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Title	Evidence based approaches to the application of Precautionary Allergen Labelling: Report from two iFAAM workshops
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Publication date	2019-07-20
Original Citation	Dunn Galvin, A., Roberts, G., Schnadt, S., Astley, S., Austin, M., Blom, W. M., Baumert, J., Chan, C.-H., Crevel, R. W. R., Grimshaw, K. E. C., Kruizinga, A. G., Regent, L., Taylor, S., Walker, M. and Mills, C. (2019) 'Evidence based approaches to the application of Precautionary Allergen Labelling: Report from two iFAAM workshops', Clinical and Experimental Allergy, 49(9), pp.1191-1200. https://doi.org/10.1111/cea.13464
Type of publication	Article (peer-reviewed)
Link to publisher's version	https://onlinelibrary.wiley.com/doi/abs/10.1111/cea.13464 - 10.1111/cea.13464
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Download date	2026-10-05 12:35:38
Item downloaded from	https://hdl.handle.net/10468/8259

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Article type : Opinion or Debate

Evidence based approaches to the application of Precautionary Allergen Labelling: Report from two iFAAM workshops

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This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/cea.13464
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Key words: allergen, food allergy, may contain, precautionary labelling

Abstract

Food allergy is a major public health concern with avoidance of the trigger food(s) being central to management by the patient. Food information legislation mandates the declaration of allergenic ingredients; however, the labelling of the unintentional presence of allergens is less defined. Precautionary allergen labelling (PAL) was introduced by the food industry to help manage and communicate the risk of reaction from the unintended presence of allergens in foods. In its current form, PAL is counterproductive for consumers with food allergies as there is no standardised approach to applying PAL. Foods with a PAL often do not contain the identified food allergen while some products without a PAL contain quantities of common food allergens that are capable of inducing an allergic reaction. Integrated Approaches to Food Allergen and Allergy Risk Management (iFAAM) was an EU-funded project that aimed to improve the management of food allergens by the food industry for the benefit of people with food allergies. Within iFAAM, a clinically validated tiered risk assessment approach for food allergens was developed. Two cross-stakeholder iFAAM workshops were held on 13th-14th December 2016 and 19th-20th April 2018. One of the objectives of these workshops was to develop a proposal to make PAL effective for consumers. This paper describes the outcomes from these workshops. This provides the basis for the development of more informative and transparent labelling that will ultimately improve management and well-being in consumers with food allergy.

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Background

Food allergy is a major public health concern affecting up to 20 million European citizens, with high costs to public health services (1-5). Avoidance of the trigger food(s) is central to management by patients but accidental ingestion is common, causing frequent and sometimes life-threatening reactions (6-10). Admission rates for anaphylaxis have increased approximately 3-fold between 2005 and 2012 in several countries (11-13). Management of both food allergy (by patients and health practitioners) and allergens (by industry) is currently hindered by gaps in the evidence and in the implementation of our current knowledge compounded by a lack of consensus.

Precautionary allergen labelling (PAL), often known as “may contain” labelling was introduced by the food industry to help manage and communicate the risk of reaction from the unintended presence of allergens in foods (recent review (14)). In its current form, PAL is counterproductive for consumers with food allergies as there is no standardised, consistent approach to applying PAL or to the wording that is used. Many products with a PAL do not contain the implicated food allergen while some products without a PAL contain quantities of common food allergens that are capable of inducing an allergic reaction in a significant proportion of the at-risk population (14-16). With this inconsistency, PAL has suffered a loss of credibility and trust and thus does not have the ability to facilitate an informed choice. This is important for consumers because these current practices result in 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. It is also important for food business operators, as it invalidates a valuable risk management and communication tool. This is a situation that all stakeholders agreed needs to be urgently addressed.

Integrated Approaches to Food Allergen and Allergy Risk Management (iFAAM) was an EU-funded project that aimed to improve the management of food allergens by the food industry for the benefit of people with food allergies (17). The project aimed to develop holistic strategies to reduce the burden of food allergies in Europe and beyond, whilst enabling the European food industry to compete effectively in the global market place. The iFAAM approach has built on e-Health concepts to allow full exploitation of complex data obtained from the work in this project, maximising sharing and linkage of data. Within iFAAM, a clinically validated tiered risk assessment approach for food allergens was developed, with PAL as an integral component of the possible risk management outcomes.

