CORA Cork Open Research Archive
Cartlann Taighde Oscailte Chorcaí

Title	Understanding how consumers with food allergies make decisions based on precautionary labelling
Authors	DunnGalvin, Audrey;Roberts, Graham;Regent, Lynne;Austin, Moira;Kenna, Fiona;Schnadt, Sabine;Sanchez-Sanz, Angel;Hernandez, Pilar;Hjorth, Bettina;Fernandez-Rivas, Montserrat;Taylor, Steve;Baumert, Joseph;Sheikh, Aziz;Astley, Sian;Crevel, Rene;Mills, Clare
Publication date	2019-08-09
Original Citation	DunnGalvin, A., Roberts, G., Regent, L., Austin, M., Kenna, F., Schnadt, S., Sanchez-Sanz, A., Hernandez, P., Hjorth, B., Fernandez-Rivas, M., Taylor, S., Baumert, J., Sheikh, A., Astley, S., Crevel, R. and Mills, C. (2019) 'Understanding how consumers with food allergies make decisions based on precautionary labelling', Clinical and Experimental Allergy, 49(11), pp. 1446-1454. doi: 10.1111/cea.13479
Type of publication	Article (peer-reviewed)
Link to publisher's version	10.1111/cea.13479
Rights	© 2019, John Wiley & Sons, Ltd. This is the peer reviewed version of the following article: DunnGalvin, A., Roberts, G., Regent, L., Austin, M., Kenna, F., Schnadt, S., Sanchez-Sanz, A., Hernandez, P., Hjorth, B., Fernandez-Rivas, M., Taylor, S., Baumert, J., Sheikh, A., Astley, S., Crevel, R. and Mills, C. (2019) 'Understanding how consumers with food allergies make decisions based on precautionary labelling', Clinical and Experimental Allergy, 49(11), pp. 1446-1454, doi: 10.1111/cea.13479 which has been published in final form at: https://doi.org/10.1111/cea.13479 This article may be used for non-commercial purposes in accordance with Wiley Terms and Conditions for Use of Self-Archived Versions.
Download date	2026-11-05 17:59:39
Item downloaded from	https://hdl.handle.net/10468/11988



University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

Accepted Article

DR AUDREY DUNNGALVIN (Orcid ID : 0000-0002-1540-3959)

PROFESSOR GRAHAM ROBERTS (Orcid ID : 0000-0003-2252-1248)

Article type : Original Article-Clinical Allergy

Title: Understanding how consumers with food allergies make decisions based on precautionary labelling.

Authors: *DunnGalvin A[1,2,3], *Roberts G[4,5,6], Regent L[7], Austin MM[7], Kenna F[8], Schnadt S[9], Sanchez-Sanz A[10], Hernandez P[10], Hjorth B[11], Fernandez-Rivas M[12], Taylor S[13], Baumert J[13], Sheikh A[14], Astley S[15], Crevel R[16,17], Mills ENC[18]
*Equal contribution

Affiliations:
1. Paediatrics and Child Health, University College, Cork, Ireland
2. School of Applied Psychology, University College, Cork, Ireland
3. Paediatrics and Child Infectious Diseases, I.M. Sechenov First Moscow State Medical University.
4. Clinical and Experimental Sciences and Human Development and Health, Faculty of Medicine, University of Southampton, UK
5. NIHR Southampton Biomedical Research Centre, University Hospital Southampton NHS Foundation Trust, Southampton, UK
6. The David Hide Asthma and Allergy Research Centre, St Mary's Hospital, Isle of Wight, UK.
7. Anaphylaxis Campaign, Farnborough, UK
8. Anaphylaxis Ireland, Eire
9. Deutscher Allergie- und Asthmabunde.V., German Allergy and Asthma Association, Mönchengladbach, Germany
10. Asociación Española de Personas con Alergia a Alimentos y Látex
11. Astma-Allergi, Denmark
12. Allergy Department, Hospital Clínico San Carlos, IdISSCMadrid, Spain
13. Food Allergy Research and Resource Program, University of Nebraska, Lincoln, Nebraska, USA
14. Allergy and Respiratory Research Group, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, UK
15. EuroFIR AISBL, Brussels, Belgium
16. Unilever Safety and Environmental Assurance Centre, Bedford, UK,
17. René Crevel Consulting Limited, Bedford, UK
18. Manchester Institute of Biotechnology, Division of Infection, Inflammation and Respiratory Medicine, School of Biological Sciences, Manchester Academic Health Science Centre, The University of Manchester, Manchester, UK

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.13479
This article is protected by copyright. All rights reserved.

Accepted Article

Corresponding author:
Audrey DunnGalvin, PhD, School of Applied Psychology, University College Cork, Co. Cork, Ireland.
a.dunngalvin@ucc.ie

Key words: Food allergy; Precautionary allergen labelling; Quantitative risk assessment

Author Contribution

ADG & GR wrote the manuscript. All other authors were involved in the study itself and in editing the manuscript.

Conflict of Interest

The authors have no conflict of interest in relation to this work.

Abstract

Background Understanding consumer perceptions is crucial if effective food safety policy and risk communication are to be developed and implemented. We sought to understand how those living with food allergy assess risk with precautionary allergen labelling (PAL) and their preference in how risks are communicated within a Quantitative Risk Assessment (QRA) framework.

Methods The Integrated Approaches to Food Allergen and Allergy Risk Management (iFAAM) labelling online survey was developed for adults and parents of children with food allergy and distributed across Germany, Ireland, Netherlands, Spain and UK via patient support groups.

