Food Safety
AUTHORITY OF IRELAND

GENERAL

MONITORING & SURVEILLANCE SERIES

Food Allergens & Labelling Survey

JUNE 2011

SUMMARY

Various estimates put the number of people affected by food allergies and intolerances in Ireland in the tens of thousands. However, this is a complex area where actual data on the overall number of people affected, as well as the prevalence of the various types of food allergies and intolerances are not available. Figures estimated for Ireland are largely extrapolated from data available in other countries such as the UK. In order to get a general indication of the food allergies and intolerances most prevalent in Ireland, the Food Safety Authority of Ireland (FSAI) set up a web-based questionnaire asking five questions. Of the 509 people who responded over a six month time period in early 2010, the vast majority (85%) claimed to have been medically rather than self-diagnosed, with a ratio of two to one females to males responding. Of the 14 food allergens covered by EU food labelling legislation, cereals containing gluten and peanuts were the most commonly reported in this survey, while none of the respondents were allergic to lupin.

In a parallel survey, the FSAI examined various food products to determine the level of compliance and accuracy of allergen labelling. A total of 267 tests were carried out on 229 food samples for the presence of peanut, egg or soya ingredients alone or in combination. Products sampled had either no indication of the presence of these ingredients or carried precautionary allergen labels relating to the possible presence of one or more of the specified ingredients such as “May contain…” or “Produced in a premises that uses….”. The results identified a total of 11 samples out of 106 (11%) analysed which were found to contain one or more of the specified allergenic ingredients even though there was no such indication on the labelling. Only seven out of the 108 (6.5%) products with precautionary allergen labels actually contained any level of the allergenic ingredient mentioned on that label. This means that the vast majority of those samples (93.5%) may have been safe for consumption by people allergic to those ingredients.

INTRODUCTION

Though precise numbers are not available, a small but significant number of people in Ireland must exercise great care when purchasing or consuming food. Not all people with food allergies may agree[1], but the most effective and preferred means of protecting people with a food allergy or intolerance is through a verifiable system of labelling[2]. People can be allergic or intolerant to a large variety of foods. However, EU legislation[3] currently lists 14 foods or their derivatives that represent the greatest risk to allergic or intolerant people in the EU and which must be indicated on the label when they are deliberately used in producing food. Though this mandatory allergen labelling provides a significant level of protection to vulnerable consumers, there are some limitations. Food allergen labelling requirements are limited to the 14 food allergens listed in EU legislation and are only required where the ingredients are intentionally added to pre-packaged foods, but not when they are present as low level unintentional contaminants or in foods sold loose (non-prepacked). In addition, with the exception of foods containing gluten or sulphites, there is insufficient scientific information available to allow specific safety thresholds[4] to be set that would provide an acceptable level of protection for people sensitive to particular food allergens. This information vacuum makes it difficult for EU Member States to carry out meaningful or harmonised risk analyses and can result in a food containing trace levels of a food allergen being subjected to variable risk management practices.

The voluntary use by the food industry of precautionary food allergen labels such as “May contain…” or “Made in a factory that uses…” seems to have increased in recent years. While such labels can help to protect vulnerable consumers when applied prudently, their random application could result in the unnecessary elimination of healthy

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[1] *Food-allergic consumers' labelling preferences: a cross-cultural comparison. Judith R. Cornelisse-Vermaat, Jantine Voordouw, Vassiliki Yiakoumaki, Gregory Theodoridis and Lynn J. Frewer. European Journal of Public Health, 2008, 18,(2), 115-120*

[2] *Preferred information strategies for food allergic consumers. A study in Germany, Greece, and The Netherlands Voordouw, J., Cornelisse-Vermaat, J.R., Pfaff, S., Antonides, G., Nielmietz, D., Linardakis, M., Kehagia, O., Frewer, L. Food Quality & Preference, Accepted for publication 2011*

[3] *Commission Directive 2007/68/EC amending Annex IIIa to Directive 2000/13/EC as regards certain food ingredients*

[4] *Scientific Opinion on lactose thresholds in lactose intolerance and galactosaemia. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), EFSA Journal, 2010, 8(9):1777*

dietary options, or in a desensitisation of food allergy sufferers[5] who could then be more liable to taking risks with foods carrying these labels. From a regulatory perspective, precautionary food allergen labels are voluntary and therefore difficult to regulate under current legislation.

