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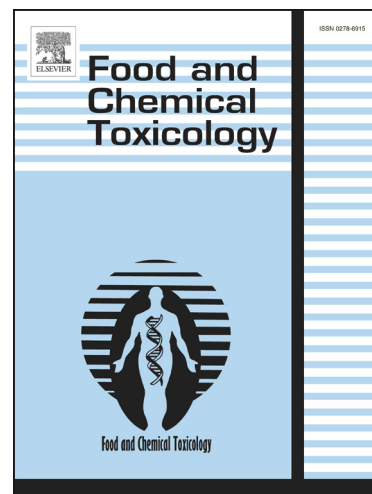
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Advances in the risk management of unintended presence of allergenic foods in manufactured food products – an overview

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Highlights

- Food allergy has become a growing food safety concern worldwide.
- The data and the methods available to assess food allergen risk have developed considerably.
- Consistent allergen management requires generally agreed evidence-based standards.
- Allergen risks need to be communicated effectively to allergic consumers for those standards to be accepted.

Abstract

Food allergy is a relatively recent newcomer to the ranks of food safety issues, only being effectively recognised as such in the last 25 to 30 years. This recognition, allied with the near impossibility of avoiding the unintended presence of small, yet potentially dangerous residues of allergenic constituents, brought with it the need to assess and manage the resulting risk. This paper provides an overview of the development and current knowledge and thinking on risk assessment and its application to risk management of food allergens. It also discusses the associated challenges, in particular those around communicating meaningfully that risk to allergic consumers, including the use of precautionary labelling. The paper also provides an introductory context to the more detailed analyses of these issues in the following papers, based on the deliberations of a recent stakeholder workshop.

The paper concludes that consistent risk management approaches using agreed quantitative action levels based on scientifically robust principles will provide optimal protection to allergic consumers. Growing amounts of data from oral food challenges along with the parallel development of risk assessment methodologies, such as probabilistic modelling, offer a realistic possibility of agreement among stakeholders on such levels in the near future.

Key words

Food allergy, public health, risk assessment, probabilistic modelling, eliciting dose, reference dose, allergic consumers

1. Introduction

Developing knowledge about the relationship between allergen dose and population reactivity, as well as the tools to translate this knowledge into practical action to improve safety and quality of life of allergic consumers means that it will now be possible to manage food allergens as effectively as other food safety hazards.

The aim of this paper is to provide an overview of recent advances in and current thinking on, best practices, challenges and progress on development of allergen risk management and communication approaches. It is targeted towards anyone who wants to improve their understanding of current thinking in the area of allergen risk assessment and management. The accompanying papers describe the outcomes of the most recent workshop where these advances were discussed along with approaches to optimal communication to the food allergic consumer of risks from the unintended presence of allergenic foods in manufactured food sold pre-packaged. In particular, they set out in more detail the application, integration, uncertainties and limitations in the input parameters for allergen risk assessment (Madsen et al. 2009) and the use of probabilistic risk modelling approaches to determine proposed allergen reference doses (Spanjersberg 2007; Kruizinga et al. 2008).

2. Food allergy: a public health and food safety issue

Food allergy is of global and growing importance to public health, affecting consumers' quality of life (mainly children) and making increasing demands on health service resources (Cianferoni and Spergel 2009; Lieberman and Sicherer 2010; Burks et al. 2012). It affects around 2 to 4% of the population, as confirmed by studies conducted to estimate prevalence (Rona et al. 2007; Zuidmeer et al. 2008; Madsen et al. 2009). Furthermore, allergic reactions to foods account for a high proportion of admissions to hospitals for acute allergic reactions (Worm et al. 2010). Foods can induce many different types of immune and allergic responses, but the primary public health concern lies with the risk to sensitised individuals who have produced IgE antibodies to proteins in the food, which are then implicated in immediate-type reactions on subsequent exposure. Such reactions can vary from very slight to severe and occasionally fatal, depending on the dose, the individual and other factors (Cianferoni and Spergel 2009; Cochrane et al. 2012). Despite recent progress in immunotherapy, for practical purposes, no cure exists currently for food allergy and

therefore food allergic consumers can only manage their condition by carefully avoiding products which contain the food(s) to which they are allergic (Taylor et al. 2009; Burks et al. 2012).

