decision making and management resulting in increased risk and reduced quality of life.

Figure 6. Consumer responses on the barriers to effectively translating our knowledge on references doses to labelling (36)

<table>
<thead>
<tr>
<th>Box 1. Key terms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Action levels</strong></td>
</tr>
<tr>
<td><strong>Eliciting doses</strong> (eg ED10)</td>
</tr>
<tr>
<td><strong>Enzyme-linked immunosorbent assays</strong> (ELISAs)</td>
</tr>
<tr>
<td><strong>Food allergy</strong></td>
</tr>
<tr>
<td>Term</td>
</tr>
<tr>
<td>------</td>
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<tr>
<td>reactions and are most frequently delayed. They are not associated with a risk of anaphylaxis.</td>
</tr>
<tr>
<td>Healthcare professional (HCP)</td>
</tr>
<tr>
<td>Low dose allergen challenge</td>
</tr>
<tr>
<td>Precautionary allergen labelling (PAL)</td>
</tr>
<tr>
<td>Quantitative risk assessment (QRA)</td>
</tr>
<tr>
<td>Reference dose</td>
</tr>
<tr>
<td>Risk management</td>
</tr>
<tr>
<td>Single dose challenge</td>
</tr>
<tr>
<td>Threshold dose</td>
</tr>
</tbody>
</table>
Box 2. The meaning and issues associated with PAL: common themes in this review

Communication

- Lack of agreed reference doses
- Lack of public health authority guidance on risk assessment as a decision making tool and enforcement activity
- Lack of confidence in the sensitivity of analytical methods and inconsistency in reporting results
- Uncertainty and inconsistency in application of PAL so that there is an unsatisfactory relationship between presence or absence of PAL and actual risk of an allergic reaction
- Uncertainty and inconsistency in advice given by HCP’s

Impact

- Increase in use of PAL by food industry, particularly by SMEs
- Reduced food choices, increased time spent shopping and preparing food by consumers
- Loss of credibility, trust, and ability to make informed choice by consumers
- Poor confidence in coping and low perception of control by consumers
- Reduced compliance, and quality of life, and increased risk taking by consumers

What could be done better?

- PAL must reflect actual health risk
- Absence of PAL should imply a clear level of safety
- PAL should be based on agreed reference doses, derived from the distribution of individual allergen threshold doses in the allergic population.
- PAL should be governed by legislation and be consistent and meaningful, while remaining flexible to allow for new technology
- Reasoning, workings, and rules underpinning any decision making programme must be communicated clearly to all stakeholders, taking into account their particular needs and requirements
Box 3. Gaps and recommendations for research

- Determine the proportion of the general population at risk of allergy to each food allergen.
- Develop reliable analytical techniques for assessing allergen content in food products including new technologies and exploiting and improving already existing methods.
- Evaluate how the use of ED10, ED05 or ED01 derived reference doses might be used to limit use of PAL where ED10, ED05 and ED01 are the eliciting doses for 10%, 5% and 1% of the population with specific food allergy.
- Better understanding of the reference doses that are reliably associated with severe reactions for different allergens. This could be achieved through data provided by low dose allergen challenges performed in a clinical context.
- Better understanding of how co-factors might influence threshold doses (eg illness, co-existing asthma, exercise). This requires the development of systems models.
- Improved ability to identify patients who may have clinically significant reaction to allergen levels below proposed reference doses.
- Improved educational approaches to provide patients with the ability to successfully undertake an individualised risk assessment that takes into account the presence or absence of a PAL, personal threshold level, intra-subject variability in threshold levels plus presence or absence of specific co-factors or co-existing diseases.
- Identify the reasons that adverse reactions occur, including: labelling type; management plans and related psychosocial factors with the aim of reducing risk behaviours and improving quality of life for those living with food allergy. This requires using qualitative and quantitative methods with a diverse range of consumers, taking into account different patterns of consumption, risk perception and behaviours.

References


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37. Hourihane JOB. Flokstra-de Blok BMJ, Dubois AEJ, Kahlon R, DunnGalvin A. Food Challenge has a Rapidly Established and Persistent Positive Effect on Quality of Life of Children 0-12 years irrespective of the Clinical Outcome of the Challenge. J Allergy Clinical Immunology 2009; 123:143.


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<table>
<thead>
<tr>
<th>Helpful to allergic consumers</th>
<th>Product without PAL</th>
<th>Product with PAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Product without PAL with low or no risk of inducing an allergic reaction, ie is safe</td>
<td>- Proper risk assessment by the food manufacturer</td>
<td>- Proper risk assessment by the food manufacturer</td>
</tr>
<tr>
<td></td>
<td>- Conclusion that the allergen is not present in the product at a level that is likely to cause an allergic reaction</td>
<td>- Conclusion that the allergen may be present in the product despite allergen management and GMP (good manufacturing practice)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not helpful to allergic consumers</th>
<th>Product without PAL</th>
<th>Product with PAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Product without PAL with unknown risk of inducing an allergic reaction, ie may be safe or unsafe to consume</td>
<td>- No proper risk assessment by food manufacturer resulting in possible allergen presence without being mentioned on the label</td>
<td>- No proper risk assessment and allergen management to reduce the risk of unintended presence by manufacturer</td>
</tr>
<tr>
<td></td>
<td>- No conclusion can be drawn about the presence of the allergen</td>
<td>- No conclusion can be drawn about the presence of the allergen</td>
</tr>
<tr>
<td>4. Product with PAL with unknown risk of inducing an allergic reaction, ie may be safe or unsafe to consume</td>
<td>- Proper risk asessment by manufacturer</td>
<td>- Decision to use PAL nethertheless by risk adverse manufacturer</td>
</tr>
<tr>
<td>5. Product with PAL with low or no risk of inducing an allergic reaction</td>
<td></td>
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