Comparative study looks at cleaning procedures for effective allergen control

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The control of allergens is a significant concern for food manufacturers. However, the absence of universally agreed acceptable allergen levels has led to the overuse of fail-safe warning or pre-cautionary labelling. This lack of guidance is causing a great deal of confusion on the best approach to control allergen risks.

In the USA, 34% of all recalls were due to undeclared allergens and the number of these recalls has almost doubled in the past 10 years. This is a similar recall rate to salmonella but the severity of the hazard differs i.e. salmonella caused 56,000 hospitalisations with 1351 deaths (2.4% mortality) compared to allergens that are estimated to cause 30,000 hospitalisations with 150-200 deaths (0.5% mortality) annually in the USA. Most allergic reactions (90%) are caused by 8 out of 160 (5%) of potentially allergenic foods and FDA Recall Enterprise System (RES) states that:

- Most product recalls involve bakery and snack type products.
- Bakery products accounted for almost as many food allergen recalls as all of the other top five foods combined.
- Milk, wheat and soy were the most common adulterants.
- Peanuts and tree nuts combined caused fewer recalls than any one of these top three allergens.
- Errors in packaging were the most common root causes.
- 88% of root causes were related to labelling issues.
- 12% of root causes were due to some form of cross contact in manufacturing of which there are many possible causes, only one of which is cleaning.

FDA RES states that 13 distinct root causes of recalls were identified, all of which are related to packaging and all of which are simple and preventable. Zoning within manufacturing facilities and operational prerequisite programs are now viewed as best practice and highly desirable for allergen management. These measures control the movement of people and equipment as well as the manufacturing environment, and minimise and contain adventitious cross-contact of potential hazards that are not immediately associated with product contact surfaces.

Monitoring

Jackson et al 2008 conducted an in-depth literature survey and overview of cleaning and other controls to prevent allergen cross contact in food processing operations. This multi-disciplinary team of experts for FDA, academia and industrial blue chip companies concluded that

- There was no agreement on the minimum level of allergen that causes a reaction in a sensitive consumer.
- There were many different causes/opportunities for cross contact in food processing both direct and indirect. Specifically:
- No agreement regarding the best cleaning methods to remove food allergens through either wet or dry cleaning.
- No agreement on safe residue levels.
- Several test methods are used in industry to measure cleanliness during allergen control. However, each has its own limitations and there is no single method that satisfies all requirements.
- The presence of an allergenic food in swab samples or rinse water indicates that the allergen cleaning protocol or its execution requires revision; it does not necessarily indicate the presence of the allergenic protein in the finished product.

Cleaning is a GMP requirement and pre-requisite for minimising the risk of cross-contamination in food manufacturing from all foreign matter including allergens.

Cleaning is a multi-stage process designed to remove all food residues that have been successfully deployed and improved over decades. It is expected that these cleaning methods conducted correctly will be sufficient to remove the allergen component, and there is no evidence to suggest otherwise.

The contribution of allergen cross contamination from a cleaned surface into subsequent finished product itself is therefore likely to add a very small non-detectable risk in the finished product. Gross failure of cleaning or lack of cleaning would be required to result in cross contact.

There are several methods to monitor and verify cleanliness. Specific detection methods alone give partial information about overall safety and risk, and should be used as a balanced analytical approach.

There are several methods for specific allergens of which immunological methods for example quantitative plate ELISA tests and qualitative lateral flow tests (LFT) in dipstick formats are the most commonly used.

However, the relatively high cost is often an impediment to their widespread adoption. Plate ELISA tests are more sensitive (typically <0.1ppm) but require a skilled analyst. LFTs are more convenient and have a limit of detection of 1-10ppm but their performance can be variable.

By contrast, simple rapid hygiene tests such as ATP bioluminescence and non-specific protein tests are widely used by industry and are well established proven methods of cleaning validation and verification.

The benefit of such methods is that they are simple, rapid, sensitive and cost effective and trend analysis of results from regular monitoring yield more valuable information than infrequent testing.

Accordingly, methods with the greatest sensitivity and broadest spectrum will give the greatest assurance of surface cleanliness and hence demonstrate a low cross contamination hazard and risk from food residues and allergens.

Jackson et al concludes that "Comparison of immunochemical allergen specific methods and non-specific methods (ATP and total protein) for determining cleaning efficiency are needed".

Comparative study

A thorough comparative study was conducted in a pilot plant to simulate a factory cleaning procedure for

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Table 1. Root causes of allergen recalls.

Cause	No. of recalls
Wrong package or label	82
Terminology	59
Failure to carry forward information from an ingredient to final label	41
Cross-contact	28
Ingredient mislabelled from supplier	21

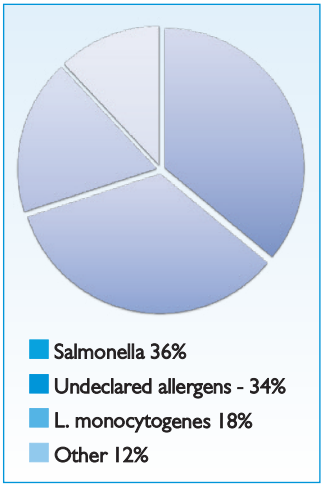

Fig. 1. Causes for food product recalls.

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the removal of food residues including four known allergens. The objective was to measure residues of ATP, total protein and the four specific allergens at appropriate stages during a simulated cleaning cycle.