In order to do this effectively, food allergic consumers are absolutely dependent on the availability, accuracy and quality of information provided on foods that they want to buy. The importance of food allergy as a public health issue has led to its recognition globally as a food safety issue, as illustrated by labelling legislation in several countries and regions (Gendel 2012). Allergen labelling represents a critical tool for management which needs to communicate the allergen status of food products unambiguously using simple, harmonized terms in local language to maximise consumer understanding and to be available upon demand. The availability of information about the presence of allergenic food ingredients that are intentionally used in a food product has improved significantly in the last 15 years. Initially a list of priority allergens was developed by the Codex Alimentarius (Codex Alimentarius 1999) and this list was then used as a starting point by the European Commission and other regulatory bodies, as they introduced specific legislation requiring the clear declaration of a list of specified allergenic food ingredients (summarised by Gendel 2012). Generally speaking, all these different legislative instruments have mandated the declaration of specified allergenic foods when they are used as ingredients in pre-packed foods, regardless of their level of use. None address the inadvertent presence of these allergenic food ingredients in other food products, for instance, as a result of possible cross contact at some point in the food manufacturing chain.

The nature of modern day food production and manufacturing means that allergenic constituents may be present inadvertently, perhaps because they are unintentionally present in the raw materials used, or because they are carried over in small amounts from a previous product during the manufacturing process (Alvarez and Boye, 2012). These small amounts may pose a risk to allergic consumers, and this risk needs to be assessed in order to be managed (Madsen et al. 2009; Taylor et al. 2009; Taylor and Baumert 2010).

3. Which allergenic foods are of most concern?

Many foods have the potential to provoke allergic reactions in sensitized individuals (Hefle et al. 1996). In practical terms, a relatively limited number of foods have been identified as priority allergenic foods based upon perceptions of the prevalence, severity and potency of those foods as allergens (Gendel 2012). In the EU, the list of priority allergenic foods comprises peanut, milk, eggs, fish, crustaceans, molluscs, tree nuts (*almonds, hazelnuts, walnuts, cashew nuts, pecan nuts, Brazil*

nuts,, pistachio nuts, macadamia nuts and Queensland nuts), soybeans, cereal containing gluten (*wheat, rye, barley and related grains*), lupin, celery, sesame seed and mustard, as well as sulphur dioxide/sulphites which can trigger asthma attacks in those that are sensitive to this ingredient (even though this latter ingredient does not meet the definition of an IgE-mediated food allergen).

Determination of the particular food allergens that should be regarded as priorities for public health control needs to be established using scientifically-based criteria, and include globally important food allergens as well as any food allergens with significant local prevalence. Criteria have been proposed to identify the most appropriate priority allergenic foods based upon defined prevalence, severity and potency (Bjorksten et al. 2008).

4. Current approaches to allergen risk assessment, management and communication

Historically, multiple approaches have been considered to assess the risk from low level residues of allergenic foods that might accidentally be present in other foods (Taylor et al. 2002; Threshold Working Group 2008; Madsen et al. 2009; Taylor and Baumert 2010). Similar approaches could equally be applied to consideration of the risk to allergic consumers posed by deliberate allergenic ingredients that are used at very low levels.

Few regulatory bodies have addressed the issue of food allergen risk assessment and risk management. However, the UK Food Standards Agency (Food Standards Agency (FSA) 2006) has published qualitative guidance to help food businesses to consider where allergen cross contact risks could arise and how they might be better managed. This voluntary guidance also addressed how any risk remaining after mitigating measures had been applied could be communicated. This FSA guidance has recently been used as a starting point for allergen risk management guidance for food manufacturers developed by FoodDrinkEurope (FoodDrink Europe 2013). This guidance includes a more detailed consideration of ways in which allergen cross contact risks can be managed and minimised, including a description of the critical preventative elements influencing the effectiveness of risk management measures.