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Cross-stakeholder iFAAM workshops were held in Winchester (UK) on 13th-14th December 2016 and Madrid (Spain) 19th-20th April 2018. One of the objectives of iFAAM was to develop a proposal to make PAL more effective for consumers (18). Stakeholder groups at the first meeting included healthcare practitioners, patient organisations, regulators (European Union Joint Research Centre –Institute for Reference Materials and Measurement, United Kingdom's Food Standards Agency and Food Safety Authority Ireland), private sector and scientists (representation from European member states & United States). The final iFAAM project findings were reviewed and discussed at the second workshop. This paper describes the different knowledge developed in iFAAM to help the food industry make PAL more transparent to consumers with allergies.

The perspective of consumers with food allergies

Patients and their parents live in fear of a life-threatening allergic reaction, where the threat is ever present but the chance and timing are unpredictable. This uncertainty can lead to extreme anxiety and avoidance on the one hand or frustration and risky behaviours on the other (19-21). Health related quality of life studies demonstrate a strong adverse impact for the child, teenager, adult and parent (22-27). Understanding patient responses to food safety issues is crucial to effective food safety policy and risk communication. It has become increasingly evident that consumers with food allergy are making decisions about the acceptability of specific foods, production technologies and both labelling format and text based on a complex interaction of perceptions of risk and benefit (28,29). Research from both the general consumer and from the food allergy population can guide us when considering issues of acceptability, and the influence of uncertainty and ambiguity. Uncertainty refers to an individual's doubt as to the correct or best option to choose when making a food choice. People generally adopt a precautionary stance in the face of uncertainty (30-35). The presence of uncertainty influences an individual's perception of the risks involved with each potential option; increasing the perceived risk in the situation (35,36). Ambiguity occurs when information is missing that could be essential to the decision-making process. PAL are helpful if they provide reliable and meaningful information on the allergen content. As current PAL use cannot be associated with any specific level of risk, both uncertainty and ambiguity are reinforced (13).

Using action levels to better inform precautionary allergen labelling

Reference doses have been developed to guide labelling decisions in the Voluntary Incidental Trace Allergen Labelling (VITAL™) system originally deployed in Australia (37,38). Reference doses refer to the amount of allergen that most (usually set at 95 or 99%) individuals with food allergy can tolerate without developing any objective allergic reaction

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(14). With information about the size of a typical meal of the specific food product, the reference dose can be used to calculate the concentration of allergen (action level) that is likely not to cause a reaction in 95 or 99% of the population with allergy. These action levels are specific for individual products. Action levels and quantitative risk assessment are now being used by food authorities in other countries, for example in Germany (39), Japan (40) and Belgium (41). However, due to the lack of official consensus, these action levels differ across countries resulting in divergent levels of risk for the food-allergic population in the various jurisdictions. This is not very helpful for consumers with food allergies and food industries. If these health related reference doses are more widely adopted by regulators and the food industry, the presence of a PAL statement would be tied to a defined level and probability of reacting, allowing patients to make informed choices with a reduced chance of experiencing an allergic reaction (14).

The key challenge here for stakeholders is to develop effective risk-benefit communication that takes account of the majority of consumers with food allergy, while protecting particularly vulnerable groups. Past research with patients has shown that lack of awareness, confusion, and 'talking past each other' are reported as major barriers to the use and application of reference doses (31,42). Addressing scientific uncertainty and providing adequate information emerged as prerequisites to consumers with food allergy being receptive to their use. Information provision, such as appropriate and consistent label information, was considered essential, particularly by more risk tolerant individuals, to inform their food choices (31,42).

Effective management of the risk from allergens must integrate multiple perspectives from different groups of consumers with food allergy (parents, adults, adolescents, those above and below certain eliciting dose thresholds), together with input from all relevant stakeholders (industry, retailers, scientists, health professionals, regulators, patient groups) in order to develop effective, coherent and creative risk-benefit communications to promote the acceptability of quantitative risk assessment in food manufacturing and labelling.

Current labelling regulations and the challenges with the current approach

In Europe, the legislation defines a list of 14 foods as the most prevalent allergens across Europe. Whenever they, or their derivatives are used in food and drink as ingredients or processing aids, they must be declared on the label or information made available to the consumer to enable them to make a safe and informed food choice (43,44). These rules build on the previous requirements for prepacked foods by introducing new requirements for non-prepacked foods. The legislation mandates the declaration of priority allergenic foods

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and for those to be emphasised from other ingredients within the ingredients list of prepacked foods and information to be made available for non-prepacked foods such as meals in a restaurant.

