

Cost effective cleaning validation for allergens

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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.

Cleaning is designed to remove food residues that contain many common components, such as ATP (adenosine triphosphate), protein and sugars and some of these foods may also contain allergens. The more effective the cleaning procedure, then the lower the amount of food residues, and hence the lower the risk. Using the most sensitive detection methods gives the greatest assurance of cleaning efficacy.

The principle of broad spectrum monitoring methods together with indicators and specific detection methods is well established in monitoring and managing risk, in microbiological analysis for example, total bacteria counts, coliforms and *Listeria* spp are used as overall indicators and then specific tests for specific pathogens are used as required.

Here we describe a similar combined approach of pre-validation and monitoring of cleaning for allergen management using a combination of three highly sensitive detection methods.

Detection methods

ATP bioluminescence provides an immediate direct objective test of cleaning efficacy that has been well established for >30 years and detects a very broad range of food-stuffs.

Recent developments in ATP bioluminescence have improved detection capabilities and sensitivity and at this level it is capable



of detecting food residues below the limit of detection of specific allergen tests.

The new EnSURE instrument and SuperSnap reagent swab from Hygiene provide additional sensitivity with low background noise and low variation for precise accurate and consistent results.

This means that the EnSURE is 10 times more sensitive than Hygiene SystemSURE Plus with UltraSnap swabs and 100 times more sensitive than other ATP systems (see Table 1).

The results are quantitative and give a linear response to increasing amounts of food residue. 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.

Most allergens are glycoproteins and can be detected by a simple protein test (such as the AllerSnap biuret method), however this non-specific protein test cannot differentiate non-allergenic protein from true allergens. This protein test can detect allergenic foodstuffs but 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. The results are semi-quantitative and the scope and sensitivity of the protein test is limited to 10-100ppm for certain allergenic foods.

Specific allergen tests, such as lateral flow dipstick formats, were originally designed to detect the presence of the allergen in food-stuff and certain extraction procedures are required for optimal performance.

This technology has been extended for surface hygiene testing for cleaning validation where the limit of detection is claimed to be 1-20µg or ppm. However, studies have shown that they only achieve 4-27% recovery and, in practice, give a qualitative result. They are recommended to be used in conjunction with other tests.

Table 2 shows results from a factory trial where high sensitivity ATP and high sensitivity protein test provided an effective monitoring tool as part of the allergen management program. Before cleaning all test results were positive and after cleaning most tests were negative.

The ATP test detects residues below that of protein tests and specific allergen were not detected, thus confirming that the highest level of cleaning has been achieved and allergens were absent.

Allergens in ready meals

We looked at a production facility that manufactures ready meals and vegetable dishes for major supermarket retailers but also makes a nut product on a less frequent basis. The site needs to ensure that its cleaning has been effective to remove nut allergens after the manufacturing of nut products and before releasing the production area back to general manufacturing.

The products contain three different tree nuts but for the sake of completeness nine nut allergens were tested in the cleaning validation exercise and all nine nut allergens need to be shown to be absent before release of the lines and equipment.

An off-site contract laboratory was used to conduct specific ELISA based allergen tests with a turnaround time of 10 working

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Table 1. Comparative sensitivity of new ATP systems.

	Hygiene Pi 102 and SuperSnap	EnSURE and SuperSnap	Others
Sensitivity (limit of detection, fmols ATP)	0.01	0.1	1.0-10.0
Repeatability (CV%)	12	9	26-123

Test (LoD)	PRE-CLEANING			POST-CLEANING		
	ATP (RLU) (0.1fmols)	Protein (1µg)	Specific allergen ELISA (16µg)	ATP (RLU) (0.1fmols)	Protein (1µg)	Specific allergen ELISA (16µg)
Low risk equipment						
	9999 Fail	Positive	Positive	2820 Fail	Negative	Negative
	677 Fail	Positive	Positive	51 Fail	Negative	Negative
	9999 Fail	Positive	Positive	1380 Fail	Negative	Negative
	25 Pass	Negative	Negative	17 Pass	Negative	Negative
High care						
	2974 Fail	Positive	Positive	2 Pass	Negative	Negative
	180 Fail	Positive	Positive	11 Pass	Negative	Negative
	2068 Fail	Positive	Positive	0 Pass	Negative	Negative
	1128 Fail	Positive	Positive	3 Pass	Negative	Negative
	332 Fail	Positive	Positive	12 Pass	Negative	Negative

Table 2. Cleaning assurance for allergen control using three high sensitivity detection methods.

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days, during which the production facility could not be used, thus losing valuable production time.

A minimum of 10 different samples were taken at various points of the production facility and each sample was tested for nine tree nut allergens at considerable cost.

Previous cleaning validation exercises using only the specific allergen tests had not always passed first time, thus requiring repeat testing and the production line out of use for further 10 days. This was an extremely costly exercise, and the facility needed a faster, more reliable, and cost effective way to validate the cleaning.

The EnSURE luminometer with SuperSnap gives a high sensitivity ATP test to a level of 0.1fmol ATP and results were obtained in 15 seconds to give immediate feedback and corrective action. Surfaces that failed at greater than 10 RLU were re-cleaned and re-tested. When all surfaces passed with SuperSnap the surfaces were then swabbed with AllerSnap protein detection swabs and incubated in a portable incubator for 30 minutes. When the protein test gave negative results showing absence at the 1µg level, then the more expensive specific allergen tests were employed.

Subsequently all the specific allergen tests were shown to be negative and the line was

released back to production within the 10 days. The staff felt extremely confident that the specific allergen tests would come back negative following the initial pre-validation using the SuperSnap and AllerSnap tests and may consider pre-releasing before 10 days is up.

Pre-validation screening enabled the site to make significant savings by avoiding repeat testing and further lost production.

The hygiene manager commented that the combined method approach was very beneficial in releasing the nut production area back into general production.

“This process gave me confidence that we would get it right first time with the allergen swabs. This not only saved on cost but more importantly guaranteed food safety. All our allergen swabs came back clear and the area was



released back to general production on plan. I would definitely employ this process again.”

The regular use of high sensitivity ATP and high sensitivity protein tests enable high standards of cleaning to be maintained that can be supplemented with specific allergen tests less frequently and as required.

Summary

Cleaning is one of the CCPs for allergen control and a variety of detection methods are available to validate the cleaning processes. Specific allergen tests have their limitations and are expensive, whereas most other methods have sensitivity but lack specificity.

A combination of three high sensitivity detection methods (ATP, protein and specific allergen tests) provides a more comprehensive, sensitive and rapid result that delivers a timely cost effective solution. ■