Food allergens management

The labelling of 14 specified allergenic foods is required by EU legislation (Annex IIIa to Directive 2000/13/EC as amended) when deliberately used (regardless of the level of inclusion) in pre-packed food. However, the legislation does not cover the adventitious presence of allergens resulting from cross-contamination.

by Chun-Han Chan
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If there is a problem with the safety of a food product, it should not be sold and two forms of action could be taken; it could be withdrawn from the shelves of shops or recalled (when consumers are asked to return the product to the point of purchase).

To communicate the risk and the actions taken as a result of a reported food allergy incident, the Food Standards Agency issues an allergy alert to provide details on the withdrawal or recall to inform consumers and local authorities about an affected product. The need to report a food allergen incident could be due to a product having incorrect packaging and subsequently incorrect allergen information, or due to significant levels of allergen cross-contamination in the absence of any allergen advisory labelling.

Since 2000, the Agency received 482 food allergy notifications submitted by food businesses, local authorities and consumers. In 2007, the Agency introduced the Allergy Alert Notice System as a more effective way to contact food allergic or intolerant consumers who may have purchased a product that was subject to a withdrawal or recall. During 2010, 79 food allergen incidents were reported to the Agency for action, of which 34 allergy alerts were issued. Common issues reported were incorrect packaging or ingredients lists, inconsistent allergy information as well as cross-contamination.

Developing adequate allergen controls does not require unique processes or principles; good allergen management foundations lay within any HACCP based system used to control other hazards in food production. However, further consideration should be given to people, raw materials and supply chain, cleaning, shared equipment and processes, reformulation and new product development (see Fig. 1).

In the event of cross-contamination or incorrect labelling occurring, action should be taken to ensure that the affected product does not reach allergic consumers. In such cases the supply chain needs to be identified so that premises which have received the affected product can help implement a withdrawal or recall to remove or minimise the risk of an adverse event occurring. The risk to food allergic consumers is then communicated through allergy alerts issued on the Agency's website (www.food.gov.uk) and through food allergy support organisations such as the Anaphylaxis Campaign, Allergy UK and Coeliac UK who contact their at risk members.

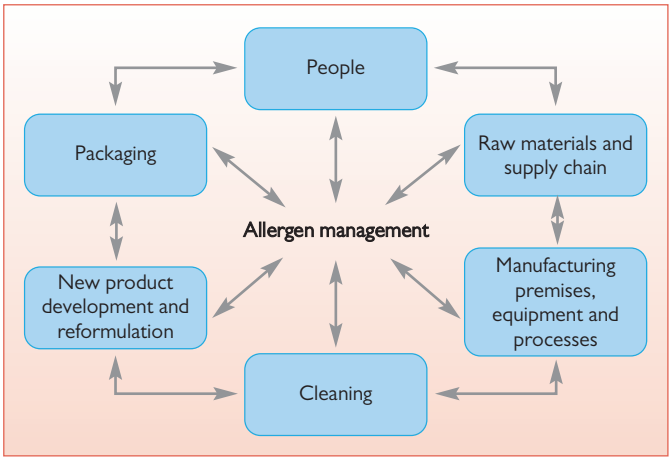

Fig. 1. Key areas for consideration.

Financial impact

There is a financial impact following a lapse in allergen management in that large volumes of food may have to be destroyed as relabelling/over-stickering can be laborious and time consuming meaning that the affected product could then pass its durability date. In some cases relabelling many not be possible due to the type of packaging used i.e. packaging for a frozen product.

Research commissioned by the Agency has shown that food allergic consumers exhibit strong brand loyalty when making purchasing decisions based on the labelling information provided and their previous experience of eating that product, which leads to assumptions about the company's policies or quality of their products. Lapses in allergen control affect perception of allergen control policies and can lead to lowered consumer confidence and possible brand damage. The Agency in partnership with the food industry and other interested stakeholders, produced voluntary best practice guidance to ensure that allergen labelling is as effective as possible. Allergen advisory labelling should only be applied following a rigorous risk assessment and a demonstration of a significant risk of cross-contamination; it also ensures that food allergic consumers are fully informed about the nature and contents of the foods they are buying.

However, in the absence of allergen management thresholds (action levels) determining a level at which an allergen can be present and be considered not to be a significant risk to the allergic consumer are yet to be agreed; as a result some businesses will use allergen advisory labelling even when the cross-contamination risk is very remote leading many allergic consumers to believe that the workings are to protect the business rather than the consumer. The Agency has commissioned a programme of work to address this research gap to gather suitable data in order to derive allergen action levels.