Food labels are critical in ensuring that consumers can make an informed choice about the food they purchase, but they are even more important in alerting vulnerable consumers to possible dangers such as food allergens. The FSAI has overall responsibility in Ireland for the enforcement of EU and Irish food labelling legislation. However, the food industry has ultimate responsibility for ensuring that food labels are accurate and are applied according to relevant legislation and with due diligence. With a view to enhancing the protection of people allergic or intolerant to particular food types, the FSAI is in the process of reviewing the effectiveness of food allergen labelling and monitoring practices in Ireland.

WEB-BASED SURVEY METHOD

A web-based application (www.SurveyMonkey.com) was utilised to provide a crude estimate of the Irish population living with the food allergies and intolerances specified in EU legislation. The survey commenced in January 2010 with the first response recorded on January 26th and the final one on June 29th. In order to encourage participation, the survey was advertised on the front page of the FSAI website for the duration, while organisations including the Irish Anaphylaxis Campaign and the Coeliac Society of Ireland were also informed. The survey was brief, with just five questions to be answered:

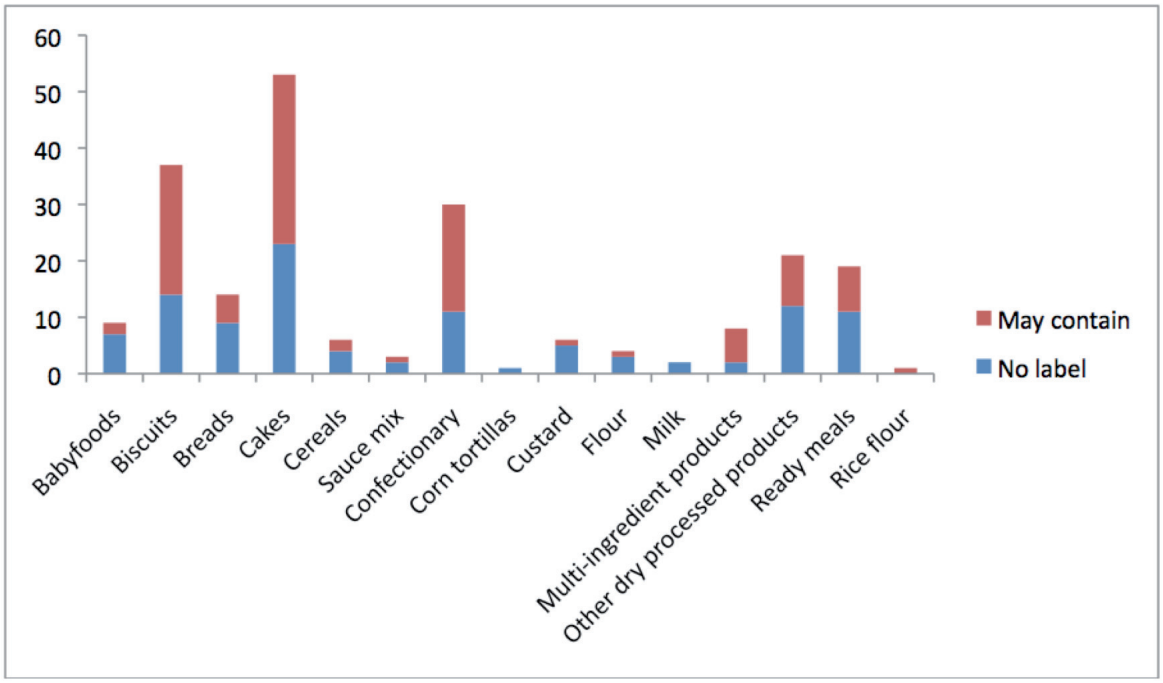
1. Do you or a member of your family suffer from a food allergy?
2. Which food allergy (EU list specified) or allergies, do you or your family member suffer from?
3. Is your food allergy (or your family member's food allergy) medically diagnosed?
4. Are you, or the food allergy sufferer if you are filling this in on their behalf, male or female?
5. Please specify the age group of the food allergy sufferer?

