Allergen control – why and what to test for?

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Certain foods contain chemical components to which a small percentage of individuals (2% of adults and 5% of children) are sensitive. The resultant allergenic response can vary from an unpleasant intolerance to a potentially life threatening condition (primarily peanut products). Clearly there is a potential hazard but how big is the risk and what reasonable precautions should be taken?

Worldwide recognition

Legislation around the world recognises the potential hazard of allergens, for example European regulations require that the presence of 14 food groups containing allergens in foods must be declared on the label.

These food groups and 'products thereof' are cereals containing gluten, fish, soy beans, milk, celery, mustard, peanuts (groundnuts), crustaceans, eggs, tree nuts, sesame seeds and sulphites.

However there are no agreed 'maximum residue limits' probably because of natural variations and uncertainties. For example, when setting gluten limits for coeliac disease sufferers, the overall potential daily intake should be considered, while wheat allergy limits should be based on single servings.

For coeliac disease sufferers this limit should lie between 10 and 100mg daily intake. For wheat allergy, the lowest eliciting doses for children lie in the lower milligram range (1000's ppm), while for adults they are most significantly higher. Similarly, tests for patient sensitivity need careful interpretation. In a survey of eight year old children 110/933 (12%) were found to be sensitive by blood or skin tests but only 12/933 (1.3%) actually showed true allergy with peanut-induced symptoms. In order to protect sensitive individuals, food processors are required to place warnings on labels and ensure that quality assurance procedures reduce the risk of cross contamination from production processes and raw materials.

This includes Good Manufacturing Practices (GMP) and the implementation of HACCP together with their respective 'pre-requisite programmes' within an effective quality management system.

The key controlling elements will include supplier quality assurance, segregation and containment of sensitive ingredients and products, effective cleaning, production scheduling, staff awareness and training, and accurate, clear product labelling.

Foodstuff	Lowest level detected by ATP tests at		
	1ppm	10ppm	100ppm
Shredded wheat	Pi 102 and Supersnap		EnSURE and Supersnap
Oat bran	Pi 102 and Supersnap	EnSURE and Supersnap	EnSURE and Supersnap
Peanut butter	Pi 102 and Supersnap	EnSURE and Supersnap	EnSURE and Supersnap
Egg white	Pi 102 and Supersnap		
Crabsticks	Pi 102 and Supersnap	EnSURE and Supersnap	EnSURE and Supersnap
Mixed nuts		Pi 102 and Supersnap	EnSURE and Supersnap
Milk powder	Pi 102 and Supersnap	EnSURE and Supersnap	EnSURE and Supersnap
Soya	Pi 102 and Supersnap	EnSURE and Supersnap	EnSURE and Supersnap
Almond	Pi 102 and Supersnap		

Table 2. Detection of allergenic foods by ATP systems.

Table 1. Comparative sensitivity of new ATP systems.

Parameter	ATP test systems		
	Hygiena Pi 102 and Supersnap	Ensure and Supersnap	Others
Sensitivity (limit of detection) (fmols ATP)	0.01	0.1	1.0 to 10.0
Repeatability (CV%)	12%	9%	26 to 123%

The Food Standards Agency root cause analysis of 166 food allergy related alerts between 2007 and 2009 showed that 36% of cases related to a processing failure and 64% were due to defective labelling.

Effective cleaning

Effective cleaning is usually identified as a pre-requisite for most GMP and HACCP plans in the food industry and cleaning is often considered a critical control point (CCP) for allergen control. However CCP's need to have acceptable limits and corrective actions, so what do you measure and how effective are the tests?

The primary purpose of cleaning is to remove product residues to an acceptable limit. Allergenic components of certain foods are a very small proportion (typically 1-100ppm) of the total residue. All food components need to be removed with equal vigour to avoid other food safety and quality issues.

Measuring a very specific and unique food component is more difficult and more costly compared to the detection of other food

Continued on page 25

Foodstuff	100ppm
Shredded wheat	✗
Oat bran	✗
Peanut butter	✓
Egg white	✓
Crabsticks	✗
Mixed nuts	✗
Milk powder	✓
Soya	✗
Almond	✓

Table 3. Detection of allergenic foods by protein tests.

Continued from page 23

components that may carry the allergens. Food components are present in much larger quantities than allergens and are easier to detect but also have to be removed to the similar level and by the same processes.

Detection methods

The FDA, FSA and Campden BRI recognise the use of ELISA technology as a suitable test method and also acknowledge that other alternative methods such as ATP bioluminescence and protein tests may have a role to play.

However, PCR is thought to have limited applications. ATP or protein tests will tell you cleanliness but not which type of protein is present so what are the relative merits of these detection systems?

