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Identifying what influences the shopping habits of food hypersensitive consumers; an island of Ireland study

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Foreword & acknowledgments

This report details the outcomes of a research project funded by *safe*food to investigate how consumers on the island of Ireland who have a food hypersensitivity (including food allergy, food intolerance or coeliac disease), and who must adhere to an avoidance diet, procure appropriate food. The goal of the research was to identify the barriers they have in this regard in terms of choice, availability and the utility of labelling and how this impacts on health, quality of life and wellbeing. It also investigated these issues from the perspective of the food industry.

*safe*food would like to thank the Principal Researcher on this project, Dr Tassos Koidis, Lecturer in Food Science and Nutrition at the Institute for Global Food Security, Queen's University Belfast. Thanks are also due to Dr Koidis' research colleague Mr Alexandros Stratakos, Queen's University Belfast and also to Dr Audrey DunnGavin, University College Cork, Mr Michael Walker of Michael Walker Consulting Limited and Mrs Hazel Gowland, Allergy Action UK. We would also like to acknowledge the assistance of Mr Michael Bell, Northern Ireland Food & Drink Association and Ms Mary Hughes, Irish Business and Employers Confederation for their participation and advice on the project. Finally, we would like to thank all those volunteers, food manufacturers and food testing companies who participated in the research.

Executive summary

Food hypersensitivity is increasingly prevalent on the island of Ireland (IOI) and globally. Since avoidance is the only personal management strategy available, accurate food labelling plays an important role in the procurement of appropriate food products. Success or otherwise in achieving this determines an individual's well-being and quality of life. The aim of this project was to understand the factors affecting the food choices of food hypersensitive consumers on the IOI, particularly with regard to product labelling, and identify any barriers to the procurement of appropriate food and trusted sources of information relied on. A market analysis of Free-from foods and the use of advisory or precautionary allergen labelling (PAL) was also conducted. Finally, the availability of analysis / testing for food allergens was explored.

Respondents to a survey of food hypersensitive consumers indicated a preference for shopping in large supermarkets; respondents rarely shop at medium supermarkets, corner shops, premium shops or food stalls. Very little research has been carried out on how these consumers balance competing values when purchasing food. Inconsistencies in the application of PAL statements by food producers results in labelling being a significant source of uncertainty that undermines their confidence, and therefore trust, in the food safety regulatory regime. Consumers respond to uncertainty around labelling by being very selective in their food purchases, giving rise to extra costs in addition to spending more time and travelling further when shopping. This uncertainty also results in increased anxiety around food purchases and increased risk taking (particularly if they no longer believe PAL). Potential predictors and models of how these consumers use labelling information when deciding to buy a food product were investigated. This analysis, controlled for a wide range of factors including: type of hypersensitivity, the number of symptoms reported, the number of foods to which they were hypersensitive, their age and gender, their parental and marital status, how they were diagnosed and their level of understanding of food labelling is presented here. The study found that attitudes to, and practices around, food labelling are not influenced by gender, age or whether the consumer has a food allergy or food intolerance. The most important predictor of how much labelling is used is the extent to which the food hypersensitive consumer is influenced by labelling in general. The paradox is that while they find labelling very necessary, they also regard it as only 'somewhat' reliable, 'somewhat adequate' or 'somewhat understandable'. Food safety and nutrition are also important factors when choosing a food. This underlines the importance of accurate user-friendly labelling.

Consumers with food allergies dislike PAL because they are uncertain about the basis for its use, their food choices are considerably reduced, and parents report negative influences on their children's nutritional status and social inclusion. Parents use food labelling, and are more influenced by food labelling, compared to adults without children. Although this finding was expected, it is important to confirm it in a large survey sample on the IOI. A wide range of PAL statements is currently used by food manufacturers on the IOI. This diversity represents something of a divergence from best practice recommendations as issued by regulatory authorities such as the UK Food Standards Agency

(FSA). It also has the potential to cause confusion amongst consumers and reduces the value of PAL as a risk communication tool as demonstrated to some extent by the main survey. The basis for using PAL differs amongst food manufacturers, the most common reason being uncertainty around different thresholds for different allergens that would trigger the need for PAL. The threshold data already available and presented here could help food manufacturers establish action plans that would lead to a more efficient use of PAL. These findings may be of use to food manufacturers in communicating these thresholds to their food hypersensitive customers. This may improve overall confidence in the reliability of PAL. Currently, a significant proportion (37%) of the food manufacturers surveyed do not base their decision to use PAL on the outcomes of any risk assessment. Rather, PAL is likely being used in a lot of cases as a substitute for a proper allergen risk assessment. This ad hoc use of PAL has further limited the dietary choices of food hypersensitive consumers, many of whom now ignore PAL thereby, putting themselves at increased risk. We found that consumers have more confidence in specific/explicit types of PAL with the expression 'not suitable for someone with X allergy' being the preferred choice.

The capacity to analyse food products for the major legislated food allergens is present on the IOI while test methods for other food allergens are still in development. In general food allergen analysis is seen as important to laboratories and is increasing despite such analyses being regarded as difficult. High technology chemical analytical methods, e.g. LC-MS or LC-MS/MS are not currently used but are regarded as having potential. The current market for food allergen analysis on the IOI was considered to be too limited to support the deployment of these types of methods.

Free-from product sales on the IOI grew by 37.5% between 2009 and 2014 with the market evenly split (on a per capita basis) between the Republic of Ireland (ROI) and Northern Ireland (NI). Projections show that the volume of sales will double by 2019, reaching €63.6 million. That said, free-from food product sales accounted for less than 0.50% of overall grocery sales in 2014. The range of food products intended for the food hypersensitive market is also increasing; over the same period, major retailers on the IOI have launched 'own-brand' allergen-free food products. There is potential for these to be marketed as a uniquely identifiable product type such as free-from which would raise awareness and ameliorate consumer confusion. Branded products accounted for the larger part of the Free-from foods launched on the market. The increased availability and range of Free-from food products represents greater choice for the food hypersensitive consumer on the IOI.

Glossary of terms

AOAC	Association Of Analytical Communities
BRC	British Retail Council
DNA	DioxyriboNucleic Acid
EFSA	European Food Safety Authority
ELISA	Enzyme Linked ImmunoSorbent Assay
EN	England
FA	Food Allergic
FARRP	Food Allergy Research and Resource Program of the University of Nebraska
FI	Food Intolerant
FODMAPS	Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols
FSA	United Kingdom Food Standards Agency
FSAI	Food Safety Authority of Ireland
GP-HPLC	Gel Permeation-High Performance Liquid Chromatography
IgE	Immunogloubulin E
IP	Intellectual Property
ISO/IEC	International Standards Organisation/International Electrotechnical Commission
LC-MS	Liquid Chromatography-Mass Spectrometry
LC-MS/MS	Liquid Chromatography-Tandem Mass Spectrometry
LFD	Lateral Flow Device
M	Mean
MANOVA	Multivariate ANalysis Of VAriance
mg	Milligram
NI	Northern Ireland
NIFDA	Northern Ireland Food and Drink Association
PCR	Polymerase Chain Reaction
PAL	Precautionary Allergen Labelling
ppm	Parts per million
QToF	Quadrupole Time of Flight
ROI	Republic of Ireland
RP-HPLC	Reverse Phase-High Performance Liquid Chromatography
RSSL	Reading Scientific Services Limited
RT	Retention time
SCO	Scotland
SD	Standard Deviation
UK	United Kingdom
US/USA	United States/United States of America

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1 Introduction

The basis for the survey

Food hypersensitivity is a global issue. Although in reality a broad spectrum of idiosyncratic adverse reactions to food, many involving an immune response, it can be narrowed down for the purposes of this study to food allergy, food intolerance and coeliac disease (while acknowledging the latter as an autoimmune condition). Robust estimates are available for the prevalence of food allergy and coeliac disease on the IOI. Recent research has shown that food allergy rates, at least in the ROI, reflect those in the UK, namely 1 to 2% of adults and 5 to 8% of children (Bock, 1987; Jansen et al., 1994; Young et al., 1994; O'Donovan *et al.*, 2015). There is some evidence that food allergy is probably increasing in prevalence and severity (Remington *et al.*, 2015). The prevalence of coeliac disease is generally given as 1% of the population. Prevalence estimates are available for some food intolerances in the general population such as lactose intolerance at 5% (Fielding *et al.*, 1981). However, many other food intolerances remain un-defined and, as such, accurate estimates of their prevalence are not possible. Some authorities put the overall prevalence of food hypersensitivity at up to 35% or 40%. Despite this, it is only recently that the impact of food hypersensitivity on health and particularly on quality-of-life has been investigated.

The primary risk management strategy for the prevention of a food hypersensitivity reaction is adherence to an avoidance diet. This requires constant vigilance and consideration when purchasing pre-packed foods at retail level. Consumers with food hypersensitivity, and those who may be responsible for them, become avid readers of the label ingredients on pre-packaged foods. Some research has been done to understand how these consumers make purchasing choices. Do food hypersensitive consumers reflect society in general in this regard? Are they also utilising new methods of purchasing food such as distance or online market places? Whatever the method of food procurement, the principle of assisting consumers in making informed choices is always required.

Regulation (EC) 1169/2011 obliges food producers and providers to make available to their customers information concerning key food allergen ingredients both at the point of decision-making and when the food is delivered. However, the Regulation doesn't really address the issue of allergen cross contamination. This information is voluntarily provided by food businesses through the application of PAL. The absence of any consensus with regard to the wording of such statements is confusing for food hypersensitive consumers who must interpret what message is being conveyed as best they can. This limits their food choices and can lead to increased risk taking (FSAI, 2011).

This research sets out to investigate the factors that underpin the food purchasing choices of food hypersensitive consumers on the IOI including the obstacles they face in this regard and the level of trust they have in food suppliers. Their food hypersensitivity undoubtedly impacts significantly on their quality of life in

terms of social, dietary and psychological factors, and research that links together all the stakeholders involved on the IOI will benefit food hypersensitive consumers and improve food supplier best practice.

2 Research aims and objectives

Objective 1: To determine how food hypersensitive consumers on the IOI make food choices in an effort to adhere to an avoidance diet. The parameters that influence their food choices (cost, quality of the product, brand, labelling information, PAL) were also investigated.

Objective 2: To identify the obstacles they face in procuring appropriate food and the potential risk to health and impact on quality of life that these obstacles represent. Food comparisons were made for similar foods.

Objective 3: To identify the information sources that food hypersensitive consumers trust and depend on to procure appropriate food. The retail market place options available were ascertained as well as the mechanisms by which they obtained information about ingredients and possible allergen cross contamination.

Objective 4: To carry out an analysis of the free-from food market, the effectiveness of PAL and the allergen testing capacity on the IOI.

3 Recommendations

1. Food hypersensitive consumers are interested in both the health benefits and safety of foods so labelling that addresses both concerns will be helpful to these consumers. Improved understanding in this area could prove beneficial for both consumers and the food industry.

2. Labelling as a means of communication must address the issues that are important to consumers. The regulatory framework needs to be sufficiently flexible to remain relevant to consumers and to facilitate new research, new ways of communicating risk and new technology.

3. Food businesses should consider if their products could carry the "free-from" label advisory. This may necessitate structural changes at production level to reduce the risk of allergen cross contamination even further but would also reduce their reliance on PAL. The cost-benefit analysis of doing so is something each food business operator has to consider on a case-by-case basis.

4. Efforts to establish allergen thresholds and eliciting doses are ongoing. However, if there is confusion or uncertainty on the part of the food hypersensitive consumer, they may reject the idea without considering the implications in full. These consumers should be kept fully informed of developments in this area.

5. Involving food hypersensitive consumers in the consultation elements of the process for defining food labels would help reduce any uncertainties in accommodating end user needs and assist food businesses in designing trustworthy and effective labelling.

6. In relation to allergen testing, there will be a need for better analysis to support allergen thresholds. This entails the availability of reference materials and further investigation and manufacturer/user collaboration in dealing with extraction and recovery issues, matrix interferences and cross reactivity of allergens. A need for greater clarity from ELISA kit manufacturers on such issues is required for all forms of analysis in the area.

7. The potential for online shopping forums/marketplaces as a means to communicate allergen content should be investigated. Comparative research between online (including phone and tablet) and other

shopping methods in terms of convenience, ease of understanding the label, cost, etc. would be informative.

4 Research methods

4.1 Understanding the needs, expectations and barriers faced by food hypersensitive consumers in purchasing safe food

4.1.1 Literature review on choices, barriers and life quality impact of food hypersensitive consumers

Databases explored for the search were PubMed, Science Direct, Embase and Google Scholar. Articles in English language were selected and included only those which were published between 2004 and April 2015. Articles were based on consumers with a) food allergy: b) food intolerance; c) coeliac disease, and d) food hypersensitivity (mixed samples were selected). Study designs involving quantitative, qualitative and mixed methods were considered. Papers and abstracts chosen for the literature review are listed in Appendix A.

4.1.2 Ethical permission for the online survey

An application was made to the School of Applied Psychology in University College Cork for permission to carry out the online survey. Section 1.3 (*Informed Consent and Freedom of Consent*) of the Psychological Society of Ireland's Code of Professional Ethics was adhered to and survey respondents consent recognised and assented their consent by clicking 'Next' at the end of the first page of the online survey (Psychological Society of Ireland, 2010). Section 1.3.4 on '*Ethics*' was also upheld by the provision of information in an easily understood language form on the study and process of completion. In line with Section 1.3.5, respondents were made aware of the purpose and nature of the survey and the choice to withdraw from the study at any time, without prejudice. In line with Section 1.2, respondents were informed, prior to completing the survey, that their identity and information would remain confidential.

4.1.3 Recruiting food hypersensitive consumers for the online surveys

An *a priori* G-Power analysis was conducted to determine the sample size needed and produced a minimum of 138 respondents needed for this analysis. Respondents were recruited from several universities on the IOI by email request (which is described in detail in the following sections). Social media was also harnessed for this purpose (Appendix B). Details of the surveys and the questionnaires are listed in Appendices C-I.

4.1.4 Market analysis of the availability of free-from foods on the island of Ireland

Governmental organisations, trade and trade support organisations' (FSA, Invest NI, Enterprise Ireland, NIFDA, etc.) databases were accessed in person and/or electronically when possible in order to identify and collect relevant information of availability of free-from foods on the IOI. In addition, market reports from credible sources were obtained, analysed and critiqued accordingly.

5 Research outcomes

5.1 Understanding needs, expectations and barriers of IOI consumers who follow an avoidance diet in purchasing safe food.

5.1.1 Literature review on choices, barriers and life quality impact of food hypersensitive consumers

An initial search from different databases generated 110 articles. After screening both abstracts and references, 30 articles were deemed eligible for the systematic review.

5.1.1.1 Prevalence of food hypersensitivity

Food Hypersensitivity is an important public health issue. A growing number of families live with food hypersensitivity on an everyday basis and the number of individuals suffering from these conditions is on the rise. The exact incidence of food allergy on the IOI is unknown but is likely to be similar to that in the UK (Cummings *et al.*, 2010). Survey research and opinion based research tend to overestimate the incidence of food allergy and intolerances; however it must be kept in mind that, even if self-diagnosed, if consumers live 'as if' they have hypersensitivity they therefore impose upon themselves the same everyday challenges when purchasing food as those who have been medically diagnosed.

Food intolerance and non-IgE mediated allergies are less well defined and therefore more difficult to diagnose. Symptoms of food intolerance usually affect the digestive system or skin and often involve delayed responses occurring some hours following ingestion of the offending food. Symptoms can range from the mild, e.g. reflux, bloating and constipation to severe e.g. persistent vomiting or diarrhoea, faltering growth, etc. (Lomer, 2015).

5.1.1.2 Legislation and labelling

As modifying one's diet through avoidance of the trigger food(s) is the only way to manage food hypersensitivity, communication of potential risk or safety via e.g. 'labelling' is a central consideration when purchasing food, eating out or visiting family and friends. Therefore, understanding how consumers perceive and handle risk is central as confusion and uncertainty towards food labelling has been found to have a negative impact on health-related quality of life (DunnGalvin *et al.*, 2007).

When purchasing food, consumers who have food hypersensitivity are influenced by many factors which contribute to their decision-making. Precautionary or 'free-from' labelling is one such factor. According to the *Food Information for Consumers* Regulation (Regulation (EC) 1169/2011), the presence of any of 14 allergen groups (peanuts, tree nuts, milk, soya, mustard, lupin, eggs, fish, molluscs, crustaceans, cereals containing gluten, sesame seeds, celery and sulphur dioxide) as ingredients in pre-packed food must be declared (Regulation (EU) No 1169/2011). The importance of labelling and information provision can further be seen by the requirement of this mandatory disclosure to be extended to include non-pre-packed foods from December 2014.

Non pre-packed refers to foods that are sold loose for instance in catering establishments (restaurants, cafes, canteens, delicatessen, in-store bakeries, etc.).

Many food producers use PAL (e.g. "may contain .....") to alert consumers to the possible unintended presence of allergens. The use of PAL is voluntary and not covered specifically by existing legislation although it has been argued that general food safety law applies. PAL was initially welcomed by food hypersensitive consumers but has been devalued through perceived over-use and inconsistent application (Voordouw *et al.*, 2012). As a method of communication relating to decisions around whether or not to purchase a product, PAL has limitations which can act as barriers to making an informed choice. The Food Safety Authority of Ireland (FSAI) conducted a survey in 2011 which found that 94% of foods with PAL did not contain detectable levels of the allergen referred to on the label (FSAI, 2011). The survey results also showed that the overuse of PAL could further limit an already restricted diet or, more seriously, eventually lead consumers to ignore the advisory altogether and take more risks when choosing food products. Two further studies, conducted in the Netherlands and Australia found that consumers feel that the information provided on the labels is unclear or insufficient, resulting in personal distress and feelings of insecurity. Although consumers favour including the maximum amount of information on a label believing that this will lower the risks, in practice they find this information frustrating when actually buying a product (Cornelisse-Vermaat, *et al.*, 2007; Zurzolo, *et al.*, 2013).

Shopping for food can therefore be a stressful event, particularly if the labels themselves are unclear or confusing. Consumers, particularly those with food allergy, have been found to dislike PAL because they are uncertain about the basis for its use, they are cynical about the reasons it is used by food manufacturers and it reduces their food choices considerably (Cochrane, *et al.*, 2013). Thus, consumers have a dilemma: observe the labelling and face a much reduced choice, or ignore it and risk a reaction to the food. This hazard-based approach to allergen management can also cause problems for the food industry by driving the implementation of measures which may go beyond what is necessary to make food safe for food hypersensitive consumers, leading to a climate of uncertainty for consumers, clinicians, regulators and industry.

PAL is intended to inform consumers with food hypersensitivity of a risk of reacting to a product. Many consumers erroneously believe that such labelling is regulated and mandatory. This perception drives consumer beliefs that variations in labelling statements reflect a hierarchy of risk of reaction, for example, that 'may contain' indicates a higher risk than 'may contain traces (Pele, *et al.*, 2007; Barnett, *et al.*, 2011a). A study in 2010 involving teenagers revealed that they avoid 'may contain' labels depending on the wording (Monks, *et al.*, 2010). However, in reality, there is no relationship between the risk of contamination and the wording employed (Hefle, *et al.*, 2007).

Many consumers believe that PAL refers to the unintended presence of allergen which is either consistently present in the products or present only in "trace" amounts. So, when a product does not cause a reaction, consumers assume that the product is 'safe' or they can tolerate traces of that allergen. This can lead to unintended risky behaviour when consumers continue to freely consume the product. Confusion can also arise when food manufacturers suddenly introduce PAL on a product. Some consumers may consider the change has been made purely for product liability reasons to protect the food manufacturer and so ignore the warning (Barnett, *et al.*, 2011b). All this creates confusion, mistrust and ultimately anxiety. Consequently, it is difficult

for consumers to make an informed choice as to whether or not they should be eating specific food products. Many people just disregard PAL entirely (Pitchforth, *et al.*, 2011).

Research over the last decade has shown that many accidental exposures occur due to poor labelling and information provision practices (Sheth, *et al.*, 2010). As the theory of 'choice under uncertainty' suggests, consumers evaluate products on the basis of a few principal attributes and each represents a potential source of risk (Anand, 1993). For those with food allergy, higher risk is associated with labelling where the description is complex and/or unclear. This absence of simplicity suggests a lack of appreciation regarding the potential difficulties experienced by such consumers. Furthermore, inconsistency in application of PAL by food producers makes labelling itself a significant source of uncertainty with direct effects on perception of control and trust, and indirect effects on emotional adjustment, social interaction, coping strategies and quality of life (Whitaker, *et al.*, 2009; Roma, *et al.*, 2010; DunnGalvin, *et al.*, 2013). As already discussed, the perception that PAL is used as a 'safety net' by manufacturers can lead, in a search for control, to increased consumer anxiety and to avoidance of many products that may in reality be safe for them to eat. This perception may also lead to avoiding or limiting social activities (birthday parties, weddings, travel, etc.).

5.1.1.3 Attitudes towards food hypersensitivity

As mentioned earlier, the theory of choice under uncertainty implies that the attitude an individual has towards risk is strongly predictive in a variety of contexts of individual consumer behaviour. A lack of confidence in the usefulness of labelling can lead to deliberate risk-taking behaviour such as disregarding all labelling (DunnGalvin & Hourihane, 2009). Many consumers with food hypersensitivity, and particularly food allergy, take deliberate risks (Gallagher *et al.*, 2011; Zurzolo *et al.*, 2013). Risk taking behaviour is directly influenced by how the risk is perceived (Sampson *et al.*, 2006). More than half of the respondents in that study had knowingly eaten a small amount of allergen-containing food because they had previously eaten that particular food without having a reaction, they really wanted to eat the food, they were reluctant to ask questions, they were curious or were subjected to peer pressure. This is particularly true for teenagers; in a 2010 study, more than 50% of the sample cohort admitted trying a food that may have contained the allergen they had to avoid (Monks *et al.*, 2010). Some reported that they taste a small amount of such food and wait to see what happens which, in a sense, is a case of trying to determine one's own 'threshold'. Food sanitation knowledge, attitudes and behaviour were investigated among university restaurant employees. The author found that knowledge did not always lead to positive change in terms of food handling behaviour and that attitude to food allergy was the most significant influence on positive practices, more so than knowledge or training (Choi, 2012). This supported previous findings which showed that increased knowledge did not always translate into good food safety practices (HenROId & Sneed, 2004; Abbot, *et al.*, 2007; Roberts, *et al.*, 2008). It has been suggested that a model for improving appropriate food handling practices in foodservice environments that incorporates food safety management programs that take workforce value, beliefs and behaviours into consideration, could be transposed into food labelling practices (Yiannas, 2009; Griffith, *et al.*, 2010). Therefore, augmenting the effectiveness of food labelling will not be achieved by simply increasing knowledge about the labels, but by changing consumer attitudes by highlighting the consequences of risk-taking behaviours.

5.1.1.4 Food allergic and food intolerant consumers

Although both conditions fall under the umbrella of food hypersensitivity, adverse reactions to food have been found to be different for food allergic and food intolerant consumers in some contexts. This has been shown to have an effect on different areas of food hypersensitivity research. For example, a comparative study between food allergic and food intolerant diners found that food allergy respondents were less adventurous when eating out and less positive about eating out (Barnett *et al.*, 2011c). The influences on food choices of food-allergic and intolerant consumers was investigated in a series of focus groups (Sommer *et al.*, 2012). Food allergic respondents expressed less satisfaction and pleasure from food, experienced more difficulties finding appropriate food, and felt they needed to be more organised when eating. It is important to note that other variables not measured in this study, including age, gender and level of education, may have influenced the differences found between food allergic and food intolerant consumers in terms of their behaviour and perception.

5.1.1.5 Consumer choice & risk reasoning (product qualities and cues)

Consumers respond to uncertainty around labelling by being very selective in their food purchases giving rise to extra costs, anxiety and impaired quality of life (Voordouw *et al.*, 2010). Consumers evaluate products on the basis of a few principal attributes and each represents a potential source of risk. Among food hypersensitive consumers, products that are viewed as particularly risky include: baked goods, chocolate, cereals, desserts, processed or ready-made meals; with fresh vegetables, fruit, and dairy being seen as less problematic. With regard to brand, well-known and reputable brand names are more trusted than less well-known brands because they are perceived to be associated with more stringent safety standards during the manufacturing process. Large companies such as chain supermarkets are more trusted because they are perceived to be strongly motivated to protect their reputation and are assumed to have enough resources to carefully check the products for ingredients (Barnett *et al.*, 2011c). Food hypersensitive consumers seem to prefer venues where they have more choice and control and street food stalls were the least popular locations for buying food.

