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Managing food allergens in the food supply chain – viewed from different stakeholder perspectives

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Abstract

The management of food allergens involves several stakeholders including food manufacturers, consumers, enforcement authorities and analytical laboratories. The MoniQA Working Group "Food Allergens" and representatives of these stakeholder groups develop a synthesis of their needs and requirements, identify gaps and suggest ways forward to address these gaps. Analysis for food allergens is an essential adjunct to hazard and risk management procedures within the food industry. These analyses are important for enforcement authorities who require reliable methods in support of both the specific food labelling legislation and the more general food safety legislation. Furthermore, analytical methods are essential in the validation/verification of cleaning protocols, which help to reduce levels of potentially contaminating allergen to one that is no longer harmful for the majority of the allergic consumers. Nevertheless, there is a general lack of validated and robust analytical methodology for analysis of most food allergens. On the one hand, universally recognized reference materials are missing, on the other hand there is an urgent need to harmonise validation protocols at an international level. Currently, members of the MoniQA WG "Food Allergens" together with the AOAC Allergen Community are developing a validation protocol for allergen ELISA-based test kits helping to provide standardised methods with known acceptance criteria for the users as well as for the method developers.The Working Group will seek to develop the initiative required to address these issues, in collaboration with other organisations e.g. the EuroPrevall project, FARRP, AOAC and the CEN WG12 Food Allergens over the coming years.

Introduction

Adverse reactions to foods can take many forms including metabolic intolerances (like lactose intolerance) or immunological hypersensitivities. Of the latter there are two predominant types, the gluten intolerance syndrome known as coeliac disease and immunoglobulin E (IgE)-mediated food allergies. The patterns and prevalence of food allergies varies among population groups and it is thought that around 2–4% of the population suffer from IgE-mediated

food allergy (Young *et al*., 1994; Sicherer *et al*., 2004), the prevalence being higher among children at around 5–8%, and apparently increasing (Sampson, 2005). There is currently no effective cure for either coeliac disease or IgE-mediated allergies. Consequently, individuals suffering from these conditions have to avoid consuming problematic foods, typically for the rest of their lives. Because avoidance is the only possible approach, allergic consumers need to be provided with relevant information about allergens in the foods they buy to make an informed choice about what is safe to eat. National and international legislation in many jurisdictions require the food industry to provide meaningful labelling for their products to satisfy this need.

In addition to consumers and the food industry other stakeholder groups are involved in managing food allergens across the food supply chain. These include national and international risk managers and authorities involved in setting and enforcing regulations, standardization and validation bodies, as well as those seeking to provide reliable tools for allergen detection in food. The MoniQA Food Allergen Working Group has sought to elaborate the current state-of-the-art on managing allergens in foods, taking into account the requirements of these stakeholders and identified key issues which must be addressed in order to develop harmonized approaches and strategies in future.

Food allergy: the challenges faced by the allergic consumer and industry

Living with a disease which is triggered by foods that pose no threat to most people presents particular problems for allergic consumers and those in their social network. So far, limited objective data regarding the impact of food allergies on quality of life (de Blok *et al*., 2007) or its economic cost (Miles *et al*., 2005) are available. Recent research has led to the development of the first validated age-specific and disease-specific quality-of-life (QoL) study instruments (de Blok *et al*., 2007; DunnGalvin *et al*., 2008). This has provided the first objective information to demonstrate that food allergic children are at risk for negative emotional and social outcomes, including anxiety, avoidance, or risky behaviour. These studies have also shown that food allergy impacts directly on a child's normal trajectory of psychosocial development in a disease-specific manner (DunnGalvin *et al*., 2007). Food allergic children have both different views of their allergy and also different coping strategies. These evolve in response to age-, gender-, and context-specific stressors. The impact of food allergy also extends to parents who appear to be extremely worried about their children and demonstrate high levels of stress and anxiety due to the constant high levels of vigilance and experience feelings of guilt when their children have a reaction. Some of this worry is maladaptive, inhibiting the normal social development of their child and may have a long-term impact on quality of life (DunnGalvin *et al*., 2007). Teenagers and young adults constitute one age group particularly at risk. Pre-adolescence is an important transition point when children must begin to gain autonomy and self-belief in their ability to control events in their lives. Recently, Sampson and colleagues (2006) found that adolescents and young adults appear to be at an increased risk for fatal food allergic reactions, and suggested that they may adopt more risk-taking behaviours with regard to their food allergy.

