Food allergens – improving control

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Food allergens is a growing food safety concern that is known to affect the lives of many people. Over 12 million Americans and a similar proportion (2-3%) of the European population are believed to be sensitised to allergenic food proteins.

Prevalence in children is higher (5-8%); some allergies (milk, egg) resolve with time but others (peanut, soy) tend not to disappear.

Symptoms range from very mild to potentially fatal. Anaphylaxis is the extreme end of the allergic spectrum. In the UK, eight children younger than 16 years died from food allergy between 1990 and 2000. Also, 229 children were admitted to hospital for food allergy between 1998 and 2000. Several studies have indicated that the prevalence of food allergy is rising in conjunction with consumer and media awareness.

Allergens responsible for over 90% of all allergic reactions include:

- Cereals containing gluten.
- Crustaceans.
- Egg.
- Milk/dairy products (including lactose).
- Fish.
- Peanuts.
- Soybeans.
- Nuts.
- Celery.
- Mustard.
- Sesame seeds.
- Sulphur dioxide/sulphites.

The appetite for foods with allergy 'free' claims is growing rapidly and such products tend to be priced at a premium. In the UK this market grew by 165% between 2001 and 2002 and is expected to be worth more than $240m in 2007, and in the USA the total allergen oriented market will top $4 billion by 2008.

A niche market is developing in the US for people suffering from coeliac disease, with sales of gluten-free products expected to top US$1.7bn by the end of 2010 after beginning the decade at a mere $210m, in 2001.

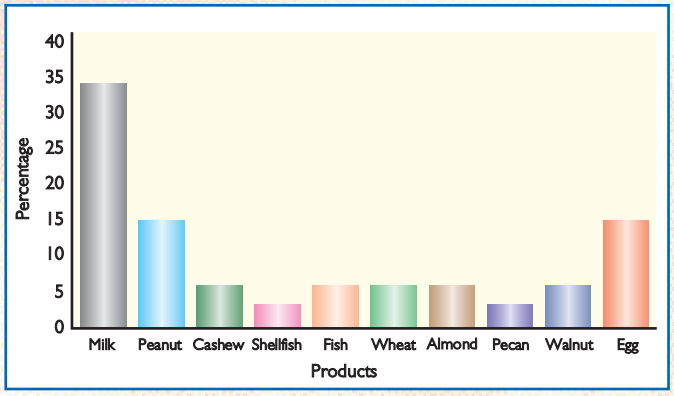
This growth is thought to be due to a number of factors including the increase in prevalence, life-style decisions to avoid foods such as wheat and milk and a growing awareness amongst doctors.

This is giving cause for concern in the food industry and governments in the developed world. All food businesses are legally bound to make sure that they carry out their operations to produce food that is safe to eat.

In response to the risk that certain foods pose to those with food allergies, countries have responded by instituting labelling laws that require food products to clearly inform consumers if their products contain major allergens or by-products of major allergens.

However, product recalls have become more regular in the food sector as diligent businesses have voluntarily withdrawn products as a precautionary measure to the perceived risk. But is there more which goes undetected?

Fig. 1. USA food allergen incidents (Total = 34). Food allergy and anaphylaxis network. March-July 2007.



	USA	Europe	Japan	Australia and New Zealand
Celery		3		
Cereals containing gluten	3	3	3 and Buckwheat	3
Crustacea/shellfish	3	3		3
Egg	3	3	3	3
Fish	3	3		3
Milk	3	3	3	3
Mustard		3		
Peanuts	3	3	3	3
Sesame		3		3
Soya	3	3		3
Sulphite		3		>10mg/kg
Tree nuts	3	3		3
Others		Lupin/ mollusc	Many others	

Table 1. Regulated food allergens.

Legislation

Regulations have been implemented in the USA, Europe, Japan, Australia and New Zealand (FALCPA 2004; Directive 2003/89/ EC; Ordinance No.23 of 2001 of the Ministry of Health, Labour and Welfare, Joint Australian New Zealand Food Standards Code, Standard: 1.2.3) to improve the labelling of food ingredients known to contain food allergens (Table 1).