Working in partnership with other industry and regulatory bodies it is reviewing population level dose response data, exposure and type of reactions reported at certain doses to ascertain levels of risk.

Using clinical food allergy study data from studies such as the EU funded Framework 6 project EuroPrevall, it is looking to develop population level data for several allergens specifically for milk, egg and peanut. Using these dose distribution data it would be possible to determine an action level with an appropriate safety margin (such as an eliciting dose for 5% of the population) at which a small number of food allergics will experience only minor reactions, such as oral allergy syndrome (i.e. itchy mouth) on occasion.

However, there is also the need to agree a level of risk and probability of experiencing a minor adverse reaction which is acceptable to the food allergic population.

In conclusion, when deriving action levels, some key criteria will need to be met in addition to protecting the safety of the allergic consumer without unduly restricting their choice. Firstly, such action levels will need to be practical for the food business operators to reasonably work to; secondly in agreeing action levels, due account will need to be given to the levels to which the current state of the art analytical methods can measure. ■

www.food.gov.uk

Table olives and spreads

by G. Siragakis, E. Christodoulou, and D. Kizis, Food Allergens Lab, Kalopsidas 38, Livadia, Cyprus.

A considerable number of food materials have been reported to be allergenic with eight of them being responsible for more than 90% of all food allergies reported.

The vast majority of them are proteins and include common foods such as milk, eggs, legumes, cereals, nuts, fish, crustaceans, celery or in products that contain them as ingredients. They can be part of the recipe/ingredients or as unwanted traces that have been incorporated accidentally during food manufacturing processes.

Common examples in Mediterranean processed products are table olives and olive spreads. These have been accused of causing various allergic responses but the allergenic proteins/compounds are not of olive origin. This is because many table olive products and spreads contain foods like cheese, almonds, onions or peppers that have been used as ingredients or have been used to produce stuffed olives. They have also been present as contamination traces.

It is very important for the consumer to know about the presence of such materials in olive products, so the detection of allergens is a prime requirement in food safety controls. Various methods have been developed for the detection of allergens in foods. There are two main approaches that detect the allergen per se (a protein) or a marker (DNA fragment or specific protein) that indicates the presence of the allergenic food.

The former approach utilises immunochemical detection protocols (ELISA, SDS PAGE) while the latter is based on detection by PCR2.

A considerable number and variety of table olives and olive food products have been tested during the last three years in our laboratory for cheese, almond and celery allergens.

The main method used is that of immuno-detection using ELISA kits (Neogen Veratox), however PCR detection has given highly reproducible results with increased sensitivity. We have tested a lot of olive products and we were able to detect cheese, almond and celery allergens in some of them due to contamination of production lines. In olive spreads the case was similar but with more contaminated packs. ■

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App control for allergies

Tesco and Asda have joined forces and, for the first time, have shared their food and drink product databases with a third party, the Food-Wiz team.

These databases can be downloaded onto the smartphones of allergy sufferers, who then input their own food requirements and can then go shopping with confidence. They simply scan the barcode of any of 100,000 products stored on their phones via the FoodWiz app and get instant feedback as to whether it is safe for them to eat or not. Some 100 new products are added to the database every day. It even works in the corner shop, as all branded products are on the database.

Children as young as six can use the app. Shopping has become fun, as they zap the barcodes on the ready meals or branded goods and all the time they are learning to take responsibility for their own food choices. Children are encouraged to take their phones when visiting friends or grandparents to double check packets and labels. This can be very reassuring for their parents.

The average shopping time for mothers shopping for families with allergies has been cut by 45 minutes and users are daring to try new products instead of sticking to the 'safe ones they always buy'.

The FoodWiz is a gadget in an age of gadgets. James Lay, the founder of Foodwiz, hopes that the NHS will take up the product.

"A GP could 'prescribe' the app for an allergy sufferer in the first instance, instead of resorting straight to medication and intervention. As all allergy doctors know, the only 'real' treatment for food allergies is avoidance. At last, a totally new idea has come to market, making avoidance easier and fun," James told International Food Hygiene. ■

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Gluten free result

Romer Labs has launched the AgraQuant Gluten G12 which is a new method to advance the analysis of gluten in foods.

The new ELISA comes ahead of European Regulation EC No. 41/2009 that comes into force from 1st January 2012 for the labelling of foodstuffs suitable for those intolerant to gluten.

Whilst existing methods are deemed sufficiently reliable and sensitive for supporting such regulations, the analytical methods do have recognised limitations.