A key part of the management strategies adopted by carers of allergic children is to control what food comes into the home. In the majority of cases, food containing the problem allergen is not allowed into the home, particularly when children are young. The consequence of this is a restriction of choice. Labelling, with regards to both content and quality of information, is therefore of crucial importance to allergic consumers in managing both their condition and the associated stress. In a focus group study involving 60 children and teenagers (DunnGalvin *et al*., 2009) food labelling has been mentioned as a significant source of uncertainty and therefore stress for most children and such uncertainty gives rise to feelings of fear and confusion. In some cases teens, in particular, feel it is 'pointless' reading ingredients labels and therefore take deliberate risks, resulting in allergic reactions with symptoms ranging from mild to severe.

It is a well-known phenomenon that food allergic consumers need more time for shopping if they want to explore other products. Additionally, the majority prefer packaged food to loose products and home cooking than catering. The impact of labelling of allergenic ingredients on the shopping experiences of food allergic consumers has been studied in detail in the Netherlands, where researchers followed 20 food-allergic consumers while doing their grocery shopping (Cornelisse *et al*., 2008). Participants in the study were given a shopping list of 15 potential problematic food products (for example a ready meal, biscuits and ice cream) and asked to buy these products as if shopping for their own household in a supermarket environment similar to the type in which they habitually shopped. During the course of shopping,

participants were observed and questioned about specific problems they experienced in selecting safe products, and their preferences for the delivery of allergen-related information. The respondents mentioned many problems about the legibility and comprehension of the food labels. For example the font size was too small, the contrast between background and text was inappropriate, the information was presented in too many languages, no standard position for the text, which often omitted useful information (e.g. information about the percentages of specific ingredients would have also been appreciated). Moreover, information placed on the label was not always trusted by the food-allergic consumer, which may cause feelings of insecurity and stress.

The respondents also reported problems with precautionary (e.g. 'may contain') labelling. Since the introduction of the new EU labelling legislation, many producers use precautionary warnings on the labels e.g. 'may contain traces of nuts', 'made in a factory where nuts are processed', 'is produced on a line where nuts are processed'. According to most participants included in the study, these warnings actually limited their food choices. In particular, participants with a severe food allergy (causing anaphylactic shock) would not take the risk and totally avoid products with 'may contain' labels.

Legislative and regulatory considerations

In addition to the general food safety legislation (Regulation 2002/178/EC), new legislation has been put in place in recent years across the world to help allergic consumers avoid problem foods by regulating labelling of major allergenic foods. The European Union brought in Directive 2000/13/EC, as amended by Directives 2003/89/EC and 2007/68/EC, to govern allergen labelling. The Directive and its amendments identify 13 foods or food groups and sulphur dioxide (listed in Annex IIIa) that are found in a wide variety of processed foods which are considered to be important relevant triggers of allergic reactions. Ingredients that are exempted from allergen declaration are listed in Directive 2007/68/EC and include certain refined oils or polydextrins, which analytical and clinical studies have shown do not present a danger for allergic consumers.

Similar legislation was passed in the United States in 2004 with the Food Allergen Labelling and Consumer Protection Act (FALCPA, 2004) which came into force on 1 January 2006. The Act mandates a shorter list of allergenic food groups, but requires indication of the species on the label in the case of fish, crustacean and tree nuts. Both Directive 2003/89/EC and FALCPA (2004) as well as legislation in other countries, such as Australia, Japan or Turkey, undoubtedly improve the labelling of allergenic foods. It is noteworthy that like the European Directive allergen labelling regulations in most countries tend to focus exclusively on labelling requirements for deliberately added ingredients considered to be priority allergens. Other risk management measures may be in place to address cross contamination. Food businesses within the European Union must comply with both product liability and product safety legislation (Directives 85/374/EC and 2001/95/EC) in addition to legislation specifically relating to aspects of food safety (notably Regulation 2002/178/EC and Regulation 2004/852/EC). There is a legal requirement for food businesses to market only foods which are safe to eat (Article 14, section 1 of Regulation 2002/178/EC). This requirement applies in respect of food allergens as well as more 'conventional' food-safety hazards. In some countries (e.g. the United Kingdom) causing injury or death through failures in food-safety management can lead to indictment under either health and safety at work or corporate manslaughter legislation.