The intention of this legislation has been to assist the increasing number of hypersensitive consumers to avoid making potentially fatal choices. However, hidden allergens, the result of cross contamination, continue to exacerbate the problem for consumers, caterers and manufacturers alike.

Control of food allergens is argued to be one of the biggest challenges facing the food industry in developed countries.

Product recalls

Undeclared food allergens are reported to be the principal underlying cause of global product recalls; problems with labelling being the most common reason.

In the UK, food businesses have to inform their local authorities when they withdraw any product and face fines if they fail to do so.

Also, when products fail to comply with European legislation they should be withdrawn. Not all contamination incidents that lead to a product recall can be avoided and it is also likely that some of the global recalls were precautionary rather than strictly necessary on grounds of food safety.

Given the general increased frequency of product recalls there is a growing need today (Figs. 1 and 2) for the industry to invest more heavily in preventative measures such as testing programmes. It would only take one significant product recall before the cost of these measures can be balanced against the 'savings' in potentially lost sales and damage to the reputation of the brand.

Preventative measures

Identifying and controlling the hazards posed by food allergens should be an ongoing process and integrated into existing food quality management systems. T oday's complex food preparation environment (where facilities, equipment and staff are often not dedicated to allergen-'free' food

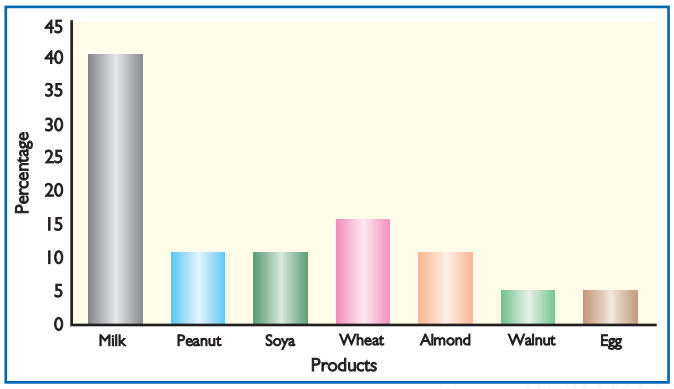


Fig. 2. UK food allergen incidents (Total = 19). Food Standards Agency alerts. March-July 2007.

production) makes verification of the effectiveness of the risk management systems vitally important. New certification schemes such as ISO2200 and the soon to be launched Anaphylaxis Campaign 'Standard to increase trust in information about allergens in food' will drive this process further for companies that need to meet and exceed food safety regulations and supply foods globally. The new perspective is to integrate the risk management, HACCP and pre-requisite operational controls to help manufacturers take control.

There are five fundamentals frequently advocated to taking control in the management of food allergens:

- Forming strong relationships with trustworthy suppliers.
- Controlling cross contamination.
- Strict label control.
- Keeping records and reviewing them 'prior to shipping the goods'.
- Testing as part of a due diligence programme.

These fundamentals are incorporated into Codes of Practise from major retailers and regulatory agencies. Such codes are designed to 'enable consumers to make informed choices' for example, UK Food Standards Agency 'Guidance on allergen management and consumer information' and the revised 'Food industry guide to allergen management and labelling' from the Australian and New Zealand Food Standards code.

It is an imperative part of these codes that all food manufacturers have an allergen control plan. These plans should include:

- Evidence of validation, verification and audits.
- Documentation of all control activities.
- Being integrated with risk management systems.
- Validation, ongoing verification and audits by testing.

Increasingly, some level of testing is considered to be a minimum 'standard of care' in the USA to ensure supply of safe foods for the allergic individual and to mitigate potential liability actions.

In Australia, Japan and the UK, testing is also considered a valuable due diligence activity.