LABELLING SURVEY METHODS

The labelling survey examined two categories of foods for the presence of soya, egg or peanut. Soyabean is a protein-rich plant and along with egg is used in many processed foods worldwide. Peanut is a common cause of anaphylaxis and was cited in the web-based survey with a similar frequency to cereals containing gluten as the cause of food allergy. Products sampled were primarily processed foods including breads, cakes, biscuits, confectionary and other multi-ingredient products (Figure 1). Samples were grouped in to those that either carried no indication of the presence of soya, egg or peanut (undeclared), or carried a precautionary food allergen label. Samples were collected at retail and manufacturing level primarily by the FSAI and environmental health officers, with a small number collected by local authorities and the Sea-Fisheries Protection Authority. Samples were delivered to the Public Analyst Laboratories in Cork (soya), Dublin (egg & peanut) or Galway (peanut) where analysis for the presence of egg and peanut was carried out using enzyme linked immunosorbent assays (ELISA) employing commercially available test kits. However, an ELISA test for soya allergenic proteins was not readily accessible and therefore analysis for the presence of soya was carried out using the DNA-based polymerase chain reaction (PCR) availing of commercially available soyabean-specific primers.

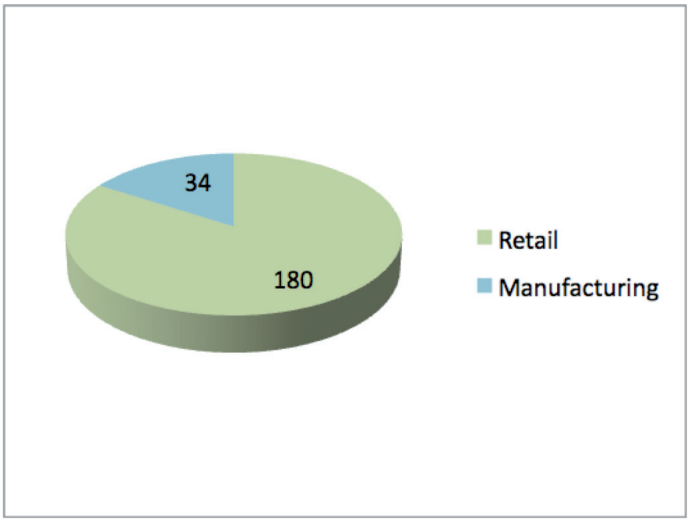
[5] *Consumer attitudes and risks associated with packaged foods having advisory labeling regarding the presence of peanuts. Susan L. Hefle PhD, Terence J. Furlong MS, Lynn Niemann, Heather Lemon-Mule MD, Scott Sicherer MD and Steve L. Taylor PhD Journal of Allergy and Clinical Immunology, 2007, 120, (1), 171-176*

Figure 1. Food categories sampled



Sampling was carried out predominantly at retail premises with a smaller number collected at manufacturing level (Figure 2). Approximately half of the foodstuffs sampled were produced in Ireland.