5.1.1.6 Consumer choice & risk reasoning (psychological and social factors)

The theory of 'choice under uncertainty' suggests that the attitude an individual has towards risk is strongly predictive of consumer behaviour. The proliferation of PAL, together with its unexpected appearance on different food products, has led to a loss of credibility and reduced observance by food hypersensitive consumers (Pele *et al.*, 2007; Sheth *et al.*, 2012; Cochrane *et al.*, 2013). There is a clear relationship between the extent to which PAL is used and the extent to which it is observed by consumers (Crevel, 2013). Since risk perception is unique to the individual, observance differs for parents, children, adolescents and adults. As with the general population, research in food hypersensitivity tells us that adults are more cautious in their everyday lives when they become parents, while teens are generally the least cautious. Higher risks are associated with labelling where the description is complex and/or unclear or there is a lack of awareness regarding food preparation. This absence of simplicity suggests a lack of appreciation of the potential difficulties experienced by those with food hypersensitivity.

Risk taking behaviour by food intolerant consumers, including non-adherence to their avoidance diet, is influenced by how complex this strategy is, their options in this regard and whether or not they have a chronic

illness (DunnGalvin & Hourihane, 2009; Zurzolo *et al.*, 2013). These consumers may also avoid more products than are necessary due to risk beliefs, including, e.g. products containing oats, starch and some types of alcohol, and also cosmetics and toiletries for coeliac disease sufferers. Therefore, subjective perception of risk often driven by word of mouth (and often online) can influence purchase choice, even when labelling is directive and relatively simple.

There is no or little research on how consumers balance competing values in decision making and what the outcomes of this 'balancing act' might be in terms of choice and consequent risk. Furthermore, there is a paucity of research on the impact of physiological or psychological factors on food purchase choices by in food hypersensitive consumers, although general consumer research on decision making suggests that stress, tiredness, hunger, embarrassment, time constraints, risk orientation, together with personality, age and gender are likely to impact or moderate risk perception, choice and behaviour.

Quality of life & well-being

Some of the strongest and most adverse impacts on health-related quality of life relate to social and dietary restrictions, including fear of new foods, new people, new places and concerns around labelling (DunnGalvin *et al.*, 2007; Flokstra-de Blok, *et al.*, 2008; DunnGalvin *et al.*, 2010). In Italy, 20% of young children with food allergy have never attended a birthday party (Kerbach *et al.*, 2010). Data from an ongoing Food Allergy Research and Resource Program (FARRP) study involving an online survey and focus group interviews with over 500 parents, teenagers, adults and clinicians from Ireland, the UK and the USA, suggests that aligning PAL statements with level of risk would greatly enhance patients' management of food allergy by allowing them to make informed decisions (DunnGalvin *et al.*, 2013). The majority of parents, teens and young adults agreed that it would be 'very useful' if 'there was some level or hierarchy of risk implied by labelling' linked to current labelling practice. It is important to note here that the level of understanding and how accurately communication matched consumer concerns both influenced the level of acceptability of labelling based on allergen thresholds.

Restrictions on diet affect extracurricular activities. Many individuals and parents avoid enjoyable activities like dining out, travelling and shopping. Anger, embarrassment, feelings of frustration, and anxiety are some of the psychological outcomes of having to live with food hypersensitivity (Rashid *et al.*, 2005; Whitaker, *et al.*, 2009). One study reported that 20% of the food hypersensitive population felt different from others because of their condition (Altobelli *et al.*, 2013). Although the majority of the respondents had successfully adjusted to their condition, one-third felt angry about having to follow a strict diet and also embarrassed at having to, e.g. bring gluten-free food to social occasions such as friends' parties. Studies also show that gluten free products are more expensive than their wheat-based counter parts and that adherence to a gluten free diet causes a negative impact on health-related quality of life (Rashid *et al.*, 2005; Lee *et al.*, 2007; Ozola & Straumite, 2014).

Labelling Preferences

In general, the selected studies show that consumers with food hypersensitivity are not satisfied with current labelling. 40% of respondents with food allergy rated labelling characteristics as a 'serious' or a 'very serious' problem with particular concerns relating to different terms or technical words for ingredients, changes in

ingredients, source of ingredients, spices and flavours not denoting allergenic ingredients (Cornelisse-Vermaat *et al.*, 2007; Vierk *et al.*, 2007). Although food hypersensitive consumers want to make appropriate food choices, the evidence suggests they appreciate the implausibility of reducing risk to zero (Roma *et al.*, 2007). In common with the general public, these consumers become confused by too much information although, paradoxically, the maximum amount of information is seen as minimising risks at purchase. Thus, it may not be the amount of information *per se*, but how it is presented and flagged in a user friendly format that may be the important criteria in terms of acceptability of a particular label type.

5.2 Behaviour, practices and barriers of food hypersensitive consumers when procuring food: the 'efficiency of food labelling' online survey

5.2.1 Demographic characteristics

652 people responded to the 'Efficiency of Food Labelling' online survey used in this study (Appendix C). Of these, 623 fully completed the survey (95% response rate). The majority of respondents (83.9%) were female (N = 523). Respondents were aged between 15 and 73, with a mean age of 37. (Table I, Appendix D).

Of the total respondents, 19.3% reported having a food allergy, 43.7% reported a food intolerance and 13.4% coeliac disease, while 25% of respondents in this study were also parents of children with either food allergy (54%) or intolerance (46%). 65.2% of respondents reported having had a previous reaction to an allergen while 20.6% did not. The majority of respondents were born on the IOI (79.8%). In total, 48.5% of respondents reported having being diagnosed by a specialist, general practitioner, nutritionist, dietician or alternative practitioner, while 19.5% stated they were not diagnosed by any of the above.

5.2.2 Descriptive statistics

5.2.2.1 Where do respondents shop most frequently?

Respondents were presented with a number of shopping locations and asked how often they shop at each. A 5-point scale was used ranging from 1 (never) to 5 (always). Respondents stated that they shopped in large supermarkets, such as Tesco or Supervalu and budget supermarkets such as Aldi and Lidl 'most of the time'. Respondents also stated that they 'rarely' shop at medium supermarkets, corner shops, premium shops and food stalls. Finally, respondents stated that they 'never' shop online. The full range of responses is presented in Table II Appendix D.

5.2.2.2 Which precautionary allergen label wording have respondents most confidence in?

Respondents were presented with five common PAL wordings and asked to rate them in order of confidence in their assurance of safety where 1 was most confident and 5 the least confident. "Not suitable for someone with X allergy" was the label type with which respondents were most confident. The second preference was for "May contain traces of X", followed by "May contain", and "Packaged in a facility that also processes X". "Manufactured on equipment that process X" was the label type respondents most frequently rated as inspiring the least confidence. Thus, the more direct and explicit the PAL, the more confident consumers are in using them. Confidence decreased as PAL wording became more 'vague'. The full range of responses is presented in Table III Appendix D.

5.2.2.3 How do respondents decide whether a food product is safe to eat or not?

Respondents were presented with ten characteristics that aid decision making as to whether or not a food product is safe to eat. They were asked to rate the importance of each of these factors with 1 being the most important and 10 the least important. "Quality of Labelling" and "I have eaten it before and not experienced a reaction" were the characteristics respondents most frequently rated as being most important. These were followed, in descending order, by 'Brand trust', 'Trust in supermarket', 'Freshness', 'Brand from well-known producer', 'Smell of product', 'Taste' and 'Texture'. 'Country of Origin' was rated least important. The full range of responses is presented in Table IV Appendix D.

As noted in the literature review, consumers evaluate products on the basis of a few principal attributes and each represents a potential source of risk or safety. Factors that affect food choice and purchasing behaviours include prior experience, brand trust, product and venue cues, and country of origin. These factors are used to aid decision making. Labelling is the most important characteristic that aids decision making in whether a product is safe to eat.

5.2.2.4 What are the characteristics of food labelling that are most helpful for consumers when deciding to purchase a food product?

Respondents were presented with seven labelling characteristics and asked to rate how helpful each was when deciding to buy a food product (1 = most helpful and 7 = least helpful). "Easy to read" and "Visible" were the characteristics respondents felt were most helpful. These were followed, in descending order, by 'Font', 'Size of letters', 'Size of label', and 'Colour or lettering on label'. "Country of Origin" was the characteristic respondents felt was least helpful. The full range of responses is presented in Table V Appendix D.

In the following analysis, it is important to note that we controlled for type of food intolerance (e.g. coeliac disease, lactose intolerance, etc.) and type of food allergy (peanut, milk, multiple, etc.). This was done in order to directly compare the groups in terms of their preferences, food choices and attitudes towards labelling.

5.2.2.5 A comparative analysis between food allergy and food intolerance on shopping preference, food choice, use, and attitudes towards labelling

The relationships between type of food hypersensitivity, age and eating preferences were investigated. The independent variables were 'age', which had 3 levels (15–30, 31–45, and 45 +) and 'food hypersensitivity' which had 2 levels (food allergy and food intolerance). Scores on various food choice statements were used as dependent variables. These were the importance of food being: (i) safe, (ii) nutritious, (iii) helping to control weight, or (iv) whether or not respondents were concerned about the effects of food on their health. Table VI Appendix D shows the detailed results.

Results showed that respondents of the age group 15-30 years old reported significantly lower scores on the importance of food being safe than those of the 31-45 age group and the 45+ age group. There was no significant difference in scores on this preference between the 31-45 and 45+ age groups. Therefore, respondents over 30 years of age felt it was more important that the food they eat is safe compared to those under 30 years of age. Respondents aged over 45 years of age scored significantly higher on the importance of food being nutritious than those of the 15-30 age group and the 31-45 age group. There was no significant difference in scores between the 15-30 and 31-45 age groups. Therefore, respondents aged over 45 years of age

felt it was more important that the food they eat is nutritious compared to those under 45 years of age. There were no further significant differences between age group and the two remaining food choice options, 'control weight' and lack of concern about the effects of food on health. Each age group 'sometimes' feel it is important that a food helps to control weight; also, each age group were generally concerned about the effects of food on their health (see Table VII Appendix D).

There was no significant effect between food allergic and food intolerant consumers on any of the eating preferences or food choice scales. Both groups felt the safety of the food they eat was 'always important', and nutritious. Both groups also felt it was 'sometimes important' for food to help control weight, while both groups were rarely concerned about the effects of food on their health (Table VIII Appendix D).

It appears therefore that consumers with food intolerance are as cautious in their food choices as food allergic consumers. This is an important finding and suggests that more explicit and direct food labelling by food manufacturers would appeal to a wide range of consumers addressing both safety and nutritional concerns. Increasing age is associated with increasing caution, with those over the age of 30 responding that it was more important that the food they eat is safe and those over the age of 45 that the food they eat is nutritious, compared to younger age groups. When controlling for parents, however, this effect disappeared, suggesting that parents are responding on behalf of the safety of their children.

The relationship between food hypersensitivity, gender and eating preferences was also investigated. The independent variables were gender, which had 2 levels (male and female) and food hypersensitivity with 2 levels (food allergy and food intolerance). Scores on various food choice statements were used as dependent variables and were identical to those stated. Both males and females reported 'always' choosing food that is safe and nutritious, 'sometimes' choosing food to help control weight and were generally concerned about the effects of food on their health. These results are presented in Table IX Appendix D.

The relationships between food hypersensitivity, age and food labelling attitudes and practices were investigated. The independent variables were age, which had 3 levels (15–30, 31–45, and 45 +) and food hypersensitivity which had 2 levels (food allergy and food intolerance). Scores on various food labelling statements were used as dependent variables. These were; (i) how often people 'used' or attended to labelling, (ii) how influenced they were by labelling, and whether they found labelling (iii) reliable, (iv) adequate, (v) understandable and (vi) necessary.

Both food allergic and food intolerant groups regularly use labelling and both food allergic and food intolerant are regularly 'influenced' by labelling when deciding to buy a food product. Although food allergic and food intolerant consumers found labelling 'very necessary' (see Table X Appendix D), they were not satisfied with its reliability and adequacy. Respondents found labelling only 'somewhat' reliable, 'somewhat' adequate, and 'somewhat' understandable.

A similar pattern was shown in scores for labelling practices and attitudes with regard to age (Table XI Appendix D).

In examining the relationships between food hypersensitivity, gender and food labelling attitudes and practices, both males and females regularly use labelling and both are influenced by labelling when deciding to buy a food

product, reporting it as 'very necessary'. Both males and females found labelling 'somewhat' reliable, 'somewhat' adequate and 'somewhat' understandable. (See Table XII Appendix D).

Respondents were asked about their food preferences, attitudes and practices towards food labelling. In general, both adults (without children) and parents reported 'always' choosing food that is nutritious. They 'sometimes' choose food that helped to control their weight, and were mostly concerned about the effects of food on their health. However, there was a significant difference in the preference of food being 'safe' with parents reporting the necessity of foods being safe as significantly more important than adults without children. With regards to labelling practices and attitudes, both adults without children and parents reported 'sometimes' finding labelling reliable, adequate and understandable; they 'always' found labelling necessary. There was a significant difference in how often respondents used labelling when purchasing food, parents reported using or attending to labelling significantly more often than adults without children. Also, parents were significantly more influenced by labelling than adults without children.

With regards to any differences between those 'diagnosed by a health professional or specialist' vs 'self-diagnosed', both groups reported choosing food that is nutritious and helping to control their weight 'most of the time'. However, there was a significant difference in the preference for food being 'safe', those that were diagnosed by a health professional or specialist reported safety of food products as significantly more important than those that were self-diagnosed. Also, those that were diagnosed by a specialist scored significantly lower on not being concerned about the effects of food on their health compared to those who were self-diagnosed. However with regard to balancing competing values, although safety is the primary concern of those who were diagnosed, both groups were also interested in health benefits of food products suggesting that labelling that addresses both concerns could be helpful to a wide range of consumers. With regards to labelling practices and attitudes, again both groups reported 'sometimes' finding labelling reliable, adequate and understandable, while 'always' finding labelling necessary. However, there was a significant difference in how often respondents used or attended to labelling. Those that were diagnosed by a specialist reported using labelling significantly more often than those that were self-diagnosed. They were also significantly more influenced by labelling, compared to those who were self-diagnosed.

Respondents were asked the number of food allergens to which they react their responses were grouped into two choices of 1 or 2 allergens, and more than two allergens. Both groups reported choosing food that is nutritious, food that helps to control their weight 'most of the time', and 'rarely' were they not concerned about the effects of food on their health. However, there was a significant difference in the preference for food being 'safe', those that react to more than two allergens reported food safety as significantly more important than those that react to less than two allergens. With regards to labelling practices and attitudes, again both groups reported 'sometimes' finding labelling reliable, adequate and understandable, while 'always' reporting labelling to be necessary.

We found a significant difference in how often respondents used or attended to labelling, those that react to more than two allergens reported using labelling significantly more than those that react to less than two allergens they were also significantly more influenced by labelling compared to those who react to less than two allergens.

Respondents were also given a list of symptoms that they experience during a reaction and could choose more than one. The total number of symptoms associated with each respondent was then calculated and this was split into two choices of either one or two symptoms, and more than two symptoms. Both groups reported choosing food that is safe and nutritious, and were 'rarely' not concerned about the effects of food on their health. However, there was a significant difference in responses to the option of not being concerned about the effects of food on their health with those that experience more than two symptoms reporting lower scores on not being concerned about the effects of food on their health than those that experience less than two symptoms. There was a significant difference in how often respondents used labelling with respondents who experience more than two symptoms reporting using labelling significantly more often than those that experience less than two symptoms. Those that experience more than two symptoms were significantly more influenced by labelling when purchasing food, compared to those who report less than two symptoms.

Modelling was carried out to identify potential predictors and models of how often consumers use or attend to labelling when deciding to buy a food product. Participant's attitudes towards how much of a problem they felt food hypersensitivity to be in Ireland (*Problem*), how influenced respondents are by labelling when purchasing food (*Influence*), whether people understand labelling information (*Understand*) and the importance of food being safe (*Safety*) and nutritious (*Nutritious*) were used as the independent variables. All models controlled for type of hypersensitivity, number of symptoms, number of foods to which hypersensitive, age, parent/adult, diagnosis, level of understanding, and gender (Table XIII Appendix D).

The significant predictors of how often labelling is actually used, or attended to, are: (i) 'nutritiousness', (ii) 'safety', (iii) whether food hypersensitivity is regarded as a problem in Ireland by the consumer, and (iv) how much a consumer is influenced by labelling when choosing what product to purchase, with the last predictor having a very large effect and the greatest influence on purchasing decision making (Cohen, 1988).

Our model shows that in making a food choice/purchasing decision, although safety and nutrition is important for hypersensitive consumers, the most important predictor of how much labelling is used (over and above all other factors) is how much a consumer is influenced by labelling in general. This highlights the importance of focusing on creating useful and useable labelling formats that will be helpful to a wide array of consumers with hypersensitivity (whether clinically or self-diagnosed).

5.3 Experiences and lessons to be learned from other countries

5.3.1 Website information

To address this task, websites of European and worldwide patient support and non-governmental organisations for food hypersensitive consumers were accessed. Non-English websites were searched by the word 'labelling' translated into the relevant language as follows: Italian 'etichettatura', German 'Beschriftung', French 'étiquetage', Danish 'mærkning', Spanish ' etiquetado'. The websites of patient support organisations, for the most part, concentrate on medical and safety issues, including diagnosis, treatment and nutrition. The European websites have considerable amounts of information on EU Regulation 1169/2011. This regulation made

significant changes to allergen ingredient labelling but doesn't really address cross contamination issues other than to permit the European Commission to make laws on the matter in the future. Anaphylaxis Australia Inc (AAI) conducted a member survey in 2003 in which 15 responses (aged 22 – 57 years) were recorded. Response rates were 98% or greater to individual questions. The information obtained indicated allergen labelling was not easy to understand (65%), did not give enough information about allergens (86%), and could not be understood by a seven year old (93%) or a babysitter (84%). AAI members would not purchase a food if there was no ingredient label (98% although this dropped to 76% if from a deli or bakery), if the labelling was in a foreign language (99%), or from the internet if not labelled (99%). AAI members phoned food manufacturers for more information 81% of the time but with mixed satisfaction (61% satisfied, 21% not satisfied). The AAI members who responded were characterised as follows: the age of the most severely allergic individual was 4 – 11 years, the allergies were peanut (87%), tree nut (53%), egg (40%), milk (23%), sesame (16%), shellfish (10%), soya (9%), fish (7%) and 'other (17%). The 'other' included (number of responses) wheat (11), kiwifruit (7), beef, banana (5), potato, peas, beans (4), rice, cashews, lentils (3), coconut, chicken, strawberry (2), orange, meat, corn, salicylic acid foods, lamb, cauliflower, rye, oats, pork, avocado, pumpkin, echinacea, gluten, preservatives, cocoa, nectarine, blackcurrant, Brussel sprouts, mango, watermelon, cherry, pawpaw, seeds, chickpeas (1). Latex was also identified by seven respondents and a number of respondents reported an allergy to different antibiotics. Exploring scenarios when people with allergies would purchase food, the survey found aversion when a label giving the information that the food contained an allergen (96% avoidance). 'May contain' was avoided by 80%. There were decreasing indications of purchase to PAL as described in Table 1. The research included questions on the medical treatment and noted that 32% had had a reaction to an ingredient that did not appear on the food label. Respondents commented on the plethora of PAL and expressed a desire for standardisation.

Table 5.1: Anaphylaxis Australia Inc survey results on PAL*

Precautionary allergen labelling	Never buy	Sometimes buy	Always buy	No response
Manufactured on Shared Equipment with products containing Allergen	79%	17%	< 1%	3%
Manufactured on the same equipment as products containing Allergen	77%	19%	1%	4%
Manufactured on a line that Processes products containing Allergen	76%	19%	1%	4%
May Contain Traces of Allergen	57%	36%	4%	3%
Manufactured in a Facility that Also uses Allergen	53%	41%	3%	3%

Packaged in a facility that also packages products containing Allergen	50%	42%	4%	4%
Manufactured on Shared Equipment with products containing Allergen	79%	17%	< 1%	3%
Manufactured on the same equipment as products containing Allergen	77%	19%	1%	4%
Manufactured on a line that Processes products containing Allergen	76%	19%	1%	4%
May Contain Traces of Allergen	57%	36%	4%	3%

(*http://www.allergyfacts.org.au/images/pdf/AAI%20Food%20Labelling%20Survey%202003.pdf)

The AAI endorses the Australian Allergen Bureau VITAL® (Voluntary Incidental Trace Allergen Labelling) system (Allergen Bureau, 2016). This is an industry-led voluntary standardised allergen risk assessment tool for food producers. VITAL® allows food producers to assess the impact of allergen cross contact and provide appropriate PAL on their products. It is the only industry initiative to articulate allergen thresholds of elicitation thereby giving a concrete risk management tool to decide when PAL is unavoidable. PAL should only be used after a thorough assessment of the risk of allergen cross contact. The Allergen Bureau emphasised that PAL statements must never be used as a substitute for good manufacturing practice (GMP) or as a generic disclaimer. Every attempt must be made to eliminate or minimise cross contact by adhering to GMP (Allergen Bureau, 2015).

The website of the Italian patient support organisation does not include any reference to PAL research but contains the following information in English:

> "The core problem comes from the search for alternative food substitutes, mainly due to legal issues, and therefore the food industry has been increasingly relying upon the issuing statements such as "could contain traces of" (può contenere tracce di) or "product manufactured where X is also used" (prodotto in uno stabilimento dove si lavora anche con X) to indicate the possibility of cross-contamination through the list indicated in the European directive 2007/68/EC."

This indicates qualitatively that Italian consumers on an avoidance diet face similar problems to those in the UK/ROI or Australia. The FARE website (USA) included the following information:

> "*May Contain" Statements*. The use of advisory labelling (i.e., precautionary statements such as "may contain," "processed in a facility that also processes," or "made on equipment with") is voluntary and optional for manufacturers. There are no laws governing or requiring these statements, so they may or may not indicate if a product contains a specific allergen. According to the US Food & Drug Administration's guidance to the food industry on this issue, advisory labels "should not be used as a substitute for adhering to current good manufacturing practices and must be truthful and not

> misleading." If you are unsure whether or not a product could be contaminated, you should call the manufacturer to ask about their ingredients and manufacturing practices." FARE's research strategy focuses on deeper understanding of the disease including prevalence and acceleration of the development of safe, practical therapies.

It does not appear to include research on PAL.

5.3.2 Questionnaire information

A simple descriptive unstructured questionnaire (not assessed for bias) was developed and circulated to European Patient Support Organisations in Belgium, Denmark, France, Germany, Greece, Italy, Norway, Spain, Sweden and the UK, as well as the European Federation of Allergy & Airway Diseases Patients Association. The information was collated and evaluated to assess if there are any learnings from overseas consumers that would benefit their counterparts on the IOI.

Only one questionnaire was returned from the UK Anaphylaxis Campaign (UKAC). The return was concerned with avoidance diets associated with IgE mediated food allergy and did not cite a study but relied upon anecdotal information from UKAC members. The overall view was that it is not easy for people with IgE mediated food allergy to eat safely. The reasons given were:

- A lack of knowledge and understanding in some catering outlets resulting in incorrect and dangerous information being given;
- A lack of knowledge and understanding amongst some members of the general public;
- Inconsistencies in PAL. Food allergic shoppers don't know whether to trust such warnings and as a result may take risks

The UKAC considers that food producers and supermarkets can improve products by only using PAL where there is a genuine risk of contamination and after a thorough risk assessment. The questionnaire is detailed in Appendix E.

5.4 Market and industry analysis of foods available to food hypersensitive consumers on the IOI.

5.4.1 Market size for free-from food products and growth predictions

An investigation on the extent of prepacked 'free-from' foods produced on the IOI, and the associated export potential, was carried out by reviewing high quality business reports for data on growth projections for specific food sectors, export potential for specific countries and other relevant information. In general, the information that was available was limited.