The approach for the unintentional presence of allergens following agricultural or manufacturing cross-contamination is less well defined in legislation. At present there are no specific rules governing the unintentional presence of allergens in food, although there are provisions within the regulation (43) that could address this issue if invoked. The application of PAL such as 'may contain' is therefore understood to be defined by Article 14 (2) (3b) and (4c) of the 'EU General Food Law' Regulation (EC) No. 178/2002 in that food must not be unsafe or injurious to health and that information should be made available to enable consumers to avoid an adverse health effect. However, what is unsafe and injurious to health can vary across different countries and the interpretation of the "EU General Food Law" and its target groups as well as across the allergic population as individuals can vary greatly in their level of sensitivity to food allergens. Due to the heterogeneity and variability in sensitivities to allergens there has been little agreement on what level is 'safe' and 'not injurious to health'. This has caused confusion and uncertainty among food regulators, the food industry and most importantly the food allergic consumer. The result has been the proliferation of PAL in terms of the proportion of products affected, as well as the diversity of PAL statements (45). The frequency with which the various types of PAL statements are used and their inconsistent application can lead the allergic consumer down the path of an unsubstantiated risk assessment and/or risk taking behaviour (14).

Given that the use of PAL remains a technological necessity, the challenge for regulators and other stakeholders is to agree, internationally, on what allergen threshold will minimise the public health risk from unintentional allergen presence to consumers with food allergies.

iFAAM risk assessment and management tools

Currently, there is no consensus on an easy-to-use, widely available and generally applicable risk assessment tool for food allergens in Europe to help food producers ensure that foods do not contain more than the recognised safe level of allergen. iFAAM has worked on a risk assessment framework that enables an evaluation of the allergen risks pertaining to a production line, process or factory. The framework comprises three elements: allergen tracking tool, Tier 1 risk assessment and Tier 2 risk assessment (see Figure 1).

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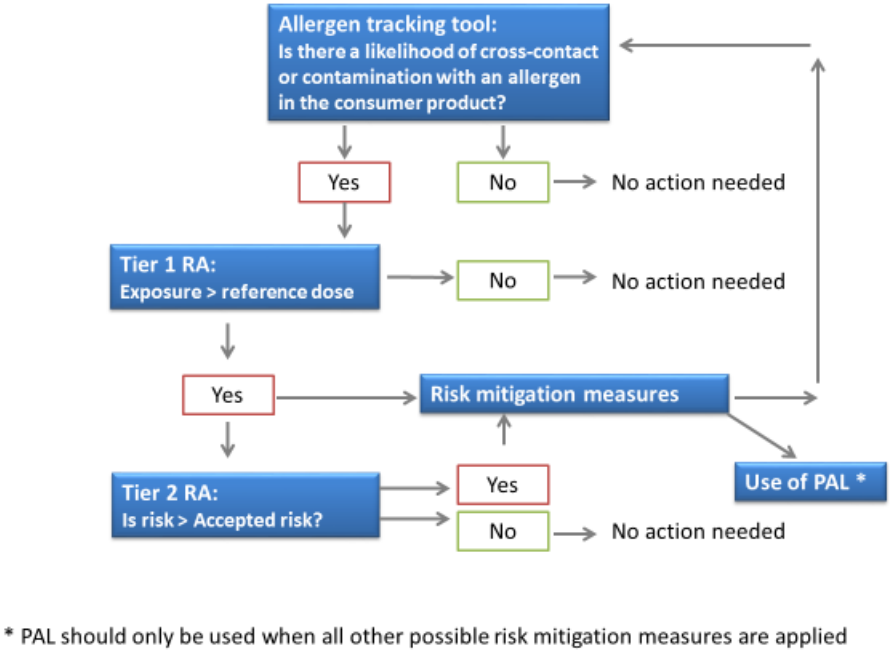

Figure 1. iFAAM food allergen risk assessment framework.

RA: risk assessment; PAL: precautionary allergen labelling.

The allergen tracking tool provides a simple guidance (or tool) to help food business operators make an initial qualitative assessment for any allergen about its potential unintended presence at any point during the production process. The basis is the hazard analysis critical control point approach and the developed allergen tracking tool will assist food business operators to start unintended allergen presence risk analysis and incorporate it in their hazard analysis critical control point plans (more details at http://new.moniqa.org/risk-assessment-tools). An extension of the tool covers a vulnerability analysis of the supply chain to highlight potential sources of allergen contamination. The allergen tracking tool is presented as a decision tree to guide users through the risk analysis steps and can help the company decide whether a more quantitative assessment of allergen risk is needed.