Precautionary labelling

From both ethical and legislative standpoints there is a need for food businesses to communicate to food-allergic individuals the presence of significant food allergens, either as ingredients or adventitious contaminants. While there are clear requirements for communicating the presence of specified food allergens as ingredients, this is not necessarily the case where the allergen's presence is due to a contamination event (e.g. cross contamination due to use of common equipment or environment). By its very nature such contamination is usually adventitious and likely to occur periodically, at varying levels and with a heterogeneous distribution. The inevitable uncertainty of such events and the current legislative environment has led to the phenomenon of precautionary labelling. Unfortunately its introduction and the indication of possibility rather than certainty has decreased the confidence of the food-allergic consumer (discussed above). Within some jurisdictions specific guidelines, directed at food businesses, have been produced by government agencies (e.g. UK Food Standards Agency) on the mechanisms of the underpinning hazard and risk assessments that should be undertaken before precautionary labelling is invoked. These assessments require subjective judgements as to whether the risk to the food-allergic consumer is significantly increased. Such assessments can be better informed through the gathering of information based on analytical data.

There are indications that there are levels of allergens (thresholds) below which an allergen poses only a small risk of causing harm to an allergic consumer (Crevel *et al*., 2008). However, commonly accepted trigger levels have yet to be established (with the exemption of gluten) and Directive 2003/89/EC gives no threshold or guidance to what constitutes a safe level.

However, in other countries there have been attempts to establish threshold values. The Swiss authorities – in close cooperation with leading allergologists – defined an action limit of one part per one thousand in 2001. This limit represented a compromise between the specific food safety needs of allergic individuals and industrial food production practices at that time. If unavoidable, contaminations of above > 1 g per kg or l must be declared as ingredients, whereas contaminations of below 1 g per kg or l may be declared ('Lebensmittelverordnung' 2002, since 2005 'Lebensmittelkennzeichnungsverordnung', LKV).

The Australian Food and Grocery Council (AFGC) published an industry guideline in 2007 as guidance for allergen management. A three level grid was developed to assist in determining if the residual protein from allergenic substances through unavoidable cross contact presents such a risk that it requires a precautionary labelling statement. Three different action levels with thresholds for each food allergen were defined, derived from published data on the lowest triggering amounts measurable. The thresholds of the first level (no cross contact statement required) range from 2 mg/kg for egg, peanuts, sesame, tree nuts, crustacean to 5 mg/kg for milk and 10 mg/kg for soy as well as 20 mg/kg for fish and gluten. Obviously, the development of acceptable thresholds is an urgent challenge in the context of international harmonization.

Food allergen testing within a food business context

The underpinning philosophy of modern food-safety management techniques rests on quality assurance. In brief this can be described as optimizing systems to reduce the probability (risk) of a defective product being produced (hazard) to an acceptable level. In many cases the food industry is not able to comply with a zero tolerance approach for food allergens for practical reasons. Different food products are manufactured on the same production line. Cross-contamination of food with food allergens can arise because of line-sharing or problems with dusts (e.g. flour or milk powders) that cannot be excluded. Consequently, there is a risk of potential contamination through the use of common equipment and/or environmental transfer. The food-safety management system favoured within the European Union for food safety issues is based on Hazard Analysis Critical Control Point (HACCP) and there is a legal requirement that all businesses manage food safety in accordance with its principles (Regulation 2004/852/EC). Irrespective of whether it is a step in the process itself, which reduces the risk of the hazard occurring to an acceptable level (critical control point) or whether it is a (more global) pre-requisite programme (e.g. sanitation), which has the same role, it is essential that the process be demonstrated to be effective (validation) and remain so during production (verification). For critical control points there is a further requirement that the process parameters themselves associated with that point should be regularly, if not continuously, evaluated (monitored) to demonstrate its continued efficacy.

The magnitude of the challenges faced by the food industry in managing allergens is indicated by the number of allergen-related product alerts [e.g. EU rapid alert system for food and feed (RASFF) system]. A case study of alerts recorded under the RASFF system for chocolate confectionery between 2005 and 2007 indicates that out of 21 alerts nine referred to milk, four to peanuts and soya, respectively, three for tree nuts (hazelnuts or almonds) and one for gluten (Figure 1). In a recent European study (Pele *et al*., 2007) 254 chocolate confectionery products sourced from 10 Member States (not including United Kingdom) and none of which declared hazelnut or peanut as an ingredient, were analysed for the presence of these allergens. Over 50% of those products for which there was no precautionary labelling actually tested positive for hazelnut (23% for peanut).