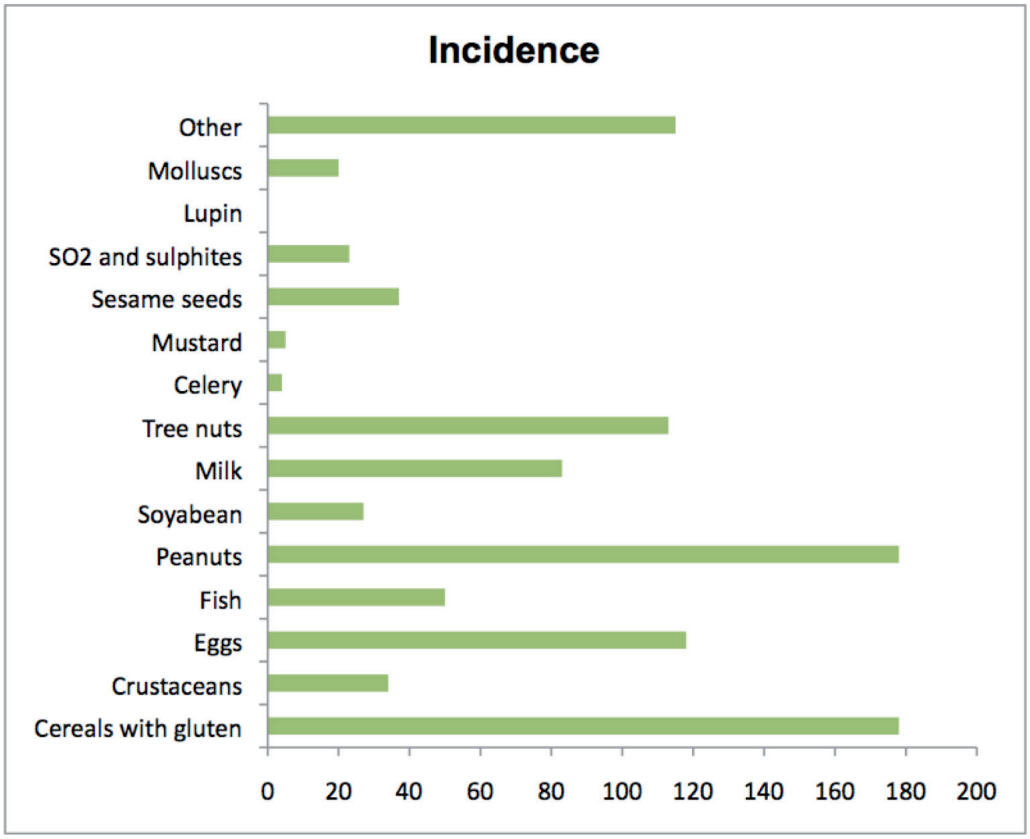
Figure 2. Sampling point



WEB-BASED SURVEY RESULTS

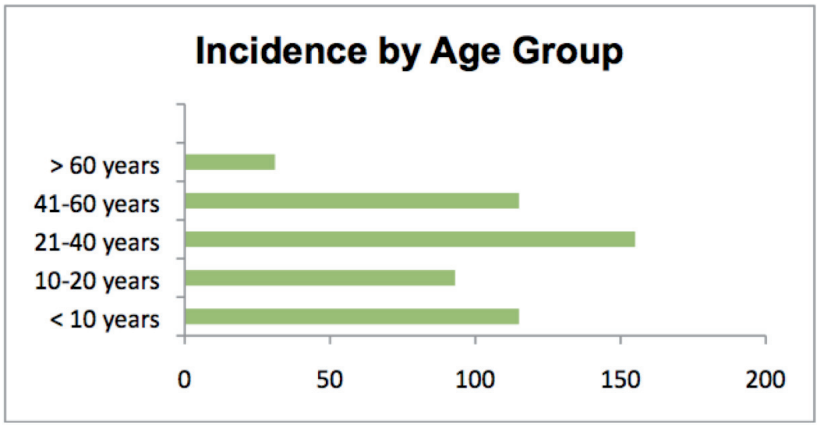
The web-based survey carried out by the FSAI represents a snapshot in time, and while 509 is a significant response, it is not considered representative of the potential number of people with food allergies or intolerances in Ireland. The results (Figure 3) show that the largest proportion of respondents were sensitive to gluten or peanut, while none were sensitive to lupin, and four and five were sensitive to celery and mustard respectively.

Figure 3. Reported prevalence of the 14 food allergens listed in EU legislation



The ratio of females (339) to males (170) responding to the questionnaire was approximately 2:1. The largest number of respondents was in the 21-40 year age bracket (Figure 4). Approximately 85% (434) reported being medically diagnosed rather than self diagnosis.