The Tier 1 risk assessment aims to provide an initial quantitative risk screen (46). The risk assessment is based on a comparison of the potential exposure to the unintended allergen with the sensitivity of the allergic population, to provide a binary ‘safe / not safe’ outcome. Within iFAAM, consumption data from three different European databases (NL, DK and FR) were combined into food groups for allergen risk assessment purposes (47). For other countries the user should use local consumption data. The thresholds representing the

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sensitivity of the allergic population are the reference doses derived by Taylor et al for VITAL™ (37) (see also above in paragraph on reference doses) complemented with the threshold dose information from EuroPrevall (48). The contamination value will be provided by the users of the tool and should take into account the uncertainty around that contamination value. The Tier 1 risk assessment tool developed can be readily applied by food business operators of all sizes, without special expertise. It incorporates a significant degree of conservatism in its underlying assumptions.

Whereas the Tier 1 risk assessment is based on point estimates for the consumption, the contamination and threshold levels, the Tier 2 risk assessment uses probabilistic methods to integrate all the available data and knowledge and to reflect variability and uncertainty (for example, taking into account the possibility of particulate contamination). The Tier 2 risk assessment therefore provides a full quantitative risk estimate (49). Compared to Tier 1, Tier 2 is more sophisticated and requires specific training and experience to use effectively. The basis was the probabilistic model already designed within TNO, French Agency for Food, Environmental and Occupational Health & Safety and Food Allergy Research and Resource Program and further developed during the course of the iFAAM project (50-52).

The total risk assessment framework envisages an iterative process, whereby the results of the initial analysis in the allergen tracking tool lead to mitigating measures and/or Tier 1 risk assessment, following which the risk is re-analysed by re-running the tools. Tier 2 risk assessment is applied when a fully quantitative analysis would be beneficial, for instance, when the tier 1 risk assessment would indicate an unsafe situation and when comparing risk mitigation measures and evaluating their feasibility.

Quantity, measurement and reporting

Being able to measure allergen concentrations in food ingredients is essential for a risk assessment to deliver safe food for the consumer with allergies (53). This requires an analysis of food allergen proteins that is valid, accurate and reproducible. Allergen levels should be the definition of quantity as ‘amount of substance’ (milligrams, or concentration, mg/kg or millimoles/kg). There needs to be agreement on what is actually being measured which will dictate the system calibrators, quality control materials or reference materials (Table 1). Traceability to the International System of Units, Système international d'unités (54) by certified reference materials is the ultimate goal (55).

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Table 1 Suggested examples of analytical targets, what is measured, calibrants and reference materials

Target	What is measured (measurand)	Calibrants	Quality control or reference material
Enzyme-linked immunosorbent assay			
A protein or group of proteins	What the capture antibody was raised to OR A well characterised protein molecule OR A selected amino acid sequence	Serial dilutions of a well-defined extract of the protein or group of proteins	Industrially relevant matrix containing clinically relevant concentration of the protein or group of proteins OR A defined proteinaceous raw material food such as skimmed milk powder or defatted light roasted peanut flour from which in-house quality control materials can be made
Liquid chromatography–tandem mass spectrometry			
A protein or group of proteins	Defined measurable epitope or epitope fragments or peptides	Synthesised peptides or purified allergen protein	As above and isotopically labelled Peptides
Real time polymerase chain reaction			
(deoxyribonucleic acid) DNA	DNA copy number	Serial dilutions of extracted DNA in DNA	A relevant food-in-food mixture

Total allergen protein concentrations for suggested clinically relevant reference materials are available (37,38) and can be used to derive concentrations (action levels) for any desired consumption amount. For example the VITAL Reference Dose for peanut of 0.2 mg peanut protein suggests a clinically relevant concentration of 2 mg/kg peanut protein for a 100g serving (53). Analytical systems should achieve limits of detection and limits of quantification sufficiently low for statistically meaningful validation. Table 2 shows examples of performance criteria along with data, derived from kit inserts for commercial ELISAs for peanut and egg. It can be seen that ELISAs are available for peanut protein with the required sensitivity although not all platforms seem able to achieve the desired criteria. For egg protein, commercial ELISAs struggle to meet the desired criteria albeit there have been anecdotal suggestions that the reference dose for egg protein may be unrealistically low owing to the use of raw egg in challenge studies. It is also possible to assess actual egg ELISA performance from unpublished data (56). Hence the practical performance of egg

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ELISAs may not currently achieve the criteria suggested by the egg reference dose. Adequate validation, third party accreditation and participation in relevant proficiency testing schemes are key to assuring the quality of analytical results. A further important aid is the inclusion in any analytical strategy of relevant positive controls containing the allergen of interest in the matrix in which it occurs. This is straightforward for food manufacturers to carry out during analysis of their own products, both in-house and by their contract laboratories but not easy for enforcement laboratories to accommodate.