These data indicate that there is a continuing need to ensure that allergen management systems are in place to minimize contamination, they are verified on an ongoing basis, and new control measures are validated. For this to occur it is necessary to have cost-effective analytical systems capable of detecting food allergens in a diverse range of food matrices.

Food allergen analysis

Overview of current methodology

Because allergens are the hazard involved in triggering food allergies and are, almost without exception, specific protein molecules within a food, they are primary analytes that should be targeted. Immunochemical methods, which exploit the specificity and high affinity interactions of antibodies with protein molecules, such as enzyme-linked immunosorbent assays (ELISAs) have therefore been much favoured in allergen analysis (Poms *et al*., 2004a, b; for

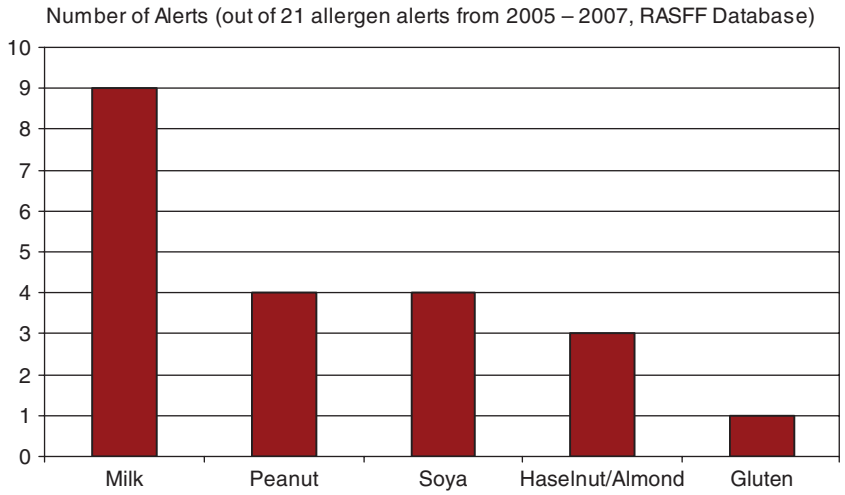

Figure 1 Alerts recorded under the RASFF system for chocolate confectionery between 2005 and 2007. Food allergens are displayed out of 21 alerts referred.

overview see Table 1). The specificity and sensitivity of ELISA technology, with limits of detection or quantification at low mg/kg level, make it a simple tool for allergen detection and quantification, allowing relatively fast and high throughput analysis. It is widely used in food industry laboratories and by official food-control bodies to detect and quantify allergens present in allergenic food or commodities. So far, ELISA test kits validated for defined matrices include peanut [in cereals, cookies, ice cream and chocolate; under the auspices of Association of Official Agricultural Chemists (AOAC) and EC Joint Research Centre, Park *et al*., 2005; Poms *et al*., 2005] and hazelnut (in cereals, ice cream and chocolate; under the auspices of the German Federal Office for Consumer Protection and Food Safety, BVL). The latter has been submitted to Comité Européen de Normalisation (engl.: European Committee for Standardization) (CEN) for consideration as a standard.

Related antibody-based technologies which are semi-quantitative include dipsticks and lateral flow devices (LFD) and are well suited to testing outside of the laboratory (e.g. monitoring clean-down of food processing lines), where a rapid result is required or qualitative results are needed for only a few samples (Koppelman & Hefle, 2006).

An alternative approach, which detects the presence of the allergenic food species, uses rapid DNA-based tests like polymerase chain reaction (PCR) (often *real time*). These can be a valuable tool to indicate presence/absence of an allergenic food or commodity if no suitable ELISA is available, if multiscreening of several allergenic foods is required or as a confirmatory analysis to ELISA (Table 1). Whilst not measuring the actual hazard they have advantages in terms of high species specificity. Despite challenges such as extreme fragmentation of DNA or inhibition by remaining metal ions, lipids or proteins after filtration, indirect monitoring of allergen-containing products at DNA level by PCR below a concentration of 10 mg/kg is possible. Currently, one validation study for detection of hazelnut DNA by real-time PCR is being accomplished under the auspices of the German Federal Office of Consumer Protection and Food Safety. However, one shortcoming is that short DNA sequences may be detectable in highly processed foods whereas the protein may no longer be present. Likewise, because cows' milk and beef, or hens' egg and chicken products are simply tissues which come from the same species they have the same DNA composition and are difficult to analyse by PCR. Furthermore, both egg and milk have low DNA concentrations impacting on sensitivity.