In the absence of guidance on agreed limits for allergenic residues, the limit of detection has been frequently used as a default criterion, making it a *de facto* action level. As noted by US Food and Drug Administration (FDA), the limit of detection is not necessarily selected on the basis of the extent of the remaining allergenic hazard (Threshold Working Group 2008) and in practice, can result in very conservative assessments of the risk. The use of surface swabs to verify cleaning illustrates this point very well. The methods are highly sensitive and it is questionable whether the amounts of

allergen detected would in many cases pose more than a negligible risk, after taking into account the rate of transfer from surfaces to products, dilution factors and other considerations.

5. Why the current situation is failing allergic consumers and other stakeholders

Faced with uncertainty over the risk and a lack of quantitative guidance, many food manufacturers opt to use some form of precautionary labelling to alert allergic consumers to the possibility of, and consequently the risks from, the inadvertent presence of allergenic food constituents, using a variety of phrases. Whilst the intention of such warnings is to help allergic consumers to make safe food choices, the use of such warnings has become widespread and it can be difficult to find examples of certain food product groups without such warnings (Food Standard Agency (FSA) 2002; Sakellariou et al. 2010; Barnett et al. 2011a; Zurzolo et al. 2012). Up to now no general agreement has been reached on international standards which could be used to set maximum tolerable levels of unintended allergen (action levels) above which precautionary labelling would be required. Faced with the resulting uncertainty, manufacturers often feel obliged to provide these additional voluntary warnings where they determine qualitatively that any risk may exist, however low or remote. Furthermore, improvements in allergen analytical detection methodologies have also meant that lower and lower levels of allergen can now be detected, exacerbating the problem (Monaci L and Visconti A 2009; Monaci et al. 2010; Diaz-Amigo and Popping 2010; Monaci L and Visconti A 2010; Monaci et al. 2011). Several regulatory authorities also have adopted a *de facto* zero tolerance approach, instigating enforcement activity if any allergen cross contact is detected, however small the amount.

Consumer research has shown that many food allergic consumers consider allergen precautionary warnings to be overused and they are therefore often ignored or mistrusted, leading to risk-taking behaviours (Food Standards Agency (FSA) 2005; Hefle et al. 2007; Barnett et al. 2011a). A further challenge to the value of precautionary labelling for consumer protection is the diversity and inconsistent application of these warning phrases signalling potential presence of unintended food allergens from cross-contamination. Recent research (Turner et al. 2011; Zurzolo et al. 2012) has confirmed that this diversity and inconsistency of precautionary warning statements has left consumers confused and anxious. There is some evidence to suggest that consumers are over-interpreting the words

used in the precautionary label wording and making judgments on the size of the risk based on the words describing how the risk could arise (Barnett et al. 2011b). The absence of a “may contain” label has even been misunderstood to mean that the product was “free from” allergens.

Furthermore, allergic consumers are not the only ones to be confused. Clinicians who advise people on how to manage their food allergy also hold conflicting opinions on how to interpret and take note of precautionary labels in the context of this medical advice (FAAM 2013).

However, it is also recognized that precautionary labels are helpful if they can provide consistently reliable warnings of the risk that an allergen might be present inadvertently, steering sensitive allergic consumers away from foods unsuitable for them. An evidence-based approach that led to the definition and adoption of quantitative allergen management action levels would result in consistency and transparency in risk management decision-making, and subsequent consumer and clinician risk communication. This would in turn allow clear discrimination between foods and their suitability for allergic consumers, thereby improving food allergy management. However before this goal could be reached a number of data gaps need to be filled, including the lack of characterisation of the allergen hazards (dose distribution curves) (Crevel et al. 2008; Threshold Working Group 2008; Madsen et al. 2009) and the relative insensitivity and lack of robustness of some analytical methods (Poms and Anklam 2004; Diaz-Amigo and Popping 2010). It is also important to ensure that clinical allergy risk management advice addresses risk at a population as well as an individual level (Schwartz 2012; Luccioli 2012).