Table 2. Examples of how low can/should we go

Allergen	Reference dose protein (Eliciting dose for 1% population [ED_{01}])	Target concentration for 100 g portion (a) (mg kg^{-1} allergen protein)	Limit of quantification (mg kg^{-1} allergen protein)		Limit of detection (mg kg^{-1} allergen protein)	
			Required target concentration /10 (b)	Achieved	Required target concentration /30 (b)	Achieved
Peanut	0.2 mg	2.0	0.2	0.25 – 2 (c)	0.07	0.05 – 0.5 (c)
Egg	0.03 mg	0.3	0.03	0.3 – 0.7 (c)	0.01	0.03 – 0.3 (c)
				0.4 – 5.5 (d)		0.1 – 1.8 (d)

(a) Target concentration, as milligrams allergen protein per kilogram food consumed, to note if the portion size is greater e.g. a typical ready meal or take-away meal of 500 g target concentration reduces to 0.4 mg kg^{-1} allergen protein and 0.06 mg kg^{-1} allergen protein for peanut and egg respectively

(b) Analytical systems should achieve limits of detection and limits of quantification sufficiently below the target concentration for method validation allowing estimation of false positive (α error) and false negative (β error) likelihoods at a 95 % confidence interval. As a rule of thumb a limit of quantification of one tenth of the target concentration should yield the desired interval with the limit of detection lower again by a factor of 3

(c) Based on ELISA kit inserts

(d) Calculated from data in ref. 54 by $Limit\ of\ quantification = x + 10s$ and $Limit\ of\ detection = x + 3s$ where x and s are the mean and standard deviation of measurements of blank (no template) controls.

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A new approach to precautionary allergen labelling: patient perspective

In a recent survey conducted by patient organisations (57), the majority of consumers with food allergies in 16 countries were not prepared to buy or eat a food if they knew that it may contain a certain amount of their allergen, even if they knew that this food would only elicit mild symptoms or indeed no symptoms at all. This is not surprising, since patients and parents have been educated by healthcare professionals as well as patient organisations to strictly avoid their allergen to be safe (9). 'Just a little bit(e) can hurt' raises vigilance but also creates anxiety regarding the unintended consumption of the culprit food. If consumers with food allergy were informed about the disadvantages of the current situation (lack of transparency and consistency of the applied method for allergen risk assessment and the related uncertainty for consumers to make informed decisions), they may feel that a consistent and transparent approach for allergen risk assessment based on scientific data would be more advantageous. This is the approach taken in a quantitative risk assessment. Based on an understanding that a guarantee of zero risk is not feasible for food, allergic consumers agreed during a German stakeholder conference in Berlin, November 2015, that an acceptable risk for them would be to know, that they or their children might only have a (low) risk of experiencing a mild reaction like itching, hives, nausea or even vomiting (42). It is acknowledged that the generalisability of this needs to further assessed.

iFAAM precautionary allergen labelling survey

The iFAAM PAL survey was developed for adults and parents of children with food allergy (DunnGalvin et al, submitted). The aim was to help us to understand more about how those living with food allergy assess risk when making decisions based on PAL ('may contain'), attitudes to current labelling practice and to the potential use of quantitative risk assessment in manufacturing. Over 1,500 respondents (UK, Germany, Netherlands, Spain, Poland) completed the survey. The results showed that a significant number of adults with food allergy or parents of children with food allergy perceive that if a PAL is not on a product, this implies that the product is safe to eat (with those who 'never' consult PAL more likely to endorse this option). Overall, there was a low level of confidence in PAL in helping adults and children avoid allergic reactions. The results also showed that a transparent and consistent quantitative risk assessment process, if used to make a decision about whether to include 'may contain', would greatly increase trust in a product, particularly for parents and those with 'low confidence' in labelling. If a PAL statement had to be applied, 'not suitable for' was rated the 'most preferred' option, among several phrases presented, including 'accidental presence of [allergen]'; and 'may contain [allergen]'. A combination of statements about unintended allergen presence and quantitative risk assessment (statement for

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unintended allergen presence + risk assessment statement + risk assessment symbol), compared to each separately, was rated as 'most useful' across groups, including subgroups such as those who do not at present consult PAL, those with low confidence in PAL, those reporting the most severe reactions, those who have experienced previous anaphylactic reactions, and parents of young children. . The outcomes from this research (Figure 2) can guide us when considering issues of acceptability and provide a basis for the development of more informative labelling.