5.4.1.1 Sales value of Free-from food on the IOI

A significant growth in the sales of free-from products was observed between 2009 and 2014 in IOI, with ROI accounting for approximately 73% of the market. It was estimated that an increase of approximately 37.5% occurred (2009-2014) and projections show (Figure 1) that sales will double in size by 2019, reaching €63.6 million (Mintel, 2013; Mintel, 2014).

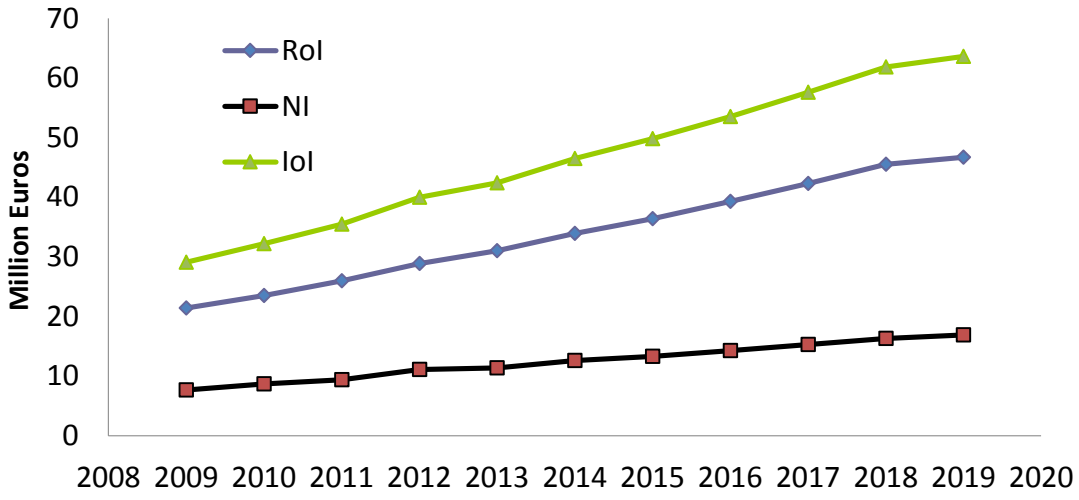

Figure 5.1: Market value of free-from foods on the IOI (2014: estimated, 2015: forecast; 2016-2018: projection)

5.4.1.2 Market share of Free-from food products

Data on market value show a substantial increase between 2009 and 2014 (estimated) of 59.79%. However, when compared to the overall grocery sales it accounted for less than 0.50% in 2014 (Table 2). Moreover, market values in NI showed a 53% increase between 2009 and 2014, reaching €12.6 million compared to €33.9 million for ROI which showed a higher growth of approximately 58% for the same period.

Table 2: Market share of free-from food and drink on the IOI 2009-14

	Free-from food	Overall grocery market	
	€m	€m	% of total grocery sales
2009	29.1	14,811	0.19
2010	32.2	14,698	0.21
2011	35.5	14,158	0.25
2012	40.0	13,575	0.29
2013	42.4	13,716	0.31
2014 (est)	46.5	13,828	0.34

The consumption of free-from products by consumers not suffering from food hypersensitivity and due to their perception that these products are healthier, or maybe just because it offers a lifestyle alternative, has helped to increase retail sales. Future growth is expected to be less pronounced, as the higher cost of some free-from foods will dissuade more non-hypersensitive consumers from buying these products (Mintel, 2014).

5.4.1.3 Levels of Free-from products launched in the UK and Ireland for the period 2007-2014

The highest launches of gluten-free and low/no/reduced allergen products were observed in 2013 (605 in total). Only data collected between January and August were available for 2014. Nevertheless, a relatively high number of free-from products had been launched by that point (although still only approximately half the volume launched in the same period in 2013) (Mintel, 2014). This increased the choices available to IOI consumers (Figure 2).

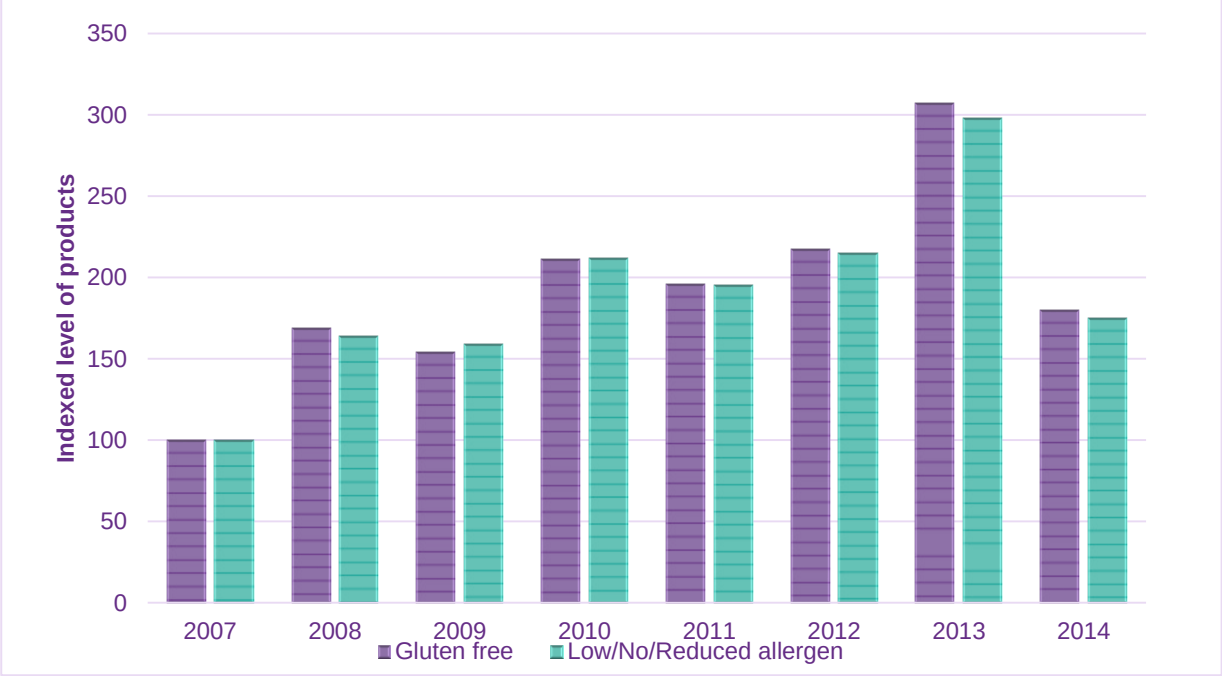

Figure 5.2: Indexed level of gluten-free and low/no/reduced allergen products launched in the UK and Ireland 2007- August 2014

5.4.2 The extent of prepacked 'free-from' food produced on the IOI and its export potential

5.4.2.1 Free-from products by category available in the ROI and UK markets

Data on the free-from products produced and available in IOI are very limited. The 2014 Mintel report presented information on the percentages of free-from products by category available in the ROI and UK. There are a variety of different product categories available to the consumer. Launches of new products are taking place every year in almost all categories. The *Snack* and *Bakery* categories have consistently dominated the free-from product launches for the period 2007-2014 (Table 3). Other important categories were *Dairy* and *Sauces & Seasonings*. *Baby Food Products* is the only category that has experienced a significant reduction during this period of around 56%.

Table 5.3: Gluten-free and low/no/reduced allergen products launched to the ROI and UK markets by product category 2007-August 2014

	2007 (%)	2013 (%)	2014* (%)
Snacks	15	11	14
Bakery	15	14	14
Dairy	5	11	11
Sauces & seasonings	14	13	10
Processed fish, meat & egg products	1	7	9
Baby food	16	9	7
Desserts & ice cream	5	4	5
Meals & meal centres	4	3	4
Side dishes	4	5	4
Chocolate confectionery	4	5	3
Other	17	18	19

The 49% of the *Snack* category was comprised of snack cereal and energy bars and fruit snacks. The *Dairy* and *Processed Fish, Meat & Eggs* categories have shown the highest increase in the number of products launched between 2007 and August 2014. This illustrates the increased importance of these categories. The *Processed fish, meat & eggs* category saw the strongest increase in the level of products launched between 2007 and August 2014 claiming to be free-from potentially harmful ingredients. *Processed fish, meat & eggs* offer meat-free and wheat free options. It appears that companies are responding not only to interest from consumers who do not wish to eat meat or those who may be hypersensitive to it, but are also increasingly launching products that are suitable for consumers with gluten or wheat intolerance issues (such as Marks & Spencer's *Made Without* range).

5.4.2.2 Number of low/no/reduced allergen and gluten-free products launched on the ROI and UK markets 2009-14

Table 4 presents the top 10 companies that launched products claiming to be gluten-free and low/no/reduced allergen in the UK and ROI during the period 2009- August 2014. This was primarily carried out by food retailers.

Table 5.4: Top 10 companies launching gluten-free and low/no/reduced allergen products in ROI and the UK 2009 - August 2014

Company	Code	2009	2010	2011	2012	2013	2014	Total
Low cost large retailer	R1	46	112	36	8	20	3	225
Premium product large retailer	R2	5	15	23	27	75	52	197
Average cost large retailer	R3	8	26	48	48	15	5	150
Multinational company specialising in soups, dressings and snacks	P1	14	22	14	22	25	11	108
Average cost large retailer	R4	31	34	21	4	6	9	105
Average cost large retailer	R5	8	15	18	11	16	20	88
Average cost large retailer	R6	2	17	24	3	23	5	74
Large private company with alternatives to milk, yogurt cream, meat and margarine	P2	1	14	10	17	14	7	63
Large company specialising in baby food products	P2	12	7	17	12	6	1	55
Large private company gluten free supplier	P3	6	12	11	1	-	-	30
Other		527	609	588	742	1,040	617	4,123
Total		614	771	774	887	1,220	727	4,993

The low cost retailer is the company with the higher launches for this period with 225 products in the market. The premium retailer has significantly increased the products launched making it the company with the higher number of product launches in 2013 and 2014. Between 2009 and August 2014, large retailers such as R1, R2, and R3 have been among the most active launchers of private label free-from gluten/allergens food products. However, branded products accounted for a larger part of the total free-from foods launched on the market, with specialist manufacturers (P1) being the most prolific launcher of branded free-from foods during the same period (Figure 3) (Mintel, 2014).

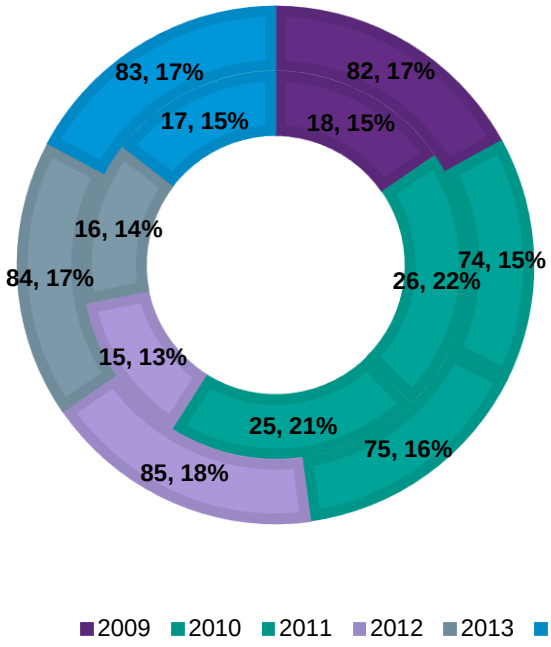

Figure 5.3: Products claiming to be gluten-free and low/no/reduced allergen, by private label and branded status, launched in the ROI and UK 2009-August 2014 (inner circle: private products from retailers; outer circle: branded products)

5.4.2.3 Free-from food products produced in ROI and the UK

The limited data available was supplemented by a survey (Appendix F). A questionnaire was distributed to food manufactures in ROI, NI and the UK in order to obtain a more in-depth understanding of this sector. The survey was administered by the online survey development cloud-based service SmartSurveyTM. The survey showed (Figure 4) that food companies in ROI and UK produced a wide range of free-from products. Each of the categories *Snacks, Bakery, Processed fish, meat & egg products, Desserts & ice cream, Meals & meal centres* are produced by approximately 17% of food companies with the *Snacks* and *Sauces & seasonings* produced by approximately 8%. The ''other'' category included, according to the replies of the respondents i) *Drinks* and ii) *Sandwich & salad* products. This market analysis shows a wide range of food products which is essential for the health and quality of life of food hypersensitive consumers.

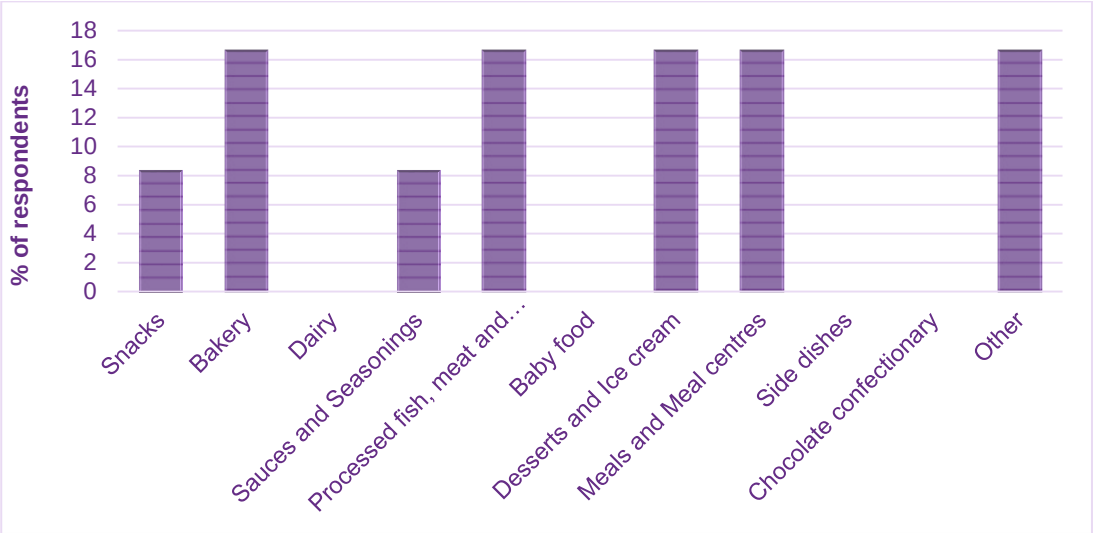

Figure 5.4: Percentages of respondents (food producers) producing free-from food products per category in ROI and the UK.

5.4.2.4 Export potential of Free-from food produced in the ROI and UK

Food producers were also asked if they were currently exporting any free-from products or were undertaking, alone or in collaboration with a trade and/or trade support organisation, any initiatives to do so in the next 5 years. The results are presented in Figure 5. 83% of food manufacturers in the ROI and UK said they have no plans to export their free-from products.

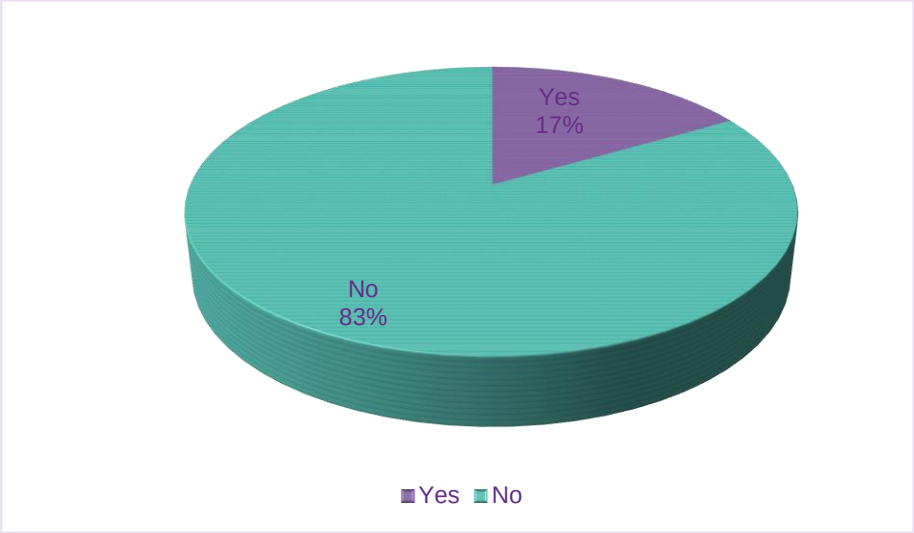

Figure 5.5: Initiative to export of free-from food products in the next 5 years

This indicates a limited export potential of these products from the IOI. Respondents were asked about the volumes of free-from products produced and the export markets for these. However, this was considered commercially sensitive and food businesses were not forthcoming with this information. The low market share for free-from food products on the IOI (< 0.5%) may well be reflected elsewhere and therefore selling into these markets is probably not viable.

5.4.3 Determination of the key factors that induce or oblige food manufacturers to apply precautionary allergen labelling

5.4.3.1 Factors that induce or oblige food manufacturers to apply PAL

In most countries, PAL is voluntary and not required by legislation (notable exceptions being Switzerland, Japan, Argentina and South Africa) (Allen *et al.*, 2014a). Thus, it can be assumed that the occasions when PAL may be used vary among food manufactures.

5.4.3.2 Factors - Evidence from scientific literature

The uncertainty over the risk posed even by very small quantities of allergen and its effect on consumers which has prompted many food manufacturers to provide advice as to the potential presence of allergens (Allen *et al.*, 2014b).

5.4.3.3 Factors - Evidence from food industry key executives

Insurance driven by cost of failure, i.e. the fear of litigation; plus restrictions on flexibility of future production: this concerns the enormous cost involved in changing the label in existing product lines in case a new production line containing potential allergens starts in the same factory.

5.4.3.4 Factors - Evidence from questionnaire sent to food manufacturers

In order to determine the key factors that induce or oblige food manufacturers to apply PAL, a survey was conducted in which food manufactures in IOI and the UK were asked for the reasons behind their company's decision to use PAL (Appendix G). Figure 6 presents the percentage of respondents for each of the factors/reasons underpinning the use of PAL. In many cases food manufacturers gave multiple reasons for using PAL.

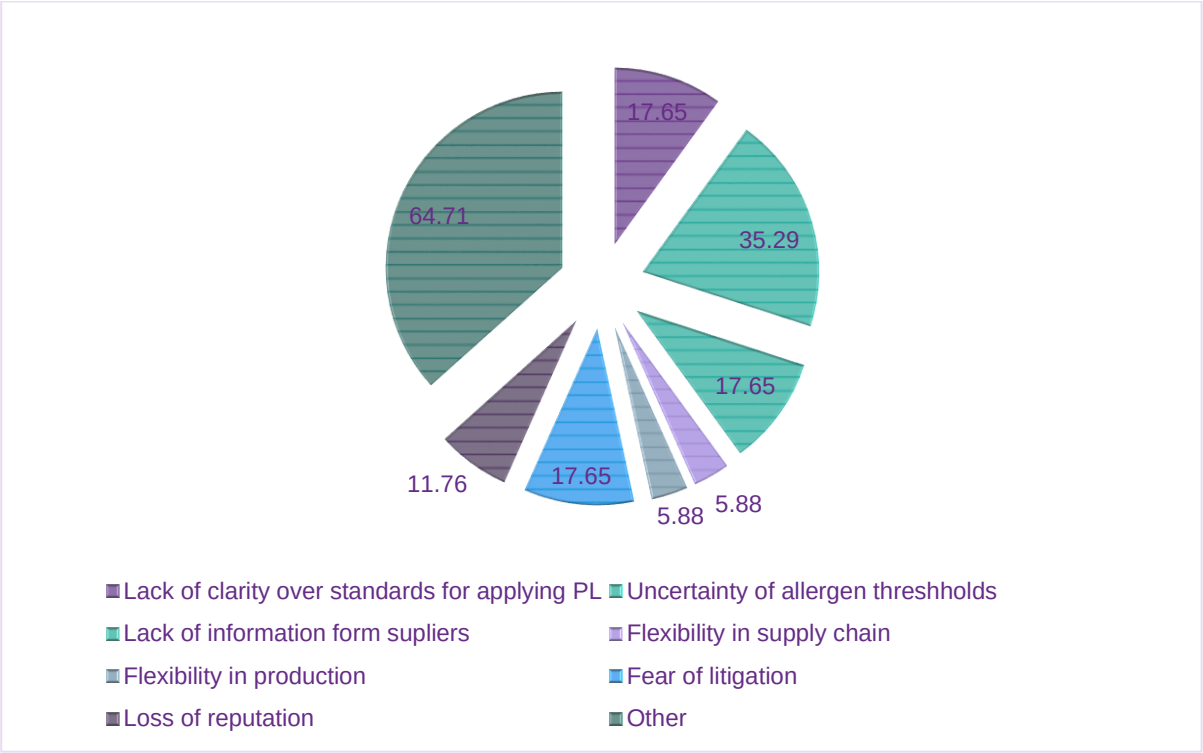

Figure 5.6: Key factors that induce or oblige food manufacturers to apply PAL

The *Uncertainty of allergen thresholds* category had the highest percentage (35.29%) followed by *Lack of clarity over standards*, *Lack of information from suppliers* and *Fear of litigation*, all with the same percentage (17.65%). Approximately 65% of respondents mentioned *Other* factors as well. This category included the following:

- Potential cross contamination in supply chain of raw materials and/or potential cross contamination on manufacturing plant.
- Need for healthcare professionals to be clear on risk
- Products are processed using the same equipment and equipment cannot be wet cleaned between batches.
- Unable to clean effectively in a dry environment.
- Food safety risk assessment determines that there is a risk of unavoidable cross-contamination.
- Precaution on human error in clean down.
- Good practise and legislation requirement.
- Ensure consumers are well informed and provide guidance if needed.

Based on these findings, there seems to be several factors that lead to the use of PAL with the most important being the uncertainty of allergen thresholds. Regulatory authorities and others have reported that although threshold doses for some allergens exist, such thresholds have yet to be defined (US FDA Threshold Working Group, 2008; EFSA, 2014). EFSA has comprehensively reviewed allergenic foods and food ingredients for labelling purposes, but declined to advocate any thresholds on the grounds that labelling and an acceptable level of risk

with regard to the level of protection for the food hypersensitive consumer, were risk management issues and therefore outside their remit.

5.4.3.5 Implementing PAL in food products

Participating food producers (n=26) were asked which allergenic/intolerance ingredient they use in their food products. Producers may use multiple allergens in manufacturing. Cereals containing gluten was used by approximately 80% of respondents. Milk and wheat were the second most used ingredients by around 65% of respondents. Sulphites, soybeans and eggs were also used by around 53%, 57% and 46%, respectively. Other allergenic ingredients were also used but to a much lesser extent including peanuts, tree nuts, celery, fish, shellfish and sesame. Respondents were also asked for which allergen they include PAL statements. 50% of respondents included PAL for milk while 44% included PAL statements for soybeans and 39% for cereals containing gluten and wheat. Mustard and celery were included the least in PAL statements (around 17% of respondents).

In order to obtain a clearer view on the decision process for making PAL statements, the following questions were asked of the food manufacturers:

(i) Did you go to regulators to ask for advice on finalising the label, and
(ii) Does the PAL wording comply with a defined standard (e.g. British Retail Consortium)

The results showed that 68% of food manufacturers that participated in this survey did not go to regulators to get advice on using PAL. Respondents relied on in-house expertise and knowledge. Furthermore, 83% of respondents said that the PAL wording they used complied with a standard (e.g. British Retail Consortium). PAL should only be used following a risk assessment when a risk of allergen cross-contamination is considered to exist and which cannot be eliminated. A proper risk assessment could potentially help in reducing the extent of PAL.

5.4.3.6 Available threshold status of specific food allergens

Setting clear allergen threshold data will provide food regulators and the food industry with a means toward the more effective use of PAL and more accurate allergen management plans. Table 5 presents the reference doses available in the scientific literature that have been obtained from human clinical data.