6. Risk assessment strategies and tolerable levels of risk

A growing recognition has evolved that consistent risk management approaches with agreed quantitative action levels based on scientifically robust principles will provide optimal consumer risk protection. In parallel, all stakeholder groups now recognise that zero risk is unrealistic (Madsen et al. 2010; Madsen et al. 2012) and indeed, EU Food Safety law explicitly enshrines risk analysis as one of its foundations (European Union 2002). These risk management approaches are founded on an understanding that minimising risk from allergenic foods is a shared responsibility across stakeholders (patients, clinicians, food manufacturers, retailers, caterers and regulators).

Allergens in food pose a health risk to humans who may become, or are already sensitised to these proteins. Terminologies and methodologies for food risk and safety assessment and management have developed over many years, mainly driven by the need for assessment and management of risks from chemicals or microorganisms that may be present in food. For a long time, it was questioned whether such classical toxicological risk assessment principles could be applied to allergy and allergenic foods. However, with increasing volumes and quality of data, major progress has been achieved and it is now widely accepted that the broad toxicological principles and approaches of chemical risk assessment can be applied to food allergens (Spanjersberg et al. 2007; Madsen et al. 2009; Spanjersberg et al. 2010) as can the same terminologies and methodologies. A joint EuroPrevall, UK FSA and Food Allergy Research & Resource Program (FARRP) workshop held in Madrid in 2007 investigated a range of classical toxicological risk assessment strategies and methodologies and their applicability for use in allergen risk assessment, considering both the advantages and limitations of the different approaches (Madsen et al. 2009). That workshop concluded that all three approaches to risk assessment could continue to be used for allergen risk assessment. However probabilistic modelling was considered to be the most promising approach to allergen risk assessment at a population level, which is of most interest to risk managers in regulatory bodies and in the food industry. This view is shared by the US FDA Thresholds Working Group (although they called this approach quantitative risk assessment-based). The workshop also considered data gaps and issues that would need to be addressed to move the discussion forward, most notably achieving agreement with all stakeholders affected on what remaining risk could still be tolerated, with the pivotal question being *'what proportion of the population should we be aiming to protect and against what type of reaction?'*

Preventing all types of reaction in all allergic individuals would be trying to achieve zero risk, which is not a realistic possibility. There is considerable variability between individuals with a food allergy in terms of the severity of any adverse reaction that they might experience, as this depends on the nature and properties of the allergen, the amount of the allergen consumed and the physiological status and genetic background of the patient. A prerequisite for public health authorities is therefore to share a broadly similar outlook on the frequency of food allergic reactions that could be accepted, differentiating between reactions of different degrees of severity and aligned with the actual needs and behaviour of allergic consumers. Agreement across all stakeholders including allergic consumers, patient organisations, food businesses, scientists and healthcare professionals on what can be achieved and the resulting risk management objectives would form a sound basis for progress, building on existing evidence about risk perception and behaviours (Health Council of the Netherlands 2007; Madsen et al. 2012).

A further workshop held in Vienna in 2009 brought together key representatives from regulatory bodies, the food industry, clinical research groups and the food allergic community to discuss how a tolerable level of risk with regard to allergic reactions could be defined at a population level. A key output from this workshop was that there was consensus between all the stakeholder groups that zero-risk was not a realistic option and that action needed to be taken to improve the existing unsatisfactory situation (Madsen et al. 2012). Once the political level has taken a decision on the tolerable frequency of different types of adverse allergic effects, as discussed above, allergen reference doses can be determined which meet the appropriate level of protection and can be used by businesses and regulators to assess the risk from levels of allergen cross contamination that have been detected in a particular product. If a business is able to ensure that this reference dose would not be exceeded by eating a serving of the food in question, then precautionary labelling should be omitted on that particular product (Health Council of the Netherlands 2007). Such an approach, with appropriate adjustments for the different distribution of allergen, could equally be used in the consideration of exemptions from allergen labelling requirements for highly processed food ingredients, such as glucose syrups and refined oils.