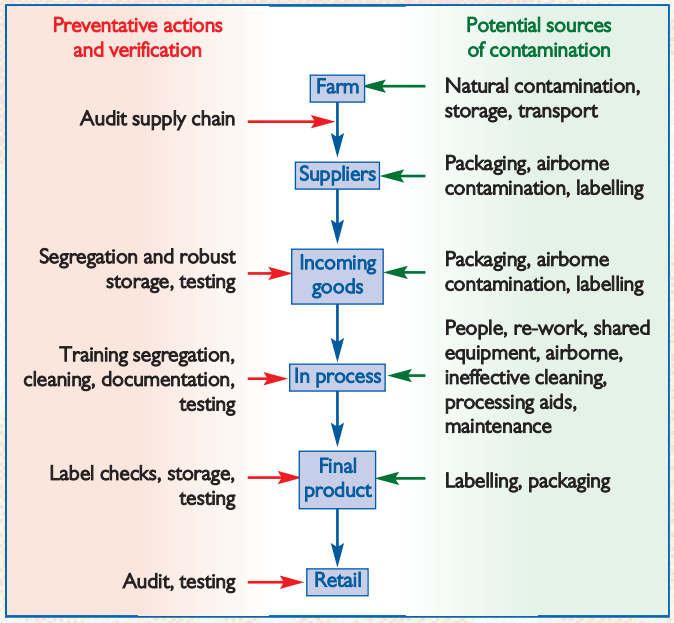
Risk analysis needs to identify which of the potential sources of cross-contamination (Fig. 3) are significant in the context of the individual factory.

These need to be prioritised based on the magnitude of the risk. An evaluation of the use of the prioritised allergenic ingredients within the factory should then be made. It will also need to identify which systems need validating particularly cleaning (Fig. 4).

This information should then be used to determine where, when and how often sampling and testing for specific food allergens should occur.

At these control points it will be necessary to establish threshold limits for deciding whether corrective actions are necessary. In the absence of international agreement on minimum levels due to insufficient clinical data, companies need to decide their own threshold levels based on their risk analysis assessment.

Fig. 3. Guide to allergen control and awareness.



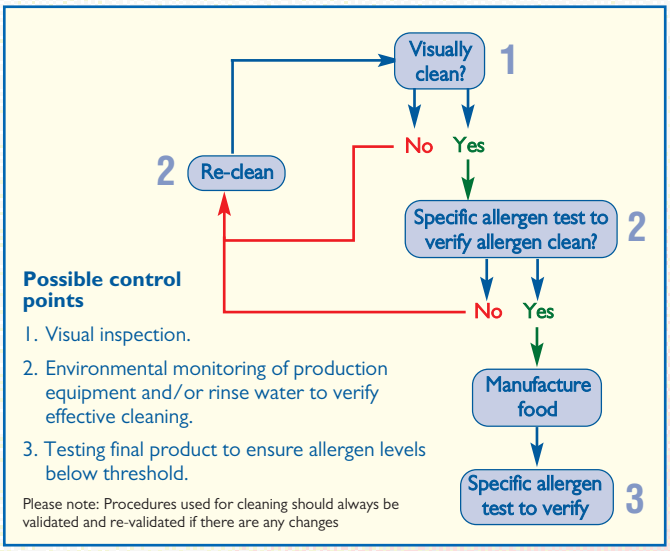


Fig. 4. In-process cleaning validation.

Testing

In order to support the demands for preventative measures there are possibilities for testing for all of the regulated food allergens through contract laboratories and through an expanding choice of commercially available test kits. These include:

- Allergen swab test (used for environmental testing).
- Hand-held rapid test (specific allergen test, lateral flow device).
- Laboratory kits often used in contract laboratories (most commonly ELISA for protein detection and PCR-based methods for DNA analysis).

This provides the capability for all manufacturers to verify their labelling claims and to validate their factory specific quality management systems.

Monitoring cross contamination may require testing of the environment as well as food samples.

To enable food manufacturers to undertake real-time, in-situ testing hand-held 'dip and test' allergen test kits are available.

The simplicity of these tests makes it suitable for anyone in food manufacturing or enforcement to check compliance with both manufacturing and HACCP procedures or food labelling regulations.