Allergens are glycoproteins which is just one very specific component of foodstuffs and allergens have varying degrees of solubility in water. If there are no agreed 'maximum residue limits' for allergens then it is difficult to set critical limits in a HACCP plan based on allergen tests.

ELISA methods are used to detect food allergens. They are designed for finished product testing in a laboratory by skilled analysts and often require certain extraction procedures although they have been adapted for use on environmental samples. Campden BRI showed that the recovery of allergens from surfaces was very variable and inefficient with 4-27% recovery when tested by ELISA methods.

These methods test on environmental samples are less sensitive compared to the same test conducted on finished products.

ELISA methods are affected by other food components, for example fat and cocoa and cooked or fermented foods, or the presence of cleaning fluids to give both false positive and false negative results. ELISA tests are generally specific for only one allergen and so multiple tests would need to be performed to cover all allergens of concern.

There is no single technology that is able to detect all specific allergens in a single test. Clearly testing for allergens is not easy and can be expensive, and environmental monitoring has limited performance. The absence of allergens in environmental samples does not mean the absence of other residues and other risks.

Cleaning is a required preventative procedure for all food processors and is a CCP for allergen control. The primary purpose of cleaning is the removal of product residues. Potentially allergenic foodstuffs are composed of other components that are present in higher quantities and are easier to detect.

Tests for some food components are able to detect at very low levels and offer an effective alternative. For example, ATP is a common component of all foodstuffs and high sensitivity ATP methods are able to offer an effective alternative. They are also simple and easy to use by non-skilled sanitation staff at point of use, giving instant results for immediate corrective action. The ATP provides a direct objective test of cleaning efficacy that has been well established for >30 years and detects a very broad range of foodstuffs.

Recent developments in ATP bioluminescence have improved detection capabilities such that it is now possible to detect food residues at levels that are equivalent to allergenic protein in the range 1-100ppm.

The new EnSURE instrument and Supersnap reagent swab from Hygiena both provide additional sensitivity with low background noise and low variation for precise accurate and consistent results. This means that this system is x10 more sensitive than Hygiena SystemSURE Plus with Ultrasnap swabs and x100 more sensitive than other ATP systems (see Table 1). Supersnap also provides more robustness and tolerance to harsh materials at extremes of pH and in the presence of sanitiser for example, it is not affected by 1000ppm hypochlorite.

Additional sensitivity can be achieved with more sensitive instruments such as Hygiena Pi 102 that detected all examples of allergenic foodstuffs at the 1-10ppm level. The EnSure system detected allergenic foodstuffs in the range 10-100ppm (see Table 2).

A simple protein test (such as the biuret method) can also be used detect allergenic foodstuffs and for maximum sensitivity (1-3µg protein) the test needs to be run at elevated time and temperature combinations such as 37°C for 30 minutes. However, the scope and sensitivity of the protein test is limited to 100ppm for certain allergenic foods (see table 3).

Table 4 shows the relative performance of ATP, protein and ELISA methods for detection of peanut butter residues.

Summary

Food allergens can come from several sources and affect a small proportion of individuals but they are seldom life threatening. Regulation exists to clearly label foods that 'may contain' allergenic components but there are no agreed maximum residue levels. There are few food safety incidents due to allergens and a large proportion of these are due to mislabelling rather than actual cross contamination.

The primary preventative measures for food manufacturers include segregation, cleaning and labelling. Cleaning is a CCP for allergen prevention but cleaning procedures are no different to those used for most foodstuffs, and methods to monitor and verify cleaning are required.

There are several methods available to demonstrate the efficiency of cleaning processes. ELISA methods are used to detect allergens and they are very specific to single allergens. They have good sensitivity when testing finished products but poor performance when used with environmental samples where they only detect a single, very specific component of food residues.

Alternative methods to detect potentially allergenic food residues in environmental samples after cleaning include ATP and protein tests.

These surface environmental tests may lack the specificity to detect the precise allergen but they give more information about cleanliness and risk. Novel developments of high sensitivity ATP detection methods can detect residues of allergenic foodstuffs in the desired range of 1-100ppm. They provide a simple, convenient, objective, instant test that can be used in production environments by non-skilled staff to facilitate immediate corrective action and minimise risk. ■

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References are available from the author on request

Table 4. Comparison of ATP, protein and ELISA tests for peanut butter.

Peanut butter	1ppm	10ppm	100ppm
Protein test	–	–	✓
Pi 102 and Supersnap	✓	✓	✓
EnSURE and Supersnap	–	✓	✓
ELISA tests*	–	✓	–

*Typical detection limit is 2.5-5.0ppm