Results There were 1560 complete responses. 'This product is not suitable for' was selected as first choice for PAL by 46% overall and 'May contain' was selected as the first choice by 44%. Seventy-three percent reported that it would improve their trust in a product if a QRA process had been used to make a decision about whether to include 'may contain'. Overall 66% reported that a 'statement + symbol' on the label indicating a QRA, would help them to understand the risk assessment process that had been used by the food manufacturer.

Conclusions Consumers want to know what process has actually taken place for the placing of a PAL and/or risk assessment statement on a particular food product. Our findings provide a basis for the development of more informative communication around food allergen risk and safety and support evidence-based policy-making in the context of the legislative requirements of the European Union's Food Information for Consumers Regulation.

This article is protected by copyright. All rights reserved.

Accepted Article

Introduction

Food allergy (FA) is a major public health concern affecting an estimated 20 million Europeans with high costs to public health services (1-4). A systematic review and meta-analysis has reported the pooled lifetime prevalence of self-reported FA as 17.3% (95% CI: 17.0-17.6)(2). Avoidance of the trigger food(s) is central to effective self-management but unintentional consumption is common causing frequent reactions, some of which may be life-threatening (5-7). Admission rates for anaphylaxis have increased approximately three-fold between 2005 and 2012 (8-10). Health related quality of life (HRQL) studies have shown a strong adverse impact of FA on HRQL across the life-course (11-13).

Uncertainty and ambiguity have been shown to be central themes in living with food allergy, leading to anxiety and avoidance on the one hand and/or frustration and risky behaviours on the other (11, 13-17). Even though there has been a proliferation of precautionary allergen labels (PAL)(18), the current use (or non-use) of PAL is not clear due to lack of consensus on when and how to apply it. Therefore, consumers with food allergies have no reference to what PAL or its absence actually means. Of particular concern is the issue of communicating the risk due to the presence of specific allergens in a particular food product. The European Union's Food Information for Consumers (and other relevant food and health and safety legislation) defines a list of 14 foods as priority allergens (cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk (including lactose), nuts, celery (including celeriac), mustard, sesame, sulphur dioxide/sulphites, lupin, molluscs); their use as ingredients or processing aids in food and drink must be declared on the label or made available to the consumer so as to make safe, informed food choices (19). For unintended allergen presence (UAP), primarily through manufacturing cross-contact, the situation is different. There are no well-defined, consistent rules governing these situations (20). This has caused confusion and uncertainty among food regulators, food industry and, most importantly consumers with FA about the meaning of PAL statements. Statements are mistakenly viewed by consumers and health care providers as conveying different levels of risk, which research has shown is not the case (21). Risk is therefore increased for the consumer while confidence and food choice is reduced. A harmonized approach is urgently needed.

Risk assessment is the evaluation of known or potential hazards of food production (22, 23,24). Current food industry approaches to safety risk assessment in relation to application of PAL lack transparency and consistency, with approaches ranging from non-existent to sophisticated, and no consensus on easy-to-use and generally applied risk tools for food allergens in Europe. A quantitative risk assessment (QRA) approach is being developed to ensure that only products likely to cause a reaction have a PAL statement. QRA aims to provide a harmonised and standardised approach to determine whether the allergen is likely to be unintentionally present in a product and is above a certain agreed threshold or level of risk with regard to UAP (23,25-26). The "threshold" (reference dose) for labelling is an amount below which only a defined proportion (e.g. 5% (ED05) or 1% (ED01)) of consumers allergic to this food could develop an allergic reaction

This article is protected by copyright. All rights reserved.

Accepted Article

(23). Manufacturers would be required to assess the amount of each unintentionally present allergen in their product. If any of these could cause a reaction in at least one in 100 allergic consumers, a PAL statement would be applied. Ideally this would be mandatory, since this would be the most efficient and helpful approach for all stakeholders. For consumers, this would mean more certainty, and perhaps even more food choice, for HCPs this would mean a better basis for advice, and clear guidelines for industry, and for regulators with regard to enforcement.

Previous work in this area has shown that consumers take into account many factors when evaluating a food hazard including allergens, beyond technical risk assessments (19-22). Integrated approaches to food allergen and allergy management (iFAAM) is an EU-funded project, one aim of which is to improve the management of food allergens by the food industry for the benefit of consumers, especially those with FA (28), thereby minimising the public health burden of allergic reactions to foods. The iFAAM labelling survey was developed for adults and parents of children of all ages with FA and distributed across five European countries. The survey related specifically to pre-packed manufactured products. Our aim was to understand how consumers living with FA assess risk when making decisions based on PAL. Our approach focused on assessing consumers' preference in how the risk of UAP was communicated on the food label within the context of a QRA framework across Europe. The outcomes from this research should help to guide on issues of acceptability and provide a basis for the development of more informative communication around food risk and safety.

Methods

We used a cross-sectional design with convenience sampling. An online survey was developed by iFAAM in 2017. Ethical approval was given by the National University of Ireland, Cork, Ireland. Patient support group leaders, clinicians and a psychologist were involved in an iterative process of questionnaire development. Six consecutive drafts were developed with the final draft subject to testing by a representative pilot group of respondent types (N=12). Modifications were made following feedback. The questionnaire was translated by a native speaker into German, Dutch and Spanish; these documents were then back translated by another person into English to ensure fact and content validity. The questionnaire can be found in the online supplement. The online survey link and information on the project was placed on the website of patient support groups in 2017 involved in the iFAAM project in Germany, Ireland, Netherlands, Spain and UK Since it is not possible to distinguish between active and non-active users of these websites, calculation of response rate relative to number of registered users would have poor validity. There were three eligible respondent types: adults with FA; parents of children with FA; and adults with an FA who also have a child with FA.. The online link remained open for six weeks.

The survey consisted of 16 questions (with 2 additional open questions) divided into 5 main sections (Figure S1 and online repository). Following basic demographic and clinical questions, respondents were asked when they read a PAL statement, how confident they were that PAL helps avoid allergic reactions, and if a product with no PAL is safe to eat.