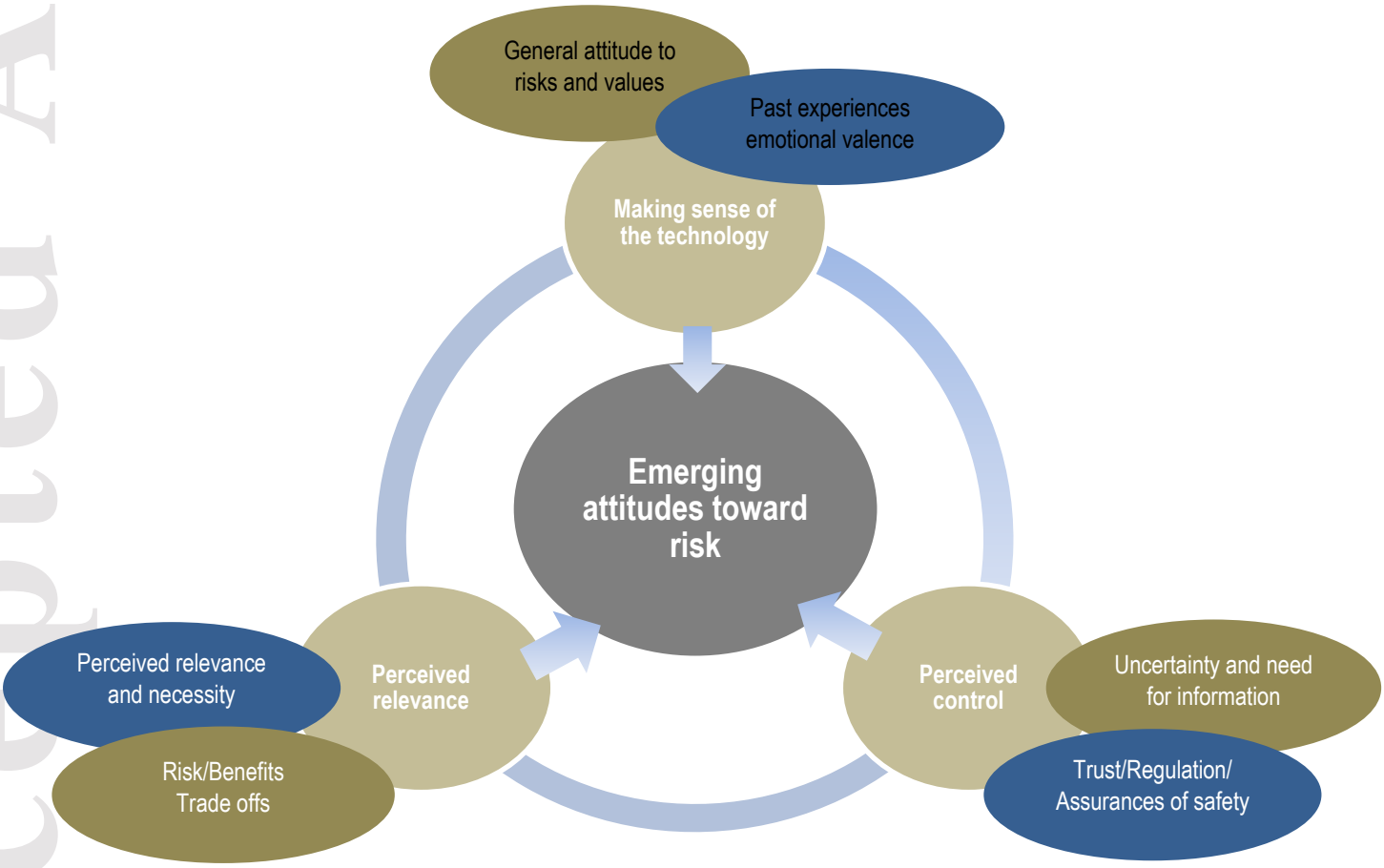

Figure 2. Factors influencing emerging attitudes towards level of risk associated with quantitative risk assessment in food manufacturing and labelling.