Figure 4. Age profile of survey respondents



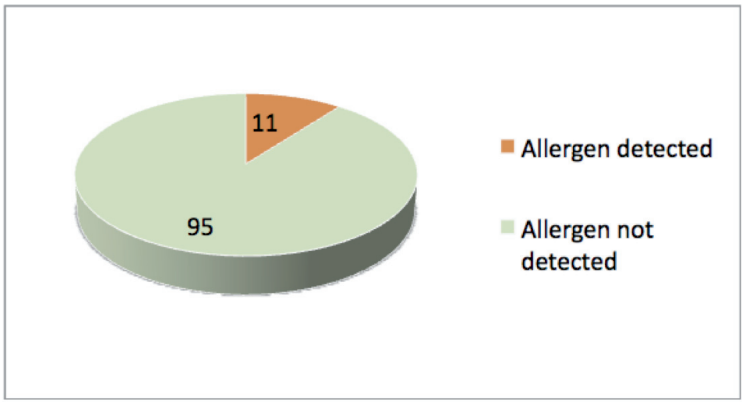
LABELLING SURVEY RESULTS

A total of 267 tests were carried out on 229 food samples for the presence of peanut, egg or soya in foods that either had no allergen declaration, or foods that carried precautionary food allergen labels. Complete results were recorded for 214 samples and only these data are considered here.

No Allergen Labels

Of the 106 samples without allergen declarations, 11 (11%) were found to contain at least one of the specified food allergens (Figure 5). Egg was detected in five (5%) samples, one of which also contained peanut. Peanut was identified in two samples (2%) and soya in five (5%) samples. One food contained undeclared egg at levels (>2 g/kg) that suggests it was used as an ingredient rather than being a contaminant.

Figure 5. Foodstuffs not declaring egg, peanut or soya



Precautionary Food Allergen Labels

Only seven (6.5%) of the 108 foods with a precautionary label tested were found to contain the specific food allergen(s) mentioned on the label (Figure 6). Five out of 75 samples with a precautionary nut label contained peanut (7%), and one each out of 18 and 30 samples contained egg (6%) and soya (3%) respectively. The numbers of Irish and non-Irish foods with precautionary labels that did not contain the food allergen was almost

identical (Figure 7).

Figure 6. Foodstuffs with precautionary labels for egg, peanut or soya

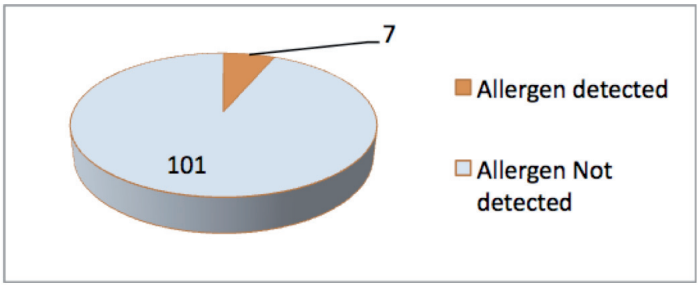
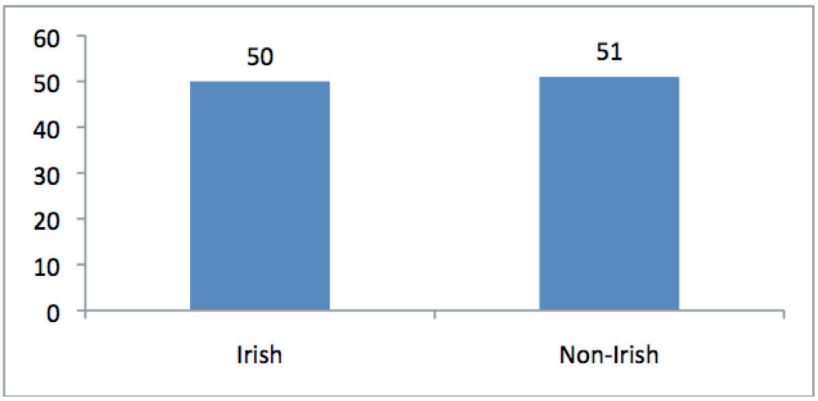