This article is protected by copyright. All rights reserved.

Accepted Article

Respondents chose among alternatives in phrasing and symbols that would make it easier for them to identify foods that may contain an allergen due to cross-contamination. Three examples using milk and egg were given, alongside phrases which could be ranked in order of preference. Respondents also ranked their preference for a single statement or a statement that distinguished between the type and frequency of allergen presence (e.g. '=used if the allergen is only likely to be found in some packets of the product'; '=used if allergen is likely to be unavoidably present in all packets of the products').

Two statements 'This product has undergone a risk assessment and found to be safe to consume'; and 'This product has undergone a risk assessment and there is risk of an allergic reaction (i.e. not safe to consume)', were rated from 1 (not at all helpful) to 5 (very helpful). Next, a combination of statements/information that may appear on a food label could be rated on the same scale.

At present the use of PAL is voluntary. To elicit responses to a hypothetical situation, participants were asked that *if* QRA was mandatory, how true (1=not at all true to 5=very true) the following 8 factors would be: easier to understand; able to buy more products; shopping would be much quicker; be more scientific; less anxious when buying a food product; make me safer when I eat a food product; make me safer when I buy a food product, and fewer products with PAL. Finally, we asked respondents 1) how well QRA has been explained to date and 2) to rank their preference (on a scale of 1 to 6, with 1 being first choice) on who should explain quantitative risk assessment to consumers with food allergies.

Statistical analysis

All data underwent preliminary tests for normality and met the requirements for the statistical tests selected, outlined below (28). Cases with missing data >20% were excluded (28). Residual and scatter plots examining assumptions of normality, linearity, and homoscedasticity met the relevant criteria (29). A series of Univariate Analyses of Variance (F test), and where appropriate Chi Square test ($\chi 2$ test) for Independence (Pearson's Chi Square, Fisher's Exact Test), were conducted to assess associations for country and participant type with regard to (1) demographic, (2) clinical and (3) all responses to questions on PAL (Figure S1). Multivariate Analyses of Variance (F test) were conducted when appropriate to control for the effects of all independent variables on dependent variables simultaneously. Finally, a Hierarchical Multiple regression was used to assess the association between feeling/attitude variables on QRA and '*trust in a product if a quantitative risk assessment* (QRA) *had been carried out'*.

Results

There were a total of 1582 responses. Of these, 64 respondents completed the questionnaire twice (because there was more than one person in their household with FA). Data from these respondents (N=64) were counted only once since there were no significant differences ($p > 0.1$ to 0.9 for all variables) between first and second responses for these 64 cases. Data was missing for 22 respondents, leaving 1560 responses for analysis (Table 1).

This article is protected by copyright. All rights reserved.

Accepted Article

Table 2 shows the profile of the participants. There were 535 (34%) adults with FA, with a mean age of 44.0 years (range 18-82). The overwhelming majority of the cases were diagnosed formally, with only 2% of the entire data set 'self-diagnosed' or diagnosed by someone other than by a health professional (e.g. by an alternative practitioner). Over half of responses (N=907; 58%) were from parents (86% Mothers) who had one or more children diagnosed with FA. The final 8% were composed of parents of a child with FA, who themselves had FA. These were placed with the 'parent group' for analysis purposes. The mean age for the first child/only child with FA was 9.4 years (range 1-35) and 61% were male. Overall, 65% reported that they or their child had experienced a severe reaction to a food, and they reported an average of three allergies. Adrenaline auto-injector prescriptions were most frequent among participants from UK and Ireland (95%) and Spain (83%)

Attitudes and feelings towards precautionary allergen labelling (PAL)

When asked whether a product that has no PAL is safe to eat, 18% answered 'yes', 22% replied 'no', 51% 'not necessarily', and 9% were 'unsure'. Table 3 shows the reasons participants gave for reading PAL. There were no associations for parents or adults on any of the reasons given except that parents (68%) were more likely than adults (55%) to check the label every time that a product is purchased [χ^2= 33.2, p=0.0001] On confidence that PAL helps avoid allergic reactions, the mean score was 2.8 (SD 1.4) which equates to "Hardly confident". Analysis of variance found no significant main effect differences across countries [F=2.5, p=0.1, η 2 =0.005] or a significant interaction with participant types [F=.0.5, p=0.8, η 2 =0.002].

Preference for labelling phrases and symbols

The survey included preferences for 3 statement formats that identify foods that may contain an allergen due to cross-contamination. 'This product is not suitable for consumers with xy allergy' was selected as first choice by 46% overall, 'May contain xy (allergen)' was selected as the first choice by 44%., and 'Accidental presence of xy (allergen)' was least popular at 7%, with 3% choosing 'other' option. A significant association was found between country and phrase type (x^2=28.3, p=0.001). 'This product is not suitable for' was ranked first by a higher proportion of respondents from the UK and Ireland (56%), and Germany (48%). 'May contain' was the first choice for Netherlands (44%) and Spain had the highest proportion of those who ranked 'Accidental presence' as first choice (11%). 'This product is not suitable for' was ranked first by a similar proportion of respondents of adults (49%) and parents (47%). A single statement was preferred by 68% of the sample compared to a statement that distinguishes between the type and frequency of allergen presence with no significant association for country [χ2= 1.2, p=0.7]. or participant type [χ2= 0.25, p=0.7],

Participants were asked how helpful a series of statements would be when choosing a product. '*This product has undergone a risk assessment and there is risk of an allergic reaction (i.e. not safe to consume)'* was seen as 'very helpful' by a slightly higher proportion (52%) than the statement *'This product has undergone a risk assessment and found to be safe to consume'* (49%). There

This article is protected by copyright. All rights reserved.