The antibody utilised in this new test was developed following clinical research which led to a better understanding of the complex proteins that cause gluten toxicity.

The resulting G12 antibody based assay targets the most immunotoxic proteins.

The method offers superior sensitivity to these toxic proteins; reliable quantitation down to 4ppm gluten in foods and 10ng/mL for surface swabs.

This new test means that Romer Labs now offer analytical tests for validation and verification of allergen controls.

These include the Agra-Quant range of quantitative laboratory ELISAs for both validation and verification and the recently launched AgraStrip Lateral Flow devices for on-site verification. ■

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Survey of allergen labelling

The UK's Food Standards Agency is inviting researchers to carry out a survey of allergen advisory labelling to provide a better understanding of whether the labelling relates to the actual level of allergen present in processed foods.

It will also help the FSA gather information on the levels of allergens present as a result of cross-contamination.

In addition, the survey will look at the different types of advisory labelling used on foods and will consider how different statements, such as 'may contain nuts' or 'not suitable for someone with a nut allergy', are used by consumers to assess the levels of risk.

To find out more about the research, you will need to register as a supplier on the FSA's electronic tendering system ePPS (see website below) and search for: 'Survey of allergen advisory labelling and allergen content of UK retail pre-packed processed foods'.

Applications should be submitted by Monday 17th October 2011. ■

www.food.gov.uk

New range of test kits

Bia Diagnostics, the specialist allergen laboratory in Vermont, USA, has now launched a range of rapid allergen test kits.

They are lateral flow devices and ELISA based and the range now covers validated testing requirements for milk, soya, coconut, egg and almond. Tests for peanut and gluten are in the final stages of development prior to validation.

The kits are supplied in packs of 25 tests and include extraction buffers and vials so that each pack contains all that is required to complete the test.

The tests and methods are validated for use against a range of finished products achieving positive results from contamination levels of low parts per million. ■

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Risk assessment and allergen management

by Simon Flanagan, RSSL, Reading Science Centre, Pepper Lane, Reading, Berks, RG6 6LA, UK.

Allergen labelling regulations differ widely around the world, so allergen management continues to present a big challenge for food producers. For example, the EU requirement to label any of the 14 allergens on its list contrasts with Japan's requirement to label only five. Even within the EU, a manufacturer that supplies its own brand and those of a variety of retailers will need to adopt different labelling practices on every product. It will also face the daily challenge of ensuring that the right product with the right ingredients goes into the right packaging with the appropriate labels.

Practical tools are needed to help manufacturers deal with this complexity, and to avoid the possibility that mistakes will happen that lead to expensive recalls.

Maximum limits

One factor that makes life difficult for all manufacturers is the absence of 'acceptable limits' for allergens (with the exception of sulphites).

This has led to an over use of 'may contain' warnings on labels even in cases of negligible risk, and an over reaction from some product managers to the actual danger from the slightest risk of cross contamination.

The fact is that not all allergens are the same, nor do they present the same risks to consumers. The EuroPrevall project, established in 2005, offers the possibility of reaching clinical agreement on safe limits. Part of the EuroPrevall project has been to obtain data on the levels at which different foods elicit an allergic response. Contributions received from outside Europe potentially mean that the project could have relevance on a global scale, and could ultimately lead to the adoption of population based 'action levels' for some or even all of the most common allergens.

This effort has been supported by the MoniQa initiative, which has sought to harmonise methods for testing allergens in food. Clearly, there is no point in setting acceptable limits if there is no means of establishing whether the limits have been exceeded.

However, even if limits are agreed, food manufacturers will still have to understand, identify and manage their allergen risks.

Understanding risk

Risk assessment forms the basis of the most practical and useful approach to allergen management. That is why risk assessment is now a requirement of all the international standards that have received approval from the Global Food Safety Initiative (including V5 of the British Retail Consortium standard).

Risk assessment is the semi-quantitative estimation of whether a potential event is likely to occur in practice. It is normally expressed as a risk factor or score, arrived at by multiplying the hazard severity score by a score indicating the likelihood of the event occurring.

Risk assessment differs from the pure HACCP approach, which has been used widely in allergen management during the past 10 years.

HACCP tends to treat all allergens as equivalent, leading to overuse of 'may contain' statements, and arguably, unnecessary cases of recall and withdrawal. The HACCP approach has also meant that many manufacturers have focused on managing inconsequential and unlikely (and hence low risk) cross contamination incidents. All the evidence suggests that the vast majority of recalls are from putting the right product in the wrong box, or putting the wrong label on the right product. That is not to say that cross contamination is irrelevant. However, it is to recognise that once control measures have been put in place, (ingredient and equipment segregation, validated cleaning etc) risk assessment – incorporating hazard characterisation and robust prerequisite programmes – is the tool that will determine where the real vulnerabilities are and where most effort should be focused.