Figure 7. Origin of foods with precautionary labels not containing the allergen



CONCLUSIONS

The web-based survey of people allergic or intolerant to various foods was not intended, or expected to provide precise data on the incidence of these conditions in the Irish population. However, the response to this survey is considered significant and has yielded some useful information on the potential prevalence of the various food allergies and intolerances. The apparently high number of people sensitive to cereals containing gluten is not a surprise as the coeliac condition is known to have a prevalence of five to ten cases per 1,000 adults in Ireland[6]. In addition, the Coeliac Society of Ireland was specifically notified about the survey which may also skew the numbers responding. The relatively high number of people reporting sensitivity to peanuts was similar to that for gluten, possibly reflecting the potential for serious and immediate health consequences related to peanut allergy. Peanut is considered one of the more common causes of food-induced anaphylaxis[7] which is why the FSAI considers remedial action in the case of foods found to have undeclared peanut, regardless of whether its presence is intentional or not. While this survey points to certain allergies being more prevalent than others, the labelling requirements for all food allergens listed in EU legislation are equally enforced. In addition, general food

[6] *"Gluten-Free Foods", Food Safety Authority of Ireland, 2008, http://www.fsai.ie/resources_and_publications/scientific_reports.html*
[7] *Declaration of allergens on the label of food products purchased on the European market.*
Arjon J. van Hengel. Trends in Food Science & Technology; 2007, 18(2) 96-100

labelling requirements provide a certain level of protection for people sensitive to those food allergens not specified in EU legislation.

It is difficult to interpret the bias of 2:1 female to male respondents as it could mean that more females than males live with these conditions, or alternatively that females have a greater awareness of health issues and thus are more likely to respond to such a survey. It is encouraging to note that the majority reported having been medically diagnosed which is always recommended, but particularly where symptoms are severe or persistent, or where children are involved.

The labelling survey provided some useful, though not unexpected information. Approximately one in ten food samples analysed were found to contain undeclared egg (5%), peanut (2%) or soya (5%). A similar study in the USA in 2010[8] reported that 3% of products tested contained undeclared egg, and none of those tested contained undeclared peanut. The presence of undeclared peanut and egg in two and five foodstuffs analysed in the FSAI survey respectively is of some concern, particularly since most fatalities related to food allergens are a result of accidental ingestion[9]. Foods with undeclared egg or soya were placed on the FSAI Food Allergen Notification Alerts[10] with any further action depending on the levels detected. In contrast, foods found to contain undeclared peanut at any level were withdrawn from sale or re-labelled, and also placed on the FSAI Food Allergen Notification Alerts[11].

Almost half of the foods with an undeclared food allergen in the FSAI study contained soya, which was detected using a qualitative PCR test that identified the presence of soya DNA but not the relative amount. PCR analysis is a sensitive and robust technique that is routinely used to detect GM food ingredients[12] and investigate food fraud[13], and which is now gaining some attention as an alternative food allergen detection method[14]. There is some debate about the suitability of DNA-based methods for food allergen testing as they target DNA rather than specific allergenic proteins detected by ELISA tests. However, current testing methodologies can only be regarded as an indicator of the presence and relative quantity of a food allergen source, with the usefulness of any data limited by the lack of scientifically determined safety or labelling thresholds.

The US study of 2010 also looked at precautionary food allergen labels relating to egg, milk or peanut and found that these allergens were not detected in 95% of samples with such labels. This is similar to the results of the FSAI study where egg, peanut or soya were not detected in 93.5% of foods sampled despite the precautionary labels. It is worth noting that this trend applied equally to Irish and non-Irish produced foods. A more focused EU study in 2007 demonstrated that 75% of the cookies carrying a precautionary nut label did not contain any peanut[15], providing further confirmation that this problem is not unique to Ireland.