Accepted Article

was one country difference – UK/Ireland reported 'safe to consume' as 'very helpful' in a higher proportion than 'unsafe to consume' (63% vs 54%), although chi-square test was not significant. Finally, participants rated four options (Table 4) in terms of how helpful they would be when choosing a product. The proportion of those who endorsed each option as 'quite a bit' or 'very' helpful increased as information became more complex. Option 4 was the most popular with 66% reporting that the statement would be 'quite a bit' or 'very' helpful. Number of allergies reported and past severe reaction did not have an impact. Significantassociations were found for country[$\chi 2$= 26.9, p=0.02] (Table 4). The Netherlands had a higher percentage endorsing option 3 (65%) compared to option 4 (53%) and Germany endorsed both option 3 and 4 equally.

Attitudes to quantitative risk assessment and to placing a label on a product.
Seventy three percent reported that it would improve their trust in a product if a QRA process had been used to make a decision about whether to include "may contain". Only 9% reported that it would slightly or considerably reduce their trust. Thirty two percent of adults and 44% of parents whose child had a past severe reaction stated that QRA would 'considerably improve their trust'. There were no significant differences between countries (p>0.05).

Participants were asked about how true a series of statements would be (Table 5) if risk assessment was mandatory. Overall, 53% of participants answered 'quite a bit true' or 'very true' for all statements on mandatory QRA for food products (Table 5). The statements with the highest agreement were 'easier to understand' (Mean 3.6, SD 1.2); 'fewer products with 'may contain' (3.5, 1.2); 'trust in the product would increase (3.5, 1.3); and 'make me less anxious when buying a food product' (3.4, 1.3). Multivariate analysis showed a significant main effect difference across countries for all statements [F=5.9, p =0.01, η 2 =0.02], however there was no significant interaction between participant type and country for any of the statements [F=0.77, p=0.9, η 2=0.008].

Next the association between feeling/attitude variables on mandatory QRA and agreement with the statement 'My trust in a food product would increase' was assessed. All the feelings and attitudes to QRA (easier to understand; able to buy more products; shopping would be much quicker; be more scientific; less anxious when buying a food product; make me safer when I eat a food product; make me safer when I buy a food product, and fewer products with "may contain") were significantly and positively associated with trust in the food product (Table 6). Together they explained 77% of the variance. The item '*Make me safer when I eat a food product'* was most closely associated with trust followed by *'able to buy more food products'*, *'shopping would be quicker'*, *more safe products* and *'less anxious'*.

This article is protected by copyright. All rights reserved.

Accepted Article

Communicating information on quantitative risk assessment

Thirty six percent of the participants in this study agreed as 'true' or 'very true' that QRA was not explained properly to date. To assess preference with regard to communication on QRA, participants were asked to rank their preference (on a scale of 1 to 6, with 1 being first choice) on 'Who do you think should explain quantitative risk assessment to consumers with food allergies?'

Overall, physicians/allergists were the most popular first choice for information on QRA (39%), together with regulators/government (39%). This was followed by food manufacturers (36%) and Patient support groups (29%). First choice varied according to country (Table S1), however there no significant associations according to participant type, or gender ($p>0.05$). Participants ranked their preference on 'Where do you think consumers with food allergy should get information about quantitative risk assessment?' Information in shops/supermarkets was the most popular first choice (50%), followed by doctor's surgery (20%), smart phone (14%), traditional media (14%) and social media (12%). Chi-square analysis showed no significant associations according to participant type, gender or country ($p>0.05$).

Discussion

Many respondents were not confident about the reliability and trustworthiness of PAL, as shown in previous research. The value of PAL has been devalued through overuse and inconsistent application; it can act as a barrier to informed decision making and increases risk to consumers with FA (19,30-32). Participants were also unsure whether a product is safe to eat if it has no PAL indicating uncertainty, a central theme in food allergy that has a negative impact on quality of life (10) (Figure S2). There is uncertainty also among food businesses about what is required by regulators, which drives the use of criteria other than the actual health risk (e.g. business risk).

Prior to this study, little information about consumers' preference for information/statements about risk assessments on labels was available. Zurzola and colleagues completed a study in 2017 (ref) where they presented a symbol "may be present" to represent a LOW level of cross contamination to 497 children (59% with food allergy) attending at the Royal Children's Hospital, Melbourne. Their findings showed that the majority of respondents would find this very useful, and the authors emphasise that appropriate education should be provided. Our study focussed on adult/parent consumers and offered multiple preference options. An important part of this study was to determine which of several alternatives in phrasing and symbols consumers felt would make it easier to identify foods that may contain an allergen due to cross-contamination.

Overall, consumers strongly welcomed seeing a label that stated clearly that a product had undergone a risk assessment, reporting that it would be both useful and helpful. Furthermore, 32% adults and 44% parents stated that mandatory use would 'considerably improve their trust'. The statement 'This product has undergone a risk assessment and there is risk of an allergic reaction (i.e. not safe to consume)' was seen as more helpful by a slightly higher proportion (52%) than a similar statement with 'safe to consume' (49%).

This article is protected by copyright. All rights reserved.

Accepted Article

We found very little variation across countries or participant types on this preference. As long as the use of PAL is voluntary, consumers with food allergy want and need to know the background for the application or the omission of a PAL statement on a particular food product. With the currently not regulated mandatory framework, there was agreement on preference for a combination of unintended allergen presence statement, risk assessment statement, and risk assessment symbol. Although all four options (with increasing levels of information) were rated as helpful by participants, level of helpfulness increased with the complexity of statements. It is likely that food industry may not favour more complex types of labelling but the underlying message is that more directive informationwould help consumers to make more informed decisions when purchasing food products and would therefore protect them better. Therefore, to avoid overly 'wordy' additions to products, information in the form of one symbol with a corresponding one or two word safety statement, would likely also suffice. Previous research has shown that the use of symbols and a safety statement were the most important food allergen-labelling attributes (32-33-35-37).