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The central message for industry is that there must be a clear indication on a food product that a quantitative risk assessment has been carried out to inform the inclusion of a PAL on a product. Furthermore, we must have a clear consensus across stakeholders about what the presence or the absence of a PAL means in terms of the safety of the product (14). At present, patients cannot obtain this information by consulting the label and both healthcare professionals and patient organisations have no clear indication on how to guide a patient or parent on the absence of labelling, which is currently ambiguous about whether a product can be considered safe for them or not.

At the iFAAM workshop, the patient groups felt that a regulated approach was required, perhaps as an extension of Regulation 1169/2011 (43). This would make it mandatory for each food business operator to undertake a risk assessment and apply or not apply a PAL according to evidence based reference doses. If a voluntary approach was to be taken, there would need to be agreement across the food industry with a clear indication on the food label that a quantitative risk assessment had been applied. Adequate and harmonised explanatory information, training, and multiple forms of dissemination are crucial when providing any new forms of risk management, and this is particularly important in the case of vulnerable populations such as those with food allergy.

A new approach to precautionary allergen labelling: health care professional perspective

Clinicians at the workshops perceived that there is a lack of understanding, confusion and cynicism about food manufacturing and PAL among health care professionals, which poses difficulty in providing useful and informed advice to patients. Communication at an individual level on risk management in different contexts, such as eating out is a challenge for clinicians, particularly with existing time restraints in consultation. In the context of improving allergen management for people with food allergies, acceptable risk can only be properly defined on a population (public health) basis. Therefore, there was consensus that we should begin by evaluating the acceptability of mild reactions, limited to one organ system, i.e. those symptoms which result in no or minimum interference with daily activities. In this context, acceptability needs to factor in not only the reaction characteristics, but also the burden of uncertainty that many people with food allergies experience.

Dose distribution data are now available for many priority allergenic foods. Single dose challenge studies, recently completed for peanut (58), will be extremely useful to characterize the risk associated with ingestion of a known low dose of an allergenic food. They would not only confirm what proportion of people with the specific allergy would react

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to that dose (as established by dose distributions) but would also reveal the spectrum of reactions experienced. Such data should help to improve the trust that consumers with food allergy need in the scientific data underpinning quantitative limits. Acceptable risk is crucially dependent on the trust of those at risk. Improvement in risk assessment (c.f. Tier 1 approach from iFAAM) is therefore critical and the outcomes of those tools need to integrate the latest scientific findings and be interpreted in the context of any extrinsic factor effect (e.g. asthma control, exercise) with consideration of a safety margin being added if there is unacceptable uncertainty.

Last but not least, the clinical group stressed that any consensus on acceptable risk needs to evolve as new data and knowledge become available; the process will thus always be iterative.

Applying the new iFAAM approach to precautionary allergen labelling

How could the food industry implement the iFAAM tiered risk approach?

The Winchester workshop felt that the implementation of the risk assessment approach by the food industry could begin through bodies such as FoodDrinkEurope (organisation representing European food businesses) as an industry-wide approach. This could be achieved by developing guidance around implementation and integrating it into existing tools used to manage food safety issues, such as hazard analysis critical control point plans. A “check mark” on food packaging would be required to show that it had been through an accepted risk assessment process. The use of such a check-mark would need to be tied into appropriate and ongoing training to accredit the process. In parallel the workshop felt that there was a need to improve the quality of allergen analytical methods with regards the sensitivity required to measure allergens below the reference doses and reduce the variance of analytical methods (currently much higher than would be accepted for other chemical hazards).

To facilitate this approach, there was a need to improve the quality and transparency of reporting of analytical test results, with clearly defined test performance criteria, and a requirement for reporting units to be expressed in total protein (the allergenic hazard). In addition there was a need for agreed conversion factors, reference materials and sampling plans.

It was felt that the support of retailers would be needed in the implementation phase and it was unclear how the application of the risk assessment process would be viewed by food industry lawyers from a legal liability viewpoint. It was clear that, in the global arena, Europe

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would need to take a lead on this but that once implementation had begun there would likely be interest from international bodies such as Codex Alimentarius.

Lastly, there is a need to engage regulators. Across the EU there is an inconsistent approach to food allergen risk assessment and management with some member states applying a risk based approach and others a “zero tolerance” approach. There is an urgent need for DG Santé and the European Food Safety Authority to address the concerns of the Member States in this regard and initiate a process to identify whether the iFAAM tiered risk assessment approach can be considered appropriate across Europe.