Table 5.5: Available reference doses for allergenic foods

Food	mg of protein	Reference	Food	mg of protein	Reference

Peanut	1.6*	Blom *et al.* 2013	Peanut	0.2 mg**	Taylor *et al.* 2014
Cow's milk	1.1*	Blom *et al.* 2013	Milk	0.1 mg**	Taylor *et al.* 2014
Hen's egg	1.5*	Blom *et al.* 2013	Egg	0.03 mg**	Taylor *et al.* 2014
Cashew nut	7.4*	Blom *et al.* 2013	Hazelnut	0.1 mg**	Taylor *et al.* 2014
Hazelnut	0.29*	Blom *et al.* 2013	Soybean	1.0 mg**	Taylor *et al.* 2014
Peanut	0.2**	Allen *et al.* 2014a	Wheat	1.0 mg*	Taylor *et al.* 2014
Cow's milk	0.1**	Allen *et al.* 2014a	Cashew	0.1 mg**	Taylor *et al.* 2014
Egg	0.03**	Allen *et al.* 2014a	Mustard	0.05 mg*	Taylor *et al.* 2014
Hazelnut	0.1**	Allen *et al.* 2014a	Lupin	4.0 mg*	Taylor *et al.* 2014
Hazelnut	8.5***	Ballmer-Weber *et al.* 2015	Sesame	0.2 mg*	Taylor *et al.* 2014
Peanut	2.8***	Ballmer-Weber *et al.* 2015	Shrimp	10 mg*	Taylor *et al.* 2014
Celeriac	1.6***	Ballmer-Weber *et al.* 2015	Celery	N.E.	Taylor *et al.* 2014
Fish	27.3***	Ballmer-Weber *et al.* 2015	Fish	0.1 mg (provisional)*	Taylor *et al.* 2014
Shrimp	2504***	Ballmer-Weber *et al.* 2015			

* Estimated dose for an allergic response to 5% of population

** Estimated dose for an allergic response to 1% of population

*** Estimated dose for an allergic response to 10% of population

N.E. Not established

Threshold doses for an allergic response to between 1 and 5% of the allergic population might be more appropriate basis for deriving action levels (Ballmer-Weber *et al*. 2015).

5.4.3.7 Mapping PAL information deriving from the literature against those encountered on foods available on the island of Ireland market

The PAL information deriving from the literature was mapped against those encountered on foods available on the IOI Market. Therefore, survey respondents were asked about the form of words they use for PAL statements in their products (Figure 7). There was a wide range of PAL statements used on the products available on IOI. The 'Other' option had the highest percentage of responses (26%) with 'may contain X' and 'may contain traces of X' at 21.8% and 17.4%, respectively. The 'Other' option included the following:

- Contains X
- X product contains X
- May also contain X
- Made in a factory that does not handle X
- Cannot guarantee free-from all traces of X
- Allergens are highlighted in bold and underlined

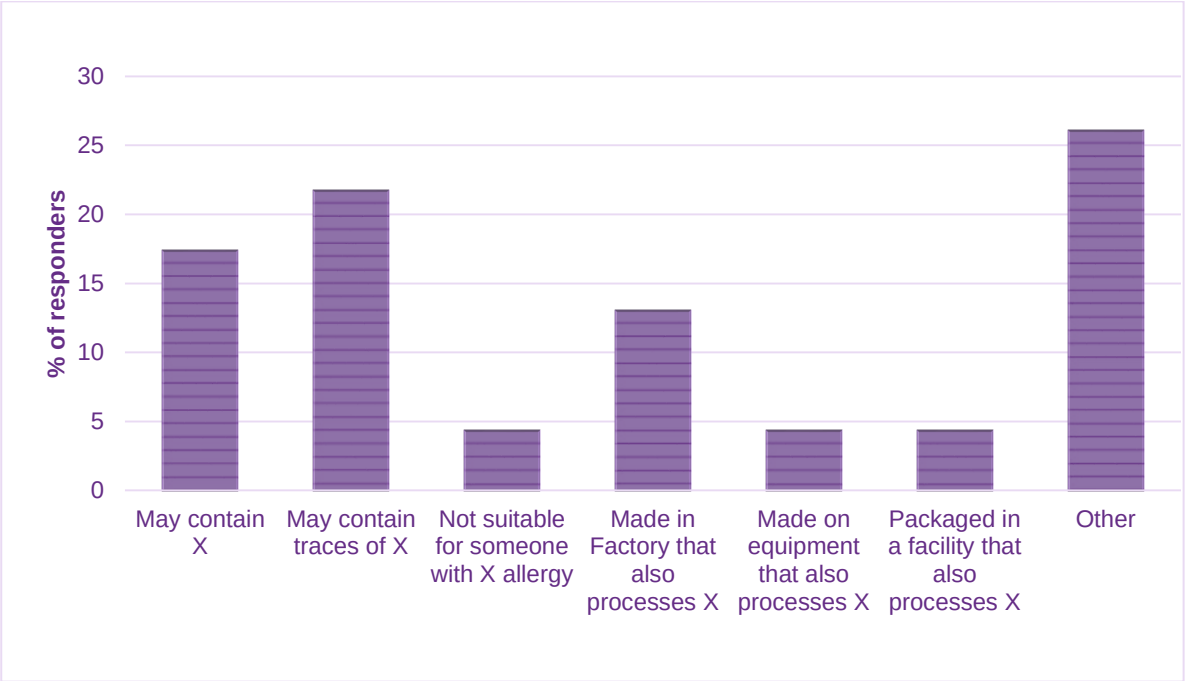

Figure 5.7: Different wording used for PAL by food manufacturers on the IOI.

Reading Scientific Services Ltd. recently carried out a review of product labels and advisory statements in the UK (FSA, 2014). They broadly grouped into the following categories the PAL statements (Table 6). Although, it is noted that other PAL statements were also used.

Table 5.6: Range of PAL statements used in the UK

1. A simple "contains" message: a) **Contains A, B and C** b) **This product contains A, B and C** c) **Allergens: contains A, B and C**
2. A "contains" message with extra information about the source of the allergen
3. A "contains" message with either extra warning or just an allergen list without distinction between ingredient level or advisory level
4. A simple "may contain" message: a) **May contain A, B or C** b) **May contain traces of A, B or C**
5. A "may contain" message with additional information
6. A simple "contains" message with a "may contain" following
7. A "may contain" message with a "contains" message following

The results have clearly demonstrated that there is a wide variety of PAL currently in use on the IOI market. PAL information derived from the literature was mapped against those encountered on foods available on the IOI

Market. The 'may contain X' and 'may contain traces of X' categories are included in the PAL categories identified in the RSSL report. The same report noted that there were other/additional PAL statements as was observed for the IOI market as well.

We examined whether the suggested PAL statements which are set out in the FSA Best Practice Guidance are being used by industry (FSA, 2006). The guidance recommends that PAL should be brief and based on facts and suggests two phrases:

(i) May contain X
(ii) Not suitable for someone with X allergy

These two categories represented just 22% of the total responses which could imply a significant divergence from the FSA recommendations.

5.4.4 Identification of the food industry sectors that are forthcoming with precautionary allergen labelling

5.4.4.1 Precautionary allergen labelling levels in the UK and Ireland

Overall, the level of food and drink products with PAL have increased strongly between 2009 and 2013 (Figure 8) (Mintel, 2014). This increase possibly points to an overall greater awareness among companies to warn consumers of any ingredients to which they may have a reaction. However, the overuse of PAL results in significant restrictions on dietary choices for consumers.

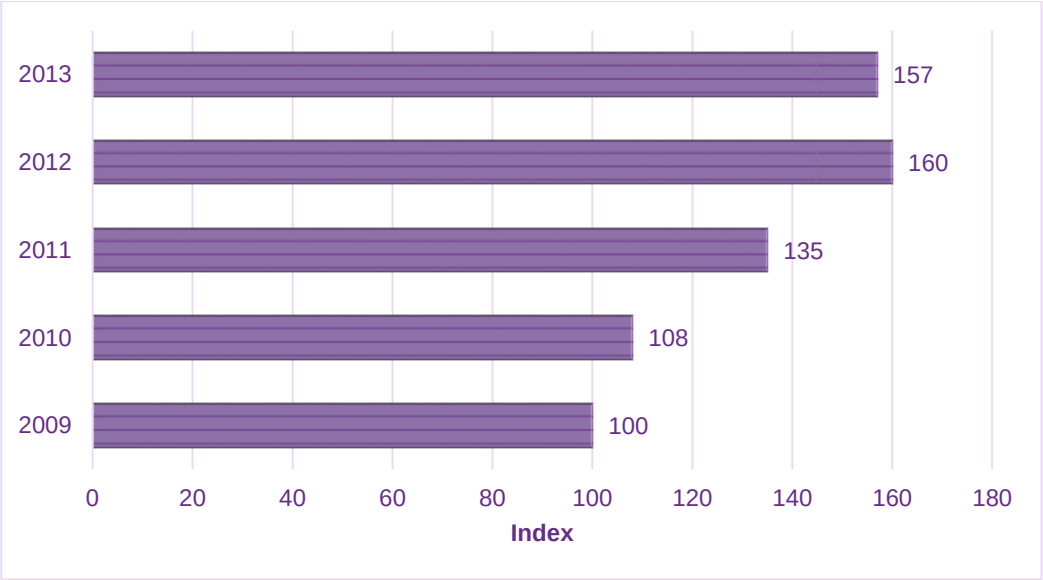

Figure 5.8: Indexed (i.e. normalised to 2009 values) level of products launched with PAL warning in the UK and ROI, 2009-13.

According to the FSA technical guidance (2015), the application of PAL should only be made after a thorough risk assessment has been conducted which has showed that there is a real risk to the food allergic or intolerant

consumers. Respondents to our questionnaire were asked if they performed a risk assessment before using PAL. The results are presented in the Figure 9.

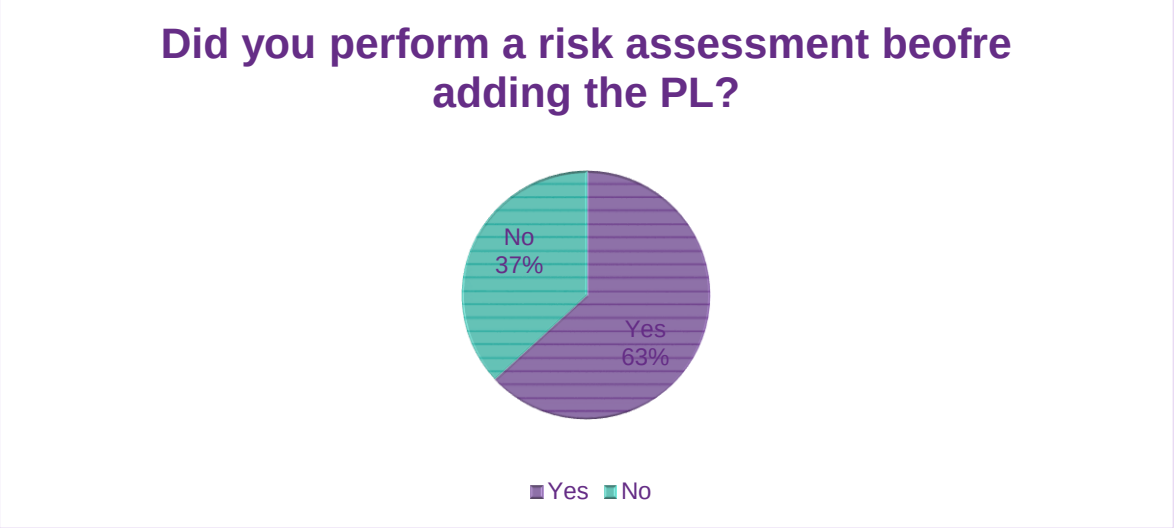

Figure 5.9: Percentage of respondents that perform a risk assessment or not before adding the PAL (n=19).

Our results showed that a significant number of the participating companies do not perform a risk assessment before adding the PAL (37%). This could be due to the high cost of involved in performing thorough allergen risk assessments. The feedback we received from key executives revealed that identifying the food sectors that are forthcoming with PAL is very challenging since manufacturers' policies in relation to how to use PAL differ. Moreover, the feedback also showed that even companies that produce similar products would not necessarily follow the same approach to PAL.

5.4.4.2 Food industry sectors forthcoming with precautionary allergen labelling

The likelihood of a food business applying PAL depends on its ability to conduct thorough a risk assessment and this can be costly. Based on the interviews with key executives, the milk products sector appears to be the most forthcoming with PAL. This is probably due to the fact that the products produced have mostly a stable composition and changes rarely take place in the labelling. The production process is likely to influence how forthcoming a company is with PAL. For example, it is harder to clean a 'dry' production process such as bakery or dried powder system compared to a 'wet' production process such as milk or soups. As a result of this, PAL will be more prevalent and also more ambiguous in products produced under 'dry' conditions. The lack of a thorough risk assessment might result in ambiguous or unnecessary use of PAL which can significantly decrease the choices of food hypersensitive consumers.

5.4.5 Assessing if non-regulated precautionary allergen labelling statements are fit-for-purpose

5.4.5.1 Fit for purpose precautionary allergen labelling statements: Republic of Ireland

The FSAI conducted a survey (carrying out 267 tests on 229 food samples) with the aim of determining the level of accuracy of PAL in relation to the presence of peanut, egg and soya ingredients (FSAI, 2011). All products were analysed using validated commercially available kits. The results are summarised in Figure 10.

5.4.5.2 Food products without PAL statements

According to the FSAI report, of the 106 samples without any PAL, 11 were found to contain at least one of the specified food allergens. Egg was detected in five samples, one of which also contained peanut. Peanut was also detected in two samples and soya in five samples and one food contained egg.

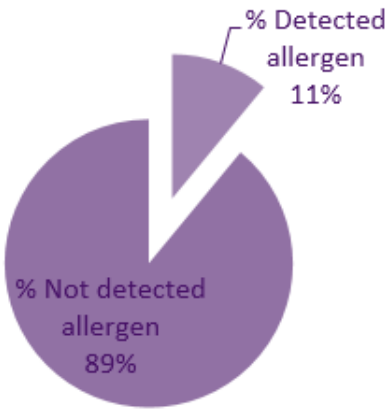

Figure 5.10: Percentages of products carrying no PAL statements where allergen was detected or not (allergens tested: egg, peanut or soya) (n = 106 samples)

5.4.5.3 Food products with PAL statements

Only seven (6.5%) of the 108 foods with PAL were found to contain the specific food allergen(s) mentioned on the label (Figure 11). Five out of 75 samples with a precautionary nut label contained peanut (7%), one out of 18 samples contained egg (6%), and one out of 30 samples (3%) contained soya.

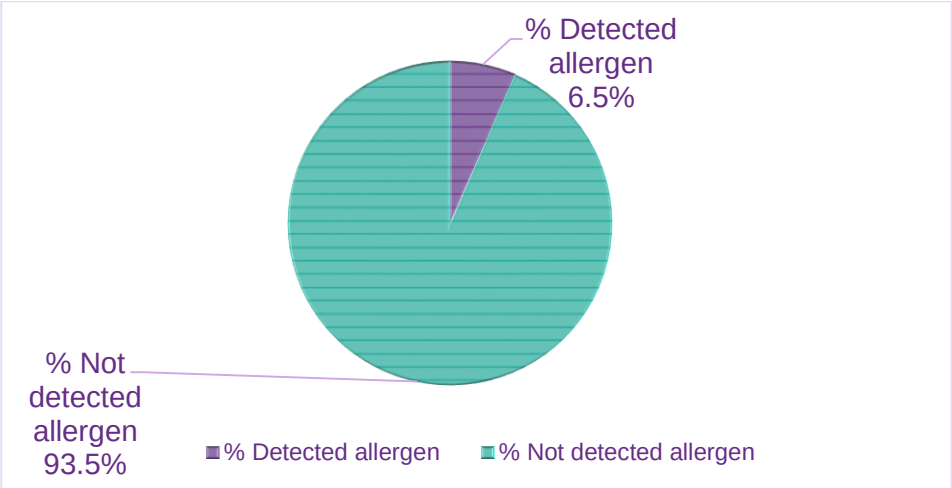

Figure 5.11: Percentages of products carrying PAL labels where allergen was detected or not (allergens tested: egg, peanut or soya) (n = 108 samples).

5.4.5.3.1 Fit for purpose precautionary allergen labelling statements: UK

The RSSL survey report in 2014 reviewed the frequency and level of allergen cross contamination (gluten, milk, hazelnut, peanut) of different categories of products with and without PAL in UK retail outlets (FSA, 2014). All products were tested using validated commercially available kits. This information will help to assess if non-regulated PAL statements are fit for purpose.

5.4.5.3.2 Food products without PAL statements

The percentages of samples with detectable allergen (gluten, milk, hazelnut, peanut), in which that allergen was not present as an intentional ingredient and which did not carry PAL are presented in Table 7. Milk and gluten were detected in products without PAL. Hazelnut and peanut were not detected in any products that did not contain PAL.

Table 5.7: Products containing detectable allergen without having a PAL statement

	Percentage (%)	Number of samples
Gluten	3.3	18/542
Milk	2.1	10/474
Hazelnut	0	0/988
Peanut	0	0/950

5.4.5.3.3 Food products with PAL statements

The percentages of samples in which no allergen (gluten, milk, hazelnut, peanut) was detected but that carried PAL in the UK are presented in the Table 8.

Table 5.8: Products not containing detectable allergen but with PAL statements

	Percentage (%)	Number of samples
Gluten	19	97/509
Milk	18	77/435
Hazelnut	44	472/959
Peanut	45	430/948

5.4.5.3.4 Linking the levels of allergens to PAL statements

Only a few studies have been conducted to evaluate whether the risks posed by allergens in food products correspond to the presence of PAL. Analysis of foods (mainly using ELISA assays) has shown that there is little correlation between the wording of the PAL and the risk of cross-contamination with allergens (Hefle *et al.*, 2007; Zurzolo *et al.*, 2011; Allen *et al.*, 2014a). A study conducted in the USA found that the rate of contamination was higher when the PAL stated "prepared in a shared facility" than when the label read "may contain" or "produced on shared equipment"(Hefle *et al.*, 2007). The data collected for the UK revealed that there is no correlation between the used of PAL and the type of allergen detected for any of the allergens examined and across the product categories. In addition there was no evidence that there was an association between the amount of allergen found in the product and the type of PAL. However, differences in detection of allergens in such studies must be taken under consideration since the quality of the analytical methods used complicates interpretation of results (Diaz-Amigo & Popping, 2010).

5.4.5.3.5 PAL situation on an international level

Studies on PAL in other countries are very limited as well. Ford *et al.* (2010) in their study investigated PAL relating to egg, milk or peanut and found that these allergens were not detected in 95% of samples that carried such labels. This is very similar to the results obtained by the FSAI study that showed egg, peanut or soya were not detected in 93.5% of foods that carried PAL. Another EU study in 2007 demonstrated that 75% of the cookies carrying a precautionary nut label on them did not contain any peanut (Pele *et al.*, 2007). These two cases may indicate that the issue with allergens not being present on food product containing PAL is widely spread.

5.4.5.3.6 Can precautionary allergen labelling information be expanded at factory level?

A thorough literature search revealed that there is no information available regarding whether PAL information can be expanded to the factory level. Wet cleaning in place is effective for many food matrices, where temperature, the use of cleaning products and pipework design all ensure the removal of allergen residues. However dry products, seeds, cereals and chocolate are more difficult to control, particularly where the use of water could introduce a microbiological risk. It is possible that changes in the factory design could help in

reducing the use of PAL statements of products. This could be done by having separate production lines for different products in order to minimise cross-contamination, different receiving areas for allergenic ingredients, investigate more efficient ways to clean a 'dry' production process such as bakery or dried powder system which is usually problematic leading to higher number of PAL statements.

5.4.5.3.7 Discussion

These two surveys represent 'snapshots' in time. PAL is not used in an ideal manner and a high level of unnecessary PAL is being applied to foods by manufacturers. The use of PAL statements is not regulated and the guidelines that have been published by the competent authorities are voluntary and have not reduced the prevalence and variety of PAL currently used in the ROI or UK (Ward *et al.*, 2010). Studies have shown that labelling ambiguities resulted in errors in safe product selection by consumers (Joshi *et al.*, 2002). A study of 40 food allergic consumers from the Netherlands and Greece, immediately after the introduction of the EU legislation, reported problems with readability and difficulty finding the relevant allergy information which was often 'lost' amongst the non-allergy information (Cornelisse-Vermaat *et al.*, 2007). A questionnaire survey of 184 parents of peanut and/or tree nut-allergic children focussed upon 'may contain' labels, not covered by legislation. It reported a large number of patients ignored 'may contain' statements or assumed that there was a gradation of risk, dependent on the wording of the statement (Noimark *et al.*, 2009). A UK study with 32 nut allergic consumers was conducted during their normal food shop and showed that they used the ingredients list as their main way for checking for allergens, but the majority used the allergy advice box. Information on the label was considered reliable, with some supermarket and brand labels being considered more trustworthy than others. Images and product names were used to draw inferences about the presence of nuts (Barnett *et al.*, 2011c). The widespread use of PAL causes considerable confusion and anxiety to people with allergies and their caregivers and it is not uncommon for consumers to miss allergy warnings altogether (Cummings *et al.*, 2010a; Sheth *et al.*, 2010). The use of different wording on PAL statements is confusing and may contribute to the increasing trend for consumers to ignore them altogether or assume falsely that terms such as ''shared equipment,'' ''shared facility,'' or ''may contain'' indicate different levels of risk (Hefle *et al.*, 2007; Barnett *et al.*, 2011c).

For both the ROI and UK the results from the two surveys showed that high percentages of food products with PAL did not contain detectable levels of the allergen referred to in the label. This finding reveals the high level of unnecessary PAL incorporated in food labels. This could lead to i) consumers with food allergies and intolerances limiting their diets even further and/or ii) influence consumers to disregard PAL and thus increase the safety risk. Furthermore, it is likely that some food producers use PAL as an alternative to allergen risk management, rather than as a way to communicate the actual risk of cross-contamination subsequently to a thorough risk assessment. Overall, based on the information mentioned above PAL statements do not seem to be fit for purpose and therefore measures need to be taken by the competent authorities and the food industry in IOI to alleviate this situation.

5.4.5.4 Food products without PAL statements

When an allergen is present in a food product (which is not intended as an ingredient) but no PAL statement is present on the label, this constitutes the highest level of risk to the food hypersensitive consumer. The results presented here for both the UK and ROI, showed that there were cases where the allergen was found above a detectable level and no advisory label was applied. Specifically 11% and 5.6% of food products tested, in ROI and UK, respectively, contained a detectable level of allergen without having a PAL. The competent authorities and the food industry must ensure that these percentages are reduced to avoid safety issues arising. However, the risk to the allergic/intolerant consumer in eating a product which could have allergen present as a result of cross-contamination is not exclusively associated to the quantity of allergen potentially present in that item. It also depends i) on the quantity of the food consumed and also ii) on the amount of allergen needed to trigger a reaction. Therefore, it is very important to establish allergen thresholds/eliciting doses which will help determine the actual risk to the consumer.

In the ROI peanut, egg and soya were detected in products without advisory labelling. In the UK, only milk and gluten were detected in products without advisory labelling. Hazelnut and peanut were not detected in any products in the UK survey where no advisory label was applied. The reason for this may be that peanut and hazelnut can often be present as fragments (i.e heterogeneous cross contaminants) whereas on the other hand gluten and milk are more likely to be homogeneously distributed, and the likelihood of detecting a heterogeneous contamination in a snapshot survey such as this, is lower. Another reason behind this finding could be that the allergen management for peanuts and hazelnuts has been in use for far longer than that for milk and gluten.

5.5 Availability and cost of testing for food allergens, food intolerance parameters and gluten on the island of Ireland

The first structured questionnaire (Appendix H) aimed to identify the analytical kits and services provided to IOI by companies on an international level. The organisations that agreed to participate in the study are listed in Table 9 including their country of origin (1st questionnaire). Respondents were asked if they supply allergen/intolerance kits/services in IOI and all of them replied yes. In the question "do you have a UK distributor (If not based in UK)", the organisations gave the following replies:

- Morinaga Institute of Biological Science: No
- R-Biopharm AG: Yes
- Public Analyst-Galway: No (an ROI based analytical service provider only, not involved in sales/distribution)
- Indoor Biotechnologies: No.