In certain cases, e.g. when analysing closely related species such as celery and other *Apiacea*, PCR could be more suitable than ELISA, because PCR detection can be easily tailored to give species selectivity by correct selection of primers.

Given the shortcomings of both antibody and DNA based-methods, most analytical laboratories will need to choose the most appropriate method, or combination of methods for analysis of an offending food. In the long term future it is possible that mass spectrometry methods will provide at least a viable alternative confirmatory method because they have the potential to detect protein (and therefore focussed on the hazard itself), provide information on sequence (giving the species specificity provided by DNA methods) and detect allergen contamination down to similar levels to those achieved by ELISA and PCR. The automated nature of mass spectrometry experiments and minimum of user involvement naturally lends itself

Table 1 Comparison of protein-based and DNA-based allergen detection and quantification methods

	Protein-based methods (ELISA, Dipstick)	DNA-based methods (***real-time*** PCR, PCR-ELISA)
Detectability	Major allergen (group) or proteins specific for the offending food	DNA-fragment
Specifity	Cross reactions possible	Highly specific
Limit of detection	Low ppm range	Theoretically 10 molecules
Quantification	Quantification of specific protein	Quantification of copy numbers, calculating the protein content
Natural variability of target	Results may vary with species variety, climatic+seasonal changes	Genotype is very stable
Matrix effect	Minor changes in protocol can improve extraction	PCR inhibitors present in food are hard to avoid
Effects of food processing (temperature, pH, fermentation)	Denatured or enzymatically modified proteins may not be detected	stable against high temperature, but DNA will be fragmented by low pH
Reference material	Not yet available	Not yet available
Sample preparation	Easy and fast	More laborious
Time required	0.3–3.5 hours	2–6 hours
Handling	simple	Training in DNA handling required
Stability of reagents	Several months at 4 °C	Several years at − 20 °C
Positive	Intermediate	Negative

ELISA, enzyme-linked immunosorbent assay; PCR, polymerase chain reaction.

to high-throughput quantitation. To date, mass spectrometry has been applied to detection of peanut allergens (Shefcheck & Musser, 2004; Chassaigne *et al*., 2007). As with any new methodology its future application on analysis of food allergens is hampered by high equipment costs and the needs for specialist expertise in method development.

Method validation – towards a harmonized approach

Very few validation data on allergen detection methodologies have been generated, which can be compared. This is partially due to the fact that different validation protocols have been used but also due to the availability of only few suitable reference materials [e.g. from National Institute of Standards and Technology (NIST)].

In 2002 AOAC, jointly with International Union of Pure and Applied Chemistry (IUPAC) and International Organization for Standardization (ISO), published a harmonized protocol for method validation. So far, the harmonized protocol does not consider some special requirements of ELISA-based test kits for food allergen analysis regarding for instance the choice of matrices or spiking methods to name a few. Members of the allergen analytical community represented by the MoniQA consortium and the AOAC presidential taskforce on food allergens have taken the initiative to develop harmonized guidelines to validate quantitative ELISA-based food allergen detection methodologies. This protocol is designed to meet or exceed the minimum requirements set forth in the joint guidelines for collaborative study procedures of AOAC/IUPAC/ISO. It is currently being developed with input from a wide range of experts. Criteria to be considered include several issues which method developers and validation and standardization bodies are faced with, these include information on key agents such as characteristics of capture antibody, conjugated antibody, test calibrators and their protein content (all of which should be provided by the method developers). Food processing procedures involving heat, high pressure or acid treatment typically modify protein structure either as a consequence of protein unfolding and aggregation, or through non-enzymatic glycation as a result of the Maillard reaction (Mills *et al*., 2007). Further problems arise with sample preparation. Often buffers used in immunoassay kits are simple and do not use the harsh denaturants that might be required to quantitatively extract proteins from foods. Cross reactions of the antibodies used are a further issue applying immunological ELISA technique (Popping, 2007).