The preference among our participants for more complex information on packaging may seem surprising, however advisory labels are helpful if they provide reliable and meaningful information on the allergen risk. This information may be augmented by medical data from oral food challenges in patients. Complexity without 'meaningfulness' increases both uncertainty and ambiguity. Furthermore, as current PAL use cannot be associated with any defined level of risk, both uncertainty and ambiguity are amplified. When consumers are provided with directive information about either the degree of risk or benefit, alongside information on risk management practices, judgments of benefit are increased, and perceptions of risk reduced (17,19). A recent study in Canada found that the QRA would statement 'does not contain' was preferred to the statement 'may contain' (33). Many food companies would be reluctant to state 'does not contain' because it implies zero. This contention underlines the importance of a mandatory approach. If all have to apply the system, the meaning is not 'zero allergen' but instead that 'consumption is unlikely to result in more than a mild allergic reaction when consuming the product'. We must also acknowledge issues of level playing field in a competitive environment, suggesting that a regulatory approach would probably be most effective.

Trust as a concept has been extensively studied in relation to consumer perceptions of food safety, and food risk management in general. Consumer trust in different actors and institutions responsible for guaranteeing and controlling food safety, as well as trust in the information provided by different information sources that communicate about food safety or food-related risks, is considered to be important for consumer confidence in the safety of food (38-40). To assess the association feeling/attitude variables on quantitative assessment and 'trust in a product if a quantitative risk assessment (QRA) had been carried out', we carried out a hierarchical multiple regression analysis. Our findings showed that perception of safety, anxiety, convenience, choice and understanding would be positively impacted when making purchasing decisions. This finding shows the potential positive impact on a wide array of factors of clearly communicating to

This article is protected by copyright. All rights reserved.

Accepted Article

consumers the process that has actually taken place to lead to the placing of a label on a particular food product.

Overall, physicians/allergists were the most popular first choice for information on QRA. The information could be given at diagnosis and patients/parents could be directed to further supporting information provided online and via phone by patient support groups and others.

This study has limitations, which means the results must be interpreted with caution. This was a cross-sectional self-report study with no random sampling frame, an unclear response rate, and respondents may not have confirmed FA. Convenience sampling was used because it has advantages, the most important being that it is cost-effective and speedy. However, our findings may not be generalizable to the target population because of the potential bias inherent in our sampling technique, and the respondents are a biased sub-population of patient support group members. Therefore, inferences based on our findings should be made only about the sample itself. However, we did obtain a large sample which allowed us to examine subgroup differences which minimised bias to some extent.

This is the first quantitative study to examine parents of consumers and consumers' preference for risk assessments on labels. Results show that consumers want to know the process that has led to a decision to place a label (or not) on a food product. Ensuring an acceptable level of risk for most consumers with food allergy presents challenges. However, it is important to remember that consumer acceptance is an evolutionary rather than a revolutionary process. Lack of awareness, knowledge and familiarity often lead to a sense of dread (triggering more emotional and negative responses). In contrast, less mystery yields less fear, which yields more trust and better quality of life (41).

The outcomes from this research should help to guide stakeholders when considering issues of acceptability of risk by outlining the potential positive impact on a wide array of factors of clearly communicating to consumers the process that has actually taken place leading to the placing of a label on a particular food product. In the context of acceptability, including them as partners/interested parties in determining what is acceptable is critical. The PAL approach coupled to QRA does NOT include declaration of the extent to which the allergen may be present – only that it is above the ED01 – ED05. Consumers may not understand that allergens are not always uniformly distributed so one product may have no detectable peanut but another package of the same product could have a whole peanut. Further research is needed on how to convey this aspect, for example a different kind of statement may be needed for large amounts that may appear due to (for example) sporadic particulate contamination.

This article is protected by copyright. All rights reserved.

Accepted Article

Acknowledgements

We would like to thank the patient organisations who contributed to distributing the questionnaire and all the consumers who completed. This study was part of the EU iFAAM project: Integrated Approaches to Food Allergen and Allergy Risk Management (Grant Agreement No 312147).