Table 5.9: Participant details (n=7)

	Questionnaire	Interview	Country
Indoor Biotechnologies	✓		U.S.A.
Exova	✓	✓	UK (international)
Morinaga Institute of Biological Science	✓		Japan
R-Biopharm AG	✓		Germany
Biocheck	✓		UK
Romer labs	✓	✓	UK (international)
Public Analyst's laboratory	✓	✓	Ireland (Galway)

Respondents were asked which kind of service they offer to the IOI. The results revealed that the organisations are able to provide both testing of food samples in their premises and also analytical kits that can be used by customers to test for the specific allergen or intolerance. The results are summarised below:

- Testing of food samples: 5 out of 7 companies
- Sell kits for testing food samples: 5 out of 7 companies
- Both testing of food samples and selling kits: 3 out of 7 companies
- Other: 1 out of 7 companies

Respondents were asked which methods you use for allergen/intolerance analysis and gave the following replies expressed in percentages:

- 100 % of respondents use ELISAs to detect allergens
- 57.1 % of respondents use LFD
- 28.6 % of respondents use DNA/PCR methods
- 57.1 % of respondents use other methods in addition to ELISA etc (the above)

Next, respondents were asked for which allergens/intolerances they can test for. The results are presented in detail in Table 10. The findings revealed that there is a relatively large number of foods/ingredients companies are able to test to provide analytical kits of analysis services.

Table 5.10: Coverage of major allergens by survey participants

Allergens	% of participants/ companies
Crustacean unspecified	85.7
Shrimp/Prawn	14.3
Crab	14.3
Lobster	14.3
Crayfish	14.3
Eggs	42.9
Molluscs	14.3
Wheat	57.1
Rye	42.9
Barley	42.9
Fish unspecified	42.9
Gluten	57.1
Lactose	28.6
Galactose	14.3
Casein	14.3
Peanut	14.3
Soya	14.3
Hazelnut	14.3
SO_2	14.3

Respondents were asked if the methods/kits they offer are validated and 66.7 % of respondents replied ''yes'' and 33.3 % replied ''yes for some''. None of the respondents replied ''No''. Moreover, 50 % of the respondents said the validation they have performed on their tests has been published.

5.5.1 Allergen testing methodologies

5.5.1.1 ELISA methods- technical specifications

As mentioned above, ELISA methods are used by all the respondents (100%). Four questions of technical nature were asked to the respondents in order to obtain more information on the ELISA tests they provide. Respondents were also asked if the ELISA methods were based on monoclonal antibodies or the less specific polyclonal antibodies. In most cases the respondents indicated that they use monoclonal primary antibodies (71.4%). Monoclonal secondary, polyclonal primary and polyclonal secondary were used to a lesser extent (57.1%).

Next questions aimed to see if raised to identify purified allergen proteins or crude allergen extracts. The results showed that 83.3 % of respondents replied that their ELISA methods identify purified allergen proteins and 66.7 % that detect crude allergen extracts.

5.5.1.2 DNA based methods- technical specifications

DNA based methods are employed only by 2 out of 7 of the respondents. Three questions of technical nature were asked to the respondents in order to obtain more information on the DNA based tests they provide. Respondents were asked if the size of the detected genome is known. The respondents were split with 50% of respondents replying ''Yes'' and 50% replying ''No''. The respondents were also asked if matrix PCR inhibition was investigated and the results showed that 100% of respondents replied ''yes''. Moreover, respondents were asked if the extraction has been optimised for recovery of allergenic protein or DNA and 100% of respondents replied ''yes''.

5.5.1.3 LC-MS methods- technical specifications

None of the respondents used LC-MS methods for allergen/intolerance analysis, although, Romer labs is currently designing a method which is not yet available commercially (It is also known to the authors that the company Eurofins, which did not take part in the survey, deploys a LC-MS based assay for some allergens).

5.5.2 Attitude of the Analytical Community

In order to assess the attitude of the analytical community in GB and the IOI to food allergen analysis a small anonymous survey (Appendix I) of prominent food analytical service providers, including Public Analysts, was carried out via SurveyMonkey®.

Respondents were asked 'how important is analysis for food allergens to your laboratory'. 86.8% of respondents mentioned that it is ''very important'' and 13.2% ''somewhat important'' The replies ''Neutral'', ''Somewhat unimportant'' and ''Very unimportant'' received no replies. For the question what is the current trend in food allergen analysis workload in your lab, the 10.5% of respondents replied ''Increasing a lot'', 65.8% ''Increasing'', 23.7% replied ''Neutral'' and 0 % replied ''Decreasing'' and ''Decreasing a lot''. Subsequently, respondents were asked "How do you find carrying out food allergen analysis to your quality criteria". The results are presented in Table 11.

Table 5.11: Difficulty of carrying out food allergen analysis

Responses %

Extremely difficult	2.6 %
Difficult	42.1 %
Neutral	52.7 %
Easy	0.0 %
Very easy	2.6 %

Respondents were also asked how they would rate the availability of reference or quality control materials for food allergen analysis. Approximately 45.9% of respondents said that they ''Available but with reservations as to usefulness or credibility'' and only 5.4% replied "Readily available, useful and credible". Lastly, respondents were asked how is easy/difficult is to confirm food allergen detection and quantification by a different technique. Approximately 73% of respondents replied that is ''very difficult'' and ''slightly difficult''. Only 2.7% of respondents replied ''easy''.

5.5.2.1 Availability of allergen analysis on IOI

Although only one of the organisations was based on the IOI all were able to offer a combination of ELISA kits for use on IOI and / or accept samples for analysis from IOI. Hence there is no obvious gap in the provision of allergen analysis (and also gluten analysis) and there appears to be sufficient competition to ensure a properly functioning market-place for such analysis. Interpretative and advisory services seem also to be available however with only one such expert laboratory (Galway Public Analyst Laboratory) on the IOI it is important that this facility is sustainably secured.

5.5.2.2 Methods of allergen analysis

The results confirm that ELISA remains the predominant form of analysis for food allergens and for gluten. Lateral flow devices (LFDs), important for point of use testing, albeit essentially qualitative, are also available. PCR DNA methods were less available with 28.6% of organisations responding deploying this technique. Where PCR was used, extraction was optimised and PCR inhibition was evaluated but in only half of cases was the size of the genome known. There was no current availability of LC-MS methods on the IOI through the respondent organisations although one company is developing such a capability.

In addition, various other technologies were described by respondents:

- Luminex xMAP (n = 1) a microsphere based bioassay with digital signal processing and proprietary identification techniques to perform multi-analyte profiling of proteins and other biological entities.
- Enzymatic methods (n = 1)
- Tanner method (a modification of the classic wet chemistry Monier-Williams method), for sulphites.
- Ion chromatography for lactose (food intolerance).

For ELISAs in most cases the respondents indicated that they use monoclonal primary antibodies and there were mixed results on asking if the antibodies were raised against purified allergen proteins or crude extracts and

against processed or unprocessed food. Pleasingly 67% of respondents replied that antibody was raised in animals fed a diet free-from allergen. However a third replied that this was not the case.

5.5.2.3 Validation of methods

European legislation (Regulation (EC) No 882/2004) promulgated in 2004 included reference to methods for sampling and analysis used in the context of official controls. Article 11 of 882/2004 states that methods of sampling and analysis must comply with relevant Community rules or if no such rules exist, (and there are none as yet for allergen detection) with internationally recognised protocols, for example those of the European Committee for Standardisation (CEN) (see below) or those agreed in national legislation. Otherwise, methods must be fit for the intended purpose or developed in accordance with scientific protocols, e.g. single laboratory validation according to an internationally accepted protocol. Wherever possible, methods of analysis must be characterised by the criteria set out in Annex III to the regulation.

Validation of analytical methods is now well described (Youden & Steiner, 1975; Thompson *et al.*, 2002). Manufacturers of food allergen test kits are known, indeed expected, to have carried out extensive in-house validation studies, but few are published in the peer reviewed scientific literature and this is confirmed in the survey. No respondents responded that their methods were not validated and the majority (66.7% 4/6) confirmed that they were. However, less reassuringly 33.3% (2/6) were able to claim only partial validation and only 50% (3/6) had published the validation.

The most common validation parameters received the most attention with all respondents assessing their method precision, repeatability, recovery and limit of detection. Applicability and selectivity were well dealt with (83%) although with the known cross reactivity of some ELISAs this aspect would be expected to be more important in the future. Sensitivity, limit of quantification, and reproducibility were also covered extensively (83%) and given the semi-quantitative nature of most ELISAs and the cost of inter-laboratory trials this is a commendable percentage. An awareness of measurement uncertainty is essential to appraise analytical results and it was somewhat disappointing that this scored only 67% with respondents. ELISAs do not exhibit linear calibration hence the reduced investigation of linearity (50%) is understandable however any attempt to quantify allergens must be done on the linear part of the calibration curve and more attention to this aspect is needed. Lastly, robustness, or ruggedness of a method, the resistance to alteration in results as a consequence of the minor deviations from the experimental conditions described in the method procedure received lower attention and should be something that is explored by all measurement scientists.

5.5.2.4 Coverage of major allergens

Regulatory risk management strategies for allergic consumers have focused on providing information about the presence of food allergens through label declarations and compared with Codex Alimentarius and those countries that have legislated the EU has the most extensive list of allergens that are subject to labelling

requirements (Gendel, 2012). In December 2014 European labelling law, Regulation 1169/2011, extended such disclosure requirements to non-prepacked food including that available in retail catering establishments. In Table 12 below are listed the EU specified allergens and the coverage by analytical methods revealed by our work.

Based on the responses we received test methods are readily available for 71% (22/31) of the common allergenic foods that are subject to EU legislation. Unprompted, our respondents failed to mention 29% (9/31) of possible EU legislated allergens indicating that, although tests are advertised, they may not be readily available or are in untrusted formats. Perhaps understandably no respondents were willing to divulge pricing information on tests.

Table 5.12: Analytical Coverage of EU allergens

Annex II Entry	Examples	Method / test available?
Cereals containing gluten and products thereof	Wheat	✓
	Rye	✓
	Barley	✓
	Oats	
Crustaceans and products thereof	Shrimp/prawn	✓
	Crab	✓
	Lobster	✓
	Crayfish	✓
Eggs and products thereof		✓
Fish and products thereof		✓
Peanuts and products thereof		✓
Soybeans and products thereof		✓
Milk and products thereof	Skimmed milk powder	✓
	Cheese etc	✓
Nuts, and nut products namely	Almond	✓ Note 1
	Hazelnut	✓
	Walnut	§
	Cashew	§
	Pecan	✓
	Brazil	§
	Pistachio	§
	Macadamia	§
Celery and products thereof		§
Mustard and products thereof		§
Sesame seed and products thereof		§
Sulfur dioxide/ sulfites		✓
Lupin and products thereof		§
Molluscs and products thereof	Mussels	✓
	Scallops	(✓)

	Cockles	(✓)
	Oyster	(✓)
	Clam	(✓)
Totals	31	22 ✓ or (✓)

Key

✓	test available on IOI
(✓)	test available for mollusc presumed to react to these species
§	test advertised but not claimed to be available (unprompted) by respondents
Note 1	Almond tests are available but known to cross react with other Prunus species

5.5.2.5 Coverage of gluten and major food intolerance analytes

Coeliac disease is a chronic inflammatory intestinal disease, with debilitating symptoms and potentially serious consequences, induced in genetically susceptible individuals by ingestion of gluten for which the only effective treatment is a lifelong diet that is as free-from gluten as possible. Gluten is a generic name for a protein fraction from certain cereal grains containing prolamins (usually estimated as 50% of gluten) and glutenins. Prolamins include the aqueous ethanol soluble proteins gliadins (wheat), secalins (rye), hordeins (barley) and avenins (oats). Despite the lack of a definition that fully chemically characterises gluten, methods for gluten are common, the most frequent being ELISA-based. PCR-based methods have also been described. Proteomics-based methods such as reversed-phase (RP-) or gel permeation (GP-) high-performance liquid chromatography (HPLC) have been widely used for characterisation of cereal proteins. LC-MS/MS methods have been described and are the most promising non-immunological approaches for accurate quantitation of gluten traces. However, due to expensive equipment and expertise LC-MS/MS is not widely used for routine analysis. New developments include immunosensors, aptamers, microarrays, and multianalyte profiling. Responses to our questionnaire confirmed gluten analysis is routine on the IOI. As for IgE mediated allergens, the need for an independent reference method and a generally applicable reference material remain (Scherf & Poms, 2016).

Food intolerance covers a broad spectrum of conditions, is non-immunological and is often associated with gastrointestinal symptoms. Food intolerance affects 15–20% of the population and may be due to pharmacological effects of food components, non-coeliac gluten sensitivity or enzyme and transport defects. Food components such as salicylates, vasoactive amines (e.g. histamine), glutamates (e.g. monosodium glutamate) and caffeine have been implicated however lactose intolerance is the best described and most easily understood food intolerance. There have been significant advances in understanding the scientific basis of gastrointestinal food intolerance due to short chain fermentable carbohydrates (fermentable oligo-, di-, mono-saccharides and polyols, FODMAPs). The most helpful diagnostic test for food intolerance is food exclusion to achieve symptom improvement followed by gradual food reintroduction. A low FODMAP diet is effective, however, it affects the gastrointestinal microbiota and FODMAP reintroduction to tolerance is part of the management strategy. As expected, survey responses indicated analysis for lactose (and other sugars) was available on IOI by ion chromatography, a well-known and widely applied instrumental method. In contrast to

IgE-mediated allergen and gluten analysis, analytical capability for sugars is not beset with problems stemming from lack of reference methods or reference materials (Lomer, 2015).

More detailed information was obtained by an in-depth interview with the international analytical service provider, one of the international ELISA manufacturing companies and the ROI Public Analyst's laboratory.

5.5.3 Attitude of the Analytical Community (in depth interviews)

Three respondents agreed to in-depth interviews. An international general analytical service provider with a food division, an international ELISA manufacturing company, and the ROI Public Analysts laboratory were interviewed providing good coverage of the analytical community. The questions dealt with the following topics.

5.5.3.1 During your allergen analysis are you trying to identify a protein or a group of proteins?

In general a mixture of both proteins and groups of proteins are detected depending on matrix and allergen or analyte. Examples cited were the various prolamins, Ara h1, ovalbumin and ovomucoid, β -lactoglobulin, and α -, β - and κ-Caseins. The commercial ELISAs used typically target one of those proteins via a monoclonal antibody; the result is scaled up to try to represent the allergenic food. The outcome depends on how the ELISA has been calibrated by its vendor. For example a whole egg powder may have been used to calibrate an egg ELISA, so the results, no matter what fraction of egg (whole, yolk, or white, powder) is actually present in the sample are calculated as whole egg. This may be misleading as to the quantity of allergen present unless corrected for by a knowledge of the ingredients and / or formulations and accepted conversion factors.

5.5.3.2 Do the tests you have at your disposal detect the allergen or a different marker?

Although one respondent claimed all tests detect the allergen this cannot be extrapolated across the range of allergens as other respondents confirmed some of their tests detect allergen and some different markers. Knowledgeable users can (and do) attempt to purchase ELISAs on the basis that they detect an allergenic protein, e.g. Ara h1 rather than a non- allergenic marker. However it is not always clear from the product literature what it is the kit reacts to it is often necessary to contact the company. It is also not always clear how the scale up calculations to the food itself are structured, hence the re-calculation mentioned above (Q1) can be problematic. This is important as contamination by the whole food may not be the issue; e.g. defatted peanut flour rather than whole peanut.

It is also important to note that where a DNA based/PCR method is used the target for the analysis is the DNA of the organism that produces/contains the allergen, therefore these methods are not suitable for the prediction of the presence of certain allergens, i.e. milk. As 'milk' is not an organism but is rather produced by a mammalian animal & therefore the detection of the DNA of that animal, for example a cow, would not be

indicative of the presence of certain cow's milk proteins to which some allergy-sufferers are allergic (the same logic also applies to egg allergy).

5.5.3.3 Do you know how food processing affects the allergenicity of the protein?

The general awareness of processing impact on allergenicity was good, for example gliadin was recognised as thermostable, and that egg and milk protein allergenicity can be reduced by thermal processing. However it seemed not always to be appreciated that the allergenicity of raw peanut is lower than that of roasted peanut. And in some cases, e.g. casein, the respondent admitted to a lack of knowledge of the influence of processing. One respondent confirmed that during kit validation the influence of how the processing will affect the allergenicity is investigated on a case by case basis. However it seems kit users are almost never told about the impact of processing on allergenicity in the kit insert and it is left to user experience and background reading. This is particularly relevant e.g. when the ELISA is calibrated with say, roasted peanut flour, and the sample contains raw peanut or where whole egg powder is the calibrant, how do readings relate back to raw egg.

5.5.3.4 Will the method detect allergen hydrolysates?

The issue of hydrolysates applies mainly to milk and beer, for example some highly processed milk powders are available and hydrolysed gluten in malted barley and fermented beers. The latter are often analysed to assess their safety for coeliacs which is very empirical. It is unknown how hydrolysed and clarified the beer is – the gluten proteins may be all hydrolysed down to amino acids which are not allergenic but equally may be cleaved into large fractions that remain allergenic. Other examples are breakfast cereals and malt vinegar. Most gluten free beer producers want 'no gluten' and standards such as <3 or <5 ppm gluten peptides can be applied. A lot more effort is now put into clarification (not just cold filtration) of beer using e.g. silica gel or proteolytic enzymes (Walter *et al.*, 2014). There was some general awareness of these issues with work on a case by case on allergen hydrolysates and validation with customer own control samples to see if the test is suitable although one respondent was aware of information only for an ELISA for β-Lactoglobulin which showed that the method will detect it even if hydrolysed.

5.5.3.5 Have matrix interferences been investigated?

Some case by case work is carried out, e.g. in chocolate, tannins bind to proteins inhibiting extraction, so fish gelatine is added in the extraction buffer to help with the extraction. However from a user perspective, this information is not readily available from ELISA companies. Users reported noticing matrix effects and have had to get back to ELISA companies – examples are spices, fenugreek interferes with peanut assay. This is an area where owing to commercial pressures companies may be reluctant to acknowledge interferences and cross reactivities as it makes their kits look less good. There is a need for further investigation and manufacturer / user collaboration.

5.5.3.6 Is cross reactivity with other allergens investigated?

Cross reactivity is an acknowledged problem, examples include (for ELISA) peanut / walnut and peas / peanut, and again work on a case by case basis is undertaken with customers own samples and controls at validation. Where a limited suite of ELISAs is used no cross reactivity was reported as found and users will get back to the ELISA companies to check. Best practice if a positive result is obtained is to use a different antibody to check for non-specific binding, or try to dilute out the interference. However the respondent noted that was advice from the published literature rather than from ELISA kit inserts (Walker *et al.* 2008).

5.5.3.7 Where tests were validated what were the problems?

Users report seeking AOAC validated ELISAs where available. In general all tests are validated, however all respondents reported lack of positive controls and scarcity of reliable reference materials as a significant problem with the consequent need to produce in house controls. One user reported great reluctance to quote a quantitative result in the absence of a material with an assigned value for the allergen - this is the biggest weakness in this area. An issue may be that having obtained ISO/IEC 17025 accreditation with one proprietary IP protected method (e.g. the Mendex R5 gluten kit) this inhibits the ability to take advantage of novel developments as it is too expensive and time consuming to switch accreditation. Having flexible ISO/IEC 17025 accreditation scope to analyse for a new allergen or in new matrices based on in-house validation work is an option that is very useful.

5.5.3.8 From the questionnaire I see you are not using LC MS. Have you any plans to do so in the future?

The deployment of LC-MS or LC-MS/MS was seen as having potential but is not currently used. Some developmental work is taking place. The main hurdles were reported as equipment, running and method development costs. For the latter preliminary exploration of a QToF MS instrument is required with subsequent transfer of the method to a triple quadruple instrument with sufficient resolution (i.e. one of the latest generation instruments) for routine multiplex use. This adds to development costs. Moreover all LC-MS/MS instruments are deployed 24/7 to amortise costs and it involves a lot of down time to switch analytes therefore this is almost never done or if so only at infrequent time intervals. It was felt the market for allergens analysis would not support deployment of LC-MS/MS on the IOI.

5.5.3.9 Anything else to add regarding the company's activities?

One respondent had nothing further to add but other responses included plan currently to validate a PCR DNA kit for celery, investigate LC-MS/MS and general aspirations are to have a large range of kits available, a DNA service and to enrich their knowledge and experience and built better kits.

6 Project discussion & key findings

Although awareness of food hypersensitivity among the general public, food producers and manufacturers has increased in recent years, many gaps still exist in research on food labelling and on purchasing behaviours. The current study focused on the key factors that influence the food choices of food hypersensitive consumers regarding labelling practices (food allergy and food intolerance) and examined the extent to which food labelling is helpful or unhelpful to these consumers. It is essential to understand these factors in order to improve safety, wellbeing, and quality of life and provide a strong foundation for an increased understanding of current labelling practice impact on food choice and purchasing behaviour and on the attitudes and behaviours of consumers living on the IOI. Most respondents in this study stated that they shopped in large supermarkets, such as Tesco or Supervalu, and budget supermarkets such as Aldi and Lidl. Previous research has shown that these large companies are trusted more by consumers because they are perceived to be strongly motivated to protect their reputation and are assumed to have enough resources to carefully check the products for ingredients (Barnett *et al.*, 2011). Food stalls were found to be one of the least used venues suggesting a lower level of trust. This could be because food stalls sell non pre-packed food products, which, until recently, did not require the presence of any of the 14 allergens as ingredients to be declared through labelling. It will be interesting to see if the updated requirements of the Food Information to Consumers (FIC) legislation (1169/2011, fully implemented on December 2014) which extends the mandatory disclosure of labelling to include non-pre-packed foods, will improve trust within such settings. A key factor here is the need for food handlers – e.g. caterers, school staff, care home staff etc. – to be able to access written product information to be able to pass it on reliably to consumers.

Online shopping was the least used method although it could be argued that online shopping could be beneficial for food hypersensitive consumers with the potential to provide allergen information on products and allowing consumers more time to make choices on food purchase. Consumers evaluate products on the basis of several key attributes and each represents to the consumer a potential source of risk or safety. These attributes should be included in any piece of research that aims to measure the acceptability of policy, technology or mode of information. These key attributes (including prior experience, brand trust, product and venue cues, and country of origin) were rated highly, labelling itself was found to be the most important characteristic that aids decision making on whether a product is safe to eat for food hypersensitive individuals when purchasing food. Respondents report placing more trust in specific/explicit types of PAL with 'Not suitable for someone with X allergy' the preferred label choice, suggesting that the more directive and explicit the label, the more confident consumers are in using them. Confidence decreased as label wording became vaguer. Labels that were easy to read and visible were the labelling characteristics that were most helpful to consumers when deciding to buy a product. This preference is supported by Article 13 of the EU Regulation 1169/2011 on presentation of mandatory particulars, which states that food information be easily visible, clearly

legible and, where appropriate, indelible. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material. However, it is likely that interpretation of what is easily visible and legible may differ between consumers, based on subjective factors including perception and needs.

The study found no significant differences between food allergic and food intolerant consumers (both groups included those sensitive to a diverse range of allergens and coeliac), gender or age groups in terms of their practices and attitudes towards food labelling. Both food allergic and food intolerant consumers regularly use and are regularly influenced by labelling when deciding to buy a food product and find labelling 'very necessary'. However, both groups found labelling only 'somewhat' reliable, 'somewhat adequate' and 'somewhat understandable'. With low scores in confidence for the more 'vague' precautionary labels, the suggestion that such labels may eventually attenuate consumers' response to the precaution with the result that they may take more risks when buying and eating food products, appears to be well supported. Sampson *et al.* found that more than half of their respondents had knowingly eaten a small amount of food containing an allergen, while Gallagher *et al.* (2011) and Zurzolo *et al.* (2013) found that many consumers with food hypersensitivity take deliberate risks. Overall, it was expected that food allergic consumers would be more cautious in their eating preferences and food choices compared to food intolerant consumers. The results showed that there was no significant difference in eating preference and food choice between both groups. Sommer *et al.* found that food allergic respondents experienced more difficulty in finding appropriate foods and were more concerned about safety than food intolerant participants. According to DunnGalvin, although a fatal reaction is not a possible outcome for those with a food intolerance, factors such as the complexity and uncertainty around which foods are safe to eat and buy, worries about health, and stigma such as minimisation of the effects and importance of food intolerance among the general public have a comparable adverse impact on everyday living (DunnGalvin, in press). Parents (food allergy & food intolerance) did report the necessity of foods being safe as significantly more important than adults without children. As a consequence, parents reported using labelling more and were significantly more influenced by labelling than adults without children.