Food matrices have also a huge influence on allergen detection. Therefore as many matrices as possible should be validated, however, priority needs to be given to those food matrices which are most likely to be contaminated.

Spiking methods using natural matrices have to be considered. Because production of large amounts of homogenous sample especially at low allergen addition level could be too difficult and cost-intensive, spiking of samples could provide an appropriate alternative.

Furthermore, questions regarding the *parameters* (LoD/LoQ), acceptance criteria and consistent expression of results need to be considered. It is suggested that three levels of allergen addition for each food matrix are used in interlaboratory validation studies: one at zero level, a second at twice the limit of quantification ($2 \times$ LOQ) and a third at five times the limit of quantification ($5 \times$ LOQ). For each food matrix and each fortification level, a minimum of 10 replicates should be analyzed by a minimum of three independent laboratories. Although the ideal percentage of correct identification range should be 80–120% a range of 50–150% shall be considered as acceptance criteria. Based on criteria suggested by AOAC and MoniQA the Working Group Food Allergens plan to implement the protocol.

The current lack of reference materials suitable for the development of allergen detection methodologies, particularly in different food matrices, must be urgently remedied in order to assess the output of different validation studies as well as to allow comparability between different methods.

There are several essential characteristics for a reference material e.g. homogeneity, stability during transport and storage and if necessary the assignment of traceable property values with an uncertainty statement. In order to produce suitable reference materials for the analysis of food allergens several issues have to be considered (Poms *et al*., 2006) in particular the right choice of analyte. A number of key proteins are implicated in adverse reactions, while both intrinsic factors (e.g. biological variability such as protein content and food composition due to geographical and seasonal variability) and extrinsic factors (such as food processing history and different protein denaturation; time of harvest, duration of storage) influence measurement results. One point of discussion is whether it is sufficient to detect the offending food (as required by the regulation) or the allergenic component itself, which might be useful from the clinical perspective. The latter may be more difficult because often one food contains several major allergens (e.g. peanut contains at least eight different allergens, InformAll: http://foodallergens.ifr.ac.uk/). Further, the matrix of the foodstuffs analyzed has a strong effect on the reliability of the method used and processing may impact various allergens differently.

It should be recognized that spiked samples may result in an artificially higher recovery than incurred samples. During the MoniQA project the Working Group Food Allergens aims to produce incurred reference material with the food allergen reference material egg and milk available e.g. at NIST (egg powder material, skimmed milk powder material). The so-called reference material incurred (RMI) will be tested in validation studies, conducted by the Working Group.

Repeat analyses of the same test sample will almost always produce varying results. Because this variation is even higher than for other analytes e.g. chemical contaminants questions regarding the sampling and measurement uncertainty of allergenic foods have to be urgently addressed in order to assess a method. Variations may be due to e.g. changes in the operating conditions, and an inhomogeneous sample from which only a small test portion is taken or varying protein/DNA extraction efficiencies.

For any given food product, the development of a scientifically sound sampling plan that includes a statistical analysis of the probability that all allergenic components are detected ensures that any allergens present are accurately measured. Important sampling questions that are already being addressed in other analytical areas also need to be considered and include whether the allergen is likely to be heterogeneously distributed within the batch; the number of samples per batch that should be tested; which batches should be tested; which portion of a run should be tested; and how to obtain a specific degree of confidence (e.g. 95% confidence) that no allergen is present and if this is economically and technically feasible. Because each step before the chemical analysis as final stage of the measurement process, such as sampling, grinding, blending and sample preparation for chemical analysis will introduce variability in the final measurement result, the measurement uncertainty has to be assessed following internationally accepted guidance. The Eurachem/EUROLAB/CITAC/Nordtest Working Group on 'Uncertainty from Sampling' established in September 2003 issued guidelines for the evaluation of uncertainties in measurement arising from the process of sampling in collaboration with relevant international bodies (Ramsey & Ellison, 2007). This guidance is applicable to all quantitative chemical measurements that require sampling and will be updated as experience is gained in its application. This document looks firstly at the methods of estimating uncertainty and uses real case studies to exemplify each method of assessment. The role of measurement uncertainty in the decision making process is also addressed, as is the assessment of fitness for purpose. Secondly, the document examines whether it is a good idea to set global fitness for purpose criteria for sampling uncertainty. In addition, Nordtest has prepared a handbook for sampling planners on sampling quality assurance and uncertainty estimation, which is based upon the EURACHEM Guide, but which is rather more 'practical' (Grøn *et al*., 2007).