What does the iFAAM tiered risk approach mean in terms of risk for individual consumers with food allergy?

Being able to accurately measure allergen concentrations in food ingredients is essential to deliver safe food for the consumer with allergies. At present, there is a low level of confidence in the ability of PAL to help adults and children avoid allergic reactions and, as PAL cannot be associated with any specific level of risk, consumers experience uncertainty and constant worry about buying and eating food products. The iFAAM risk assessment framework, and easy to use tools will enable a systematic and consistent evaluation of the allergen risks pertaining to a production line, process or factory. A standardised applied risk tool which can ensure that foods do not contain more than the recognised safe level of allergen, would greatly increase trust in a product if used as a basis to make a decision about whether to apply a PAL warning. Although different types of products need different methods of analyzing for risk (e.g. processed versus commodity products), the same standards can be applied with the message being that a quantitative risk assessment has been carried out on a product to inform whether a label is applied or not applied. So the presence as well as the absence of a PAL actually has a tangible meaning in terms of the safety for the consumer.

How can we better help patients to utilise labelling?

From the survey conducted by iFAAM it is evident that consumers with food allergies prefer a clear indication on the food label regarding both an actual risk of unintended allergen presence indicated by PAL as well as a reference on the food as to whether a quantitative risk assessment has been carried out by word and logo. Representatives from industry at the workshop felt that they had to balance needs from the general population versus those from consumers with food allergy. However it was also recognised that subgroup interests are accepted and catered for in general by industry. Providing clear information on labelling may provide a market benefit, particularly for small to medium sized businesses which are

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currently viewed as 'more risky' in terms of safety by those with food allergy. The information on food packaging must be relevant, meaningful and cater to the needs of those with a food allergy. Although different types of products need different methods of analyzing for risk (e.g. processed versus commodity products), the same standards should be applied. The PAL should clearly indicate whether a quantitative risk assessment has been carried out on a product to inform the decision on whether a label is applied or not applied. At present consumers cannot obtain this information from consulting the label and healthcare professionals and patient organisations have no clear indication on how to guide a patient or parent on the absence of PAL (14).

How can healthcare professionals better help patients to utilise labelling?

Healthcare professionals, as well as patients, need to be educated about quantitative risk assessment and PAL and how individual patients can use this approach depending on their personal threshold. Population thresholds need to be explained within this context and linked to individual thresholds. 'Single dose' challenges (58) can help to reassure all stakeholders on the validity of the science and help individual patients make better informed food decisions. In addition they can be used to assess the risk for the individual patient. This information should be integrated across clinical (diagnosis, reactions) and real life (management) contexts. In this way, those who are at low risk and those who are at high risk, according to their personal threshold and clinical history, can feel confident in undertaking a personal risk assessment and management plan that works for them. Training and education is vital and must be consistent and standardized across all stakeholders. This will help patients to ask the right questions and help industry, healthcare professionals and retailers to answer them in the right way, and with confidence. We can learn from the experience in Australia with the take up of VITAL 2.0™ (37,38,59). When expectations were raised among consumers, industry felt that these expectations should be met. The widest acceptance across stakeholders would be achieved when the use of when and how to apply PAL is regulated by law.

Summary

The four year iFAAM project has worked to make precautionary allergen labelling transparent. The consortium has surveyed consumers and the food industry to understand the current situation. To assist health care professionals and patients navigate the current system, the consortium has published short online guides for patients and healthcare professionals (18). Groups in the consortium have developed a two-tiered approach that provides much improved risk assessment and management tools to inform the consistent use of precautionary allergen labelling. These tools are being supported and informed by

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data on reaction thresholds collected in the EuroPrevall and iFAAM projects and beyond. Such an approach has the potential to provide allergic consumers with the accurate and reliable information that they need to decide what is safe for them to eat. Much work is still required. It will also be impossible to provide a 100% guarantee of safety especially with the variability induced by intrinsic and extrinsic cofactors. A consistent regulatory approach is required, initially across Europe. The European food industry bodies need to be involved to ensure that this can be implemented industry wide to provide a consistent picture for allergic consumers to navigate. Finally, with the interconnectivity across the world, a global initiative would be ideal.

Acknowledgements

This report was generated as part of the EU iFAAM project: Integrated Approaches to Food Allergen and Allergy Risk Management (Grant Agreement No 312147). We would like to acknowledge the input of all our colleagues in the iFAAM consortium. We would also like to acknowledge the support of ILSI Europe in arranging the second workshop.

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