Implementing an allergen cleaning validation program: practical tips

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The most prominent food safety topics within the industry are allergen control and cleaning validation. The most commonly issued recalls involve allergens, a life threatening contaminant which is often overlooked through labelling and/or operational errors, cross contact, cleaning techniques, and lack of monitoring within an environment.

Allergen cleaning validation is a multi-step process that, in many cases, requires a period of data collection and trial and error to determine the most effective cleaning methodologies.

Common practices while performing an assessment and validation may include production volume changes, product hold/destruction/non-conformance procedures and also, costly testing and/or sampling which could lead to unexpected results or potential needs for root cause analysis or immediate corrective actions to resolve such findings.

Ultimately, putting consumers at risk for allergens associated with food processing practices can be a dangerous risk and a very frightening situation for a business to manage.

These practical tips will help you create and implement an allergen cleaning validation program that will handle and minimise associated risks within a facility.

Test type	Frequency
Visual examination	Each changeover
ATP swabs	Weekly at pre-op
Allergen surface swabs	Weekly after a changeover
Allergen testing of product	Quarterly

Table 2. A sample set-up for a facility.

Allergen awareness

Each global region has a regulatory guidance list on what is considered a declarable allergen. It is recommended to be conscientious not only of the allergens within the country of processing, but also countries where product will be exported to. The allergen type identified and physical state it is in plays an important role to determine adequate cleaning methods for validation. Knowing if the allergen is present in liquid, powder, or solid form can affect residue removal capabilities.

Peanuts and tree nuts that contain a high oil content may require a detergent to effectively remove residuals from the surface, equipment, utensil, or area. The objective with allergen cleaning is to eliminate as much residual as possible without compromising the area and also maintain within approved concentration ranges for any agents that may be used as a detergent or cleaner.

Allergens in powdered form will typically create a greater risk in product zones due to potential dustiness and airborne dispersal of the ingredient. The affected surfaces for powdered allergens expand beyond the physical limits of a direct food contact surface.

Product contact areas

Although food manufacturing design standards are improving within the industry, much of the processing equipment or product contact surfaces are made of stainless steel which does not oxidise like

Table 1. The crosses indicate a combination of method/surface/soil that is not in use.

	Dry clean: vacuum + brush				Wet clean: warm water + detergent				Product purge			
	Soy flour	Almond paste	Liquid egg	Coconut shavings	Soy flour	Almond paste	Liquid egg	Coconut shavings	Soy flour	Almond paste	Liquid egg	Coconut shavings
Smooth stainless steel		✗	✗	✗					✗	✗	✗	✗
Stainless steel mesh belt	✗	✗	✗	✗					✗	✗	✗	✗
Polyethylene		✗	✗	✗					✗	✗	✗	✗
Vinyl tubing	✗	✗	✗	✗	✗	✗	✗	✗				

the galvanised version and is considered smooth and easily cleanable for allergens and other types of product residue. It is important to inspect non-smooth areas, such as rough welds, die-cut rollers and mesh belts, and devise cleaning mechanisms to assure no residue remains hidden within these hard to reach product contact areas.

Other types of surfaces commonly found in food plants include various types of plastic (polyethylene, UHMW, polycarbonate, PVC, vinyl), rubber, glass, wood and cloth. Some of these are easily cleaned on the line, while others, such as cloth, may need to be laundered to remove allergens.

Absorbency and smoothness are two characteristics of surfaces that will largely influence the ability for residue (allergen or otherwise) to be removed. For this reason, the effectiveness of cleaning must be validated for each type of surface.

Cleaning methods

There are three categories of cleaning for allergen removal:

- Dry cleaning.
- Wet cleaning.
- Product purge (can be wet or dry).

Dry cleaning does not involve water or chemicals. It may be done by brushing, wiping, or vacuuming. The use of air hoses is strongly discouraged for allergen removal since the risk of dispersing the allergen is too great. Dry cleaning is appropriate for dry allergens with little to no oil content.

Wet cleaning involves water and often chemicals (alkaline or acid cleaning compounds).

A great deal of emphasis is put on sanitising food contact surfaces for obvious reasons. However, it must be understood that sanitisers do not remove residue, including allergen protein.

