ALLERGEN CLEANING VALIDATION

UNDECLARED ALLERGENS ARE A LIFE-THREATENING CONTAMINANT. THE TIME TO ACT IS NOW. CONSUMERS’ LIVES AND YOUR COMPANY’S REPUTATION COULD BE AT RISK.

Much of the processing equipment found in food manufacturing facilities is stainless steel. The reason for this is that stainless steel is considered smooth and easily cleaned. This is true for allergens, as well as other types of product residue. However, there may be locations where the stainless steel is not smooth, such as areas with rough welds, die-cut rollers, or mesh belts.
The same variables must be considered for allergen cleaning validation as with any type of cleaning validation. The difference, however, is how much is at stake. Undeclared allergens are a life-threatening contaminant and incomplete validation data or inaccurate data could put lives at risk. In addition, there may be some “trial and error” in determining which cleaning methods are effective. During this period, production lines may be down, product may need to be destroyed, and potentially costly testing must be performed. In fear of finding out that cleaning practices are not effective, some companies are not doing the testing. This is a frightening thought as it is putting food-allergic consumers at risk. Provided here is practical guidance for establishing and implementing an Allergen Cleaning Validation Program.

The variables that must be considered in cleaning validation are:

1. Soil Type
2. Surface Texture
3. Cleaning Method

SOIL TYPE
The soil type will not only depend on the allergen, but also on the form the allergen is in. For example, a different method is likely needed for removal of liquid egg residue versus the removal of powdered egg. In most forms, peanut and tree nut protein will have a high oil content, which will require a detergent to remove the soil from the surface of the equipment, container, or utensil. Allergens in powdered form will typically create a greater risk in product zones. The dusty nature of the ingredient will allow for airborne dispersal. The affected surfaces for powdered allergens expand beyond the direct food contact surfaces.

SURFACE TEXTURE
Much of the processing equipment found in food manufacturing facilities is stainless steel. The reason for this is that stainless steel is considered smooth and easily cleaned. This is true for allergens, as well as other types of product residue. However, there may be locations where the stainless steel is not smooth, such as areas with rough welds, die-cut rollers, or mesh belts.

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 will be easily cleaned on the line. 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 METHOD
There are three categories of cleaning for allergen removal:

- Dry Cleaning
- Wet Cleaning
- Product Purge (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 also involves chemicals (alkaline or acid cleaning compounds). A great deal of emphasis is put on sanitizing food contact surfaces for obvious reasons. However, it must be understood that sanitizers do not remove residue, including allergen protein.

Product purge is 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 not easily accessed, and the
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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 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 onsite, or samples may be taken and sent to an outside laboratory such as AIB or FARRP. For validating allergen change-over 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. The chart provided here is an overview of the combinations you may have. Detailed written cleaning procedures must also be established beyond the information provided in this table.

The steps involved in testing are as follows:
1. Run a product with an allergen.
2. Clean the line/equipment with the established method.
3. Swab the surface(s) after cleaning.

<table>
<thead>
<tr>
<th>Surface Type 1</th>
<th>Surface Type 2</th>
<th>Surface Type 3</th>
<th>Surface Type 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soy Flour</td>
<td>Almond Paste</td>
<td>Liquid Egg</td>
<td>Coconut Shavings</td>
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<table>
<thead>
<tr>
<th>Dry Clean: Vacuum + Brush</th>
<th>Wet Clean: Warm Water + Detergent</th>
<th>Product Purge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smooth Stainless Steel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stainless Steel Mesh Belt</td>
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<td></td>
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<tr>
<td>Polyethylene (Scoops, Containers)</td>
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<td></td>
</tr>
<tr>
<td>Vinyl Tubing</td>
<td></td>
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</tr>
</tbody>
</table>

*The grayed out boxes indicate a combination of method/surface/soil that is not in use.
and test for the allergen in question.

4. Sample the first bit of product from the subsequent run (not containing the same allergen) and test it for the allergen in question.

5. Hold all product produced in the subsequent run until results have been obtained.
   a. If the results indicate the absence of detectable allergen, the line may be used and any held product may be released.
   b. If the results indicate allergen carryover:
      i. The held product must be destroyed (or used in a formula that declares all carryover ingredients).
      ii. 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 onsite to expedite results, especially when dealing with short shelf-life product.

If product that has shipped tests 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, it is likely susceptible to a Class I Recall.

### IF PRODUCT THAT HAS SHIPPED TESTS 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, IT IS LIKELY 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’s 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 different allergens on the same line is to:

1. Run the peanut butter cookie.
2. 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.
3. 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 whenever 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:

1. **Visual inspection** (minimum requirement)
2. **ATP swabs** (not directly related to allergens, but can be used as a general indicator)
3. **Allergen surface swabs**
4. **Allergen testing of product**

Here is a sample set-up for a facility:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Frequency</th>
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</thead>
<tbody>
<tr>
<td>Visual Examination</td>
<td>Each Changeover</td>
</tr>
<tr>
<td>ATP Swabs</td>
<td>Weekly at Pre-op</td>
</tr>
<tr>
<td>Allergen Surface Swabs</td>
<td>Weekly After a Changeover</td>
</tr>
<tr>
<td>Allergen Testing of Product</td>
<td>Quarterly</td>
</tr>
</tbody>
</table>

**ACT NOW**

The absence of customer complaints or regulatory action cannot be taken as evidence of an effective Allergen Cleaning Program. Because allergen cross contamination is not likely to affect 100% of your product and a small percentage of the population is allergic to one of the Big 8 Allergens (estimated as 3.5% to 4% in the U.S.), it is possible to be free from allergen complaints when the risk is still very real.

The time to act is now. Consumers’ lives and your company’s reputation could be at risk. Take the steps necessary to ensure a safe product.

The focus of this article has been strictly on allergen cleaning validation. An effective Allergen Control Program consists of multiple elements including, but not limited to: formulation, storage practices, engineering controls, scheduling, labeling, personnel practices, and operational methods.

If you need assistance, please contact AIB at FoodSafetyEducation@aibonline.org or 800/633-5137. **AIB**

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