Risk assessment in practice

RSSL has developed its own quantitative risk assessment tool kit, which is an evolution of existing best practice guidance and has proved extremely useful in evaluating the premises and practices of a diverse range of food manufacturing companies. This approach provides documented evidence in support of sensible labelling statements, and more importantly, is the precursor to developing a consistent approach to allergen management, and improving ingredient sourcing and handling.

The outcome of this process is to derive a hazard rating for the various ingredients used, after which one can determine whether appropriate control measures are currently in place or can be implemented to minimise the allergen risks. The effectiveness of these control measures must also be scientifically evaluated before they are relied on.

Even where the control measures are known to be effective, it should be recognised that ongoing verification will still be needed. Routine, daily monitoring of the effectiveness of control measures, using simple to apply, 'real time' tests will help to ensure they are working well, and will enable corrective action to be taken in a timely manner. These checks might include visual inspections or other rapid assessment measures, such as testing of the finished products or swabs of equipment after cleaning.

It is worth remembering though that the laboratory testing must be validated. Off-the-shelf test kits for a given allergen must be proven to be effective for a specific product or sample in order for the results to have any merit. Our laboratories have rescued several customers from initiating recalls based on 'positive' results for contamination that we were able to show were false positives arising from the use of non-validated testing methods.

Conclusion

Many food companies have struggled with their response to allergen labelling. Hence many products are packaged with confusing and conflicting messages, and many have been the subject of costly recalls due to the mis-labelling, mis-packing or mis-application of testing methods.

Clearly, the industry is in need of an improved approach to allergen management. Risk assessment offers a reliable way of handling allergenic ingredients, and of labelling products sensibly where risks of cross contamination do exist, but can be shown to be minimal and under control. ■

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Wide range of rapid tests

It is now possible to carry out tests for the food allergens that are of most concern to the regulators, food industry and its consumers.

Neogen Europe's wide range of rapid food allergen tests can detect a target allergen in ingredients, liquids, clean-in-place rinses, finished foods, and on environmental surfaces, thereby enabling quick screening and quantitative analysis.

Rapid food allergen test kits give a company a method of easily determining if its product has been subjected to cross-contact with an undeclared food allergen. Companies can use rapid allergen test kits on raw material, before it enters production, or on equipment or product at any point throughout the production process. The tests' flexibility and ease of use allow users to pinpoint and eliminate possible risks for cross-contact and provide the essential information to enable effective and efficient management of the allergen contamination risk.

Neogen's rapid food allergen tests include its unique Reveal 3-D products. These tests screen for the presence of low levels of allergen in clean-in-place rinse waters and environmental swabs virtually anywhere. The tests utilise a 'three-line' readout. Within 10 minutes a control line confirms that the method has been performed successfully and two further lines differentiate between low and high levels of detection.

The test packs come with everything needed to complete the test including the swabs.

Neogen offers Reveal 3-D testing products for:

- Almond.
- Casein.
- Crustacea.
- Egg.
- Gluten.
- Hazelnut.
- Peanut.
- Soy.

To test food ingredient or finished food products, Neogen has built up its comprehensive line of Veratox, Alert or BioKits food allergen test kits. ■

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Turning supply chain allergen risk assessments into a competitive gain

by Stephen Whyte, Director, QADEX, Sileby, Loughborough, LE12 7PU, UK.

Keeping up with allergen risk assessments in your supply chain can be a tricky, time consuming responsibility which puts unwanted pressure on your business.

In addition, the greater media interest and the increasingly stringent requirements of retailers make it an area that is attracting even more attention from food safety auditors and legislators.

If you find it a challenge to keep on top of allergen risk assessments and meet the growing demands of customers and auditors then this article will give you some useful top tips and sensible, tried and tested advice. It will show you how to comply with best practice and turn what was formerly an administrative pain into a competitive gain.

Common problems and issues often encountered by food businesses dealing with allergen risk assessments in the supply chain include:

- A lack of resources in the technical department.
- Poor knowledge at some suppliers.
- Difficulty gathering current information from all suppliers.
- An inability to track the status of all outstanding requirements.
- Information submitted by suppliers which is incomplete/out of date.
- Irresponsible or uninformed agents/traders and distributors.
- Missing information identified by auditors resulting in non-conformances.
- Insufficient raw material specification information.