Multiple regression modelling was carried out to determine what factors best predict how often consumers use labelling when deciding to buy a food product. The analysis controlled for a wide range of factors including type of hypersensitivity, number of symptoms, number of foods to which sensitive, age, parent/adult, the level of understanding, diagnosis, and gender. The model shows that in making a food choice/purchasing decision, although safety and nutrition is important for hypersensitive consumers, the most important predictor of how much labelling is used or attended to (over and above all other factors) is how much a consumer is influenced by labelling in general. This highlights the importance of focusing on creating useful and useable labelling formats, that will be helpful to a wide array of consumers with hypersensitivity (whether clinically or self-diagnosed).

Our findings also go some way to elucidate how consumers balance competing values. There is little research on this topic to date within the field of food allergy. We found that safety and nutrition are important concerns for those who were diagnosed by a health professional or specialist and to a lesser extent for those who self-diagnosed, suggesting that labelling that addresses both concerns could be helpful and useful to diverse

consumer types. Further, there may be a perceived advantage for consumers with and without hypersensitivity to have access to information on allergen content, which would guide both healthy eating and safety and have a wider appeal. Consumers without coeliac disease, but who perceive a health benefit in avoiding gluten choose these foods in increasing numbers, guided by the labelling. Improved understanding in this area could prove beneficial for both consumers and the food industry, suggesting that more explicit and directive food labelling that addressed both safety and health concerns by food manufacturers would appeal to a wide range of consumers. Labelling, as a means of communication, must address the issues that are important to consumers. This study goes some way to describing these issues.

When considering 'trust', it is important we can distinguish between trust in the information source and purchasing context, and trust in the information itself. In either case, information is rated as equally persuasive, relevant and trusted if based on salient, consumer-held concerns. An 'informed risk' based approach can help to increase a sense of control and trust, provide for effective and transparent communication among all stakeholders, and reduce uncertainty. For example, in our literature review we noted that the majority of parents, teens and young adults in three countries agreed that it would be 'very useful' if 'there was some level or hierarchy of risk implied by labelling' linked to current labelling practice (Roma *et al.*, 2010). However, it is important to note here that 'level of understanding' and 'communication based on consumer concerns' modified the level of acceptability of the translation of the science of thresholds to labelling.

A regulatory framework needs to be sufficiently flexible to remain relevant to consumers and to facilitate new research, new ways of communicating risk and new technology. Future research could compare the general consumer's attitudes and practices towards food labelling compared with those of consumers with food hypersensitivity to provide a framework for an all-population strategy for governing bodies to develop and implement specific guidelines to improve quality of life through proper food labelling procedures and practices. Extant research suggests that the concerns of consumers in general are very similar to those with food allergy, which is both interesting and reassuring. Our findings on differences between those who were diagnosed by a specialist or other health professionals, and those who were self-diagnosed support this view to some extent. Although online shopping was not a preferred option for our sample of consumers, the potential for online shopping as a means to communicate allergen content should be investigated. Comparative research between online and other shopping in terms of convenience, efficiency of label reading, cost etc. would be informative.

The evidence regarding the experiences of consumers in other countries showed that there appears to be a lack of any or at least any up to date information on the experiences of food hypersensitive consumers in countries other than the UK. This corresponds with the emphasis in the UK on labelling as a key means of conveying information about food choices and the pre-eminent position of the FSA's Food Allergy and Intolerance Research Programme which is highly regarded world-wide. The Programme includes a specific strand on food allergen labelling and consumer choice research. FSA also exhibits well-developed policy, guidance and training resources. The information gathered from Australia, the USA and Italy confirms that PAL is a 'live issue' and is best summed up by the AC UK recommendation that food producers and supermarkets can improve product labelling by only using PAL where there is a genuine risk of contamination and after a thorough risk assessment.

Even though, there is a paucity of information about PAL among patient support organisations outside the UK and Australia, it is reasonable to assume that consumers on avoidance diets face similar challenges globally.

On the other hand, free-from product sales on the IOI have been increasing the past few years and projections reveal that this increasing trend will continue and sales will reach €63.6 million by 2019. Growth in the ROI market is estimated to have been slightly higher at 58% compared to NI for the same time-period (2009-2014). However, sales of free-from food still account for less than 1% of total grocery sales in 2014. Our research into market reports and discussions with the industry showed that new launches of free-from products are taking place in different product categories. The snack and bakery categories had the highest number of free-from products launched to the UK and Ireland in 2014. While these sectors account for the largest level of product launches, other categories such as dairy and processed fish, meat and eggs had the highest increase in number of products launched between 2007 and 2014. It appears that producers are trying to meet the demands not only of consumers who have allergies/intolerances, but also consumers with no food hypersensitivities but who consider some free-from foods (e.g. gluten-free) healthier alternatives for them.

Overall, the level of food and drink products with PAL statements has increased significantly for the period 2009 to 2013. The factors behind the use of PAL differ amongst food producers, and a wide a range of PAL statements is used in the products available on the IOI market. Based on these findings, there seems to be several factors that lead to the use of PAL by food manufacturers with the most important being the uncertainty of allergen thresholds. There is a significant divergence from the FSA recommendations (Best Practice Guidance, 2006) regarding PAL wording. This wide use of different wording on PAL might confuse the consumers and reduce the value of PAL as a risk communication tool. Regulatory authorities and others have reported that although threshold doses for different allergens exist below which allergic reactions are less likely to take place, such thresholds have yet to be defined (EFSA, 2014; US FDA, 2008). The threshold data already available and presented here (Table 5) could help to establish action plans and evidence-based allergen management strategies in order to help food manufactures to use PAL in a more efficient manner and thus reducing its unnecessary use. The establishment of a reliable PAL system will enhance safety, consumer confidence as well as consumer choice.

Our findings showed that a high level of unnecessary precautionary labels is being placed on foods by manufacturers in ROI and the UK and they are in agreement with previous studies (FSAI study and beyond). It is also important to mention that a comparison of IOI with other countries showed that the use of unnecessary precautionary labels is not confined to IOI. The high level of unnecessary PAL incorporated in food labels can potentially lead to i) consumers with food allergies and intolerances limiting their diets even further and/or ii) make consumers disregard PAL increasing the safety risk. It seems that PAL is likely to be used as a substitute to allergen risk assessments if producers are unwilling or unable to perform them. In order to avoid these, competent authorities should introduce more effective procedures in order to provide a higher level of protection to consumers with food allergies/intolerances as well as help them regain confidence in food labelling. Overall, PAL statements do not seem to be fit for purpose in their current form and therefore measures need to be taken by the competent authorities and the food industry in IOI to alleviate this situation.

The food industry has ultimate responsibility for ensuring that food labels are accurate and are applied according to relevant legislation and recommendations and with due diligence.

With regards to availability of analytical techniques for allergens, gluten and major food intolerance parameters on the IOI, it seems there is some considerable capacity. However there are some gaps in that for 29% (9/31) of possible EU legislated allergens, although tests are advertised, they may not be readily available or are in untrusted formats and hence more unlikely to be used by IOI industry and consumers. In general food allergen/gluten/ intolerance testing is seen as important to laboratories, and demand is increasing. However, carrying out such analysis was deemed to be difficult and in particular confirmation and quantification by an orthogonal technique was seen as challenging. There are several reasons for this. All respondents reported lack of positive controls and reference materials as a significant problem with the consequent need to produce in house controls. One user reported great reluctance to quote a quantitative result in the absence of a material with an assigned value for the allergen – "this is the biggest weakness in this area [of analysis]". There is a need for further investigation and manufacturer/user collaboration on extraction and recovery issues, matrix interferences and cross reactivity. A need for increased clarity from ELISA kit manufacturers on such issues is called for and this is certain to be required for all forms of analysis in the area. There is also a need for clarity on the factors used to convert what is detected by ELISAs (or indeed PCR DNA or LC-MS/MS methods) to the food itself which is the hazard identified in law. An issue may be that having obtained ISO/IEC 17025 accreditation with one proprietary IP protected method (e.g. the Mendex R5 gluten kit) this inhibits the ability to take advantage of novel developments as it is too expensive and time consuming to switch accreditation. Having flexible ISO/IEC 17025 accreditation scope to analyse for a new allergen or in new matrices based on in-house validation work is an option that is very useful. The deployment of LC-MS or LC-MS/MS was seen as having potential but is not currently used. Some developmental work is taking place, according to our sources. The main hurdles were reported as equipment, running and method development costs. It was felt the market for allergens analysis would not support deployment of LC-MS/MS on the IOI.

In conclusion, the results of this present research could be used to improve satisfaction with, and confidence in, information provision and labelling for consumers with all types of food hypersensitivity. Findings could be used as a guide for food businesses and retailers to improve understanding of the factors that impact on the decision to buy a particular product and to point in the direction of how to provide the 'right' information to consumers who need to avoid certain ingredients because of an allergy or intolerance.

7 Project conclusions

The main findings in this study are:-

- Consumers with food hypersensitivity procure pre-packed food in large supermarkets 'most of the time' and 'rarely' shop at medium supermarkets, corner shops, premium shops or food stalls.
- Factors that affect food choice and purchasing behaviours include a) prior experience, b) brand trust, product and venue cues, and c) country of origin. These factors are used to aid informal decision making. Labelling was the most consideration in determining whether or not a food product is safe to eat.
- Consumers dislike PAL because they are uncertain as to the basis for using it, it reduces their food choices considerably, and parents in particular perceive adverse effects on their children's nutrition.
- The strongest and most adverse impacts on health-related quality of life has to do with dietary and social restrictions including concerns around labelling.
- No significant differences were found between food allergic and food intolerant consumers in terms of their practices and attitudes towards food labelling.
- Consumers who self-diagnose are less likely to be concerned about the safety of the foods they buy and are not as influenced by product labelling compared to consumers who have been medically diagnosed.
- Parents valued the safety of foods significantly more than adults without children. Parents also use labelling more and are significantly more influenced by labelling.
- Between 2009 and 2014, free-from product sales experienced a significant increase on the IOI and currently there is a wide range of free-from product categories available. That said, free-from food products sales still accounted for less than 0.50% of the overall grocery sales in 2014.
- There was no evidence of any significant export market in free-from foods by ROI or UK food producers.
- According to market analysis the level of PAL statements have increased in recent years. Unfortunately, the evidence suggests their presence is not corroborated by the presence of the allergen they are warning against implying they are being used as a substitute for allergen risk assessment.
- This has led to a lack of consumer confidence in the usefulness of labelling which can therefore be disregarded – a high risk behaviour for food hypersensitive consumers.
- There is reasonable availability of analytical capacity for allergens, gluten and major food intolerance testing in IOI. However, for 29% of the possible EU legislated allergens, although tests are advertised, they may not be readily available or in non-trusted formats in IOI.
- Food allergen testing is conducted mainly using ELISA and to a lesser extent DNA based and other techniques.
- Food allergen analysis is important to food laboratories and demand for allergen testing seems to be increasing.

8 Appendices

Appendix A: Papers and abstracts selected for inclusion in the literature review

Table A: Papers selected for the review

Authors, country & Year	Study designs/ Methods	Study aims	Methods	Findings
de Rosa *et al*, Italy, 2004	Cross-sectional/ Quantitative	To evaluate the illness behaviour of patients with coeliac disease and examine the influence of the disease and dietetic treatment on the major personality components and the level of general adherence to dietary recommendations.	Illness Behaviour Questionnaire Eysenck Personality Questionnaire Psychophysiological Questionnaire	Coeliac disease may be associated with changes in personality that may interfere with patients' adaptation to living with a chronic disease. Patients who received the diagnosis in adulthood had a lower score for nonconformist, a greater tendency to pretend to be sociable, and higher levels of psychophysiological reactiveness, relative to the comparison subjects
Rashid *et al*, Canada, 2005	Cross-sectional/ Quantitative	To characterize the clinical features at presentation as well as the associated disorders, family history, and evaluation of compliance with a gluten-free diet in children with coeliac disease from across Canada.	Canadian coeliac Health Survey	10% to 20% reported major disruptions in lifestyle. 23 % felt angry all or most of the time about following a gluten-free diet. Coeliac adult population adhering to gluten free diet reports a negative impact on health related quality of life
Sampson, Furlong & Sicherer, USA, 2006	Focus group discussions/ Qualitative	To gain insight toward devising interventions, risk-taking behaviours and coping strategies of person's age 13 to 21 years with food allergy were queried.	Internet based anonymous questionnaire.	Twenty-nine respondents were designated at high risk because they did not always carry epinephrine and ate foods that "may contain" allergens.

				Respondents variably (60%) tell their friends about their allergy, but 68% believe education of their friends would make living with food allergy easier.
Hu, Grbick & Kemp, Australia, 2007	Focus group discussions/ Qualitative	To examine information needs and preferences of parents regarding food allergy.	In-depth semi-structured interviews	Parents of children with food allergy have unmet information needs
Voordouw *et al*, Netherlands, 2006	Cross cultural/ Qualitative	To investigate what the preferences are of Food allergic consumers regarding food labelling.	In-depth semi structured interviews	Food allergic consumers are not very satisfied with the current labelling practises. They find them inadequate, inappropriate and difficult to use. PAL was not viewed positively by consumers in the study as it caused unnecessary restrictions in the diet of food allergic consumers. The new EU regulation is not clear how allergens should be listed on the product labels.
Cornelisse-Vermaat *et al*, Netherlands, 2007	Cross cultural/ Qualitative	To evaluate if current food labelling practices are perceived to be adequate by food-allergic consumers, and whether further policy changes need to be implemented in order to optimize consumer protection.	Unstructured interviews/ Observation	Food-allergic consumers were not satisfied with the current labelling practices. Consumers felt that the information provided was thought to be unclear or insufficient, which resulted in personal stress and feelings of insecurity.
Lee, Zivin & Green, USA, 2007	Quantitative	To evaluate the economic burden of adhering to a gluten-free diet.	Cost Utility Analysis	Every gluten-free product was more expensive than their wheat-based counterpart.
Vierk *et al*, USA, 2007	Quantitative	To report the prevalence of self-reported food allergy, to identify the characteristics of food allergy reactions, and to describe the use of	US Food and Drug Administration's 2001 Food Safety Survey	The prevalence of food allergy to the 8 most common allergens (peanut, tree nuts, egg, milk, wheat, soybeans, fish, and crustacean shellfish) is self-reported as 2.7% among respondents with doctors' diagnoses.

		labels among adults with food allergy.		Several label issues, such as words on some ingredient lists being too technical or hard to understand and food labels not always alerting persons to new ingredients, were reported as serious or very serious obstacles for managing an allergy.
Leffler *et al*, USA, 2008	Cross sectional/ Quantitative	To determine factors influencing gluten-free diet adherence in adults with coeliac disease.	The Global Coeliac Assessment Scale	Thirteen factors hypothesized to contribute to gluten-free diet adherence were found to be significantly associated with improved adherence , which includes: Understanding of the gluten-free diet, membership of a coeliac disease advocacy group, and perceived ability to maintain adherence despite travel or changes in mood or stress.
Stevens & Rashid, Canada, 2008	Quantitative	To compare gluten free and regular foods.	Cost Utility Analysis	All the commercially available products labelled gluten-free were significantly more expensive than comparable products
Pieretti *et al*, USA, 2009	Quantitative	To determine the frequency and language used in voluntary advisory labels among commercially available products and to identify labelling ambiguities affecting consumers with food allergy.	Super market survey focusing on advisory labelling and another detailed survey to identify additional labelling ambiguities.	Overall, only 17 % of products contained advisory labels. Numerous products have advisory labelling and ambiguities that present challenges to consumers with food allergy
Whitaker *et al*, UK, 2009	Pilot study, Cross-sectional	To assess patients' views as to the diagnosis and treatment of coeliac disease.	Specially developed questionnaire	The condition of most patients with coeliac disease was continuing to have a substantial impact on their lives several years after diagnosis. The study revealed that the patients reported reduced enjoyment of food, less social activity, regular frustration with the

				dietary restriction and greater anxiety about their health.
Sheth *et al*, Canada, 2010	Cross-sectional/ Quantitative	1) To determine the proportion of food allergic individuals (FAIs) attributing accidental exposures to: a) complex, incomplete, or mislabelling, b)failure to read a food label, c) Ignoring a precautionary statement and 2) To determine which Precautionary statement and allergen-free statement (AFS) most strongly influence purchasing practices.	Questionnaires regarding accidental exposures due to specific food labelling issues	A considerable proportion of accidental exposures are attributed to inappropriate labelling, failure to read labels, and ignoring precautionary statements
Monks *et al*, UK, 2010	Qualitative	To understand the practical challenges that teenagers with food allergy experience using a qualitative approach and generate potential interventions for tackling these.	Semi-structured interview	The majority of teenagers reported eating foods labelled as 'may contain' an allergen as they perceive that they are actually very unlikely to contain an allergen indicating, a significant number of teenagers demonstrate risk-taking behaviour in the management of their food allergies.
Roma *et al*, Greece, 2010	Cross sectional/ Quantitative	To investigate the compliance with a gluten free diet and the impact of coeliac disease and gluten free diet on the lifestyle of patients and their families, together with proposed recommendations for improvement of quality of life.	Specially developed questionnaire	Most families experienced difficulties detecting gluten from the food label. Proposed factors for improvement of quality of life were: better labelling of gluten-containing ingredients and more gluten-free foods in supermarkets and restaurants.
Sakellariou *et al*, Greece, 2010	Quantitative	To estimate consumers' ability to recognize food allergens in labels, depending on the existence of personal food allergy history, educational level and professional	A list of 59 terms, used on food labels, describing common allergenic ingredients on products been sold in the Greek market was created.	The study reveals consumers' confusion on ingredients contained in commercial food products. Food Standards Code has not eliminated two significant problems, dealing with the use by manufacturers of 'may contain'

		direction and suggest potential changes in labelling.	Respondents were asked to match only one food with each putative term that has been used to describe food	statements, as well as complex terminology which are still extensive. This shows that guidance is insufficient.
Barnett *et al*, UK, 2011a	Qualitative	To understand the complex risk assessment decisions made by peanut and nut-allergic adults when purchasing food, with particular reference to use of printed package information.	Semi structured interview/ Observation	Food labels are used in conjunction with non -packet based strategies to make choices. peanut and nut-allergic individuals develop a range of strategies to ensure avoidance of these allergens, and various elements of the packet are used as part of the process of risk assessment
Pitchforth *et al*, UK, 2011	Focus group discussions, Qualitative	To explore the experiences of children and their parents living with nut allergy.	A short online survey (collecting basic demographic and food allergy information)	The diagnosis of nut allergy signalled critical transition or biological disruption in the life of the family. The social consequences of nut allergy were amplified by poor labelling and control of foods and products containing nuts, which causes considerable difficulties for families.
Gallagher *et al*, UK, 2012	Qualitative	To explore the experiences and healthcare needs of adolescents living with the risk of anaphylaxis; to understand the perspectives of their parents; and to look at how care might be improved.	Semi structured interviews	Risks were often difficult to judge, with reactions sometimes taking place even after careful checking of meal ingredients. Most respondents admitted taking some risks with trace-labelled foods. Appropriate healthcare support for adolescents in learning to manage the risk of anaphylaxis independently and advice and support for their parents was inconsistently provided.
Sommer *et al*, UK, 2012	Focus groups, Qualitative	To describe the food choice behaviour of diagnosed food-allergic (DFA), self-reported food-allergic or intolerant (SFA) and non-food-allergic (NFA) consumers, and	A topic guide from previous studies was prepared to elicit the focus group discussion.	Diagnosed food-allergic respondents consistently expressed dissatisfaction with current food labelling practice. The risk of accidental exposures because of inappropriate food.

		explore the differences between them.		
Zurzolo *et al*, Australia, 2013	Cross sectional/ Quantitative	To examine the behaviour and perception of parents of food-allergic children with and without a history of anaphylaxis in relation to PAL on packaged foods and to understand consumers' perception of the "may be present" statement advocated by VITAL (voluntary incidental trace allergen labelling).	Self-administered questionnaire.	Parents of food allergic children, including those with a child with a past history of anaphylaxis who might be considered to be at greater risk of an adverse reaction, appear complacent about PAL. Parents of food-allergic children are assuming a gradient level of risk based on the wording of the precautionary statements.
Cochrane *et al*, UK, 2013	Cross sectional/ Quantitative	To understand the characteristics and buying behaviours of food-allergic consumers in Great Britain (GB) and people buying food for them.	Specially designed online survey	A substantial proportion of consumers regularly take risks when purchasing food including those reporting severe allergic reactions. It also confirms the application of PAL to mitigate and communicate risk of limited effectiveness.
Altobelli, Italy, 2013	Cross sectional/ Quantitative	To assess health related quality of life in children and adolescents with coeliac disease and explore how several demographic and clinical characteristics and gluten free diet adherence affect their perceived health status.	Canadian Coeliac Health Survey. Italian language version of the questionnaire on the Health Status SF-12	More than one third of the respondents with coeliac disease reported feeling angry always or most of the time having to follow the gluten-free diet. Nearly, 20% reported feeling different from others and misunderstood because of coeliac disease.
Ozola & Straumite, Latvia, 2014	Quantitative	To study a coeliac patient's attitude to gluten-free product quality and availability in the Latvian market and purchasing habits.	Specially designed survey focussing on consumers' opinion about quality of gluten-free products & Consumption patterns of gluten-free products.	Latvian coeliac patients have to spend more for purchase of gluten-free products.

Table B: Abstracts chosen for systematic review

Authors & year	Purpose of review	Findings
Simons *et al.*, 2005	To investigate current responses to food labels so that the impact of future label changes can be anticipated.	Improved product allergen labelling will reduce allergic reactions and simplify allergy management
Taylor & Hefle, 2006,	To check if the new legislation in the USA and European Union will increase the amount of information available to food-allergic consumers.	The ingredient statement on packaged food labels in the USA and European Union now contains more information than ever before.
Kalb, B. *et al.*, 2013	To evaluate, how commonly used food allergen labelling or the absence of these notes is interpreted by concerned parents in Germany.	There is a pressing need of a legally regulated, clear and consistent labelling of allergen traces in order to not compromise the health and safety of persons with food allergies.

Appendix B: Twitter page and social media

Appendix C: 'Efficiency of Food Labelling' survey

Behaviour, practices and barriers of food hypersensitive consumers when procuring food

Design of the 'Efficiency of Food Labelling' online survey

An independent subjects design was used to examine and characterise the views of a national sample of food allergic and food intolerant consumers relating to their attitudes, preferences and practices towards food labelling.

1. We first investigated whether there was a difference in eating preferences and food choice between 'age' and 'type' of food hypersensitivity which was an independent dichotomous categorical variable with two levels: food allergy and food intolerance. Age was originally collected as a continuous variable but was collapsed into a categorical variable for the purpose of this analysis and had three levels; 15-30 year olds, 31-45 year olds and above 45 years old. Age was treated as an independent variable. The four dependent variables examined were: (i) the importance of food being safe, (ii) being nutritious, (iii) helping to control weight, or (iv) if the respondents cared about the effects of food on their health. This was operationalised using a 5-point scale which will be discussed in the 'Measures' section.

2. We next investigated any differences in the practices and attitudes towards food labelling. Food hypersensitivity and age were independent categorical variables with the same levels, described above. The six dependent continuous variables were; (i) how often people used labelling, (ii) how influenced they were by labelling and whether they found labelling (iii) reliable, (iv) adequate, (v) understandable and (vi) necessary. To investigate these differences respondents were asked to respond to a statement regarding each dependent variable using a 5-point scale.

3. We used a multiple regression analysis to identify potential predictors of how often respondents use labelling when purchasing food, which was a continuous dependent variable. The independent continuous variables were: (i) how much of a problem people felt food hypersensitivity is in Ireland; (ii) how influenced respondents are by labelling when purchasing food; (iii) if people understand labelling information; and (iv) the importance of food being safe and nutritious.

