Cost effective cleaning validation for allergens

Effective cleaning is usually identified as a pre-requisite for most GMP and HAACP 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. 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 specific detection methods is well established in monitoring and managing risk. In microbiology 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 well established for >30 years and detects a very broad range of foodstuffs. 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 (Hygiena) provide additional sensitivity with low background noise and low variation for precise, accurate and consistent results. This means the EnSURE is x10 more sensitive than Hygiena SystemSURE Plus with UltraSnap swabs and x100 more sensitive than other ATP systems (see Table 1; for further details contact

Hygiena for a copy of the Comparative report). 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, e.g. it is not affected by 1000ppm hypochlorite.

Most allergens are glycoproteins and can be detected by protein tests (such as the biuret method, ALLER-Snap) however, this non-specific protein test cannot differentiate non-allergenic protein from true allergens. Protein tests can detect allergenic foodstuffs, and for maximum sensitivity (1–3μg protein) the test is run at elevated time and temperature combinations such as 37°C for 30min. The results are semi-quantitative and the scope and sensitivity of the protein test is 10–100 ppm for certain allergenic foods.

Specific allergen tests such as lateral flow formats were originally designed to detect the presence of the allergen in foodstuffs and certain extraction procedures are

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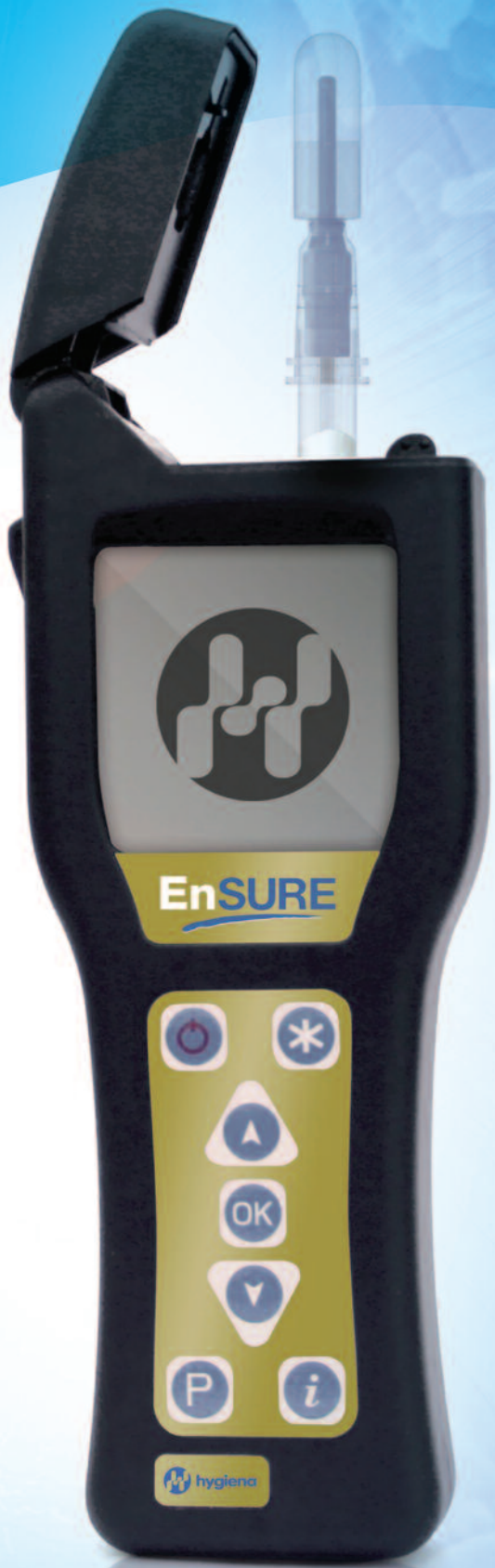

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required for optimal performance. This technology has been extended for surface hygiene testing for cleaning validation where the limit of detection is claimed to be 1–20μg or ppm, however, studies have shown that they only achieve 4–27% recovery and in practice give a qualitative presence/absence result.

Table 2 demonstrates results from a factory trial where high sensitivity ATP and high sensitivity protein tests provided an effective monitoring tool as part of the allergen management programme. Before cleaning all test results were positive and after cleaning most were negative. The ATP test detects residues below that of protein tests and specific allergens were not detected, thus confirming that the highest level of cleaning had been achieved and allergens were absent.

Detecting allergens in a ready meal factory

A production facility manufacturing ready meals and vegetable dishes for major supermarket retailers also makes a nut product on a less frequent basis. The site needed to be sure that its cleaning had been effective to remove nut allergens after the manufacturing of nut products and before releasing the production area back to general manufacturing. The products contained 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 needed 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 days during which the production facility could not be used, thus losing valuable production time. A minimum of ten 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 sensitivity level of 0.1 fmol 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 ALLER-Snap protein

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) (fmol ATP)	0.01	0.1	1.0 to 10.0
Repeatability (CV%)	12%	9%	26 to 123%

Table 2: Cleaning assurance for allergens control using 3 high sensitivity detection methods

	PRE-CLEANING			POST-CLEANING		
Test (LoD)	ATP (RLU) (0.1fmols)	Protein (1 μg)	Sp. Allergen ELISA (16 μg)	ATP (RLU) (0.1fmols)	Protein (1 μg)	Sp. Allergen ELISA (16 μg)
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

detection swabs, when they passed, then the specific allergen tests were used. 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 ALLER-Snap 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 and that: "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."

When all surfaces passed with SuperSnap the surfaces were then swabbed with ALLER-Snap protein detection swabs, when they passed, then the specific allergen tests were used

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 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 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 sensitivity and rapid result that delivers a timely cost-effective solution.■

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