References

1. Prescott S, Allen KJ. Food allergy: riding the second wave of the allergy epidemic. Pediatr Allergy Immunol 2011;22:155-60.
2. Nwaru BI, Hickstein L, Panesar SS, Muraro A, Werfel T, Cardona V, Dubois AE, Halken S, Hoffmann-Sommergruber K, Poulsen LK, Roberts G, Van Ree R, Vlieg-Boerstra BJ, Sheikh A; EAACI Food Allergy and Anaphylaxis Guidelines Group.The epidemiology of food allergy in Europe: a systematic review and meta-analysis. Allergy. 2014 Jan;69(1):62-75.
3. Burks AW, Tang M, Sicherer S, et al. ICON: food allergy. J Allergy Clin Immunol 2012;129:906-20.
4. Liew WK, Williamson E, Tang ML. Anaphylaxis fatalities and admissions in Australia. J Allergy Clin Immunol 2009;123:434-42.
5. Mullins RJ, Dear KB, Tang ML. Time trends in Australian hospital anaphylaxis admissions in 1998-1999 to 2011-2012. J Allergy Clin Immunol 2015;136:367-75.
6. Turner PJ, Gowland MH, Sharma V, et al. Increase in anaphylaxis-related hospitalizations but no increase in fatalities: An analysis of United Kingdom national anaphylaxis data, 1992-2012. The Journal of Allergy and Clinical Immunology. 2015;135(4):956-963.
7. Blom WW Michelsen-Huisman AD (2018) JACI (in press) Accidental food allergy reactions: products and undeclared ingredients. DOI: 10.1016/j.jaci.2018.04.041
8. Branum AM, Lukacs SL. Food allergy among children in the United States. Pediatrics. 2009;124:1549–1555.
9. Sicherer SH, Forman JA, Noone SA. Use assessment of self-administered epinephrine among food-allergic children and pediatricians. Pediatrics 2000;105:359-62.
10. de Silva IL, Mehr SS, Tey D, Tang ML. Paediatric anaphylaxis: a 5 year retrospective review. Allergy 2008;63:1071-6.
11. DunnGalvin A, Hourihane JOB. Health-related quality of life in food allergy :Impact, correlates, and predictors.2016 Bundesgesundheitsbl © Springer-Verlag Berlin Heidelberg
12. Cummings, A.J. et al.The psychosocial impact of food allergy and food hypersensitivity in children, adolescents and their families: a review. Allergy, 2010. 65(8), pp.933–45.
13. Flokstra-de Blok, B.M.J. et al. Health-related quality of life of food allergic patients: comparison with the general population and other diseases. Allergy, 2010. 65, pp.238–244.
14. Soon, J.M. & Manning, L. J Consum Policy (2017) 40: 447.
15. Goossens NJ, Flokstra-de Blok BM, van der Meulen GN, Arnlind MH, Asero R, Barreales L, et al. Health-related quality of life in food-allergic adults from eight European countries. Ann Allergy Asthma Immunol. 2014;113(63–8):e1

This article is protected by copyright. All rights reserved.

Accepted Article

16. DunnGalvin A et al. An Examination of the Food Allergy Quality of Life Questionnaire Performance in a Countrywide American Sample of Children: Cross-Cultural Differences in Age and Impact in the United States and Europe The Journal of Allergy and Clinical Immunology: In Practice 2016 , Volume 5 , Issue 2 , 363 - 368.e2
17. Polloni, L., Baldi, I., et al.Multidimensional analysis of food-allergic children and adolescents' self-concept: A comparison with a healthy matched sample. Journal of health psychology, 2015. 20(6), pp.850–7.
18. DunnGalvin, A., Gaffney, A., & Hourihane, J.O'B Developmental pathways in food allergy: a new theoretical model. Allergy 2009; 64, 560-568.
19. Abdellaoui M, Baillon A, Placido L, Wakker P. The Rich Domain of Uncertainty: Source Functions and Their Experimental Implementation. American Economic Review, 2011. 101 no. 2: 695-723.
20. EAACI Food Allergy and Anaphylaxis Guidelines. Protecting consumers with food allergies: understanding food consumption, meeting regulations and identifying unmet needs. Allergy, 69 (11), pp. 1464–1472
21. Using "may contain" labelling to inform food choice: A qualitative study of nut allergic consumers. BMC Public Health, 11 (734), pp. 1-9
22. Zurzolo GA, Peters RL, Koplin JJ, de Courten M, Mathai ML, Allen KJ. Are food allergic consumers ready for informative precautionary allergen labelling?. Allergy Asthma Clin Immunol. 2017;13:42.Increase in anaphylaxis-related hospitalization but no increase in fatalities: An analysis of United Kingdom national anaphylaxis data, 1992-2012. Journal of Allergy and Clinical Immunology, 135 (4), pp. 956–963
23. The EU Food Information for Consumers Regulation No. 1169/2011 describes the rules and requirements for food businesses to provide allergen ingredients information for the consumer.website
24. B Madsen, C & Hattersley, S & Allen, Katrina & Beyer, K & Chan, Chun-Han & Godefroy, Samuel & Hodgson, R & N C Mills, E & Muñoz-Furlong, A & Schnadt, Sabine & Ward, Rachel & Wickman, Magnus & Crevel, René. (2011). Can we define a tolerable level of risk in food allergy? Report from a EuroPrevall/UK Food Standards Agency workshop. Clinical and experimental allergy : journal of the British Society for Allergy and Clinical Immunology. 42. 30-7.
25. DunnGalvin A, Chan C-H, Crevel R, Grimshaw K, Poms R, Schnadt S, Taylor SL, Turner P, Allen KJ, Austin M, Baka A, Baumert JL, Baumgartner S, Beyer K, Bucchini L, Fernández-Rivas M, Grinter K, Houben GF, Hourihane J, Kenna F, Kruizinga AG, Lack G, Madsen CB, Mills ENC, Papadopoulos NG, Alldrick A, Regent L, Sherlock R, Wal J-M, Roberts G. Precautionary allergen labelling: perspectives from key stakeholder groups. Allergy 2015; 70: 1039-51.
26. Worm M, Moneret-Vautrin A, Scherer K, Lang R, Fernandez-Rivas M, Cardona V, Kowalski ML, Jutel M, Poziomkowska-Gesicka I, Papadopoulos NG, Beyer K, Mustakov T, Christoff G, Bilò MB, Muraro A, Hourihane JO, Grabenhenrich LB. First European data from the network of severe allergic reactions (NORA). Allergy 2014; 69: 1397-404.

This article is protected by copyright. All rights reserved.