The majority of food businesses encounter some or all of these problems. So, how can they implement best practice and turn allergen risk assessment into a competitive advantage?

By improving allergen risk assessments in the supply chain a food business will:

- Reduce allergen labelling mistakes.
- Decrease risk by gathering higher quality information that will achieve higher confidence in labelling and internal controls.
- Be able to provide better information that will be readily available during audits.

At QADEX we have developed in the past five years to the point where we are handling over 9,000 suppliers globally on behalf of more than 150 food manufacturers and from this experience we have produced six top tips for improving allergen risk assessments

Tip 1: Make your supplier audit questionnaires and product specifications requirements context specific.

Many food businesses have a single supplier self audit questionnaire format for all suppliers and often a single format for specifications. This means that a lot of suppliers are being asked for information that is not relevant.

Supplier audit questionnaires and specifications should be specific to the type of raw materials being supplied and in as many formats as reasonable, for example meat, dairy, ingredient, contact packaging, non-contact packaging. This allows detailed information to be requested by ingredient type and encourages greater co-operation when suppliers recognise you are asking for data that is relevant.

Tip 2: Ensure that supplier audit questionnaires and raw material specifications contain identical allergen listings.

Though this seems obvious it is often missed in practice because the questionnaires and the specifications are created by different people at different times. You should also ensure that there is enough detail and guidance to support suppliers who may not be as switched on to allergen controls and where allergens may exist within the suppliers own sub-supply chain.

Tip 3: Know what is in the raw material and understand the process and supply chain behind the raw material.

An example is the organic cocoa process and supply chain in which many suppliers have not fully audited their supply chain and may not realise that some cocoa farmers use their drying beds to dry nuts outside of the cocoa drying season. It is essential that you appreciate an ingredient's complete process and supply chain all the way from field to your processing site. By knowing about its 'journey' you will be better placed to identify risks the ingredient is being exposed to – and better positioned to make sure those risks are being managed.

Although many supply chains contain multiple steps which make it more difficult to gain full understanding, this complexity should not be used as an excuse to hide behind.

To learn about the supply chain for a particular ingredient start with a web search. You will be amazed at the amount of information immediately available. For additional information ask your suppliers because they should know.

Tip 4: Understand fully what activities are carried out at suppliers' sites.

Your factory processes food all year around so you may have assumed that the mango puree cannery in India is packing mango puree all year round. However, you may be wrong.

Consider the seasonality of fruit and vegetable crops. There may be processing capacity near the crop source which has the capacity to process large seasonal volumes quickly. Do you know what is being processed out of season and do any out of season activities present allergen cross contamination risks to the ingredients used by your business?

A QADEX technologist recently visited a seafood cannery. In the warehouse he spotted labels for items used in pet food manufacture. On further investigation it was identified that due to fluctuating volumes of seafood raw material, the site was keeping itself busy canning pet food. Some ingredients used were not fit for human consumption.

Armed with this knowledge how would your supplier approval process be modified for this site?

Tip 5: Validate information gathered on self audit questionnaires against information provided by suppliers on raw material specifications.

Imagine your supplier audit questionnaires and raw material specifications have been returned within days of being requested.

- Missing documents have been chased up and returned.
- Missing information on questionnaires and specifications have been asked for and subsequently provided by suppliers.
- Everything is now collected and complete.

The above scenario may be idealistic but we live in hope!

You should cross check completed questionnaires carefully against the raw material specifications.

- Are all allergens on site entered on the self audit either listed as contained in the ingredient or as a cross contamination risk?
- If an allergen is not listed on the raw material specification review the supplier's allergen policy in detail.
- If you have doubts, assume that the raw material specification is wrong until proven correct.
- Suppliers who have not returned questionnaires or who do not provide complete information are, in our experience, likely to be high risk.

It is not possible to risk assess suppliers who refuse to complete supplier questionnaires so you need to audit these suppliers yourself or initiate a planned de-list programme.

Tip 6: Use software solutions to remove the burdens of gathering, assessing and managing all of the information required.

The amount of information to be gathered, assessed and managed may overwhelm paper-based systems – resulting in substantial cost but little tangible business benefit. Software solutions have emerged in recent years to assist supplier approval management. The best systems will:

- Look after gathering, assessing and managing all of your supplier approval management information.
- Generate substantial cost savings compared to existing manual processes.
- Automatically complete allergen validations for you and alert you to possible problems.

The greatest risks to a food business may be those beyond your control.

By reaching out down the chain of supply to gather information from your suppliers you acquire the means of assessing those risks.

What you do with and how you respond to that information is within your control. ■