4. Finally, we investigated where respondents shop, the type of label with which they place the most confidence and trust, the most helpful characteristics of labelling and how respondents decide if a food product is safe to eat.

Measures

The online survey included a cover page with consent form and study information to ensure all respondents understood the process and what was required of them. The remaining survey was divided into of three sections. The process of item development for these three sections is discussed in 'Procedure', below. The first

consisted of demographic information where respondents were asked their age, gender, educational level (secondary school, higher level training or degree), nationality, whether they were a parent of a child with food hypersensitivity, whether they reported food allergy or food intolerance and by whom, and how they were diagnosed (e.g. food allergy specialist, general practitioner or self-diagnosed). Respondents were also allowed to input 'Other' means of diagnosis and to comment on the reality of living with food hypersensitivity. This was assessed using a 4-point scale, with 1 being 'very problematic' and 4 being 'not problematic at all'.

Respondents were asked where they shop with the options; (i) food stalls/farmers markets, (ii) corner shops, (iii) small to medium supermarkets (e.g. Mace), (iv) large supermarkets (e.g. Tesco), (v) large budget supermarkets (e.g. Aldi), (vi) premium supermarkets (e.g. Marks & Spencer), and (vii) online shopping. We used a five-point scale, ranging from 1 (never) to 5 (always). Respondents were asked about which type of PAL they are most confident with and to rank each option in order of importance. Questions on the perceived characteristics of food safety and characteristics of food labelling were also included. The second section consisted of four statements intended to garner information on respondent's eating preferences and food choices. These were: (i) the importance of food being safe, (ii) being nutritious, (iii) helping to control weight, or (iv) whether respondents were concerned about the effects of food products/ingredients on their health on a five-point scale, ranging from 1 (Never) to 5 (Always). The final section consisted of six statements on practices and attitudes towards food labelling; (i) how often people used labelling, (ii) how influenced they were by labelling and whether they found labelling (iii) reliable, (iv) adequate, (v) understandable and (vi) necessary. Responses ranged from 1 to 5, with 1 = 'Never' and 5 = 'Always' for the first two statements on practices and 1 = 'Not at all' and 5 = 'Very much' for the statements on attitudes.

Procedure

The 'Efficiency of Food Labelling' online survey was developed based on an extensive review of the literature and a further expert review of items to establish content and construct validity. The survey aimed to gather information regarding attitudes, preferences and practices towards food labelling for food allergic and food intolerant consumers. A small cohort matched with the target sample was also used to determine face validity. Ethical approval to distribute the survey and carry out the study was obtained from the School of Applied Psychology in University College Cork. An email was sent to Universities on the IOI requesting that only respondents with food allergy or food intolerance complete the survey. The universities targeted included; University College Cork (UCC), University of Limerick (UL), National University of Ireland, Galway (NUIG), Dublin City University (DCU), Trinity College Dublin (TCD) and Queen's University, Belfast. A web-link was used so that respondents could access the survey. The information sheet and consent form were included in the materials on the online survey. The participants' responses were then exported from SurveyMonkey.com to Statistical Package for Social Sciences (SPSS) version 22 (IBM©) for analysis.

Data Analysis

Data was analysed using SPSS version 22 (IBM©). Each item from the online survey was coded which included defining variable names, formats and labels. Next, data screening and cleaning took place to ensure no violation of the assumptions of normality, linearity and homoscedasticity, and to assess the suitability of the data for parametric statistics. The survey consisted of three sections; (i) demographic information, (ii) statements regarding eating preference and food choice, and (iii) statements regarding practices and attitudes towards food labelling. In total, 516 people responded but if part two or part three of the survey, or both, were not completed the participant's remaining data were not used. In cases where respondents completed the majority of the survey but random scores were missing, Little's Missing Completely at Random (MCAR) Test (Little, 1998) was used to ensure that this data was missing at random. In these cases, the mean of each variable was calculated and inserted into the missing response to ensure a robust sample. This process resulted in 379 fully completed survey responses.

An in-depth examination was performed for all variables in the data set. Descriptive statistics were run for each continuous dependent variable and it was found that each response was within the possible range of 1 to 5. Baseline characteristics were examined. An inferential analyses of the data set was carried out on (a) eating preferences and food choice, (b) practices and attitude towards food labelling, (c) the importance of food being safe, (d) being nutritious, (e) helped to control weight, (f) if respondents were concerned about the effects of food on their health, (g) if labelling was used, (h) how influenced respondents are by labelling, and (i) whether they found labelling reliable, adequate, understandable and necessary.

Preliminary data checking was conducted to ensure the suitability of data for analysis. In addition, all assumptions for each step were checked. A multivariate analysis of variance (MANOVA) was used to compare groups (Field, 2013). Each group exceeded the minimum cell count of 20 (Tabachnick & Fidell, 2013). Data also did not violate the assumptions of multicollinearity and linearity of associations between quantitative outcome variables. In order to identify potential predictors of how often respondents use labelling when purchasing food, a multiple regression was used to explore the predictive ability of a set of continuous independent variables on one continuous dependent variable i.e. how often respondents use labelling when purchasing food, while the continuous independent variables included how much of a problem people feel food allergy and food intolerance is on the IOI, how influenced respondents are by labelling when purchasing food, whether people understand labelling information and the importance of food being safe and nutritious. The analysis did not violate the test's associated assumptions. There was no evidence of multicollinearity between the independent variables and the inspection of outliers left no cause for concern. The use of a multiple regression here is justified as examining potential relationships between predictors in this way has been used in many studies in this field (Choi, 2012; Williams & Hankey, 2015).

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Content, information sheet of the respondents and consent form

PART 1

Q1. What age are you? _____

Q2. What is your gender? Male/ Female

Q3. Which of the following best describe your highest educational level?

Secondary School

Higher Training

Degree

Q4. Were you born in Ireland? Yes/No

Q5. Which among the following problems do you have?

Food Allergy

Food Intolerance

Q6. Are you the parent of a child with adverse reaction to food? Yes/No

Q7. When you have an adverse reaction to food, do you experience any of the symptoms in the adjacent sections?

Section 1: (Tick yes if you have one or more of the symptoms in this box): Itching, rashes, tiredness, lethargy, weakness, anxiety or depression: Yes/No/Not applicable

Section 2: (Tick yes if you have one or more of the symptoms in this box: swollen lips, swollen glands, swollen limps, nausea, vomiting, diarrhea, stomach cramps, runny nose, blocked nose, itchy eyes. Yes/No/Not applicable

Section 3 (Tick yes if you have one or more of the symptoms in this box): bloating, wind, indigestion, dizziness, shortness of breath, wheezing, rattling in the throat. Yes/No/Not applicable

Section 4 (Tick yes if you have one or more of the symptoms in this box): Fainting, collapsing, weak bladder, bowel incontinence, low blood pressure. Yes/No/Not applicable

If you have any other symptom, please write them in the box below

Q8. How did you come to realize that you have an adverse reaction to some food?

- Diagnosed by specialist
- Diagnosed by general practitioner
- Diagnosed by a nutritionist or dietician
- Diagnosed by an alternative practitioner
- Not diagnosed by any of the above

Q9. How often do you shop in the following settings (Never-1, Rarely-2, Sometimes-3, Most of the time-4 or Always-5)?

- Food stalls
- Corner Shops
- Medium Supermarket (Mace, Londis, etc)
- Large Supermarkets (Tesco, Super value, etc)
- Budget Supermarkets (Aldi, Lidl, etc)
- Premium Shop (Waitrose, Marks & Spencer, etc)
- Online Shopping

Q10. Please rate in order of confidence in safety each of the label types below-(Rate as 1, 2, 3, 4 ,5 where 1 being the most confident and 5 is the least confident statement)

- May contain
- May contain traces of X
- Not suitable for someone with X allergy
- Packaged in a facility that also processes X
- Manufactured on equipment that processes'

Q11. How do you decide whether a food product is safe to eat (you/your child will not experience an adverse reaction)? Please rate in order of importance from 1 to 10, where 1 is the most important one and 10 is of least importance.

- The quality of labelling
- I have eaten it before and not experienced a reaction
- I trust the brand
- I trust supermarket
- If possible, I taste a little bit and see what happens
- Smell of product
- I judge by the texture (smooth, grainy, etc.)
- The brand is from large well-known food producer
- Freshness
- Freshness
- Country of Origin

Q12. Please rate in order of importance, the most helpful characteristics of the nutrition facts panel/labelling when deciding to buy a food product from 1 to 7, where 1 is most important and 7 is least important.

- Font
- Colour or lettering on label
- Colour of label

- Size of letters
- Size of label
- Visible
- Easy to read

PART 2

Q 13. Please answer the following questions on eating preference/ food choice (Never, Rarely, Sometimes, Most of the time or Always)?

- It is important that the food I eat is safe
- It is important that the food I eat is nutritious
- It is important that the food I eat helps me control my weight
- I like to eat tasty food and I do not worry about its effects on my health

PART 3

Q14. How big of a problem do you think food hypersensitivity is in the island of Ireland?

- Very problematic
- Somewhat problematic
- Minimally problematic
- Not problematic at all

Q15. How often do you use labelling when deciding to buy a food product? (Never, Rarely, Sometimes, Most of the time or Always)?

Q16. How influenced are you by labelling, when deciding to buy a food product? (Never, Rarely, Sometimes, Most of the time or Always)?

Q17. Do you find the information on labelling? (Never, Rarely, Sometimes, Most of the time or Always)?

- Reliable
- Adequate
- Understandable
- Necessary

End of questionnaire

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Information sheet for respondents on the preferences, attitudes and practices of food allergic and food intolerant consumers towards Food Labelling Study

Purpose of the Study. The study is concerned with comparing and contrasting the attitudes and practices of food labelling between individuals with food allergy or food intolerance.

What will the study involve? The study will involve completing an online survey which will take no longer than 15 minutes to complete.

Why have you been asked to take part? You have been asked because you are specifically suitable to provide data for the study because of your food-related condition.

Do you have to take part? Participation is voluntary. If you agree to participate you will sign a consent form, and you will get to keep a copy of this information sheet and the accompanying consent form. You can withdraw at any time even if you have agreed at first to participate. You can withdraw your permission to use your data within two weeks of completing the survey; if you withdraw permission, then your data will be permanently deleted.

Will your participation in the study be kept confidential? Yes. No clues to your identity appear in the thesis.

What will happen to the information which you give? The data will be kept confidential for the duration of the study and will be analysed by myself or a third party under my supervision. On completion of the study, the data will be retained for a further two months and then destroyed.

What will happen to the results? The results will be presented in a study. They will be seen by a supervisor, a second marker and the external examiner. The study may be read by future students on the course. The study may be published in an academic journal.

What are the possible disadvantages of taking part? I don't envisage any negative consequences for you in taking part. It is possible that talking about your experience in this way may cause some distress.

What if there is a problem? If you subsequently feel distressed after completing the survey, you should contact your GP.

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Who has reviewed this study? Approval must be given by the school of applied psychology (SOAP) in University College Cork before studies like this can take place, and this approval has been granted to this study.

Any further queries? If you need any further information, you can contact me: Brian Murphy, 0879548630, 114222429@umail.ucc.ie.

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Consent Form for Preferences, Attitudes and Practices of Food Allergic and Food Intolerant Consumers towards Food Labelling Study

I _____ agree to participate in the **Preferences, Attitudes and Practices of Food Allergic and Food Intolerant Consumers towards Food Labelling** research study.

The purpose of the study has been explained to me and I understand it.

I am participating voluntarily.

I give permission for the use of my data from this survey to be recorded and such personal details as I have provided to be kept on record.

I understand that I can withdraw from the study, without repercussions, at any time whether before it starts or while I am participating.

I understand I can withdraw my permission to use the data within two weeks of the study, in which case the material I have provided will be deleted.

I understand that anonymity will be ensured in the write-up by disguising my identity.

I understand that disguised extracts from what I say may be quoted in the thesis and any subsequent publications if I give permission below.

I agree to quotation/ publication of extracts from my data

I do not agree to quotation/ publication of extracts from my data

Signed: _____ Date:_____

Appendix D: Statistical information on behaviour, practices and barriers of food hypersensitive consumers when procuring food: the 'efficiency of food labelling' online survey

D (I) Demographic characteristics

Table I: Demographic characteristics of respondents (n=652)

		n	%
Demographic Characteristics			
Gender	Male	100	16.1
	Female	523	83.9
Age			
	15-30 years old	207	31.7
	31-45	179	27.5
	Older than 45	177	28.5
Food condition			
Adult/Parent/Teen	Food allergy	126	25
	Food intolerance	285	58
	Coeliac disease	84	17
Child of Parent	Parent of child with food allergy	86	54
	Parent of child with food intolerance (including coeliac disease)	72	46
Origin			
	IOI	520	79.8
	International	80	21.1
Educational level			
	Secondary School	108	16.6
	Higher Training	76	11.7
	Degree	444	68.1

D (II) Descriptive statistics

Where do respondents shop most frequently?

Respondents were presented with a number of shopping locations and asked how often they shop at each. A 5-point scale was used to capture the preferred shopping locations. This ranged from 1 (never) to 5 (always). The full range of responses is presented in Table II.

Table II: Respondent's shopping locations in order of preference

Shopping location	Score
Large Supermarkets (Tesco, Supervalu)	3.93
Budget Supermarkets (Aldi, Lidl)	3.57
Medium Supermarket (Mace, Londis)	2.47

Corner Shop	2.40
Premium Shop (Waitrose, Marks & Spencer)	2.31
Food Stalls	2.21
Online	1.42

Which precautionary allergen label wording have respondents most confidence in?

Respondents were presented with five common PAL wording and asked to rate them in order of confidence in their assurance of safety where 1 was most confident and 5 the least confident. The full range of responses is presented in Table III.

Table III: Rank order of respondent's confidence in precautionary allergen label wording

Precautionary Label Wording	Score
Not suitable for someone with X allergy	1.84
May contain traces of X	2.95
May contain	3.12
Packaged in a facility that also processes X	3.37
Manufactured on equipment that process X	3.72

How do respondents decide whether a food product is safe to eat or not?

Respondents were presented with ten characteristics that aid decision making as to whether or not a food product is safe to eat. They were asked to rate the importance of each of these factors with 1 being the most important and 5 the least important (Table IV)

Table IV: Rank of characteristics that assist respondents in deciding if a food product is safe

Food product characteristic	Score
Quality of labelling	2.37
Eaten it before and experienced no reaction	2.40
Brand trust	3.42
Trust in supermarket	5.19
Freshness	5.65
Brand from well-known producer	5.96
Smell of product	7.01
If possible, I taste a little bit and see what happens	7.26
Judge the texture (smooth, grainy, etc.)	7.67
Country of Origin	8.06

What are the characteristics of food labelling that are most helpful for consumers when deciding to purchase a food product?

Respondents were presented with seven labelling characteristics and asked to rate how helpful each was when deciding to buy a food product (1 = most helpful and 5 = least helpful). The full range of responses is presented in Table V.

Table V: Rank order of labelling characteristics that are most helpful when deciding to buy a product

Most helpful labelling characteristics	Score
Easy to read	2.84
Visible	3.57
Font	4.41
Size of letters	4.47
Size of label	5.25
Colour or lettering on label	5.33
Colour of label	6.16

A comparative analysis between food allergy and food intolerance on shopping preference, food choice, use, and attitudes towards labelling

The relationships between type of food hypersensitivity, age and eating preferences were investigated using a 3 x 2 multivariate analysis of variance (MANOVA). The independent variables were 'age', which had 3 levels (15–30, 31–45, and 45 +) and 'food hypersensitivity' which had 2 levels (food allergy and food intolerance). Scores on various food choice statements were used as dependent variables. These were; (i) the importance of food being safe, (ii) nutritious, (iii) helping to control weight, or (iv) whether or not respondents were concerned about the effects of food on their health. The preliminary data screening carried out did not indicate any violations of the assumption of multivariate normality or of the assumptions of linearity of associations between quantitative outcome variables. Pillai's Trace was used as the test statistic because of its robustness (Warner, 2012). Table VI shows the averaged within-cell correlations among the four eating preference and food choice statements used as the outcome variables. Because of the relatively small sample sizes per group, an Alpha level of .10 was used as the criterion for significance for the Box's M test as this test is also known to be very sensitive (Warner, 2012). Results did not indicate a significant violation of the assumptions of homogeneity of variance/covariance matrices across conditions.

Table VI: Averaged within-cell correlation matrix for important food choice factors in the 3 x 2 MANOVA

Important food choice factors	Safe	Nutritious	Weight control	Don't Care
Safe	1			
Nutritious	.284	1		
Weight control	.110	.295	1	
Not concerned about health benefits	-.116	.002	.090	1

For the overall MANOVA, significant multivariate effects were found for age – [Pillai's Trace = 0.061, F(8, 554.00) = 18.09, p < 0.01], partial eta squared = 0.03 (which is a small effect size), but not for food hypersensitivity, nor for any interaction (Cohen, 1988). Therefore, the remaining results section will focus on the main effects where 1 = least important and 5 = most important. *Post-hoc* comparisons were conducted using the Tukey HSD test for each independent variable. Results showed that respondents of the age group 15-30 years old reported significantly lower scores on the importance of food being safe than those of the 31-45 and 45+ age groups. There was no significant difference in scores on this preference between the 31-45 and 45+ age groups (p > .05). Therefore, respondents over 30 years of age felt it was more important that the food they eat is safe compared to those under 30 years of age. Respondents aged over 45 years of age scored significantly higher on the importance of food being nutritious than those of the 15-30 and 31-45 age groups. There was no significant difference in scores between the 15-30 and 31-45 age groups (p> 0.05). Therefore, respondents aged over 45 years of age felt it was more important that the food they eat is nutritious compared to those under 45 years of age. There were no further significant differences between age group and the two remaining food choice options, 'control weight' and lack of concern about the effects of food on health. Each age group 'sometimes' feel it is important that a food helps to control weight with an average score of 3.66 across the three age groups. Also, each age group were generally concerned about the effects of food on their health with an average score of 2.36 across the three age groups (see Table VII).

Table VII: Importance of food choice factors per age group

Age	15-30	31-45	45+
Important food choice factors	Score	Score	Score
Safe	4.70	4.88	4.88
Nutritious	4.31	4.38	4.62
Weight control	3.65	3.63	3.70
Not concerned about health benefits	2.41	2.31	2.34

There was no significant effect between food allergic and food intolerant consumers on any of the eating preferences or food choice scales. Both groups felt the safety of the food they eat was 'always important' and nutritious. Both groups also felt it was 'sometimes important' for food to help control weight, while both groups were rarely concerned about the effects of food on their health (Table VIII).

Table VIII: Importance of food choice factors for food allergic and food intolerant consumers

Important food choice factors	Food allergy	Food intolerance
	Score	Score
Safe	4.80	4.86
Nutritious	4.35	4.47

Weight control	3.57	3.68
Not concerned about health benefits	2.34	2.40

The relationship between food hypersensitivity, gender and eating preferences was also investigated using a 2 x 2 multivariate analysis of variance (MANOVA). The independent variables were gender, which had 2 levels (male and female) and food hypersensitivity with 2 levels (food allergy and food intolerance). Scores on various food choice statements were used as dependent variables and were identical to those already stated. For the overall MANOVA, no significant multivariate effects or interaction effects were found. Both males and females reported 'always' choosing food that is safe and nutritious, 'sometimes' choosing food to help control weight and were generally concerned about the effects of food on their health. These results are presented in Table IX.

Table IX: Gender differences in the importance of food choice factors

Important food choice factors	Male	Female
	Score	Score
Safe	4.84	4.82
Nutritious	4.27	4.43
Weight control	3.33	3.69
Not concerned about health benefits	2.37	2.40

The relationships between food hypersensitivity, age and food labelling attitudes and practices were investigated using a 3 x 2 multivariate analysis of variance (MANOVA). The independent variables were age, which had 3 levels (15–30, 31–45, and 45 +) and food hypersensitivity which had 2 levels (food allergy and food intolerance). Scores on various food labelling statements were used as dependent variables. These were; (i) how often people 'used' or attended to labelling, (ii) how influenced they were by labelling, and whether they found labelling (iii) reliable, (iv) adequate, (v) understandable and (vi) necessary.

For the overall MANOVA, no significant multivariate or interaction effects were found. Both food allergic and food intolerant groups regularly use labelling and are regularly 'influenced' by labelling when deciding to buy a food product. Although both groups of consumers found labelling 'very necessary' (see Table X), they were not satisfied with its reliability and adequacy. Respondents found labelling only 'somewhat' reliable, 'somewhat' adequate and 'somewhat' understandable.

Table X: Practices and attitudes of food allergic versus food intolerant respondents to food labelling

Effect of food labelling	Food allergy	Food intolerance
	Score	Score
Frequency of using labelling	4.43	4.40
Influenced by labelling	4.33	4.34
Find labelling reliable	3.40	3.52
Find labelling adequate	2.96	3.00

Find labelling understandable	3.27	3.12
Find labelling necessary	4.63	4.59

A similar pattern was shown in scores for labelling practices and attitudes with regard to age (Table XI).

Table XI: Practices and attitudes to food labelling per age group

Effect of food labelling	15-30	31-45	45+
	Score	Score	Score
Frequency of using labelling	4.43	4.38	4.48
Influenced by labelling	4.32	4.32	4.39
Find labelling reliable	3.60	3.32	3.69
Find labelling adequate	3.15	2.82	3.15
Find labelling understandable	3.27	3.15	3.25
Find labelling necessary	4.55	4.62	4.75

Examining the relationships between food hypersensitivity, gender and food labelling attitudes and practices, both males and females regularly use labelling and both are influenced by labelling when deciding to buy a food product, reporting it as 'very necessary'. Both males and females found labelling 'somewhat' reliable, 'somewhat' adequate and 'somewhat' understandable. (See Table XII).

Table XII: Gender differences in practices and attitudes to food labelling

Effect of food labelling	Male	Female
	Score	Score
Frequency of using labelling	4.27	4.35
Influenced by labelling	4.15	4.29
Find labelling reliable	3.66	3.44
Find labelling adequate	3.10	2.97
Find labelling understandable	3.39	3.18
Find labelling necessary	4.76	4.59

Respondents were asked about their food preferences, attitudes and practices towards food labelling. In general, both adults (without children) and parents reported 'always' choosing food that is nutritious (score=4.39). They 'sometimes' choose food that helped to control their weight (score=3.61) and were mostly concerned about the effects of food on their health (score=2.44). However, there was a significant difference in the preference of food being 'safe' with parents reporting the necessity of foods being safe as significantly more important (score=4.96) than adults without children (score=4.78). With regards to labelling practices and attitudes, both adults without children and parents reported 'sometimes' finding labelling reliable (score=3.44),

adequate (score=2.97) and understandable (score=3.24): they 'always' found labelling necessary (score=4.62). There was a significant difference in how often respondents used labelling when purchasing food. Parents reported using or attending to labelling significantly more often (score=4.47) than adults without children (score=4.25). Also, parents were significantly more influenced by labelling (score=4.45) than adults without children (score=4.18).

With regards to any differences between those 'diagnosed by a health professional or specialist' vs 'self-diagnosed', both groups reported choosing food that is nutritious (score=4.41) and helping to control their weight (score=3.63) 'most of the time'. However, there was a significant difference in the preference for food being 'safe'. Those that were diagnosed by a health professional or specialist reported safety of food products as significantly more important (score=4.86) than those that were self-diagnosed (score=4.73). Also, those that were diagnosed by a specialist scored significantly lower on not being concerned about the effects of food on their health (score=2.30) compared to those who were self-diagnosed (score=2.68). However with regard to balancing competing values, although safety is the primary concern of those who were diagnosed, both groups were also interested in health benefits of food products suggesting that labelling that addresses both concerns could be helpful to a wide range of consumers. With regards to labelling practices and attitudes, again both groups reported 'sometimes' finding labelling reliable (score=3.45), adequate (score=2.99) and understandable (score=3.22), while 'always' finding labelling necessary (score=4.60). However, there was a significant difference in how often respondents used or attended to labelling. Those that were diagnosed by a specialist reported using labelling significantly more often (score=4.43) than those that were self-diagnosed (score=4.05). They were also significantly more influenced by labelling (score=4.35) compared to those who were self-diagnosed (score=3.99).