Accepted Article

27. Abbott, M., Hayward, S., Ross, W., Godefroy, S.B., Ulberth, F., van Hengel, A.J., Roberts, J., Akiyama, H., Popping, B., Yeung, J.M., Wehling, P., Taylor, S.L., Poms, R.E., Delahaut, P., 2010. Validation procedures for quantitative food allergen ELISA methods: community guidance and best practices. J AOAC Int 93, 442-450.
28. Hefle, S.L., Furlong, T.J., Niemann, L., Lemon-Mule, H., Sicherer, S., Taylor, S.L., 2007. Consumer attitudes and risks associated with packaged foods having advisory labeling regarding the presence of peanuts. J Allergy Clin Immunol 120, 171-176.
29. Poms, R.E., Klein, C.L., Anklam, E., 2004. Methods for allergen analysis in food: a review. Food Addit Contam 21, 1-31.
30. Remington, B.C., Baumert, J.L., Marx, D.B., Taylor, S.L., 2013. Quantitative risk assessment of foods containing peanut advisory labeling. Food Chem Toxicol 62, 179-187.
31. Allen, K.J., Remington, B.C., Baumert, J.L., Crevel, R.W., Houben, G.F., Brooke-Taylor, S., Kruizinga, A.G., Taylor, S.L., 2013. Allergen reference doses for precautionary labeling (VITAL 2.0): Clinical implications. J Allergy Clin Immunol.
32. Kruizinga, A.G., Briggs, D., Crevel, R.W., Knulst, A.C., van den Bosch, L.M., Houben, G.F., 2008. Probabilistic risk assessment model for allergens in food: sensitivity analysis of the minimum eliciting dose and food consumption. Food Chem Toxicol 46, 1437-1443.
33. iFAAM http://www.inflammation-repair.manchester.ac.uk/iFAAM/, accessed 6th August 2018
34. Tabachnick B.G. & Fidell L.S., "Using Multivariate Statistics," 4th ed. 2001. Allyn & Bacon, Boston, 2001.
35. Orr D.B., "Fundamentals of Applied Statistics and Surveys," 1995. Chapman and Hall, New York.
36. Sheth, S.S., Ben-Shoshan, M., Harrington, D.W., Fragapane, J., Soller, L., Joseph, L., St. Pierre, Y., La Vieille, S., Elliott, S.J., Waserman, S., Alizadehfar, R., Harada, L., Allen, M., Allen, M., Clarke, A.E., 2012. Effect of precautionary statements on the purchasing practices of Canadians directly and indirectly affected by food allergies. J Allergy Clin Immunol 129, 1401-1404.
37. Zurzolo, G., Koplin, J.J., Mathai, M.L., Tang, M.K.L., Allen, K.J., 2013a. Perceptions of precautionary labelling among parents of children with food allergy and anaphylaxis. Med J Aust 198, 621-623.
38. Brown KM, Fenton NE, Lynd LD, Marra CA, FitzGerald JM, Harvard SS, Rosenthal M, Chow BYL, Clarke AE, Elliott SJ. Canadian policy on food allergen labelling: consumers' perspectives regarding unment needs. Univers J Public Health. 2015;3:41–48.
39. Marra CA, Harvard S, Grubisic M, et al. Consumer preferences for food allergen labeling. Allergy, Asthma, and Clinical Immunology : Official Journal of the Canadian Society of Allergy and Clinical Immunology. 2017;13:19.
40. Leonidou, L et al. 2011. Evaluating the green advertising practices of international firms: A trend analysis. International Marketing Review 28(1):6-33

This article is protected by copyright. All rights reserved.

Accepted Article

41. Cornelisse-Vermaat JR, Voordouw J, Yiakoumaki V, Theodoridis G, Frewer LJ. Food-allergic consumers' labelling preferences: a cross-cultural comparison. Eur J Public Health. 2008;18:115–120.
42. Turner PJ, Kemp AS, Campbell DE. Advisory food labels: consumers with allergies need more than "traces" of information. BMJ. 2011;343:d6180.
43. Noimark L, Gardner J, Warner JO. Parents' attitudes when purchasing products for children with nut allergy: a UK perspective. Pediatr Allergy Immunol. 2009;20:500–504. Brunel, O., Pichon, P.-E. (2004). Food-related risk-reduction strategies: Purchasing and consumption processes. Journal of Consumer Behaviour, 3/4, 360-374.
44. De Jonge, J., Frewer, L., Van Trijp, H., Renes, R. J., De Wit, W., Timmers, J. (2004). Monitoring consumer confidence in food safety: An exploratory study. British Food Journal, 106, 837-849.

This article is protected by copyright. All rights reserved.

Accepted Article

Table 1. Total number of responses per country (N=1582)

Country	Number of Responses*	Percentage of Total Sample	Number of Missing Responses
Ireland & UK	496	31.4%	5
Germany	673	42.5%	14
Spain	225	14.2%	0
Netherlands	182	11.5%	3
Total	1582	100%	22
Total (missing responses)	1560	97.2%	-

*N=64 completed the questionnaire more than once because they had more than one person with food allergy in their household. The Ireland and UK responses were combined for analysis purposes.

This article is protected by copyright. All rights reserved.

Accepted Article

Table 2. Profile* of the participants from the UK & Ireland, Germany, Spain and Netherlands who took part in the study (N=1582).

Country	UK & Ireland	Germany	Spain	Netherlands	Total
	N (%)	N (%)	N (%)	N (%)	N (%)
Parent of 1 or 2 children with FA **	330 (67)	310 (46)	177 (79)	90 (50)	907 (61)
Adult with FA **	139 (28)	295 (44)	26 (12)	75 (42)	535 (32)
Adult & Parent with FA	22 (5)	54 (8)	22 (10)	14 (8)	112 (8)
Parent/Adult Female Gender	394 (85)	553 (89)	178 (85)	158 (92)	1283 (88)
Child Female Gender	137 (41)	129 (39)	66 (36)	39 (40)	371 (39)
Past severe reaction (yes)	331 (69)	387 (60)	136 (63)	119 (69)	973 (65)
Prescribed Adrenaline Auto-Injector **	456 (95)	361 (56)	181(83)	114 (64)	1112 (298)
Diagnosed by Allergist/Consultant**	380 (80)	524 (82)	210 (96)	147 (83)	1261 (85)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Child Age ***	12 (8.2)	11 (5.8)	8.5 (5.1)	7 (4.3)	9.6 (5.4)
Number of Allergies ***	2.8 (1.8)	3.9 (2.7)	3.1 (2.3)	3.9(2.5)	3.4 (2.2)

*There is missing data (<20%) for some cases. FA: food allergy.