Product purge involves running product through a line in an effort to remove the residue left from prior production. This typically becomes an option when the surfaces that need to be cleaned are enclosed and are not easily accessed and the material that will be used for the purge can be recovered and re-used in a formula that contains all of the material purged or is inexpensive and can be discarded.

When working with product purge as the allergen removal method, the amount of product that must be purged must be established in the procedure and validated through testing. Keep in mind, product purge may address an allergen concern without addressing a microbial issue.

Testing

There are two approaches to testing: testing the cleaned surface and testing the product that is produced after the surface has been cleaned. Both testing methods have limitations, primarily from the nature of sampling. By conducting both types of testing, the most variables are addressed.

Test kits may be purchased and used on site or samples may be taken and sent to an outside laboratory to conduct testing. For validating allergen changeover cleaning, allergen specific testing is necessary, where available.

Other types of post-cleaning validation tests, such as general protein residual or ATP tests, will not provide the specific information that is needed to demonstrate that allergenic protein has been removed.

If you are validating removal of an allergenic protein for which there has not yet been a test developed, you will need to rely on results from similar allergens that you run on the line in combination with visual examination and/or ATP results.

Each combination of method, soil, and surface type that will be used must be validated. Table 1 is an overview of the combinations that you may have. Detailed written cleaning procedures must be established beyond the information provided in this table.

The steps involved in testing are:

- Run a product with an allergen.
- Clean the line/equipment with the established method.
- Swab the surface(s) after cleaning and test for the allergen in question and/or
- Sample the first bit of product from the subsequent run (not containing the same allergen) and test it for the allergen in question.
- Hold all products produced in the subsequent run until results have been obtained.
- If the results indicate the absence of detectable allergen, the line may be used and any held product may be released.
- If the results indicate allergen carryover: the held product must be destroyed (or used in a formula that declares all carryover ingredients).
- The line must be re-cleaned (with a different method, which could be a modification of time, temperature, and/or chemical, etc).

Since there will be product held, many companies opt to perform the tests on site to expedite results, especially when dealing with short shelf-life product.

If product has shipped and has tested positive for an undeclared allergen it will need to be reported on the Reportable Food Registry and depending on where it is in the supply chain, is likely to be susceptible to a Class I Recall.

There are some other testing considerations that may be made. For example, a company may currently have a dedicated line for a given allergen. However with a demand to expand production capabilities, the company may wish to be able to run more varied products on a given line.

Let us use a cookie facility as an example. A company may currently have one line dedicated just to peanut butter cookies. However, the line may have downtime that could be used for other cookies.

A first step in validating the viability of running the different allergens on the same line is to run the peanut butter cookie. Clean the line and swab the line. Test the swab for peanut protein. Continue to run peanut butter cookies on the line until tests indicate the cleaning method selected effectively eliminates allergen residue. No product would need to be held, since the subsequent product has the same allergens. Since no product is held and no product is at risk, this is often a preferred starting point when first establishing the effectiveness of cleaning methods.

It must be noted that 'May Contain' statements and similar declarations do not eliminate the need for allergen cleaning validation or allow for product that has tested positive for an allergen not listed in the ingredient statement to be put into the supply chain.

Frequency

As with most validation programs, the best approach is to revisit it at least annually and when there are any significant changes.

Changes would include changes to soil type, surface type, or cleaning method.

It may also include a more sensitive test methodology that has been developed and has become available. The annual assessment would include all the variables in the soil x surface type x method table.

The ongoing validation of allergen cleaning typically involves a combination of the following after each allergen changeover:

- Visual inspection (this is a minimum requirement).
- ATP swabs (not directly related to allergens, but can be used as a general indicator).
- Allergen surface swabs.
- Allergen testing of product.

A sample set up for a facility is shown in Table 2.

Yearly assessment

Although the focus of this article has been strictly allergen cleaning validation, an effective allergen control program consists of multiple elements.

These include, but are not limited to formulation, storage practices, engineering controls, scheduling, labelling, personnel practices, and operational methods that complement additional prerequisite programs within the facility.

Yearly assessments for food safety effectiveness and potential changes required is highly recommended for situations such as: equipment design modifications, allergen monitoring and sampling procedures, product changeover protocols, hazard analysis, labelling, and regulatory requirements. ■