A slurry was prepared from a common commercial ready meal (beef with noodles) consisting of several main food groups and known allergens of egg, wheat (gluten), soya, peanut and milk.

The slurry was spread evenly and dried on 10 stainless steel sheets and subsequently cleaned with detergent/disinfectant using an industrial power spray. Surface swabs were collected using a randomised sampling plan. Ten replicate samples were collected and tested for each of eight methods at each stage of cleaning i.e.

- Stage 1: before drying.
- Stage 2: after pre-rinse.
- Stage 3: after detergent and rinse.
- Stage 4: after disinfectant and rinse.

The applied test methods included two quantitative ELISA tests for gluten and peanut as benchmarks and a range of rapid specific and non-specific tests for measuring product residues.

High sensitivity ATP: EnSURE Luminometer with SuperSnap swab device sensitive (limit of detection) to 0.1 fmols ATP and giving quantitative results in Relative Light Units (RLU).

High sensitivity Total Protein: AllerSnap incubated for 30 minutes at 37°C yields a semi-quantitative result based on colour change from green to purple with a limit of detection of 1-3 microgram (µg) total protein.

Lateral Flow Device (LFD) for casein, gluten (gliadin), peanut and egg with sensitivities of 1-10ppm.

Table 2 summarises the results at each stage of cleaning and for each test as the number of positive samples where the product residue was detected out of the total number of replicates (X/Y).

The ELISA tests were performed in triplicate (X/3) whereas all other test used 10 replicates (X/10).

- The most sensitive tests were shown to be ELISA and the high sensitivity ATP test.
- The high sensitivity total protein test (AllerSnap) had a similar or better sensitivity to the LFD.
- The gluten LFD had a better sensitivity than all the other LFD.
- The LFD for egg did not give any meaningful results.

ELISA gluten test showed a gradual reduction in the amount of allergen detected during all stages of the cleaning cycle. ELISA peanut also showed a gradual reduction in the amount of allergen detected during the cleaning cycle but it was less sensitive than the ELISA gluten test.

The high sensitivity ATP test (EnSURE and SuperSnap) successfully detected the removal of the food residue at all stages of cleaning. It was as sensitive as the ELISA Gluten test and more sensitive than the ELISA peanut test. Closer inspection of the ATP swab data revealed that the median measurement after the disinfectant step was 14 RLU. Any result above 2 RLU (0.1 fmols ATP) would be considered a positive hence the ATP test had sufficient sensitivity to be able to detect a further ten-fold lower residue levels of this slurry.

The high sensitivity total protein test (AllerSnap) detected product residues at stages 1, 2 and 3 but not after the disinfectant and rinse step. The limit of detection of AllerSnap is 1-3µg protein per swab and gave a similar performance to the ELISA peanut test.

AllerSnap provided consistent and reliable results and detected residues at all stages of cleaning except the disinfectant stage. AllerSnap gave results equivalent to or better than LFDs that gave variable results and did not detect specific allergen residues at all stages of cleaning.

	Pass/Fail			
	Stage 1 dry slurry	**Stage 2 pre clean**	**Stage 3 detergent & rinse**	**Stage 4 disinfectant & rinse**
ELISA gluten	1/1	3/3	3/3	3/3
ELISA peanut	1/1	3/3	1/3	0/1
EnSURE/ SuperSnap	10/10	10/10	10/10	10/10
AllerSnap	10/10	10/10	5/10	0/10
LFT gluten	9/10	10/10	10/10	0/8[a]
LFT peanut	9/10[b]	7/10[c]	0/10	0/10
LFT casein	10/10[d]	10/10[e]	3/10[e]	0/6[a]
LFT egg	failed in this study			

[a] invalid results removed, [b] 2 faint results, [c] 5 faint results, [d] 3 faint tests, [e] 1 faint result

Table 2. Product residues detected by eight methods during the four stage cleaning process.

Conclusion

The results from the study described above demonstrate that good cleaning can remove all food residues including its allergenic components to levels at or below the limit of detection of the test. Several methods can be applied to monitor and verify the cleaning process including specific and non-specific methods that can be equally effective. A combination of methods can provide a greater assurance of cleanliness. An earlier case study showed a cost benefit. Most allergen recalls and non-compliances are caused by labelling issues. Jackson's excellent survey and overview (2008) states that there are many different causes/opportunity for cross contact in food processing both direct and indirect and suggested several preventative measures.

The cleaning process itself is but one factor and although dry cleaning has more potential to create allergen problems it needs to be balanced against the requirements for pathogen control. Where cleaning has been cited as a probable cause of allergen cross contact in recalls involving egg and peanut, the likely reasons were gross lapses in cleaning practice or failure to schedule cleaning during product changeover.

Residual levels of allergen would also have to be extremely high to create a non-compliant at risk scenario yet most post-cleaning verification tests show a negative result or not detected at the limit of detection typically 1-10ppm.

There are no international standards for any method to measure the efficacy of cleaning because each processing facility is unique and 'one size does not fit all'. Manufacturers are expected to do their best and are encouraged to frequently monitor performance and gather data for trend analysis.

Whereas cleaning is often considered a CCP in the control of allergens, the risk of cross contamination due to inadequate cleaning is relatively low. The management of procedures to prevent cross contact within the entire the manufacturing process together with the control of labelling is more important to minimise risk, non-compliance and expensive recalls. ■