Any given benchmark, such as a reference dose, actually protects to a greater degree than the nominal level of protection. If a business is controlling allergen cross contamination to a certain target or action level, almost all products will in fact contain lower levels of the allergenic food than the action level, if it is there at all, although there is still a risk that the allergenic food could be present at or just below that action level. Moreover, most patient challenges are conducted using model foods designed to maximise 'bioavailability', which in real food products may be less due to the effects of food processing and cooking and interactions with the matrix components, such as fats, resulting in a lower level of risk (Mackie et al. 2012).

7. Determination of population management thresholds

Progress over the last twenty years in the assessment and management of the risk from food allergens with the aim of minimising the incidence of reactions among food allergic consumers was discussed at an ILSI Europe workshop in Nice in 2010 (Chan et al. 2011). The ever-growing dataset arising from oral food challenges now allows minimum eliciting doses to be determined for many of the major food allergens currently included on regulatory lists. The parallel development of risk assessment methodologies also allows quantitative allergen management thresholds, or reference doses to be derived. The quantity of data points available for a particular allergen will influence the decision on the endpoint that can

be derived. Very recently, the Scientific Expert published proposed allergen reference dose values for use in the Australian Allergen Bureau's Voluntary Incidental Trace Labelling (VITAL) Program upon review of the available clinical allergen challenge data (Allen et al 2013).

Any public health protection endpoint or action level chosen needs to be highly protective for the overall population at risk. In clinical challenge tests, the lowest dose of food allergen found to elicit an independently observable objective reaction in an individual subject (called the minimum eliciting dose or MED) has been proposed as the threshold dose for an adverse food allergic reaction (Crevel et al. 2007). To determine a reference dose suitable for protecting the overall allergic population, data from multiple subjects and studies are then combined to model the distribution of MEDs in the allergic population (Crevel et al. 2007; Taylor et al. 2009). From this dose distribution, it is possible to identify the "eliciting dose" (ED) for any fraction of the allergic population, where ED_p refers to the dose of allergen that produces a response in p% of the allergic population. The choice of reference dose for management of food allergens implies a judgement about the level of protection: for instance, the ED₀₅ (dose at which 5% of the subject population is predicted to react) or the ED₀₁ (dose at which 1% of the subject population is predicted to react). As well as the likely nature of the reaction at the selected reference dose, this choice needs to take into account not only the size of the dataset, but ultimately practicability, both in terms of achievability and verifiability. Otherwise, they could result in unintended outcomes, which could even be diametrically opposite to those being sought (i.e. an increase rather than a decrease in precautionary labelling). Whilst it would superficially appear that choosing an ED₀₅, or even an ED₀₁, might still allow for a significant number of reactions to occur in the community, this may not be the case in practice. It must also be understood that the individual threshold dose used in the modelling is usually the dose at which a subject starts to report a reaction, and in most cases this will be a mild objective reaction, thus protecting the allergic population against more severe reactions.

The primary aim in defining allergen action levels is to provide benchmarks that facilitate the assessment of the risk posed by accidental presence of an allergenic food, not used as a deliberate ingredient in a mainstream food product, but that could be eaten by a food allergic consumer as part of a varied diet. The same methodologies and approaches could be utilised to define allergen 'free

from' claims, albeit with the aim of setting a different level of protection, given that such foods are targeted at the allergic population and will be eaten in potentially large amounts. The situation is similar to that for baby foods where more stringent levels may be set for certain contaminants in foods intended for infants and young children where these are likely to form a major proportion of the child's overall dietary exposure.