** Significant association for Country $p < 0.05$ Asymp.Sig.

*** Significant differences for Country $p < 0.05$ ANOVA

This article is protected by copyright. All rights reserved.

Accepted Article

Table 3. The reasons precautionary labelling is read by participants* from UK & Ireland, Germany, Spain, and Netherlands (N=1560)

Country	UK & Ireland	Germany	Spain	Netherlands	Total
	N (%)	N (%)	N (%)	N (%)	N (%)
When not familiar **	187 (38)	219 (33)	26 (12)	58 (32)	490 (30)
When buying a new product **	197 (40)	288 (43)	47 (21)	65 (36)	597 (35)
To check nothing has changed **	163 (33)	250 (38)	54 (24)	69 (38)	536 (33)
Every time product is bought **	288 (59)	434 (66)	178 (82)	109 (60)	1009 (67)

*Participants could choose one option or as many options as were relevant for them.

** Significant association for country $\chi 2.=8.5$, $p=0.01$.

This article is protected by copyright. All rights reserved.

Accepted Article

Table 4. Percentage of participants across 4 countries* who felt each statement type was helpful (N=1560).

Statement Type	UK & Ireland	Germany	Spain	Netherlands	Total
	N (%)	N (%)	N (%)	N (%)	N (%)
1. Statement for unintended allergen presence*	177 (36)	303 (46)	77 (34)	90 (50)	647 (42)
2. Statement for unintended allergen presence + risk assessment statement	304 (62)	389 (59)	133 (59)	97 (54)	903 (59)
3. Statement for unintended allergen presence + risk assessment symbol	290 (59)	422 (64)	137 (61)	116 (65)	965 (62)
4. Statement for unintended allergen presence + risk assessment statement + risk assessment symbol *	357 (72)	424 (63)	171 (76)	96 (53)	1048 (66)

*Significant association for Country. $\chi 2 = 26.9$, $p=0.02$

Figures are percentage of participants across 4 countries who selected 'quite a bit' (=4) and 'very much' (=5) on level of helpfulness of statements /information that may appear on a food label.

This article is protected by copyright. All rights reserved.

Accepted Article

Table 5. Participants' feedback on quantitative assessment approach*by country ** (N=1560).

	UK/Ireland	Germany	Spain	Netherlands
	M(SD)	M(SD)	M(SD)	M(SD)
Easier to understand	3.7 (1.2)	3.5 (1.3)	3.8 (1.3)	3.3 (1.2)
I would be able to buy more products	3.4 (1.4)	3.3 (1.4)	3.6 (1.4)	2.9 (1.4)
Shopping would be much quicker	3.0 (1.4)	3.0 (1.4)	3.5 (1.4)	2.7 (1.3)
My trust in a food product would increase	3.5 (1.2)	3.5 (1.3)	3.7 (1.3)	3.1 (1.3)
Be more scientific	3.7 (1.3)	3.1 (1.3)	3.9 (1.2)	3.1 (1.2)
Less anxious when buying a food product	3.4 (1.3)	3.4 (1.3)	3.4 (1.4)	3.0 (1.3)
Make me safer when I eat a food product	3.3 (1.3)	3.3 (1.3)	3.7 (1.3)	3.0 (1.3)
Fewer products with "may contain"	3.8 (1.3)	3.4 (1.3)	3.6 (1.4)	3.5 (1.2)
More safe products to choose from	3.6 (1.3)	3.3 (1.2)	3.7 (1.4)	3.2 (1.3)

*Mean scores and standard deviations for level of agreement for statements on 'If a quantitative assessment was mandatory,how true would the following be for food products?'.Scale of 0= do not agree to 5 = agree very much.

** Significant differences across countries for all items F=5.9 (p =0.001) Analysis of Variance..

This article is protected by copyright. All rights reserved.

Accepted Article

Table 6: Hierarchical multiple regression* showing the associations between feeling/attitude variables and increased in trust in a product if a quantitative risk assessment (QRA) had been carried out (N=1560).

	Standardized Coefficients			95.0% Confidence Interval for Beta	
*Model	**Beta	*** t	Sig. (p value)	Lower Bound	Upper Bound
Constant		3.1	0.002	0.43	1.70
Easier to understand	0.09	3.0	0.003	0.03	0.15
I would be able to buy more products	0.19	5.4	0.000	0.11	0.24
Shopping would be much quicker	0.13	4.0	<0.001	0.06	0.18
Be more scientific	0.09	3.3	0.001	0.04	0.15
Less anxious when buying a food product	0.12	3.0	0.003	0.04	0.19
Make me safer when I eat a food product	0.28	6.4	<0.001	0.19	0.36
Fewer products with "may contain"	0.07	3.3	0.001	0.12	0.03
More safe products to choose from	0.12	3.7	<0.001	0.06	0.19

Dependent variable :'My trust in a food product would increase' (1=not at all to 5 =very much).

*Controlling for country (UK/Ireland; Germany; Spain; Netherlands), participant type (parent or adult), child gender, number of allergens (adult), number of allergens (1-6), severity of past reactions (yes/no), and prescription of auto-injector, entered in Step 1.

**A standardized beta coefficient compares the strength of the effect of each individual independent variable to the dependent variable. The lower and upper bound represent the 95% confidence interval for the beta statistic.

***T statistic is the coefficient divided by its standard error.

This article is protected by copyright. All rights reserved.