A small proportion of the Irish population must take extraordinary precautions on a daily basis to do what most people take for granted, enjoy food without undue risk of an adverse reaction. While zero risk is not feasible where food is concerned, the plight of people with a food allergy or intolerance can be alleviated to some extent by appropriate and accurate food labelling alongside good manufacturing and processing procedures. The new food information for consumers legislation currently under discussion at EU level is likely to bring non-prepacked foods within the food allergen labelling gambit, but this is the only additional benefit anticipated for people with a food allergy or intolerance. Long term improvements in the way food allergies and intolerances are monitored and managed have been discussed in recent years and could assist risk assessors and risk managers to better

[8] *Food allergen advisory labelling and product contamination with egg, milk and peanut. Lara S. Ford, Steve L Taylor, Robert Pacenza, Lynn M. Niemann, Debra M. Lambrecht & Scott H. Sicherer. J Allergy Clin Immunol; 2010, 126 (2) Letters to the Editor.*
[9] *Threshold of allergenic proteins in foods. Jonathan O'B Hourihane & Andre C. Knulst.Toxicology and Applied Pharmacology; 2005, 207, 152-156*
[10] *www.FSAI.ie*
[11] *FSAI allergen alert notifications, 2010. http://www.fsai.ie/news_centre_/allergen_alerts/Lituanica_cake.html*
[12] *FSAI GM Food Monitoring. http://www.fsai.ie/monitoring_and_enforcement/monitoring/surveillance/genetically_modified_food_surveillance.html*
[13] *FSAI Fish Labelling Survey, 2011. http://www.fsai.ie/resources_and_publications/surveys.html*
[14] *Multiplex real-time PCR using SYBR® GreenER® for the detection of DNA allergens in food. Simona Pafundo, Mariolina Gulli and Nelson Marmiroli. Analytical and Bioanalytical Chemistry; 2010, 396 (5) 1831-1839*
[15] *Peanut and hazelnut traces in cookies and chocolates: Relationship between analytical results and declaration of food allergens on product labels. Pele, Maria; Brohée, Marcel; Anklam, Elke; Van Hengel, Arjon. Food Additives and Contaminants; 2007, 24, (12), 1334-1344*

safeguard vulnerable consumers. For example, a national and European registry of severe allergic reactions[16] would provide better information on the prevalence of the most serious food allergies, while the establishment of safety or labelling thresholds for the various food allergens[17] (similar to that for gluten) would help to ensure proportionate regulatory responses to the detection of undeclared food allergens. In Ireland, the FSAI is in the process of reviewing how foods associated with food allergies and intolerances are sampled and tested, with a view to putting in place a more effective monitoring regime while simultaneously developing a robust risk assessment process. In the FSAI survey, five foods with precautionary nut labels were found to contain peanut, thereby providing a valuable warning to peanut allergy sufferers. However, consumer confidence in such labels is low, and such scepticism is justified given the results of this and similar surveys which demonstrate that the vast majority of foods with precautionary labels do not contain those food allergens, thereby calling into question the prudence or motivation for these labels. A risk-based system that can guide the application of precautionary food allergen labelling is required if consumers are to regain confidence in precautionary labels. The food industry is already active in this area[18] and therefore it is up to all stakeholders to collectively develop and facilitate such initiatives in order to ease the burden on people with food allergies and intolerances.

[16] *Towards a European registry of severe allergic reactions: current status of national registries and future needs. M. Worm, F. Timmermans, A. Moneret-Vautrin, A. Mauraro, I.I. Malmeheden Yman, M. Lovik, S. Hattersley & R. Crevel. Allergy; 2010, 65, 671 – 680*
[17] *Thresholds for food allergens and their value to different stakeholders.*
R.W.R. Crevel, B.K. Ballmer-Weber, T. Holzhauser, J. O'B. Hourihane, A.C. Knulst, A.R. Mackie, F. Timmermans, S.L. Taylor. Allergy; 2008, 63, 597-609
[18] *A vision for allergen management best practice in the food industry. R. Ward, R. Crevel, I. Bell, N. Khandke, C. Ramsay and S. Paine*
Trends in Food Science & Technology; 2010, 21, (12), 619-625

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