8. Vision for the future

The main aim of the development and implementation of a framework for allergen risk management anchored in evidence-based reference doses is to help ensure that food allergic consumers can make safe and informed decisions about what to eat and ensure that the range of products available to them is not unduly restricted. Reference doses that are developed for the allergenic foods subject to regulatory controls could be used in a number of ways in the evaluation of the safety of a product for a food-allergic consumer:

- for businesses when deciding whether or not allergen precautionary labelling is appropriate for their products;
- for regulators and enforcement bodies when assessing the risk from observed levels of allergen cross-contact in a particular food product marketed without allergen precautionary labelling;
- a secondary use would be for determining whether a highly processed ingredient derived from an allergenic food that is used under defined conditions should be exempt from allergen labelling requirements.
- as an effective foundation for communicating allergen risks in mainstream foods to both allergic consumers and clinical practitioners involved in their care.

A critical consideration for public authorities will be the effectiveness with which new standards can be applied and monitored by businesses, and enforced by authorities. The lower the level at which a reference dose is set, the more protective it is, provided it can be adhered to, but the more likely it will be that products need a precautionary label. Thus an important consideration to avoid unintended consequences is where to strike the balance of minimising the number of reactions whilst not unnecessarily restricting choice. Setting of reference doses also needs to consider the capability of analytical techniques to detect allergens reliably at the concentrations around the action level in a wide range of different food matrices.

Allergen precautionary labelling, and particularly the phrase 'May Contain' is currently so devalued that it is ignored by a large proportion of food-allergic consumers and some health professionals do not contradict their patients when they ignore such warnings. A risk/benefit balance is needed between protecting the allergic consumer as much as is practicable, through clear and credible risk communication based on allergen reference values, whilst enabling businesses to manufacture products that are economically viable and that do not result in unnecessary restrictions in consumer choice. This needs to be explained to the consumer and to health professionals and the improvements in comparison with the current situation set out.

In view of the global nature of the food supply chain, good practice in allergen risk management needs to be implemented consistently across all jurisdictions worldwide by all stakeholders i.e. regulators, food manufacturers, retailers and caterers alike. One approach to achieve this would be to enshrine these principles in a CODEX code of practice for the risk management of food allergens that would reach out globally and set a consistent standard approach.

Whilst the use of precautionary warning labels remains voluntary, it is accepted that food should be manufactured according to best practice using processes validated through HACCP. Any new system based on scientifically-derived allergen reference doses must be able to communicate that a positive decision has been taken that no precautionary warning label is necessary. There would need to be two clearly different messages concerning the interpretation of labelling:

- A risk assessment has been conducted using a specified system with agreed allergen action levels and a decision taken that a precautionary warning is warranted.
- A risk assessment has been conducted and a decision taken that the risk is negligible.

The challenge remains as to how most effectively to identify these two scenarios for consumers. Consumers with food allergies could then actively seek out the second category of products without a need for a guarantee that there is zero cross contact risk. Of course, a corollary of the above system is that consumers will need to understand that the second category does not imply an absolute absence of risk. They should therefore have been advised by their healthcare practitioners that their degree of allergic sensitivity was such that the risk to them was indeed negligible, ideally knowing their individual threshold.

The aims in terms of public health protection are to have a spectrum of products that are labelled in such a way as to enable a food allergic consumer to avoid the foods that could provoke an allergic reaction if consumed. There will be a number of categories of food:

- a) 'free-from' foods which are specifically developed and marketed for the food allergic consumer. These foods could be eaten under any circumstances and could form a substantial part of that persons' diet;
- b) 'mainstream' foods where the levels of unintended presence of the allergenic food have been managed and assessed as being below an agreed reference dose. These foods could be eaten by the food allergic consumer as part of varied diet but might need to be avoided in certain circumstances, as advised by their health professional, for example where the person is unwell because of infection or their asthma is poorly controlled or where medical support is remote;
- c) foods with precautionary warning labels which are foods where the levels of accidental presence of the allergenic food have been managed but have been assessed as being above an agreed reference dose and for which a decision has been made that they should carry an allergen precautionary warning label. Such foods should not be chosen by the food allergic consumer.
- d) "allergen-containing" food products in which the particular allergenic food is intentionally used as an ingredient and which are correctly labelled. These should not be chosen by the food allergic consumer under any circumstances.

