**ALLERGEN CLEANING VALIDATION & VERIFICATION**

A guide on how to validate and verify that your allergen cleaning procedure meets the requirements of your customers.

Where production equipment is not dedicated to either specific allergens or allergen free products then full and thorough cleaning is critical to product safety.

**STEP 1**
PREPARING TO CLEAN – RISK ASSESSMENT
As part of an allergen risk assessment the equipment must be fully understood in order to identify the ‘hard to clean’ and the ‘debris trap points’.
These form the **Key Inspection Points**.

**STEP 2**
PREPARING TO CLEAN – PROCEDURES
Make sure the procedures fully cover the dismantling and cleaning of the equipment. These should cover all equipment involved no matter where it is cleaned.

**STEP 3**
PREPARING TO CLEAN – TRAINING
All staff involved in cleaning and inspection must be trained on the procedures and have some degree of allergen awareness.

**STEP 4**
CLEANING AND INSPECTION
Ensure that cleaning staff are supervised and that the quality of cleaning is to the highest standard. Post cleaning inspection should be a manager independent of the cleaning team.

**STEP 5**
VALIDATION
The cleaning procedures need to be validated as being effective. This is achieved through inspection and testing.

**STEP 6**
REVIEW OF VALIDATION
The test results and inspections are reviewed to determine if the validation is successful.
If the validation fails then the risk assessment, cleaning procedures and testing need to be reviewed and amended.

**STEP 7**
VERIFICATION
Is the on going procedure to ensure the cleaning procedures remain effective.
This may be a simple physical inspection of the cleaning or may involve ATP checks or rapid allergen testing.

**NOTE** Rapid allergen testing is not considered adequate as a replacement for the validation step.
ALLERGEN CLEANING
VALIDATION & VERIFICATION

VALIDATION PROCESS
Validation is intended to check the cleaning procedure to ensure that it is effective in removing all traces of allergens. It is a combination of inspection and quantitative testing. Samples and swabs are taken, before and after cleaning, and samples are taken from the subsequent production run.

NUMBER OF VALIDATION PROCESSES REQUIRED
The validation is carried out on the cleaning between an allergen containing and non allergen containing product. To be sure the cleaning process is fully effective the validation should be carried out on 3 separate but consecutive production runs. All 3 checks must pass for the validation to be successful.

| BEFORE CLEANING STARTS | Samples of the allergen containing product and swabs of the unclean surfaces after the production of the allergen containing product represent the ‘worst case scenario’.
1. Identify which allergens are present in the product being tested.
2. Retain 3 samples of the allergen containing product.
3. Swab the surfaces of the production equipment before cleaning using specific allergen swabs. Pay particular attention to the hard to clean places. There is no specific number of swabs that need to be taken; the number and locations should be sufficient to check all aspects of the cleaning. |
| AFTER CLEANING | Once cleaning has been completed and inspected.
4. Swab the same locations as covered in Section A. |
| AFTER PRODUCTION STARTS | Start the production of the non allergen product and proceed through to packing. Product from the start of production represents the highest potential for cross contamination.
5. Take packed product samples from the first batch produced after the cleaning. The number of samples taken will be determined by considering the product, risk assessment and process flow. As a guide take a minimum of 3 samples for testing and retain a further 3 for repeat testing if required. |
| SAMPLES | 6. Testing must be qualitative, quantitative rapid tests are not acceptable for the validation process. Testing should be carried out by an accredited laboratory. The following samples should be available to be sent away for testing.
  ✓ Allergen containing product x3
  ✓ Food contact surface swabs before cleaning (as required)
  ✓ Food contact surface swabs after cleaning, same locations
  ✓ First production of non allergen product x3
  ✓ First production of non allergen product x3 (retained) |
| REVIEW | Once the results are available they can be reviewed.
7. If all samples, product and swabs, taken after cleaning are negative then the validation is successful.
8. If any samples, product and swabs, taken after cleaning are positive then the validation has failed. |
UNDERSTANDING THE VALIDATION TESTING RESULTS

The table below provides some guidance on the actions that should be taken depending on the results obtained. Both product and surface testing are required, swab testing alone is not sufficient.

<table>
<thead>
<tr>
<th>PRODUCT TESTING</th>
<th>SURFACE SWABS</th>
<th>RESULT</th>
<th>ACTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEGATIVE</td>
<td>NEGATIVE</td>
<td>PASS</td>
<td>A successful validation requires a negative result for both product and surface swabs on 3 consecutive cleaning procedures between allergen and non allergen products.</td>
</tr>
<tr>
<td>-</td>
<td>POSITIVE</td>
<td>FAIL</td>
<td>Compare with the swab result before cleaning. It is possible the surfaces were very dirty and were difficult to clean leaving traces of allergens. If the pre and post cleaning swab results are very similar this suggests that the area is hard to clean or has been missed.</td>
</tr>
<tr>
<td>POSITIVE</td>
<td>POSITIVE</td>
<td>FAIL</td>
<td>Review the risk assessment and cleaning procedures. Repeat the validation process.</td>
</tr>
<tr>
<td>NEGATIVE</td>
<td>POSITIVE</td>
<td>FAIL</td>
<td>Allergens are present on the surfaces but not found in the product. Review the cleaning procedures. Repeat the validation process. Increase the number of samples of the non allergen product to be tested.</td>
</tr>
<tr>
<td>POSITIVE</td>
<td>NEGATIVE</td>
<td>FAIL</td>
<td>Allergens were detected in the product but not on the surfaces. Review the cleaning procedures. Review the swabbing locations, it is possible the areas retaining the contamination are not being swabbed. Repeat the validation process.</td>
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SUCCESSFUL VALIDATION – ANNUAL CHECK

Once 3 consecutive set of tests have passed then the cleaning process is considered to have been validated. All traces of allergens are being removed by the cleaning.

The validation does not need to be repeated on every production run. A validation exercise should be carried out annually to ensure the process is still effective.

UNSUCCESSFUL VALIDATION

If it has not been possible to get 3 consecutive negative results then the risk assessment and whole Allergen Management process should be reviewed. Any possible areas for cross contamination should be examined. Once all feasible options for avoiding cross contamination have been discounted then the declaration of “may contain …..” can be defended.
ALLERGEN CLEANING
VALIDATION & VERIFICATION

VERIFICATION PROCESS
Verification is an on-going process; required to ensure that the cleaning remains consistently effective. Verification occurs after every cleaning process and can be combination of physical inspection, rapid allergen testing or ATP rapid testing.

VALIDATION
To ensure you are doing the right thing
- Must be carried out at least annually
- 3 consecutive sets of validation checks must pass
- Testing must be quantitative
- Testing is combination of products and food surface contact swabs

VERIFICATION
To ensure you are doing it right
- Must be carried out after each cleaning
- Can be inspection and/or testing
- Testing can be qualitative using rapid techniques
- Product testing is not part of verification

SUMMARY

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CONTACT
FBA provides technical assistance to food manufacturers across a wide range of products and processes.

For help and advice with
- Allergen Management
- Risk Assessments
- Control Procedures

Please contact Food Business Assistance.

Genon Labs are a specialist allergen testing laboratory with expertise across a range of tests procedures and products.

For help and advice with
- Allergen Testing
- Sampling procedures
- Swabbing procedures

Please contact Genon Laboratories.

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