These allergen specific tests should

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Some major food retailers are trying to clarify this issue in their own codes of practice and more recently Food Standards Australian New Zealand (FSANZ) have published manufacturing guidelines on allergen management including threshold levels (Table 2).

The voluntary incidental trace allergen labelling (VITAL) action levels are:

- Action level 1 – precautionary cross contact statement is not required for the relevant allergen under evaluation.
- Action level 2 – precautionary cross contact statement is required for the relevant allergen using the standard vital statement.
- Action level 3 – significant levels of the allergen are likely to be present. Labelling of the relevant allergen as present is appropriate.

The vital cross contact statement is 'May be present'.

A further initiative in Europe (EuroPrevall) has established a consortium of interested parties to predict the outcome of exposure of susceptible individuals to allergens in real foods and this will include investigation of food allergen management threshold levels.

From the analytical perspective it could be argued that if an allergen is detected through testing it is declared no matter what the level found and the consumer informed.

In the UK, there is a body of opinion to move away from 'may contain' labelling with stronger emphasis on allergen control to produce safe food.

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not be confused with non specific hygiene tests such as those which measure the presence of ATP (Adenosine Triphosphate).

While these are effective for the measurement of general cleaning, these tests are not suitable for ensuring that the allergen specific proteins have been removed from a production surface.

For the quantification of specific allergens ELISA based laboratory methods have become the 'gold standard' approach as used in contract laboratories.

These methods are sufficiently sensitive to differentiate low ppm levels of contamination and they detect proteins, the agents implicated in causing allergic reactions in sufferers.

PCR based methods are finding a unique role for confirmation of ELISA results, because they are highly specific, though drawing conclusions from the presence of DNA cannot always be reliably correlated to protein levels.

Validation is crucial for ensuring the applicability of a method. The performance of any method is determined partly by the type and form of the sample being analysed.

While every effort is made by well established kit manufacturers to validate as many food matrices and production surfaces as possible it should always be recommended that the user perform 'in house' validation work to ensure that with any test kit it can detect the food residue down to the desired level in the their own sample matrices and environment.

Kit manufacturer's product literature should aid selection of applicable methods and identify limitations. Units of measurement need to be understood before kits compared.

Test kits either detect specific proteins or food residues and report results in different ways, for example, casein, milk protein and whole milk. Methods rarely detect all the known allergenic proteins; they are effective at indicating or measuring the presence of potentially allergenic food residues; so that they can be managed.

Recommendations

Awareness through training of all staff (for example, Tepnel's laboratory training day on 10th October) together with checking and validating cleaning operations are amongst the minimum prerequisites of any allergen control plan.

Cleaning routines need to be validated for removal of protein films using swabbing techniques in combination with ELISA (Fig. 4). Ongoing verification can then also be achieved through the use of lateral flow devices.

A similar approach should be adopted for investigating other elements of the plan including: production processes (for example, shared equipment and staff practises); ingredient supplies (storage, packaging); and re-work material (use, storage).

If the decision is taken not to validate and verify any or all parts of the plan this should be documented as part of the risk management assessment. Though when the number of voluntary product recalls have almost doubled in the UK in the past year, the cost of taking such a risk is potentially vast both in monetary and human terms.

Many of these instances could have been avoided by establishing and validating an allergen control plan and taking control. n

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References are available from the author on request

Table 2. Voluntary Incidental Trace Allergen Labelling (VITAL) threshold levels (Allergen Bureau, 2007).

Allergen[a]	Milk	Egg	Soya[b]	Fish	Peanuts	Tree nuts	Sesame Seed	Crustacea	Gluten[c]
FSANZ Action Level 1 (ppm)	<5	<2	<10	<20	<2	<2	<2	<2	<20
FSANZ Action Level 2 (ppm)	5-50	2-20	10-100	20-200	2-20	2-20	2-20	2-20	20-100
FSANZ Action Level 3 (ppm)	>50	>20	>100	>200	>20	>20	>20	>20	>100

[a]mg/kg (ppm) of total protein. [b]Action levels for soy is highly conservative. [c]Gluten includes all gluten type proteins as defined in the Food Standards Code.