Future perspectives

Elaboration of reliable, reproducible and sensitive methods for detecting and measuring the allergenic constituents in food makes a critical contribution to managing allergens but is not an end in itself. Instead its purpose is to permit food manufacturers to manage allergen risks in order to protect allergic consumers and to comply with regulatory requirements. Risk is defined as the probability of an adverse outcome and can be represented as a function of hazard and exposure. Analytical techniques address the exposure side of this function, but only have meaning if the hazard in question has been characterized, i.e. if the amount of allergen can be related to the probability of a reaction occurring and, ideally, to its severity. These data on thresholds and the distribution of minimum eliciting doses in the population form a critical set of data required to assess the risk from food allergens, in particular when they are present inadvertently (Crevel *et al*., 2008).

Legislation in relation to the safety of foods is complex (discussed above) however this complexity could be reduced if there was a consensus on what constitutes the amount of an allergen, which renders a food 'unsafe'. The discussion on threshold values for allergens is of major concern for all affected stakeholder groups, allergic consumers seek for 'safe' food, food industry would like to provide them, and enforcement has to ensure the compliance with the food regulation, supported by testing labs. The MoniQA Allergen Working Group will seek to place its activities within a wider context, where its findings can be integrated with data from other groups like EuroPrevall (Mills *et al*., 2007) and the Food Allergy Research and Resource Programme (FARRP), which are generating data that can be used in risk assessment and developing the tools necessary to use these data in food safety management.

A practical way to deal with unintentional allergenic 'cross-contact' could be the adoption of an upper limit for non-ingredient allergenic food components, which minimizes risk to the allergic consumer. For example, Switzerland requires the declaration of specified allergenic constituents whenever present in concentrations greater than 1 g per kg or l. The suggestion of thresholds faces different challenges. An upper limit for non-ingredient allergenic food components also needs therefore to consider the No Observed Adverse Effect (NOAEL) reported for each of the important allergenic foods. A further proposal might be a 10 mg/kg (as established in Japan) or 50 mg/kg limit as pragmatic practical approach. However, for one target on the list, Codex Alimentarius has already agreed on levels: in the course of its meeting in Geneva in June–July 2008 it was agreed to adopt gluten levels of 100 mg/kg for foods which have been especially processed to reduce gluten and 20 mg/kg for naturally gluten free products. Subsequent to this, the European Commission prepared a draft regulation that prescribes the labelling of dietetic produces with reduced gluten levels. According to this regulation, which is due to be published in final form in February 2009, dietetic foods which contain one or more ingredients with gluten but which have been specifically processed to reduce the level of gluten to below 100 mg/kg shall bear the label 'very low gluten' and the same products with a gluten level below 20 mg/kg may bear the label 'gluten-free'.

A key contribution to assuring the safety of the food-allergic consumer is the development of reliable tools for allergen detection. Issues that need to be addressed include the development of rapid test kits of sufficient sensitivity not only to detect food allergens at low levels, but also to overcome methodological problems like matrix effects etc. Furthermore, a harmonized validation procedure will help to provide standardized methods for the users as well as for the developers of these methods. An important part of this activity will be to develop universally recognized reference materials for food allergens. As mentioned before, the Working Group Food Allergens aims to produce reference material incurred (RMI) with the food allergen reference materials egg and milk. Combining the efforts of MoniQA, with international initiatives ongoing under the auspices of the AOAC Presidential Taskforce on food allergens and the CEN WG12 Food Allergens will lead to improved consistency in method validation study protocols used to validate the performance characteristics of quantitative food allergen ELISA methods in the future. A first step will be the implementation of the harmonized validation protocol for quantitative food allergen ELISA methods by the MoniQA Working Group Food Allergens. During the project ring trials will be conducted in order to prove the use of RMI as well as the validation protocol developed. This will further promote availability of a greater number of documented/validated ELISA-based allergen detection test kits and ultimately lead to more comparable results.

One further important issue generated by the discussion on thresholds is the labelling of allergenic ingredients as well as unintended allergenic residues present by cross contamination. Consumer organizations have special requirements regarding the allergen declaration. One of the major problems with food labels is their illegibility. In order to deliver information on allergen risk one possible option is the use of modern technologies like mobile phones and the internet.

