THE IMPORTANCE OF ALLERGEN SCREENING

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Why is Allergen screening so important? 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 (Alldrick, 2009). Effective cleaning is usually identified as a pre-requisite for most BRC, GMP and HAACP plans in the food industry and cleaning is usually considered a critical control point (CCP) for allergen control (Mortimer and Wallace, 1998).

The primary purpose of cleaning is to remove product residues to an acceptable limit. Allergenic components of most foods are a very small proportion (typically 1 – 100 ppm) 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 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.

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 can be used or even ideal in some applications. However Polymerase Chain Reaction (PCR), a DNA-based method, is thought to have limited applications whereas 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?

SPECIFIC 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 required 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 e.g. fat and cocoa, 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.

ALLERGEN SCREENING

The principle of allergen screening is quite simple. If proteins or other materials (ATP) are present then allergens may be present. If the proteins or ATP are absent or low enough, we can also state the allergens are below detectable limits. Allergen screening is ideal for testing surfaces that have just been cleaned. If the surface has been cleaned well enough to remove the Allergens, then all the proteins and ATP detectable limits will be gone also. The advantage is that this method replaces doing several specific allergen tests to save money, it is faster (no need to wait for lab results to come back) and it is easier allowing line workers or supervisors to conduct the test. In some instances the allergen screening test is actually more sensitive than the GOLD standard PCR tests.



Phone: 416-261-4865 Email: <u>quotes@scigiene.com</u> www.scigiene.com TABLE 4: Comparison of ATP, protein and ELISA tests for peanut butter

PEANUT BUTTER	10 PPM	100 PPM
Protein Test		
EnSure and SuperSnap		
Elisa Tests*		
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*Typical detection limit is 2.5 -5.0 ppm

ALLERGEN SCREENING can in turn be broken into 2 main types:

ULTRA LOW PROTEIN RESIDUES

Using special models of proteins test swabs (<u>Allersnaps</u>) requiring short incubation you can get the required sensitivity needed for <u>ALLERGEN screening</u>. Most allergens are proteins so this works very well

Table 3: Detection of allergenic foods by protein tests

Foodstuff	Lowest	level detect	ed by protein tests at
roousiuli	1 ppm	10 ppm	100 ppm
Shredded Wheat			Not detected
Oat Bran			Not detected
Peanut Butter			detected
Egg White			detected
Crabsticks			Not detected
Mixed Nuts			Not detected
Milk Powder			detected
Soya			Not detected
Almond			detected

The exceptions (so far) are Sulphites. The ratio of sulphites to proteins is usually extremely low so if you are using ingredients that have low levels of sulphites present then this may still work for you. It is important to keep in mind that this is a screening test to verify the surface is clean enough to produce products that will test negative for the specific allergen. Thus if you are getting final product results back that are positive for specific allergens, then you should revaluate your process and contact us and your consultants.



FEATURES

- Detects protein residues down to 1 ug, but for lowest level detection requires incubation for 15 to 30 minutes.
- Proteins are present in detectable levels in most raw or finished foods.
- Is a qualitative colorimetric test so it is not as sensitive at lower levels.
- Sensitivity equivalent to ELISA may not be necessary on work surfaces as the dilution factor of these proteins in finished goods will not lead to detectable number in finished goods using official ELISA methods.
- <u>See Sulfite screening Method</u>
- Proteins detected are unlikely to be even close to 100% of the allergens of concern so again low detection may not be deemed necessary.



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ULTRA LOW ATP TESTING

There is much confusion around this method. First let us be clear, not all <u>ATP swabs</u> are alike. Most have nowhere near the detection limits needed for conducting this test. Our Supersnap swabs have 10X to 100X greater sensitivity than other makes of ATP swabs and it is this increased sensitivity that allows for a correlation between low ATP and low protein residues

TABLE 1: Comparative sensitivity of new ATP systems

	ATP TEST SYSTEMS			
Parameter	SCIGIENE ENHANCED SYSTEM & <u>SUPERSNAP</u>	ENSURE & SUPERSNAP	OTHERS	
SENSITIVITY (Limit of Detection: fmols of ATP)	0.01	0.1	1.0 to 10.0	
Repeatability (CV%)	12%	9%	26% to123%	



Secondly you must be sure that the correlation of ATP to proteins is high in the foods being processed in the area to be tested. Therefore if you are using fresh products with high ATP loads then the ATP to protein to allergen ratio is high and therefore <u>Supersnap</u> Ultra Sensitive ATP test swabs are ideal (fresh meats, vegetable processors).

If on the other hand you are testing surfaces that have had cooked or dried products on them then the ATP in these products may be low or may have been destroyed in the cooking process and the ATP to Protein ratio may be low.

- **EXAMPLE #1** a meat packing plant. All the products are raw. Therefore ATP levels are high. Therefore ATP screening is ideal here.
- **EXAMPLE #2** a <u>Ready-to-Eat</u> (RTE) facility bringing in raw meats and produce. The SuperSnaps would be ideal in the raw goods and preparation area, but for the finished cooked goods you might want to stick to using Allersnaps for your screening process.
- **EXAMPLE #3** a bakery just dealing with flour and other dry incoming goods. The ATP levels in the incoming goods are much lower and the finished goods will have extremely low ATP to protein ratios and therefore the <u>ALLERSNAP</u> protein residue test is superior.
- These are examples only so please consult us to determine which screening methods are ideal for you.

FEATURES

- Detects ATP residues within 15 seconds.
- Has potential for greater sensitivity than ELISA for some products.
- Shifts the focus of food allergen avoidance toward prevention and pre-production verification
- Eliminates all reagent preparation and extraction
- SuperSnap is the most sensitive ATP test device



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Method Comparison

Foodstuffs	Scigiene Enhanced Method	Method 3	Method 4	Method 5
	Supersnap + Ensure	Supersnap + SystemSURE PLus	ALLER-Snap*	Allergen Test* (ELISA)
Shrimp	1 ppm	1 ppm	10 ppm	5 ppm
Wheat (Flour)	100 ppm	100 ppm	10 ppm	5 – 75 ppm
Peanut Butter	10 ppm	100 ppm	1 ppm	0.5 - 5 ppm
Egg whites	1,000 ppm	1000 ppm	1 ppm	4 – 25 ppm
Milk powder	10 ppm	100 ppm	10 ppm	2.5 - 10 ppm
Soy	10 ppm	100 ppm	1 ppm	2.7 - 5 ppm
Almonds (Raw)	1,000 ppm	1,000 ppm	10 ppm	5 - 12.5 ppm
Sesame	10 ppm	100 ppm	10 ppm	5 – 48 ppm

* Studies show that the recovery of allergens from surfaces are very variable and inefficient with * Methods 1-4 are nonspecific 4 - 27% recovery when tested by ELISA methods. Sensitivity data shown is based on information available online.

product residue test. Methods 5 is a specific allergenic protein test.

SUMMARY

Notes:

* ALLER-Snap sensitivity levels

at 55°C for 15 minutes.

shown are based on incubation

While specific allergen testing should remain the requirement for finished goods, these specific tests are costly and could presents a hazard if used for validation of cleaning programs to remove allergens. Known interferences may lead to false results and the time lag to get results back from your labs may result in processing occurring on surfaces that did not meet required standards.

The use of Allergen screening methods when properly implemented gives faster results allowing for re cleaning of the affected equipment prior to production start-up. They are easy to integrate with existing hygiene programs allowing for decreased costs and improved documentation using software designed to track and flag lapse in hygiene. In many instances they will even allow for greater sensitivity than specific allergen tests.

See Scigiene Enhanced Method

REFERENCES

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