9. What is currently happening?

Given the current lack of harmonisation in the risk management approaches used by authorities, the food industry may be reluctant to move forward and adopt any reference doses that are developed unless these are clearly supported by regulatory and enforcement bodies. However, if agreement on quantitative action levels can be achieved, this will lead to clear, agreed and reasonable harmonised standards based on scientifically robust reference doses, and a common framework to describe food categories according to their allergen composition status, to the benefit of both allergic consumers and the food industry. This would be evident from:

- Well-defined and consistent standards for allergen management for the food industry, leading to greater consistency of allergen management and better allergen management throughout the food industry;
- Consistent application of precautionary labelling for consumers together with clear communication, enabling a clear understanding and aiding decision making for food choices;

- Improved quality of life for allergic consumers through safer products and wider food choices;
- More consistent risk management decisions by industry and public authorities, based on robust allergen risk assessments;
- Improved tools to guide dietary advice by clinicians, dieticians and other health professionals.

10. What still needs to be done?

Whilst much work has gone into the development of allergen reference doses using population dose distribution curves and probabilistic modelling (Taylor et al. 2002; Spanjersberg et al. 2007; Madsen et al. 2009), these are theoretical doses derived from challenges conducted using an ascending dose protocol. It will be important to validate these population dose distributions by carrying out single dose challenges for the various allergenic foods to determine whether the proportion of unselected allergic subjects reacting to this single dose matches predictions. There is also a need for better food consumption data in allergic consumers as it is not known whether either the pattern of foods consumed or the average amounts of particular types of foods consumed by people with different food allergies will mimic that in the non-allergic population.

One of the assumptions made in deriving allergen reference doses is that for people already sensitised to a particular allergen, those reacting to the lower end of the eliciting dose range will have more severe reactions to any given amount of allergen than those for whom higher triggering doses are required. This assumption needs to be investigated further. The derivations that have been undertaken have also not included any additional safety or uncertainty factors. It will be important to investigate the effects of extrinsic factors, such as illness, stress, exercise etc, on a subject's threshold dose and severity of reaction to understand the extent to which these factors can affect an allergen threshold dose in an individual in order to ensure that clinical advice on management of their allergy is appropriately tailored.

For some allergens on the EU regulatory list such as fish, shrimp and celery and for some individual tree nuts, currently there are insufficient challenge data to enable robust reference doses to be derived. Filling these data gaps will be important.

Finally, it is of course essential that there is education so that consumers and health professionals understand the principles underpinning any new precautionary label scheme based on allergen reference doses that might be introduced and be able to use the information that is provided on food labels to make properly informed choices about foods that are safe for them. Consumers also need to be given diagnostic information by their health professionals about their individual levels of sensitivity in order that they can most effectively manage their own allergies.

11. Conclusion

There have been discussions over many years on how to assess the risk of the inadvertent presence of allergic foods in other food products. It is now considered by a wide range of stakeholders taken from the food industry, allergic consumer groups, clinicians and regulatory bodies that recent developments in risk assessment methodologies can be applied to allergen risk assessment and that there are sufficient data currently available to derive initial reference doses for most of the allergens on the current EU regulatory list. Whilst there is always a temptation to wait for better and more robust data, it would not serve allergic consumers well to continue to defer decisions on quantitative benchmarks for allergen management, whilst accepting that there is a need for regular reviews of the initial reference doses, as and when new data and knowledge emerge.

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Declaration of interest

A Baka is employed by ILSI Europe.

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