Respondents were asked the number of food allergens to which they react. The responses were transformed into a dichotomous variable of (i) one or two allergens, and (ii) more than two allergens. Both groups reported choosing food that is nutritious (score=4.39), food that helps to control their weight 'most of the time' (score=3.61), and 'rarely' were they not concerned about the effects of food on their health (score=2.44). However, there was a significant difference in the preference for food being 'safe'. Those that react to more than two allergens reported food safety as significantly more important (score=4.91) than those that react to less than two allergens (score=4.79). With regards to labelling practices and attitudes, again both groups reported 'sometimes' finding labelling reliable (score=3.44), adequate (score=2.97) and understandable (score=3.24), while 'always' reporting labelling to be necessary (score=4.62).

We found a significant difference in how often respondents used or attended to labelling. Those that react to more than two allergens reported using labelling significantly more often (score=4.51) than those that react to less than two allergens (score=4.19). They were also significantly more influenced by labelling (score=4.40) compared to those who react to less than two allergens (score=4.18).

Respondents were also given a list of symptoms that they experience during a reaction and could choose more than one. The total number of symptoms associated with each respondent was then calculated and this was transformed into a dichotomous variable of (i) one or two symptoms, and (ii) more than two symptoms. Both groups reported choosing food that is safe (score=4.83) and nutritious (score=4.39) and 'rarely' were not

concerned about the effects of food on their health (score=2.44). However, there was a significant difference in responses to the option of not being concerned about the effects of food on their health with those that experience more than two symptoms reporting lower scores on not being concerned about the effects of food on their health (score=2.29) than those that experience less than two symptoms (score=2.59). There was a significant difference in how often respondents used labelling with respondents who experience more than two symptoms reporting using labelling significantly (score=4.43) more often than those that experience less than two symptoms (score=4.18). Those that experience more than two symptoms were significantly more influenced by labelling when purchasing food (score=4.37) compared to those who report less than two symptoms (score=4.14).

A series of standardised multiple regression analyses (modelling) was performed to identify potential predictors and models of how often consumers use or attend to labelling when deciding to buy a food product. Participant's attitudes towards how much of a problem they felt food hypersensitivity to be (Problem), how influenced respondents are by labelling when purchasing food (Influence), whether people understand labelling information (Understand) and the importance of food being safe (Safety) and nutritious (Nutritious) were used as the independent variables. All models controlled for type of hypersensitivity, number of symptoms, number of foods to which hypersensitive, age, parent/adult, diagnosis, level of understanding, and gender. Normality, constant variance, linearity, and outliers were examined for verifying assumptions necessary for multiple regression analysis (Field, 2013). The results met the requirements and no assumptions were violated. As shown by Table XIII, the absolute value of the correlation coefficient (R) is 0.78. The overall model was significant and explained a high proportion of the 60.8% of the variance in explaining 'how often people use labelling when purchasing food'.

Table XIII: Summary of regression analysis

R	R^2	Adjust R^2	df	F	Sig.
.78	.61	.60	4	111.59	.000*

Note: Dependent variable = Often, significant at *p<0.05

The 'weight' of each of the factors (indicated by β) can be seen in Table XIV. The larger the β value, the more 'important' it is in explaining why consumers use labelling. The significant predictors of how often labelling is actually used, or attended to, are 'nutritiousness' (β = .10), 'safety' (β = .04), whether food hypersensitivity is regarded as a problem in Ireland by the consumer (β = .10), and how much a consumer is influenced by labelling when choosing what product to purchase (β = .74). The latter β is considered a very large effect (Tabachnick & Fidell, 2013). This 'influence' makes the strongest unique contribution to explaining the dependent variable, when the variance explained by all other variables in the model are controlled for (Tabachnick & Fidell, 2013). It is particularly noteworthy considering that the final model controlled for a wide range of factors including type

of hypersensitivity, number of symptoms, number of foods to which hypersensitive, age, parent/adult, level of understanding, diagnosis, and gender.

Table XIV: Multiple regression analysis measuring 'how often' labelling is used

Predictor		β
Age		-0.09**
Safety		0.04*
Nutritious		0.10*
Influence		0.74**
Understand		0.09*
Adjusted R^2	0.60***	

Controls: type of hypersensitivity, number of symptoms, number of foods to which hypersensitive, age, parent/adult, level of understanding, diagnosis, and gender. *p <.05, **p <.01, ***p<.001.

Our model shows that in making a food choice/purchasing decision, although safety and nutrition is important for food hypersensitive consumers, the most important predictor of how much labelling is used (over and above all other factors) is how much a consumer is influenced by labelling in general. This highlights the importance of focusing on creating useful and useable labelling formats that will be helpful to a wide array of consumers with hypersensitivity (whether clinically or self-diagnosed).

Appendix E: Survey on experiences and lessons to be learned from other countries

As well as accessing websites of European and worldwide patient support and non-governmental organisations for food hypersensitive consumers, a simple descriptive unstructured questionnaire (not assessed for bias) was developed and circulated to European Patient Support Organisations through the good offices of Frans Timmermans, Chair of the EAACI Patient Support Organisations Committee. The questionnaire was circulated on 24th September 2015 to the Patient Support Organisations in Belgium, Denmark, France, Germany, Greece, Italy, Norway, Spain, Sweden and the UK, as well as the European Federation of Allergy & Airway Diseases Patients Association. The information was collated and evaluated to assess if there are any learnings from overseas consumers that would benefit their counterparts on the IOI.

Main survey

1. Which of the following conditions does your Patient Support Group support? (Please delete those that do not apply)

- IgE mediated food allergy
- other forms of food allergy
- coeliac disease
- food intolerance
- All of the above

2. Have you investigated the availability of food for people on an avoidance diet? (Please delete those that do not apply)

- Yes, a study was undertaken and a report was published
- Yes an informal study took place and a web story was published
- We are undertaking a study which is yet to be completed
- No study has been carried out but from anecdotal information from our members we can give a view
- We do not have any information or opinion on this matter

3. If you have information to share on the availability of food for people on an avoidance diet please give a reference or a weblink below

4. If you have anecdotal or informal information to share on the availability of food for people on an avoidance diet how would you rate availability in your country? (Please delete those that do not apply)

- I have no information
- Yes It is easy for people with IgE mediated food allergy to eat safely
- No It is **not** easy for people with IgE mediated food allergy to eat safely

- Yes It is easy for people with other forms of food allergy to eat safely
- No It is **not** easy for people with other forms of food allergy to eat safely

- Yes It is easy for people with coeliac disease to eat safely
- No It is **not** easy for people with coeliac disease to eat safely

- Yes It is easy for people with food intolerance to eat safely
- No It is **not** easy for people with food intolerance to eat safely

5. If you have answered 'yes' to any question in question 4 please tell us why

6. If you have answered 'no' to any question in question 4 please tell us why

7. Please tell us how you think food producers and supermarkets can improve products (particularly with regard to labelling) for the benefit of the hypersensitive consumer

Identifying what influences the shopping habits of food hypersensitive consumers; an island of Ireland study.

Email approach letter

Dear Colleague

University College Cork is conducting a study in collaboration with Queen's University, Belfast. The research project entitled ''Food security for the food hypersensitive consumer on the island of Ireland'' is funded by ***Safefood*** (the Food Safety Promotion Board) http://www.safefood.eu/Home.aspx.

We would like to explore, in a narrative fashion, the experiences of patient support groups in Europe in accessing appropriate food by those on an avoidance diet. The avoidance diet may be as a result of a diagnosed IgE mediated food allergy, other forms of food allergy, coeliac disease or food intolerance. We would like to invite you to complete the following brief 7 question questionnaire. Please contact walkermj@ntlworld.com if you have any questions.

- Your Name (options)
- Your Country
- Your affiliation (optional)

Appendix F: Information on the extent of prepacked 'free-from' food produced on the IOI and its export potential

An investigation on the extent of prepacked 'free-from' foods produced on the IOI, and the associated export potential, was carried out by reviewing high quality business reports for data on growth projections for specific food sectors, export potential for specific countries and other relevant information. The information available was limited so a more targeted approach was followed. A survey was conducted by sending a questionnaire to food manufactures in ROI, NI and the UK in order to obtain a more in-depth understanding of this sector. This was a survey administered by the online survey development cloud-based service SmartSurveyTM.

Basics

- Name of company (if you wish to)
- Location (e.g. EN, SCO, WA, NI, ROI)
- Food sector mainly involved in (necessary)
- Contact information (if you wish to)

1. 1. Are you producing free-from* products? Yes/No
2. Please mention the type(s) and quantity of free-from* products produced

- Snacks
- Bakery
- Dairy
- Sauces and Seasonings
- Processed Fish, Meat and egg Products
- Baby Food
- Desserts and Ice Cream
- Meals and Meal Centres
- Side Dishes
- Chocolate Confectionery
- Other (please specify)

3. If you export these free-from* products please mention quantity and country of destination.

- Snacks
- Bakery
- Dairy
- Sauces and Seasonings
- Processed Fish, Meat and egg Products
- Baby Food
- Desserts and Ice Cream
- Meals and Meal Centres
- Side Dishes

- Chocolate Confectionery
- Other (please specify)

4. If you are not exporting any free-from* products, have you undertaken alone or in collaboration with trade and/or trade-support organisations any initiatives to do so in the next 5 years? Yes/No

End of survey

Email approach letter

Overview: Queen's University Belfast is conducting a research project funded by safefood entitled ''Food security for the food hypersensitive consumer on the island of Ireland''. This project brings together a team of experts with strong track records in their fields. This consortium is composed of scientifically acclaimed food science and allergy experts, and a psychological medicine expert with clinical experience in food allergy and coeliac disease. The objectives of the project are to: a) Understand needs, expectations and barriers in purchasing appropriate food of Island of Ireland consumers following an avoidance diet and b) Conduct a wide market and industry analysis of foods available to food hypersensitive consumers on the Island of Ireland.

In order to achieve these objectives we would like to invite you to participate in this short survey.

Data sharing. We guarantee that your responses will remain anonymous at all stages. The report will be published in safefood's website and will not link responses with names or brands.

Appendix G: Survey on use of precautionary allergen labelling (e.g. 'may contain…'): Are they working?

Assessing if non-regulated precautionary allergen labelling statements are fit for purpose and if precautionary allergen labelling information can be expanded in a factory level

There is limited information evaluating if PAL is fit for purpose in IOI but also in general. Although, this report is aims to evaluate the situation in IOI, a lack of available data on an all-island basis means that separate findings are reported for ROI and NI, as available. When information specific to NI are not available, UK data were used. The sources of information were Food Standards Authority reports and peer reviewed academic literature on consumer attitude and PAL. When possible, comparisons were made on an international level.

Determination of the key factors that induce or oblige food manufacturers to apply precautionary allergen labelling

A thorough search of commercially available electronic databases (i.e. PubMed, Scopus and Web of Science) was conducted for articles on allergen threshold levels and on the reasons that induce or oblige food manufacturers to apply PAL. Moreover, a wide range of information sources was used to identify relevant information including scientific committees, governmental and industrial organisation reviews and information on websites (e.g. WHO, FAO, FSA, NIFDA). The information was analysed and critiqued. A further survey conducted by the cloud-based service SmartSurveyTM was used to supplement this information (Appendix I).

Identifying the food industry sectors that are forthcoming with precautionary allergen labelling

A structured questionnaire was sent to food companies on the IOI and in the UK to gain an insight into the food sectors that conduct risk assessment before applying PAL thus using it in line with best practice guidance. This survey was also administered by the online survey development cloud-based service SmartSurveyTM (Appendix F). Moreover, short interviews (email contacts) with key executives of businesses and organisations providing PAL information were conducted in order to shortlist some of food industry sectors that that are forthcoming with PAL. NIFDA, FDII, Heinz, and Food and Drink Federation (UK) were contacted. A thorough review of scientific literature and market reports from credible sources was also conducted to identify potential relevant information.

Basics

Name of company (if you wish to)

Location (e.g. EN, SCO, WA, NI, ROI)

Food sector mainly involved in (necessary)

Identifying what influences the shopping habits of food hypersensitive consumers; an island of Ireland study.

Contact information (if you wish to)

Do you use precautionary allergen labelling in your products? Yes/No

Which allergenic ingredient you use in the products you produce?

- Milk
- Cereal containing gluten
- Wheat
- Soybeans
- Eggs
- Mustard
- Sulphur dioxide/sulphites
- Peanuts
- Tree nuts
- Celery
- Other (Please specify)

For what allergen(s) do you make precautionary statements on your labels?

- Milk
- Cereal containing gluten
- Wheat
- Soybeans
- Eggs
- Mustard
- Sulphur dioxide/sulphites
- Peanuts
- Tree nuts
- Celery
- Other (Please specify)

What are the reasons behind your company's decision to use precautionary allergen labelling?

- Lack of clarity over standards for applying PL
- Uncertainty over allergen thresholds
- Lack of information from suppliers
- Flexibility in supply chain
- Flexibility in production
- Fear of litigation

- Loss of reputation
- Other (Please specify)

To what extent you use PAL on the produced food products?

- Less that 25%
- Less that 50%
- Less than 75%
- 100 % of products
- Other (Please specify)

Did you perform a risk assessment before adding the PL? Yes (please specify)/No

How often do you update your PAL statements?

- Every year
- Every 6 months
- Never
- Other (please specify)

What is the form of words you use for P?

- 'May contain X'
- 'May contain traces of X'
- 'Not suitable for someone with X allergy'
- 'Made in a factory that also processes X'
- 'Made on equipment that also processes X'
- 'Packaged in a facilitate that also processes X'
- Other (Please specify)

Did you go to regulators (e.g. FSA) to ask for advice before finalising the label? Yes (please specify)/No

Does the PAL wording comply with a defined standard (e.g. BRC)? Yes (please specify)/No

Do you get customer queries or complaints about PAL statements in your products? Yes/No/Other

End of survey

Email approach letter

Overview: Queen's University Belfast is conducting a research project funded by *safe*food entitled ''Food security for the food hypersensitive consumer on the island of Ireland''. This project brings together a team of experts with strong track records in their fields. This consortium is composed of scientifically acclaimed food science and allergy experts, and a psychological medicine expert with clinical experience in food allergy and coeliac disease. The objectives of the project are to: a) Understand needs, expectations and barriers in purchasing appropriate food of Island of Ireland consumers following an avoidance diet and b) Conduct a wide market and industry analysis of foods available to food hypersensitive consumers on the Island of Ireland.

In order to achieve these objectives we would like to invite you to participate in this short survey.

Data sharing. We guarantee that your responses will remain anonymous at all stages. The report will be published in *safe*food's website and will not link responses with names or brands.

Appendix H: Survey on availability of testing for food allergens, food intolerance parameters and gluten in the IOI

A structured questionnaire was developed with the aim to identify the analytical kits and services provided to IOI by companies on a worldwide level (n=7). Private companies and research organisations (research institutes and universities) on an international level were directly targeted by e-mail for the study. The organisations contacted are involved in allergen and intolerances testing and comprised of all sizes. In total 30 organisations were contacted and 7 replies were received. Respondents were also asked to participate in a telephone interview which was aimed in obtaining more in depth details regarding some technical specifications of the testing they provide. 3 out of 7 respondents agreed to take part in the interview. The respondents were:

- An analytical service provider (n=1) which is a multinational general laboratory services company that includes a general food analysis offering (chemistry and microbiology) including allergens.
- Enzyme Linked Immunosorbent Assay, ELISA, kit manufacturing companies (n = 4) that offer both ELISAs for sale for use by the customer laboratory and a general food analysis offering including allergens.
- Enforcement (Public Analyst) laboratory (n= 1) in the ROI with a general food analysis offering and specialising in allergens and gluten analysis providing this service on a national basis for the Health Service Executive, other State agencies and to some private food business operators as well as research activity in allergens.
- An air quality and environmental company (n = 1) specialising in products and services for allergy and asthma.

Do you supply food allergen or food intolerance testing services to the island of Ireland offer (e.g. testing itself, sale of kits to test for allergens?)

- Yes
- Yes, but only in Great Britain
- No

If answered *No*, thank you for participating

If answered *Yes* please indicate which of the following you offer (tick all that apply)

- Testing of food samples
- Sell kits for testing food samples
- Other (please specify)

Do you have a UK distributor? (Please answer if you are not based in the UK) Yes/No

Which methods do you use for allergens/intolerance analysis? (Tick all that apply)

- ELISA
- Lateral flow devices
- PCR / DNA
- LC-MS or LC-MS/MS

- Other (please specify)

For which Allergens/Intolerances you test for? (Complete the following matrix- tick all that apply)

Allergen/other compound	ELISA	LFD Lateral flow devices	DNA	LC-MS	Other
Wheat					
Rye					
Barley					
Oats					
Crustaceans					
Crustacean unspecified					
Shrimp/Prawn					
Crab					
Lobster					
Crayfish					
Other					
Eggs					
Fish					
Fish unspecified					
Anchovies					
Bass					
Catfish					
Cod					
Flounder					
Grouper					
Haddock					
Hake					
Halibut					
Herring					
Mahi Mahi					
Perch					
Pike					
Pollock					
Salmon					
Scrod					
Swordfish					
Sole					
Snapper					
Tilapia					
Trout					
Molluscs					
Mussels					
Scallops					
Cockles					
Oyster					
Clam					
Other					
Emerging Allergens					
Kiwi					
Banana					
Pea					
Lentil					
Other					
Intolerances					
Gluten					
Lactose & other					

Additional information about the allergens your test(s) covers: This question will be part of a telephone conversation if you are happy to take part and is included here to give you an indication of what we would like to discuss. For the first column *(A)* please fill in the test and allergen analysed (e.g. ELISA/gluten).

	Test 1 allergen 1	Test 2 allergen 2	Test 3 allergen 3	Test 4 allergen 4	Test 5 allergen 5
Cost					
Has the allergen been identified as a protein or group of proteins	*Protein/ group of proteins*				
Test detects the allergen or a different marker?	*Allergen/* *Marker*				
Do you know how food processing affects the allergenicity of the protein	*Yes/no. If yes how*				
Are allergen hydrolysates used in the food industry and will the method detect such material?	*Yes/no/ other*				
Have matrix interferences been investigated?	*Yes no other*				
Is there cross reactivity with other allergens?	*Yes/no/ not determined*				

Please give some further information about the allergens your test(s) covers

Has the allergen been identified as a protein or group of proteins?

Over the phone: We will ask for clarification/additional info

Is the analyte detecting the allergen or a different marker?

Over the phone: We will ask for clarification/additional info

Do you know how food processing affects the allergenicity of the protein?

Over the phone: We will ask for clarification/additional info

Are allergen hydrolysates used in the food industry and will the method detect such material?

Over the phone: We will ask for clarification/additional info

Have matrix interferences been investigated (e.g. for inhibition of extraction) in sufficient sample types and by spiking of unprocessed and processed foods?

Over the phone: We will ask for clarification/additional info

Is cross reactivity with other allergens investigated?

Over the phone: We will ask for clarification/additional info

- which allergens cross react
- how you tackle the issue

Is the method(s)/kit(s) you offer validated?

- Yes, for all kits
- Yes, for some
- No

If you answered *Yes* at question 6 please indicate if the validation has been published and if so where

- Yes, for all kits
- Yes, for some
- No

If you answered *Yes* in question 6 indicate what the validation covered (tick all that apply)

- Accuracy
- Applicability (matrix and concentration range)
- Limit of detection
- Limit of determination
- Precision
- Repeatability
- Reproducibility
- Recovery
- Selectivity
- Sensitivity
- Linearity
- Measurement uncertainty
- Robustness

Over the phone: if it is an in house validation - Can you send it to us?

If your allergen tests cover ELISA methods, please provide some information on the following.

Are ELISA antibodies Monoclonal or polyclonal?

- Monoclonal primary
- Monoclonal secondary

- Polyclonal primary
- Polyclonal secondary

Raised to identify purified allergen proteins or crude allergen extracts?

- purified allergen proteins
- crude allergen extracts

Over the phone: Do you use an in house antibody or buy commercial ones?

Raised to antigen sourced from processed and/or unprocessed food?

- processed antigen
- No
- Both

Raised in animals fed a diet free-from the allergen? Yes/No

If your allergen tests cover DNA based methods, please provide some information on the following.

Size of the detected genome known? Yes/No

Matrix PCR inhibition investigated? Yes/No

Has the extraction been optimised for recovery of allergenic protein or DNA? Yes/No

If your allergen tests cover LC-MS, please provide some information on the following.

If your allergen tests cover LC-MS, please provide some information on the following.

Topic	Question	Yes / No and comment
Prior knowledge	Is a full protein amino acid sequence available for the protein(s) of interest	
Uniqueness	Is the amino acid sequence(s) you rely on unique to foodstuff to be detected or at least not present in typical matrixes & other food ingredients.	
Abundance	Do you know the abundance of the protein(s) of interest in foodstuff/ingredient.	
Expression variability	Has protein expression (tissue, species / cultivar, temporal),response to environmental/disease/stress factors,	
	post-harvest treatment, been characterized and is expression variability minimal or high?	
Modification	Has post-translational or processing protein modification been investigated?	
	If present, how was it considered when developing peptide targets and MS method?	
Stability	Do you know if the protein(s) of interest are hydrolysed (in storage or processing)	
Extractability	Has protein release from matrix into solution for detection been investigated and would you rate it high, medium or low	
Digestibility	Has protein digestion reproducibility been investigated and what endoprotease used in the chosen sample preparation technique. Was it reproducible?	

Mass Spectra transitions and LC

Topic	Question	Yes / No / comment
Reproducible	Peptide and M2 fragment reproducibly produced from analysis of various matrixes	
Unique	Peptide/M2 fragment produced only from digestion of protein target	
Minimize potential modifications	Preferably lacking cysteine, methionine, and glutamic acid	
RT (LC)	Reproducible single RT	
Charge	2+ or 3+ ions generally give the best fragmentation	
Size	Typically 6-12 residues	

End of survey

Email approach letter

Overview: Queen's University Belfast is conducting a research project funded by safefood entitled ''Food security for the food hypersensitive consumer on the island of Ireland''. This project brings together a team of experts with strong track records in their fields. This consortium is composed of scientifically acclaimed food science and allergy experts, and a psychological medicine expert with clinical experience in food allergy and coeliac disease. The objectives of the project are to: a) Understand needs, expectations and barriers in purchasing appropriate food of Island of Ireland consumers following an avoidance diet and b) Conduct a wide market and industry analysis of foods available to food hypersensitive consumers on the Island of Ireland.

In order to achieve these objectives we would like to invite you to participate in this short survey.

Data sharing. We guarantee that your responses will remain anonymous at all stages. The report will be published in ***safe***food's website and will not link responses with names or brands.

Appendix I: Attitude of the analytical community

A second structured questionnaire was developed to identify the attitude of the analytical community to allergen analysis. This was a 5 question survey administered by the online survey development cloud-based service SurveyMonkey®. The questions were tested by the SurveyMonkey® software for bias elimination.

In order to assess the attitude of the analytical community in GB and the IOI to food allergen analysis a small anonymous survey of prominent food analytical service providers, including Public Analysts was carried out (8/07/2015 – 21/07/2015) via SurveyMonkey®.

Q. 1 How important is analysis for food allergens to your laboratory?

Answer Choices	Responses
Very important	
Somewhat important	
Neutral	
Somewhat unimportant	
Very unimportant	

Q. 2 What is the current trend in food allergen analysis workload in your lab?

Answer Choices	Responses
Increasing a lot	
Increasing	
Neutral	
Decreasing	
Decreasing a lot	

Q. 3 How do you find carrying out food allergen analysis to your quality criteria?

Answer Choices	Responses
Extremely difficult	
Difficult	
Neutral	
Easy	
Very easy	
Total	

Q. 4 How would you rate the availability of reference or quality control materials for food allergen analysis?

Answer Choices	Responses
Readily available, useful and credible	
Available but with reservations as to usefulness or credibility	
Available but of limited relevance to my samples	
Available but not used	
Not available	
Total	

Q. 5 Confirmation of food allergen detection and quantification by a different technique?

Answer Choices	Responses
Very easy	
Easy	
Neutral	
Slightly difficult	
Very difficult	
Total	

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