For example, new developments are now making it possible to use mobile phones as personal shopping assistants (PSAs), using 2D Data matrix technology (interactive bar code-like symbols that can be placed next to product information cards, on posters, on signage or on websites). By scanning the tags, the consumer will receive in-depth product information instantly on his/her phone from the retailer and/or manufacturer. The current technology is based on the so-called 'QR codes' (quick response codes), which are a form of 2D barcode. The phone handset can scan the barcode using its camera or other input, decodes the information, and then takes actions based on the type of content e.g. providing allergy information. While the most popular usage of these QR codes is in advertising these could lend themselves to providing more detailed information for allergic consumers linked to the bar code. As similar option maybe offered by a PSA, a small mobile computer with a touch screen and barcode scanner attached to the shopping trolley. Another new development is the so-called 'Smart shelf', which is equipped with an RFID (Radio Frequency Identification) reader that enables the system to display information from the RFID on screens. These new methods offer a means of providing allergic consumers with the information they require in a rapid and easy to use format whilst shopping. The crucial factor is the link to adequate hazard control procedures and the testing framework in which food manufacturers work that underpins the information encoded in a data matrix, barcode or RFID tag.

In conclusion, harmonization of analytical standards and norms against which contamination by food allergen contamination can be assessed will assist the food industry in delivering information of greater precision to the food allergic consumer. Application of new forms of information transfer technology will further optimize delivery of that information, thus enabling the consumer to purchase foods with greater confidence.

Managing allergens in foods requires the involvement of several stakeholder groups. Each of these groups, such as food manufacturers, control authorities, retailers, caterers and allergic consumers have their own requirements regarding appropriate handling of food allergens. The MoniQA Working Group Food Allergens seeks to establish a 'round table' allowing discussion with all the stakeholder groups concerned in managing allergens in foods. During the coming years acceptable solutions will be discussed, elaborated and tested leading to proposed harmonized strategies for allergen management. These include the development and implementation of a harmonized validation approach for quantitative ELISA methods. Further activities of the Working Group Food Allergens within the MoniQA project include training for students and academia in allergen analysis, dissemination activities as well as the development of a database on methods (Table 2).

Table 2 Activities of the working group food allergens within the MoniQA project

Deliverables of the Working Group Food Allergens	Further activities within MoniQA
Development of a harmonized validation protocol for quantification of ELISA methods	Method collection – Supporting database
Design and production of reference material incurred (RMI) with egg and milk, and later gluten	Training activities for students and academia - MoniQA FST: Food safety and analytical challenges in the cereal based food chain, Hungary, December 2008
Implementation of validation protocol using RMI (Kit validation by conducting ring trials)	Dissemination activities, workshops and meetings - Food Allergen Workshop, Halifax, May 2008 - AOAC Meeting, Dallas, September 2008 - AOAC Meeting, Singapore, September 2009

MoniQA, Monitoring and Quality Assurance in the Food Supply Chain; FST, Food Scientist Training; AOAC, Association of Official Agricultural Chemists.

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Abbreviations and Acronyms

AFGC, Australian Food and Grocery Council

AOAC, Association of Official Agricultural Chemists

CEN frz., Comité Européen de Normalisation (engl.: European Committee for Standardization)

DNA, Desoxyribonucleic acid

ELISA, Enzyme Linked Immunosorbent Assay

EuroPrevall, Acronym of the EU project 'The Prevalence, Cost and Basis of Food Allergy across Europe'

FALCPA, Food Allergen Labelling and Consumer Protection Act

FARRP, Food Allergy Research and Resource Program

FST, Food Scientist Training

IgE, Immunoglobulin E

ISO, International Organization for Standardization

IUPAC, International Union of Pure and Applied Chemistry

JRC, Joint Research Centre

LFD, lateral flow devices

LoD, Limit of Detection

LoQ, Limit of Quantification

MoniQA, Acronym of the EU project 'Monitoring and Quality Assurance in the Food Supply Chain'

NIST, National Institute of Standards and Technology

NOAEL, No observable adverse effect level

PCR, Polymerase Chain Reaction

PSA, Personal Shopping Assistant

QoL, Quality of life

QR, Quick Response

RASFF, Rapid Alert System for Food and Feed

RFID, Radio Frequency Identification

RMI, Reference Material Incurred